

MONITORING AND EVALUATION

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7 MONITORING AND EVALUATION

7.1 Introduction

As countries adapt and implement these guidelines, monitoring and evaluation (M&E) frameworks and systems will need to collect and analyse information to support the implementation and maximize the impact of the new recommendations. M&E will help programme managers assess the effectiveness of interventions and linkages between services along the cascade of testing, treatment and care for HIV and associated conditions. Such information is essential to detect and respond to bottlenecks or gaps in programme performance and to adequately characterize and respond to patient attrition. Patient monitoring systems are also important to support people receiving treatment over time and as they move between clinics and districts, to ensure retention in care. As programmes mature, monitoring is also essential of individual- and population-level outcomes, such as toxicity and adverse events, drug resistance, viral suppression, mortality, survival and incidence, to assess and optimize the impact of country programmes.

Data can be collected in many ways, including from routinely reported data from all facilities or sentinel sites; district health information systems; population-based surveys; surveillance data; observations from cohorts of people living with HIV; and periodic evaluation. Programme inputs and processes can also be monitored through facility surveys or updated lists of service availability; documenting the availability and training of human resources; and monitoring the availability of HIV medicines and diagnostics at various geographical and facility levels. Special studies can be considered where routine monitoring is not feasible or appropriate.

In considering how best to collect critical data, efforts should be made to review current monitoring systems, such as better linkages between the monitoring of services for TB and ART, and integrating HIV drug resistance (HIV-DR) monitoring into routine health information systems.

Involving civil society in M&E activities is also critical to better understand successes and failures, especially in assessing the determinants, perceptions, values and experiences of people living with HIV, key populations and the broader community in accessing and using services.

7.2 Selection of indicators

The 2015 WHO *Consolidated strategic information guidelines for HIV in the health sector* provide comprehensive guidance on monitoring national and global health sector responses to HIV, including the use of ARV drugs for treatment and prevention (1).

The guidelines propose 50 national, including 10 global indicators to help national HIV programmes monitor and evaluate HIV programme performance and assess its impact along the cascade of prevention, treatment and care.

The 50 **national programme indicators** can be used to describe what the status of the HIV epidemic is and identify how the HIV response could be improved. Countries should select relevant indicators to be included in the national M&E system, as appropriate to the country context and the services that are delivered. Typically, countries will opt to collect most of these indicators to obtain a focused but comprehensive overview that informs tracking and management of their HIV programme. To ensure comparability, WHO recommends that reporting from countries and donors adhere to the same definitions of these indicators, which have been agreed with major partners and in extensive consultation with countries. National programme indicators that are of particular importance to the implementation of these guidelines include those that relate to the following:

- services for key populations;
- post-exposure and pre-exposure prophylaxis (PrEP);
- HIV testing services;
- linkage, enrolment and retention in care;
- provision of ART;
- treatment and care for pregnant and breastfeeding women (prevention of mother-to-child transmission [PMTCT])
- paediatric HIV treatment and care;
- TB/HIV coinfection;
- other comorbidities and coinfections;
- toxicity monitoring;
- HIV-DR;
- viral suppression; and
- impact evaluation (mortality, prevalence and incidence).

Detailed indicator tables for each of these programme areas along the testing, treatment and care cascade may be found in Chapter 2 of the 2015 WHO *Consolidated strategic information guidelines for HIV in the health sector*.

The **10 global indicators** are a subset of the 50 proposed national indicators and provide the essential information needed to identify key issues for improving the health sector response to HIV. Each of these indicators reflects a key step in the HIV prevention, treatment and care cascade. Together, the 10 global indicators represent the **minimum** set of information needed for global reporting. To provide a common platform for global monitoring and comparison among countries, national managers should include the 10 global indicators among the national indicators selected for their M&E framework. The 10 indicators are shown in Table 7.1.

Table 7.1. Ten global monitoring indicators of the health sector response to HIV

Indicator	Relevance to cascade	Rationale for global monitoring	Disaggregation	Sources and issues
1. People living with HIV Number and % of adults and children living with HIV N: Number of people living with HIV D: Population	Target population for the HIV care cascade. Serves as numerator or denominator for several other estimates along the cascade.	Reflects epidemic and service needs	Sex, age, key population, ¹ pregnancy status, ART eligibility, HIV prevalence among TB patients (LINK.5), location	NEEDS.1 ² Derived from surveillance, surveys and programme data, “know your epidemic” review, internationally consistent modelling
2. Domestic HIV financing % contribution of domestic public expenditure to total HIV expenditure N: HIV domestic public expenditure D: Total HIV expenditure	Important for the sustainability of financing the response to HIV	Used to assess government commitment and ownership and to identify funding gaps	Key population and other target population, programme categories such as prevention, treatment and care	RES.31 Health accounts and national AIDS spending assessment can help capture expenditures and track trends.
3. Prevention by key population a) for sex workers, % reporting condom use with most recent client b) for men who have sex with men, % reporting condom use at last anal sex with a male partner c) for people who inject drugs, needles and syringes distributed per person d) for general population, % of women and men age 15–49 years who used a condom during last sexual intercourse	Reflects prevention interventions in key population groups and the general population to control transmission risk and prevent new HIV infections	Condom use with non-regular or high-risk sexual partners and clean needle and syringe provision reflect key interventions and can be consistently measured across all countries.	Sex (female, male, transgender), age, location	a) PREV.1.a b) PREV.1.b c) KPOP.2 d) PREV.1.d Collected through surveys. Needs to be interpreted based on coverage and sampling of survey. Include use of PrEP where relevant.

¹ In many settings, key population-specific data cannot be collected from routine programme monitoring; surveys are required.

² Indicator labels in this column, such as NEEDS.1, represent specific indicators referred to in the 2015 WHO Consolidated strategic information guidelines for HIV in the health sector.

Table 7.1. (continued)

Indicator	Relevance to cascade	Rationale for global monitoring	Disaggregation	Sources and issues
<p>4. People living with HIV diagnosed % of people living with HIV who have been diagnosed</p> <p>N: Number of people living with HIV who have been diagnosed and received their results</p> <p>D: Number of people living with HIV</p>	<p>Diagnosis and awareness of HIV-positive status are precursors to care and treatment. Also, HIV testing may influence adoption of preventive behaviour among both HIV-positive and HIV-negative people.</p>	<p>HIV testing is key to effective responses to HIV.</p>	<p>Sex, age, key population, pregnant women, TB patients, other target populations, location</p>	<p>HTS.1</p> <p>The proportion of people living with HIV in specific populations who have been tested should also be globally monitored, including (a) key populations, (b) pregnant women, and (c) TB patients. Information captured through programme data, population-based surveys and key population-focused special surveys</p>
<p>5. HIV care coverage Number and % of people living with HIV who are receiving HIV care (including ART)</p> <p>N: Number of people living with HIV who received HIV care in the past 12 months OR CD4 count or viral load testing OR currently receiving ART</p> <p>D: Number of people living with HIV</p>	<p>Reflects linkage to care by measuring HIV care coverage and progress towards universal access to care (including ART)</p>	<p>Helps to track global trends in coverage of care and treatment across populations of people living with HIV</p>	<p>Sex, age, key population, treatment status (i.e. pre-ART or ART), location</p>	<p>LINK.2</p> <p>The numerator is based on programme data counting people living with HIV, who receive a clinical or laboratory assessment or are on ART, as proxies for receipt of care. The denominator is usually estimated.</p>
<p>6. Currently on ART Number and % of people living with HIV who are receiving ART</p> <p>N: Number of people living with HIV who are currently receiving ART</p> <p>D: Number of people living with HIV</p>	<p>Measures the extent to which needs for ART are met</p>	<p>Tracks trends in ART coverage nationally and globally</p>	<p>Sex, age, key population, regimen, location</p>	<p>ART 3.</p> <p>The numerator is based on programme statistics; the denominator is usually estimated using an internationally consistent model. For consistency of global reporting, people living with HIV is used as a denominator. For national use, coverage should also be calculated by applying national eligibility criteria to estimate the denominator (ART.2).</p>

Table 7.1. (continued)

Indicator	Relevance to cascade	Rationale for global monitoring	Disaggregation	Sources and issues
<p>7. ART retention % of people living with HIV and on ART who are retained on ART 12 months after initiation</p> <p>N: Number of ART patients alive and on ART at 12 months (or 24, 36, 48, 60 months, etc.) after initiating ART</p> <p>D: Number of patients initiating ART up to 12 months (or 24, 36, 48, 60 months) before the beginning of the reporting year. This includes those who died since starting therapy, those who have stopped therapy and those lost to follow-up as of month 12 (or 24, 36, 48, 60 etc.).</p>	<p>Once on ART, treatment is lifelong. Retention on ART is important to achieve the desired outcomes of the HIV care cascade.</p>	<p>Indicates quality of services and continuing engagement of people living with HIV on ART</p>	<p>Sex, age, pregnancy or breastfeeding at initiation; optional: coinfection with TB also by 24, 36 months and longer periods</p>	<p>ART.5</p> <p>Follows cohorts of people living with HIV initiating ART. Systematic analysis of those lost to follow-up is required to determine true outcomes, including mortality patterns.</p>
<p>8. Viral suppression % of people living with HIV who have suppressed viral load</p> <p>N: Number of people living with HIV and on ART who have suppressed viral load (<1000 copies/ml). Population level denominator: Number of people on ART in the past 12 months Programme-based denominator: Number of people on ART who had a viral load measurement in the past 12 months</p>	<p>Gauges the proportion of people on ART who have suppressed viral load. A large proportion with suppressed viral load implies a low rate of onward transmission. Viral load suppression among a cohort 12 months after ART initiation should also be monitored (VL.1).</p>	<p>Viral suppression is an indicator of treatment success and reduced potential for transmission.</p>	<p>Sex, age, location</p>	<p>VLS.3</p> <p>Provides a cross-sectional view of viral load suppression among people on ART. Can also be assessed by time since initiation of ART, as a cohort. Suppressed viral load is defined as <1000 copies/ml.</p>

Table 7.1. (continued)

Indicator	Relevance to cascade	Rationale for global monitoring	Disaggregation	Sources and issues
<p>9. AIDS-related deaths Number of AIDS-related deaths per 100 000 population</p> <p>N: Total number of people who have died of AIDS-related illness in a 12-month period</p> <p>D: Population (100 000)</p>	Measures the ultimate negative outcome of past incidence and care and treatment failure	Shows trends in deaths among people with HIV; can be compared with other causes of death	Sex, age, HIV-positive TB, location	IMP.1 Analysis of sample and site mortality data Ongoing improvement of vital registration will facilitate measurement of this indicator. Number of deaths can be compared to the number of people living with HIV to review trends.
<p>10. New infections Rate of new HIV infections: number of new HIV infections per 1000 uninfected population</p> <p>N: Number of new infections</p> <p>D: 1000 uninfected population, which is the total population minus people living with HIV.</p>	Reflects the impact of HIV prevention and treatment	Important for monitoring epidemic trends, detecting possible shifts in pattern and projecting needs	Sex, age, mode of transmission (for children), key population, other target populations, location	IMP.2 Estimates should be calculated through internationally consistent modelling, cohorts and age-specific HIV prevalence data. Predicts the direction of epidemics.

Source: Consolidated guidelines for strategic information for HIV in the health sector. Geneva: World Health Organization; 2015 (<http://www.who.int/hiv/pub/guidelines/strategic-information-guidelines/en>).

7.3 Data collection and disaggregation

Disaggregation of data by age, sex, key population, location and pregnancy and breastfeeding status is critical to assist in the analysis of selected indicators. Disaggregation makes it possible to focus the country's response to achieve maximum impact.

Confidentiality must be maintained for all collection of data, specifically for key populations, who face significant stigma and discrimination. All data should be stored securely and staff collecting and storing data correctly trained to maintain confidentiality.

7.4 Reviewing and strengthening monitoring and evaluation systems

The recommendations in these guidelines may require certain adaptations to the M&E system, including:

- consolidating and prioritizing indicators for consistent reporting, as M&E plans are updated;
- investing in data sources and surveillance priorities to strengthen data;
- planning disaggregation and building analysis capacity to assess data in a linked manner along the health sector cascade;
- using data for decisions within regular programme reviews;
- evaluating the impact of each stage of the cascade on outcomes to prove and improve the response; and
- adapting M&E systems to support outcome assessment for differentiated models of care, including patient identifiers for improved follow-up and tracking.

Chapter 3 of the 2015 WHO *Consolidated strategic information guidelines for HIV in the health sector* provides guidance on the five key sources of strategic information on HIV in the health sector (Box 7.1). The crucial elements for measuring the cascade of care will depend on the integration of different sources of data. Routine patient monitoring and case reporting form the backbone of the data required to measure the cascade of services over time, and as patients move between facilities. Robust M&E systems that can accurately measure the cascade of care and address the new recommendations in these guidelines will require:

- improving the monitoring of enrolment and retention in HIV care;
- accurate accounting of transfers and losses;
- updating data elements required for patient monitoring in line with new recommendations (such as treating all people with HIV regardless of CD4 count, provision of PrEP, changes in regimens, viral load monitoring and frequency of clinic and pharmacy visits);
- revisiting disaggregation categories and links and synergy among systems for monitoring ARV drugs for PMTCT, TB and ART; and
- moving to electronic systems where feasible.

Box 7.1. Overview of the five key sources of strategic information on HIV in the health sector

1. FACILITY AND OUTREACH REPORTING SYSTEMS

(continuously collected minimum datasets)

- a. Patient monitoring data: extracted from individual patient records. Data are entered into electronic databases or in paper-based systems, transferred to written registers and aggregated on routine reporting forms. Includes data from laboratory and pharmacy records.
- b. Case reporting data: from routine surveillance, based on newly diagnosed HIV cases reported to the central level by health facilities and providers, preferably as individual electronic records with key information (age, sex, transmission mode, CD4 count and viral load at diagnosis).
- c. Outreach data: based on records maintained by NGOs conducting outreach and/or community health and outreach workers, who may or may not be linked to a facility, of peer education, HIV testing (or referrals) and linkage to care for specific populations, for example, key populations, pregnant women and HIV-exposed infants, or in specific locations.

2. ADMINISTRATIVE SOURCES

(routine, periodic or one-time data collection)

- a. Financial and health systems data: budgets, financial records, health accounts (HA), national AIDS spending assessment (NASA), procurement and supply management system data, human resources data and key policies related to HIV, prevention, treatment and care.
- b. Facility list (with unique facility IDs).

3. POPULATION-BASED SURVEYS

(periodically collected)

- a. General population: for example, Demographic and Health Survey (DHS), AIDS Indicator Survey (AIS), Multiple Indicator Cluster Survey (MICS)
- b. Key populations: integrated biological and behavioural surveillance surveys (IBBS).

4. FACILITY ASSESSMENTS

(periodically collected)

- a. Facility census or survey: for example, service availability and readiness assessment (SARA), service provision assessment (SPA), surveys of pre-treatment HIV drug resistance (PDR) and acquired HIV drug resistance (ADR).
- b. Sentinel surveillance data collected over time at sentinel sites.

5. VITAL REGISTRATION

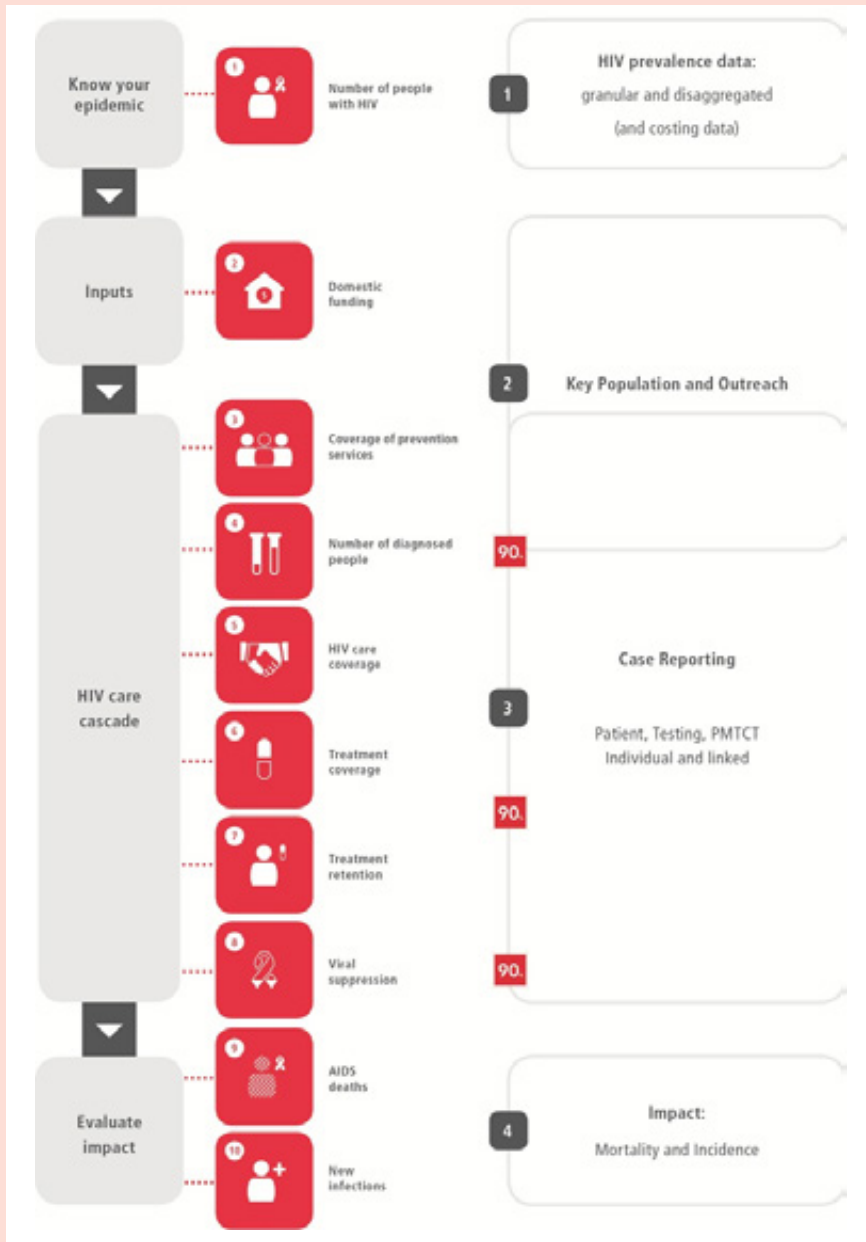
(continuous, compulsory recording)

- a. Civil registration system data: birth and death records; death records may include information on cause of death.

Source: Consolidated guidelines for strategic information for HIV in the health sector. Geneva: World Health Organization; 2015 (<http://www.who.int/hiv/pub/guidelines/strategic-information-guidelines/en>).

The relationship between these five key sources of strategic information and the 10 key global indicators of the cascade is shown in Fig. 7.1.

Figure 7.1. Global indicators for the health sector response to HIV



Source: Consolidated guidelines for strategic information for HIV in the health sector. Geneva: World Health Organization; 2015 (<http://www.who.int/hiv/pub/guidelines/strategic-information-guidelines/en>).

7.5 Evaluation, including impact and programme performance

The ultimate goal of M&E is to provide data for decision-makers to use at all points of the HIV programme cycle. Regular programme reviews allow data to be used for decisions and help to inform policy to improve the delivery of prevention and treatment services. Routine monitoring should therefore be complemented by systematic evaluations and programme reviews to assess the performance and effects of HIV programmes, either comprehensively or with respect to specific priority areas. Social science and implementation research are also important to assess perceptions and values of service recipients and communities, including the barriers and facilitators that people encounter and their experiences in the delivery and receipt of services.

7.5.1 Analysis of the cascade

The defined indicators support analysis across the cascade of testing, treatment and care for people living with HIV. Cascade analysis helps to identify trends, progress, gaps and bottlenecks in service delivery and to develop solutions and improvements. The cascade shown in the 2015 WHO strategic information guidelines allows individual indicators to be linked to each other and to outcomes and impact. Cascade analysis can be cohort based or cross-sectional.

Information needs vary across levels of the national health-care system, and all national strategic plans for HIV should include an explicit data use plan to assist in the effective use of data for decision-making.

Regular programme reviews should assess each stage of the testing, prevention and treatment cascade to identify and measure progress, gaps and relations to trends in incidence and mortality.

7.6 Other key monitoring considerations

7.6.1 ARV toxicity monitoring

People taking ART may develop toxicity to one or more ARV drugs or to other drugs that they are taking. The major ARV-related toxicities are described in section 4.6.2. As more people experience earlier and prolonged exposure to ARV drugs, toxicity monitoring needs to become a basic component of treatment and prevention programmes. ARV-associated toxicities are among the most common reasons reported for non-adherence to ART, treatment discontinuation or substitution of drugs. Routine monitoring provides data on the incidence and clinical significance of serious ARV toxicities and their impact on adherence, patient outcomes and retention. WHO recommends that routine monitoring be complemented by active sentinel toxicity surveillance through special studies and surveys at sentinel sites.

WHO recommends that countries use a standardized approach to integrate toxicity monitoring into national M&E systems. This approach defines a minimum set of data elements for reporting on the magnitude of toxicities and their impact on treatment discontinuation.

Routine monitoring for ARV toxicity

The key indicator for routine toxicity monitoring is “the percentage of patients on ART with treatment-limiting toxicity, defined as life-threatening illness, death, hospitalization, disability or resulting in treatment discontinuation or substitution”. In 2015, WHO designated this indicator for national programme monitoring. Disaggregation by ART regimen, sex, age, pregnancy, TB/HIV coinfection and, if data are available, key population, using data collected from patient clinical records and ART registers, provides additional information on populations at higher risk for toxicity due to environmental and behavioural factors, comorbidities and concomitant use of other medications. It is also important that toxicity be assessed in the context of overall reasons for treatment adherence and loss to follow-up.

Surveillance for ARV-related toxicity

When more data are needed to inform policy and improve treatment outcomes, WHO recommends strengthening surveillance of key ARV drug toxicities at sentinel sites. WHO provides guidance on conducting special studies in two main areas:

- active surveillance for specific ARV drug toxicities in existing sentinel cohorts. There is a benefit to nesting active toxicity surveillance within existing cohorts set up in a country for M&E purposes, as these cohorts have a reliable system for capturing clinical and toxicity data. A focus on one drug or the incidence of key toxicities will improve the accuracy of the assessment.
- surveillance of ARV toxicity during pregnancy and breastfeeding: this involves a prospective pregnancy-exposure registry for toxicity among pregnant women and neonates, a birth defects surveillance system for assessing birth outcomes, and prospective monitoring of cohorts of mother–infant pairs for toxicity from birth through the breastfeeding period.

WHO offers technical guidance and assistance on toxicity monitoring for routine M&E or through special surveys at http://www.who.int/hiv/topics/arv_toxicity/en/index.html.

A supplement to the 2013 WHO consolidated guidelines on the use of antiretroviral drugs published in March 2014 includes specific chapters on incorporating toxicity surveillance into ART programmes and ARV toxicity surveillance during pregnancy and breastfeeding (2). WHO has also developed a series of technical briefs on ARV toxicity monitoring (3).

Special considerations for pregnant and breastfeeding women

WHO recommends that routine monitoring of ARV drug toxicity during pregnancy and the breastfeeding period focus on three areas:

- maternal adverse outcomes: monitoring treatment-limiting toxicities associated with ART in pregnant women;
- adverse birth outcomes: monitoring toxicity in the fetus in utero, manifesting as stillbirths, preterm births, low birth weight, major congenital anomalies or early infant deaths;
- adverse infant and child outcomes: monitoring health outcomes in infants and young children exposed to ARV drugs via breast milk, particularly any impact on growth and development. Adverse birth outcomes may be routinely monitored by integrating an additional indicator into the national M&E system. If preterm deliveries (<37 weeks) are

reported at a frequency equal to or higher than a rough estimate of their expected incidence, a formal assessment is warranted.

7.6.2 Drug resistance surveillance

As ART is scaled up, the emergence of significant population-level HIV-DR has become a global concern. HIV-DR threatens the effectiveness of ART and sustained reductions in HIV-related morbidity and mortality. As documented in WHO's global report on HIV-DR in 2012 (4), levels of drug resistance have been slowly increasing. Resistance has not yet reached the level that endangers the effectiveness of ART programmes, but the trend is of concern and signals of high levels of resistance to NNRTI drugs among PLHIV starting ART are starting to emerge. Efforts to slow the development of HIV-DR are a priority. WHO recommends that HIV-DR prevention and assessment be integrated into every national HIV programme.

Routine monitoring of early warning indicators for HIV-DR

Comprehensive HIV-DR surveillance involves both routine monitoring with early warning indicators (EWIs) of performance of the ART programme in treatment facilities and conducting periodic HIV-DR surveys in specific populations. The WHO HIV-DR strategy (3) (developed in 2005 and revised in 2015) promotes the monitoring of key EWIs and using them for quality improvement. The EWIs are clinic-level quality-of-care indicators that alert clinic and programme managers to conditions favouring virological failure and the emergence of population-level resistance. Drug resistance may not necessarily result immediately if an indicator shows poor performance; however, achieving the best possible performance as measured by these indicators will help to minimize preventable HIV-DR and maximize long term population-level viral suppression. EWIs are included in the ART and viral suppression indicators recommended by WHO.

The EWIs of HIV-DR are:

- on-time ARV drug pickup (proxy for adherence)
- retention on ART at 12 months
- ARV drug stock-out
- viral load suppression at 12 months after ART initiation
- coverage of viral load testing.

WHO has recommended methods for making site-specific estimates of EWIs through a sampling of patient records. This guidance will be updated in 2016 to elaborate on operationalization of EWI data collection, including methods that will allow for nationally representative estimates through a random sampling of clinics providing ART.

The primary source used for EWI reporting should be routine programme data. However, routine data may not be optimally available. If the coverage of routine data is less than a certain percentage representative of the eligible population (such as the 70% or 80% used as a cut-off in some settings), clinic-level EWI results should not be aggregated to create a national estimate. Depending on the level of coverage of routine data, results may be useful at a subnational level for informing and improving local performance. Indicator analysis and action plans based on the results support optimization of HIV treatment and minimize the emergence of HIV-DR.

HIV drug-resistance surveys

In addition to routine monitoring of EWIs, periodic surveys in specific populations are important to inform the selection of regimens and the frequency of viral load monitoring and should be included in national HIV strategic plans. WHO provides detailed guidance on how to perform surveys for HIV-DR (3). These periodic surveys allow nationally representative assessments of the prevalence of HIV-DR and tracking its evolution in four populations:

- people initiating ART (PDR), to inform the national choice of first-line ART, PrEP regimens and recommended frequency of viral load measurement (http://www.who.int/hiv/pub/drugresistance/pretreatment_drugresistance/en) (6);
- people already on ART (ADR), to inform the selection of second-line regimens, with a survey in this population also providing nationally representative estimates of retention in treatment and viral load suppression (http://www.who.int/hiv/pub/drugresistance/acquired_drugresistance/en) (5);
- people recently infected with HIV (transmitted HIV-DR), to document and characterize the transmission of drug-resistant virus;
- infants under 18 months of age, to inform selection of the first-line regimen for children.

WHO recommends that countries prioritize PDR and ADR surveys, and assess PDR every three years, for example, in years 1, 4 and 7, and ADR assessment in years 2, 5 and 8. Alternatively, the two survey types can be combined and conducted concomitantly. Countries should consider how best to sequence the surveys depending on the type of the epidemic and on the status and coverage of the national ART programme. HIV-DR data should be available to support national decision-making, especially when updating adult and paediatric ART guidelines.

The HIV drug resistance surveillance guidance 2015 update provides additional information on developing national strategies for monitoring HIV-DR (3).

Comprehensive information on HIV-DR is available on the WHO website at <http://www.who.int/hiv/topics/drugresistance/en/index.htm>.

References

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