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Measurement Guidance for Global Fund Supported HIV Prevention
Programmes
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List of Abbreviations

AGYW	Adolescents Girls and Young Women
CSE	Comprehensive Sexuality Education
DHIS	District Health Information Systems
DHS	Demographic Health Survey
GBV	Gender Based Violence
HIV	Human Immunodeficiency Syndrome
HSS	HIV Sentinel Surveillance
HTS	HIV Testing Services
IBBS	Integrated Bio-Behavioural Survey
KP	Key Populations
M&E	Monitoring and Evaluation
MICS	Multiple Indicator Cluster Surveys
NSP	National Strategic Plans
OST	Opioid Substitution Therapy
PBS	Polling Booth Survey
PEP	Post Exposure Prophylaxis
POMT	Prevention Outcome Measurement Toolkit
PrEP	Pre-exposure Prophylaxis
PSE	Population Size Estimates
RF	Results Framework
SRHS	Sexual Reproductive Health Services
STI	Sexually Transmitted Infections
ТА	Technical Assistance
TERG	Technical Evaluation Reference Group
тос	Theory of Change
UIC	Unique Identifier Codes
UNAIDS	United Nations Programme on HIV/AIDS
VACS	Violence Against Children and Youth Surveys
VMMC	Voluntary Medical Male Circumcision
WHO	World Health Organization

1. Background and Purpose

With the renewed emphasis on prevention and push to expand investments in HIV prevention programmes, it's imperative to strengthen monitoring and evaluation efforts. This is crucial to effectively demonstrate progress towards the objective of ensuring that by 2025 95% of people at risk of HIV infection have access to and use appropriate, prioritized, person-centred and effective combination prevention options; and the goal of reducing new HIV infections to less than 370,000 by 2025^a and ending HIV by 2030.^b

The UNAIDS 10-point plan for accelerating HIV prevention at the country level emphasizes the need to "Establish or strengthen prevention programme monitoring systems" as a critical ingredient to successful implementation of HIV prevention programmes^c. Specifically, improve country routine monitoring systems that are gender and population specific to identify and address challenges and track programme performance at all levels.

The measurement guidance for Global Fund HIV prevention programmes aims to support country programmes and country monitoring and evaluation systems to align to the UNAIDS 10-point plan. The measurement guidance emphasizes essential components of Monitoring and Evaluation (M&E) systems necessary for effective programming. In instances where these components are deficient or absent, it's essential to consider allocating resources to strengthen them as part of HIV prevention programmes mainly for, key populations, adolescent girls and young women, PrEP, condoms and voluntary medical male circumcision. Majority of HIV prevention programmes are implemented at the community level that also experience weak M&E systems.

In addition, recent findings from the Technical Evaluation Reference Group (TERG) Thematic Review on HIV Primary Prevention (2020) indicated a lack of overarching framework and approach to measuring results citing **inconsistencies in reporting and monitoring of Global Fund supported HIV prevention programmes in countries** and recommends that **guidance could be improved** to address this gap.^d

In response, the Global Fund team has developed **a measurement guidance for Global Fund supported HIV prevention programmes.** The measurement guidance provides guidance to the Global Fund supported HIV prevention programmes, specifically the document identifies critical M&E system components, analytics, data use cases and indicators for consideration during planning and resource allocation. The primary users of this guidance are the Global Fund principal recipients (PR) and sub-recipients (SR).

^d <u>TERG Thematic Review on HIV Primary Prevention</u>

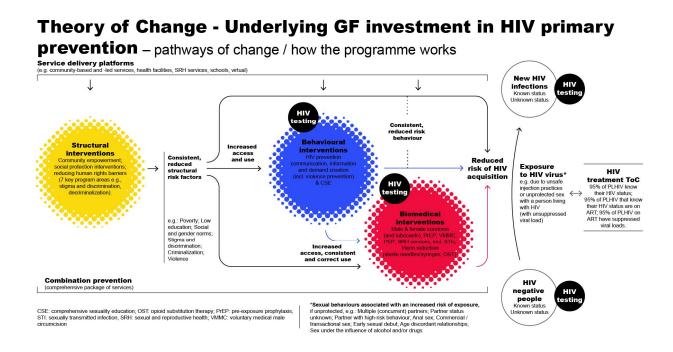
^a Global AIDS Strategy 2021-2026 — End Inequalities. End AIDS.

^b The path that ends AIDS. 2023 UNAIDS Global AIDS Update

[•] UNAIDS HIV Prevention 2025 Road Map-Getting on track to end AIDS as a public health threat by 2030

2. Theory of Change

The Theory of Change underlying the Global Fund's investment in HIV primary prevention highlights the importance of combination HIV prevention. At the same time, it makes clear that biomedical interventions have a "shorter" pathway to reducing the risk of HIV acquisition compared with behavioural and structural interventions. This is relevant for how the Global Fund and its implementing partners track results.



3. Results Framework

For the Global Fund, it is important to know if its investments in HIV primary prevention are leading to the results it aims to achieve. This Global Fund HIV prevention Results Framework clarifies the relationships between input (investment), outputs (coverage), and outcomes (use, behaviour) for HIV impact (new infections). It highlights the importance of focusing measurement on a set of primary outcomes that are proximal to the reduction of new HIV infections. The TERG review also found that at the country grant level, monitoring focuses on outputs/coverage indicators, rather than measuring prevention-related outcomes and achievements. This Results Framework seeks to inform discussions and decisions on how the Global Fund can make the best investments, by prioritizing interventions or outcomes, targeting populations at substantial risk, to contribute to improved HIV prevention outcomes in the countries in which it invests.

Global Fund HIV primary prevention Results Framework

- results chain (from inputs to impact)

What the Global Fund invests in			Partly as a result of Global Fund investments			
INPUTS	>	MODULAR FRAMEWORK INTERVENTIONS (made available/accessible via service delivery platforms)	(programme level) – availability and access # and % out of population in programme calchment area	(country leve	ICOMES () – use / behaviours focus population Primary	IMPACT (country level)
Country allocations and Catalytic	omedical eventions	Condom & lubricant programming P(EP SRH services, incl. STIs, hepatitis, post-violence care (PEP) Needle & syngle programmes OST VMMC HIV prevention communication, information and demand creation (incl. violence prevention) CSE in/out of schools	cation, information and demand creation • Reached with CSE (in/out of school)	 HIV risk behaviours (e.g., # of – concurrent – sex partners, type of partners, (risk, age), age of sexual debut) Knowledge about HIV, risk behaviours, prevention options Prevalence of violence 	 Used a prevention option during potential HVV exposure opportunity Consistent and correct condom use during high-risk sex Consistent use of PEP Used PEP when needed STI prevalence Maintained on OST Circumcision prevalence 	Reduction in new HIN infections
	tructural erventions	Community empowerment for key populations Removing human rights-related barriers to prevention Social protection interventions for AGYW		 Prevalence of stigma and discrimination AGYW completing secondary school AGYW with sufficient financial resources 		

4. M&E System Strengthening Considerations

A robust monitoring and evaluation system is essential for accurately tracking, monitoring, and evaluating HIV prevention programmes. Table 1 outlines key considerations that can inform planning and implementation of effective measurement of HIV programmes at output/coverage, outcome, and impact levels. Table 2 describes timelines of different data points and use cases.

Component	Specific challenges	Considerations				
Routine monitoring of programme coverage						
Counting and	 Difficulty in accurately 	Support availability of tools and a				
reporting unique	determining	reliable system for routine monitoring				
individuals reached	populations reached	of unique individuals who receive a				
with a combination of	with HIV prevention	combination of HIV prevention				
HIV prevention	services. This is	interventions, specifically:				
services/ interventions mostly due to		 Generation and use of programme 				
	inaccurate counting of	level unique identifier codes,				
	unique individuals	District Health Information System				
	reached with	(DHIS) longitudinal database – at				
	combination HIV	least at programme level while				
	prevention	informing district and national level				

	 interventions in the absence of unique identifiers at district or national levels. Lack of a standard definition of HIV prevention package of interventions across programmes/countries as well as differences in the frequency or dose that is required before counting individuals as having received a specific intervention/service. 	 discussions. Link to DHIS tracker toolkit. De-duplication of reported data to improve data quality. For example, having a mechanism to identify and record new and repeated clients. See Table 4 developed by Global Fund team on "Methods used to avoid double counting". Mechanism to track individuals reached with context specific defined package of service as per national or program level guidance.
Estimation of population in need and at higher risk of HIV prevention services	 Lack of timely and accurate data on population size at national and sub- national levels (denominator). Definition of who to include in the denominator, i.e., the most at-risk portion and reachable portion of specific groups and subgroups. For example, in the case of AGYW - should this be the entire population in a high incidence district or only sub-set of those individuals at risk of HIV? 	 Use best available and empirically derived population size estimates where this is available e.g., key population size estimates. Refer and implement available technical partner guidance on estimation of populations in need of HIV prevention services e.g., UNAIDS guidance for estimating AGYW at risk of HIV. Link to UNAIDS AGYW PSE tool. Support TA, funding for planning and implementation of regular key population size estimation exercise, triangulation of programme and existing integrated bio-behavioural survey (IBBS) data to estimate population size for key populations. Where needed use online and offline vulnerability or risk assessment tools to identify the nature and magnitude of vulnerabilities/risk. This further inform targeted planning and allocation of resources.

Longitudinal/individual level tracking and reporting Effective referrals and linkages as a means towards comprehensive HIV prevention services	 Lack of individual level information on services received and outcomes. Lack of mechanisms that provide information on completeness of referrals making it difficult to identify individuals who fall through the referral network and need follow-up to ensure they receive interventions not provided at primary service delivery point. 	 Strengthen individualized data systems that enable continuous/longitudinal follow-up over time to assess individual level pathway from service/s offered to outcomes of HIV prevention interventions. Develop systems/mechanism for monitoring linkages and referrals within community platforms and between community and health facilities. Strengthen coordination with service providers in other critical sectors such as education, social protection, legal, health to facilitate referrals and linkages and ensure key and vulnerable populations receive comprehensive HIV prevention services and interventions. Generation and use of common and agreed unique identifier codes across services/programmes and facilities will facilitate tracking of referrals as well as completion of referrals.
Technical assistance/Capacity building for principal and sub-recipients (PRs/SRs)	 Community level programmes and staff often have limited capacity on M&E and mostly lack strong data systems to monitor programmes. 	 Tailored M&E support to PRs/SRs to strengthen community level data systems and M&E practices.
Tracking and monitoring	1 0	
(Rapid) surveys, studies, assessments that produce timely outcome data and other strategic information	 Lack of timely programme level outcome data to inform effectiveness of programmes. Traditional surveys are often not tailored 	 Continue to support IBBS and population-based surveys (e.g., DHS, VACS, MICS). In addition, support innovative approaches to monitoring outcomes; rapid and cost-effective methods as defined in Annex 2,

	to the changing need	discussing the HIV prevention
	for timely programme level outcome data. These take 3-5 years to implement, are costly in nature (planning and implementation) and often do not provide sub-national data closer to programmes. • There is a need for simple and low-cost methodologies to routinely monitor the effects of HIV prevention programmes.	 outcome monitoring toolkit (POMT), such as BBS-Lite, Rapid Coverage Survey and polling booth surveys. Support and conduct targeted systematic program and thematic reviews. Ensure appropriate technical assistance for developing systems that monitor programme outcomes as part of programme monitoring for PRs/SRs as needed.
Monitoring client feedback on a regular	Client perspective on the quality of convices	• Support community-led monitoring
basis	the quality of services and care provided is	(CLM) approaches as a means of identifying opportunities for
	often missing. This is an important part of	strengthening quality of services, access barriers to HIV prevention
	ensuring a person-	programmes by key and vulnerable
	centred approach in HIV prevention	populations and programme coverage. <u>Link</u> to CLM guide.
	programmes.	
Tracking and monitoring	g impact (new HIV infect	ions)
Monitoring impact of	-	Ensure availability of relevant
HIV programmes	key variables required to inform modelling	data/information to inform modelling, for example, population
	exercise, such as	level programme coverage and
	programme coverage	outcome data (condom use, PrEP,
	and outcome data.	teenage pregnancies etc).Where possible conduct in-
		depth/longitudinal analysis of
		individually linked data on service
		uptake, risk practices and HIV status over time. This analysis can
		provide important insights on impact
		of programmes at individual and population levels.

Table 2. Timelines of different data points and use cases

	Result framework elements					
	Input	Output (Coverage)	Outcome (use, behaviour)	Impact	Use cases and decision points in the grant cycle	
	Resource mapping				Country dialogue, Funding Request development, Grant making	Grant design
Data points;		Routine indicator-	Outcome	HIV incidence estimates, sub- national Population Size	Year 1: PUDR/Performance monitoring/Grant rating Year 2: PUDR/Performance	
platforms, methodologies & tools	Service delivery & M&E systems readiness assessments, Commodity availability	based reporting, IBBS, population- based surveys), annual reviews and program reviews (3 yearly)	monitoring (POMT), IBBS, Population- based surveys	Estimates (AGYW, KP), Case surveillance, IBBS, Population- based surveys	monitoring/Grant rating Year 3: PUDR/Performance monitoring/Grant rating	Grant implementation

5. Qualitative and Quantitative Data Analysis and Use

Improving availability of quantitative and qualitative granular data and analytical capacity of providers, programme staff and donor organizations to conduct basic and complex analysis should be an integral part of HIV prevention programmes. This includes leveraging existing technical partner guidance and support for other qualitative and quantitative data sources such as surveys, special studies, operation research, programme evaluations and reviews and community-led monitoring. Table 3 provides examples of analyses to be conducted to inform HIV prevention programmes.

Table 3. Analytics and data use cases for HIV prevention programmes

Type of Analysis	When/Who	How	Use of analysis
Programme	Monthly,	Program level data	Monitor progress
coverage	quarterly	on numbers of key	towards:
		and vulnerable	 Addressing country
Key question: are	Program staff	populations reached	need for key
programmes reaching		based on agreed	services/interventions
the target of key and		performance	both at programme
vulnerable populations		indicators (Annex 1).	and population level.

(at program and population levels)?		Denominator/ population at risk of HIV from population size estimates (PSE) for KP/AGYW	 NSP target. Set program targets and reporting to donors.
Layered analysis (service layering) Key question: Is layering happening as planned/intended? Are key and vulnerable populations receiving needed services/interventions?	Quarterly, annually Program staff	Programme level data on number of beneficiaries (KP/AGYW) completing/receiving required package of service (at site and/or at a referral site)	 Indicative of comprehensiveness of interventions received by key and vulnerable populations.
Referral and linkage completeness analysis	Quarterly, annually Program staff	Program level data tracking referrals and completion status	 Effectiveness of referral and linkage systems Identified gaps will be opportunities for strengthening and ensuring effective referral system.
Outcome analysis (based on agreed desired outcomes) Key question: are desired behavioural, structural, and biomedical changes occurring at individual and population level?	Annual or biannual Program staff, supporting donor organizations.	Special outcome monitoring tool as in Annex 2. Explore rapid cost-effective methods such as BBS-Lite, Rapid Coverage Surveys, Polling Booth Surveys, as well as other surveys (HSS plus or exit surveys).	 Demonstrate if programme is in the right trajectory towards desired outcomes. Demonstrate individual level effect of the programmes. Effectiveness of HIV prevention programmes
Intervention and cost efficiency and effectiveness analysis Key question: are programmes implementing effective	Annual or biannual Donor organizations, technical partners	Based on existing technical guidance	Demonstrate value for money.

interventions and in efficient ways?			
Impact analysis Key question: Is there a reduction in new HIV infections among targeted key and vulnerable populations?	Annual or biennial Donor organizations, technical partners	Based on existing technical guidance against available quality data	Demonstrate if programmes are attaining desired effect at population level.

6. Learning and Adapting for Program Improvement

Continuous actionable learning and adaptation using data and information from analyses listed above is important for evidence-based programme improvement. Activities that produce data and the process for analysing and using data/information need to be complementary and supported and budgeted for during program planning. This should include strengthening and supporting mechanisms and platforms that enhance learning at the Secretariat and country levels through sharing of best practices, challenges, and innovative approaches etc. This should include targeted support to community level and health facility staff to analyse, interpret and use data to improve targeting approaches and monitor progress towards set objectives. Important in this process is enhancing mechanisms that trigger use of available information such "pause and reflect" sessions creating opportunities for deeper questions about the programme based on continuous interaction between programmes and data at all levels – country (national and subnational) and secretariat levels. At the secretariat level, strengthening platforms for cross-country sharing and learning in collaboration with other technical partners is important in addressing existing programmatic and implementation challenges.

In addition, evaluations, specific thematic and in-country reviews aimed at answering specific programmatic, operational, and cost related questions will be critical sources of information for a successful HIV prevention programme. Evaluations/operational research and reviews serve as platforms for identifying what is working and what is not working providing a platform for identifying programmatic gaps and opportunities to make necessary course correction for programme improvement.

Table 4. Method developed by the Global Fund teams for use to address double counting

Reporting methods	Key features	Description	Practical use	Target cumulation
Basic	No system to report on individual people - Information recorded only on contacts or services provided (Newly established programs)	 To perform brief survey of clients during a week/month. Ask all contacts "Is this first time you have received this service here? If no, when was the last time you received the service (week/month)? 	 For assessment of ratio between contacts and clients to set baseline and project future targets for actual number of clients. Used only in new program where no system to avoid double counting is in place. Meanwhile, ensure that system is put in place 	Non-cumulative (other)
Moderate	Information is recorded for each client reached, without using a UIC - paper based records that track new and repeat clients	 Record if the clients visit in the specific period is the first one? If yes, then it is recorded as new client. If not, record if the visit is the first one since the beginning of the reporting period (semiannual) or the year (annual) 	 Reporting on individual clients (new and repeated clients for the period/year). Not possible to avoid double counting among different service providers and if client is reached in the 1st and 2nd period. 	Non-cumulative (Other) Work on establishing UIC system across service providers
Advanced	Electronic UIC is in place and used across locations and service providers	 At the time of service provision, each service provided is recorded using a UIC. It links the services provided to the same client over time. 	 Reporting on individual clients (per month, quarter, semester & annually). It also allows reporting on the frequency of reach and type of services provided (commodities per client) 	Non-cumulative (Other)

Annex 1. Summary of HIV prevention indicators

A summary of HIV prevention indicators based on internal and external partner consultations. Detailed definition including numerator/denominator, required disaggregations, frequency and data source is available in the <u>HIV indicator reference sheet</u>.

Module	Type of Indicator	Indicator Code	Indicator Name
	Impact	HIV I-14	Number of new HIV infections per 1000 uninfected population
	Impact	HIV I-9a (M)	Percentage of men who have sex with men who are living with HIV
	Impact	HIV I-9b (M)	Percentage of transgender people who are living with HIV
es	Impact	HIV I-10 (M)	Percentage of sex workers who are living with HIV
All Modules	Impact	HIV I-11 (M)	Percentage of people who inject drugs who are living with HIV
AIIA	Impact	HIV I-12 (M)	Percentage of other vulnerable populations (specify) who are living with HIV
	Outcome	HIV O-10	Percent of high risk AGYW (15-24) who say they used a condom the last time they had sex with a non-regular partner, of those who have had sex with such a partner in the last 12 months.
	Outcome	HIV O- 4a(M)	Percentage of men reporting using a condom the last time they had anal sex with a male partner.
	Outcome	HIV O- 4.1b(M)	Percentage of transgender people reporting using a condom during their most recent sexual intercourse or anal sex
	Outcome	HIV O- 5(M)	Percentage of sex workers reporting using a condom with their most recent client
	Outcome	HIV O- 6(M)	Percentage of people who inject drugs reporting using sterile injecting equipment the last time they injected.
	Outcome	HIV O-9	Percentage of people who inject drugs reporting using a condom the last time they had sexual intercourse.
dules	Outcome	HIV O-7	Percentage of other vulnerable populations who report the use of a condom at last sexual intercourse.
All modules	Outcome	HIV O-13	Proportion of ever married or partnered women aged 15-49 who experienced physical or sexual violence from a male intimate partner in the past 12 months.

Modular Framework Handbook (Allocation 2023-2025).

len with	Coverage	KP-1a(M)	Percentage of men who have sex with men reached with HIV prevention programmes - defined package of services.
Prevention package for men who have sex with men and their partners	Coverage	KP-6a	Number of men who have sex with men who received any PrEP product at least once during the reporting period.
Prevention package fo who have s men and th partners	Coverage	KP-7a	Percentage of men who have sex with men tested for STIs during the reporting period.
r their ners	Coverage	KP-1b(M)	Percentage of transgender people reached with HIV prevention programmes - defined package of services.
Prevention package for Transgender people and thei sexual partners	Coverage	KP-6b	Number of transgender people who received any PrEP product at least once during the reporting period.
Preven packaç Transg people sexual	Coverage	KP-7b	Percentage of transgender people tested for STIs during the reporting period
· Sex ∋ir other ìers	Coverage	KP-1c(M)	Percentage of sex workers reached with HIV prevention programmes - defined package of services.
Prevention package for Sex workers, their clients, and other sexual partners	Coverage	KP-6c	Number of sex workers who received any PrEP product at least once during the reporting period.
Preven packag worker clients, sexual	Coverage	KP-7c	Percentage of sex workers tested for STIs during the reporting period
ople exual	Coverage	KP-1d(M)	Percentage of people who inject drugs reached with HIV prevention programmes - defined package of services.
e for People I their sexua	Coverage	KP-4	Number of needles and syringes distributed per person who injects drugs per year by needle and syringe programmes.
backage ugs and	Coverage	KP-5	Percentage of individuals receiving Opioid Substitution Therapy who received treatment for at least 6 months.
Prevention package for People who Use Drugs and their sexua partners	Coverage	KP-6d	Number of people who inject drugs who received any PrEP product at least once during the reporting period.
Prevent who Use partners	Coverage	KP-8	Percentage of people who inject drugs receiving opioid substitution therapy
Prevention package for People in prisons and other closed	Coverage	KP-1f(M)	Number of people in prisons and other closed settings reached with HIV prevention programmes - defined package of services.
Prevention package for Other vulnerable population	Coverage	KP-1e	Percentage of other vulnerable populations reached with HIV prevention programmes - defined package of services

AGYW s in Igs	Coverage	YP-2	Percentage of high-risk adolescent girls and young women reached with HIV prevention programmes- defined package of services	
	ckage for <i>I</i> al partners ence settin	Coverage	YP-4	Number of high-risk adolescent girls and young women who received any PrEP product at least once during the reporting period
	ention packa male sexual HIV inciden	Coverage	YP-5	Percentage of high-risk adolescent girls and young women tested for STIs during the reporting period
	Preven and má high H	Coverage	YP-6	Number of medical male circumcisions performed according to national standards

Annex 2: HIV Prevention Outcome Monitoring Toolkit (POMT)

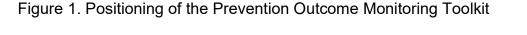
Introducing the HIV Prevention Outcome Monitoring Toolkit

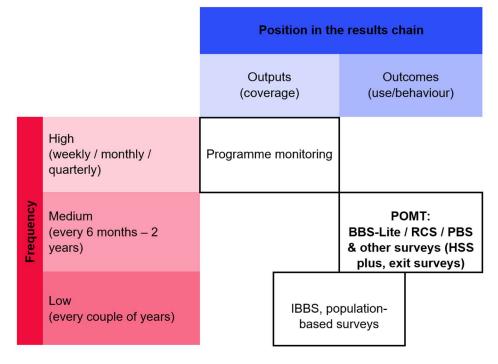
For an HIV prevention programme, it is not sufficient to know if people that are at an increased risk of acquiring HIV were reached/covered with services (output), but also if they are using prevention options (outcome). In addition, programme coverage is also difficult to measure: there are multiple interventions that should be delivered with different frequencies; countries use different operational definitions of reach; and there are health system limitations to collect the information. Furthermore, people may use prevention options accessed outside of programmes/facilities (e.g., pharmacies, online), which are increasingly available. Even though prevention options are meant to reduce the number of new infections (impact), this measure is heavily influenced by the number of people living with HIV that are virally suppressed.

There is a need to increase the focus on measuring HIV prevention outcomes in the Global Fund Grant Cycle 7 (GC7) (2024-2026). However, outcome indicators as included in the Modular Framework Handbook are based on biobehavioural surveys (BBS) or population-based surveys. These are only conducted every couple of years due to time and resource (money, technical staff) requirements. Hence, there is an additional need for rapid, easy to administer and cost-effective methodologies that provide more frequent HIV prevention outcome data for priority populations (key populations, adolescent girls and young women and male sexual partners in settings with high HIV incidence). This is needed to inform HIV prevention programming and supplements data collected in programmes on e.g., services provided. This data will inform the design of programmes, strengthen implementation and improve investment practices.

The HIV Prevention Outcome Monitoring Toolkit (POMT) provides programme implementers with methodologies to generate their own data on what is working in HIV prevention and what needs improving. The POMT is a collection of methodologies ("tools") that are developed as alternatives to large scale surveys to provide a feasible option to conduct regular data collection. These methodologies have been developed by technical partners, they have clear implementation guidance or have been documented by countries, and the methodologies can be adjusted to fit different country contexts. They have been piloted (tested) and used to collect outcome data in various countries.

The most important difference between these newly developed methodologies as compared with large scale surveys is that they do not aim to include a representative, random sample of the population of interest. So, unlike large scale surveys, the results are not generalisable to the population at large, nor are these suitable for population size estimation. As such the Global Fund will continue to support BBS as well as populationbased surveys. Similarly, routinely collected programme data^{e,f} should continue to be used to measure for example coverage of a prevention programme (people reached, commodities provided)^g and to track the program performance. Outcome monitoring is intended as a complementary (Figure 1)^h, low cost and accessible methodology of checking whether HIV prevention interventions are having an effect in a defined setting. Furthermore, the methodologies included in the POMT are distinct from Community-Led Monitoring whereby qualitative and quantitative data on quality HIV service delivery is routinely collected and analysed by local community-led organizations.





The objective of this toolkit user guide is to provide an overview of different methodologies, to link to the respective source documents, and to indicate how the methodologies could be optimized to improve regular monitoring of HIV prevention outcomes in the context of Global Fund grants. The goal is that in GC 7 HIV prevention program implementers in different countries experiment with one of these methodologies and learnings are generated. This will subsequently inform monitoring guidance for future GF grant cycles.

^e For forms/registers to track e.g., the number of individuals being reached, see: FHI 360. Monitoring guide and toolkit for HIV prevention, diagnosis, treatment, and care programs with key populations. Durham (NC): FHI 360, 2020. [Note: UNAIDS guidance under development.

^f For information on Individual level data collected through routine health information systems, see: Chapter 2 – Person-Centred HIV Prevention Monitoring, in: WHO. Consolidated guidelines on person-centred HIV strategic information: strengthening routine data for impact. Geneva: World Health Organization; 2022.

⁹ See also: The <u>prevention component</u> of the DHIS2 Toolkit for HIV is based on the latest <u>WHO Consolidated guidelines on personcentred HIV strategic information</u>: strengthening routine data for impact & FHI 360. <u>Monitoring guide and toolkit</u> for HIV prevention, diagnosis, treatment, and care programs with key populations. Durham (NC): FHI 360; 2020.

^h The methods are also distinct from Community-Led Monitoring whereby qualitative and quantitative data on quality HIV service delivery is routinely collected and analysed by local community-led organizations.

Methodologies included in the toolkit

Even though a range of methodologies could be used to measure HIV prevention outcomes routinely, the toolkit includes the key characteristics of three of those (Appendix A), with the purpose to assist countries that do not have a system established in their decision making. These methodologies are:

- BBS-lite A simplified biobehavioural survey methodology developed by WHO and • UNAIDS. It is intended to gather actionable information on key populations between rounds of full-scale BBSs. This to supplement programmatic data for the purpose of improving service delivery and to guide decisions on programming for HIV, viral hepatitis and sexually transmitted infections (STIs).
- Rapid Coverage Survey (RCS) (also called 'small area surveys') among key populations developed by FHI 360: It provides community-based organisations with a simple and inexpensive but robust way to obtain regular updates on the reach and coverage of interventions targeting key population individuals.
- Polling Booth Surveys (PBS) as applied by the University of Manitobaⁱ: It is a group interview method which has been used to measure sexual, behavioural and structural outcomes among key populations, adolescent girls and young women and the general population in several African and Asian countries.

These methodologies can be adjusted to different country contexts. Optimising the methodologies for HIV prevention outcome monitoring within Global Fund grants can be taken into account and this is discussed in the next section. As indicated, other methodologies could be proposed for funding if these are already piloted / established in a country. For example: 1) HIV sentinel surveillance plus (HSS+) is an evolution from traditional sentinel surveillance with an addition of simple behavioural questionnaire which has been implemented in many Asian countries and some Latin American countries (called VICITS): 2) exit surveys similar to those used for assessing care experiences of HIV patients. Note that, methodologies to monitor online HIV prevention programmes are out of scope of this user guide^k.

The purpose of these methodologies is to generate data for programming as distinct from more formal research purposes. The chosen methodology needs to be implemented consistently each year (including geographies, participant eligibility criteria, questions) to ensure comparable data that can support trend analysis over time within the programme. Providing comparable data between countries is not the aim. When reporting the results, the limitations of the selected methodology due to sampling and other methodological limitations should be reported. Once the data is collected, one way to use it, is the creation of HIV prevention cascades^I.

¹ The PBS was developed as an alternative to face-to-face interviews (to limit social desirability bias and be quicker and less costly) and hence is primarily a data collection method. However, the other elements related to the methodology have been taken from studies in which PBS was used. For more information see: Lowndes CM, et al. Polling booth surveys: a novel approach for reducing social desirability bias in HIV-related behavioural surveys in resource-poor settings. AIDS Behav. 2012

¹ For more information see: <u>HIV sentinel surveillance Plus 2021 Antenatal Clinic Attendees 2021</u>; <u>HSS Plus 2019 Central prison sites</u>. ^k For more information see: Digital implementation investment guide: integrating digital interventions into health programmes. Geneva: World Health Organization; 2020 UNAIDS. Creating HIV prevention cascades. Geneva: UNAIDS; 2021.

Optimizing the methodologies for programmatic HIV outcome monitoring

In order to improve programmatic HIV prevention outcome monitoring within the Global Fund grants, application of one of the methodologies listed in Appendix A is promoted with some considerations for optimizing the methodologies, as these were not necessarily developed for this purpose. At the same time, some of these adaptions will further increase the simplicity of the execution of the surveys which positively impacts on the duration and the costs.

These considerations are:

- <u>Population</u>: The Global Fund investments focus on both key populations in all settings, as well as adolescent girls and young women and male sexual partners in high incidence areas. BBS-Lite has so far been used for key populations only and although RCS has only been piloted among adolescent girls and young women in one country. Adaptations of the BBS-Lite will be needed when the methodology is applied for adolescent girls and young women e.g., the setting where participants will be recruited, content of the questionnaire, establishing the need for ethical clearance due to the inclusion of minors (which might require parental consent or a waiver).
- <u>Sampling of individuals</u>: This can either be programme-based (only clients included) or population-based (both clients and those not enrolled in the programme included). Only PBS has been piloted using both sampling methods. In general, it is important to highlight for which population the monitoring results are applicable and to avoid that the results are incorrectly generalised to the population at large or compared to full-scale survey results.
- <u>Sample size determination</u>: To reduce complexity, the sample size does not have to be calculated based on a calculation including a set of assumptions. It can be determined by the number of key populations in the area that are serviced (as done in the RCS) and/or looking at the time and resources available (as done in the BBS-Lite).
- <u>Data collection</u>: In settings where it is considered feasible, alternative options to face-to-face interviews could be explored. For example, the collection of data via a written or computer-assisted survey (as already done for the BBS-Lite), a survey shared via SMS or an online link or an app as long as this does not result in a biased sample of programme clients and confidentiality of personal information is ensured.

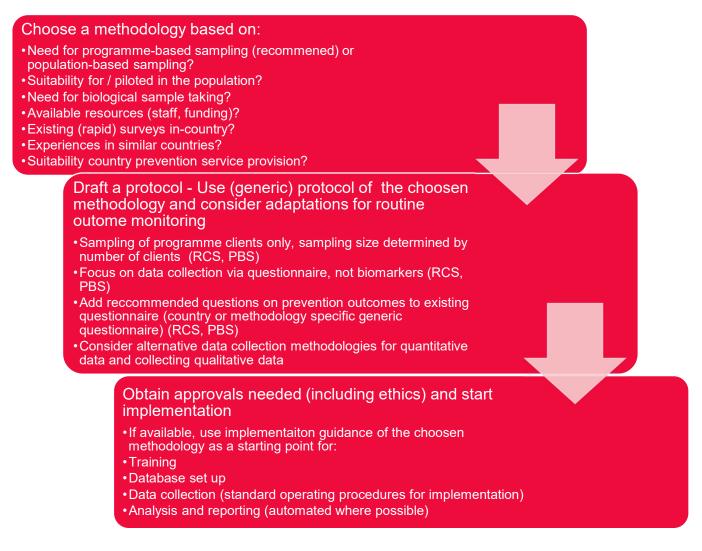
- <u>Data collected</u>: For HIV prevention outcome monitoring purposes, it is proposed to collect only questionnaire. Taking a biological sample to test for selected biomarkers like HIV, viral hepatitis, and STIs is not recommended unless this can be considered as a being part of (and costs are covered by) routine service provision. This is in line with the RCS and PBS methodologies that have HIV and other tests as optional^m.
- <u>Questionnaire content</u>: The starting point for the questionnaire should be existing survey questionnaires in the country and/or the standard BBS-Lite, RCS or PBS questionnaires. These should be adapted to ensure that the main focus of the questionnaire is measuring use of HIV prevention services and risk behaviours. This makes the RCS and the PBS most suitableⁿ: The PBS survey as implemented includes a number of questions on this already; the RSC focusses on access / reach / coverage of prevention services, but in recent iterations also prevention outcomes are included. If there are questions missing (especially a question on coverage of the last potential HIV exposure with a prevention option) these should be added to the questionnaire (see Appendix B), but the interview should not take more than 10-20 minutes.
- <u>Ethical approval and considerations</u>: The intention is to establish outcome monitoring as part of routine programmatic monitoring, and therefore it is not research. Requirements need to be checked locally, but this might avoid the need for repeated, lengthy ethical clearance processes. Another option is to seek ethical clearance for episodic monitoring over a number of years. Informed consent for taking part in interviews is still needed.
- <u>Data analysis</u>: Data analysis and reporting should as much as possible be automated (as currently done for the RCS), focussing on basic descriptive statistics, potentially disaggregated by HIV status, age, etc. and looking at trends over time.
- <u>Staff</u>: It is important that routine monitoring can be conducted by programme staff. For recruitment and data collection this should preferably not be the same staff as the participants are regularly in contact with. This to increase the sense of confidentiality, hence respondents are more likely to report more accurately on sensitive and personal information, reducing social desirability bias.
- <u>Other</u>: If there is a need for qualitative data, in-depth interviews or focus group discussions can additionally be undertaken amongst service recipients and service providers to deepen understanding of service needs, issues, and practices in accessing and using available prevention options, as well as contextual issues such as structural barriers. From ethical approval perspective, this should be done as part of regular programming activities, not as a stand-alone research activity.

^m Note that WHO / UNAIDS indicated that dropping the collection of biological specimens compromise the BBS-lite methodology. ⁿ Note that WHO / UNAIDS indicated that there is very limited scope to expand the current BBS-lite questionnaire.

A step-by-step approach

In summary, how should programmers use this toolkit to implement routine HIV prevention outcome monitoring? This is explained in the step-by-step approach in Figure 2. Deciding which methodology to choose depends on two things: 1) characteristics of each of the methodologies and 2) country context including practices in applying any methodologies and implementation capabilities in-country. The first has been discussed in the previous section, indicating strengths, weaknesses, and issues with each proposed methodology. However, it is also important to define which methodology would work best in each country context. For example, alignment with an existing monitoring methodology that may have been used in the past, by other programmes in the country or by programmes in a similar country. Or, for instance, will it be easier to do one-on-one or group interviews based on the geographical distribution of the population? Finally, Appendix C explains how prevention outcome monitoring using this toolkit is embedded in the Global Fund grant process.

Figure 2. Step-by-step approach to implement routine HIV prevention outcome monitoring



	BBS-Lite ^o	Rapid Coverage Survey ^p	Polling Booth Survey ^q
Design	Cross-sectional (information on each participant is collected at only one point in time).	Cross-sectional (information on each participant is collected at only one point in time).	Cross-sectional (information on each participant is collected at only one point in time).
Population currently used for	Key populations (piloted in Uganda and Georgia).	Key populations (piloted in Nepal, Eswatini) and adolescent girls and young women (Eswatini).	Key populations (KP) (Kenya, Bhutan, Sri Lanka); adolescent girls and young women (AGYW) (Botswana, Cameroon, Lesotho, Malawi and Namibia); and the general population (India and Nigeria).
Sampling	Non-probability sampling (non-random selection): consecutive sampling of clients (facility-based and outreach) and snowball sampling (a type of chain- referral) of peers not enrolled in the programme.	Non-probability sampling (non-random selection) of districts. Probability sampling (random selection) of hotspots in each district. All key populations present at the selected hotspots on the day(s) of the survey are invited to participate in the survey – clients and those who are not enrolled in the programme	Probability sampling (random selection) of 1) districts, 2) villages and towns, 3) hotspots (KP) or households (AGYW and general population), 4) individuals. In case of population-based sampling of individuals, clients and those not enrolled in the programme, are included: all or a random selection (every n th individual) of key populations present at the selected hotspots on the day(s) of the survey; Or, in case of AGYW or the general population, if there are more than one eligible individual, one is randomly selected.
			In case of programme-based sampling of individuals, clients are randomly sampled using the client register.
			Stratification (creating subgroups before sampling): a) to have a more or less

Appendix A. Key characteristics of BBS-Lite, Rapid Coverage Survey and Polling Booth Survey

^o Sources: 1) WHO, UNAIDS. 2023. The BBS-lite. A methodology for monitoring programmes providing HIV, viral hepatitis and sexual health services to people from key populations. Implementation tool (In Press); 2) Consultation: Developing a simplified survey methodology for HIV, viral hepatitis and STI surveillance among key populations, 28 - 30 March 2023; 3) Review by WHO.

^p Sources: 1) LINKAGES. Guideline for conducting a rapid coverage survey among key populations. Durham (NC): FHI 360; 2021; 2) Presentation: FHI 360. 2022. Rapid coverage survey among key populations. Measuring reach and coverage of KP programs. Methodology and Results of Nepal Pilot; 3) Review by FHI 360.

^q Sources: 1) National AIDS & STI Control Programme, Ministry of Health. 2018. Third National Behavioural Assessment of Key Populations in Kenya: Polling Booth Survey Report; 2) Republic of Botswana, Ministry of Health & Wetness. 2020. Implementation of Outcome Measurement in Global Fund supported Adolescent Girls & Young Women Programmes, Botswana. Outcome measurement assessment research protocol; 3) University of Manitoba. Implementation of outcome specific measurement in Global Fund supported AGYW programmes in 5 African countries (Botswana, Cameroon, Lesotho, Malawi and Namibia). Final Report 2023; 4) Review by University of Manitoba.

			homogeneous group of participants in each session; b) to generate estimates for different characteristics. This can be done based on age, gender, marital status, enrolled in the programme, key population subpopulation, type of hotspot (e.g., public, home, brothel) etc.
Sample size determination	What is possible considering time / resources; division clients / snowball can vary.	Minimum number of key populations that must be included can be calculated using an Excel Tool. This is based on the total number of key populations in the area serviced.	Sample size calculation (assuming a percentage of change in the outcomes of interest, 95 percent statistical confidence, 80 or 90 percent statistical power, design effect).
Data collection	Individual interview when recruited at the facility or outreach site: self-completed or interviewer administered. Digital where possible.	Individual interview when selected at hotspot: interviewer administered.	Group interview (10-12 participants per group) when all individuals are selected at hotspot or household. Responses to questions are dropped into polling booth boxes.
Questionnaire data collected	Focus on prevalence (HIV, viral hepatitis, STIs) and access to/coverage of services, including barriers to accessing services.	Focus on access to/coverage of services, but also includes biomedical outcomes, awareness of HIV status, and access to ART among those who are HIV positive. Screening for HIV and other STIs optional.	Focus on behavioural, biomedical, structural outcomes. Furthermore, sometimes PBS is followed by a focus group discussion (qualitative group interview) with participants to understand critical issues better and in-depth interviews with programme staff / service providers.
Biological data collected	Biological specimen to test (using routine services) for selected biomarkers, including HIV, HIV viral load, viral hepatitis and sexually transmitted infections.	HIV and other tests are optional.	HIV and other tests are optional. Note: Kenya has recently piloted ^r an enhanced PBS (ePBS) with KP that included biological specimen to test for selected biomarkers, including HIV, HIV viral load, recency, urine assays for tenofovir concentrations), and an individualised data questionnaire in order to match individual data to the laboratory component.
Questionnaire content	Selection of 37 questions from full scale BSS.	22-36 questions.	KP: 30-35 questions; AGYW: 42 questions; General population: 30 questions. Questions are framed in a way that only Yes/No//Not applicable responses are possible.
Questionnaire duration	10-15 min per individual.	20 min per individual.	1 hour for all individuals in the group together. Additional time for biological sample collection,

^r This was done with support from the Bill and Melinda Gates Foundation, technical support from the Global Fund through Partners for Health and Development in Africa (PHDA) (University of Manitoba local organization) in partnership with SWOP network of clinics and with engagement of the MSM and FSW networks.



			individual questionnaire and/or focus group discussion if added to PBS.
Ethical considerations and approvals	Verbal or written (signed) informed consent. Might be considered a quality improvement exercise and not require the same approval as research activities, but likely ethical clearance needed in most settings (possibly once off).	Verbal informed consent. The survey is designed to be a part of routine programme work and should be categorized as a non-research activity. However, to be checked with local institutional review board.	Verbal or written (signed) informed consent (assent for those <18 years as minors cannot legally agree). The PBS is used as a programme monitoring and / or evaluation tool. However, some countries did submit the protocols to the ethical review boards. If planned well, this approval can be valid for multiple years.
Data analysis	Basic descriptive statistics (measures of central tendency, measures of variability (or spread), and frequency distribution); Results can be triangulated with that from full-scale BBS.	Basic descriptive statistics (measures of central tendency, measures of variability (or spread), and frequency distribution); Results can be compared with that from a BBS.	Basic descriptive statistics (measures of central tendency, measures of variability (or spread), and frequency distribution); Results can be compared with that from a BBS/population-based survey. Where required based on sampling method used, appropriate weights are applied at the analysis stage.
Frequency	Annually.	Annually.	Every 1-2 years.
Staff for recruitment and data collection	Health service staff and peer outreach workers.	Community-based organisation staff and peer outreach workers.	Trained research team (2 members) – involvement of community researchers (KP / AGYW) encouraged. Peer outreach workers are involved to help the research team to identify participants for recruitment.
Staff for implementation support (planning, design, analysis)	Programme staff.	Programme staff.	University (related) staff.
Duration data collection	6 -7 weeks (pilot studies).	4 weeks (pilot study).	KP: 2 months (Kenya – all countries). AGYW: 1.5-6 weeks (pilot studies).
Total duration (planning to dissemination)	12-13 months (pilot studies) but will be shorter after pilot phase.	12 weeks (pilot study).	KP: 5 months (Kenya – all counties). AGYW: 3-9 months (pilot studies).
Cost	USD 80 000 (expected to be less when repeated)	USD 25 000 (excluding implementation support) (Pilot study in Nepal, 6 districts, n=1137 FSW & MSM)	AGYW: USD 250 000 for 5 countries (USD 50 000 per country)

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	(Pilot study in Georgia, 7 cities, n=2000 PWID; Pilot study in Uganda, 9 towns, n=1276 PWID & SW)		
Limitations	Uses non-probability sampling methods therefore subject to selection bias (the outcomes from the study might be different due to the participants included which are not a random sample of the target population)	Includes non-probability sampling methods therefore subject to selection bias (the outcomes from the study might be different due to the participants included which are not a random sample of the target population) Those not visiting hotspots (regularly) will be missed	Group interview limits social desirability bias and is quicker and less costly than individual interviews. The method is not individualised and is, therefore, not suitable for analysing correlates between answers. For example, although instructions are given to put the card in the white box if a question is not applicable, during the analysis it cannot be checked if those that for example indicated that they did not have sex with a non-regular partner in the past 12 months, indeed did not answer the question whether they used a condom during the last sex with this partner.
Guidance document / generic protocol	WHO, UNAIDS. 2023. The BBS-lite. A methodology for monitoring programmes providing HIV, viral hepatitis and sexual	Meeting Targets and Maintaining Epidemic Control (EpiC) project. Guideline for conducting a rapid coverage survey of HIV	KP not visiting hotspots (regularly) will be missed. Partners for Health and Development in Africa, University of Manitoba. Expanded Polling Booth Surveys (ePBS) for Assessing HIV Outcomes
[Additional documents on request from TGF secretariat]	health services to people from key populations. Implementation tool (In Press)	services among key populations. Durham (NC): FHI 360; 2023.	among Key and Prioritised Populations. Implementation guide and manual. 2023.



Appendix B. Recommended interview questions on HIV prevention outcomes

Risk behaviour/use of HIV prevention services

The starting point for the questionnaire should be existing BBS or population-based HIV survey questionnaires in the country and/or the standard questionnaires that are part of the chosen methodology. These should be adapted to ensure that the main focus of the questionnaire is measuring use of HIV prevention services or options and HIV risk behaviours. The recommended interview questions listed below are adapted from a proposition from the Global HIV prevention coalition.^s This is supplemented by additional suggestions for questions not covered in that document.

The questionnaire can be supplemented with other questions important for the programme (e.g., on participant characteristics, HIV testing, HIV status, receipt of prevention options both within and outside of the programme, HIV/Hepatitis C/STI treatment cascade. An important consideration when selecting questions is time. Interviews should ideally not take more than 10-20 minutes. Therefore, it could be an option to have a set of questions that are asked annually, while there are other questions that are only asked every other year. Furthermore, when using PBS, the answer options should be limited to Yes/No/Not applicable which might require a different phrasing of some of the questions proposed.

Part I: Measuring combination HIV prevention outcomes

Prevention outcome measures require the use (and/or consistent use) of evidence-based prevention interventions appropriate for the targeted individual or the individual's population group. The Global AIDS Strategy targets call for 95% Condoms/lubricant use at last sex by those not taking PrEP with a non-regular partner whose HIV viral load status is not known to be undetectable (includes those who are known to be HIV-negative). It is proposed that these elements form the core of a combination HIV prevention utilization indicator. The following questions are proposed:

The last time you had sex*: What, if any, precautions against HIV did you take? (Choose all that apply).

- □ Condom (and lubricant as required)
- □ PrEP (in the form of an oral pill, vaginal ring or long-acting injectable)
- □ You have an HIV-positive partner who is on HIV treatment and virally suppressed [Note: that we don't ask you about your partners identify.]
- □ You have a partner that is confirmed HIV negative and who is not at risk of acquiring HIV
- □ None of the above HIV prevention methods used

*The partner this relates to differs by population: For sex workers this is sex with a client (possibly distinguish new and regular clients & note that the answer options relating to

^s <u>New directions in measuring combination HIV prevention; A think tank series to align measurement of HIV prevention to the Global</u> <u>AIDS Strategy 2021 – 2026</u>

partner status are not relevant); for MSM this is anal sex with a male partner (distinguish between regular and non-regular partners); for TG this is sexual intercourse or anal sex with a partner (distinguish between regular and non-regular partners); for AGYW this is sex with a non-regular partner.

Note that for injection-related transmission, an additional question will be:

The last time you injected drugs: What, if any, precautions against HIV did you take? (Choose all that apply).

- □ A new, sterile needle and syringe [By new, sterile needle and syringe, we mean one that has never been used before by anyone, even you.]
- □ PrEP (in the form of oral pills, vaginal ring or long-acting injectable)
- □ None of the above prevention methods used

The above questions can be followed by a question on consistent use (if any of the above prevention methods were used): Did you use one of more of the indicated prevention methods every time you had sex/injected during the last three months?

Part II: Other prevention outcomes

Other elements of combination prevention that are included in the global targets should continue to be measured separately including PEP, VMMC, OST, and STI service use:

- PEP: In the past three months, have you received PEP (post exposure prophylaxis)? Yes/No/Don't know
- VMMC: Some men are circumcised. Are you circumcised? (Yes/No) If so, traditionally circumcised by a traditional practitioner, family member or friend OR medically circumcised, that is, the foreskin is completely removed from the penis by a healthcare worker.
- OST: Are you currently using opioid substitution therapy? (OST) (Yes/No/not applicable)
- STI service use: Have you been treated for a sexually transmitted infection in the last three months?

Countries are also encouraged to include questions related to the following outcomes where relevant: sexual partnerships (number, concurrency, age), unintended teenage pregnancy, HIV knowledge, gender based/intimate partner violence, stigma and discrimination and other barriers to services, criminalization, school enrolment, school dropout, economic empowerment, gender equity, use of alcohol and other drugs etc.

Appendix C. Implementation requirements as part of the grant

The table below lists a number of questions and answers about how prevention outcome monitoring through the use of this toolkit is embedded in the Global Fund grant process.

Question	Answer
Is this mandatory?	It is highly recommended for countries earmarked as Incidence reduction focus countries ^t and AGYW priority countries ^u , but also advised for all other countries where the Global Fund grants support HIV prevention programmes
Who is going to implement this?	The Global Fund grant principal recipient or sub-recipient
How often will this be implemented?	Every year for Incidence reduction focus countries, every two years for other countries
Who is responsible and accountable for timely and appropriate implementation?	The Global Fund grant principal recipient
How will this be funded?	It is funded in the grants, under the M&E Module It is recommended that countries include a budget of USD 50 000 – 100 000 for high impact and core countries and 30 000 – 50 000 for focused countries, per round. Due to limited information currently available on costs, this is an estimation per survey round for two populations, but the actual amount will differ depending on the methodology used, the number of different key or vulnerable groups, the geographical areas, the number of participants ^v .
Who will quality assure the implementation?	The Local Fund Agent, as done for other routine programmatic monitoring

Table. Questions and answers on the use of the POMT in GC7

^t Congo, India, Indonesia, Kenya, Madagascar, Mozambique, Nigeria, Pakistan, Philippines, South Africa, South Sudan, Tanzania, Uganda, Zambia.

^u Botswana, Eswatini, Kenya, Lesotho, Malawi, Mozambique, Namibia, South Africa, Swaziland, Tanzania, Uganda, Zambia, Zimbabwe.

^v A useful Budget template / cost estimator is included in the BBS-Lite guidance (in press) and a Sample budget in the ePBS manual.

Who will analyse the data, and where?	Grant principal recipient, in-country
To whom at the Secretariat will the results be reported and by whom?	From the grant principal recipient to the Country Team
What mechanism will be used to report the results?	Grant Progress Update/Disbursement Request
How will the data be managed- where will it be stored?	To be managed by the Country Team with access granted to relevant teams, not in GOS
Who owns the data at the Secretariat?	The Country Team
How will the data be used?	Data are used for grant oversight, not directly for grant performance rating but can be considered as a qualitative factor
How will the data be shared?	Follow the same sharing rule for programmatic results
Are there any roles for partners?	There are no specific roles for partners, similar to other routine programmatic monitoring
Technical assistance	Technical assistance can be requested for the first round of implementations to develop a protocol including questionnaires, submit for ethics, training of staff, set up structures for data collection, analysis and reporting etc.