

PrEP IMPLEMENTATION STATUS UPDATE 2025

SKPA-2 Learning Brief



OVERVIEW

This brief provides an update on the implementation of oral pre-exposure prophylaxis (PrEP) in Bhutan, Mongolia and Sri Lanka under the SKPA-2 program. It highlights what has been achieved to date, the key stakeholders involved, and what still needs to happen to support scale-up and sustainability. All three countries have made progress in line with the 2024 WHO Implementation Tool for PrEP. However, each country also has distinct challenges and opportunities (see **Table 1**).



Bhutan successfully launched PrEP in 2024 and has established a solid operational foundation within its health system, including national PrEP guidelines, national standard operating procedures (SOPs), training systems, community outreach structures, and information, education and communication (IEC) tools. As of May 2025, 93 individuals have initiated PrEP. Remaining priorities include expanding service delivery to additional sites, strengthening outreach and demand creation in underperforming areas, and integrating PrEP service utilization data into national monitoring and evaluation (M&E) systems.



Following a successful demonstration project in 2021-2022, PrEP implementation has stalled due to policy and regulatory barriers. No individuals are currently on PrEP. While PrEP SOPs and eligibility guidance are in place, tenofovir disoproxil fumarate/emtricitabine (TDF/FTC) is not yet registered with the regulatory authority for market authorization and the national e-health system does not have a reimbursement code for prescribe PrEP

prescription. A roadmap for PrEP registration and availability has been developed. Future implementation will depend on resolving policy and regulatory barriers, supported by new commitments outlined in Mongolia's national HIV strategy and Global Fund national grant.



Sri Lanka has the most long-standing and community-based PrEP program of the three countries. It has built a comprehensive foundation for community-led PrEP delivery, including updated guidelines, SOPs and community service organization (CSO) training materials. Although PrEP is not yet being delivered at scale, the country is well-positioned for rollout in 2025. Plans include initiating PrEP among men who have sex with men in high-risk districts, expanding access for female sex workers and transgender women, and launching digital outreach and education strategies that emphasize PrEP as a key HIV prevention tool. Integration with HIV self-testing and differentiated service delivery models is also planned, supported by strong CSO engagement and Global Fund investment.



Table 1. PrEP Implementation Status Cross-Country Comparison, 2025

| 2024 WHO PrEP Guidance Domain | Bhutan | Mongolia | Sri Lanka |
|---|--|--|---|
| PrEP products | | | |
| <i>Oral (TDF/FTC, TDF/3TC)</i> | Available | Not available | TDF/FTC available |
| <i>Long-acting injectable cabotegravir (CAB-LA)</i> | Not yet introduced | Not available | Not yet introduced |
| <i>Dapivirine vaginal ring (DVR)</i> | Not yet introduced | Not available | Not yet introduced |
| Product Registration <i>Registered and approved for use</i> | TDF/3TC approved for PrEP; included in national formulary | Not approved; registration required under revised Medicines Law | TDF/FTC approved for PrEP in the public sector only; included in the national formulary TDF/FTC is not registered with the National Medicines Regulatory Authority. Included in the National Medicines Formulary and approved for PrEP in the public sector only |
| Eligibility Criteria <i>Anyone at substantial risk (including adolescents)</i> | Men who have sex with men, transgender women, female sex workers prioritized; adolescents not yet included | Criteria developed but inactive. Men who have sex with men prioritized in Global Fund targets | Initial rollout focuses on men who have sex with men, transgender women, female sex workers; all sexually active adults and adolescents included in national guidance |
| On-Demand/Event-Driven PrEP <i>Recommended for men who have sex with men and trans people not on estrogen</i> | Messaging developed, guidance emerging | Included in national HIV guidelines | Under review |
| SOPs and Guidelines <i>"Living" clinical documents updated regularly</i> | SOPs and PrEP clinical guidelines finalized and disseminated | PrEP guideline developed and endorsed by Ministry of Health Professional Committee on STI, HIV and AIDS; disseminated nationally | National guidelines, SOPs, and community manual of procedures (MOP) finalized and disseminated |

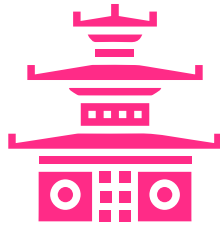
¹ Community/mobile PrEP sites are non-facility-based service sites; they still require a clinician to conduct PrEP consultation and/or prescribing.



| 2024 WHO PrEP Guidance Domain | Bhutan | Mongolia | Sri Lanka |
|---|---|--|--|
| Service Delivery Models <i>Differentiated service delivery (DSD), including facility, community, pharmacy and mobile outreach</i> | Facility-based (Jigme Dorji Wangchuck National Referral Hospital, Health Information and Service Centers, Paro hospital); strong referral model with planned expansion to additional sites as part of phased implementation | PrEP service delivery put on hold since demonstration project ended due to regulatory barriers linked to health financing reform | Clinician-led delivery at STD and community clinics; Community and additional service expansion/sites planned |
| Provider Roles Prescription and follow-up shared across provider cadres, including physicians, nurses, pharmacists, and trained lay or peer providers | Facility-based clinicians prescribe PrEP; outreach workers have a formally recognized role in client education, referral and follow-up, as outlined in national SOPs | PrEP reimbursement code not available in e-health system, which prevents prescribing | CSO providers support adherence and follow-up, but prescribing remains limited to National STD/AIDS Control Programme (NSACP) clinicians |
| Monitoring and Evaluation Integrated into Health Management Information System; real-time data entry encouraged | Custom-built data entry tool in place; not yet integrated into the electronic patient information system (ePIS) | No current system | PrEP data captured in Prevention Information Management System (PIMS) national integration and real-time tracking is being expanded |
| Demand Generation/IEC Culturally tailored IEC for key populations and providers | IEC tools developed; >250 people reached in pilot districts | Developed under SKPA-1, but not currently active; new plans in Global Fund proposal | Digital outreach, peer-led education, and targeted social media strategies are under development to support prevention messaging |
| Community Involvement Peer educators and community-based organizations (CBOs) involved in outreach, demand generation, and delivery | Strong partnerships with key population organizations (e.g., Pride Bhutan, Red Purse Network) | CBOs active in demonstration project (e.g., Youth for Health, Perfect Ladies) and engaged in future planning | Active CSO engagement in planning, advocacy, and future DSD delivery |
| PrEP Country Targets² | Men who have sex with men 2026: 558 2027: 705 Transgender women 2026: 150 2027: 200 Female sex workers 2026: 223 2027: 282 | Men who have sex with men 2024: 100 2025: 125 2026: 150 Transgender people 2024: 17 2025: 19 2026: 21 | Men who have sex with men 2025: 2,375 2026: 3,638 2027: 5,166 |

² Mongolia and Sri Lanka figures derived from NSP PrEP targets in the GC7 Programmatic Gap Table; Bhutan figure derived from Country Implementation Roadmap.





BHUTAN



Overview

Bhutan launched its first phase of PrEP service implementation in October 2024, following over a year of preparatory work that included national consultations, technical assistance visits by international PrEP experts, development of clinical guidelines and SOPs, and targeted training. Initial rollout was conducted in Thimphu and Paro, with plans to scale up nationally by the end of 2025. Service delivery is currently facility-based, supported by a strong referral model led by community-based key population organizations. Implementation is led by the National AIDS and STI Control Program (NACP) under the Ministry of Health, with technical support from Save the Children, Health Equity Matters and UNAIDS under SKPA-2.



Progress to Date

- 93 people enrolled in PrEP as of May 2025 (41 via Thimphu HISC, 22 via Paro Hospital, 15 via Phuentsholing HISC, 9 via Gelephu HISC, 6 via JDWNRH)
- Clinical SOPs, job aids, and IEC tools developed and distributed to all implementation sites
- Training completed for providers and outreach teams across Phase 1 and Phase 2 sites
- Facility assessments conducted and referral pathways developed between hospitals and community sites
- Custom data entry tool developed and being adapted based on user feedback
- Demand generation efforts, including virtual outreach, have reached over 250 men who have sex with men, transgender women, and female sex workers in pilot districts



Implementation Strengths

Bhutan's PrEP rollout has benefited from strong national leadership and close coordination between the Ministry of Health, civil society organizations and development partners, particularly SKPA-2 experts, UNAIDS and WHO. The use of a phased implementation approach has enabled stakeholders to identify and address challenges early before expanding nationwide. IEC materials, along with provider training tools, were developed with key population input and are both accessible and user-friendly. Community service organizations, such as Pride Bhutan and Red Purse, are fully integrated into outreach and follow-up, reinforcing the community-led nature of the program.





Key Challenges

Despite solid groundwork, several challenges persist. Uptake in Paro has lagged behind that in Thimphu, largely due to weaker outreach infrastructure and lower levels of key population engagement. Access to services outside the Phase 1 districts remains limited, with clients in other regions facing barriers due to distance or lack of information. While outreach workers have a formally recognized role in demand generation and referral, PrEP consultations and provision remain clinician-based, with no formal task-sharing mechanisms, limiting client convenience and accessibility, and scalability.

A National AIDS Control Program assessment of early uptake challenges identified burdensome testing protocols, limited outreach coverage, and client preferences for services at Health Information Service Center (HISC) during off-peak hours. In response, the program expanded its outreach workforce and extended HISC operating hours to better serve clients, especially sex workers. Retention remains a challenge due to the burden on clients of ongoing follow-up and testing. In addition, while a customized monitoring tool is in use, it requires integration into the ePIS to ensure long-term sustainability.



Planned Next Steps

- Country targets for 2026: 150 transgender women, 223 female sex workers, 558 men who have sex with men; and for 2027: 200 transgender women, 282 female sex workers, 705 men who have sex with men
- IEC development for broader key population engagement and awareness
- Scale-up of PrEP sites beyond Thimphu and Paro
- Additional training and sensitization for outreach workers in new districts
- Monitoring and evaluation workshops
- Review PrEP SOPs and clinical guidelines to ensure required changes are incorporated



Future Considerations

Bhutan's early implementation phase shows strong alignment with WHO normative guidance, laying a solid foundation for scale-up. To ensure long-term success, however, several areas require strategic attention. Expanding task-shifting policies to allow nurse-led or peer-supported PrEP delivery could improve accessibility and reduce clinical burden. Outreach and PrEP literacy efforts need to be strengthened in underserved districts like Paro and beyond the Phase 1 sites to ensure more equitable access and to normalize PrEP use, particularly within key populations. Integrating the current data collection tools into the ePIS will be critical for sustainability, monitoring and reporting. Finally, while the current eligibility criteria prioritize adult key populations, future policy updates could consider extending PrEP access to adolescents and other vulnerable populations to further align with WHO recommendations.





MONGOLIA



Overview

Mongolia piloted PrEP delivery during a successful demonstration project under SKPA-1 (2021-2022), establishing national SOPs, eligibility criteria, and community-based service delivery models. However, implementation has since stalled due to policy and regulatory barriers. As of June 2025, no individuals are on PrEP. The national program is working to resolve key issues including product registration, financing mechanisms, and commodity access. Nevertheless, the initial groundwork during the demonstration project, strong stakeholder engagement and forward-looking Global Fund proposal place Mongolia in a strong position for future scale-up.



Progress to Date

- PrEP SOPs, eligibility criteria and training tools developed under SKPA-1
- TDF-based PrEP included in HIV clinical guidelines
- Community-based and DSD models tested during the pilot, including peer and nurse-supported PrEP
- Key populations reached through outreach via Youth for Health and Perfect Ladies, which remain engaged in future planning
- Global Fund proposal (2024–2027) includes a detailed plan for restarting PrEP delivery once structural barriers are addressed



Implementation Strengths

Mongolia's demonstration project laid the foundation for future PrEP rollout. Clinical SOPs and community outreach models were piloted and refined during SKPA-1 and stakeholders remain engaged and committed to implementation. The inclusion of PrEP in national HIV clinical guidance reflects policy commitment. Organizations like Youth for Health Center and Perfect Ladies have strong community credibility and capacity to support reactivation. There is also a clear roadmap for resolving current barriers, with next steps articulated in the Global Fund proposal.





Key Challenges

Mongolia's ability to take forward PrEP implementation has been limited by structural issues. A revised national law now requires formal market authorization for all imported medicines, including those sourced via UNICEF, resulting in PrEP medications being unavailable for prescription since the demonstration project ended. Given small market size, manufacturers may have little incentive to pursue registration, which may further limit access. Additionally, PrEP cannot currently be prescribed through the national insurance system, as a specific claims code – required for reimbursement – has not yet been established. This means that it is not feasible for providers to deliver PrEP, even where trained personnel and clinical protocols exist. Compounding these challenges is the lack of an integrated M&E system, which will be required for routine PrEP data tracking once services resume.



Planned Next Steps

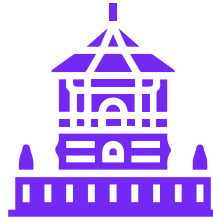
- Complete registration of TDF/FTC for PrEP use under Mongolia's revised Law on Medicines
- Push for inclusion of PrEP in the national Essential Medicines List during the 2025 review cycle
- Collaborate with the National Center for Communicable Diseases (NCCD), Health Insurance General Office (HIGO), and health authorities to establish a PrEP-specific claims code within the national e-Health system
- Reinitiate community engagement and IEC activities through trained CSOs and key population-led outreach
- Relaunch PrEP service delivery models at pilot sites with phased geographic expansion
- Integrate PrEP data into Mongolia's national HIV M&E system



Future Considerations

To re-establish and sustain PrEP services, Mongolia must prioritize and accelerate structural policy reforms and operational readiness. Accelerating product registration and the establishment of a reimbursement claims code will be essential to ensure legal prescribing pathways and future commodity supply. The country's SOPs, training curricula, and service delivery models from the pilot will need to be implemented alongside strengthened monitoring systems and renewed CSO mobilization. Continued technical and financial support may also be required to ensure that PrEP access is equitable, community-led, and aligned with WHO guidance.





SRI LANKA



Overview

PrEP implementation in Sri Lanka is supported by national leadership, policy alignment, and engagement with civil society organizations. Clinical protocols, SOPs and training tools have been finalized and, in 2023, PrEP delivery reached over 1,000 individuals. However, expansion has since slowed, due to low awareness and limited demand among the key populations. Although PrEP is now available through all government STD clinics, uptake remains uneven. Current national guidance limits PrEP initiation to clinician-led (facility-based) settings, and DSD models remain in the planning phase. The next phase will focus on reinforcing the role of PrEP in HIV prevention, scaling delivery models, and strengthening data systems to track progress.



Progress to Date

- Inclusion of TDF/FTC in national formulary with PrEP indication
- National SOPs and s finalized, with CSO reference manuals distributed
- CSO providers trained to support PrEP initiation, delivery and client follow-up
- PrEP and HIV self-testing guideline alignment workshops conducted with NSACP and CSO stakeholders



Implementation Strengths

Sri Lanka is well-positioned for PrEP rollout due to strong collaboration between national health authorities and CSOs. The development of context-specific SOPs and training materials has laid the groundwork for DSD models. CSO-led platforms have proven highly effective for outreach to men who have sex with men and transgender women. Planned pairing of HIV self-testing with PrEP offers a client-centered entry point. The presence of trained personnel, policy support and targeted outreach strategies represents a high degree of readiness. Additionally, planned integration of PrEP into broader programming, such as chemsex support and legal literacy, reflects a rights-based approach that reduces stigma and enhances access.





Key Challenges

Despite strong momentum, Sri Lanka's PrEP rollout has struggled with retention. By 2023, over 1,000 individuals had reportedly initiated PrEP through 41 STD clinics. Though the government has made efforts to reach communities through community PrEP clinics, continuation among clients remains low. Program documents also cite low uptake and limited expansion due to economic and operational challenges. In addition, stigma related to sexuality and gender identity remains a barrier for many potential users, highlighting the need for ongoing community sensitization and digital engagement strategies. While SOPs and provider guidance are in place, PrEP commodities are not yet routinely available. Clinical monitoring and follow-up protocols remain in development.



Planned Next Steps

- Initiate PrEP among at least 10% of men who have sex with men reached in 2025, scaling to 15% in 2026 and 20% in 2027, with the aim of reducing new HIV infections, particularly among young men who have sex with men
- Launch differentiated PrEP service delivery models in Colombo, Gampaha, and other priority sites
- Expand access to transgender women, female sex workers and beach boys by targeting geographic hotspots using size estimates and risk mapping
- Integrate HIV self-testing as an entry point for PrEP initiation
- Field test and integrate PrEP IEC materials into legal literacy and chemsex harm reduction interventions
- Integrate PrEP into peer-led and virtual outreach strategies, including digital platforms targeting men who have sex with men and female sex workers
- Offer PrEP integration at STD clinics, select community service centers, and holiday clinics
- Build on current PIMS integration, which is already capturing PrEP data, and strengthen CSO-led monitoring to enhance overall M&E



Future Considerations

To successfully transition to implementation at scale, Sri Lanka will need to focus on operationalizing its DSD models in parallel with expanding community demand. Continued investment in virtual outreach, peer navigation and IEC campaigns will be critical to reach men who have sex with men and transgender women who may be less visible to traditional health systems. Strengthening clinical follow-up protocols and ensuring consistent monitoring through the PIMS platform are required to improve PrEP continuation rates and ensure long-term success. Finally, sustaining the collaborative relationship between the NSACP and CSOs will be essential to deliver a rights-based PrEP program that responds to community priorities.



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