

Next-Generation M&E for Next-Generation PrEP

Country experiences rolling out oral PrEP have exposed gaps in our current ability to monitor and assess who is using PrEP, how they use it, and how to assess whether PrEP programs effectively reduce HIV risk for individuals and communities. This information is essential to ensure that PrEP programs meet users' needs and to assess their impact and effectiveness at the community and national levels. Following extensive analysis over the past five years and a [series of think tanks](#), the HIV Prevention Market Manager project and partners have identified the following approaches to better understand and improve on the impact of daily oral PrEP today, and on potential new prevention options in the future.

Lessons for Monitoring for Impact

- Define simpler and better ways to assess PrEP's impact.
- Harmonize and simplify data collection systems.
- Standardize and improve measures of PrEP cost-effectiveness.
- Paint a more detailed picture of PrEP users.
- Understand how long people continue to use PrEP, and why they stop (and re-start).

Define simpler and better ways to assess PrEP's impact

Initial indicators used to evaluate the impact of PrEP were based on HIV treatment program. With treatment, consistent, lifelong, often daily pill adherence is essential to effectively help people living with HIV stay healthy. But research has shown that oral PrEP use can substantially reduce HIV acquisition even when most users discontinue PrEP at least once.¹ That calls for new ways and indicators to assess short-and long-term impacts as PrEP users start, stop or switch products as their risk changes, or when new product options become available.

Family planning programs may provide a better model for PrEP. Contraceptive users have a range of method options that they may start, stop or switch based on their circumstances and preferences. Data show that over 20 percent of people using shorter-term contraceptive methods, such as pills and injectables, stop use within a year.² The goal of family planning programs isn't to keep people locked into a single method but to ensure that everyone who wants to prevent or delay pregnancy has the contraceptive supplies and support they need.

To assess the extent of their coverage in this context, family planning programs use a "couple-years of protection" indicator based on the volume of contraceptives distributed across a population over a given period of time. A similar measure could be used for PrEP, combining relatively easy-to-collect data points: the volume of PrEP distributed (independent of product, as additional products become available); the average duration of HIV prevention per "dose" (allowing for incorporation of longer-acting methods into the model); and the number of people in a community or geographic area who are at risk for HIV and have a user indication for PrEP.

This is one in a series of four issue briefs highlighting key insights from a decade of oral PrEP programs and their implications for next-generation prevention products, programs and platforms. Developed as part of the AVAC-led HIV Prevention Market Manager project, all four briefs can be found at prepwatch.org/PrEP-Lessons.

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Once this estimate of programmatic coverage has been obtained, it can be used together with data on HIV incidence to model the impact of PrEP programs, in terms of infections prevented, as long as robust data are available to account for confounding factors such as HIV treatment scale-up and viral suppression.³

Harmonize and simplify data collection systems

Governments, funders and implementers can reduce the burden of collecting and analyzing these essential categories of information by working together in a more streamlined way. This means identifying a standard set of core PrEP indicators across national health management information systems (HMIS), WHO, PEPFAR and Global Fund programs. Strengthening the connections between the data collected through national HMIS, community-led monitoring and population-level or surveillance surveys would provide a more accurate picture of trends in PrEP use, programmatic gaps, and prevailing attitudes and perceptions of users, providers and communities.

There may also be ways to collect data on PrEP impact at the population or community level, and track trends over time through population-based surveys such as the Population-based HIV Impact Assessment (PHIA) surveys funded by PEPFAR and implemented by ICAP. For example, some PHIA surveys have started to collect data on PrEP awareness, acceptability, use and adherence. Additional indicators could be incorporated to assess the use of ART-based HIV prevention methods at the population level and the impact of PrEP in reducing HIV infections.

Proposed Modifications to Current PrEP Indicators and M&E Approaches

- Ensure PrEP initiations for each product are disaggregated not only by key population and age, but also by pregnancy/breastfeeding status.
- Add and pilot an indicator to measure “person-years of protection” derived by dividing the volume of PrEP products distributed by the size of the at-risk population; in settings where PrEP is sufficiently scaled up, add an impact measure that correlates PrEP uptake with reductions in new HIV diagnoses to serve as an indicator of PrEP impact.
- Assess and compare PrEP uptake across delivery settings to better understand if PrEP uptake and effective use improves when PrEP is offered via different delivery channels (i.e., family planning clinics, mobile clinics, safe spaces, drop-in centers, etc.).

Standardize and improve measures of PrEP cost-effectiveness

In the context of overall declining global HIV funding, with cuts often affecting prevention programs in particular,⁴ efforts to assess and demonstrate the cost-effectiveness of PrEP are more important than ever. While the cost-effectiveness of PrEP interventions will necessarily be lower than that of HIV treatment programs (since treatment can provide health benefits to people living with HIV and to their sexual and drug injecting partners), people at risk for HIV still have a critical need for independent options like PrEP that they can use to protect themselves. As new products become available, cost-effectiveness data should be used to inform decisions about the arsenal of prevention options and delivery strategies.

The indicators for coverage and impact proposed above can help countries, implementers and funders understand and assess the benefits of PrEP programs. To model cost-effectiveness, programs and policy makers also need to standardize which cost elements are included in PrEP costs, and to collect more comprehensive data on the costs both of commodities and of delivering PrEP.

All cost-effectiveness models should be updated and adapted with new data as longer-acting products with different distribution needs and frequency, and future combination prevention methods, become available. To help countries better estimate costs and assess the potential impact of new products, product developers should share cost information early in the research and development pipeline.

Beyond the expenses of PrEP products and related clinical care, cost-effectiveness models should also account for the cost of activities designed to increase demand and community support for PrEP. This information can inform decisions about where PrEP is best delivered, e.g., at HIV clinics, family planning clinics, drop-in centers, mobile clinics, community depots, or home delivery.

Paint a more detailed picture of PrEP users

As the number of PrEP users increases, it will continue to be important to understand whether PrEP is reaching those who could benefit the most from it. When new products are eventually introduced, implementers will also want to learn which prevention options appeal most to which users and whether there are differences in how effectively different groups can use the methods. Such information can support targeted marketing and distribution efforts. This will require disaggregating data by age, pregnancy or breastfeeding status, and population group (i.e., AGYW, FSW, MSM) of PrEP users.

Understand how long people continue to use PrEP, and why they stop (and re-start)

Currently, only a minority of people who begin using oral PrEP continue with the method for more than a few months.⁵ Longer-acting methods in the pipeline, such as rings, implants and injectables that provide one or more months of protection without further action, may make it easier for some people to sustain protection for longer periods of time. But programs can still do more to help those at ongoing risk for HIV acquisition to sustain daily oral PrEP use for longer periods of time. Research to date has identified multiple barriers to sustained use, including concerns about product-related side effects and branding; societal and self-stigma; a lack of support from partners and family; providers who lack PrEP knowledge and/or are unwilling to prescribe it; and inadequate access to efficient, culturally-appropriate, people-centered PrEP services.⁶

Importantly, however, it is essential that PrEP discontinuation, or cycling on and off, not be indiscriminately labeled a “failure”. People initiate PrEP use because they believe they’re at risk for HIV infection (or will be in the future), and evidence suggests that some people stop when they believe that risk has declined. Among participants in the SEARCH study, conducted in Kenya and Uganda, , over half of participants who returned for follow-up visits reported at least once that they weren’t currently at risk, and half who stopped PrEP later restarted it when they felt they needed it. Study results showed significant reductions in HIV incidence among PrEP users, even with modest uptake, precisely because people used it when they needed it.⁷

What’s needed, therefore, is a deeper, more contextualized understanding of PrEP continuation, one that can help identify and remove barriers to ongoing use without judging people—or penalizing programs—when someone makes a reasonable choice to stop a given method. Implementation research (not routine monitoring) that follows people over time in real-world conditions offers the best way to better understand why people stop and restart PrEP, and what interventions can help them continue use during periods of risk. When new products become available, implementation research will also be important to assess when and why people might switch from one method to another.

Key Considerations for PrEP M&E

Ministries of Health, Donors, Implementers and Providers can:

- Agree on a set of core PrEP indicators across donors and national health systems, including one that measures impact.
- Distinguish between data needs for routine monitoring and evaluation as opposed to data needs for improving support to help individuals stay on PrEP.
- Collect data and information on patterns of use, switching methods, and the reasons people may discontinue PrEP via program evaluations and implementation science.
- Collect data on costs and utilization of PrEP-related programming such as demand generation, community outreach, and implementation of combination prevention programs.
- Adapt existing costing and cost-effectiveness models to incorporate new, longer-acting methods as part of combination prevention.

For more information:

Reframing PrEP Continuation: Highlights from the PMM-Jhpiego USAID Think Tank on Prevention Effective Use of PrEP, May 27, 2021. Global PrEP Learning Network. View slides at https://www.prepwatch.org/wp-content/uploads/2021/05/May27_2021_PLN.pdf and webinar recording at <https://www.youtube.com/watch?v=dtIJsuve930>

Evaluating, Scaling up and Enhancing Strategies for Supporting Continuation and Effective Use, Think Tank Meeting Report, September 29, 2020. HIV Prevention Market Manager and Jhpiego. <https://www.prepwatch.org/resource/scaling-up-and-enhancing-strategies-for-supporting-prep/>

Defining and Measuring the Effective Use of PrEP, Think Tank Meeting Report, June 1, 2019. Jhpiego and the HIV Prevention Market Manager. <https://www.prepwatch.org/resource/prep-think-tank-report/>

¹ Koss CA et al. Lower than expected HIV incidence among men and women at elevated HIV risk in a population-based PrEP study in rural Kenya and Uganda: Interim results from the SEARCH study. International AIDS Conference. Abstract OAC0805; Evidence for Contraceptive Options and HIV Outcomes (ECHO) Trial Consortium. 2019; HIV Incidence Among Women Using Intramuscular Depot Medroxyprogesterone Acetate, a Copper Intrauterine Device, or a Levonorgestrel Implant for Contraception: A randomized, multicentre, open-label trial. *Lancet*. 394(10195):303-313. doi:10.1016/S0140-6736(19)31288-7. Published correction appears 27 July 2019. *Lancet*. 394(10195):302; Smith DK et al. Evidence of an Association of Increases in Pre-exposure Prophylaxis Coverage With Decreases in Human Immunodeficiency Virus Diagnosis Rates in the United States, 2012-2016. *Clin Infect Dis*. 2020 Dec 15;71(12):3144-3151. doi: 10.1093/cid/ciz1229; <https://pubmed.ncbi.nlm.nih.gov/32097453/>.

² FP 2020: Momentum at the Midpoint, 2015-2016. Chapter 3: Measurement. <http://2015-2016progress.familyplanning2020.org/page/measurement/contraceptive-discontinuation>.

³ Koss CA et al. Lower than expected HIV incidence among men and women at elevated HIV risk in a population-based PrEP study in rural Kenya and Uganda: Interim results from the SEARCH study. International AIDS Conference. Abstract OAC0805; Smith DK et al. Evidence of an Association of Increases in Pre-exposure Prophylaxis Coverage With Decreases in Human Immunodeficiency Virus Diagnosis Rates in the United States, 2012-2016. *Clin Infect Dis*. 2020 Dec 15;71(12):3144-3151. doi: 10.1093/cid/ciz1229; <https://pubmed.ncbi.nlm.nih.gov/32097453/>.

⁴ Kates J, Wexler A, Leif E. Donor Government Funding for HIV in Low- and Middle-Income Countries in 2019. Kaiser Family Foundation, July 6, 2020. <https://www.kff.org/report-section/donor-government-funding-for-hiv-in-low-and-middle-income-countries-in-2019-report/>.

⁵ Rousseau-Jemwa et al. Early persistence of HIV pre-exposure prophylaxis (PrEP) in African adolescent girls and young women (AGYW) from Kenya and South Africa. *AIDS Research and Human Retroviruses* 2018;34(68); Kinuthia et al. Pre-exposure prophylaxis uptake and early continuation among pregnant and post-partum women within maternal and child health clinics in Kenya: results from an implementation programme. *Lancet HIV* Epub 2019 Dec 5;7(1):e38-e48; Mugwanya et al. Integrating preexposure prophylaxis delivery in routine family planning clinics: A feasibility programmatic evaluation in Kenya. *PLOS Medicine* 2019.

⁶ Celum CL et al. HIV Pre-Exposure Prophylaxis for Adolescent Girls and Young Women in Africa: From efficacy trials to delivery. *J Int AIDS Soc*. 22 July 2019, Suppl 4; Kanny D et al. National HIV Behavioral Surveillance Study Group. Rep. 20 Sept. 2019; Racial/Ethnic Disparities in HIV Preexposure Prophylaxis Among Men Who Have Sex with Men: 23 urban areas, 2017. *MMWR* 68(37):801-806; Eakle R et al. Understanding User Perspectives of and Preferences for Oral PrEP for HIV Prevention in the Context of Intervention Scale-up: A synthesis of evidence from sub-Saharan Africa. *J Int AIDS Soc*. 2019 July; 22 Suppl 4 (Suppl 4).

⁷ Koss CA et al. Uptake, engagement and adherence to pre-exposure prophylaxis offered after population HIV testing in rural Kenya and Uganda: 72-week interim analysis of observational data from the SEARCH study. *Lancet HIV*. 2020 Apr;7(4):E249-E261. DOI: [https://doi.org/10.1016/S2352-3018\(19\)30433-3](https://doi.org/10.1016/S2352-3018(19)30433-3). [https://www.thelancet.com/journals/lanhiv/article/PIIS2352-3018\(19\)30433-3/fulltext](https://www.thelancet.com/journals/lanhiv/article/PIIS2352-3018(19)30433-3/fulltext).



The HIV Prevention Market Manager (PMM), led by AVAC and CHAI with funding from the Bill & Melinda Gates Foundation, works with partners to expand the portfolio of HIV prevention options and ensure appropriate products are available, accessible and used. Since 2016, the PMM has generated key insights into HIV prevention programming, centering the people who most need, want and can use prevention, including the identification of motivators and

barriers to product use and adherence. PMM has also supported evidence-based PrEP implementation strategies in multiple countries and catalyzed solutions to improve HIV prevention delivery and monitoring of PrEP impact. PMM isn't about a specific HIV prevention product; it's about paving the way for more robust and comprehensive options; accelerating their delivery; and reducing time to impact.

PMM also established the Biomedical Prevention Implementation Collaborative (BioPIC), an innovative mechanism that coordinates key stakeholders including product developers, civil society, donors, researchers, policy makers, normative agencies, and implementers to develop a product introduction strategy for emerging and future biomedical prevention options, including injectable cabotegravir and the dapirine vaginal ring.

A [summary of PMM activities is online](#), and a wide range of relevant data, research insights and practical PrEP implementation tools created by PMM is available at prepwatch.org.