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Introducing long-acting injectable lenacapavir as HIV pre-exposure prophylaxis: implementation considerations

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Introduction

Background

The UNAIDS 2026–2031 Global AIDS Strategy *(1)* calls for an urgent, country-led and people-centred sustainable HIV response that integrates biomedical innovations in resilient national health systems, amid sharply declining international funding and persistent inequalities.

The Strategy sets an ambitious target of 90% of people in need using HIV prevention options by 2030. In 2024, fewer than 4 million people used pre-exposure prophylaxis (PrEP) options, a fraction of the estimated annual need of 20-million-person-years of use. *(2)*

Long-acting injectable lenacapavir (LEN) was recommended by the World Health Organization (WHO) in 2025 *(3)*, alongside oral PrEP containing tenofovir, the dapivirine vaginal ring and long-acting injectable cabotegravir, as part of combination HIV prevention approaches[1].

LEN is a safe, acceptable and highly efficacious twice-yearly injectable PrEP option, administered with a mandatory oral loading dose. Eswatini and Zambia began programmatic delivery of LEN for PrEP in December 2025. Overall, 24 countries[2] are expected to have begun programmatic delivery by the end of 2026 with the support of the Global Fund and/or the U.S. President's Emergency Plan for AIDS Relief (PEPFAR). The addition of new, long-acting PrEP options could contribute to dramatic reductions in new HIV infections.

This guide provides practical guidance for countries considering whether and how to introduce LEN for PrEP as part of their HIV prevention response. It supports context-based decision-making on whether and how to introduce LEN, recognizing that decisions should reflect epidemiological need, health system readiness, PrEP programme maturity, financing, supply, and community priorities.

Although this guide focuses on a single product (LEN) as its organizing framework, the phased approach and activities outlined are broadly applicable to other emerging HIV prevention products. Most elements—including stakeholder engagement, policy and regulatory readiness, service delivery planning and demand generation—are expected to remain relevant across new pipeline products, requiring only minor adaptations to reflect product-specific characteristics and implementation considerations.

Key principles for LEN introduction

1. **LEN is one PrEP option within the HIV prevention method mix.** LEN introduction should expand, not replace, HIV prevention choice and complement effective existing options.

[1] As a concept, combination HIV prevention includes a range of behavioural, biomedical and structural elements, which can then be narrowed down to a specific, optimized mix of specific interventions that are offered as part of a service or to specific populations and places.

[2] Benin, Botswana, Dominican Republic, Eswatini, Fiji, Georgia, Haiti, Honduras, Indonesia, Kenya, Lesotho, Malawi, Morocco, Mozambique, Nigeria, Papua New Guinea, the Philippines, Rwanda, Thailand, South Africa, Uganda, Ukraine, Zambia and Zimbabwe.

2. **LEN introduction should build on existing PrEP experience.** Countries should leverage the delivery platforms, partnerships, systems and lessons learned from peer countries and previous PrEP product introduction.
3. **LEN should be integrated in ways that strengthen health systems.** Introduction should reflect country contexts, avoid parallel systems, and strengthen HIV prevention and broader health system functions.
4. **Community partnership is essential throughout LEN introduction.** Communities must be meaningfully engaged in planning, implementation, monitoring, learning and scale-up.
5. **Country ownership and leadership underpin successful LEN introduction.** Ministries of Health should lead and oversee the planning, implementation and monitoring of introduction efforts, with partner support aligned to national priorities, context and health system capacity.

How to use this guide

The document outlines the key considerations and decision points to support a phased, country-adapted approach to LEN introduction, with the goal of accelerating equitable access while ensuring sustainable implementation. It emerges from extensive engagement with experts, civil society, PrEP implementers, researchers and partners. The guide has been designed to complement WHO guidance *(3, 4)* and existing implementation frameworks. *(5, 6)*

This guide is not prescriptive. The proposed phases and timeframes are illustrative and should be adapted to the country context, health system capacity, PrEP programme maturity and experience with oral or other long-acting PrEP options, resource availability, and political and community readiness. *(7)* Although presented in a stepwise manner, phases and activities will often run concurrently and/or as part of an improvement loop (Figure 1).

The purpose of the guidance is to support countries in assessing their optimal prevention options, while ensuring that the introduction of LEN strengthens rather than fragments the prevention landscape. Countries should draw on their previous experience with oral and other long-acting PrEP options.

As countries consider introducing LEN, it is important for decision-makers to understand that LEN efficacy has been scientifically established. However, implementation science can provide valuable evidence for outstanding issues such as real-world product choice and persistence, optimal service packages and delivery approaches, health system integration, costs and impact.

Approaches for introducing LEN can also seek to:

1. Build health system capacity for delivery of LEN and other new HIV prevention options as part of an integrated HIV response;
2. Develop, test and/or refine scalable and sustainable differentiated service delivery models;
3. Document costs and other data to inform economic analyses to support financing and resource allocation decisions;
4. Inform national policy and approvals processes, including for health technology assessments;[3]

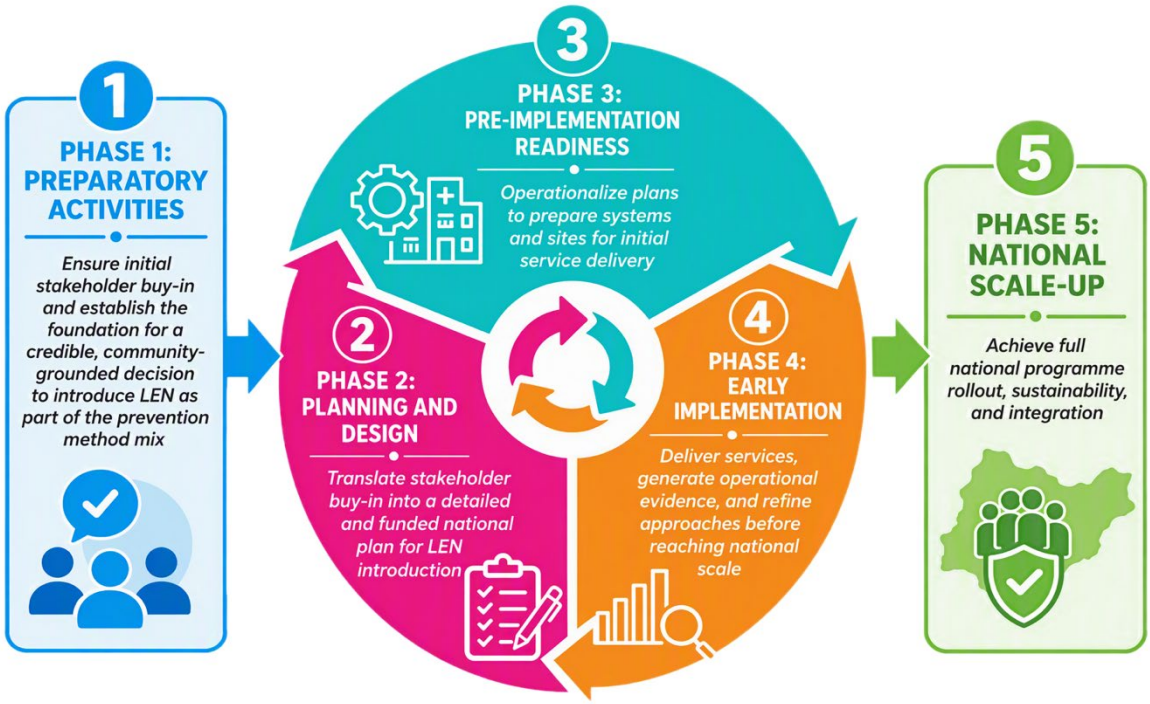
[3] Health technology assessment is a systematic and multidisciplinary evaluation of the properties of health technologies and interventions, including pharmaceuticals, covering both their direct and indirect consequences. Countries may use such an or an equivalent approach to make evidence-based decisions about adoption and funding of new health technologies and assessments, including LEN. Further information is available at: https://www.who.int/health-topics/health-technology-assessment.

5. Generate operational evidence on how best to deliver LEN in the specific country context; and/or
6. Learn and adapt rapidly to support full-scale implementation.

A comprehensive list of resources to support implementation is available in Annex 4.

Figure 1.

LEN implementation pathway towards national scale-up.



Implementation phases overview

Phase 1: Preparatory phase

Achieve initial stakeholder buy-in and establish the foundation for a credible, community-grounded decision to introduce LEN as part of the prevention method mix	Illustrative timeframe: 1–3 months

Key activities

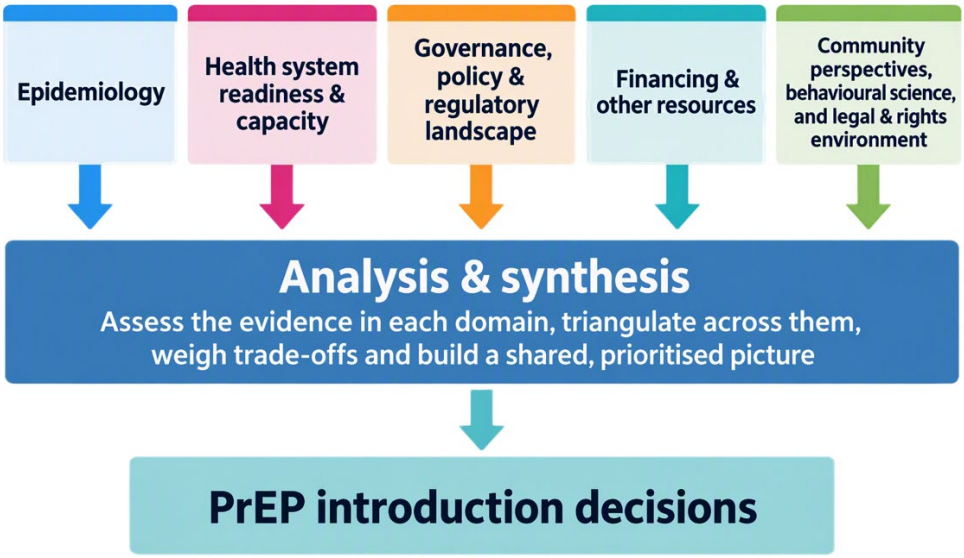
1. **Stakeholder mapping.** Identify key stakeholders among government (national and subnational), donors, implementing partners, healthcare providers and administrators, community-led organizations (including key population networks and organizations representing people living with HIV), researchers, and the private sector.

2. **Rapid situational analysis.** Perform a rapid situational analysis to gather evidence for decision-making on LEN introduction. Analysis should cover epidemiology; health system readiness and capacity; governance; the policy and regulatory landscape, including the political context and entry points; financing and other resources; and community perspectives, behavioural science and legal and rights environment (see Figure 2; for more information, see Annex 1) leading to an explicit decision.

   Consider lessons that can be drawn from the introduction of other technologies or medicines, such as contraceptives. The situational analysis should lead to an explicit decision about whether and how to introduce LEN.

Figure 2.

Situational analysis: main topics for assessing whether a country is ready to introduce LEN as a PrEP option



3. **Consultation and securing buy-in.** Conduct initial consultations with key stakeholders (from decision-makers to communities) to build awareness, garner interest, identify concerns, ensure shared understanding and secure process buy-in.

4. **Preliminary decisions on approach, priority populations and geographies.** Drawing on consultations and the rapid situational analysis, including a review of existing epidemiological and programme data, agree on the general approach for introducing lenacapavir and determine the criteria for establishing implementation priorities. Countries may use a systematic approach such as the "Five Ps" prioritization matrix to structure this analysis.[4] *(5)*

   Preliminary decisions on priority populations and geographies should be made in consultation with key stakeholders. Modelling can be used to explore scenarios and confirm prioritization (see Phase 2).

5. **Governance and advisory structures established.** Ideally, leverage existing governance structures, such as prevention technical working groups, to oversee and coordinate planning and implementation, rather than create new structures.

   All primary stakeholder groups, including community organizations, should be meaningfully engaged to ensure that community perspectives influence decision-making and shape implementation.

   Involvement or establishment of a community advisory board on HIV prevention will enable communities to elect representatives, thereby ensuring strong representation and supporting "two-way" information flows between communities and governance structures.

6. **Regulatory approvals.** Engage the relevant national regulatory authority early in the process to avoid unnecessary delays. Ministries of Health and national regulatory authorities should explore whether, in addition, the regulatory authority approval processes can benefit from leveraging complementary processes such as the EU-Medicines for all (EU-M4all) procedure;[5] the WHO Collaborative Registration Procedure;[6] and/or national public health urgency pathways, to accelerate approvals depending on country context and product source (originator versus generic).

7. **Supply and procurement dialogue.** Contact manufacturers of the originator and/or generic product, as well as relevant donors, to initiate dialogues on supply and procurement.

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[4] The *HIV Prevention 2030: A global access framework for country-led responses* publication provides a framework for prioritization that is focused on the "Five Ps" to help countries maximize the impact of prevention. The "Five Ps" are: the **People** in greatest need of prevention (including key populations); the right **Places** (geographic areas with high incidence/prevalence/burden); access through the right mix of trusted **Platforms** (appropriate service delivery platforms)**;** the right prevention **Packages** (optimal prevention method mix that offers choice); at the right **Prices** (financing sustainability and value for money)**.** See: https://hivpreventioncoalition.unaids.org/en/resources/hiv-prevention-2030-global-access-framework-country-led-responses. Specific criteria for LEN prioritization can include: HIV incidence, number of new infections, historical PrEP uptake, condom coverage, people living HIV who do not have viral suppression, and population-specific low HIV treatment coverage, as well as health service and civil society organization metrics.

[5] The European Medicines Agency, in cooperation with WHO, can provide scientific opinions on high-priority medicines, including vaccines, that are intended for markets outside of the European Union. See: https://www.ema.europa.eu/en/partners-networks/international-activities/medicines-assessed-under-eu-m4all-procedure

[6] Through the WHO Collaborative Registration Procedure, national regulatory authorities can access product assessment reports from stringent regulatory authorities or WHO Prequalification, allowing for a faster, verification-based or abridged review process to make their own decisions. See: https://www.who.int/teams/regulation-prequalification/regulation-and-safety/facilitated-product-introduction/collaborative-registration-procedure/procedure-for-prequalified-med-vax.

Identify timelines and processes, including any prerequisites such as registrations/approvals, grant timing, supply volumes, costs and financing.

Clarify with suppliers the required volume commitments, post-importation testing logistics and costs, and buffer stock requirements. For countries receiving donor funds, coordinate with donors to secure volume and pricing commitments.

Early legal, regulatory and market-access analysis can help countries identify and respond to arrangements that unintentionally limit affordable access to LEN for non-donor recipient countries.[7]

Critical considerations

Phase 1 establishes the foundation for successful LEN introduction through stakeholder engagement, situation analysis, and preliminary decision-making. It is not purely an administrative step. The political will, community trust, and stakeholder engagement it establishes will influence the speed and equity of the subsequent phases.

Countries should recognize that there is an inherent trade-off between speed and readiness. Efforts should be made to support timely introduction and avoid unnecessary delays. However, while rushing early phases may reduce the time before service delivery begins, they can compromise stakeholder ownership, community trust, implementation quality, and equitable access.

Phase 2: Planning and design

Translate stakeholder buy-in into a detailed and funded national plan for LEN introduction	Illustrative timeframe: 1–4 months

Key activities

1. **Implementation plan.** Develop an overarching implementation plan that details the geographic and/or population priorities, approaches, timelines, funding, and roles and responsibilities. The plan should be grounded in a phased scale-up logic that favours continuous learning for programme adjustment during roll-out.

   The plan should be considered a working document that can be updated in line with emerging implementation data. The implementation plan will harmonize with and be supported by additional specialized documents.

   - Geographic expansion. Phased roll-out expansion with prioritization criteria based on HIV burden, health system capacity and experience, and equity considerations; site selection and preparation timelines; expansion wave scheduling; monitoring triggers for pace adjustments.

[7] Regulatory approval and service readiness do not guarantee access. Countries should assess how patent status, licensing terms, TRIPS-related flexibilities, data exclusivity, trade arrangements, procurement eligibility and market size may affect LEN access over time.

- Site selection. Based on epidemiological and programme data with transparent, community-informed criteria.
- Service delivery models. A range of initial delivery platforms selected based on previous programme experience and community feedback (these can be adapted later based on Phase 4 experience); integration points with existing services (sexual and reproductive health, HIV testing/treatment, sexually transmitted infections, harm reduction); balance of community- and facility-based services; differentiated approaches according to client characteristics (location, provider type, scheduling, service bundling); quality standards for scaled services.
- Target populations and demand. Prioritization should be based on epidemiological, programme and available research data, including for the delivery of other PrEP products, and recognizing the importance of individual choice.
- Provider training. Training package development; training scale-up plan with specific numbers, timelines and resources; provider certification and recertification approach; cascade training model implementation; ongoing mentorship and supportive supervision systems; task-shifting expansion.
- Community mobilization and demand generation. Engage community-led organizations; build capacity; design a costed, phased and community-led demand generations and communications plan.
- Supply chain and logistics. Procurement plans aligned with demand forecasts; distribution systems from central to service delivery points; inventory management and buffer stock planning; generic transition planning.
- Financing and sustainability. Multiyear budget with domestic and external funding sources; costed implementation plan with realistic resource requirements; domestic resource mobilization strategy; sustainability plan beyond initial donor commitments; preparation for cost reductions through generic transition.
- Risk matrix. Include a robust, phase-specific risk matrix to identify and prioritize evolving risks and constraints, including those identified during the situational analysis; guide mitigation measures; and support timely, evidence-informed decisions throughout roll-out.

2. **Impact modelling and cost-effectiveness analysis.** Mathematical modelling provides crucial evidence that can inform implementation by identifying potential strategies to maximize epidemiological impact (e.g. HIV infections averted) and support economic efficiency (e.g. return on investment, cost-effectiveness, allocative efficiency). Based on the preliminary population and geographic prioritization (Phase 1), use modelling to explore scenarios and establish final priorities for roll-out, including population and geographic targets, procurement volumes, and cost quantification. Modelling must be grounded in programmatic realities and use realistic scale-up assumptions, not optimistic projections. See Annex 2 for further details.

3. **Financing strategy.** Identify opportunities for financing LEN-related products and services, using domestic and/or donor funds.

   Develop an investment case to justify budget impacts, using mathematical modelling of scenarios.

Include financing for LEN within existing documents and strategies such as budget allocations and sustainability roadmaps.[8]

4. **National guidelines and standard operating procedures.** Develop or update clinical guidelines to include LEN for HIV prevention,[9] including guidance on differentiated service delivery elements such as task-sharing and community-based delivery sites, as appropriate. Implementing differentiated service delivery options may require policy changes; those should be identified and resolved prior to roll-out and training.

   Engage with non-traditional, community and private sites at this stage, depending on the local context.

   Develop standard operating procedures that are appropriate for site-level implementation and that cover eligibility/suitability assessment, HIV testing procedures, injection administration, follow-up scheduling, adverse event management, and seroconversion management.

5. **Procurement strategy and orders.** Identify procurement strategies for LEN-specific products and determine whether pooled procurement, regional negotiation, voluntary licensing or other access pathways can be leveraged. Procurement plans should consider originator and generic supply availability, immediate and long-term affordability, eligibility for market access arrangements; and pricing implications, especially for middle-income countries.[10]

   Orders should be placed based on the quantifications or forecasts that are conducted. They should provide for sufficient buffer stock and should consider supply chain timelines (e.g. regulatory waivers, Value Added Tax exemptions, shipment, post-importation testing, depot distribution, facility delivery shipping, customs and import clearance timelines, and shelf life).

   Make use of established procurement mechanisms, such as through the Global Fund, PEPFAR, regional mechanisms such as the PAHO Strategic Fund, or national systems. Ensure that all products meet WHO prequalification standards and follow procurement and supply management guidance[11] for quality assurance, competitive pricing, and timely delivery.

[8] To help countries and partners develop roadmaps and navigate the path towards sustainability, the "HIV response sustainability primer" proposes a new approach to ensure the sustainability of the HIV response, while the "Companion guide" includes country-specific analytical resource packages and a sustainability assessment tool. See: https://sustainability.unaids.org/technical-guidance/

[9] The WHO guidelines on lenacapavir for HIV prevention and testing strategies for long-acting injectable PrEP provide high-level guidance (https://www.who.int/publications/i/item/9789240111608), while a complementary standard operating procedures template for countries has also been developed (https://www.hivinterchange.com/blog/lenacapavir-prep-rollout-a-standard-operating-procedure-template-available-for-countries).

[10] Generic product availability is expected from 2027. At least 120 low- and middle-income countries are expected to be able to access a price of about US$ 40 per person per year for injections plus US$15–17 for the oral loading component at initiation. See: https://www.thelancet.com/journals/lanmic/article/PIIS2666-5247(25)00245-9/fulltext; https://www.gilead.com/responsibility/global-health-and-access/access-in-low--and-middle-income-countries/access-strategy-for-long-acting-prep.[11] The Global Fund provides helpful tools and guidance for the management and sourcing of health products. See: https://www.theglobalfund.org/en/sourcing-management/.

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Critical considerations

Phase 2 translates initial readiness into detailed and actionable plans, budgets, and operational protocols that are needed to ensure effective introduction of LEN. This phase requires balancing technical rigour with context-specific practical constraints.

In most countries, roll-out will begin in a limited number of sites and services, expanding over time. The roll-out plan, including prioritization criteria[12] for early roll-out, must be transparent and community-informed and must be clearly communicated to stakeholder groups so expectations can be managed.

Sustainability planning, even in the context of external funding, is essential, and should take account of political commitment, system strengthening and domestic financing commitment.

From 2027, the generic price point (for eligible countries) should be incorporated into financial modelling.

Impact modelling must demonstrate that LEN introduction does not displace funding or services from the broader HIV prevention programme. LEN must be positioned as one option within the full prevention and PrEP method mix. *(7,8)*

Phase 3: Pre-implementation readiness

Operationalize plans to prepare systems and sites for initial service delivery	Illustrative timeframe: 1–6 months

Key activities

1. **Provider training.** Develop or adapt existing comprehensive training materials, including job aids for all cadres of LEN providers (e.g. doctors, nurses, midwives, clinical officers, pharmacists, community health workers and peer providers), with clearly defined roles and responsibilities, and task shifting.[13]

   Consider requirements for and facilitate accreditation of training through relevant professional boards and/or regulatory agencies. Training should constitute a complementary module to other PrEP training and should reflect the approved national guidelines and standard operating procedures. Topics covered should include general PrEP and HIV prevention clinical procedures (including assessing for acute HIV infection and post-exposure prophylaxis); LEN-specific clinical management (including procedures for starting, continuing, stopping and restarting LEN); sub-cutaneous injection technique; adverse event management; and counselling, including PrEP choice counselling) and non-

[12] Criteria may be used to prioritize certain geographies, sites or service types and populations. Criteria should be aligned with the aims of early implementation (e.g. demonstrating roll-out feasibility or maximizing impact). Criteria could include HIV incidence, number of new infections, historical PrEP uptake, condom coverage, people living HIV who do not have viral suppression, and population-specific low HIV treatment coverage, as well as health service and civil society metrics. The *HIV Prevention 2030: A global access framework for country-led responses*' "Five Ps" can be used to structure the prioritization. See: https://hivpreventioncoalition.unaids.org/en/resources/hiv-prevention-2030-global-access-framework-country-led-responses.

[13] WHO and Jhpiego have developed comprehensive online training for PrEP providers, including LEN, alongside all other WHO-recommended PrEP products. The training can be adapted for in-country use. See: https://www.jhpiego.org/hivpreptoolkit. This training is consistent with the *WHO Guidelines on lenacapavir for HIV prevention and testing strategies for long-acting injectable pre-exposure prophylaxis* and the *WHO implementation tool for pre-exposure prophylaxis (PrEP) of HIV infection: provider module for oral and long-acting PrEP*.

clinical aspects (appointments and scheduling, monitoring and evaluation). Training may be differentiated depending on the provider type.

Involve community-led organizations in training design and delivery, especially regarding stigma, counselling, choice and sensitive service delivery.

Training can be delivered through a cascade training model, with central-level master trainers who train district and facility-level providers, initially targeting early adopter sites/geographies. Plan additional refresher training and ongoing mentorship and support.

2. **Site assessment and preparation.** Conduct a comprehensive site readiness assessment[14] at each selected site.

   The assessment should include: site volumes; accessibility (opening days/hours, location, security); human resources and personnel (provider types and numbers, experience, capacity, workload, training); PrEP/HIV prevention service delivery; communications; health product management; monitoring and evaluation; infrastructure (laboratory, pharmacy, storage, clinic, complementary services); priority population needs/services; new product readiness; and opportunities for LEN preparation to strengthen routine service delivery, supply management, data use and quality improvement.

3. **Health product supply chains**. Ensure that site-level quantification forecasts are conducted.

   Following procurement and supply management guidance,[15] coordinate national, subnational and/or site levels for supply allocations and delivery based on quantifications and forecasts.

   Integrate LEN within existing HIV prevention products systems for real-time inventory monitoring.

4. **Monitoring and evaluation, surveillance and data systems**. Embed LEN in the monitoring and evaluation framework and health management information systems that are used for HIV PrEP and/or HIV prevention.

   Disaggregate LEN appropriately within key indicators at national, subnational, facility and client-level for reporting and quality improvement, and ensure that patient information systems are updated to include LEN.

   Engage community organizations in monitoring service quality, accessibility and human rights as part of community-led monitoring to translate findings rapidly into implementation.

   As LEN is a new drug, enhanced surveillance of adverse drug outcomes may be warranted. Wherever possible, such enhanced surveillance should leverage established frameworks and processes. Incorporate LEN into routine pharmacovigilance systems for adverse events, as part of post-market surveillance.

[14] Tools such as the MOSAIC PrEP Site Implementation and New Product Readiness Assessment Tool provide a standardized framework for evaluating PrEP service delivery capacity and determining site-level preparedness for new product introduction.

[15] The Global Fund provides helpful tools and guidance on the management and sourcing of health products. See: https://www.theglobalfund.org/en/sourcing-management/.

Include LEN also in existing registries to monitor uncommon and rare pregnancy and infant outcomes. Additionally, update policies and procedures for monitoring of seroconversions and drug resistance to incorporate LEN.

Finalize and test all data tools across initial implementation sites before service delivery begins. Ensure staff are trained on the tools. See Annex 3 for more details.

5. **Community engagement, communication and demand generation.** As community-led organizations play an important role in ensuring awareness, acceptability and accessibility of LEN, capacity building and systems strengthening is crucial, including for outreach, counselling, community-led monitoring and demand generation.

   Engage community-led organizations to co-design a comprehensive communication and demand generation plan.[16, 17] The plan should use person-centred design principles and stigma-sensitive messaging, proactively address misinformation, and position LEN as one option within the HIV prevention method mix.

   The plan should be reviewed by representatives from concerned communities, including key populations and people living with HIV. It should also be tailored to the implementation plan, including prioritization and pace of roll-out.

Critical considerations

Phase 3 operationalizes the plans developed in Phase 2, thereby readying strategies for implementation. This "last mile" of preparation determines whether implementation will proceed smoothly or encounter preventable obstacles.

Phase 3 focuses on concrete activities, such as training providers, preparing sites, mobilizing communities, and ensuring that supply systems are functional before the first client receives LEN. Countries should allow adequate time for this phase, rather than rush to service delivery.

Phase 4: Early Implementation

Deliver services, generate operational evidence, and refine approaches before reaching national scale	Illustrative timeframe: 6–12 months

Key activities

1. **Launch LEN at initial sites, with progressive expansion.** Launch LEN at selected initial sites to test systems, policies and procedures. Make programme adjustments as required before expanding to additional sites. Provide intensive support to sites during the initial weeks.

[16] This document presents practical advice for designing, implementing and communicating effective HIV prevention strategies that are people-centred. It also offers suggestions and frameworks for prioritizing, planning and budgeting those activities, and for tracking and interpreting the results. See: https://hivpreventioncoalition.unaids.org/en/resources/people-centred-hiv-prevention-communication-consolidated-approaches-demand-generation-and.

[17] The PrEP Communication / Demand Generation Strategy Template provides an overview and outline of the different sections of a national communication or demand generation strategy for countries developing new PrEP or HIV prevention strategies or updating their strategies with new PrEP options. See: https://www.prepwatch.org/resources/prep-communication-and-demand-generation-strategy-template/.

2. **Activate communications, demand generation and community mobilization.** Co-design specific communications materials (e.g. local media, social media, peer networks, community events) and demand-generation messages consistent with the communications plan.

   Launch communications in local languages and demand-generation activities in accordance with the comprehensive communication and demand-generation plan.

   Schedule the demand-generation activities to reflect the intended pace of scale-up. Around initial sites, ensure community mobilization is happening concurrently with facility preparation.

3. **Real-time monitoring of key indicators.** This will include initiations (absolute numbers, proportion of new clients versus current or previous PrEP users to document prevention coverage expansion); on-time re-injection; continuation at 6 and 12 months; and seroconversions. Implement enhanced surveillance for adverse events, pregnancy and infant outcomes and drug resistance.

   Systematically capture implementation data, analyse findings, and adapt implementation in real time. Implementation of the monitoring and evaluation framework must drive real-time adaptations and not merely generate retrospective reports.

   Programme coordinator(s) must conduct ongoing at-site and above-site monitoring from day one of service delivery for mentorship, problem-solving and quality assurance. Use the findings to refine protocols and training. See annex 3 for more details.

4. **Refinement of implementation plans and associated policies, protocols, and procedures.** Do this based on early implementation experience and implementation science. The purpose is to refine and improve the programme clinical protocols, guidelines other key documents based on real-world implementation and in-country experiences. *(9)* Focused implementation research studies should be appropriately resourced and tailored to priority questions that can have a tangible impact on implementation.

5. **Site network expansion based on evidence.** This should be phased and evidence-based, and supply allocation must remain flexible.

   Note that demand has outpaced supply in early-adopter countries. Frequent stock monitoring and proactive funder communication are essential to prevent stock-outs.

Critical considerations

Phase 4 marks the transition from planning to actual practice. It encompasses initial service delivery, real-time problem-solving, and systematic learning to inform scale-up at national level (Phase 5).

Phase 4 is deliberately structured as a learning phase, with progressive expansion from a set of pre-selected sites, including troubleshooting operational issues, and then expanding to additional sites based on lessons learned.

Utilizing rapid learning cycles that feed relevant monitoring data back to the national technical working group can allow sufficient time for decision-makers to make appropriate programme adjustments and mitigate risks. For example, monitoring uptake can help identify unanticipated poor uptake by certain populations or in certain geographical areas where additional training is

needed or service access has to be improved. Additionally, proactive monitoring of initiation and continuation numbers at each site against the available stock can help identify potential stock-outs and allow mitigation measures to be put in place (e.g. communications, stock transfers from other sites, early ordering and/or a slow-down in expansion).

Implementation science should run in parallel with service delivery throughout this phase, operating as a dynamic learning system that links product delivery with policy (rather than only starting after implementation is established). At this stage, the technical working group and/or decision-makers need to determine whether the programme model is sufficiently robust, and the necessary support is in place to proceed to national scale-up. If significant gaps remain, address these before committing to full scale-up to avoid implementation failures.

Phase 5: National scale-up

Achieve full national programme rollout, sustainability and integration	Illustrative timeframe: Ongoing

Key activities

1. **Expansion and integration into routine service delivery.** Systematically expand LEN services to and integrate LEN as an additional HIV prevention option within all appropriate platforms (public facilities, private sector, community-based organizations, pharmacies) based on epidemiological need.

   Institutionalize community-based delivery through formal partnerships with community-based organizations and key population networks.

2. **Cascade provider training scale-up and workforce development.** Expand provider training nationwide through trainer-of-trainers cascades, targeting all cadres of providers (including doctors, nurses, midwives, clinical officers, pharmacists, community health workers and peer providers).

   Establish professional accreditation and/or certification requirements across all cadres. Identify additional opportunities for task shifting.

   Build capacity for local and regional training delivery to ensure sustainability beyond project phases.

3. **Continuous quality assurance and improvement.** Establish quality assurance and improvement frameworks at site and subnational levels and embed these into routine systems including for accreditation.

   Establish or utilize existing feedback loops for continuous quality assurance and programme improvement, ensuring linkages to the relevant technical working group for programme monitoring.

4. **Sustainability including domestic financing transition.** Secure multiyear domestic budget allocations for LEN products and service delivery.

Commence processes for LEN integration into universal health coverage and/or national health insurance schemes, as appropriate.

Establish sustainable financing mechanisms for community organizations, for example through social contracting or performance-based grants.[18]

Establish transparent budget tracking, demonstrating value for money.

Engage the private sector for complementary service delivery.

5. **Elimination of structural barriers.** Ongoing efforts, including during national scale-up, are needed to address stigma, criminalization, as well as geographic, economic, gender-based and age-related access barriers during national roll-out to support programme success. These barriers would have been identified during the Phase 1 situational analysis. As the programme expands, efforts may have to evolve in response to new products.

Critical considerations

Phase 5 involves the transition from early implementation to full, national scale-up. National implementation requires balancing speed with quality; prioritizing high-burden areas and underserved populations; maintaining an equity focus as services expand; ensuring domestic financing sustainability; and integrating LEN as one option within a mix of PrEP options.

National roll-out requires maintaining and adapting essential activities from earlier stages, including governance, stakeholder engagement, communications and demand generation, provider training, budgeting, procurement and supply chain, data systems, monitoring and evaluation, ongoing quality assurance, and human rights-focused efforts.

In addition to the health product costs, domestic financing must cover training, supervision, HIV testing, and demand generation to ensure equitable reach. To protect this expanded investment, countries must guard against a major risk: fragmentation of the prevention landscape. LEN must strengthen, not disrupt existing PrEP and HIV prevention programmes. Governance structures must ensure coordinated planning across the HIV prevention programme, transparent resource allocation, and protection of funding for proven modalities while scaling up new options. Community organizations must be appropriately resourced, ideally with domestic funding, to participate meaningfully in policy decisions and programme monitoring, not merely consulted retrospectively.

Lastly, LEN must be firmly embedded and integrated in the national HIV programme.

Successful LEN introduction requires balancing speed with preparation. It must uphold equity principles even during supply-limited and scale-up phases. It must engage communities meaningfully from the outset. And it must build adaptive systems that can incorporate future prevention innovations.

This guide provides a roadmap for countries to navigate those considerations and realize LEN's potential to fundamentally transform HIV prevention.

[18] *Scalable and sustainable primary HIV prevention models for people from key populations* provides illustrative models and best practices based on real-world examples that can support delivery of community-led models for HIV prevention including for LEN. See: https://www.unaids.org/en/resources/documents/2026/20260608_prevention_models_for_kps.

Annex 1. Rapid situational analysis

A comprehensive situational analysis identifies readiness factors, gaps, and opportunities for LEN introduction. This analysis should build on existing assessments, rather than create parallel processes. Countries applying for GC8 should leverage national HIV programme reviews to conduct such analyses.

Countries should synthesize findings to:

- **Identify critical gaps and bottlenecks** that could impede LEN introduction (e.g. regulatory delays, workforce shortages, supply chain weaknesses);
- **Prioritize readiness-building activities** based on which gaps are most urgent or feasible to address in Phases 1–2;
- **Inform preliminary decisions** on implementation approach, target populations, and geographic scope;
- **Develop Phase 2 detailed planning** with evidence-based strategies that build on strengths and address identified barriers;
- **Establish baseline metrics** for monitoring progress; and
- **Engage stakeholders** with concrete data to support resource mobilization and political commitment.

The expedited analysis should be documented in a report shared with decision-making bodies in the country (e.g. the prevention or PrEP technical working group that guides Phase 1 planning decisions).

The following elements should be assessed systematically.

1. Epidemiological assessment

Key questions

- What is the current HIV incidence and prevalence trend overall and by population?
- Which populations/geographic areas have the highest HIV incidence and/or number of new HIV infections?
- For populations and geographic areas with a high prevalence, what is the treatment coverage?
- What is the HIV prevention coverage by population and geographic area?
- What are current PrEP coverage levels (if applicable)? What are current PrEP targets?
- What is the rate of oral PrEP effective use and/or continuation rate (if applicable)?
- Are there populations for whom oral PrEP uptake has been suboptimal (e.g. people who inject drugs and their sexual/injecting partners, younger populations, migrants or refugees)?
- Any indication of interest/preferences for LEN based on survey data?

Potential data sources

- HIV surveillance among key populations and trends from antenatal care clinic data
- Epidemic modelling such as Spectrum (AIDSinfo.unaids.org)
- PrEP programme monitoring data

- Population size estimation studies for key populations
- Behavioural surveys (Integrated Bio-Behavioural Surveillance (IBBS)
- Demographic and Health Surveys (DHS), Population-based HIV Impact Assessment (PHIA), etc.
- Subnational HIV estimates (see Naomi-Spectrum.unaids.org)
- Subnational HIV estimates by key population (aidsinfo.unaids.org key population atlas)
- Research studies.

2. Health system assessment

Current PrEP service delivery landscape

Key questions

- What service types and locations offer PrEP services currently?
- Who provides services?
- What is current PrEP demand vs. capacity?
- What differentiated service delivery models have been successful for reaching different populations?

Workforce capacity

Key questions

- Who is authorized to deliver PrEP services and administer injections (doctors, nurses, midwives, clinical officers, pharmacists, community health workers, peer providers)?
- What is the current provider workload and capacity for additional services?
- What experience exists with injectable products (contraceptives, CAB-LA)?
- What task-shifting policies exist and are they feasible to implement? Are there restrictions on task-shifting?
- What is the capacity for provider training at scale?

Supply chain, storage and handling

Oral and injectable LEN formulations do not require cold chain (room temperature storage is adequate), which is a significant advantage over some other long-acting products. However, countries should consider the following questions as part of their assessment:

- What is the secure storage capacity at different levels of the health system?
- What inventory management systems are in place?
- What are the distribution logistics from central to service delivery points?

Building on the existing health system

Successful LEN introduction builds on existing strengths rather than creating parallel systems. Countries should identify and leverage established delivery platforms, provider networks, and community infrastructure that can be adapted for LEN services.

- What successful oral PrEP delivery models and provider networks exist?
- What experience exists with injectable contraceptive programmes (DMPA-SC, Sayana Press)?
- What long-acting HIV treatment experience is available (CAB-LA where relevant)?
- What community health worker networks and outreach capacity can be leveraged?
- What mobile or outreach services currently reach key populations?
- What monitoring and evaluation systems are in place for HIV prevention?

3. Policy and regulatory landscape

Key questions

- Is long-acting injectable PrEP included in the national strategic plan or HIV prevention strategy?
- Do the current national PrEP policies and guidelines include long-acting injectable PrEP, and LEN specifically?
- Who is eligible for PrEP? (e.g. are there stricter suitability criteria for accessing subsidized PrEP?)
- What regulatory approvals are needed for LEN introduction? What is the process and timeline for regulatory approval?[19]
- Is a Health Technology Assessment required for LEN introduction and reimbursement, and what are the processes, requirements and timelines?
- What is the current patent and intellectual property status of LEN and relevant companion products in the country?
- Are there data exclusivity, patent linkage, regulatory reliance, trade agreement or market-access provisions that could delay registration, importation, generic competition or procurement?
- What TRIPS-related flexibilities are available under national law, and what processes would be required to use them if needed to protect access?
- What domestic funding mechanisms and budget allocations exist for PrEP procurement and scale-up?

Documents to review

- National HIV prevention strategy
- HIV prevention roadmaps
- PrEP national guidelines
- Standard treatment guidelines
- HIV response sustainability roadmaps and plans
- National HIV programme reviews (e.g. WHO, PEPFAR, Global Fund, or other entities)
- HIV prevention self-assessment tools, developed by the Global HIV Prevention Coalition
- Essential medicines list
- Task-sharing and task-shifting policies and scope of practice regulations.

4. Financing and resource assessment

Key questions

- What is the current HIV prevention budget (total and per capita)?
- How is the HIV prevention budget allocated across health products (e.g. medicines, diagnostics), service delivery (e.g. clinical, outreach), provider remuneration, demand generation, monitoring and evaluation, and programme management?
- How is the HIV prevention budget allocated across different populations and geographies?
- In the current budget, what are the proportions of domestic and external funding?
- What proportions of PrEP services are currently funded through e.g. government budgets, external donors, national health insurance, private insurance, and out-of-pocket payments?
- Do national health insurance or social health insurance schemes cover PrEP? If “yes”, what is the coverage scope (products only, or including services and monitoring)?

[19] Countries should engage the regulatory authorities early to understand timelines and requirements, and to have access to data included in dossiers which they can access through mechanisms such as CRP/EU-M4all.

- What role do private health insurance schemes play in PrEP provision, and could they support LEN scale-up?
- Are there any upcoming funding or budget transitions (Global Fund grant cycles, PEPFAR planning)?
- Is there political commitment for domestic resource allocation to new health technologies, including prevention?
- What funding mechanisms exist for community-based organizations that deliver HIV prevention services (e.g. social contracting, direct grants, subcontracts)?
- Are community-based and other civil society organizations funded to deliver LEN-related services, and if so, through what mechanisms?
- How is demand generation for PrEP currently funded, and what resources would be needed for LEN demand creation activities?
- Is the country eligible for voluntary licensing, donor-supported concessional pricing, donor-mediated pooled procurement mechanisms (e.g. the Global Fund's WAMBO platform), and/or other affordable access arrangements for LEN?
- If the country is not eligible for concessional pricing or access agreements, can it use compulsory licensing pathways, such as TRIPS flexibilities, region-based pooled procurement mechanisms (e.g. the PAHO strategic fund), engagement via the Medicines Patent Pool, or direct price negotiation with the manufacturer on their own behalf or jointly with neighbouring countries?
- What health technology assessment is required for financing decisions?
- What is the budget allocation process and decision-making timeline?

Critical planning requirement: comprehensive costing data for modelling

Country consultations identified the need for detailed costing information as essential for meaningful introduction planning and modelling. This includes:

- LEN pricing scenarios, recognizing that final prices may vary by procurement mechanism and volume;
- HIV product costs such as diagnostic tests (HIV testing, creatinine, pregnancy tests), other PrEP options, treatment regimens;
- Service delivery costs such as clinical consultations, counselling, adherence support, monitoring visits;
- Programme costs such as training, supervision, demand generation, community mobilization, pharmacovigilance; and
- Infrastructure and system costs, such as storage, waste management, supply chains and data systems.

5. Community engagement, accountability and demand generation

Community engagement should be assessed as an operational function across the entire LEN introduction continuum.

Key questions

- What is the awareness and/or acceptability of injectable PrEP? How does this compare with other HIV prevention and PrEP options?
- What aspects of LEN (e.g. long-acting dosing, convenience, efficacy) resonate most with target populations and how can these benefits be communicated in ways that generate interest and demand?

- What delivery models would be most acceptable and accessible to target populations?
- What are the key concerns and cited potential benefits about LEN?
- What community-led monitoring and feedback mechanisms will be used, and how will findings influence programme decisions and accountability?
- What roles do community-led organizations currently have in HIV prevention programmes and PrEP delivery?
- What formal roles, resources, funding mechanisms or agreements are needed for community organizations to participate meaningfully in LEN introduction planning, training, demand creation, service delivery, monitoring, accountability and scale-up?

Methods

- Insights from research examining values and preferences or experience in PrEP use.
- Focus group discussions with populations that can benefit from LEN access.
- In-depth interviews with community leaders and influencers.
- Reviews of community consultations from oral PrEP, dapivirine ring and/or CAB-LA introduction, where relevant.
- Social media listening and digital engagement (where appropriate).
- Consultations with PrEP champions and peer navigators, as well as community-led organizations for people living with HIV.

Annex 2. Impact modelling and cost effectiveness

Mathematical modelling is useful for informing LEN introduction decisions. It can be used to project both epidemiological impact (e.g. HIV infections averted) and economic value (e.g. cost-effectiveness, return on investment, allocative efficiency).

Countries should conduct modelling exercises during Phase 1 to support evidence-based targeting, budgeting, and stakeholder engagement. Ideally, LEN should not be modelled independently but rather as one option within the HIV prevention method mix. The examples presented here are based on a consultation held in June 2025 (UNAIDS-Gates Foundation consultation).[20]

1. Why model LEN introduction?

Modelling can address key policy and programme design questions, including:

- What volume of LEN is needed to meaningfully reduce HIV incidence in our context?
- Which populations and geographies should be prioritized for maximum impact?
- How does LEN introduction affect the optimal prevention method mix?
- Modelling provides directional estimates (guidance on how much impact can be expected) which can guide planning and which should be updated as new implementation data become available. Modelling should not delay implementation.

2. What are the potential approaches to modelling LEN?

Targeting scenarios. Model universal access versus risk-prioritized versus key-population-focused approaches.

HIV incidence impact. Impact modelling estimates the number of infections averted under different LEN implementation scenarios, considering local epidemic dynamics and existing prevention coverage. Critical modelling parameters include:

- coverage scenarios,
- population prioritization,
- product mix optimization,
- persistence assumptions, and
- practical Implementation

Cost-effectiveness analysis. Cost-effectiveness modelling can determine the maximum per-person-per-year cost at which LEN remains cost-effective in your setting. Cost-effectiveness improves dramatically with risk-based targeting. Key considerations include:

[20] Consultation on the projected impact and cost-effectiveness of long-acting injectable lenacapavir as pre-exposure prophylaxis: a meeting in collaboration with the Gates Foundation. Geneva: UNAIDS; 2025. Available at: https://jointsiwg.unaids.org/wp-content/uploads/2025/09/LEN-meeting-report-30Aug2025.pdf.

- At what price point is LEN cost-effective compared to oral PrEP and other prevention investments?
- What is the budget impact on the overall PrEP programme?
- Price threshold analysis. At what per-person-per-year cost does LEN meet cost-effectiveness thresholds?
- Service delivery costs. Include health product costs plus provider time, HIV testing, training, and demand creation. LEN's twice-yearly dosing may substantially reduce delivery costs compared to more frequent oral PrEP or CAB-LA visits.
- Budget impact. Assess total programme costs over 3–5 years across different coverage scenarios to demonstrate that LEN introduction causes no harm to the overall prevention budget.

Essential model inputs. Countries need four categories of data:

- epidemiological data (age-sex-specific HIV incidence, key population size estimates, current PrEP coverage);
- LEN parameters (96–100% efficacy from PURPOSE trials, anticipated uptake and persistence rates);
- cost data (product price scenarios including projected generics at US$ 41–96 per-person-per-year, service delivery costs, programme costs); and
- existing prevention coverage (oral PrEP, condoms, voluntary medical male circumcision, antiretroviral treatment coverage and viral suppression rates).

3. What tools are available to support LEN modelling?

Table 1 provides a list of existing tools to help understand the epidemiological impact of introducing LEN in different populations and geographic areas. Support for using these models and adjusting them to match current contexts is available from multiple organizations (see Table 1).

Countries should use existing tools where possible to avoid delays. Options include the PrEP-it tool (the UNAIDS country planning tool is being updated for LEN in 2026); the Goals model (deterministic compartmental model used in multiple countries, available through UNAIDS); EMOD-HIV (agent-based model for detailed population dynamics); and country-specific models such as Thembisa in South Africa. Countries should engage UNAIDS, WHO, or academic partners for technical support in model selection and implementation.

Once the impact modelling is completed it is important to then layer on a cost-effectiveness analysis.

Table 1.

Available modelling to help determine potential impact of LEN roll-out and take informed decisions on costs

Model / tool	Key features & advantages	Limitations
Goals	▪ Deterministic model of HIV transmission to address key questions for strategic planning. ▪ Applied worldwide for UNAIDS Global AIDS Strategy, resource needs modelling, national strategic plans, investment cases and Global Fund applications.	▪ Not fully age-structured. ▪ Limited network dynamics. ▪ Large number of country files

	▪ Most countries have already received training to use the model.	means less attention to each. ▪ No subnational estimates.
PrEP-it	▪ Decision-making and analysis tool for target setting, cost forecasting, estimating impact, and product forecasting. ▪ Can be applied at national, subnational, donor, implementer or site level, multiple PrEP methods. ▪ Currently available for 48 countries.	▪ Does not model incidence over time. ▪ Does not address every planning need for PrEP programmes. ▪ Does not support all low- and middle-income country settings.
Gates Foundation simple model	▪ Simple equations to estimate impact, cost-effectiveness, and budget impact of HIV prevention interventions. ▪ Allows for multiple interventions and heterogeneity in risk.	▪ Does not include the complexity of dynamic models, including lack of indirect effects of preventing an infection. ▪ Costs and health metrics are averages across populations.
Naomi and SHIPP tool	▪ Bayesian small-area estimation model that provides subnational estimates of HIV incidence, prevalence, and antiretroviral treatment coverage. ▪ Stratified by sex and 5-year age group (SHIPP tool also by behavioural categories). ▪ Provides short-term projections for programme planning. ▪ Webtool used annually by 39 countries available at naomi-spectrum.unaids.org. ▪ Subnational HIV Estimates in Priority Populations Tool | GPC	▪ Extrapolates spatial incidence from prevalence of viraemia. ▪ Complex and computationally intensive to run. ▪ Direct measures of HIV incidence at small areas impractical. ▪ Is a model input for programmatic decision-making.
Forecasting tools	▪ UNAIDS/WHO Annual Forecasting Consultation with Pharmaceutical Companies involves the participation of key stakeholders (Global Fund, Unitaid, Medicines Patent Pool, procurement agencies, governments and civil society, among others). ▪ Unitaid Checklist of key product-specific supply chain considerations.	▪ Tools in ongoing development. ▪ Specific to individual country needs, so may be poorly generalisable to other countries / contexts.

	▪ Simple, adaptable quantification tool to allow for country-specific inputs and accounting for current stock for supply chain forecasting.	
Global Prevention Coalition package for prevention prioritization	▪ Slide deck on right populations, interventions, locations, modalities and cost for prevention. ▪ Simple spreadsheet to roughly estimate cost-effectiveness of different options. ▪ Both are available at: Supporting Prioritization in the Context of HIV Funding Cuts | GPC	▪ Cost-effectiveness spreadsheet requires reliable country-specific inputs and is not a dynamic model for tracking intervention interactions.

4. Data sources

- Existing PrEP programme data (initiations, continuation rates, costs)
- Community consultations and key population size estimates
- National Health Accounts and budget documents
- Health facility assessments and service delivery mapping
- WHO costing tools and templates
- PrEP-it model outputs for demand forecasting
- National HIV surveillance data and UNAIDS estimates

5. Key considerations for countries

Do not wait for perfect data. Models can inform decisions even with uncertainty. Use sensitivity analyses to bound estimates and identify key drivers. Model various choices, not just LEN, since the optimal PrEP product mix provides more actionable insights than modelling LEN in isolation.

Link modelling to planning. Ensure that findings directly inform target setting (Section 4.6), site selection (Phase 2), and evaluation frameworks (Phase 4). Given pricing uncertainties, always conduct threshold analyses to determine maximum affordable per-person-per-year cost.

Risk-based targeting maximizes efficiency. Models consistently show that prioritizing populations at highest risk of HIV acquisition produces substantially greater impact and better cost-effectiveness than untargeted approaches.

Build capacity for iterative modelling. LEN introduction is dynamic. Train local teams to update models as real-world data becomes available from implementation.

Annex 3. Incorporating LEN into a monitoring and evaluation framework

Robust monitoring and evaluation systems are essential for safe and effective LEN introduction. Countries should build on existing HIV strategic information frameworks, integrating LEN-specific indicators into national systems rather than creating parallel structures. During early introduction and scale-up it will also be important to be able to systematically capture and analyse implementation data to adapt implementation in real-time.

1. Multi-level monitoring approach

Monitoring systems should operate at multiple levels, with distinct but complementary roles. At the **clinic/facility level**, service providers must capture individual-level longitudinal data through electronic medical records or client management systems, documenting injection dates, adverse events, continuation status, and HIV testing results.

Those granular data support clinical decision-making, individual client management, and detection of safety signals. Facility-level monitoring should align with WHO's person-centred HIV strategic information guideline, which emphasizes individual-level data collection that captures clients' movements across products and services over time.

At the **district and regional levels**, aggregated data from facilities should be compiled to identify trends, monitor programme performance, and support supervision activities. The national level focuses on strategic indicators for policy decisions, resource allocation, and international reporting through Global AIDS Monitoring frameworks. Not all indicators collected at facility level need routine national reporting. Countries should prioritize essential indicators that inform programme management and policy while minimizing reporting burden.

2. Enhanced versus routine monitoring

Countries should implement a dual monitoring strategy.

Enhanced monitoring at sentinel sites involves proactive, intensive data collection with dedicated capacity-building and mentoring to generate high-quality safety data with denominators. This approach is critical for detecting rare or delayed adverse events, monitoring outcomes in populations who are underrepresented in clinical trials (e.g. adolescents, pregnant women, key populations) and characterizing long-term toxicities. The WHO toolkit for monitoring safety and toxicity of injectable LEN provides standardized tools, core data elements, and implementation guidance for enhanced monitoring at sentinel sites.

Routine monitoring embeds LEN surveillance in existing national HIV monitoring and evaluation systems, capturing data during standard service delivery. This approach tracks programmatic indicators across all service delivery points, enabling population-level assessment of LEN uptake, persistence and outcomes. The WHO LEN guidelines specify a

minimum dataset for routine monitoring (Table 2), which should be captured in national data systems for all PrEP products including LEN.

3. Community-led monitoring

Community-led monitoring (CLM)[21] is an accountability mechanism for HIV responses. It is led and implemented by community-led organizations of people living with HIV, key population networks, and other affected groups. CLM uses trained peer monitors to systematically collect qualitative and quantitative data on service quality, including people not accessing healthcare, and it establishes rapid feedback loops with programme managers and decision-makers. For LEN, CLM is particularly important given the twice-yearly dosing schedule which reduces the frequence of facility contact. CLM can capture user experiences which are often missed by routine health information systems, as well as document adverse events and hold programmes accountable for quality of care. Community feedback should directly inform programme adaptation and quality improvement.

4. Core indicators

Core indicators can capture: initiation rates (disaggregated e.g. by population, product, geography); on-time re-injection rates (follow-up injections for LEN are scheduled every 26 weeks with a +/- two-week window); persistence on LEN (e.g. at 6 and 12 months); adverse events (e.g. pregnancy and infant-related, severe injection site reactions, drug-drug interactions and events leading to LEN discontinuation); HIV seroconversions; and drug resistance. Countries should also monitor user satisfaction and choice, including product switching patterns, as individuals may transition between oral PrEP, DVR CAB-LA, and/or LEN based on changing needs and preferences.

5. Monitoring in pregnancy and breastfeeding

Given the limited data on LEN safety during pregnancy and breastfeeding, enhanced surveillance of pregnancy outcomes is essential. Countries should consider implementing sentinel site monitoring using standardized protocols from WHO's antiretroviral pregnancy research toolkit, which provides harmonized definitions for adverse pregnancy outcomes, including: miscarriage, stillbirth, preterm birth, low birth weight, and congenital anomalies. Where feasible, countries may establish pregnancy exposure registries or adapt existing birth outcome surveillance systems to include LEN.

6. Integration and interoperability

LEN monitoring should integrate into existing HIV information systems, pharmacovigilance platforms, and routine data collection mechanisms. Digital systems should capture longitudinal individual-level data while enabling aggregation for programme reporting.

Systems must accommodate the unique characteristics of long-acting PrEP, including: biannual dosing intervals; the need for appointment tracking and reminder systems; the potential for delayed adverse events requiring long-term follow-up; and management of clients who miss injection windows. Systems must also accommodate switching between PrEP options.

[21] The UNAIDS *Community-led monitoring in action: Emerging evidence and good practice report* synthesizes the available information on the value of community-led monitoring in four key areas: HIV and health services; creating an enabling environment; community systems strengthening; and crafting better-defined policies and investments. See: https://www.unaids.org/sites/default/files/media_asset/JC3085E_community-led-monitoring-in-action_en.pdf.

Data should flow bidirectionally, i.e. upward for surveillance and accountability, and downward to inform clinical care and quality improvements (including twice-yearly dosing intervals; need for appointment tracking and reminder systems; potential for delayed adverse events requiring long-term follow-up; and management of clients who miss injection windows).

7. Learning and adaptation

Technical working groups should establish clear processes to capture, analyse, report and act on implementation data as part of continuous quality assurance and improvement throughout LEN introduction and scale-up. Monitoring and review should be most intensive during early implementation, then transition to routine programme management as LEN becomes embedded in-service delivery.

7.1 Data collection and analysis

Collect and analyse indicators from the monitoring and evaluation framework at appropriate intervals, with more frequent review during early implementation. Disaggregate findings by site, population, delivery model and geography to identify trends, implementation challenges, inequities and promising practices.

- **Dashboards integration.** Establish integrated data dashboards that provide real-time visibility of key implementation indicators. Dashboards should enable disaggregated analysis by site, population group, delivery model, and geographic area. Include visualization tools for tracking uptake trends, retention rates, adverse events, and supply chain indicators. Ensure that dashboards are accessible to relevant stakeholders at national, regional and site levels.
- **Technical working group review.** The technical working group should conduct regular reviews of implementation data, with monthly reviews during early implementation (first 6 months) and quarterly reviews thereafter. The Group's meetings should systematically examine data quality, analyse trends and patterns, identify implementation challenges, and recommend corrective actions. The Group should prepare data interpretation briefs for governance structures to inform strategic decision-making.
- **Governance structure review and programme adjustments.** National governance structures should regularly review implementation data and technical working group recommendations at least every three months. Those reviews should lead to timely programme adjustments, including modification of targeting strategies, reallocation of resources to higher-performing sites, enhancement of training and support for underperforming areas, and refinement of service delivery models based on user feedback and outcomes data. Establish clear decision-making pathways and timelines for translating data insights into programmatic action.

7.2 Implementation research

Conduct focused implementation research on priority questions that can directly improve programme delivery and decision-making. Methods may include mixed-methods studies, cost analyses and qualitative research with LEN users, providers and communities.

7.3 Learning collaboratives

Establish forums for delivery sites to share experience, compare results and solve common implementation problems. Connect country learning to regional and global networks, and disseminate relevant findings through appropriate reports, publications and conferences.

7.4 Adaptive management

Use monitoring, community feedback and research findings to refine protocols, training, resource allocation and delivery models in a timely manner. Give sites appropriate flexibility to adapt within nationally agreed standards, with changes documented and reviewed through established governance processes.

Annex 4. LEN implementation tools and resources compendium

Table 2 summarizes key tools and resources that are available to support countries with LEN implementation. The tools are publicly available and have been developed through coordinated efforts between AVAC, CHAI, CIFF, the Global Fund, PEPFAR, PSI, Unitaid, Wits RHI and WHO, under the Coalition to Accelerate Access to Long-Acting PrEP. For the most up-to-date tools and additional resources, visit PrEP Watch (https://www.prepwatch.org) and AVAC's LEN resource page (https://avac.org/lenacapavir/).

Table 2.

Tools and resources to support countries with LEN implementation

Category	Tool/resource	Purpose	Link
Normative guidance	WHO guidelines on LEN for PrEP (July 2025)	WHO guidelines provide a basis for the development of national guidelines.	https://www.who.int/publications/i/item/9789240111608
Normative guidance	WHO LEN safety and toxicity monitoring toolkit	WHO adaptable toolkit for monitoring LEN safety and toxicity, including in pregnancy and breastfeeding	
Normative guidance	Standard operating procedure (SOP) for LEN for PrEP	Adaptable SOP supports development of national SOPs aligned with WHO guidelines.	https://www.hivinterchange.com/blog/lenacapavir-prep-rollout-a-standard-operating-procedure-template-available-for-countries
Normative guidance	Template for technical working group terms of reference	Template to aid in setting up a technical working group to develop national LEN guidelines.	https://www.prepwatch.org/wp-content/uploads/2016/10/TWG_ToR_Template.pdf
Normative guidance	Policy review tool for WHO-aligned HIV prevention service delivery	For assessing whether national LEN guidelines are comprehensive, equitable and aligned with current WHO guidance, and to identify opportunities for improvement.	https://www.prepwatch.org/resources/policy-review-tool-for-who-aligned-hiv-prevention-service-delivery/

Planning Monitoring & evaluation	PrEP-it	Web-based tool to set PrEP targets, estimate costs/impact, identify priority areas, and forecast health products.	https://www.who.int/tools/prep-it
Provider training	WHO and Jhpiego provider training toolkit	Toolkit for training clinicians to provide multiple PrEP methods, including LEN.	https://new.express.adobe.com/webpage/c1ob5FqyHxfrE
Provider training	LEN provider tools and job aids	Editable tools including client fact sheets, counselling job aids, and charts for initiation, injection or switching.	https://www.prepwatch.org/resources/lenacapavir-provider-tools-and-job-aids/
Site assessment	PrEP site implementation and new product readiness assessment tool	For assessing and improving existing PrEP services and prepare for optimal delivery of new products like LEN.	https://www.prepwatch.org/resources/prep-site-assessment/
Site assessment	Site readiness assessment template	Adaptable template to determine which sites are ready to begin delivering LEN.	https://www.prepwatch.org/resources/site-facility-readiness-assessment-tool-to-support-lenacapavir-for-hiv-prevention-introduction/
Monitoring and evaluation	WHO Consolidated guidelines on person-centred HIV strategic information	Standard minimum dataset, priority indicators, and recommendations to develop LEN indicators.	https://www.who.int/publications/i/item/9789240055315
Monitoring and evaluation	PrEP clinical reporting tools	This suite of clinical reporting forms, developed by South Africa's National Department of Health, can be used for PrEP reporting, including injectable LEN.	https://www.prepwatch.org/resources/prep-clinical-reporting-tools/
Monitoring and evaluation	HIV drug resistance (HIVDR) monitoring toolkit	Assists in developing HIVDR monitoring strategies for LEN PrEP users.	https://www.prepwatch.org/resources/mosaic-hiv-drug-resistance-monitoring-program/

Demand generation	HIV prevention ambassador training package and toolkit	This toolkit can prepare potential and current PrEP users to be leaders or “ambassadors” in the roll-out of PrEP for HIV prevention in their communities. It has been updated to include LEN.	https://www.prepwatch.org/resources/ambassador-training-package-toolkit/
Advocacy	An advocates’ checklist for Lenacapavir for PrEP introduction	Checklist designed to support faster, community-centred roll-out ahead of broader generic availability in 2027.	https://avac.org/resource/len-intro-checklist/

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