

Proposed New National-level Indicators for M&E for all forms of PrEP (oral, ring, injectable, etc.)

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Acknowledgments

PROMISE/CHOICE M&E Working Group

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Executive Summary

The promise of new HIV prevention options on the horizon offers an opportunity for countries to re-evaluate their systems for measuring the performance of pre-exposure prophylaxis (PrEP) programs. Rather than simply adapting current monitoring and evaluation (M&E) indicators, they can apply lessons from their experiences with oral PrEP to develop measures that are more useful and easier to integrate in routine data collection.

The current global indicators for oral PrEP are challenging to collect and interpret and do not enable program managers to estimate program impact or future resource needs. In addition, each funder and national Ministry of Health requires slightly different indicators with different reporting periods, which adds to the burden of data collection, reporting, and interpretation (see [Challenges with current indicators](#)).

Moreover, current indicators are based on [continuation](#), but we have learned that effective use of oral PrEP does not always mean continuous use. Studies in eight countries have revealed that PrEP clients tend to use oral PrEP when they need it most. This finding of high levels of “prevention-effective adherence” during periods of increased potential exposure to HIV suggests that M&E may be able to focus on *any* PrEP use rather than on continuous, uninterrupted use.

Building on the recommendations from a series of think tanks on PrEP M&E led by AVAC through the Prevention Market Manager project with support from Jhpiego, the M&E Working Group of the USAID-funded PROMISE and CHOICE collaborations has proposed [new indicators](#) that could be used to monitor and evaluate programs providing oral PrEP and all other forms of PrEP as they become available. These indicators aim to simplify routine data collection and reporting to focus on the essential performance metrics of a PrEP program.

The primary indicators proposed are *PrEP Dispensed*, or product volume dispensed by PrEP method, and *PrEP Visits*, comprised of the total number of visits during which PrEP is provided, disaggregated by visit type, PrEP method, and priority population. Examples of the data collection required for these indicators are detailed in [data reference sheets](#).

PrEP Dispensed and *PrEP Visits* can be used to calculate a third indicator, *Person-Years of PrEP Product Dispensed (PYP) by method and priority population*. PYP can then be used in combination with other data to estimate the impact, coverage, and resource needs of a PrEP program ([see Indicator applications](#)).

In 2022, the proposed indicators will be piloted in demonstration projects supported by the Maximizing Options to Advance Informed Choice for HIV Prevention (MOSAIC) project to assess ease and reproducibility of data collection; refine indicator definitions, disaggregations, and reporting tools; and demonstrate how these indicators can be used to monitor and evaluate PrEP program implementation. In parallel, the M&E Working Group will assist interested countries and global organizations to incorporate the indicators into their routine reporting systems.

Introduction

As countries prepare to introduce new forms of PrEP such as vaginal rings and injectable PrEP, they are adapting systems designed for the delivery of oral pre-exposure prophylaxis (oral PrEP), including those developed for monitoring and evaluation (M&E). Lessons from their experiences with oral PrEP suggest that what is needed is a re-evaluation of the current M&E indicators to provide more meaningful measures of program performance for all forms of PrEP.

A series of think tanks on PrEP M&E, led by AVAC through the Prevention Market Manager project with support from Jhpiego, brought together PrEP experts to examine these lessons. Their findings centered on the need to harmonize and revise national, global, and funder PrEP indicators to address learnings from oral PrEP implementation as well as family planning.¹

The M&E Working Group of the PEPFAR- and USAID-funded PROMISE and CHOICE collaborations has built on the recommendations from those think tanks to define and refine indicators that can be collated from routinely collected data to address key M&E questions at the national and global levels. This document examines the challenges posed by the current PrEP indicators, proposes new indicators for consideration, and describes how the new indicators would be calculated and used.

The proposed indicators will be tested in pilot studies in several countries supported by the PEPFAR- and USAID-funded MOSAIC project in 2022.

PrEP M&E

Data collection on PrEP implementation serves different purposes at the service delivery level versus the program management (subnational, national, or international) level. Program managers primarily use M&E data to address the following types of questions about inputs, outputs, outcomes, and impact. (Those involved in direct PrEP service delivery will likely collect additional data to facilitate client management and quality improvement.)

Inputs

- Are resources (such as PrEP product, laboratory tests, other commodities, staff time, and physical infrastructure) sufficient to meet the needs of the program?
- What future resources will be needed, based on scale-up plans and past implementation trends?

Outputs

- Is the program meeting its service delivery targets?
- Are implementers achieving deliverables required by donors and health ministries?

Outcomes

- How is the PrEP program progressing in terms of uptake and coverage of key and priority populations?
- Are clients using PrEP in a way that effectively prevents HIV acquisition?

Impact

- How is the program contributing to reductions in HIV incidence?

Currently, most oral PrEP programs report on the global indicators used by one or more funders, including the US President’s Emergency Plan for AIDS Relief (PEPFAR), the Joint United Nations Programme on HIV/AIDS (UNAIDS), the World Health Organization (WHO) and The Global Fund to Fight AIDS, Tuberculosis and Malaria (see Table 1). Many countries have also developed additional reporting requirements, which are not included in the table.

Table 1. Current PrEP indicators

Indicator Type	Indicator Name	Definition	Funder
PrEP Uptake	PrEP_NEW	Number of individuals who were newly enrolled on oral PrEP to prevent HIV infection in the reporting period	PEPFAR
	PrEP Uptake	Percentage of eligible people who initiated oral PrEP during the reporting period	WHO (suggested PrEP M&E core indicator)
	KP6 + YP4	Percentage of eligible key population who initiated oral PrEP during the reporting period	Global Fund
PrEP Continuation	PrEP continuation (at 3 months)	Percentage of PrEP users who continued oral PrEP for 3 consecutive months after having initiated PrEP during the reporting period	WHO (suggested PrEP M&E core indicator)
	PrEP_CT	Number of individuals, excluding those newly enrolled, who return for a follow-up visit or re-initiation visit to receive PrEP to prevent HIV during the reporting period	PEPFAR
Current PrEP Use	People who received PrEP	Number of people who received oral PrEP at least once during the reporting period	UNAIDS/WHO

PrEP M&E Challenges

The PEPFAR, UNAIDS/WHO, and Global Fund indicators have been instrumental in laying the foundation for monitoring PrEP rollout globally; however, they present several difficulties with definition, collection, and interpretation and may not serve to answer key program management questions. Furthermore, each funder and national Ministry of Health requires slightly different indicators with varying definitions and reporting periods, putting immense strain on implementers for data collection, reporting, and interpretation.

Continuation vs. effective use

Patterns of PrEP use have proved more complex than was initially understood when the global indicators were created. In many cases, the current indicators were modeled after those used

for antiretroviral therapy (ART), but unlike ART, PrEP does not require continuous use to be effective.

We have learned that many clients use PrEP during periods of elevated potential exposure to HIV, starting and temporarily discontinuing PrEP based on their changing life circumstances and needs.² Studies among men who have sex with men (MSM) in Europe, North America, and Australia demonstrated high levels of such “prevention-effective adherence” to oral PrEP,^{3,4} and additional studies have confirmed this finding among other populations in sub-Saharan Africa.^{5,6,7} M&E indicators for PrEP need to account for different patterns of use while still efficiently measuring service delivery and providing data for projecting resource needs.

Challenges with current indicators

In general, existing PrEP indicators aim to measure three things — PrEP uptake, PrEP continuation, and current PrEP use — each presenting its own challenges.

PrEP Uptake: Given high rates of discontinuation and varying patterns of use, PrEP uptake may be a poor basis from which to estimate PrEP coverage and program impact, and ultimately, may be an incomplete indicator of program success. Measurement of uptake may be difficult in a context of multiple PrEP methods, where it may be unclear whether the indicator captures first time initiation of *any* PrEP method or first time initiation using a specific PrEP method (e.g., are method switchers considered “new?”). It may also be difficult to verify that those reported as new users are truly initiating for the first time.

PrEP Continuation: This indicator may pose challenges in counting those who do not conform to standard schedules for continuation visits (e.g., continuers returning late for refills or those who have an adjusted schedule of multipurpose visits aligned with other health needs) or accounting for different visit schedules with multi-month dispensing. In addition, the indicator is limited to first use, so it does not capture clients through multiple cycles of use. Because continuation indicators do not measure prevention-effective use, they may fail to measure program success. They are also difficult to relate to PrEP coverage and program impact.

Current PrEP Use: Measurement of use is based on the receipt of PrEP at least once during a defined period, but this indicator is often interpreted to mean the total number of clients currently actively using PrEP. Given that unique initiators or continuers must be counted only once within each reporting period, data collection and calculation can be burdensome and confusing in the absence of an electronic data system with unique identifiers. This indicator is also difficult to relate to PrEP coverage, program impact, and program success because it does not address the cumulative duration of PrEP use within the reporting period.

With all three indicator types, attempts to measure numbers of individuals initiating or continuing PrEP may result in over- or undercounting as clients move between sites or reinstate PrEP use within or between reporting periods. Without unique identifiers and linked electronic medical records, it is difficult to track clients across access points and over time. As a result,

initiators may be counted multiple times across different sites and continuers may be undercounted if they seek care at different sites.

Considerations for PrEP M&E

Given the limitations of the current PrEP indicators and the challenges they pose for data collection and interpretation, the M&E Working Group of the PROMISE and CHOICE collaborations has developed new indicators that could be used to monitor and evaluate programs offering oral PrEP and other forms of PrEP as they become available.

Proposed indicators and data collection

To account for varying patterns of PrEP use, the M&E Working Group has proposed replacing indicators counting numbers of individual clients receiving PrEP or numbers of individual clients continuing for a specified duration with two primary indicators. The first, *PrEP Dispensed*, is an indicator of product volume dispensed by PrEP method. The second, *PrEP Visits*, is an indicator of the total visits during which PrEP is provided, disaggregated by visit type, PrEP method, and priority population. These two indicators, in combination, can better answer the key M&E questions related to the program inputs, resources required, and direct outputs of a program.

PrEP Dispensed and *PrEP Visits* can be used in combination to calculate a third indicator related to program outcomes, *Person-Years of PrEP Product Dispensed (PYP) by PrEP method and priority population*. PYP will provide a better understanding of the magnitude of PrEP delivery to each priority population while avoiding the risk of under- or over-counting associated with movement between sites and eliminating the burden of collecting individual-level data with paper-based systems. Such an indicator can then be used in combination with other data to estimate the impact, coverage, and resource needs of a PrEP program (see [examples of indicator applications](#)).

Depending on the sources of data available in each country, data on product volume dispensed may not consistently be associated with information about the priority population receiving the product. Therefore, we propose that service delivery units report data on numbers of PrEP visits, disaggregated by PrEP method, visit type, and population. These visit data can be used to disaggregate the total amount of product dispensed by priority population. Visit data can also be used to report numbers of new users of each method.

Examples of the data to be collected for these indicators are shown in tables 2 and 3.

Table 2. Example data reference sheets: PrEP Dispensed

Indicator Name	PrEP Dispensed	
Description	Number of units of each method of PrEP product dispensed by the PrEP program within the reporting period	
Numerator	Number of units of PrEP product dispensed	The numerator can be generated by counting the number of units of PrEP products dispensed by method. Units will vary by method, e.g., bottles of pills, rings, or injections.
Denominator	n/a	
Reporting Level	Lowest organizational unit or access point	
Reporting Frequency	Quarterly	
Source	Pharmacy/distributor records/supply chain management system/LMIS	
How To Calculate Annual Total:	Sum results for each PrEP method across quarters	
Disaggregations	<i>Numerator Disaggregations</i>	
	<i>Disaggregate Groups</i>	<i>Disaggregates</i>
	PrEP Method	Oral PrEP (single bottle – month supply) Monthly PrEP Ring (single ring) CAB PrEP (single injection)
Disaggregate Descriptions and Definitions	To be further defined through stakeholder consultation and indicator pilot studies	
Data Visualization & Use Examples	See figures 1–3.	

Table 3: Example data reference sheet: PrEP Visits

Indicator Name	PrEP Visits	
Description	Number of client visits to a health facility or access point during which PrEP to prevent HIV infection was provided/prescribed/administered within the reporting period, including first-time initiation visits for each method and all other visits in which product is provided	
Numerator	Number of client visits during which PrEP to prevent HIV infection was provided/prescribed/administered	The numerator can be generated by counting the number of client visits during which PrEP was provided/prescribed/administered.
Denominator	n/a	
Reporting Level	Lowest organizational unit or access point	
Reporting Frequency	Quarterly	
Source	Service delivery records (facility registers/electronic medical records/monthly facility/regional reporting/health management information systems (HMIS))	

How To Calculate Annual Total	Sum results for each method/visit type/population combination across quarters		
Disaggregations	<i>Numerator Disaggregations</i>		
	<i>Disaggregate Groups</i>		<i>Disaggregates</i>
	Method by Visit Type/Age/Sex	Method x	Oral PrEP, Monthly PrEP Ring, CAB PrEP
		Visit Type x	New initiation, Any other dispensing visit
		Age x	15–19, 20–24, 25–29, 30–34, 35–39, 40–44, 45–49, 50+, unknown
		Sex	Male (M), Female (F), Non-Binary (N), Unknown (U)
	Method by Visit Type/Population	Method x	Oral PrEP, Monthly PrEP Ring, CAB PrEP
		Visit Type x	New initiation, Any other dispensing visit
Population		People who inject drugs Men who have sex with men Transgender people Sex workers People in prison and other closed settings Serodifferent couples People who are pregnant or breastfeeding General population	
Disaggregate Descriptions and Definitions	The optimal typology of methods, visits, populations, age categories, and sex categories will need to be determined through pilot testing of the indicators and further stakeholder consultation.		
Data Visualization & Use Examples	See figures 1–3.		
Notes	Pilot testing will help determine if it makes sense to include amount of product dispensed as further disaggregation of some of the visit types. Alternatively, estimates of the amount of product dispensed per visit per population can be gleaned using knowledge of the different implementation models for each method and population.		

Indicator applications

Data collected on PrEP visits and the amount of PrEP dispensed (see examples in tables 2 and 3) can be used to calculate proposed composite indicators. This section details how to calculate those indicators and explains how the indicators could contribute to meaningful measurement of national programs.

Total Person-Years of PrEP Product Dispensed (PYP)

An aggregate output measure — *Person-Years of PrEP Product Dispensed* — could be calculated from *PrEP Dispensed* to provide a single measure of product volume dispensed, expressed in terms of the person-years of prevention provided across all methods. This indicator is comparable across methods, despite methods having different units and durations of use. Going forward, *PYP* could be easily adapted to incorporate new PrEP products of different units or durations as they become available.

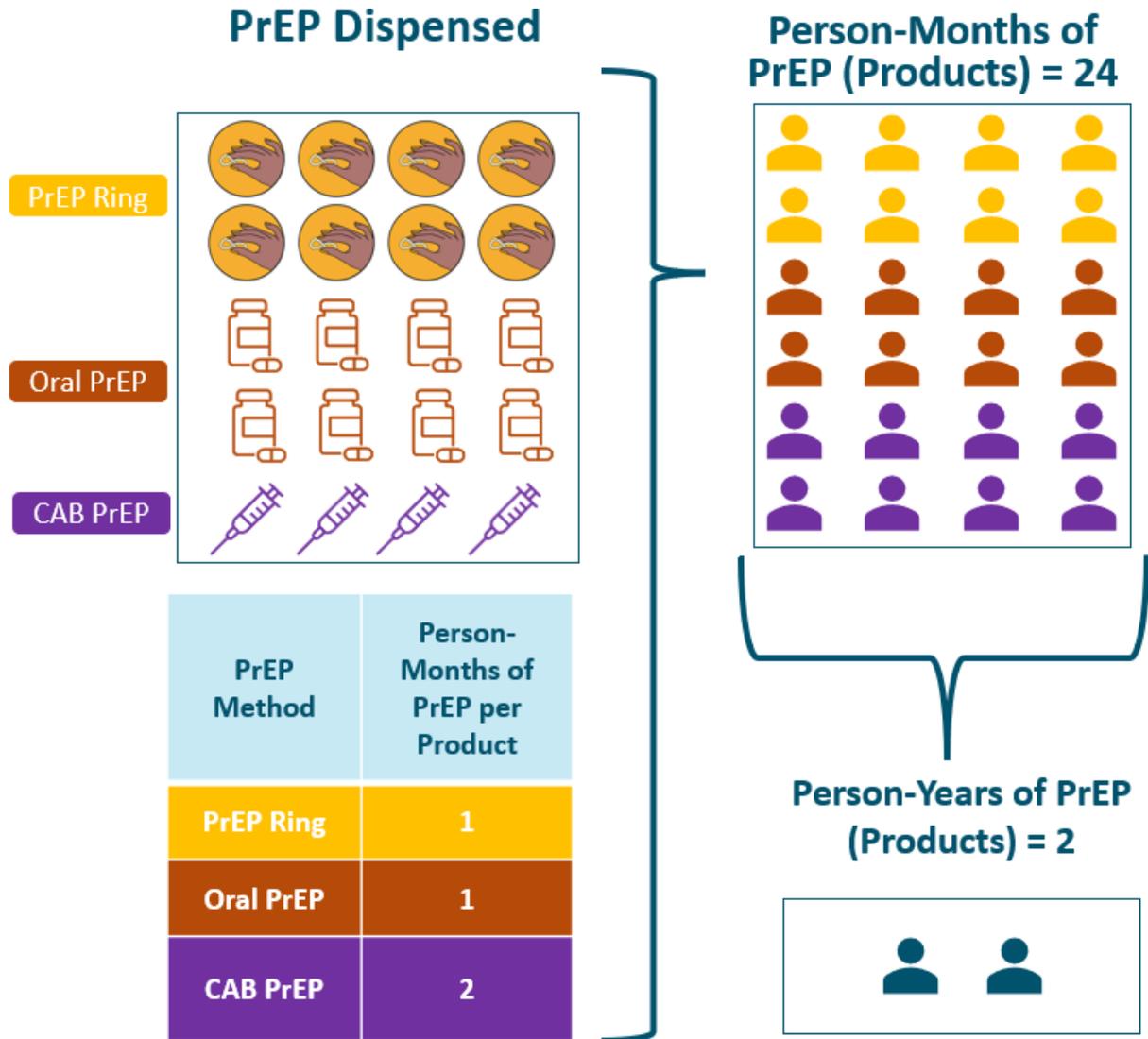
For each method (oral/ring/injectable), the total number of units is multiplied by the duration of HIV prevention provided by one unit of that method.

It is assumed that:

- 1 bottle of Oral PrEP = 1 Person-Month of PrEP = 1/12 Person-Year of PrEP
- 1 Monthly PrEP Ring = 1 Person-Month of PrEP = 1/12 Person-Year of PrEP
- 1 CAB PrEP injection = 2 Person-Months of PrEP = 2/12 Person-Year of PrEP

Figure 1 provides an example of how *PYP* can be calculated from *PrEP Dispensed* across multiple methods. First, the amount of *PrEP Dispensed* for each method is multiplied by the number of person-months of PrEP for each unit of that method. Then, the total number of person-months is summed across methods. The number of person-months of PrEP dispensed is divided by 12 to produce the number of person-years of PrEP dispensed.

Figure 1. Calculating Person-Years of PrEP Product Dispensed from PrEP Dispensed



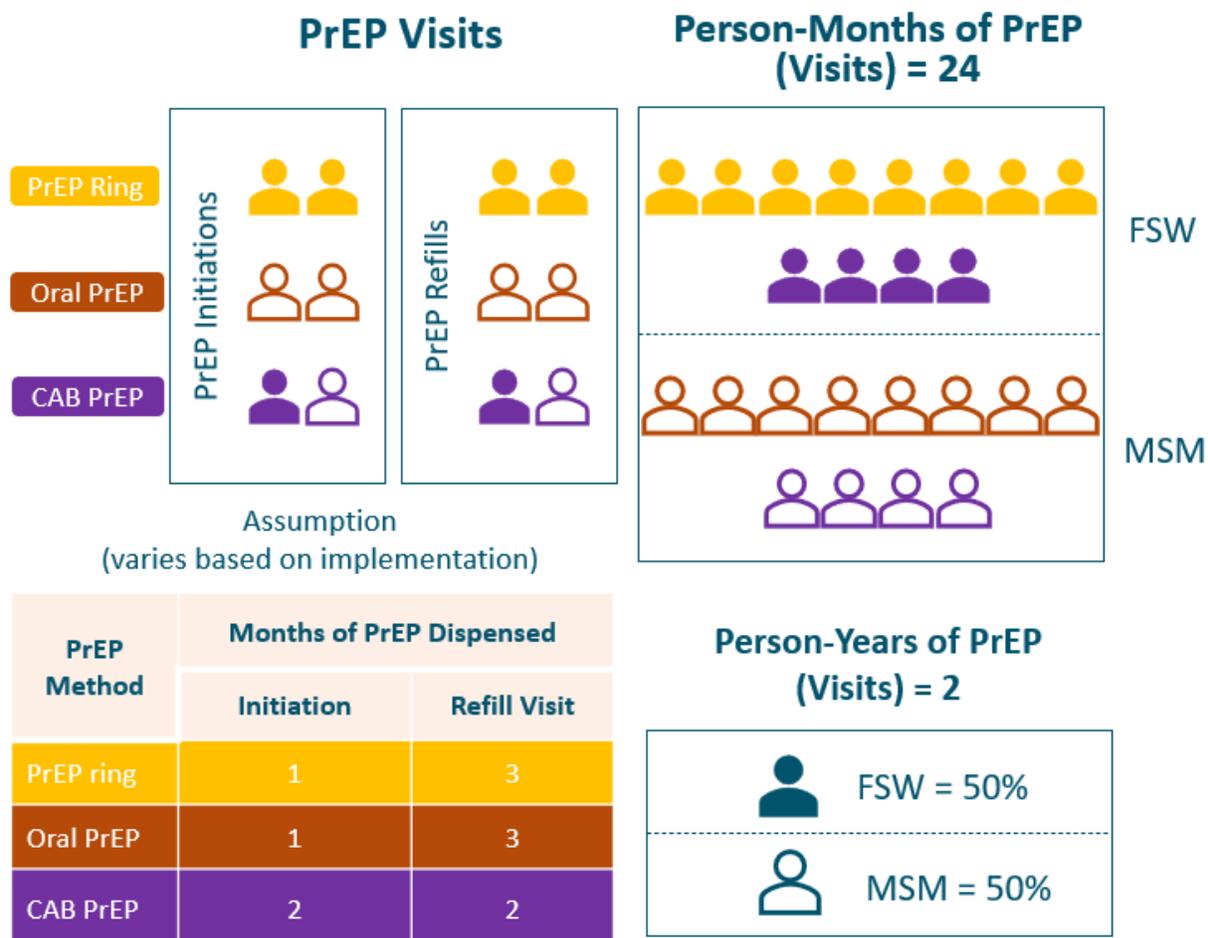
PYP for each priority population

PYP can be combined with data about the priority populations receiving each method, obtained from the visit indicators and assumptions about the volume of PrEP product distributed at each visit type for each population, to estimate the total *PYP* provided to each priority population. This indicator can be used to assess the progress of implementation by priority population.

Figure 2 provides an example of how *PrEP Visit* data can be used to estimate the distribution of *PYP* by priority population. First the number of visits (initiation vs. refill) are counted by method and priority population. Then, based on assumptions about the amount of product distributed at each type of visit and the estimated duration of each product, the number of person-

months/person-years of PrEP can be estimated for each priority population. Finally, the priority population *PYP* can be divided by the total *PYP* estimated from the visit data to get the proportion of *PYP* per priority population.

Figure 2. Estimating the distribution of Person-Years of PrEP Dispensed by priority population



Coverage of each priority population

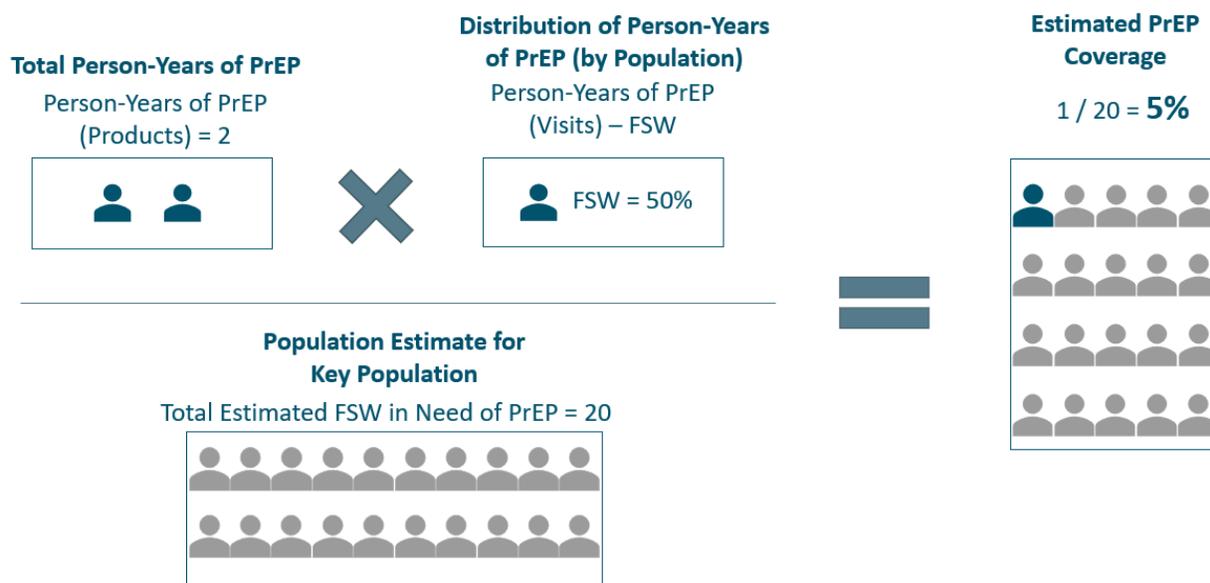
PYP for each priority population, combined with estimates of the size of each priority population in need of PrEP, can be used to estimate annual coverage of each priority population. Figure 3 provides an example of how to combine *PYP* (calculated from product data) with the distribution of estimated PYP by priority population from visit data, and then convert that to PrEP coverage for a priority population.

The total *PYP*, calculated from product data, can be multiplied by the estimated proportion of PYP attributable to the selected key population, calculated from visit data. This provides an estimate of PYP per key population anchored in the product dispensation data. In the example in Figure 3, product data indicate a total of 2 PYPs have been dispensed. Based on the visit data,

we estimate that 50% of PYPs were dispensed to female sex workers (FSWs). As a result, we estimate that 1 PYP was dispensed among FSWs.

The *PYP*, which represents the equivalent of one person-year’s worth of product dispensed among the selected key population, is divided by the estimated number of people in need of PrEP within that key population to estimate coverage. In this example, 1 PYP (distributed among FSWs) is divided by 20 (the estimated total population of FSWs in need of PrEP) to produce an estimated 5% PrEP coverage among FSWs.

Figure 3. Calculating PrEP coverage from Person-Years of PrEP Dispensed and PrEP Visits



New initiations

Numbers of first-time initiation visits by method can be used to report numbers of clients initiating each method for the first time.

Other applications of collected data

PrEP Dispensed

PrEP Dispensed measures the volume of each type of PrEP product dispensed over a given period. These data can be used to track the success of the program in distributing PrEP products and can inform procurement planning and quantification.

Resource use

PrEP Visits, disaggregated by visit type (initiation, other dispensing visits), combined with information about national policies and standards of practice, could help program managers estimate utilization of resources, such as staff, HIV tests, other lab tests, and other

commodities. For example, the total number of visits is correlated with the number of HIV tests performed within PrEP programs. These data would be useful for procurement and would allow for better estimates of the number of HIV-positive tests among all HIV tests performed.

Strengths and limitations of this approach

The advantages of using the proposed indicators and their limitations are summarized in Table 4.

Table 4. Strengths and limitations of the proposed indicators

Strengths	
Both indicators (<i>PrEP Dispensed</i> and <i>PrEP Visits</i>) are sourced from existing data, requiring minimal new effort to track.	<i>PrEP Dispensed</i> is sourced from product volume data, which is already collected and generally reported through HMIS or logistics management systems (LMIS).
	<i>PrEP Visits</i> is an aggregate of data that is generally already recorded in client registers and could be reported through HMIS, if it is not already.
Both indicators are simple to calculate and straightforward to interpret. They are also not subject to some of the quality and interpretation issues of existing PrEP measures.	Compared to efforts to track current or continuous use of PrEP, data on product volume is not affected by discontinuous use, method switching, re-initiation, or site switching.
	<i>PrEP Visits</i> does not require tracking individual PrEP users over time but reflects the collective utilization of PrEP services, simplifying the calculation and providing a more direct measure of service provision. It also includes the data required for population disaggregations (age, sex, and key population).
<i>Person-Years of PrEP Product Dispensed</i> is a more epidemiologically meaningful indicator than those generally used to monitor PrEP (initiations, duration of continuation, and number of clients currently on PrEP), because it measures the total volume of protection provided without confounding by different patterns of use. With the assumption of prevention-effective adherence and estimates of incidence in each priority population, <i>PYP</i> for each method for each priority population can be converted into estimates of the impact of the PrEP program without detailed information about duration of use or individual temporal patterns of exposure to HIV.	
Limitations	
The proposed indicator <i>Person-years of PrEP Product Dispensed</i> does not directly measure product use for user-dependent methods such as oral PrEP and the ring. This limitation has also been discussed in the family planning field, as it applies to standard indicators collected and reported on contraceptive use.	Research studies will be needed to estimate the ratio of product dispensed to product used, to estimate outcome and impact using the proposed product volume and client visit indicators.
Population size estimates for each priority population are required to estimate proportional coverage of the PrEP program (an outcome indicator of interest). Population size estimates for priority populations are not always available, and when they are available require some assumptions, face their own limitations, and may be contentious.	

Event-driven PrEP (ED-PrEP) poses unique challenges for measurement and may not be adequately addressed by collecting information about product volume dispensed and visits. Further evidence will be required to develop effective ways to measure the success of ED-PrEP programs.

Pilot Testing the New Indicators

In 2022, the proposed indicators will be piloted in demonstration projects supported by the PEPFAR- and USAID-funded Maximizing Options to Advance Informed Choice for HIV Prevention (MOSAIC) project to assess ease and reproducibility of data collection; refine indicator definitions, disaggregations, and reporting tools; and demonstrate how these indicators can be used to monitor and evaluate PrEP program implementation. In parallel, the M&E Working Group will assist interested countries and global organizations to incorporate the indicators into their routine reporting systems.

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