Development and Country Applications of a Program Planning and Monitoring and Evaluation Tool for Oral Pre-exposure Prophylaxis

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ACRONYMS

3TC	lamivudine
AGYW	adolescent girls and young women
AIM	AIDS Impact Model
ARV	antiretroviral
ART	antiretroviral therapy
FSW	female sex worker
FTC	emtricitabine
M&E	monitoring and evaluation
MSM	men who have sex with men
PEPFAR	U.S. President's Emergency Plan for AIDS Relief
PrEP	pre-exposure prophylaxis
PrEP-it	PrEP Implementation, Planning, Monitoring, and Evaluation Tool
PWID	people who inject drugs
SDC	serodifferent couple
TDF	tenofovir disoproxil fumarate
UNAIDS	Joint United Nations Programme on HIV/AIDS
USAID	United States Agency for International Development
WHO	World Health Organization

EXECUTIVE SUMMARY

Governments, donors, and other stakeholders in countries at the forefront of delivery for oral pre-exposure prophylaxis (PrEP) have encountered challenges in setting targets, estimating costs, and tracking PrEP delivery. In response, the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) funded the development of a Microsoft Excel-based tool called the PrEP Implementation, Planning, Monitoring, and Evaluation Tool, or "PrEP-it." This paper describes the development of PrEP-it, lessons learned during development, and the application of PrEP-it for target-setting in Eswatini and Zimbabwe and drug supply management in Ghana and Vietnam.

PrEP-it development occurred from October 2018 through September 2019. The development stages included: (1) a literature review to serve as a knowledge foundation and identify research gaps; (2) the assembly of national data sources to assist with tool inputs; (3) information-gathering visits to Mozambique and Zimbabwe; (4) consultation calls with PrEP experts; (5) tool development; (6) pilot testing in Eswatini, Kenya, Mozambique, and Zimbabwe; and (7) tool revision and release in September 2019. Key data sources used in the tool development include HIV prevalence estimates from Spectrum's AIDS Impact Model (AIM), PrEP costing studies from six countries, and Spectrum's Goals Model outputs on PrEP impact. In country applications, PrEP-it was used as an organizing framework to help stakeholders assemble data and make key decisions required for target-setting and commodity forecasting.

The primary need was for a tool to assist with target-setting, estimating capacity, forecasting costs and epidemiological impact, tracking program delivery, and projecting future client flow and commodity needs. Testing the tool with country-level stakeholders was critical in finding the right balance between flexibility, specificity, and user-friendliness in PrEP-it development. The calculations for targets, costs, and impact are all dependent on the continuation rates of populations on PrEP at months 1, 3, 6, and 12 after initiation. Country applications of PrEP-it demonstrated the importance of incorporating continuation rates in setting targets and forecasting drug supply needs, resulting in lower projected costs and drug needs than originally expected.

PrEP-it advances prior approaches to program planning, monitoring, and evaluation for PrEP by performing multiple complementary functions and incorporating PrEP continuation and implementation scale-up patterns, which had not previously been considered in target-setting and costing. A forthcoming software version of PrEP-it will enhance successful scale-up of PrEP in low- and middle-income countries.

INTRODUCTION

In 2015, the World Health Organization recommended oral PrEP for individuals at substantial risk of HIV infection who may not consistently use condoms.[1] Since then, more than 80 countries have introduced ongoing PrEP delivery for those at substantial risk of HIV infection.[2] In sub-Saharan Africa, where 70% of the people accessing antiretroviral (ARV) drugs for HIV treatment reside, PrEP programs have focused primarily on serodifferent couples (SDCs), female sex workers (FSWs), men who have sex with men (MSM), and adolescent girls and young women (AGYW).[3] Some countries have identified additional priority populations for PrEP provision, such as truck drivers and incarcerated persons.[4, 5]

PrEP implementation has varied both within and among countries in terms of service delivery models and populations of focus. While these variations allow adaptations to different contexts, they also pose challenges in planning and monitoring and evaluation (M&E) of programs supported by large donors such as PEPFAR, the Global Fund to Fight AIDS, Tuberculosis and Malaria, and host national governments. These stakeholders are often tasked with establishing targets for how many people should be reached with PrEP in a given time period.

Rapid scale-up of PrEP is one of the five prevention pillars for achieving the Joint United Nations Programme on HIV/AIDS (UNAIDS) goals of ending the HIV/AIDS epidemic; however, gaps in demographic, epidemiological, and behavioral data have impeded efforts to generate evidence-based targets.[6, 7] The uncertainties around the continuation of PrEP after initiation and the expectations for scale-up make annual target-setting and forecasting particularly challenging, with the risk that programs' assumptions about high continuation rates could result in overestimates of drug supply needs.[8, 9]

During a PrEP mathematical modeling exercise conducted in 2017 in collaboration with stakeholders in Eswatini, Lesotho, Mozambique, and Uganda,[10] country stakeholders expressed a need for assistance with target-setting, costing, and monitoring of PrEP programs. In response, PEPFAR and the U.S. Agency for International Development (USAID) funded the development of an innovative multi-module PrEP Implementation Planning, Monitoring, and Evaluation Tool (PrEP-it) to support setting targets, estimating capacity, forecasting costs and impact, tracking program delivery along the PrEP initiation cascade, and projecting future client flow and commodity needs.

This paper describes the development, structure, and features of PrEP-it and the lessons learned during the development and initial applications of the tool.

PrEP-IT DEVELOPMENT

Development Process

Most of the PrEP-it development occurred from October 2018 through September 2019. The development process included a literature review to provide a knowledge foundation; collation of national data sources for 35 countries and regional programs to assist with data inputs; information-gathering visits to Mozambique and Zimbabwe; global consultations with PrEP experts; tool development; pilot visits to Eswatini, Kenya, Mozambique, and Zimbabwe; and tool revision and release.

From October through December 2018, members of the PrEP-it team conducted a literature review to assess what was known about PrEP implementation in scaled-up settings, including target-setting, monitoring, and costing. We searched the peer-reviewed literature in the PubMed, Popline, and Global Health databases using keywords aimed at PrEP implementation, such as targets, costs, and scale-up. In addition, we reviewed abstracts from recent (2016–2018) International AIDS Society and HIV Research for Prevention conferences, as well as the prepwatch.org website and the AVAC database of current, planned, and completed PrEP demonstration projects, national guidelines, and implementation initiatives.[2, 11]

Because PEPFAR/USAID emphasized a need for default values, the team assembled several data sources (Table 1) to inform estimates of the number of potential PrEP users for 35 countries/regions. In addition, we analyzed cost data from PrEP programs in six sub-Saharan Africa countries[12–18] and combined them

with country-specific salary data[19, 20] to generate default values for visit costs. Finally, we used outputs from the Goals Model[21] for impact factors, expressed as HIV infections averted per person-year of PrEP.

Table 1. Data Sources

Module	Data Sources
Target-setting	United Nations population estimates (2018) UNAIDS report 2018 Key Populations Atlas HIV prevalence estimates (AIM 2018) Various peer-reviewed literature sources Most recently available Demographic and Health Survey data
Costs	Country-specific salary data PrEP reference cost studies from six countries (Eswatini, Kenya, Lesotho, South Africa, Zambia, Zimbabwe)
Impact	Goals Model outputs

The PrEP-it team also held consultations with country stakeholders in Mozambique and Zimbabwe, including Ministry of Health officials, PEPFAR country teams, and PEPFAR partners implementing PrEP programming. Information was collected on the priority populations being served, implementation approaches, health information systems, and support needs for program planning and M&E. In Mozambique, team members visited two facilities implementing PrEP services to review data collection tools and gain further insight into different implementation models.

To obtain global input on the tool, the PrEP-it team held a series of nine remote consultations with 32 experts from organizations involved in PrEP policy, research, or delivery. The stakeholders discussed important assumptions to incorporate in PrEP-it, such as the most common M&E metrics, scale-up patterns, and measures for estimating elevated likelihood for HIV acquisition.

The tool was field-tested in Eswatini, Kenya, Mozambique, and Zimbabwe. These field tests included holding meetings and workshops with Ministry of Health officials, PEPFAR teams, and PEPFAR implementing partners delivering PrEP, reviewing how the tool worked, and soliciting feedback on how it could be improved.

After revision, PrEP-it was released in September 2019, along with a user guide, introductory webinar, and instructional videos. In March 2020, we added a module to PrEP-it that allows users to identify localities that should be prioritized for PrEP provision to AGYW based on cost-effectiveness. Since the initial tool release, further updates to the modules have been made based on user feedback.

Findings

The literature review yielded a repository of 311 references, including 10 from peer-reviewed sources and eight from conference abstracts. The remaining references consisted of global and national guidelines, project descriptions from the AVAC database, and reports from prepwatch.org. Studies

suggested relatively high uptake of PrEP and a high discontinuation rate, with up to half of those initiating not returning for a one-month visit due to side effects, stigma, negative attitudes among health care workers, limited access to clinics, and tedious refill processes.[22–24] Reinitiation of PrEP was also observed, with one study finding 17% of AGYW restarting PrEP within three months of discontinuation.[25] While useful, the review identified many gaps in the literature, confirming the need for interactions with country partners and global experts to ensure the tool would help the intended users fill critical gaps in knowledge and planning practice.

> *The review confirmed the need for interaction with country partners and global experts to ensure the tool would help the intended users fill critical gaps in knowledge and planning practice.*

The initial consultations with country policy makers and program implementers highlighted specific challenges that PrEP-it could address for two primary audiences. First, it could serve a program planning function for governments and donors, to help them set targets and consider the corresponding coverage of potential users, estimated costs, and expected impact in terms of the number of HIV infections averted. Second, it could help implementers assess capacity for the delivery of PrEP, track the efficiency of the PrEP initiation cascade,[26] and project future client flow based on initiation and continuation rates.

In Mozambique, participants were interested in the use of PrEP-it for target-setting, particularly for annual PEPFAR planning. Participants in Zimbabwe expressed a need for assistance in estimating patterns of PrEP use, such as continuation rates, re-initiation, and episodic use. In response, a Continuation Calculator was included, allowing users to input client-level data to estimate continuation rates and the percentage of clients reinitiating during the data collection period.

The global consultations yielded several contributions that guided tool development. To maximize potential utility, experts recommended that the tool be designed to work at any level, including at the national, regional, implementing partner, and site levels. This flexibility means that in Microsoft Excel, the tool cannot be set up to allow for geographic breakdowns for most of the inputs and outputs, such as tracking the PrEP initiation cascade and drug forecasting. However, some components of the tool do allow users to conduct sublocation analyses, including the Capacity module, the AGYW Geographic Prioritization module, and the function enabling them to disaggregate targets by district.

Experts also emphasized the diversity of approaches that programs use to implement and manage PrEP and the differing access to data for data inputs, noting that some users would need suggested default values for population size estimates, continuation rates, and costs. The tool accommodates those differences by allowing a smaller set of required data inputs for less complex analyses. Furthermore, while a Detailed Cost module allows for a rigorous costing approach, a "Costs Lite" module with less detail was also included to allow for simpler cost analyses.

Feedback from the field tests provided several suggestions for clarifications, adjustments, and improvements. Throughout the consultation and tool development process, ease of use was underscored as a priority. The team included several features to improve the user interface, including color-coding and a navigational panel to direct users based on their specific objectives. In the Capacity module, the way drug capacity was entered for each site was altered to provide an algorithm for allocating national supply to sites.

PrEP-IT STRUCTURE AND FEATURES

PrEP-it can be used at any level (e.g., national, provincial, district, country, facility, or implementing partner) and users can select which functions of the tool they want to use. Required inputs and available outputs for each of the seven functions are summarized in Table 2. In addition, the tool identifies the minimum inputs needed to interact with the rest of the modules and to access additional functionality. The most prominent feature of PrEP-it is the breadth of functions available, addressing many aspects of PrEP planning and service delivery.

By addressing and linking target-setting, capacity, the initiation cascade, costing, drug supply, and impact in one tool, PrEP-it greatly expands the number and type of available outputs in comparison with tools that examine only one or two of these dimensions. A critical feature of the tool is that all calculations within the tool are based on continuation rates, i.e., the percentages of initiating clients who continue to take PrEP at months 1, 3, 6, and 12 after initiation. Continuation rates are used in target-setting to calculate the number of persons on PrEP each month, which then feeds into estimates of PrEP coverage, costs, impact, and drug supply needs.

Table 2. PrEP-it Functions

	Minimum Inputs	Additional Inputs	Within-Module Outputs
CONTINUUM	Monthly initiation visits	Monthly tracking of additional data related to uptake and other recommended PrEP indicators	Summary of PrEP cascade from HIV testing to initiation
	At least 1 continuation curve (% clients continuing PrEP at months 1, 3, 6, and 12 after initiation without a gap in service)	Allows up to 6 different continuation curves Client-level data to calculate continuation curves	Forecasts for the coming months based on recent past initiations and continuation rates
CAPACITY	Overall monthly capacity for initiation and continuation visits	If overall capacity is not known, capacity is calculated based on sub-unit (e.g., site-level) data on: • Staffing capacity (up to 2 staff types) • Laboratory capacity • Aggregated antiretroviral (ARV) supply • Potential PrEP clients (e.g., monthly demand for PrEP)	Calculations of overall capacity Bottlenecks identified for each sub-unit Efficiency analyses to maximize resource allocation

	Minimum Inputs	Additional Inputs	Within-Module Outputs
TARGET-SETTING	Priority populations Target time period Continuation curve(s) and scale-up pattern(s) Previously established targets	For targets based on coverage: • Priority population size • HIV prevalence • Percentage of each priority population at high risk • Percentage desired to be taking PrEP at the end of the target period For targets based on capacity: • Complete Capacity module	Annual and monthly targets per priority population Targets can be disaggregated by sublocation, age, and sex
COSTS	Annual visit schedule(s) Monthly ARV and adherence support costs Initiation and continuation visit costs using Costs Lite module Above-site costs	Detailed Cost module allows for further specification of costs: • More detailed staffing data, including task-shifting analyses • Service delivery models (e.g., fixed vs. mobile, urban vs. rural, different populations within a site, different geographic areas) • Greater specification of lab schedules • Pre-initiation visit costs	Cost per person initiated on PrEP, accounting for discontinuation Cost per person on PrEP for a full year
AGYW GEOGRAPHIC PRIORITIZATION	Selected threshold criterion HIV prevalence for each geographic area	Adjust defaults for PrEP efficacy, effective use, and annual discount rate Cost per infection averted threshold HIV prevalence among adolescent girls and young women (AGYW) ages 10–14 by geographic area Population AGYW and number initiating PrEP by geographic area Continuation rates by geographic area Delivery strategy by geographic area (based on Detailed Cost module) Costs per person-year on antiretroviral therapy (ART)	Identified areas for geographic prioritization Total number of AGYW and HIV prevalence in selected areas Total PrEP costs and total cost savings for AGYW in selected areas Total cost savings across all areas Additional cost savings achieved by targeting

	Minimum Inputs	Additional Inputs	Within-Module Outputs
IMPACT	No required inputs	Specify which ART/voluntary medical male circumcision scale-up scenario to use for impacts Assign impact factors for custom populations Adjust impact factors to account for selection of higher-risk individuals within one of the listed populations	No impact-only outputs
DRUG SUPPLY	Number of pills distributed at initiation and continuation visits Cost per pill	No additional inputs	Monthly pills needed and associated costs for ARVs associated with projections based on program implementation data or targets

CROSS-MODULE OUTPUTS

Continuum + Capacity = View potential capacity gaps based on service delivery forecasts
Continuum + Targets = Compare service delivery with targets
Continuum + Costs = Estimate costs associated with service delivery to see if costs are in line with expectations
Continuum + Impact = Estimate the number of HIV infections averted based on service delivery
Continuum + Targets = Set targets based on capacity for service delivery
Continuum + Targets = View potential capacity gaps with established targets
AGYW + Targets = Generate targets based on selection of areas with potential for most impact
AGYW + Impact = Identify more accurate impact factor for AGYW in selected geographic areas
Costs + Targets = Estimate costs based on targets
Impact + Targets = Estimate number of HIV infections averted associated with targets
Costs + Impact + Targets/Cascade = Estimate costs per HIV infection averted

The **target-setting** functions in PrEP-it allow for three different approaches to calculating or examining targets for initiations: (1) use the Microsoft Excel Solver add-in to set targets by the desired proportion of the eligible population taking PrEP at the end of the target-setting period based on the continuation rates and scale-up patterns; (2) set targets by allocating health system capacity among different priority populations; or (3) enter previously established targets to estimate population-level coverage and produce outputs in conjunction with other modules related to capacity, costs, drug supply, and impact. For all three approaches, users must define the priority populations (for example, SDCs, MSM), enter the continuation rates for each priority population, and specify the scale-up pattern anticipated for rolling out PrEP in each priority population.

PrEP impact is calculated via impact factors, which are the numbers of HIV infections averted over five years per person-year of PrEP, for each indicated population. Default impact factor values were derived for each of the 35 countries and for each population using the Spectrum Goals Model, a dynamic compartmental model of HIV transmission by risk group.[27] PrEP efficacy was assumed to be 90%, and adherence was assumed to be 100%. We assumed 50% coverage in 2020 for each population and output HIV infections averted over the five-year period from 2020 to 2024. We then used Calibrated Goals files for each of the 35 countries to project average infections averted per year in the total population over a

five-year period following a one-year temporary increase in PrEP coverage. Infections averted were projected under two scenarios of ART coverage over five years: constant ART coverage and a 90-90-90/95-95-95 scenario (percentage of the population who know their HIV status, percentage of those testing HIV positive who are on ART, and percentage of those on ART who have achieved viral suppression). The resulting estimates of infections averted per person-year on PrEP can be adjusted by users.

Estimating the **costs of PrEP** required a new approach that incorporates a visit schedule to account for high discontinuation rates and the different costs of initiation visits and continuation visits. While the costs of the drugs used for PrEP were frequently known, default data were needed for the other components of visit costs. We analyzed facility-level cost data to extract staff minutes per visit for different priority populations. These data were combined with country-specific salary schedules to estimate personnel costs, which are the foundation for calculating default values for other cost components, including laboratory, overhead, capital, and above-site-level costs. Users can either use the default values or enter their own cost data; these data are then linked to continuation rates and visit schedules to estimate the annual cost per person initiating on and continuing to take PrEP.

For a more detailed cost analysis, users can elect to use the Detailed Costs module, which allows for multiple "service delivery modes" (ways in which costs may vary, such as implementation model, type of site, urban/rural, population served, subnational geographic area, implementer) with different cost structures aimed at each population. A simpler Costs Lite module is also available for users with less detailed costing needs or data available. Costs are specified in terms of personnel time, laboratory tests, capital costs, and other recurrent costs (e.g., commodities, training) for initiation and continuation visits separately, by population in Costs Lite and by both population and service delivery mode in Detailed Costs. Above-site costs, such as demand creation or training, can be specified as annual lump sums by population and service delivery mode. The schedule of continuation visits following initiation (e.g., every month or every three months) can be specified for each population/service delivery mode; visit costs are accrued over time according to visit schedules and subject to continuation rates. Cost results include total cost per year, cost per HIV infection averted, and cost per person initiated, each available by population and service delivery model.

PrEP-it contains an **AGYW Geographic Prioritization** tool that allows users to identify localized pockets of high HIV risk among AGYW that are not captured by national- or provincial-level surveys. The user can specify a list of sites, along with HIV prevalence (or test positivity rates) among AGYW, costs of PrEP and ART, and other optional inputs for each area. A formula derived from a regression model estimates HIV incidence from local prevalence among AGYW ages 15–24 (and, optionally, among AGYW ages 10–14, for a better estimate).[28] PrEP-it then identifies which catchment areas are cost-saving (where it is less expensive to deliver PrEP than to pay for lifetime ART), or which catchment areas are cost-effective, subject to a user-defined threshold for cost per infection averted.

The **Drug Forecasting** module builds on the infrastructure of the target-setting process, where users select populations, enter continuation rates, and specify scale-up patterns. This module requires only the number of pills distributed at initiation and continuation visits and the cost per pill. The tool then calculates the number of ARVs needed each month and the estimated ARV costs.

Since its release, PrEP-it has been downloaded more than 200 times. The governments of Eswatini, Kenya, Tanzania, Zambia, and Zimbabwe have used PrEP-it as part of the target-setting process; the experiences of Eswatini and Zimbabwe are documented in this paper. In addition, Vietnam and Ghana used PrEP-it for drug forecasting, and their experiences are described below.

Eswatini

In Eswatini, PrEP is delivered to numerous priority populations, including SDCs, sex workers, transgender persons, AGYW, MSM, and other men with increased likelihood of HIV acquisition. The Eswatini National AIDS Programme, a part of the Ministry of Health, used the June 2019 PrEP-it field visit workshop as an opportunity to set five-year national targets. During the workshop, participants discussed the various questions the PrEP-it framework poses. For the priority populations, targets were set for SDCs, FSWs, MSM, AGYW, transgender women, pregnant women, breastfeeding women, and a custom population of men 30–34 years old. Continuation curves relied on demonstration project data for most priority populations, but the team adjusted them to higher continuation rates for SDCs and pregnant women based on the special needs of these populations. Default data for HIV prevalence and percentage indicated for PrEP were used as a starting point for discussion, and three different S-shaped curves for scale-up were assumed, allowing for variation in the peak scale-up month by priority population.

The group elected to set targets based on coverage, using the tool to estimate the number of initiations needed to reach a specified coverage level at the end of the target period. The specified coverage levels ranged from 10% for pregnant and breastfeeding women, transgender women, and AGYW ages 15–19 to 35% for SDCs. Based on these inputs, PrEP-it projected that a total of approximately 85,000 PrEP initiations would be required over five years. Earlier in the target-setting process, higher coverage levels had been selected, but they were adjusted downward after the group considered the feasibility of implementation.

Zimbabwe

Zimbabwe's national PrEP targets had been set for 2018–2020. In January–February 2020, the PrEP Technical Working Group began setting new national PrEP targets for 2021–2023. The priority populations included SDCs, FSWs, MSM, people who inject drugs (PWID), transgender persons, AGYW ages 15–19 and 20–24, and pregnant and lactating women. The PrEP-it team used recent population size estimates for SDCs, FSWs, and MSM. Where data were more uncertain, different population size estimates for PWID and transgender persons were examined. Targets were set by coverage, ranging from 4% for AGYW ages 15–19 to 24% for PWID, and different continuation rates were entered for each priority population, based on partner data. An S-shaped scale-up pattern was selected for all populations except SDCs, for whom a constant trend was assumed. Based on the different population size estimates, the team presented two sets of targets to the PrEP Technical Working Group: 1) an estimate of 126,000 initiations and 2) a more ambitious estimate of 142,000 initiations based on larger population size estimates and a higher proportion of those estimated to be at elevated risk for HIV. The PrEP Technical Working Group selected the 126,000 initiations targets as a more realistic goal to achieve in the next three years.

Ghana

In Ghana, PrEP delivery was aimed at SDCs, MSM, FSW, and transgender women; however, questions arose as to whether PrEP provision might interfere with the ARV supply for HIV treatment. Ghana's national AIDS program was using tenofovir disoproxil fumarate/emtricitabine (TDF/FTC) and TDF/lamivudine (3TC) for HIV treatment and planned to use them for PrEP. To estimate the impact of starting PrEP provision, the team used PrEP-it to estimate the quantity of ARVs that would be needed each month to reach PEPFAR PrEP targets. The previously established targets for October 2020 through September 2021 were entered into the Targets module, with 1,418 projected users over the period. In addition, alternate scenarios of PrEP scale-up were estimated to determine the number of initiations that would be needed each month to reach targets by the end of the fiscal year under different scenarios.

The team estimated continuation rates using study and programmatic data from the peer-reviewed literature and entered them in the Continuation module, with 55% of expected clients continuing at the first month post-initiation and a gradual decline in continuation at month 3 (45%), month 6 (35%), and one year (25%). An S-shaped curve with peak scale-up at month 6 was selected in the Targets module. Based on these inputs, the team used PrEP-it to estimate the target number of people on PrEP each month and, from that, the number of ARVs needed each month to fulfill the entered targets. The results showed that PrEP provision would have a minimal impact on the ARV stock available at the national level. As a result, it was determined that PrEP provision could commence.

Vietnam

Like Ghana, Vietnam used PrEP-it to estimate the number of ARVs needed, in this case as part of the PEPFAR Country Operational Plan for 2020. The previously established target of 30,000, focusing on the SDC, MSM, sex worker, PWID, and transgender populations, was entered into the Targets module. For the Continuation module, the continuation rates were obtained from in-country programmatic data showing relatively high levels of PrEP continuation after initiation: 95% at month 1, 89% at month 3, 76% at month 6, and 69% at one year. An S-shaped curve was selected with a peak scale-up at three months. Based on these inputs, PrEP-it was able to forecast the number of ARVs needed each month over 12 months from October 2020 through September 2021. As a result, PEPFAR Vietnam adjusted the amount of ARVs originally planned for and shifted some of the funding that had been budgeted for ARVs to efforts to drive demand for PrEP and increase the quality of PrEP service provision.

LESSONS LEARNED

Each step in the PrEP-it development process affirmed the need for an innovative tool to help users navigate the myriad of challenges associated with PrEP program planning and implementation. PrEP-it addresses these challenges by allowing users to set targets, track PrEP delivery, analyze patterns of PrEP use, and estimate capacity, costs, drug supply needs, and impact in one accessible tool, ultimately ensuring that planning meets the demand for PrEP commodities and is informed by concrete program implementation at the service-delivery level.

The most important lesson learned from the tool development is the need to test the draft tool with country partners to ensure that it meets their needs and is developed with the available data in mind. Key insights were gleaned from each initial country visit and subsequent application of PrEP-it, resulting

in tool adaptations and new modules, such as the Costs Lite, Drug Forecasting, and AGYW Geographic Prioritization modules.

A key lesson from applying PrEP-it, observed in all the applications discussed here, is that continuation rates have important implications for costs, target-setting, and drug forecasting. For costs, those projecting budgetary needs for PrEP based on targets outside of PrEP-it often assumed PrEP continuation rates far higher than the reality, and therefore projected high annual costs associated with each client. The inclusion of more accurate assumptions about continuation rates produces a much more realistic picture of the implementation costs and ARV needs associated with targets. For target-setting, the inclusion of continuation rates and scale-up patterns allows users to estimate the number of individuals on PrEP at any given point in time and understand how many PrEP initiations are needed to reach desired coverage levels. In the applications, higher numbers of initiations were often needed than were originally planned for due to discontinuation.

The ability to generate more accurate estimates of PrEP use also has important implications for drug forecasting, enabling governments to predict their drug needs and not be constrained by unwarranted fears that the introduction of PrEP will significantly affect the supply of ARV drugs for people living with HIV who need life-long ART. In this sense, PrEP-it can be used as a tool to advocate for initiating PrEP rollout.

Understanding coverage is particularly important in PrEP-it, where coverage means the proportion of the eligible population taking PrEP at the end of the target period, not the proportion who have been exposed to PrEP throughout the target period. By using coverage in the last month of the target period, when programs have typically attained scale-up, PrEP-it users can focus on what is needed to achieve epidemiological impact. During the application process, it became clear that low continuation rates combined with high coverage goals led to unrealistically high targets. To achieve these targets, PrEP clients would need to cycle on and off PrEP repeatedly during the year, and thus initiation targets far exceeded the number of potential users. Therefore, we recommend setting target coverage levels below the specified six-month continuation rates. If higher coverage levels are desired, planners and implementers may wish to use aspirational continuation rates, with the understanding that increasing continuation is critical to achieving program goals. Alternatively, if PrEP users are cycling on and off PrEP multiple times per year and program planners want to capture that dynamic, they need to understand that the number of initiations (which include reinitiations) can reasonably exceed the population size.

An additional lesson is the need to set aside sufficient time for applying PrEP-it. Time is required for internal discussions about which PrEP-it functions, data sources, and assumptions should be used. In this sense, PrEP-it serves as an organizing platform that can help program planners and implementers who have different priorities and foci work together to better plan for and provide PrEP; however, multiple meetings are typically required for these negotiations before targets can be finalized.

> *PrEP-it serves an organizing platform that can help program planners and implementers work together to better plan for and provide PrEP.*

As with every tool, PrEP-it has limitations. First, it does not address every planning and management need for PrEP programs. For example, several in-country stakeholders expressed a need for assistance with demand creation tools. PrEP-it can indicate when demand creation is needed by identifying where the ability to reach targets may be limited by demand, but it does not provide guidance on demand generation. Second, although PrEP-it provides default data inputs for some variables, they are often

based on assumptions or data aggregated at the national level; users should tailor inputs to their specific program contexts. Third, PrEP-it does not address PrEP cycling, when individuals start, stop, and restart PrEP, or event-driven PrEP, when PrEP is used for a specific exposure. Fourth, the current version of PrEP is limited to oral PrEP, but a forthcoming version will be expanded to incorporate a method mix of oral and vaginal ring PrEP.

Finally, although Microsoft Excel is readily available to most potential users, version control and difficulty managing updates are concerns. In addition, the two-dimensional nature of Excel makes it difficult to easily capture the multidimensionality of PrEP programs. A forthcoming software version of PrEP-it, planned for release in 2021, will allow for a more user-friendly interface and additional features, including planning for and tracking multiple PrEP modalities, such as oral, vaginal ring, and injectable PrEP.

CONCLUSION

Prior to PrEP-it, few PrEP planning and M&E tools were available beyond the existing systems that track PrEP initiations for PEPFAR reporting purposes. PrEP-it's increased focus on continuation rates, scale-up, and population coverage provides an important advancement for PrEP planning and management. In the coming years, PrEP programming will undoubtedly evolve, and PrEP-it is designed to co-evolve to enhance successful scale-up of PrEP. In the meantime, the current version of PrEP-it and the accompanying user guide are available at no cost to any program interested in using it to help improve planning, monitoring, and evaluation of the delivery of PrEP.

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