

Guidance Note

HIV surveillance options for key and vulnerable populations in Global Fund grants

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This document is formulated to help the discussion with principal recipients and in-country partners during concept note development, grant making and impact assessment, applicable to country-specific grants or regional grants with components targeting key populations. It aims at addressing practical questions raised frequently from the Public Health and Monitoring Evaluation Specialists in the country teams but not addressed in the existing WHO/UNAIDS guidelines on HIV surveillance and surveys for key populations.

Ethical considerations

The basic principles of ethical medical research in human subjects should be applied to HIV surveillance and surveys, programmatic mapping and size estimation: individuals should be respected; all efforts involving human subjects should be conditional to informed consent; the endeavor should provide benefits and must have community buy-in, approvals, and careful consideration of the legal and societal environments. It should be noted that drawing attention to stigmatized populations has the potential to create harm. To this regard the principles outlined by the Helsinki declaration should always guide any surveillance effort: *“the rights of patients including those who are involved in medical research, the rights and interest of individual research subjects should be the primary consideration; medical research should promote and ensure respect for all human subjects and protect their health and rights; and all vulnerable groups and individuals should receive specifically considered protection to **ensure that no harm is done**”* (WMA Declaration of Helsinki as revised 2013).

Key and vulnerable populations

Broadly speaking, key populations in the context of HIV/AIDS are those that experience a high epidemiological impact combined with reduced access to services and/or being criminalized or otherwise marginalized.

For the purposes of this document, a group will be deemed to be a key population if it meets all three of the criteria below:

- Epidemiologically, the group faces increased risk, vulnerability and/or with request to at least one of the three diseases – due to a combination of biological, socioeconomic and structural factors;

- Access to relevant services is significantly lower for the group than for the rest of the population – meaning that dedicated efforts and strategic investments are required to expand coverage, equity and accessibility for such a group; and
- The group faces frequent human rights violations, systematic disenfranchisement, social and economic marginalization and/or criminalization – which increases vulnerability and risk and reduces access to essential services.

Based on these criteria the key populations groups, which can apply these surveillance and surveys, include sex workers (male or female or transgender women) (MSW, FSW or TGSW), men who have sex with men (MSM), people who inject (or use) drugs (PWID or PWUD) transgender persons (TG) with an emphasis on transgender women, and prisoners.

Other vulnerable groups such as miners, truck drivers, refugees, people with disabilities, TB patients, migrants, fishermen, etc. may be considered based on the criteria mentioned above and supported by the evidence of increased HIV transmission risk.

Public health surveillance is the continuous, systematic collection, analysis and interpretation of health-related data needed for the planning, implementation, and evaluation of public health practice. Its purpose is to:

- Serve as an early warning system for impending public health emergencies;
- Document the impact of an intervention, or track progress towards specified goals; and
- Monitor and clarify the epidemiology of health problems, to allow priorities to be set and to inform public health policy and strategies.

HIV/STI surveillance and surveys are the major data sources for HIV prevalence, STI prevalence, risk factors and behaviors, coverage of interventions and its impact. There are several types of surveillance and/or surveys, including HIV sentinel surveillance, HIV sentinel surveillance plus (with some behavior components), integrated bio-behavioral surveys (IBBS), and national population-based household surveys, and programmatic mapping and size estimation exercises. HIV surveillance and surveys should be complementary to a routine case-based surveillance system. Whenever possible, disaggregated data from the sub-groups within key populations, for example, by age groups, people who inject drugs by gender, sex workers and MSM who also inject drugs, etc.

The sampling methods used include cluster (household-based) sampling, convenience and snowball sampling, respondent driven sampling, time-location sampling, etc. The choice of sampling methods depend on whether the group is hidden or hard to reach, catchment area, pre-existing aggregation, resources available, local implementation and analysis capacity. All approaches mentioned in this paper require informed consent, return of HIV and other biomarker results, and take into account gender consideration. For example, PWID are usually mostly males, but female PWID play a critical role in transmitting HIV, as many of them are sex workers also.

Use of surveillance data should be in combination with programmatic results, such as HIV counseling and testing, PMTCT, ART, blood screening, etc. Increasingly and where possible, programmatic results should be used for surveillance purposes to monitor the trend and impact. Data quality should be assessed before any analysis is undertaken in order to understand the potential limitations of data sources and methods. Networks of key populations and other stakeholders should be involved at all stages, in assessing the need, survey method, data

collection and analysis. These groups are also key to the interpretation of findings and the design, implementation and evaluation of programs.

HIV/AIDS case-based surveillance captures the case information from all sources where HIV testing service is provided. It captures all HIV infections, irrespective of clinical staging, with demographic information (usually names or unique identification code, age and gender and basic contact information), categorization of transmission risks (heterosexual, homosexual, mother to child, blood borne such as unsafe injection drug use or unsafe blood/blood product transfusion, etc.), clinical staging and/or CD4, whether on ART and in some cases viral load.

HIV surveillance specific for key and vulnerable populations includes HIV sentinel surveillance or plus, and IBBS.

HIV sentinel surveillance usually includes consecutive/take-all sampling of defined sentinel groups in a defined period of time. Some countries also collect syphilis prevalence data. Groups can be any of the above mentioned. Target sample sizes are estimated based the projected HIV prevalence, and desired precision, usually 300-400 per group and location. The time period for collection is usually a few months. Sampling methods usually include cluster sampling, convenience sampling or snow ball sampling. In some cases, data are collected from program clients. Program client data produce strongly biased results and this approach should be discouraged. It has been a common surveillance option for key populations in Asia, Central America (VICITS, Spanish acronym for Sentinel Surveillance of STIs and HIV) and Eastern Europe and Central Asia. It can be implemented with minimum financial and human resources. Data analysis is straight-forward but representativeness/generalizability may be biased or limited to the locations sampled.

HIV sentinel surveillance plus adds basic behavioral information to HIV sentinel surveillance. The behavioral information included in the surveillance are limited to a few key variables for each group; the questionnaire is often just half a page long. However, such collection of primary data requires informed consent. Countries like China and Viet Nam have implemented this option. It can be implemented with minimum financial and human resources especially where sentinel surveillance is already routine. Data analysis is easy with similar caveats as above. Population size may be conducted in this system, depending on the sampling method used.

IBBS aim at generating population (not just sample) estimates through the collection of representative samples or samples with known sampling probabilities. Usually respondent driven and/or time-location sampling methods are used. IBBS captures HIV and STI prevalence, behaviors and coverage/use of interventions among a predefined sample size of any of the high risk groups, every 3-5 years. Population sizes can be estimated using object and service multipliers built in the questionnaire, or through the use of Bayesian statistics built into the RDS-A software. The extended contact time with respondents allows for multiple biological specimens

collection and administration of counselling. IBBS has been implemented among sex workers, MSM, PWID, miners, trucker drivers, etc. in many countries. It takes usually 6-9 months, sometimes a year or more from formative research to preliminary report. It is finance-, time- and human resource intensive. The management and analysis of data require trained skills with specialized software (RDS-A, Stata or other statistical packages).

Categorization of surveillance/survey data

The prevalence and/or behavioral data of at least two time points can be categorized as '**nationally acceptable**' when,

- Survey is performed with a national sampling design, at least two time points, with most recent on in past 5 years; for at least two groups of national interest;
- Or, having systematically operated, annual or biennial, and nationally representative sentinel surveillance for at least two groups of national interest, and
- Half of all first-order subnational divisions (provinces, regions, states, etc.) have sentinel surveillance or IBBS sites, even they are all urban (for key populations)

In some cases, the data can be locally acceptable only for those sites when survey or surveillance was done. In this case, the Global Fund should work with partners to ensure the funding of additional surveys to provide more nationally representative data.

Extrapolation of prevalence and behavioral data can be done when the country's surveillance system is classified as 'nationally acceptable', through

- Pairing the surveillance sites with non-surveillance sites by groups, by socioeconomic variables, including GDP per capita, adult male and female, etc.
- Comparing the case-based surveillance results between surveillance sites and non-surveillance sites, the number of cases per 100,000 general population
- Comparing HIV testing results, i.e., HIV prevalence by population groups between surveillance sites and non-surveillance sites
- Proportionating/weighing the urban and rural populations by age groups

The extrapolation should be done only from a few sites to more geographic locations, but should not be done from one risk group to other groups.

A simple calculation of mean or median HIV prevalence from surveillance sites to represent the entire country can be misleading, and is not recommended, although it is widely practiced. When a mean or median prevalence is calculated, its geographic coverage should be clearly stated. There is no globally agreed approach to extrapolating from the sites to the national figures. In countries where a large heterogeneity in the HIV epidemic exists and program focuses only on those high burden areas, such an extrapolation may not be appropriate. Innovative approaches are encouraged.

Decision for funding

Certain surveillance options depends on the existing surveillance systems, technical capacity and available funding. The surveillance system should be developed with the country's data needs in

mind. Ideally, countries should develop a multi-year plan that incorporates key data needs and existing partner support. Unsustainable (one-off) surveys to meet donor needs may be deemed ethically unacceptable if they are not attached directly to programmatic interventions for the surveyed population.

- Case-based surveillance should be routinely implemented, with links to patient monitoring, follow-up care and treatment programs.
- HIV sentinel surveillance should be the first choice for key populations whenever HIV prevalence data are required.
- Wherever HIV sentinel surveillance exists, HIV sentinel surveillance plus should be considered to annually collect both prevalence and basic behavioural data.
- IBBS should be planned and implemented at an interval of 3 years only when 1) there have been historical IBBS data points unless there is compelling evidence that something new will be detected with IBBS; 2) adequate technical and implementation capacity locally; 3) establishment and maintenance of sentinel surveillance system is not possible. Such as in operationally challenging environment, and 3) there is adequate allocated funding.

An ideal HIV surveillance system should have a case-based surveillance system that is evaluated regularly, plus either of the following depending on the funding situation,

- Sentinel surveillance or HIV Sentinel Surveillance+ of the most important populations in every major epidemic area and a few minor ones. Or
- IBBS in rationally selected sites that may be extrapolated to broader areas of the country.

For regional grants, an IBBS is not recommended in general. Data from country specific IBBS or sentinel surveillance and/or programmatic data in relevant countries should be analyzed to monitor the epidemic trend. In case the service delivery accounts for vast majority of the grants, grant specific surveillance sites may be included with consideration of flexibility to integrate into respective national surveillance systems.

Funding decisions for HIV surveillance activities should be made in the country and/or regional context. In the meantime, programmatic results, especially testing results, should be analyzed to track the trend of the epidemic. When using the programmatic data for the purpose of tracking HIV epidemic, basic demographic and behavioral information should be collected for analysis.

Indicative budget level

Surveillance activities	Frequency	Suggested budget source	Indicative budget level (US\$)	Possible TA
IBBS	Every 3 years	High Impact and Core: grants Focused: domestic*	50-100k per group, each group with 3-5 sites	Required, 50-100K
Sentinel surveillance	Annual	Domestic*	1,000 per site	N/A
Sentinel surveillance plus	Annual	Domestic*	1,500 per site	N/A
HIV case-based surveillance	On-going	Domestic	N/A	Required, 50-100K
Population size estimation	Every 3 years	High Impact and Core: grants Focused: domestic*	100K per group with national coverage if not embedded in the IBBS, such as programmatic mapping	Required, 50-100K

*Grant can consider a budget line when a domestic budget line is not possible due to legal issues, such as Anti-Homosexuality Act

References

- CDC. Lexicon, Definitions, and Conceptual Framework for Public Health Surveillance (http://www.cdc.gov/mmwr/preview/mmwrhtml/su6103a3.htm?s_cid=su6103a3_w)
- WHO. Public health surveillance (http://www.who.int/topics/public_health_surveillance/en/)
- WHO. Strategic Information: Surveillance (<http://www.who.int/hiv/strategic/surveillance/en/>)
- WHO. Guidelines for second generation HIV surveillance. An update: know your epidemic (<http://www.who.int/hiv/pub/surveillance/2013package/module1/en/>)
- UNAIDS/WHO. The second generation surveillance of HIV: the next decade. http://www.who.int/hiv/pub/surveillance/en/cds_edc_2000_5.pdf?ua=1
- UCSF. Most-at-risk-Populations, Sampling strategy and design tools. (<http://globalhealthsciences.ucsf.edu/sites/default/files/content/pphg/surveillance/CDC-MARPs/index.htm>.)
- WHO. Guiding principles on ethical issues in HIV surveillance. (<http://www.who.int/hiv/pub/surveillance/2013package/module2/en/>)
- CDC. Guidelines for National Human Immunodeficiency Virus Case Surveillance, Including Monitoring for Human Immunodeficiency Virus Infection and Acquired Immunodeficiency Syndrome (<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr4813a1.htm>)
- Thanh, et al. Brief behavioural surveys in routine HIV sentinel surveillance: a new tool for monitoring the HIV epidemic in Viet Nam. WPSAR Vol 6, No 1, 2015 | doi: 10.5365/wpsar.2014.5.1.008 (www.wpro.who.int/wpsar)
- Handcock MS, Gile KJ, Mar CM. Estimating the size of populations at high risk for HIV using respondent-driven sampling data. Biometrics. 2015 Mar;71(1):258-66. doi: 10.1111/biom.12255. Epub 2015 Jan 13.
- WHO. Guidelines on Person-Centered HIV Patient Monitoring and Case Surveillance, 2017