

EpiC Supports Countries to Develop Policies and Guidelines for HIV Pre-exposure Prophylaxis

SUCCESS STORY | OCTOBER 2023

EpiC has helped create an enabling environment for PrEP access in many countries, owing to the global nature of the project and the regular exchange of lessons at regional and interregional levels. The project is preparing to use these lessons learned to support the future rollout of new HIV prevention methods, including injectable cabotegravir.

Background and Context

Clinical trial research began showing antiretroviral (ARV) pre-exposure prophylaxis (PrEP) as effective for preventing new HIV infections in 2010.¹ Since then, additional ARVs have joined the list of options, and drug delivery mechanisms for PrEP have expanded from oral pills to include a vaginal ring and, most recently, a long-acting injectable.

However, getting PrEP from research to implementation has been a lengthy process. At the global level, the World Health Organization (WHO) has led by developing recommendations for PrEP implementation, incrementally expanding its recommendations on user populations, eligibility requirements, regimens, and methods as new evidence emerges.² Country-by-country approvals of PrEP methods and drugs, as well as realization of the other [requisites for PrEP product introduction](#) (i.e., policies, plans, and budgets; supply chain management, delivery issues, and best practices; promotion of uptake and demand; and monitoring and evaluation systems), have moved unevenly.

Also critical to PrEP access is the development of country policies and guidelines. This process includes deciding who will be able to access PrEP and where, incorporating PrEP into national guidelines on HIV services, updating the guidelines to reflect the latest WHO recommendations, and developing standard operating procedures (SOPs), among other steps. Country ministries of health (MOHs) leading these efforts often invite a range of HIV stakeholders to participate in the process, as a breadth of experience and expertise ensures that each country's PrEP guidelines are grounded in both global science and local context.

One contributor to PrEP policy and guideline development in sub-Saharan Africa and the Asia-Pacific region is the Meeting Targets and Maintaining Epidemic Control (EpiC) project through its work with national and local governments. Funded by the United States Agency for International Development (USAID) and the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) and led by FHI 360, EpiC provides technical assistance to countries in a range of technical areas as governments seek to close the gaps in their HIV cascade to achieve epidemic control (Box 1).

Box 1. EpiC Project Description

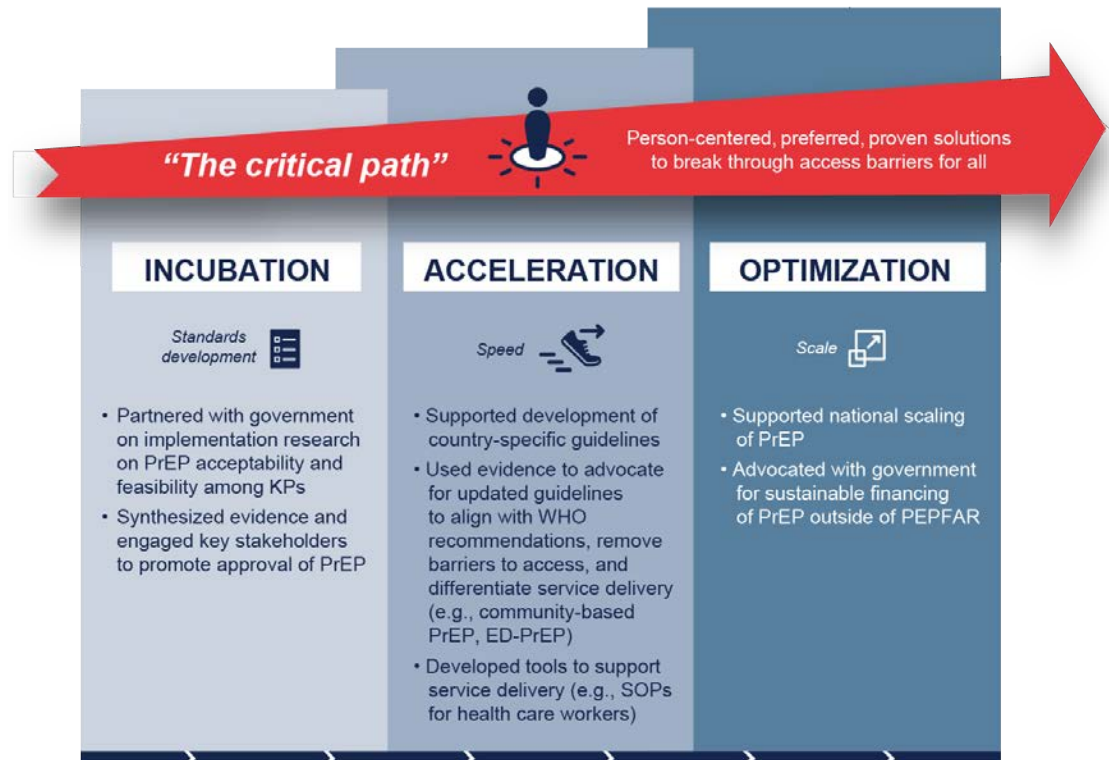
The USAID- and PEPFAR-funded Meeting Targets and Maintaining Epidemic Control (EpiC) project is an eight-year global initiative led by FHI 360 with core partners Right to Care, Palladium International, and Population Services International (PSI) that provides strategic technical assistance and direct service delivery to achieve control of the HIV epidemic and promote self-reliant management of national HIV programs—specifically by improving case finding,

prevention, treatment programming, and viral load suppression. The EpiC project partners with and strengthens the capacity of governments, civil society organizations, other PEPFAR implementing partners, and the private sector to introduce innovations and expand evidence-based HIV services to unprecedented levels of scale, coverage, quality, effectiveness, and efficiency. EpiC has supported PrEP implementation in more than 30 countries.



Interventions

EpiC's role in policy and guideline development has varied by country in response to need. For example, via technical assistance to MOHs, advocacy, and participation in technical working groups (TWGs), EpiC has supported the development of national PrEP guidelines, piloting and developing SOPs for oral PrEP, decentralized service delivery, telePrEP services, and jumpstart strategies for PrEP. Whatever the project's specific contributions in a country, the desired impact across contexts is the same: to help lay the groundwork for PrEP availability and create an enabling environment for PrEP services.



Results and Impact

Three countries with notable EpiC support in PrEP policy and guideline development are Malawi, Nepal, and Thailand, as described below. Highlights of the project's contributions in other countries are shown in Box 2.

Box 2. Highlights of EpiC Project Contributions to PrEP Policies and Guidelines

EpiC has supported global and country development of PrEP policies and guidelines in diverse ways, including:

- **Burundi:** Worked with in-country stakeholders to develop PrEP operational guidelines using the [PrEP guidelines template](#) (2020).
- **Eswatini:** Worked with the MOH to draft and finalize the SOP for event-driven PrEP (ED-PrEP) for men who have sex with men (MSM) (2021); updated national PrEP guidelines to include ED-PrEP, dapivirine ring (DVR), and CAB-LA (2021); and drafted new national PrEP guidelines (2022) using the PrEP guidelines template.
- **Ghana:** Engaged the National PrEP and HIV Self-Testing Implementation Committee and WHO to draft the guidance document ABC of Ghana PrEP Implementation Guide (2020) using the PrEP guidelines template, revised the document to reflect WHO's 2021 updated PrEP guidance (2021–2022), and implemented the 2020 guidance document's policy on ED-PrEP for MSM (2022). Also supported the inclusion of cabotegravir as long-acting injectable PrEP in the updated guidance document (2021).
- **Vietnam:** Through participation in the national HIV TWG as a key member, assisted the government to update the national PrEP guidelines (2020) and develop telePrEP guidance to improve client access to online PrEP follow-up and prescriptions for PrEP (2022). Also provided inputs for the mid-term assessment to evaluate the effectiveness of the telePrEP pilot.
- **WHO guidance:** Contributed to the systematic review of evidence that included data on creatinine clearance and PrEP from the Linkages across the Continuum of HIV Services for Key Populations Affected by HIV (LINKAGES)/EpiC demonstration projects in Malawi, Nepal, and Eswatini, the results of which informed the global body's recommendations about requirements for creatinine clearance among various age groups.

Malawi

EpiC Malawi has supported the MOH to put in place several foundational pieces needed to deliver oral PrEP as an essential HIV service. Oral PrEP was first included in the national HIV guidelines in 2018, following a recommendation by the MOH HIV Prevention TWG. The TWG gave EpiC the mandate to conduct an implementation science study on PrEP acceptability and the feasibility of integrating PrEP in public clinics to inform MOH decision-making. The first clients were initiated in the PrEP study in February 2019, and the following year, EpiC's study findings informed MOH revision of the guidelines to include SOPs for health care workers.

In 2020, the country's resources and attention shifted toward the COVID-19 threat, and the MOH suspended all new client initiations on PrEP. This move was reversed a few months later, when PrEP was reclassified as an essential HIV service. As per WHO guidelines, EpiC recommended that the MOH switch from monthly PrEP refills to multimonth dispensing (MMD) for all individuals at substantial risk of HIV acquisition; this change was made, and MMD of PrEP remains MOH policy.

The project has also provided technical assistance to the MOH in the revision of PrEP guidelines for health care workers and development of a PrEP Community Strategy. Through advocacy efforts, EpiC Malawi has supported the MOH to modify Malawi's PrEP guidelines as new scientific evidence emerges. When WHO updated its PrEP guidance in 2021 and 2022 to phase out the requirement for creatinine clearance in PrEP initiation,^{3,4} EpiC presented the scientific justification to the MOH and successfully advocated for removal of the requirement through an addendum to Malawi's PrEP guidelines. EpiC Malawi has also provided technical assistance through the preparation of technical briefs for the senior management team at the Department of HIV and AIDS, informing their approval of ED-PrEP, and in the development of ED-PrEP SOPs for health care workers.

Nepal

“Oral HIV PrEP was introduced in Nepal as part of demonstration study in November 2018 to June 2019 conducted by United States Agency for International Development (USAID) and The U.S. President's Emergency Plan for AIDS Relief (PEPFAR)-supported LINKAGES Nepal project in collaboration with NCASC and National Public Health Laboratory (NPHL). Based on the findings and recommendations of the study, National HIV Testing and Treatment Guidelines 2020 recommended PrEP as an alternative approach of HIV prevention. PrEP is currently being provided from USAID- and PEPFAR-supported nongovernment organization (NGO) sites. I would like to acknowledge the technical support provided by USAID- and PEPFAR-supported Epic Nepal project for coordinating and drafting these standard operating procedures.”

—Dr. Sudha Devkota, Director, National Centre for AIDS and STD Control, Nepal,
from foreword of National Standard Operating Procedure for Implementation
of Oral HIV Pre-exposure Prophylaxis in Nepal, NCASC 2022

EpiC Nepal supported the government to lay the groundwork for oral PrEP rollout in a stepwise manner, including through advocacy and research. Linkages across the Continuum of HIV Services for Key Populations Affected by HIV (LINKAGES), the predecessor project to EpiC, helped introduce PrEP as a new approach in the country by sensitizing government and key population (KP) stakeholders (e.g., MSM and transgender people). Government stakeholders and LINKAGES/EpiC staff were then co-principal investigators for a PrEP demonstration project in Kathmandu Valley on the feasibility and acceptability of oral PrEP among KP individuals. At the close of the project, EpiC began small-scale implementation of PrEP in Kathmandu Valley in late 2020, followed by scale-up to all 19 PEPFAR-supported districts.

Results of the project and lessons from EpiC-supported PrEP implementation helped form the basis for the country's PrEP guidelines. Working closely with the National Centre for AIDS and STD Control (NCASC) and the Ministry of Health and Population (MOHP), EpiC Nepal drafted the PrEP section of the National HIV Testing and Treatment Guidelines, 2020, and in 2022 provided technical support to reflect WHO's 2021 updated recommendations.³ EpiC's technical assistance also supported the development of the National HIV Strategic Plan 2022–2026 and target setting for PrEP implementation. EpiC is currently rolling out ED-PrEP at some sites, the lessons from which will inform national decision-making and updates to guidelines.

SOPs and job aids are other areas where EpiC Nepal has provided technical assistance. EpiC supported the MOHP to develop and finalize the national SOP for oral PrEP implementation in 2022, which includes MMD. In addition, EpiC worked with NCASC to adapt the project's PrEP-related job aids and guidelines, and a tool being used in their DHIS2-based National HIV Information System to record and report PrEP service delivery for future use in PrEP implementation at the national level.

Thailand

After approving oral PrEP in 2016, the Government of Thailand added the method to the HIV guidelines in 2017. EpiC Thailand has been a strong contributor to the development of policies and guidelines governing PrEP access in the country. As in Nepal, co-led research on PrEP implementation among KPs in Thailand has established a scientific evidence base grounded in local context to inform decision-making and policy development for KP-led PrEP service provision in the country. For example, some research has focused on the epidemiological impact and cost-effectiveness of KP-led PrEP services,⁵ while another study identified factors in nonadherence under this model among subpopulations of users.⁶

Notably, drawing on the research findings and EpiC's experience supporting PrEP implementation in Thailand, the project helped shape policy to make community-based PrEP services available in Thailand, rendering oral PrEP a more feasible option for many individuals.

Currently, EpiC Thailand and its partners are leveraging their experience and EpiC Asia regional funds to help other countries in the region create an enabling environment to deliver PrEP services. In Laos, for example, they helped write the national PrEP guidelines. In the future, EpiC Thailand seeks to convince the government to provide reimbursements for their PrEP operational costs of around US\$35 (not including laboratory, test kit, and PrEP), much as they do for HIV testing costs under the national universal health coverage scheme.

Reflections and Lessons Learned

Researchers, public health stakeholders, country ministries, local partners, and technical assistance projects like EpiC have a challenging job when it comes to achieving PrEP access. To make PrEP a tangible option, they must weave together the science on PrEP for HIV prevention, the realities of health systems and potential user populations, and budget and human resource constraints, among so many other elements. Furthermore, this process must be repeated individually in every country.

EpiC is privileged to be one of the many players with strengths to contribute to the process. The common thread in the project's technical assistance across countries is its grounded application of the science within local health systems. In some countries, EpiC has been involved in multiple steps prior to larger-scale PrEP service delivery, as in Nepal and Thailand. There, EpiC and its partners have been able to start small with PrEP implementation, respond to challenges, and modify and adjust the strategies and tools used prior to the development of national policies and guidelines. In other countries, EpiC has played a technical assistance role at later stages.

Regardless of when and how EpiC has become involved in creating an enabling environment for PrEP access, the global nature of the project and the regular exchange of lessons at regional and interregional levels have made it a valuable contributor. EpiC is preparing to use these lessons learned to support the future rollout of new HIV prevention methods, including injectable cabotegravir. (For example, see factsheets on injectable cabotegravir developed for [MSM](#) and [transgender and non-binary](#) communities in the Asia Pacific region.)

Suggested citation:

EpiC. Success story: EpiC supports countries to develop policies and guidelines for pre-exposure prophylaxis. FHI 360: Durham (NC); 2023.

¹ Grant RM, Lama JR, Anderson PL, McMahan V, Liu AY, Vargas L, et al. Preexposure chemoprophylaxis for HIV prevention in men who have sex with men. *N Engl J Med*. 2010;363(27):2587–99.

² World Health Organization (WHO). Global HIV Programme: pre-exposure prophylaxis publications. Geneva: WHO; 2012–2022. Available from: <https://www.who.int/teams/global-hiv-hepatitis-and-stis-programmes/hiv/prevention/pre-exposure-prophylaxis>.

³ World Health Organization (WHO). Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach. Geneva: WHO; 2021. Available from: <https://www.who.int/publications/i/item/9789240031593>.

⁴ World Health Organization (WHO). Differentiated and simplified pre-exposure prophylaxis for HIV prevention: update to WHO implementation guidance. Technical document. Geneva: WHO; 2022. Available from: <https://www.who.int/publications/i/item/9789240053694>.

⁵ Versteegh L, Amatavete S, Chinbunchorn T, Thammasiha N, Mukherjee S, Popping S, et al. The epidemiological impact and cost-effectiveness of key population-led PrEP delivery to prevent HIV among men who have sex with men in Thailand: a modelling study. *Lancet Reg Health Southeast Asia*. 2022 Oct 29;7:100097.

⁶ Seekaew P, Nguyen E, Sungsing T, Jantarapakde J, Pengnonyang S, Trachunthong D, et al. Correlates of nonadherence to key population-led HIV pre-exposure prophylaxis services among Thai men who have sex with men and transgender women. *BMC Public Health*. 2019;19(1):328.

For inquiries, please contact  Hally Mahler, EpiC Project Director: hmahler@fhi360.org

This factsheet is made possible by the generous support of the American people through the United States Agency for International Development (USAID) and the U.S. President's Emergency Plan for AIDS Relief (PEPFAR). The contents are the responsibility of the EpiC project and do not necessarily reflect the views of USAID, PEPFAR, or the United States Government. EpiC is a global cooperative agreement (7200AA19CA00002) led by FHI 360 with core partners Right to Care, Palladium International, and Population Services International (PSI).