World Health Organization

CONSOLIDATED GUIDELINES ON

PERSON-CENTRED HIV STRATEGIC INFORMATION

STRENGTHENING ROUTINE DATA FOR IMPACT

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Consolidated guidelines on person-centred HIV strategic information: strengthening routine data for impact

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ABBREVIATIONS AND ACRONYMS

AEM	AIDS Epidemic Model
AIM	Spectrum AIDS Impact Model
AIS	AIDS Indicator Surveys
ANC	antenatal care
ART	antiretroviral therapy
ARV	antiretroviral
BBS	bio-behavioural survey (also called IBBS – integrated bio-behavioural survey)
CAB-LA	long-acting injectable cabotegravir
CAG	community ART group
CDC	United States Centers for Disease Control and Prevention
CHW	community health worker
CLM	community-led monitoring
CPT	co-trimoxazole preventive therapy
CRVS	civil registration and vital statistics
CTX	co-trimoxazole
DAK	digital adaptation kit
DDCC	digital documentation of COVID-19 certificates
DHIS2	District Health Information Software 2
DHS	Demographic and Health Survey
DPV-VR	dapivirine vaginal ring
DQA	data quality assessment
DQI	data quality improvement
DSD	differentiated service delivery
DTG	dolutegravir
EID	early infant diagnosis
EMR	electronic medical record
EPP	Estimation and Projection Package
EU/EEA	European Union/European Economic Area
EWI	early warning indicators
FHIR	Fast Health care Interoperability Resources
FRR	false recent ratio (sometimes also known as "false recent rate")

GAM	Global AIDS Monitoring
GDPR	General Data Protection Regulation
GHSS	Global Health Sector Strategy
GRSH	Global Reporting System for Hepatitis
HBsAg	hepatitis B surface antigen
HBV	hepatitis B virus
HCV	hepatitis C virus
HEI	HIV-exposed infant
HIS	health information system
HIV	human immunodeficiency virus
HIVDR	HIV drug resistance
HIVST	HIV self-testing
HPV	human papillomavirus
HSS+	HIV sentinel sero-surveillance survey
HSV	herpes simplex virus
HTLV-1	human T-lymphotropic virus type 1
HTS	HIV testing service
ISO	International Organization for Standardization
IT	information technology
LAg	limiting antigen avidity assay
LF-LAM	lateral flow urine lipoarabinomannan assay
LMIS	Logistics Management Information System
LPVr	lopinavir/ritonavir
LTFU	lost to follow-up
MDR	multidrug resistant
M&E	monitoring and evaluation
MDRI	mean duration of recent infection
MIP	mother–infant pair
MMD	multi-month dispensing
MNCH	maternal, neonatal and child health
MOU	memorandum of understanding
MPI	Master Patient Index
mWRD	molecular WHO-recommended diagnostic

NAAT	nucleic acid amplification test
NGO	nongovernmental organization
NRTI	nucleoside reverse transcriptase inhibitors
NSP	needle–syringe programme
OAMT	opioid agonist maintenance treatment
PAHO	Pan American Health Organization
PCR	polymerase chain reaction
PEP	post-exposure prophylaxis
PEPFAR	United States President's Fund for AIDS Relief
PHIA	Population-based HIV Impact Assessment
PI	protease inhibitor
PIRL	point-of-care interactive record linkage
PLHIV	people living with HIV
PMTCT	prevention of mother-to-child transmission
PNC	postnatal care
POC	point-of-care
PrEP	pre-exposure prophylaxis
PYFU	person–years of follow-up
QI	quality improvement
QOC	quality of care
RDT	rapid diagnostic test
RITA	recent infection testing algorithm
RTRI	rapid test for recent infection
SDG	Sustainable Development Goal
STI	sexually transmitted infection
SVR	sustained virological response
TB	tuberculosis
TDF	tenofovir disoproxil fumerate
TPT	TB preventive treatment
UCD	user-centred design
UID	unique identification or unique identifier
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNICEF	United Nations Children's Fund
USAID	United States Agency for International Development
VL	viral load
VMMC	voluntary medical male circumcision
WHO	World Health Organization

GLOSSARY

Active TB disease case A person who exhibits signs or symptoms of active disease and tests positive for *Mycobacterium tuberculosis* on smear examination, culture or a molecular WHO-recommended rapid diagnostic test such as Xpert MTB/RIF, or who is clinically diagnosed as a TB case by a clinician or other medical practitioner with a decision to treat with a full course of TB treatment. This is synonymous with confirmed TB case.

Advanced HIV disease For adults, adolescents and children five years and older, advanced HIV disease is defined by a CD4 cell count <200 cells/mm^3 or a WHO clinical stage 3 or 4 event at presentation for care. At presentation all children living with HIV younger than five years should be considered as having advanced disease.

Aggregate data Includes data elements that are entered into a data system reflecting a combination of individuals or services with shared characteristics, for example, number of positive HIV test results or number of people tested ages 15–19.

Confidentiality The right of individuals to have their data protected during storage, transfer and use to prevent unauthorized disclosure of that information to third parties.

Data element A logical unit of data that has a name, precise definition and a set of permissible values (if applicable). Indicators are made up of formulas of data elements and other components.

Differentiated service delivery A person-centred approach that simplifies and adapts HIV services across the cascade of care to reflect the needs and preferences of people living with HIV or who are vulnerable to infection and optimizes the use of available resources in health systems.

Digital adaptation kit (DAK) A distillation of WHO guidelines and operational resources into standardized formats that can be easily incorporated into digital patient tracking and decision-support systems. For each defined health programme area, the kit details essential components that inform the content of these digital systems, such as workflows, core data elements, decision support logic, metrics and reporting indicators, and functional requirements.

Electronic health information system A computerized system used to store, manage and analyse routine service data, including both aggregate and individual-level data systems. In these guidelines the terms "electronic" and "digital" are used synonymously.

HCV RNA Hepatitis C virus viral genomes that can be detected and quantified in serum by nucleic acid testing.

HCV core antigen Nucleocapsid peptide 22 [p22] of hepatitis C virus, which is released into plasma during viral assembly and can be detected from early on and throughout the course of infection.

HCV sustained virological response (SVR) An undetectable level of HCV RNA in the blood at a defined time point after the end of treatment, usually at 12 or 24 weeks (SVR12 or 24).

Health information system Used to manage data to inform decisions on the design or management of health services; the system encompasses data collection, compilation, analysis, synthesis and use.

HIV care Routine clinical assessment, monitoring and management of HIV, including antiretroviral treatment (ART), as appropriate to a patient's needs.

HIV case surveillance The reporting of an initial diagnosis of HIV infection and defined sentinel events related to public health actions, from every person diagnosed with HIV (a case), to a public health agency responsible for monitoring and controlling the epidemic; includes a set of data elements critical for programme management and programme monitoring.

HIV self-testing A process in which a person collects their own specimen (oral fluid or blood) using a simple rapid HIV test kit and then performs the test and interprets the result, when and where they want.

Indicator A quantitative or qualitative measure that provides a valid and reliable way to assess performance or reflect changes connected to an activity, project or programme.

Individual-level data Information that relates to a single person, possibly collected over time and across different points of care, and that may be related to their clinical or research encounters – for example, data of an individual receiving HIV care at multiple points in the cascade of services along with that individual's sociodemographic characteristics. Individual-level data can allow longitudinal and multivariate analysis of indicator data. In this document the term "individual-level data" is synonymous with "patient-level data" and "personal health data".

Infant diagnosis The testing of infants and children to determine their HIV status following possible exposure to HIV during gestation, delivery and breastfeeding, to ensure access to life-saving HIV treatment. **Early infant diagnosis** is the testing of HIV-exposed infants before two months of age. For infants under 18 months of age, diagnosis should be performed using molecular (nucleic acid) technologies; serological assays can be used for children ages 18 months and older.

Integrated care Delivery of multiple health services or interventions to a patient during the same visit by a single health worker or clinical team. By extension, integration within a patient monitoring system is the use of a single folder, patient card, electronic medical record (or register) when managing or monitoring a patient's care over time for multiple conditions (for example, HIV, TB, pregnancy, diabetes).

Key populations Defined groups who, due to specific higher-risk behaviours, are at increased risk of HIV, viral hepatitis or STIs irrespective of the epidemic type or local context. Also, they often have legal and social issues related to their behaviours that increase their vulnerability to HIV. These guidelines focus on five key populations: 1) men who have sex with men; 2) people who inject drugs; 3) people in prisons and other closed settings; 4) sex workers; and 5) trans and gender diverse people.

Latent TB infection (LTBI) A state of persistent immune response to stimulation by *Mycobacterium tuberculosis* antigens without evidence of clinically manifest active TB. Persons with LTBI do not have active TB disease but may develop it in the near or remote future, a process called TB reactivation; hence, LTBI therapy has been renamed TB preventive therapy.

Lay provider Any person who performs functions related to health care delivery and who has been trained to deliver specific services but has not received a formal professional or paraprofessional certificate or tertiary degree.

Minimum dataset A standardized set of essential data elements relevant for patient or client management and programme monitoring. It defines the key data to be collected by a health information system through any paper, electronic or mobile device. As described in these guidelines, the minimum dataset captures key events in an individual's interaction with the health system along the cascade of HIV prevention, testing, treatment and related health services and is used in the calculation of priority indicators needed for programme management and monitoring.

New TB case A person who has never had treatment for TB or who has taken anti-TB drugs for less than one month.

Partner services (sometimes referred to as disclosure, contact tracing, index testing or partner notification): a voluntary process whereby a trained provider asks people diagnosed with HIV about their sexual partners and/or drug injecting partners, and then, if the HIV-positive client agrees, offers the partner voluntary HIV testing services (HTS). Partner services are provided using provider-assisted referral or patient referral approaches.

Patient management The provision of care and treatment for and in consultation with a patient over time. Patient management may also be referred to as "patient care", "clinical management" and "clinical monitoring".

Person-centred health services An approach to services that consciously adopts the perspectives of individuals, families and communities who are the intended beneficiaries of these health services and sees them as participants as well as beneficiaries of trusted health systems that respond to their needs and preferences in humane and holistic ways.

Person-centred monitoring The routine collection, compilation and analysis of data on health service clients over time and across service delivery points, with the primary purpose of guiding the continuity of clinical management of a person over time and across locations. **Person-centred HIV monitoring** applies this approach to monitoring a sequence of health services for HIV. In the context of this document, it refers to a shift from measuring services (for example, the number of HIV tests administered) to measuring support for people receiving HIV services (for example, number of people tested or who know their HIV status).

Point-of-care testing (POC) Testing conducted at the site at which clinical care is being provided, with the results being returned to the person tested or that person's caregiver on the same day as sample collection and test so that clinical decisions can be made in a timely manner.

PrEP (pre-exposure prophylaxis) HIV PrEP is the use of ARV drugs by people who are not infected with HIV to prevent the acquisition of HIV.

Privacy In this document "privacy" refers to the legal protection that has been accorded to an individual to control both access to and use of personal information; it provides the overall framework within which both confidentiality and security are implemented.

Programme management Includes real-time direction and decision-making of multi-faceted health programme services and resources, made on the basis of health information on programme inputs, outputs, outcomes and impact.

Programme monitoring Routine tracking (and reporting) of priority information about a programme, including its outputs, quality, gaps and outcomes, typically in relation to a national plan, goals and targets.

Rapid ART initiation ART initiation within seven days of HIV diagnosis.

Relapse TB case A person who has previously been treated for TB, was declared cured or treatment completed at the end of their most recent course of treatment and is now diagnosed with a recurrent episode of TB (either a reactivation of the original infection or a new episode of TB caused by reinfection). This does not include people who failed a previous treatment or who returned to treatment (bacteriologically positive) following interruption of treatment for two or more consecutive months.

Repeat testing A situation in which additional testing is performed for an individual immediately following a first test and during the same testing visit, due to inconclusive status or discrepant test results. The same assay(s) is used and, where possible, the same specimen.

Retesting When a second specimen from the same individual is tested again following the same testing algorithm. It is not contemporaneous and can occur when individuals have been tested in the past and are tested again at different time points. Retesting to verify an HIV-positive diagnosis prior to ART initiation can also be done as a quality assurance step.

Routine surveillance In the context of public health, surveillance is the continuous, systematic collection, analysis and interpretation of health-related data needed for planning, implementing and evaluating public health practice. Surveillance builds on routine data, including patient or client monitoring, but also includes other data to describe the overall health context for public health action.

Security Technical approaches that address the physical, electronic and procedural aspects of protecting information collected as part of the scale-up of HIV services. Security must address protection of data from inadvertent or malicious inappropriate disclosure, ensure the availability of data even when there is system failure or user errors and protect data from unauthorized alteration.

Sentinel event A predefined key event in the context of surveillance for which relevant data are transmitted to the public health agency responsible for HIV surveillance to support public health action. Sentinel events may include HIV diagnosis, initiation of ART, immunological test results, such as viral load, and death. Sentinel event data are typically a priority subset of data drawn from patient monitoring systems.

Social network-based HIV testing An extension of partner services. A trained provider asks people with HIV, or those who are HIV-negative but at ongoing risk of HIV, to encourage and invite individuals in their sexual, drug-injecting or social networks to participate in voluntary HIV testing services.A social network refers to a group of individuals linked by a common set of relationships and includes sexual and drug-injecting partners, as well as social contacts.

Strategic information Data that are interpreted and used for planning and decision-making to improve the direction and results of a programme. Relevant information may be derived from a wide variety of sources (for example, monitoring systems, evaluations, programme reviews, surveys, models and case studies). It should be analysed holistically and strategically to improve the programme.

Trans and gender diverse people An umbrella term for those whose gender identity, roles and expression does not conform to the norms and expectations traditionally associated with the sex assigned to them at birth; it includes people who are transsexual, transgender, or other wise gender nonconforming or gender incongruent. Transgender people may self-identify as transgender, female, male, transwoman or transman, trans-sexual or one of many other gender nonconforming identities. They may express their genders in a variety of masculine, feminine and/or androgynous ways. The high vulnerability and specific health needs of trans and gender diverse people necessitate a distinct and independent status in the global HIV response.

Unique identifier An alphanumeric code that helps individuals to identify themselves when accessing a variety of health services over time and to support health workers in linking relevant health information and de-duplicating records when providing services. A content-free unique identifier can be issue at time of registration to avoid any additional personal information from being collected when accessing HIV services.

Viral suppression Defined as an HIV viral load that is equal to or less than 1000 copies/mL.

Undetectable viral load Defined as an HIV viral load that is not detected.

Vulnerable group/population A group of people who are particularly vulnerable to HIV infection in certain situations or contexts, including adolescents (particularly girls and young women in sub-Saharan Africa), orphans, people with disabilities, and migrant or mobile workers. These populations are not affected by HIV uniformly in all countries and epidemics, although they may include key populations. Each country should define the specific populations that are vulnerable and key to their epidemic and response, based on epidemiological and social context.

EXECUTIVE SUMMARY

Person-centred data for improved health outcomes and impact

Now into the fourth decade of the global response to HIV, a wealth of data exists on where and among whom new infections occur, methods of prevention and treatment, viral suppression and programme coverage and performance. Yet, substantial gaps in the response remain. New infections are occurring at a rate far above global targets, and, while treatment coverage is high in many settings, retention in care continues to be a challenge, and late diagnoses persist. To help address such challenges, these consolidated strategic information guidelines focus on improving individual-level routine data to strengthen person-centred services for HIV and for HIV-related infections. They aim to strengthen linkage to prevention and treatment, reduce attrition and improve health outcomes and impact.

> The evolution of health information systems toward digital, person-centred data yields a double benefit: improved patient management and better programme performance.

As the HIV response moves to focusing on closing the remaining gaps in treatment, testing and prevention services, an evolution in the underlying routine data systems is needed to more rapidly identify epidemiologic patterns and service gaps and accelerate focused interventions. HIV prevention, testing and treatment services can be improved by increasing the capability of the health system to identify and address clients' health needs as they change over their life course. Person-centred data, which are generated when an individual receives health services, are collected and used daily for patient care and to improve health service delivery. These data are a powerful tool for sustainable programme monitoring and management.

As countries strive to reach the 95–95–95 HIV targets, with the goal of eliminating AIDS by 2030, several strategic information priorities will be essential. The 2022 *Consolidated guidelines on person-centred HIV strategic information* provide a foundation for three such priorities:

1. **A greater focus on impact**, with more granular data so that there is a stronger results chain linking services to reduced incidence and mortality.
2. **Building HIV monitoring systems for chronic health care** as people remain on treatment for life. This requires stronger person-centred, longitudinal monitoring to retain and re-engage people in prevention and treatment and to link people to services for tuberculosis (TB), sexually transmitted infections (STIs), viral hepatitis, noncommunicable diseases and other conditions as needed.
3. **Digitization of health data**, which makes the interconnection of different data sources possible for improved patient management, service delivery and programme performance. These sources include clinical services, laboratories, and drug and diagnostics procurement. Also, as differentiated care is increasingly implemented, digital systems can collect, analyse and integrate data from community-delivered services.

Digital health information transforms person-centred care

The shift from paper to digital health records is transforming the way that data can be organized and used to support person-centred services in health and beyond. A person-centred digital tracking system is used by health workers at the point of care. It builds a continuous record of health events and clinical encounters that links to clinical decision-support systems to reinforce good practice. It also links to reporting and management tools to support programme management. Such digital systems simplify the collection and analysis of data and improve the accuracy, reliability, completeness and timeliness of data used for decision-making. The fundamental principle is to "collect data once, and use it many times". Programme innovations such as differentiated service delivery, where services are delivered at the community level to better meet clients' needs, has necessitated changes to develop and integrate facility and community-based data systems to better track service delivery and outcomes. By generating measures of current and long-term programme performance, digital systems help managers identify problems and opportunities for improvement in health services and health outcomes. Moreover, access to their own digital data through a protected personal health record enables people to be partners in their own health care.

Ensuring the security and confidentiality of all health data, and of digital health data in particular, is critical. Digital systems need transparent governance, technical interoperability standards and legal protections for patient data. Data security and confidentiality are particularly important for people from key populations, who are disproportionately affected by HIV, STIs and viral hepatitis – men who have sex with men, sex workers, people who inject drugs, people in prisons and other closed settings and trans and gender diverse people. The criminalization and stigmatization of same-gender sexual activity, sex work, and drug use or possession in many settings creates barriers to health service access for these individuals and makes collection of information about these attributes sensitive. Person-centred data, in combination with biobehavioural surveys, community-led monitoring and other data sources, are important to understanding access to services for people from key populations. Using data effectively, while protecting the safety and security of people from key populations, to prioritize and address their health needs is essential for a successful health sector response to HIV, STIs and viral hepatitis. Programmes for key populations have been some of the pioneers in the use of data to support sustained service provision and engagement in care.

> Prioritizing and addressing health needs across key populations on the basis of data is essential for increasing an effective health sector response to HIV, STIs and viral hepatitis.

Objectives and organization of the guidelines

The overarching goal of these guidelines is to support countries in generating and using responsive person-centred data, collected from routine national health information management systems, across the HIV cascade – from prevention, testing and treatment to longer-term health care. Keeping the person at the centre and understanding an individual's access to and use of services can improve health decision-making and health outcomes.

> These guidelines aim to strengthen analysis and use of routinely collected data at each stage of a person-centred cascade of care for HIV and HIV-related infections.

These guidelines consolidate 2017 and 2020 WHO guidelines and present a standard minimum dataset, indicators and recommendations for data systems and data use in one place. They are organized to focus on six technical areas, each addressed by a chapter. The first three chapters focus on **HIV prevention** (Chapter 2), **HIV testing and treatment** (Chapter 3) and **HIV-related infections** – STIs, viral hepatitis, TB and cervical cancer (Chapter 4). The next two chapters address the use of **routinely collected data for HIV surveillance** (including measurement of HIV prevalence and incidence) (Chapter 5) and **digital health data** (focusing on data governance, interoperability, unique identifiers, and privacy and security) (Chapter 6). The final chapter (Chapter 7) emphasizes **strengthening the use of data from all sources** to supplement routine data. Triangulating other HIV-related strategic information, including from population-based surveys, modelling, quality of care measures and community-led monitoring, is important to assess the representativeness of findings from routine data systems.

Key features of the guidelines

These guidelines make **22 key data recommendations**. Together, they support person-centred HIV monitoring, better integration of TB, STIs, viral hepatitis, cervical cancer and other health services, use of routine data for HIV surveillance to track the epidemic and response, and building a secure, interoperable digital data system.

The guidelines focus on the use of a **minimum dataset** that captures key events in an individual's interaction with the health system. These data, associated with the date of each event and a robust unique identification standard, can be transformed into the **priority indicators** needed for programme management and monitoring. The guidelines propose a clear hierarchy of indicators, with 25 core indicators (including STIs, viral hepatitis, TB and cervical cancer) among 80 priority indicators for reporting. A wider set of additional indicators can be used to supplement those in the priority set. Chapter 8 provides reference sheets for each priority indicator, detailing indicator definition, rationale, numerator, denominator, method of measurement and disaggregation.

These guidelines are pertinent to all data collection contexts. In settings where individual-level data systems are not yet mature or at scale, priority indicators can still be calculated using existing reporting practices. During a transition from paper to digital systems, data from facilities using digital systems and data from facilities using paper-based or other systems for reporting can be combined for subnational and national analysis and use.

Improved person-centred HIV data collected through a minimum dataset, combined with a priority set of indicators for monitoring, will help close gaps in access, coverage and quality across the HIV prevention and treatment service cascade. In addition, by including a minimum dataset and priority indicators for STIs, TB, viral hepatitis and cervical cancer as part of HIV prevention and treatment data systems, these guidelines take the next step towards comprehensive and holistic health care in HIV data guidelines.

SUMMARY RECOMMENDATIONS

Chapter 2 – Person-centred HIV prevention monitoring	
NEW	1. The collection of a **minimum dataset of individual-level data elements on HIV prevention interventions** is recommended to measure interventions received and health outcomes among individuals seeking HIV prevention.
NEW	2. **Individual-level data on HIV prevention** should be used, alongside other available data sources, to strengthen the measurement of: a) the **coverage of interventions** provided to populations affected by HIV, to increasingly measure individual people reached rather than services delivered b) **prevention impact** through longitudinal assessment of HIV status at the facility, subnational and national levels.
NEW	3. The collection of **clinical and behavioural information on factors associated with HIV acquisition** in routine health information systems is suggested to aid in offering HIV prevention interventions to those who may benefit from them and to estimate service-level denominators for the calculation of programme monitoring indicators. An individual's need for HIV prevention changes over time, based on individual, structural and contextual factors. Therefore, for the purposes of service delivery and M&E, information on HIV prevention need should be collected frequently.
NEW	4. **It is recommended that HIV data systems that capture an individual's sensitive clinical and behavioural information (that is, on stigmatized and criminalized behaviours) do not link these data to personally identifying information.** This separation of sensitive behavioural and personally identifying information should be maintained when linking HIV prevention data systems to other clinical datasets (such as for HIV treatment) containing personal identifiers.
Chapter 3 – Person-centred HIV patient monitoring for testing, early diagnosis and treatment	
NEW	1. Promote the analysis and **use of routinely collected testing data** to optimize HIV testing services, reaching populations and settings with the largest proportion of people living with HIV who do not know their status and supporting early HIV diagnosis. a) Improve the **monitoring of time to HIV diagnosis** to support rapid ART initiation and engagement in care, thus reducing morbidity and mortality.
UPDATE	2. Use of person-centred patient data is recommended to **continuously assess interruption of HIV treatment to improve re-engagement and retention in care**. a) Strengthen the routine analysis and use of data to assess treatment interruption and facilitate tracing interventions to support ART re-initiation and re-engagement in care. b) Longitudinal monitoring of people on ART is recommended, through linkage of data across services via improved referral and follow-up and integrated service delivery. c) Use standardized and digitalized tools for health facilities and community-delivered services to optimize data collection, reporting and flow of data for linkage and monitoring.
NEW	3. Integrate and strengthen data collection and reporting of **differentiated service delivery** in HIV patient monitoring systems to improve treatment outcomes and programmatic efficiency. a) Integrate and **strengthen data collection and reporting of differentiated service delivery** within the HIV patient monitoring system, linking to monitoring of community-delivered services while ensuring that health facilities retain overall responsibility for clinical care and follow-up. b) Monitor the impact of differentiated service delivery on treatment outcomes, including retention, VL suppression and programme efficiencies, for example, reduced clinical visits and staff time.

UPDATE	4. **Data quality and use:** Include routinely scheduled data quality assessments in long-term data quality improvement to strengthen data use and improve HIV treatment outcomes. a) **Integrate routine assessment of the quality of data on HIV treatment and VL testing** with broader, long-term data quality improvement processes to support a systems approach to strengthening data quality and use. b) **Strengthen the use of data** by supporting enhanced data analysis, frequent feedback to data custodians and users, use of standardized information products, and mentorship and training to improve treatment outcomes and service delivery.
NEW	5. **Drug stock data: Use aggregated, deduplicated individual-level patient treatment data to more accurately inform drug inventory management, dispensing, procurement and logistics** at national, district and facility levels, thus reducing drug wastage and stockouts.
Chapter 4 – Integrating related infections into HIV surveillance systems	
NEW	1. **Person-centred data** should support the improved health and quality of life of people over their lifetimes, with **routine HIV systems monitoring related infections** such as TB, STIs, hepatitis B and C, pre-invasive cervical disease and cancer and noncommunicable diseases.
NEW	2. **STI testing and treatment** should be measured as part of HIV prevention, testing and treatment programmes.
NEW	3. A recent record of **STI symptoms, diagnoses or treatment should be recorded** in HIV data systems and included as a key event to trigger HIV testing and prevention services.
NEW	4. **Hepatitis B and C testing and treatment services** should be provided and measured as part of HIV prevention, testing and treatment programmes among people living with HIV and priority populations, including people who inject or use drugs, sex workers, men who have sex with men and people in prisons and other closed settings.
NEW	5. **Screening and treatment for cervical cancer** is recommended and should be recorded in routine HIV reporting systems that monitor services received by women living with HIV.
Chapter 5 – Harnessing the strength of routine data for HIV surveillance	
NEW	1. **It is recommended** that national health information systems **include and strengthen individual-level HIV surveillance** that: a) routinely links individual data on HIV prevention, diagnosis and treatment over time as people move between facilities and locations b) provides granular, subnational strategic information for public health action.
NEW	2. **Collection of a minimum dataset of routine clinical health information** is recommended for national surveillance to monitor and guide the HIV response and support measurement of incidence. a) Methods using person-centred data, including back-calculation and retesting, should be considered together with data from other sources and modelling to improve incidence measurement.
NEW	3. **A CD4 test conducted at HIV diagnosis** is recommended for use in clinical staging, providing clinical information on entry or re-entry to care and estimating HIV incidence.
NEW	4. **Mortality and causes of death (AIDS-related and non-AIDS-related) should be reported** for all people registered in routine HIV information systems. Vital registration records should be consulted to measure the overall burden of AIDS mortality, including as a proportion of total deaths.
NEW	5. Expanding and strengthening HIV case surveillance systems that use simple electronic interfaces and built-in validation mechanisms is recommended in order to better capture new HIV diagnoses and risk factors for HIV acquisition.

Chapter 6 – Digital health data	
Interoperability	
UPDATE	1. Explicitly build in interoperability standards, data use rules and obligations and transparent data governance in digital health systems to allow the secure exchange and use of health data:
UPDATE	a) Use technical, organizational and legal interoperability standards to facilitate data governance and to smooth data exchange and use between health care sector partners.
NEW	b) Publish agreed-upon standards, rules, frameworks and conditions for data use by health ministries, partners and civil society to improve transparency, data sharing and use.
Unique identifiers	
UPDATE	2. Use unique identifiers that replace names and personal information with anonymous alphanumeric codes to allow person-centred data to support a person accessing services over time and across facilities, districts, health and disease programmes:
UPDATE	a) Unique identifiers, supported by data protection policies, should preserve individual anonymity, thereby separating personal and confidential data from health data that are being routinely shared.
UPDATE	b) Unique identifiers should be progressively introduced across facilities, districts, disease programmes and other health care to promote person-centred services.
NEW	c) Adopt national technical and legal protections for an individual's unique identifier and for individuals to access the data associated with their unique identifiers.
Privacy, security, data access and control	
UPDATE	3. Invest in secure and confidential data systems, protected by policies and rights, with different data security levels for different data elements and different health care users:
UPDATE	a) Establish different data security levels for data elements and appropriate data access based on health care needs and data users (care givers, implementers, health ministries, partners and civil society).
NEW	b) Personal data should be kept confidential and not be disclosed to unauthorized parties; personal data should be accessible only to the data subject and to other explicitly authorized parties.
NEW	c) Security includes suitable policies and regulation, not simply technical security.
NEW	d) Patients should have access to their own health data through a portable, persistent, protected personal health record. Over time, person-centred data should support people to increasingly use and shape how their data are used.
NEW	e) Both the benefits and risks of data are elevated for key populations. Confidentiality and security issues are, therefore, paramount, and personally identifying data should never be used beyond the care giver and point of access to services if not protected by clear policies and rights.

SUMMARY LIST OF PRIORITY INDICATORS

Programme indicators

Ref.no	Short name	Indicator definition
Condom programming		
PRV.1	Condoms distributed	Total number of condoms distributed during the reporting period
Pre-exposure prophylaxis (PrEP)		
PRV.2 ●	Total PrEP recipients	Number of people who received PrEP at least once during the reporting period
PRV.3 (NEW)	PrEP coverage	% of people prescribed PrEP among those identified as being at elevated risk for HIV acquisition
PRV.4 (NEW) ●	Volume of PrEP prescribed	Total volume of PrEP product prescribed
Post-exposure prophylaxis (PEP)		
PRV.5 (NEW)	Number of PEP recipients	Number of people prescribed PEP during the reporting period
PRV.6 (NEW)	PEP completion	% of PEP recipients completing PEP course
PRV.7 (NEW)	HIV in PEP recipients	% of PEP recipients testing HIV-positive three months after PEP was prescribed
Needle-syringe programme (NSP)		
PRV.8 (NEW)	NSP coverage	% of people who inject drugs provided with needles-syringes during the reporting period
PRV.9 (NEW)	Regular NSP access	% of people who inject drugs accessing a NSP at least once per month during the reporting period
PRV.10 ●	Needles-syringes distributed	Number of needles-syringes distributed per year per person who injects drugs
Opioid agonist maintenance treatment (OAMT)		
PRV.11 ●	OAMT coverage	% of opioid dependent people receiving OAMT at a specified date
PRV.12 (NEW)	Total person-years on OAMT	% of person-years of follow-up on OAMT among opioid dependent people
PRV.13 (NEW)	OAMT minimum duration	% of OAMT recipients who received treatment for at least six months
PRV.14 (NEW)	OAMT minimum dose	% of OAMT recipients receiving a maintenance dose greater than or equal to the recommended minimum dose
Voluntary medical male circumcision (VMMC)		
PRV.15 ●	VMMC scale-up	Total number of voluntary medical male circumcisions (VMMCs) performed according to national standard during the reporting period

Ref.no	Short name	Indicator definition
PRV.16	VMMC adverse events	(a) Number or (b) % of adverse events during the reporting period
HIV testing		
HTS.1 ●	People living with HIV who know their HIV status who know their HIV status (first 95)	Number and % of people living with HIV who know their HIV status
HTS.2	HTS test volume and positivity	Number of HIV tests performed (volume) and the % of HIV-positive results returned to people (positivity)
HTS.3 (NEW) ●	Individuals testing positive for HIV	% testing positive among people who received an HIV test in the reporting period
HTS.4 ●	Linkage to ART	% of people newly diagnosed with HIV initiated on ART
HTS.5	HTS partner services	Number of people who were identified and tested using partner services and who received their results
HTS.6	HIVST distribution	Total number of HIV self-test (HIVST) kits distributed during the reporting period
HTS.7 (NEW)	HTS linkage to prevention	Among those testing HIV-negative and identified as being at elevated risk for HIV acquisition, % of people who receive an HIV prevention intervention within defined period
HTS.8 (NEW)	HIV retesting coverage	% of people testing HIV-negative who tested again within a defined period after their previous test
HIV treatment and care		
ART.1 ●	People living with HIV on ART	Number and % of people on ART among all people living with HIV at the end of the reporting period
ART.2 (updated) ●	Total attrition from ART	Number and % of people living with HIV on ART at the end of the last reporting period and those newly initiating ART during the current reporting period who were not on ART at the end of the current reporting period
ART.3 ●	People living with HIV on ART who have suppressed VL	% of people living with HIV on ART (for at least six months) who have virological suppression
ART.4	New ART patients	Number of people living with HIV who initiated ART
ART.5 ●	Late ART initiation	% of people living with HIV who initiate ART with a CD4 count of <200 cell/mm^3
ART.6	VL testing coverage	% of people living with HIV on ART (for at least six months) with viral load test results
ART.7	Early VL testing (at six months)	Number and % of people living with HIV on ART who had a viral load result reviewed by six months after initiation of ART
ART.8	Appropriate second VL test after adherence counselling	% of people receiving ART with VL ≥1000 copies/mL who received a follow-up VL test within three months
ART.9	ARV toxicity prevalence	% of ART patients with treatment-limiting ARV toxicity
Vertical transmission		
VER.1 ●	Viral suppression at labour and delivery	% of HIV-positive pregnant women who are virally suppressed at labour and delivery

Ref.no	Short name	Indicator definition
VER.2	Early infant diagnosis (EID) coverage	% of HIV-exposed infants who receive a virological test for HIV within two months (and 12 months) of birth
VER.3	Infant ARV prophylaxis coverage	% of HIV-exposed infants who initiated ARV prophylaxis
VER.4	ART coverage in pregnant women	% of HIV-positive pregnant women who received ART during pregnancy and/or at labour and delivery
VER.5	ART coverage in breastfeeding mothers	% of HIV-exposed breastfeeding infants whose mothers are receiving ART at 12 (and 24 months) postpartum
VER.6 ●	Final outcome of PMTCT	% of HIV-exposed infants whose final HIV outcome status is known
VER.7 (NEW)	HIV prevalence among women attending ANC	% of pregnant women who are HIV positive at the time of their first test during the current pregnancy
TB/HIV		
TBH.1 ●	TPT initiation	Number and % of eligible people living with HIV on ART who initiated TB preventive treatment
TBH.2 ●	TPT completion	Number and % of people living with HIV on ART who completed a course of TB preventive treatment among those who initiated TPT
TBH.3	TB diagnostic testing type	% of people living with HIV with TB symptoms who receive a rapid molecular test, for example, Xpert MTB/RIF, as a first test for diagnosis of TB
TBH.4	People living with HIV who know their HIV status with active TB disease	% of people living with HIV newly initiated on ART who have active TB disease
DFT.1	TB screening coverage among new ART patients	% of people living with HIV newly initiated on ART who were screened for TB
DFT.2	TB symptom-screened positive among new ART patients	% of people living with HIV newly initiated on ART who were screened for TB symptoms and who screened positive
DFT.3	TB testing among those symptom-screened positive	% of people living with HIV newly initiated on ART and screened positive for TB symptoms who then are tested for TB
DFT.4	TB diagnosis among those tested for TB	% of people living with HIV newly initiated on ART and tested for TB who are diagnosed with active TB disease
DFT.5	TB treatment initiation among diagnosed	% of people living with HIV newly initiated on ART and diagnosed with active TB who initiated TB treatment
Multi-month ARV dispensing		
DSD.1 (NEW) ●	Multi-month ARV dispensing	% of people living with HIV and currently on ART who are receiving multi-month dispensing of ARV medicine during the reporting period
DSD.2 (NEW) ●	Uptake of DSD ART models among People living with HIV who know their HIV status	% of people newly enrolled in DSD ART models among those eligible
DSD.3 (NEW) ●	Coverage of DSD ART models among People living with HIV who know their HIV status on ART	% of people living with HIV enrolled in DSD ART models among those eligible for DSD ART (for facilities with electronic HIS) or among people living with HIV currently on ART (facilities with paper-based systems) during the reporting period

Ref.no	Short name	Indicator definition
DSD.4 (NEW) ●	Retention in DSD ART models	% of people retained in DSD ART models during the reporting period
DSD.5 (NEW) ●	Viral suppression among people living with HIV engaged in DSD ART models	% of people living with HIV engaged in DSD ART models who have virological suppression
Sexually transmitted infections		
STI.1 (NEW) ●	Syphilis testing coverage	% of people tested for syphilis during the reporting period
STI.2 (NEW)	Syphilis test positivity	% of people who tested positive for syphilis during the reporting period
STI.3 (NEW)	Syphilis treatment coverage	% of people tested positive for syphilis who were treated based on national guidelines during the reporting period
STI.4 (NEW) ●	Gonorrhoea testing coverage	% of people tested for gonorrhoea during the reporting period
STI.5 (NEW)	Gonorrhoea test positivity	% of people who tested positive for gonorrhoea during the reporting period
STI.6 (NEW)	Gonorrhoea treatment coverage	% of people tested positive for gonorrhoea who were treated based on national guidelines during the reporting period
STI.7 (NEW)	Presence of STI syndrome	% of people diagnosed with a particular STI syndrome during the reporting period
STI.8 (NEW)	Repeat diagnosis of STI syndrome	% of people diagnosed with a particular STI syndrome who were diagnosed with the same syndrome two or more times during the reporting period
Viral hepatitis		
HEP.1 (NEW) ●	HBV test coverage	% of people who were tested for hepatitis B surface antigen (HBsAg) during the reporting period
HEP.2 (NEW) ●	HCV test coverage	% of people who were tested for HCV (HCV antibody, HCV RNA or HCV core antigen) during the reporting period
HEP.3 (NEW)	HBsAg positivity	% of people who were tested for HBsAg and had a positive HBsAg test during the reporting period
HEP.4 (NEW)	HCV positivity	% of people with a positive HCV test result (HCV antibody, HCV RNA (PCR) or HCV core antigen) during the reporting period
HEP.5 (NEW)	HBV treatment among people living with HIV	% of people living with HIV diagnosed with HBV infection who are on TDF-based ART
HEP.6 (NEW)	HCV treatment among people living with HIV	% of people living with HIV diagnosed with HCV infection who initiated HCV treatment (direct acting antivirals) during the reporting period
HEP.7 (NEW)	HCV cured among people living with HIV	% of people living with HIV and co-infected with HCV who were confirmed to be cured of HCV during the reporting period

Ref.no	Short name	Indicator definition
Cervical cancer		
CCa.1 (NEW) ●	Cervical cancer screening	Number of women living with HIV who were screened for cervical cancer using any screening test
CCA.2 (NEW) ●	Pre-invasive cervical disease treatment	% of women living with HIV who screened positive for pre-invasive cervical disease and received treatment for it
CCA.3 (NEW)	Invasive cervical cancer treatment	% of women diagnosed with invasive cancer who were treated
CCA.4 (NEW)	Cervical cancer survival	Crude probability of surviving 1 year after a diagnosis of cervical cancer
Impact		
INC.1 ●	HIV incidence	Estimated number of people newly infected with HIV per 1000 uninfected population
MOR.1 ●	AIDS mortality	Total number of people who have died from AIDS-related causes per 100 000 population

● Core indicator

Survey indicators

Ref.no	Short name	Indicator definition
Condom programming		
PRV.17	Condom use (key populations and general population)	• % of people who used condoms with a non-regular partner in the last 12 months (general population) • % of sex workers who used a condom the last time they had sex with a client • % of men who used a condom the last time they had anal sex with a non-regular male partner • % of trans or gender diverse people who used a condom during last anal sex with a non-regular partner • % of people who inject drugs who used a condom the last time they had sex with a partner in the last month
HIV testing		
HTS.9	People from key populations who know their status	% of key population respondents who tested positive for HIV in the past 12 months or who know their current HIV status
HIV treatment and care		
ART.10 (NEW)	People from key populations living with HIV on ART	% of key population survey respondents testing positive for HIV who are on ART
Stigma and discrimination		
SDC.1	Avoidance of health care due to stigma and discrimination (key populations)	% of key population members who avoid health care because of stigma and discrimination
SDC.2	Avoidance of health care due to stigma and discrimination (people living with HIV)	% of people living with HIV who avoid health care because of stigma and discrimination

CHAPTER 1 – INTRODUCTION

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1.1 Background and rationale

1.1.1 Evolving data needs for a new phase of the HIV response

Enormous gains have been made in the HIV response over the four decades since the first identification of the virus. Treatment has expanded to an estimated 28 million people of the 38 million people living with HIV in 2021, and eight countries have achieved the UNAIDS 90–90–90 targets *(1)*. These gains have increased life expectancy and enabled people living with HIV to lead healthier lives.

As large numbers of people living with HIV are followed over time, new challenges have come to the fore. Loss to follow-up from antiretroviral treatment (ART) is one such challenge. It has implications not only for individuals who may have stopped taking their medication but also for programme managers who need to better understand whether individuals are accessing treatment elsewhere, have died, have moved away or are truly disengaged with health services and need follow-up efforts.

Compared with treatment coverage, the annual trends in new HIV diagnoses have not been as encouraging. Although HIV incidence has been decreasing steadily, the pace of the decline over the past 10 years has been slow, with 1.5 million new infections occurring in 2020 against a target of less than 500 000 *(1)*. A better understanding of these new infections and missed opportunities for prevention will be critical for focusing efforts on the populations that need services but who, for one reason or another, have not used them effectively. Better understanding and optimizing testing strategies will be key for improving early diagnosis of and treatment initiation by those newly tested positive and reaching the 95–95–95 targets towards AIDS elimination by 2030.

As the HIV response shifts towards a phase of sustaining the gains made in treatment access and better identifying and addressing testing and prevention needs, an evolution in the underlying routine data systems is needed to more rapidly identify epidemiologic patterns and service gaps that need intervention. The delivery of HIV prevention, testing and treatment services depends on the capability of the health system to identify and address clients' health needs as they change over their life course. Gaining different perspectives on the epidemic and the response is key, for example, to assessing gender equity and age-specific differences in coverage, to ensuring quality of services for specific subgroups, to reviewing current or long-term performance and to comparing population-based and programme-based measures of performance. By definition, strategic information provides managers with the essential data needed to improve health services and health outcomes. Analysing data and generating analytic outputs that help managers and stakeholders identify problems and areas for focus is a key aspect of the use of data for decision-making.

An evolution in routine data systems is needed to more rapidly identify epidemiologic patterns and service gaps that need intervention.

Data on HIV come from many sources. These include population-based cross-sectional surveys such as the Population-based HIV Impact Assessments (PHIAs) *(2)*, long-running cohort studies *(3, 4)*, bio-behavioural surveys of different key populations *(5)*, randomized controlled trials *(6)*,

implementation science and other epidemiologic studies *(7)*, routine programmatic data from health service delivery *(8, 9)* and modelled estimates *(1, 10, 11)*. Taken together, these pieces of data provide information on aspects of the HIV epidemic and the health sector response that can inform national policies and programme decisions. Routine programmatic health data collection as part of clinical services is an area where progressive changes have been made in data collection, recording and reporting systems and where the movement to use individual-level data, facilitated by the development of digital health data systems, is already underway. These data systems have the potential to improve both patient or client care and the accuracy of aggregate data used for surveillance. While maintaining security and confidentiality in all data collection systems is critical, digital systems need additional layers of protection for access at different levels of analysis and reporting. It is important to also encourage interoperability, such as adopting international technical standards, so that data from many sources can work together cohesively and efficiently.

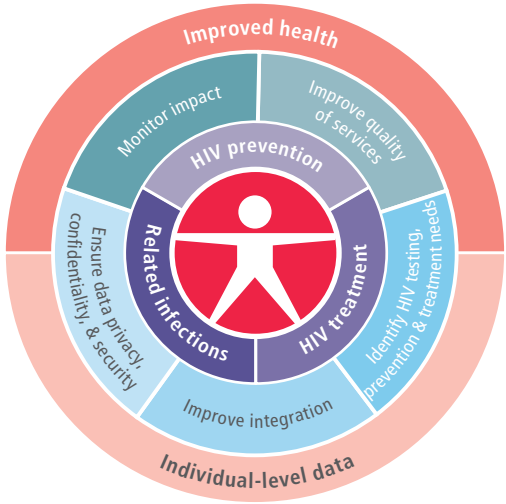
In the past, routine data reporting systems relied heavily on paper-based registers and aggregate forms that summed numbers of individuals receiving different services by age, by gender and, in some cases, by key population status. However, challenges with aggregated data include the potential for double-counting individuals who either receive multiple services at a single facility or who move between facilities; allowing only broad categories of disaggregation; the loss of detail at each level of aggregation; difficulties in rechecking reports against individual-level data; and a lack of ability to interrogate data further due to the time and effort needed to manually go through paper forms and registers. With the expansion of digital health information systems globally, opportunities for the use of person-centred data captured in routine national health information systems have growing importance. It is critical that, as these systems are scaled up, steps are taken to ensure the safety and security of individuals whose data are collected.

1.1.2 Advancing from aggregate to individual-level data use

The major source of strategic information used to monitor the HIV response in the health sector is aggregate routine facility data. Understanding the strengths and limitations of this type of data is critical to their proper use and interpretation. Individual-level data, as reflected in primary data collection tools such as patient records, have always been viewed as critical to patient care, supporting the longitudinal monitoring of clients as they access services over time. At the client–provider interface, individual-level data can improve the quality and continuity of care that a client receives by ensuring that multiple aspects of health care are visible to the provider over time – whether related infections, treatment gaps or other aspects that require follow-up. Similarly, tracking the delivery of prevention services (for example, pre-exposure prophylaxis (PrEP) or harm reduction services) to individuals also benefits from the ability to observe individual-level data. By comparison, aggregate counts of such service delivery can be difficult to deduplicate. Also, they make it difficult to assess whether programme coverage is over-saturating a small population or has broader reach across a priority population.

As electronic health information systems become more integrated and expand, the use of individual-level data for reporting purposes will continue to grow. The accuracy and potential quality of automatically aggregated individual-level data constitute a key comparative advantage over data compiled by summing categories of subpopulations (for example, by age bands or gender). For programme monitoring, the use of individual-level routine data that involves unique identification of individuals increases the accuracy of counts of individuals receiving care, since duplication of records is minimized, and in digital systems can be automated, reducing room for human error. Compared with paper-based or manual approaches, reporting of aggregate statistics using data derived from electronic medical records has been shown to be more complete, more accurate and faster for health care staff tasked with reporting *(12)*.

Fig. 1.1 Harnessing person-centred data to improve HIV services and impact



Large numbers of people in care move between facilities and geographic locations, making it difficult to accurately count numbers of clients, even for foundational indicators such as the number of people receiving ART. Thus, strengthening the collection of individual-level data to improve person-centred monitoring is critical for improving both patient care and programme planning.

Information obtained from person-centred routine data systems can provide regular, granular and timely evidence that policy-makers, programme directors and line managers need to make informed decisions to improve programmes (Fig. 1.1). This information also can be used to document outcomes and impact that are crucial to the focus of programmes. The availability of this information is central to the accountability and transparency of decision-making in the health sector. The potential of individual-level data has driven countries' increasing investment in digital health information systems. Electronic medical records can further support person-centred care and patient monitoring in addition to (and, typically, as the source of) aggregate reporting of service indicator data. Additionally, the capacity to conduct HIV case surveillance is an important component of the programme management data use case, using a subset of individual-level data linked by unique identifiers.

Advantages of electronically collected individual-level data

- support longitudinal monitoring of clients as they access services over time
- improve quality and continuity of multiple aspects of health care
- more complete
- more accurate
- faster for health care workers.

Strengthening person-centred health information systems to improve person-centred monitoring is critical for improving both patient care and programme planning.

In settings where person-centred data systems are not yet mature or at scale, aggregated reporting using paper-based or a mixture of systems for programme monitoring will continue. During the process of health information system maturation and scale-up, there may be two tracks of reporting for standardized indicators used by different facilities: 1) paper-based or other aggregate methods of reporting and 2) electronic systems, potentially with automated aggregation. Data from the two sources can be combined for summary statistics at sub-national or national levels. Higher-volume urban health services are likely to be the first to use digital reporting systems, and, as more health facilities come online, the percentage of facilities reporting electronically will grow. Even at smaller scale use, person-centred systems can contribute to the enhancement of data quality and improve the outcomes of health services and the continuity of care for individuals, which is the primary purpose and use of health data.

A key principle of individual-level data is to "collect it once and use it many times".

These 2022 consolidated guidelines recommend the use of a minimum dataset of data elements to capture key events in an individual's interaction with the health system. Combining these data elements with a unique identification standard can link a single client's engagements with the health system across time and locations. These data can be transformed into the key indicators needed to monitor HIV testing, prevention and treatment cascades. By integrating and aligning the components of these systems – for example, linking the electronic patient monitoring system to a case surveillance data repository and/or to aggregate reporting systems, countries benefit from the efficiency of a common data source to serve all three fundamental data functions: patient care, programme management and programme monitoring. The principle is to "collect data once, and use it many times". This principle relates to the concept of a prioritized minimum dataset across all data use cases, from prevention, testing and treatment to related infections, and is central to building stronger, more efficient and more effective health information systems in support of the HIV response.

Shortcomings in overall quality and reliability of the data are often-cited general limitations of routine programmatic data. Due to the high work burden on service providers and clerical staff to collect and collate routine data, lapses in completeness, timeliness and accuracy occur. For example, failure of some facilities to report consistently may appear as drops in programme coverage, but they do not reflect actual utilization levels. Many countries have limited resources to invest in the infrastructure or human resource capacity needed to ensure the high quality of data. At the very least, the assessment of data quality (particularly for completeness and identification of outliers) must be integrated into the steps used to analyse and interpret routine facility data.

Whether used for patient monitoring, case surveillance or monitoring of prevention services, all applications of individual-level data systems require standard protocols for data collection, management, security and privacy protection. Due to the higher risk that data breaches could result in loss of patient privacy and confidentiality, the data security requirements for individual-level data systems must be more stringent than those applied to safeguard aggregate data. When using indicators based on individual-level data, it is important to review the extent to which these data systems cover all patient or client populations and to assess both their completeness and quality as part of data interpretation.

1.1.3 Integration of sexually transmitted infections, viral hepatitis, tuberculosis and cervical cancer into HIV reporting systems

Every day, worldwide, people acquire more than 1 million curable sexually transmitted infections (STIs). More than one in every seven women is estimated to be infected with human papillomavirus (HPV), and more than 500 million people are estimated to have genital herpes simplex virus (HSV) infection *(13, 14)*. An estimated 5–25% of people living with HIV worldwide also have chronic hepatitis B and/or hepatitis C infections. The need to better integrate, screen and treat infections related to HIV is critical to improve health outcomes among people at elevated risk for, and living with, HIV. The modes of transmission and epidemiology of a number of these infections are similar to those of HIV, with overlapping risk profiles, and services are often delivered to the same populations. Also, interventions to prevent, diagnose and treat these infections are often similar and delivered through integrated or closely related services. As countries move toward operationalizing the wider use of individual-level data, it will become an important tool for ensuring effective, high-quality services across not only the HIV cascade but also for the prevention, diagnosis and treatment of other, related infections. Better integration of health services across diseases also will advance the goals of universal health coverage *(15)*.

Of the infections that are related to HIV, STIs, viral hepatitis and cervical cancer have been identified as important for any country implementing HIV prevention and treatment programmes because of their shared modes of transmission, their contribution to the risk of acquiring HIV and their substantial burden *(16-21)*. Incident STIs can serve as both an early warning of the potential of HIV infection in a particular population and an indication of ongoing unprotected sexual activity that may call for HIV prevention interventions. HIV coinfection increases the severity of infections with hepatitis B and C viruses (HBV and HCV) and, in the absence of ART, may increase the risk of death due to cirrhosis, hepatocellular carcinoma and other liver-related conditions and reduce the response to hepatitis C treatment. A better understanding of clinical service use and health outcomes for each of these infections can improve the health of people living with HIV and of people at elevated risk of HIV acquisition, and it also can reduce transmission to partners. Tuberculosis (TB), another important infection associated with HIV, is a significant cause of mortality in people living with HIV. It is critical to address TB through integrated programmes and data systems. TB is covered in detail in Chapter 3, on testing and treatment.

These 2022 *Consolidated guidelines on person-centred HIV strategic information* seek to strengthen programmes' ability to identify and close gaps in service access, coverage and quality through better integration of STIs, viral hepatitis, TB and cervical cancer screening and treatment within person-centred HIV monitoring and surveillance systems. They include a suggested minimum dataset for each area (STIs, viral hepatitis, cervical cancer, TB–HIV) and related indicators for inclusion in HIV prevention, testing and treatment monitoring programmes.

1.1.4 Data considerations for key populations

Five key populations are disproportionately affected by HIV and in almost every setting have a higher prevalence and incidence than people outside of these groups *(1)*. These key populations are men who have sex with men, sex workers, people who inject drugs, trans and gender diverse people, and people in prisons and other closed settings. Members of these populations are also disproportionally affected by viral hepatitis and STIs, and there is increasing acknowledgement of the importance of addressing all three infectious disease areas in an integrated, community-led and person-centred manner.

Therefore, all countries – those with high HIV burden across all populations as well as those with epidemics centred largely in key populations – must prioritize and address the health needs of members of key populations for an effective, accelerated response *(22)*.

Members of key populations face social, legal, structural and other contextual challenges that increase their vulnerability to HIV, viral hepatitis and STIs and obstruct their access to health and other essential services. In many settings one or more aspects of key population members' behaviour, work or gender expression are criminalized and members are subject to punitive legislation and policing practices. Criminalization perpetuates stigma from and discrimination by the general population, health care workers and law enforcement officials. This also means that legal or policy change is more difficult to achieve. Stigma and discrimination in health care settings are common experiences among members of key populations, and they create significant barriers to achieving universal health coverage.

Putting members of key populations at the centre of health systems – by organizing services around people's needs rather than around diseases, and by promoting integrated person-centred approaches and linkages with primary health care services – is key to ending these epidemics. Person-centred data are, therefore, crucial to supporting access to services for key populations and to monitoring gaps in access. Different service delivery approaches, including task shifting to key population peers, decentralizing provision of services to key population community-led programmes, providing services online, and service integration are also needed to increase access and availability of HIV, viral hepatitis and STI services for key populations.

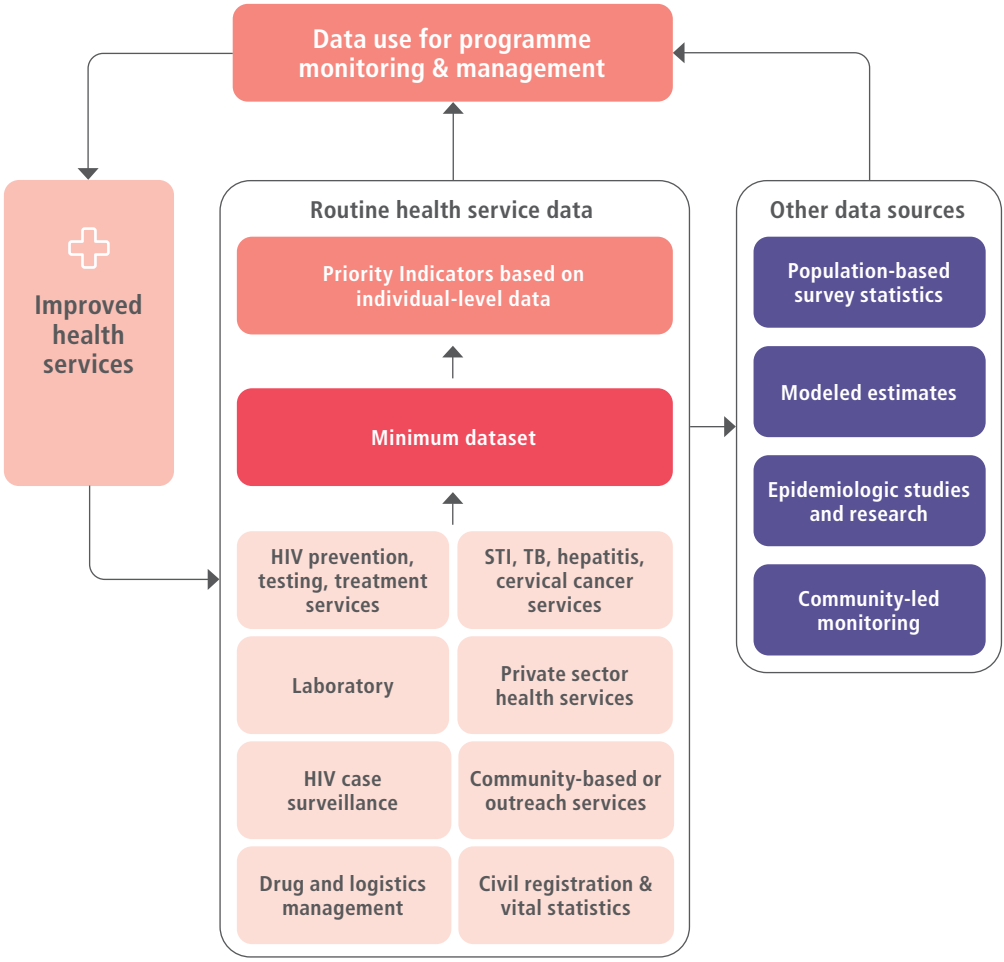
Various data sources can be used to monitor and evaluate the success of HIV programmes for key populations. These include biobehavioural surveys, which can provide in-depth information on a particular key population group. However, these are conducted infrequently, in a limited geographic area and may not be representative of the entire key population group. Routine programmatic data are another source of data on key populations; programmes for key populations have been some of the pioneers in the use of data to support sustained service provision. In routine health information systems where health services are provided for the general population, key population clients may not disclose information indicating their key population status, making the availability of information disaggregated by key population status difficult to obtain and potentially inaccurate. However, some facilities cater specifically to key populations and in some instances provide HIV prevention interventions that are relevant only for members of certain key populations, such as harm reduction interventions for people who inject drugs. In these settings patients/clients may be more comfortable with the discussion and recording of risk factors. Therefore, where there are benefits for the population concerned, and where it is possible to do so safely and securely, data elements and indicators should be disaggregated for each key population group.

In settings where it is safe to do so, or where anonymized case reporting systems are in place, capturing probable route of infection for all new HIV diagnoses will be important in monitoring trends in HIV incidence, prevalence and risk factors. Although, because of differential disclosure, routine data will not capture all key population members who access services, such information has been successfully gathered in routine information systems or case surveillance systems and makes an important contribution to understanding the HIV response for key populations. However, where issues of safety and the potential to discourage individuals' access to services are a concern, collection of key population information in routine data systems is not advised.

1.1.5 Strengthening the use of data from other sources

For sustainability, the strategic information system of the health sector response to HIV must align with the broader health information system (HIS) as part of an integrated architecture (Fig. 1.2). Guidance for national HIS standards and tools are available to support development of appropriate HIS and digital health policies, guidelines, strategic plans and roadmaps, including for system interoperability (see Chapter 6).

Fig. 1.2 Integrated data system architecture



By definition, routine programmatic data capture only information on individuals who seek health services in facilities or through community outreach. Therefore, for a complete picture that includes individuals who are not reached by services, the review of routine data should be supplemented with data from surveys (for example, Demographic and Health Surveys (DHS) and PHIA household surveys among the general population and bio-behavioural surveys (BBS) among specific groups such as key populations), models (for example, Spectrum AIDS Impact Module (AIM)) and special studies to triangulate and validate assessments of programme performance, including impact.

Many health services are delivered in community settings to increase and simplify access for those who may prefer these settings over health facilities. These outreach activities can be associated with health facilities or may be delivered through community-led organizations. Data systems must be able to capture and integrate data on the delivery of community-based services, delivered via mobile or satellite clinics or by peer or outreach workers. Enabling systems to allow the flow of data in both directions between community-delivered services and health facilities in a standardized manner will facilitate programme monitoring and data use by both types of services. With differentiated care, HIV prevention, testing and treatment increasingly will be provided together at the community level, with links to facility services and data systems.

Community engagement of people living with and affected by HIV, through community-led monitoring, is important to improve the quality of HIV services. Community engagement creates an enabling environment for stakeholders to work together to address health-related issues, promote well-being and, ultimately, achieve positive health impact and outcomes. In 2021 the World Health Organization (WHO) *Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring* incorporated guidance on community-led monitoring and how it supports improving the quality of HIV service delivery for people living with HIV *(23)*. Structured input from community-led monitoring is an essential component of a national HIV health information system.

Community engagement of people living with and affected by HIV, through community-led monitoring, is fundamental to improve the quality of HIV services.

Community-led monitoring is independent from routine health care service delivery and information systems based on clinical data. As such, it functions as an accountability mechanism that puts power in the hands of communities to monitor access to and the quality of health services and to bring about change. It places community groups as key actors in decision-making processes to improve and shape services. Chapter 7 addresses these approaches.

1.2 What's new in this consolidation of WHO strategic information guidelines

The aim of this consolidation of strategic information guidelines is to provide in one place the recommended data elements, indicators and guidance on data systems and use across the spectrum of health sector HIV services and to reference technical guidelines published by WHO and its partners that detail recommended interventions and how to operationalize the collection and use of related strategic information. WHO and the Joint United Nations Programme on HIV/AIDS (UNAIDS) collect information about the uptake of strategic information recommendations including patient monitoring and case surveillance, along with unique identification and aspects of health information systems. Overall, this information shows that important implementation gaps remain, which need to be addressed to improve data quality and use.

Previous to these guidelines, there were two primary WHO HIV strategic information guidelines: the 2017 *Consolidated guidelines on person-centred HIV patient monitoring and case surveillance (24)*, which describe information that should be collected in primary patient monitoring tools, and the 2020 *Consolidated HIV strategic information guidelines: driving impact through programme monitoring and management (25)*, which cover aggregate indicators for managing and monitoring programmes. Some of the 2020 indicators would be obtained from surveys, and other, additional indicators on burden and impact would come from modelled estimates. Both these guidelines are derived from WHO HIV clinical guidelines and describe the link between individual-level and aggregate data. There is now a major opportunity to more effectively define the technical and functional relationships between these data types and related data use cases, in support of the "collect data once, and use it many times" principle. This principle is reflected in these guidelines through a recommended minimum dataset across all data use cases, from prevention, testing and treatment to related infections, which is central to building stronger, more efficient and more effective health information systems in support of the HIV response.

> A prioritized minimum dataset for HIV prevention, testing and treatment and for related infections is central to building stronger, more efficient and more effective health information systems in support of the HIV response.

These 2022 *Consolidated guidelines on person-centred HIV strategic information* cover all essential data use cases, grounding measurement in client monitoring as the source of data required for management of facility, subnational and national programmes. These strategic information guidelines define *what data should be recorded and reported* (recommended data elements and indicators) and *how this information should be used*. They consolidate clinical recommendations from across primary HIV prevention, testing, treatment and care and include for the first time a minimum dataset for HIV prevention, STIs, viral hepatitis and cervical cancer as part of HIV prevention and treatment data systems. This is intended as a next step in the evolution of HIV guidelines towards comprehensive, holistic, living and SMART guidelines products. (See Box 1.1.)

Box 1.1 New areas covered in these guidelines

- The role and utility of individual-level data in HIV prevention services, for example, in monitoring persons at substantial risk of HIV through prevention services;
- a focus on monitoring and enhanced data use to address early diagnosis, late ART initiation, re-engagement in care, advanced HIV disease and differentiated service delivery;
- integration of individual-level data on viral hepatitis, STIs, TB and cervical cancer, to build stronger links to person-centred health services over the life course of people at elevated risk of HIV acquisition and those living with HIV;
- the role and utility of routine programmatic data in the measurement and monitoring of HIV incidence in programmes, to strengthen focus on impact;
- governance of digital health data in the transition from paper-based to digital systems and the importance of interoperability, unique identifiers, data security, privacy and confidentiality, and data access;
- incorporating and strengthening use of data from community-led monitoring, quality of care measures, surveys, modelling and other studies.

These 2022 consolidated guidelines address data for HIV services in national health sector responses; they do not directly address multi-sectoral global monitoring data and data use. They promote and support managers' practice of regularly reviewing available data from across the HIV services cascade, from primary prevention among those at substantial risk of HIV acquisition to viral suppression among people living with HIV and on treatment.

1.2.1 Data system maturity for use of person-centred data

While these 2022 guidelines focus on the collection, analysis and use of person-centred data at the facility, subnational or national level, in many places fully integrated systems are not yet operational. These guidelines contain information pertinent to all contexts. In settings where person-centred electronic data systems are not yet mature or at scale, priority indicators that are proportions can still be calculated with existing reporting practices to monitor programmes. In other settings, or within individual programmes, electronic person-centred data may be used for facility-level management and then automatically aggregated for reporting at subnational and national levels. During a transition from paper to digital systems, data from facilities using person-centred digital systems and data from facilities using paper-based or other systems for reporting can be combined for subnational and national analysis and use. In these cases it may not be possible to deduplicate data across programmes or subnational areas with different systems. Since data from digital person-centred data systems will likely be more accurate and reliable than those from manually aggregated systems, the resulting improvement in accuracy, even if only a few facilities are using such systems, will benefit programme management and reporting. Countries are at different stages of digital health maturation and can choose which interventions, datasets and indicators are appropriate for a given context. Enabling interoperability among services and programmes during the expansion of national HIS can facilitate data exchange and use for action during progress towards comprehensive person-centred data systems.

WHO SMART (Standards-based, Machine-readable, Adaptive, Requirements-based and Testable) guidelines *(26)* support efforts to expand digitization, ease the gradual transition from paper-based systems and simplify the incorporation of WHO clinical and data recommendations into the digital systems that countries are adopting. These guidelines are formulated to aid the development of health information systems with progressive levels of digitization so as to enable scalability and to minimize the introduction of inadvertent errors in the incorporation of WHO guidelines when transitioning from paper to digital. These include digital adaptation kits (DAK) *(27-29)*, that are software-neutral, structured documentation based on WHO clinical, health system and data use recommendations to inform the design of digital systems. The DAKs inform the design of person-centred digital tracking and decision-support systems, which are digitized job aids that combine an individual's health information with the health worker's knowledge and clinical protocols to assist health workers in making diagnosis and treatment decisions aligned with WHO recommendations *(30)*. A person-centred digital tracking and decision-support system is one used by health workers at the point of care; it includes a continuous record of health events and encounters that links to clinical decision-support systems to reinforce good practice. It also links to reporting and management tools to support accountability. The aim is to provide a common language across various audiences – managers of HIV programmes and other programmes, software developers and implementers of digital systems – to ensure a common understanding of the appropriate health information content within the defined health programme area of HIV.

1.3 Objectives and guiding principles

The overarching goal of these guidelines is to support countries in generating responsive person-centred data from routine national health information management systems. Keeping the person at the centre and understanding how people access services can improve health decision-making and health outcomes. These guidelines aim to strengthen the analysis and use of data at each stage of the cascade and to emphasize person-centred HIV prevention, testing and treatment, integration of HIV-related infections, the use of routine surveillance data to measure impact, and the development and use of digital health data systems and their governance.

Depending on the country context, these guidelines provide a path for making longer-term progress towards the sustainability and use of routinely collected patient and programme data. This includes supporting countries in:

- increasing and more sustainable use of routine individual-level data – linked by unique identifiers – for client/patient care and for most ongoing reporting needs, supplemented by surveys, models and other epidemiologic data;
- strengthening HIV prevention, testing and treatment linkages, follow-up and retention in care as individuals move between different health services and facilities;
- expanding existing HIV surveillance systems to adopt or strengthen HIV case surveillance approaches that routinely capture and link individuals' data on all reported cases of HIV over time, based on a minimum dataset. These data may come from HIV testing sites, health facilities, laboratories and vital statistics registries;
- transitioning from paper to electronic health information systems, which will support the routine disaggregation of data by person, time and place;
- investing in the adoption or expansion of unique identifiers to link individual records within facilities and programmes and across different health services;
- promoting standards for governance, safety, security, privacy, interoperability and the ethical use of data within and outside the health sector.

Digital technologies are an essential component and enabler of sustainable health systems and universal health coverage. Digital health is an integral part of health systems strengthening and addressing health priorities to benefit people in a way that is ethical, safe, secure, reliable, equitable and sustainable. To realize their potential, digital health initiatives must respond to wider health information needs and be guided by a robust strategy that integrates leadership, financial, organizational, human and technological resources. This strategy should be used as the basis for a costed action plan that enables coordination among multiple stakeholders *(31)*. Digital health initiatives should be led through strong governance structures that work across multiple health priorities, underpinned by standards and an architecture that enables this integration. Digital health solutions should be developed with principles of transparency, accessibility, scalability, replicability, interoperability, privacy, security and confidentiality *(31)*.

While promising great advantages and benefits, digitization poses inherent risks to the security, confidentiality and interoperability of data that are used for health care services. All individual-level health data are to be classified as sensitive personal data, or personally identifiable information, which require a high standard of safety and security. Therefore, there needs to be a strong legal and regulatory base to protect privacy, confidentiality, integrity, the availability of data and the processing of personal health data. Furthermore, the system must deal with cybersecurity, trust building, accountability and governance, ethics, equity, capacity building and digital literacy. This will ensure that good quality data are collected and shared to support the planning and the transformation of health services.

1.4 Process of development

WHO staff and consultants developed these guidelines based on review of recent global and regional guidance documents, consultative meetings and inputs of technical experts. The minimum datasets and priority indicators included in these guidelines were identified through consultation with technical experts with country-level, regional and global perspectives.

The Core Advisory Group, which had responsibility for oversight of guidelines development, included two co-chairs and members with expertise in strategic information and monitoring and evaluation (M&E), with additional representation from WHO regions, Member States (health ministries), civil society, partners and academic institutions. This advisory group provided inputs on the overall approach to the guidance and indicators and reviewed drafts of the chapters at different stages.

For each programme area, a technical working group was established, including two co-chairs, WHO technical staff and members who represented health ministries, nongovernmental and academic partners, programme implementers, civil society and development partner agencies. These agencies included among others UNAIDS, the United Nations Children's Fund (UNICEF), the United States President's Fund for AIDS Relief (PEPFAR) and the Global Fund to Fight AIDS, Tuberculosis and Malaria (The Global Fund). These technical working groups, which met virtually, focused on prioritizing and organizing the programmatic sections, minimum datasets, and indicators to align with the most recent programmatic recommendations.

WHO headquarters provided overall direction, coordination and oversight. All external contributors to the development of the guidelines completed a WHO declaration of interests form.

1.5 Organization of the guidelines

These guidelines are organized into six technical chapters on person-centred HIV prevention monitoring; person-centred HIV patient monitoring for testing, early diagnosis, and treatment; integrating related infections into HIV surveillance systems; harnessing the strength of routine data for HIV surveillance; digital health data; and strengthening data use. Each chapter includes a brief description of critical measurement issues, reasons for selecting the data elements included in the minimum dataset and priority indicators for that programme area. Each chapter also includes references to published materials that provide additional details for operationalizing the collection and use of these data.

Chapter 8 contains detailed metadata for priority and core indicators, including those derived from programmatic data and from surveys. Web annexes to the guidelines contain a complete minimum dataset across all programme areas in Excel format that can be downloaded directly for use (Web Annex A), and a list of additional indicators that can be considered according to programmatic need and context (Web Annex B). Web Annexes C–M are specific to the chapter on person-centred HIV patient monitoring for testing, early diagnosis, and treatment and can be used directly or adapted to country context.

1.6 Intended audiences

This guideline is intended primarily for national and subnational HIV programme managers, surveillance officers, partners and other stakeholders involved in the design and use of M&E systems, surveillance and tools for the collection, analysis and use of HIV health sector data. These include national-level staff establishing strategic information policy, guidelines, frameworks, tools and HIS as well as staff involved with national, subnational and service delivery (facility and community) level collection, analysis and use of HIV-related data to monitor and improve programmes. The guidelines will also be of interest and use to technical partners and other stakeholders who support the design and implementation of HIV health sector M&E systems and related tools. Other potential users include stakeholders concerned with developing and analysing strategic information, including nongovernmental organizations (NGOs), private-sector care providers, civil society organizations and academic groups involved in teaching and research.

References

1. Global AIDS Update 2021. Confronting inequalities: lessons for pandemic responses from 40 years of AIDS. Geneva: United Nations Joint Programme on HIV/AIDS (UNAIDS); 2021 (https://www.unaids.org/en/resources/documents/2021/2021-global-aids-update, accessed 23 June 2022).
2. Justman JE, Mugurungi O, El-Sadr WM. HIV population surveys - bringing precision to the global response. N Engl J Med. 2018;378:1859-61. doi: 10.1056/NEJMp1801934
3. Grabowski MK, Serwadda DM, Gray RH, Nakigozi G, Kigozi G, Kagaayi J et al. HIV prevention efforts and incidence of HIV in Uganda. N Engl J Med. 2017;377:2154-66. doi: 10.1056/NEJMoa1702150
4. Gregson S, Mugurungi O, Eaton J, Takaruza A, Rhead R, Maswera R et al. Documenting and explaining the HIV decline in east Zimbabwe: the Manicaland General Population Cohort. BMJ Open. 2017;7:e015898. doi: 10.1136/bmjopen-2017-015898
5. Hakim AJ, MacDonald V, Hladik W, Zhao J, Burnett J, Sabin K et al. Gaps and opportunities: measuring the key population cascade through surveys and services to guide the HIV response. J Int AIDS Soc. 2018;21:e25119. doi: https://doi.org/10.1002/jia2.25119
6. Hayes RJ, Donnell D, Floyd S, Mandla N, Bwalya J, Sabapathy K et al. Effect of universal testing and treatment on HIV incidence - HPTN 071 (PopART). N Engl J Med. 2019;381:207-18. doi: 10.1056/NEJMoa1814556
7. Hargreaves JR, Mtetwa S, Davey C, Dirawo J, Chidiya S, Benedikt C et al. Implementation and operational research: cohort analysis of program data to estimate HIV incidence and uptake of HIV-related services among female sex workers in Zimbabwe, 2009-2014. J Acquir Immune Defic Syndr. 2016;72:e1-8. doi: 10.1097/QAI.0000000000000920
8. Jacob N, Rice B, Kalk E, Heekes A, Morgan J, Hargreaves J et al. Utility of digitising point of care HIV test results to accurately measure, and improve performance towards, the UNAIDS 90-90-90 targets. PLoS One. 2020;15:e0235471. doi: 10.1371/journal.pone.0235471
9. Szwarcwald C, Souza J, Pascom A, Ferreira J. Results from a method for estimating HIV incidence based on the first CD4 count among treatmentnaïve cases: Brazil, 2004–2013. J AIDS Clin Res. 2016;7:2.
10. Dwyer-Lindgren L, Cork MA, Sligar A, Steuben KM, Wilson KF, Provost NR et al. Mapping HIV prevalence in sub-Saharan Africa between 2000 and 2017. Nature. 2019;570:189-93. doi: 10.1038/s41586-019-1200-9
11. Mahy M, Penazzato M, Ciaranello A, Mofenson L, Yianoutsos CT, Davies MA et al. Improving estimates of children living with HIV from the Spectrum AIDS Impact Model. AIDS. 2017;31 Suppl 1:S13-S22. doi: 10.1097/QAD.0000000000001306
12. Kariuki JM, Manders E-J, Richards J, Oluoch T, Kimanga D, Wanyee S et al. Automating indicator data reporting from health facility EMR to a national aggregate data system in Kenya: An Interoperability field-test using OpenMRS and DHIS2. Online J Public Health Inform. 2016;8:e188-e. doi: 10.5210/ojphi.v8i2.6722
13. Looker KJ, Welton NJ, Sabin KM, Dalal S, Vickerman P, Turner KM et al. Global and regional estimates of the contribution of herpes simplex virus type 2 infection to HIV incidence: a population attributable fraction analysis using published epidemiological data. Lancet Infect Dis. 2020;20:240-9.

14. de Sanjosé S, Diaz M, Castellsagué X, Clifford G, Bruni L, Muñoz N et al. Worldwide prevalence and genotype distribution of cervical human papillomavirus DNA in women with normal cytology: a meta-analysis. Lancet Infect Dis. 2007;7:453-9. doi: 10.1016/s1473-3099(07)70158-5

15. Tracking universal health coverage: 2021 Global Monitoring Report (Conference edition). Geneva and Washington (DC): World Health Organization and World Bank; 2021 (https://www.who.int/publications/i/item/9789240040618, accessed 23 June 2022).

16. Stelzle D, Tanaka LF, Lee KK, Khalil AI, Baussano I, Shah AS et al. Estimates of the global burden of cervical cancer associated with HIV. Lancet Glob Health. 2020;9:e161-e9.

17. Ibrahim Khalil A, Mpunga T, Wei F, Baussano I, de Martel C, Bray F et al. Age-specific burden of cervical cancer associated with HIV: A global analysis with a focus on sub-Saharan Africa. Int J Cancer. 2022;150:761-72. doi: 10.1002/ijc.33841

18. Wu MY, Gong HZ, Hu KR, Zheng H-y, Wan X, Li J. Effect of syphilis infection on HIV acquisition: a systematic review and meta-analysis. Sex Transm Infect. 2021;97:525-33.

19. Fleming DT, Wasserheit JN. From epidemiological synergy to public health policy and practice: the contribution of other sexually transmitted diseases to sexual transmission of HIV infection. Sex Transm Infect. 1999;75:3-17. doi: 10.1136/sti.75.1.3

20. Sexton J, Garnett G, Rottingen JA. Metaanalysis and metaregression in interpreting study variability in the impact of sexually transmitted diseases on susceptibility to HIV infection. Sex Transm Dis. 2005;32:351-7. doi: 10.1097/01.olq.0000154504.54686.d1

21. Jones J, Weiss K, Mermin J, Dietz P, Rosenberg ES, Gift TL et al. Proportion of incident human immunodeficiency virus cases among men who have sex with men attributable to gonorrhea and chlamydia: a modeling analysis. Sex Transm Dis. 2019;46:357-63. doi: 10.1097/olq.0000000000000980

22. Consolidated guidelines on HIV, viral hepatitis, and STI prevention, diagnosis, treatment and care for key populations. Geneva: World Health Organization; 2022 (https://www.who.int/publications/i/item/9789241511124).

23. Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach. Geneva: World Health Organization; 2021 (https://www.who.int/publications/i/item/9789240031593, accessed 23 June 2022).

24. Consolidated guidelines on person-centred HIV patient monitoring and case surveillance. Geneva: World Health Organization; 2017 (https://apps.who.int/iris/handle/10665/255702, accessed 24 June 2022).

25. Consolidated HIV strategic information guidelines: driving impact through programme monitoring and management. Geneva: World Health Organization; 2020 (https://www.who.int/publications/i/item/9789240000735, accessed 24 June 2022).

26. Mehl G, Tunçalp Ö, Ratanaprayul N, Tamrat T, Barreix M, Lowrance D et al. WHO SMART guidelines: optimising country-level use of guideline recommendations in the digital age. Lancet Digit Health. 2021;3:e213-e6.

27. Digital adaptation kit for antenatal care: operational requirements for implementing WHO recommendations in digital systems. Geneva: World Health Organization; 2021 (https://www.who.int/publications/i/item/9789240020306, accessed 15 June 2022).

28. Digital adaptation kit for family planning: operational requirements for implementing WHO recommendations in digital systems. Geneva: World Health Organization; 2021 (https://www.who.int/publications/i/item/9789240029743, accessed 15 June 2022).

29. Digital adaptation kit for HIV. Operational requirements for implementing WHO recommendations in digital systems Geneva: World Health Organization; 2022.

30. Classification of digital health interventions v1.0: a shared language to describe the uses of digital technology for health. Geneva: World Health Organization; 2018 (https://apps.who.int/iris/handle/10665/260480, accessed 2 July 2022).

31. Global strategy on digital health 2020-2025. Geneva: World Health Organization; 2021 (https://apps.who.int/iris/handle/10665/344249, accessed 23 June 2022).

CHAPTER 2 – PERSON-CENTRED HIV PREVENTION MONITORING

2

CHAPTER 2 – PERSON-CENTRED HIV PREVENTION MONITORING

Key recommendations

NEW 1. The collection of **a minimum dataset of individual-level data elements on HIV prevention interventions** is recommended to measure interventions received and health outcomes among individuals seeking HIV prevention.

NEW 2. **Individual-level data on HIV prevention** should be used, alongside other available data sources, to strengthen the measurement of:

a) the **coverage of interventions** provided to populations affected by HIV, to increasingly measure individual people reached rather than services delivered

b) **prevention impact** through longitudinal assessment of HIV status at the facility, subnational and national levels.

NEW 3. The collection of **clinical and behavioural information on factors associated with HIV acquisition** in routine health information systems is suggested to aid in offering HIV prevention interventions to those who may benefit from them and to estimate service-level denominators for the calculation of programme monitoring indicators. An individual's need for HIV prevention changes over time, based on individual, structural and contextual factors. Therefore, for the purposes of service delivery and M&E, information on HIV prevention should be collected frequently.

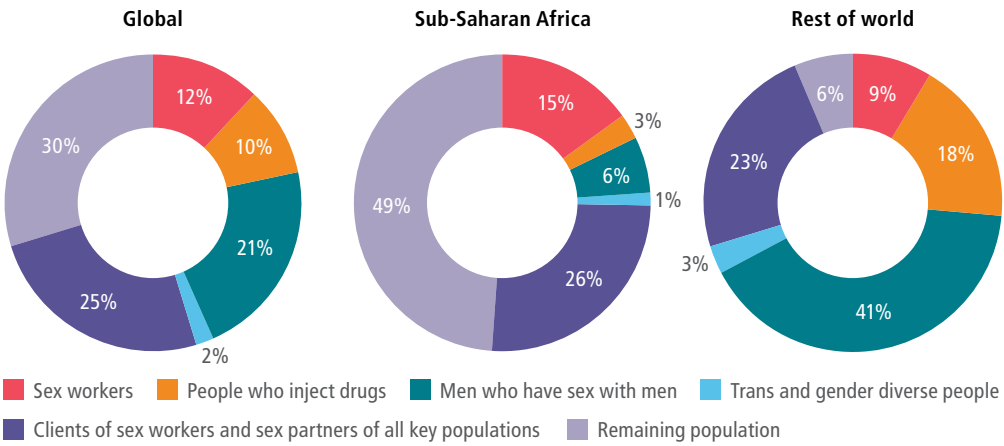
NEW 4. It is recommended that **HIV data systems that capture an individual's sensitive clinical and behavioural information (that is, on stigmatized and criminalized behaviours) do not link these data to personally identifying information.** This separation of sensitive behavioural and personally identifying information should be maintained when linking HIV prevention data systems to other clinical datasets (such as for HIV treatment) containing personal identifiers.

2.1 Introduction

2.1.1 Epidemiology of HIV and prevention need

The prevention of new HIV infections remains critical to achieving the goal to end the HIV epidemic by 2030, as set out in the 2016 United Nations Political Declaration *(1)*. Yet, declines in HIV incidence have been slow, far short of the global target of reducing annual new HIV infections to under 370 000 by 2025 *(2-4)*. In 2020, 1.5 million (1.0 million–2.0 million) people became newly infected with HIV, with women and girls accounting for half of all new infections globally and 63% in sub-Saharan Africa *(4)*. While the overall incidence of new infections has been declining since the peak in 1997, the proportion of these new infections that occur among people from key populations (men who have sex with men, sex workers, people who inject drugs, trans and gender diverse people, and people in prisons and other closed settings) continues to increase *(5)*. In 2021 people from key populations and their sexual partners accounted for 70% of new infections globally and 94% of new infections outside of sub-Saharan Africa *(4, 5)*. In sub-Saharan Africa as well, key populations and their sexual partners make up an increasing proportion of new infections, from 25% in 2016 to 51% in 2021 *(4-6)* (Fig. 2.1).

Fig. 2.1 Distribution of new HIV infections, by population, global, sub-Saharan Africa and rest of world, 2020



Source: UNAIDS Special analysis and epidemiological estimates, 2022.

Other groups within the general population may be identified as priority populations affected by HIV or experiencing barriers in access to services in certain settings. These include adolescent girls and young women, ages 15–24 years, in sub-Saharan Africa, who are twice as likely to be living with HIV than their male counterparts *(4)*. Adolescent boys and young men, particularly those who belong to key populations, face elevated risk for HIV acquisition and yet, as with adolescent girls, also have low levels of knowledge, awareness and uptake of HIV services, including prevention services *(4)*. While the overall HIV burden is higher in girls and women, men are less likely to get tested for HIV and, if infected, less likely to be on treatment and less likely to be virally suppressed *(7)*. A growing body of evidence shows that men have less access than women to HIV prevention, testing and ART *(8)*. In other settings migrants, refugees and internally displaced populations are also considered priority populations for HIV prevention.

HIV prevention interventions must reach those who would most benefit from them. This includes key populations and, in settings with high HIV prevalence or incidence, also adolescents, women and men when they experience increased vulnerability to HIV acquisition. Population-level data on age-, gender- and location-specific HIV incidence or prevalence can help define where and among whom focused approaches to prevention are most needed.

Legal, structural and economic barriers that hamper access to HIV prevention interventions reduce the impact of HIV prevention *(9, 10)*. Other barriers include a lack of awareness of prevention options, lack of a perception of risk among individuals at risk and among providers who may not recognize their clients' need for prevention, as well as criminalization, stigmatization and discrimination around certain behaviours *(11-13)*. Barriers across all groups must be addressed to ensure equitable access to HIV prevention in a safe environment without the involvement of law enforcement *(2, 3, 9, 10, 14)*.

2.1.2 Strategic information for HIV prevention

Measuring HIV prevention programmes against health outcomes (such as individuals remaining HIV-negative or new HIV infections) can be challenging. This is because, by its very nature, HIV prevention can be started and stopped at will according to an individual's need. Therefore, as with all other areas of the HIV response, data from multiple sources are necessary to obtain a full picture of HIV prevention service availability, access and coverage. These sources include surveillance data from population-based surveys *(15)*, bio-behavioural surveys of different key populations *(16, 17)* and routine programmatic data on health service delivery.

These guidelines focus on routine programmatic data, which are critical for tracking the delivery and potential impact of health services. Routine programmatic data also can be used to identify individuals who may be at elevated risk of HIV acquisition and, accordingly, prioritize efforts to generate prevention demand, to follow up on whether interventions were received, and to identify and address barriers to access. Table 2.1 presents a framework for monitoring HIV prevention using person-centred or individual-level programme data.

HIV treatment services commonly collect individual-level programme data routinely, but HIV prevention services in many settings currently do not. Where individual-level programme data for prevention are not available, priority indicators can still be calculated using existing aggregated reporting practices; interpretation of these findings will differ from that derived from individual-level data.

Surveys are able to estimate service uptake and coverage within the broader population, while routine programme data capture only information on individuals who seek health services. Surveys, however, typically are conducted infrequently and can require substantial financial and technical resources. Routine programmatic data should be supplemented by data either from population-based surveys in the general population or from bio-behavioural surveys among key populations, as appropriate and when available. Guidance on survey methods is available:

- *Monitoring HIV impact using population-based surveys*. UNAIDS/WHO Working Group on Global HIV/AIDS and STI Surveillance (2015) *(15)*
- *Biobehavioural survey guidelines for populations at risk for HIV*. WHO, CDC, UNAIDS, FHI 360 (2017) *(16)*.

Table 2.1 Framework for monitoring HIV prevention using person-centred programme data

Objectives	Systematically identify and record individuals who may benefit from HIV prevention	Measure HIV prevention service uptake and use	Monitor the HIV prevention response over time	Build sustainability
Person-centred monitoring strategies	1) Self-identification 2) Prioritize HIV prevention efforts 3) Refer in from other health services 4) Capture key population status 5) Ensure confidentiality	1) Location: facility, community, other outreach 2) Include option for use of multiple services (for example, PrEP, STI, condoms, OAMT, NSP) 3) Capture laboratory test results (HIV, STIs) 4) Client management, including follow-up as needed	1) Priority outcomes: HIV status, STI and hepatitis incidence and testing and treatment outcomes 2) Measure outcomes at multiple time points 3) Measure start/stop/continuation/restart of prevention services as appropriate 4) Capture use of related services (for example, contraception)	1) Build in aggregation for national reporting 2) Conduct data quality assurance checks, including to de-duplicate records 3) Summarize data for use at three levels – facility, subnational, national 4) Assess acceptability of services and strategies to clients and providers 5) Integrate with other systems where appropriate
Foundational data system needs	1) Unique identification of individuals (anonymous/confidential and delinked) 2) Utility across all service settings – facility, community, outreach 3) Integration possible across service providers (public, community, private) 4) System architecture that enables differing levels of user access, depending on need, secure data storage and backup 5) Programmable for different indicators for ministries, donors and other stakeholders 6) Customizable dashboards providing simple user interfaces, to encourage data use 7) Enables linkage of individuals across diseases/the health sector.			

Abbreviations: NSP = needle–syringe programme; OAMT = opioid agonist maintenance therapy; PrEP = pre-exposure prophylaxis; STI = sexually transmitted infection

2.1.3 HIV prevention interventions

A *person-centred approach* should address the range of HIV prevention and other health needs that individuals might have and make appropriate interventions available in a manner acceptable to them. The design of HIV prevention programmes should be informed by the local context and the nature of the local HIV epidemic and tailored to meet the HIV prevention needs of the individuals and communities they serve.

To meet users' needs, HIV prevention interventions can be provided in a variety of settings and by a range of service providers, including primary, secondary and tertiary health facilities, community-based services, community-led services, educational settings, online and through outreach *(18-21)*. The Global AIDS Strategy (2021–2026) recognizes the importance and effectiveness of community-led delivery of HIV prevention services and community-led monitoring (see Chapter 7), which prioritizes the "scale-up of community-led service delivery to ensure that the majority of HIV prevention programmes are led by key populations, women and young people, and that all HIV testing, treatment and care programmes include community-led elements" *(2)*.

To achieve universal access and have the greatest impact on reducing new HIV infections, combination prevention activities, including *biomedical, behavioural* and *structural interventions*, are required.

Biomedical and health sector interventions seek to reduce the probability of HIV transmission per contact event. Evidence-based interventions are listed in Box 2.1. Many of these health sector interventions address numerous health risks in addition to HIV and are important components of the response to STIs and viral hepatitis.

A recent WHO review of counselling as a *behavioural intervention* for key populations did not find evidence that these interventions changed behaviours or reduced HIV, viral hepatitis or STI incidence *(10)*. However, information-sharing can be a key component of engagement with people who may benefit from HIV prevention, testing or treatment. Information should be delivered in a non-judgemental manner alongside other prevention interventions and with involvement of peers *(10)*. Various communication approaches may be used, such as school-based comprehensive sexuality education *(22, 23)* and peer-based, community-level and interpersonal education to disseminate messages that support individuals' decision-making on safer sexual activity and on drug use *(9)*.

Structural or enabling environment interventions address social, legal and political factors that contribute to vulnerability, potentially increase HIV transmission or reduce the accessibility and impact of behavioural and biomedical interventions *(24)*. These strategies include: developing supportive legislation and policy (maintained through financial commitment), including the decriminalization of sex work, same-gender sex, gender identity and expression, drug use and possession, and the transmission of HIV; measures to reduce stigma and discrimination (including in the health sector); promoting gender equality and preventing gender-based violence and violence against people from key populations; economic and social empowerment; and mobilization of communities affected by HIV *(10)*.

This chapter provides guidance on the routine collection and use of data, including individual-level data, through programmes to monitor HIV prevention interventions. The collection and use of data to monitor HIV treatment as prevention and strategies for the prevention of mother-to-child transmission are discussed separately in Chapter 3. Chapter 4 provides guidance on data collection and use for STI and hepatitis services in the context of HIV prevention.

Box 2.1 Evidence-based biomedical and health sector HIV prevention interventions

- ART for people living with HIV to achieve viral suppression and prevent HIV transmission to sexual partners
- prevention of mother-to-child transmission
- condom programming
- pre-exposure prophylaxis (PrEP) (all dosing regimens and products)
- needle–syringe programmes (NSP)
- opioid agonist maintenance treatment (OAMT) for opioid dependence
- evidence-based treatment of drug dependence (other than OAMT)
- voluntary medical male circumcision (VMMC)
- post-exposure prophylaxis (PEP)
- peer education or support
- STI diagnosis and treatment
- reproductive health services.

The range of HIV prevention interventions means that their delivery and, therefore, their measurement in strategic information systems differ. Some are delivered to an individual at a single point in time (for example, VMMC, PEP); others are episodic (for example, STI testing and treatment); while still other interventions continue as long as an individual needs them to prevent HIV during periods of elevated risk for HIV acquisition (for example, condom provision, NSP, OAMT, PrEP). As new prevention modalities and systems for delivering them are developed and implemented (for example, long-acting PrEP), HIV prevention services and data systems must be able to record their delivery and use. Delivery modes include telemedicine, community-based service delivery, online community engagement and mobile apps. Moreover, HIV prevention interventions are sometimes delivered together and integrated with other health services, such family planning, maternal and child health care, sexual and reproductive health services, cervical cancer screening, TB and hepatitis services, and mental health and drug dependence services *(9, 10, 25)*. This delivery, ideally, should also be recorded to give a provider a holistic view of a clients' health care needs. In addition to improving accessibility, integration improves individual-level and health system outcomes, boosts the sustainability of the HIV response and supports progress towards universal health coverage *(26-28)*.

Since people need HIV prevention at differing periods of their lives and for different durations – because sexual and drug using behaviour changes across different periods of life – longitudinal data systems must be able to capture and accurately report current information that can be used for programme management and improvement.

Monitoring the implementation of essential strategies for an *enabling environment* (or *structural interventions*) is a critical component of HIV programming. Through surveys, it is possible to document individuals' experiences of stigma and discrimination and structural barriers. Guidance on monitoring the implementation of structural interventions for a comprehensive response to HIV among key populations is available: *Tool to set and monitor targets for HIV prevention, diagnosis, treatment and care for key populations*, 2015, WHO *(29)*.

2.2 Individual-level HIV prevention data

2.2.1 Using routine programme data to measure HIV prevention interventions

Individual-level data on people living with HIV across HIV treatment and care has proved critical to understanding the effectiveness of HIV treatment at the individual and population levels and has enabled the construction of HIV treatment cascades *(24)*. By comparison, collection and use of individual-level data on HIV-negative people to monitor HIV prevention services and to develop "HIV prevention cascades" has been more limited *(30, 31)*.

Individual-level data on HIV prevention can be used to observe a range of factors affecting the accessibility and coverage of interventions provided to different subpopulations who attend health services, as well as to measure changes in patterns of new diagnoses. Outcomes that are important to monitor vary for different interventions but can relate to:

- incident infection (HIV, STIs, viral hepatitis)
- known risk factors for HIV, hepatitis and STIs
- initiation of HIV prevention interventions
- follow-up and regular engagement with services or regular receipt of commodities (NSP, condoms, STI screening, HIV testing).

The collection of individual-level data across HIV prevention programmes offers an opportunity to monitor how well programmes are meeting the needs of individuals and to inform the prioritization of prevention interventions at the individual and programme levels. Individual-level data can be used for the management of individuals and aggregated to understand programme performance at the facility, subnational or national levels. Data systems must meet certain requirements to collect individual-level data (Box 2.2) and, at the same time, should be able to adapt to collect meaningful data on new prevention modalities and delivery methods as these are introduced.

Box 2.2 Requirements of a system to collect and use individual-level data to monitor HIV prevention

- a system of unique identification to track each individual within a service and, ideally, across different services to allow for deduplication;
- a system to identify individuals and priority populations who might benefit from HIV prevention interventions;
- a health information system that maintains confidentiality and anonymity;
- standardized data collection tools and processes;
- collection of a minimum dataset of essential data elements for monitoring.

2.2.2 Anonymity, confidentiality and the use of unique identification (UID) codes

Maintaining the confidentiality of individual-level health information is important for all people and particularly for populations who may experience criminalization, stigma and discrimination, such as key populations and adolescents. In many settings same-gender sexual activity, sex work, or drug use or possession are stigmatized and, in some settings, criminalized. Health services collecting personally identifying information from clients linked to these behaviours raises the potential for negative consequences both for individuals and for service providers and can discourage people from using services. These consequences may include the following:

- Data recorded in health information systems related to criminalized behaviours, if shared, could be used to identify individuals for questioning, detention or arrest by law enforcement.
- Awareness among clients that information on criminalized behaviours is being recorded may result in underreporting of risk behaviours and/or avoidance of that health service.
- Health care workers and other service providers may discriminate against people based on their behaviour or identity; such discrimination may include denial of services.

Health workers have a central role in assuring confidentiality. Staff collecting individual data and those with access to these records should receive training on the sensitivity of these data, on stigma and discrimination, and on the importance of ensuring that data are protected. Supervisors should make adherence to confidentiality procedures an explicit element of personnel evaluations. Some programmes may require staff with access to data to sign confidentiality agreements. National legislation for the protection of personal data should be in place, and programmes should adhere to these laws.

To reduce the risks associated with collection of sensitive information on stigmatized or criminalized behaviours, it is advised to not use an individual's name, national ID number (for example, social security, national health care number or the like) or other personally identifying information to identify them within the data collection system. (See also Chapter 6, Digital health data.) Most importantly, where HIV prevention services capture an individual's sensitive clinical and behavioural information (that is, on stigmatized and criminalized behaviours) in data systems, these data should not be linked to personally identifying information. This separation of sensitive behavioural information from personally identifying information should be maintained when linking HIV prevention data systems to other clinical datasets (such as for HIV treatment) that do contain personal identifiers. For any data analysis, reporting, and aggregation outside of clinical service provision, all individual-level data should be de-identified (using no personal identifiers) or anonymized (stripped of any personal identifiers, including content-free UID). The principle of data minimization (see Section 6.4 Privacy, security, data access and control) should be applied in all settings where data are collected and analysed.

The use of anonymous UID codes allows services to still be effectively and efficiently provided, and individuals to be followed longitudinally, without the collection of personally identifying information. People can be reassured that they do not have to disclose their personally identifying information. UID codes should be assigned at the point of first engagement with the data system and used whenever individual-level information is collected. UID codes can be composed of information that the client can easily recall, allowing codes to be easily reconstructed when accessing services. To observe and follow individuals across different services and programmes, it is ideal if all services and programmes consistently use the same UID codes.

It may take some time before comprehensive health information systems are in place to implement UIDs and apply uniform UIDs across services. In the meantime, using individual-level prevention data for a given programme or at a subnational level still will increase the accuracy and reliability of data used for monitoring and planning at this local level. Chapter 6 provides further guidance on UID systems.

2.2.3 Prioritizing HIV prevention services

It is important that HIV prevention programmes and service providers understand the different vulnerabilities and risks of HIV acquisition of the individuals and communities they serve as well as their values and preferences. It is critical to consider how the intersection of society's attitudes toward people based on factors such as their age, gender, ethnicity, disability and the criminalization of key populations leads to greater risk of HIV acquisition and may limit the availability and accessibility of HIV prevention interventions.

A number of different factors can influence whether people are at substantial risk for acquiring HIV. Important determinants of this risk include an individual's own, or their partners', sexual and drug-using behaviour, whether their sexual partners are living with HIV and, if so, whether they are virally suppressed. Also, an individual's behaviours and the potential level of exposure to HIV will vary over time; for example, people may stop or start drug use, their sexual partnerships may change; or their partners' viral suppression status may vary *(9, 10)*.

The overall background HIV prevalence and incidence where they live is also an important factor. In populations or geographies where HIV prevalence is high or viral suppression is low, even lower-risk behaviours may carry relatively higher risks of HIV acquisition *(32)*. Combining population-level data on age- and gender-specific HIV incidence or prevalence by subnational geographic region with individual-level risk differentiation can help prioritize prevention services *(33)*. National HIV programme or public health jurisdictions will need to review the most recent epidemiological data on HIV at national, regional and municipal levels and, depending on the setting, identify subpopulations with higher HIV incidence/prevalence that may benefit from prioritized HIV prevention services.

Globally, key populations (men who have sex with men, sex workers, people who inject drugs, trans and gender diverse people, and people in prisons and other closed settings) are disproportionally affected by HIV. Some may have overlapping vulnerabilities that multiply their risk of HIV acquisition. For example, sex workers, men who have sex with men and trans and gender diverse people may also inject drugs *(10)*. Other population groups at substantial risk of acquiring HIV include, particularly in southern and eastern Africa but elsewhere as well, adolescent girls and young women and serodiscordant couples where the partner with HIV is not virally suppressed on ART. However, not all people within these groups may be at substantial risk for HIV acquisition or at high risk at all times. At the same time, it can be challenging to identify groups and individuals who may benefit from prevention services but do not seek them out.

Prioritizing HIV prevention services and the associated monitoring systems for populations and individuals who may benefit most can enable providers to more efficiently offer follow-up to those testing HIV-negative, as the human resources needed to follow the large number of people testing HIV-negative would be substantial.

In all settings a process for differentiating individuals who may be at substantial risk of HIV and may benefit from HIV prevention can be considered and built into the HIS to aid providers in offering appropriate services and follow-up.

A process for differentiating individuals most likely to benefit from HIV prevention services can be built into the HIS.

2.2.4 Understanding person-centred HIV prevention need

Conversations between service providers and clients during a consultation are key to understanding an individual's HIV prevention needs. Such conversations may take place before or after HIV testing, during a sexual health consultation, or when providing HIV prevention services. It should be noted that discussing issues such as sexual behaviours, sexual identity and expression, and drug use can be uncomfortable for both client and provider, especially when these behaviours are stigmatized or criminalized. Providing privacy and confidentiality are key; community-led services and peer workers have an important role in providing trusted and safe settings to have these conversations.

Providers should offer prevention interventions to all people who request HIV prevention services, even if they are unwilling to discuss their reasons for concern; these persons may recognize their own potential exposure to HIV. Some people may not be able or willing to discuss HIV, either due to fear of stigma or reticence to talk to providers about sexual and drug using behaviour. Young people may be reluctant to disclose sexual activity in settings with laws that restrict adolescent access to sexual and reproductive health services. In such situations, where individuals have chosen the services best suited to them, the fact that an individual has self-identified as needing services should be captured in a data system, without requiring other information.

> Providers should offer prevention interventions to all people who request them.

Alternatively, sometimes an individual's perception of their own vulnerability to acquiring HIV may be low, even among those who have known risk factors such as a recent STI; this is particularly so for adolescents and young adults *(34)*. In such cases a possible approach is using a prevention prioritization tool), a series of questions about HIV risk factors (also called a risk differentiation or risk assessment tool) to help individuals who may be unaware of their own vulnerability, or who may be uncomfortable bringing it up with health care workers, to start a conversation about HIV prevention. The HIS can record the answers to these questions.

Questions for HIV prevention prioritization

Questions to ascertain a person's risk factors for HIV can be helpful as a programmatic counselling tool to expand or extend access to HIV prevention. HIV prevention prioritization tools have been developed and validated for different population groups, for example, men who have sex with men in the United States of America *(35)*, pregnant women and heterosexual serodiscordant couples in eastern Africa *(36-38)*, and adolescent girls and women of reproductive age in South Africa *(34, 39, 40)*. A recent large prospective validation study on HIV risk differentiation in Zimbabwe found that a 9-question tool identified 77% of adolescent girls and young women who acquired HIV or HSV-2 in the following 12 months (Moorhouse, L and Gregson, S, Imperial College London, personal communication, 6 March 2022).

A recent systematic review on validated HIV prevention prioritization tools in sub-Saharan Africa found that younger age, non-cohabiting and having a history of STIs (at baseline or lifetime, both laboratory-confirmed and self-reported) consistently predicted future HIV infection. Another critically important factor for predicting HIV acquisition has been HIV prevalence in the surrounding geographic area *(32, 41),* indicating the importance of taking context into consideration. However, most of the tools reviewed had only low to moderate ability to distinguish individuals at high risk of HIV acquisition *(32)*.

The implications of the evidence thus far on the ability of tools to identify individuals at risk of HIV acquisition are that:

- Prevention prioritization tools can identify individuals at higher risk of HIV acquisition and prompt discussion about HIV prevention options in all settings. However, these tools identified a proportion, but not all, individuals among whom HIV infection occurred and, therefore, should not be expected to capture all people who may need HIV prevention. Therefore, risk differentiation questions should not be used to exclude access for individuals who request HIV prevention services.

> Prioritization questions should never be used to exclude people from HIV prevention interventions, especially if individuals have self-identified as concerned about HIV and are motivated to use HIV prevention.

- Risk can change rapidly. In the Zimbabwe study a large number of HIV infections occurred among young adults with no risk factors at baseline but who later became sexually active and whose risk situation changed. Therefore, information on HIV prevention need should be collected frequently to ensure that it stays relevant.

In geographic settings or populations with high HIV prevalence or incidence, health care providers can use questions on risk factors for HIV to begin conversations about HIV, prioritize prevention services and prompt regular follow-up, where appropriate, for individuals who may not recognize their own risk for HIV. These client-provider interactions may take place at any of the potential entry points for HIV prevention listed in Box 2.5 in section 2.2.6, and any others that are locally relevant, to better direct people to HIV prevention services. Questions may also be self-administered, enabling individuals to assess their own HIV risk and motivating those at risk to protect themselves. Box 2.3 presents an example of these clinicals tools. People already engaged in HIV prevention services may not need such questions asked of them.

Information gathered on the following factors indicating potential need for HIV prevention services can be included in the HIV prevention data system captured in the HIS:

- a recent STI (having had STI symptoms, diagnosis or treatment);
- having a non-regular/casual sexual partner (appropriate language for describing these types of sexual partners will differ in different settings – for example "someone who is not a spouse or co-habiting partner"; "a partner you have sex with but don't feel committed to");
- having a sexual partner who is HIV-positive;
- having a sexual partner who has a recent STI (having had STI symptoms, diagnosis or treatment);
- a recent history of having sex in exchange for money or goods;
- a recent history of injecting drug use;
- cis-gender men and transgender women who have had sex with men.

While HIV prevention prioritization tools have a role in identifying HIV prevention needs that might not be immediately apparent, their value and utility is more limited in contexts where an individual is already engaged with HIV prevention services. If people self-identify as requiring services, or if an individual is from a key population and their prevention needs are already clear, asking multiple questions on HIV risk might be an unnecessary encumbrance to easy access.

Box 2.3 Example of HIV prevention prioritization questions used after an HIV-negative test result

Please be sensitive to privacy and confidentiality; open the conversation in listening mode: "Now that you know your status and have tested HIV-negative, I would like to refer you to the appropriate HIV prevention services to keep you negative, using a few short questions."

Questions for HIV prevention prioritization	Lower prevention benefit	Higher prevention benefit
During the past 12 months, did you have a non-regular sex partner? *A non-regular partner is someone who is not a spouse or boyfriend/girlfriend.*	☐ No	☐ Yes
During the past 12 months have you had sex with someone who was HIV-positive or whose HIV status you don't know?	☐ No	☐ HIV-positive ☐ HIV status unknown
During the past 12 months, have you been diagnosed with or received treatment for a sexually transmitted infection?	☐ No	☐ Yes
During the past 12 months, have you received money or goods in exchange for sex?	☐ No	☐ Yes
During the past 12 months, have you ever injected drugs?	☐ No	☐ Yes
Men only: During the past 12 months, have you had sex with a man?	☐ No	☐ Yes

The wording of these questions should be adapted to the local context.

2.2.5 Capturing information on HIV prevention demand in a health data system

The collection of individual-level data on HIV prevention need allows for the monitoring of how well HIV prevention services are meeting this demand.

There are two main sources of data indicating HIV prevention need captured by health data systems:

1. **Data from HIV prevention prioritization questions or information gathered in the course of providing services** can be recorded directly in HIV prevention data systems to document differential risk, where this is possible, appropriate and safe to do so. This information can also indicate that an individual is a man who has sex with men, a sex worker, a person who injects drugs, or a trans or gender diverse person. It is important to understand the limitations of this information: Individuals may not be asked or may not want to respond to behavioural questions, and, therefore, prevention prioritization questions may underestimate HIV prevention need.
2. **Individual-level data indicating an individual has received a certain HIV prevention or related service** can indicate potential ongoing demand for this and other HIV prevention services. For example, data recording that an individual has been provided with injecting equipment is an indication that this is a person who injects drugs and so may also benefit from further engagement with an NSP as well other services such as HIV testing or drug dependence treatment (such as OAMT if the person is opioid dependent). Data recording that an individual has been diagnosed as having an STI indicates that person is likely to require future testing or assessment for STIs, as well as HIV testing.

Individual-level data elements suggesting potential HIV prevention needs are listed in Box 2.4. These data on HIV prevention demand can be used to derive denominators for a range of indicators examining the population of individuals accessing services (see section 2.4).

Since an individual's risk of HIV acquisition and HIV prevention needs vary over time, it is important to record the date that any information on risk differentiation was collected and to consider this when assessing an individual's likely current prevention needs. When deriving indicator denominators for individuals at risk or in need of HIV prevention, inclusion criteria should consider when the data on prevention need were collected. Data collected in the past may not reflect current need for prevention interventions; information collected within the last three to six months is more likely to be pertinent.

Box 2.4 Individual-level data indicating potential HIV prevention need among adults and adolescents

- has a non-regular sexual partner
- reports recent STI (symptoms, diagnosis, or treatment)
- has a sexual partner who has a recent history of STI (symptoms, diagnosis or treatment)
- reports having sex in exchange for money or goods
- reports injecting drug use
- cis-gender man or transgender woman reporting sex with men.

Demographic data

- trans or gender diverse[a]
- adolescent or young person in a setting with high HIV prevalence.

Service provision data

- received condoms for HIV and STI prevention (rather than contraception), if collected
- requested PrEP
- received PrEP
- received PEP
- received injecting equipment
- received OAMT
- received evidence-based drug dependence treatment other than OAMT
- receives a positive STI screening test result
- receives a STI syndromic diagnosis
- receives a positive HBV test result
- receives a positive HCV test result
- receives any intervention from a key population HIV prevention programme
- receives any intervention from a programme for orphans and vulnerable children or for adolescent girls and young women in a setting with high HIV prevalence.

[a] Trans and gender diverse people can be identified in the dataset from the following two data elements: 1) sex assigned at birth; 2) current gender identity that includes trans and gender diverse people who choose an identity other than male or female.

2.2.6 Entry points to the data system for the collection of individual-level prevention data

Entry or referral to HIV prevention interventions can come from a number of prevention and allied programmes in whatever setting the intervention is provided, such as a facility, outpatient clinics, community settings and outreach. Individual-level data may be recorded at the referral or entry point where the HIV prevention intervention is provided. Various potential entry points are listed in Box 2.5.

Box 2.5 Potential entry points for providing HIV prevention interventions

- HIV testing
- STI services
- PrEP services
- PEP services
- VMMC
- various services specifically for key populations
- services for people who use drugs, including NSPs and other harm reduction services, OAMT and other drug treatment modalities
- services addressing gender-based violence where PEP or PrEP might be offered
- peer outreach programmes and community-led services and organizations
- reproductive health and family planning services
- maternal health services providing antenatal and postnatal care
- viral hepatitis testing and treatment
- programmes for orphans and vulnerable children and for adolescents and young people.

2.2.7 Registration process

Data systems collecting individual-level data on HIV prevention will need to collect basic demographic information on each individual and to assign some form of unique identification so that individuals can be followed longitudinally. Since collecting personally identifying information is not advisable when providing HIV prevention interventions, an anonymous UID code can be issued at the time of registration (see section 2.2.2). In some circumstances, however, it may be appropriate or necessary to record contact details for the purposes of follow-up or access to telemedicine services. This information should be collected only if the individual gives informed consent to do so and robust processes and protections for confidentially and security are in place. Information that might be recorded in prevention data collection systems at registration is detailed in Box 2.6.

Box 2.6 Registration data

- assigned UID
- date of registration
- facility/site of registration
- age/year of birth *(to ensure anonymity, date of birth should not be collected)*
- gender
- sex assigned at birth
- area or residence *(the geographic area reported should be large enough to ensure anonymity – for example, city, district or municipality)*
- information on HIV prevention need and key population-related behaviours
- contact information *(collect only if essential for service delivery and policies and procedures to ensure confidentiality and data security are in place)*.

Considerations when collecting data about gender

Trans and gender diverse people is an umbrella term for people whose gender identity and expression do not conform to the norms and expectations traditionally associated with the sex assigned to them at birth. Since gender is described differently in different countries and cultures, gender identity categories include male, female and other, where "other" includes trans and gender diverse people, including those who choose an identity other than male or female.

In settings where being trans or gender diversity is highly stigmatized or penalized, and to increase client safety, it is acceptable to include only two categories (male or female) for gender on facility records. In other settings consideration should be given to including the following two questions when recording gender on clinical records. The answers will allow better patient management and disaggregation of data by variously gendered groups:

1. **Gender**
   male
   female
   other (includes trans and gender diverse people who choose an identity other than male or female)
2. **Sex assigned at birth**
   male
   female
   other.

2.2.8 A minimum dataset for HIV prevention

In the course of delivering each HIV prevention intervention, collection of a minimum set of individual-level data is suggested (Table 2.2). In this minimum dataset, the date that an event occurs (for example, date of HIV test, date PrEP prescribed, etc.) serves to indicate that the event occurred as well as when it occurred. These data can be collected at the point where an HIV prevention intervention is provided. Standardized paper forms, electronic systems or mobile devices such as a phone or tablet can be used to record the data. A comprehensive minimum dataset for all programme areas is given in Web Annex A.

Table 2.2 Recommended minimum dataset for HIV prevention interventions

Intervention	Minimum dataset
HIV testing	• HIV test sample date • type of HIV test (for example, rapid test, dual syphilis/HIV) • HIV test result
Condom programming	• date individual was provided with condoms (where recording this information is practical and appropriate, this could include provision of condoms to people from key populations in the context of outreach)
Pre-exposure prophylaxis (PrEP)	• date PrEP prescribed (includes initial prescription and repeats) • date PrEP dispensed (if available from dispensing pharmacy or community distribution) • PrEP product prescribed (for example, oral; long-acting formulation/device, such as dapivirine vaginal ring (DPV-VR), injectable cabotegravir (CAB-LA)) • volume of PrEP product prescribed/dispensed (for example, number of pills, number of devices) • date individual attends follow-up appointment
Post-exposure prophylaxis (PEP)	• date PEP prescribed • date individual completes PEP course (ascertained at follow-up)
Needle–syringe programmes (NSP)	• date injecting equipment provided • number of needles–syringes provided
Opioid agonist maintenance treatment (OAMT) for opioid dependence	• date OAMT initiated • date OAMT dose received • date OAMT take-away dose(s) dispensed • first date maintenance dose received • date of loss to follow-up or OAMT stopped
Voluntary medical male circumcision (VMMC)	• date VMMC received • date of follow-up • date of adverse event related to VMMC reported • type of severe adverse event.

2.3 Use of individual-level data on HIV prevention

2.3.1 Use of individual-level HIV prevention data for client management

Health care providers can use individual-level HIV prevention data to improve the personalized management of a person's prevention needs. Follow-up actions relevant to different interventions can be flagged by regularly reviewing data records or through alerts generated by an automated system. If an individual has not attained a relevant outcome (for example, they have missed an appointment or not received a service when due), they can be followed up and provided with this missed services. Reminders can be issued in person or through phone calls, text messages, email or social media, where individuals have given consent for these contact methods. When contacting individuals, by whatever means, for the purpose of follow-

up, individuals' privacy and safety should always be considered and protected. Messages sent should not reveal personal information, such as the recipient's name, or sensitive information such as test results. If contacting a person by phone, it should be ascertained that the individual on the phone is the person of concern and that they are able to speak privately.

If other needs are identified while providing an HIV intervention, referral to and follow-up by other appropriate services may be required – for example, referral for STI, hepatitis or sexual and reproductive health services.

2.3.2 Use of individual-level data for programme management

Providers can use individual-level data aggregated at the level of the site or facility to monitor service utilization and outcomes among the clients accessing the service.

This information can be used to improve service delivery by:

a) monitoring service utilization and delivery

b) evaluating service delivery by monitoring intervention outcomes

c) ensuring that commodities are appropriately stocked

d) identifying individuals and groups that may benefit from HIV prevention interventions

e) monitoring rates of follow-up for different interventions

f) monitoring referrals made and successfully completed

g) identifying priorities for service delivery and programming.

While summary reporting can be performed manually, it is more efficient, accurate and timely for these reports to be generated automatically. Electronic databases can use analytic tools, such as District Health Information Software 2 (DHIS2), to provide summary information at specified reporting intervals or in real time. Information can be displayed through dashboards that present selected indicators relevant to service delivery.

2.3.3 Longitudinal individual-level data as the basis for routine aggregated reporting

Indicators derived from aggregated routinely collected individual-level data can provide important information on trends, programmatic gaps and various other aspects of HIV prevention programme delivery, which previously required research or surveys to obtain – for example, whether individuals continue to face elevated risk, which prevention methods they choose, the presence of related infections and whether they remain HIV-negative. HIV prevention indicators can be derived to examine the extent to which an intervention is reaching those who would benefit from it and the level at which it is provided. This can be done by tracking the number of (unique) individuals receiving the intervention within a reporting period and the volume of commodities that they receive (for example, needles–syringes). Several recommended indicators in this section make use of this approach. An additional advantage is that routine individual-level data allow for cohort-type longitudinal analyses. For example, individual-level data collected over time can be used to calculate person-years of follow-up and to examine the incidence of various outcomes and the coverage of interventions over time. Person-years of follow-up can be calculated by totalling the duration of time each individual in the population has been observed within the reporting period.

Indicators using aggregated individual-level data for each HIV prevention intervention are listed in Table 2.3 and described in detail in Chapter 8. The aggregated indicators can be reported at the national level or at various subnational levels (for example, city, district, province or region). Some indicators can be calculated from manual aggregate reporting even if data systems collecting individual-level data are not yet in place; Chapter 8 provides guidance on how to calculate and interpret these indicators without individual-level data. However, some indicators, such as those using measurements of person–time, do require aggregation from individual-level data. Different denominators are defined for each indicator because not all individuals included in a data system will be relevant to each indicator on HIV prevention.

Indicator results should be disaggregated by different intervention service providers and by population characteristics, including the following:

a) age

b) gender

c) key population

d) cities and other administrative areas of epidemiologic importance

e) setting: facility-based service (including hospitals, health clinics, general practice offices, etc.) or community-based service (including drop-in centres, community service delivery points, mobile clinics or vans, outreach teams, community support groups, etc.)

f) provider type: key-population or community-led services versus those that are not key-population or community-led.

Distinguishing (disaggregating) between key population-led or community-led services, on one hand, and services that are not key-population or community-led, on the other hand, is essential to monitor progress in achieving the target, set out in the Global AIDS Strategy (2021–2026), of scaling up community-led service delivery to ensure that the majority of HIV prevention programmes are led by key populations, women and young people. The governance, leadership, staff, spokespeople, members and volunteers of these services reflect and represent the experiences, perspectives and voices of their constituencies *(42)*.

2.3.4 Use of individual-level data to construct HIV prevention cascades

While HIV treatment cascades can be derived across the continuum of care from initial HIV diagnosis to receiving ART and achieving viral suppression, construction of HIV prevention cascades is more complicated due to a number of factors:

a) HIV prevention interventions are delivered in a variety of ways (at a single point in time, episodically or continuously) *(9, 10)*.

b) An individual's level of HIV risk and, therefore, the total population exposed to elevated risk change over time.

c) Relevant outcomes vary and, for some prevention interventions, do not reflect a linear progression of outcomes, as the HIV treatment cascade does.

d) Some commodities (for example, condoms, needles–syringes) may be available outside the programme being monitored; hence, for example, the total volume of condoms distributed and the number of people receiving them are greater than those provided by or reached by the programme.

For these reasons HIV prevention cascades can be more easily derived from survey data, where questions can be used to collect information on each step of the cascade for individual interventions.

Recent UNAIDS guidance provides methods for aggregating individual-level data to construct HIV prevention cascades. These methods use cohort or cross-sectional approaches to identify successes and gaps in HIV prevention programming *(30)*. The Pan American Health Organization (PAHO) Framework for Monitoring HIV/STI Services for Key Populations in Latin America and the Caribbean provides a method for deriving cascades for key populations by tracking regular retesting and linkage with prevention services *(31)*.

HIV prevention cascades should be interpreted alongside HIV testing and treatment cascades to gain a holistic view of the HIV response.

2.4 HIV prevention indicators

Priority indicators for HIV prevention are listed in Table 2.3; additional indicators are listed in Web Annex B. These indicators use data from a range of sources, including individual-level programme data, programme data that are not linked to individuals using some form of unique identification but are reported in aggregate form, and survey data.

The recommended priority and additional indicators that utilize individual-level data draw on elements from the minimum dataset listed in Table 2.2. While countries are in transition to HIS that collect individual-level data electronically, the indicators relying on aggregated non-individual programme data will remain useful and important to monitor the implementation of HIV prevention. Chapter 8 provides guidance on how to calculate and interpret these indicators using either individual-level data or non-individual-level aggregated data.

A number of indicators refer to a defined reporting period. These reporting periods can be set as required for differing programming and reporting purposes; Chapter 8 provides guidance on this.

Each indicator should be reported for standard disaggregations of age, gender, key population status and provider type. Since gender is described differently in different countries and cultures, gender categories include male, female and other, where "other" includes trans and gender diverse people who choose an identity other than male or female. Data systems should capture information on an individual's different and overlapping vulnerabilities and where they may be included in more than one key population. Accordingly, individuals may be counted in more than one group when disaggregating by key population. Additional disaggregations for specific indicators are listed where recommended.

Table 2.3 Priority indicators for HIV prevention

Condom programming

Ref. no.	Short name	Indicator definition	Numerator	Denominator
PRV.1	Condoms distributed	Total number of condoms distributed during the reporting period	Total number of condoms distributed and sold during the reporting period	NA
PRV.17 ●	Condom use (key populations and general population)	% of people who used condoms with a non-regular partner in the last 12 months (general population)	Number of respondents reporting condom use at last specified sexual encounter	Number of respondents
		% of sex workers who used a condom the last time they had sex with a client		
		% of men who used a condom the last time they had anal sex with a non-regular male partner		
		% of transgender people who used a condom during last anal sex with a non-regular partner		
		% of people who inject drugs who used a condom the last time they had sex with a partner in the last month		

Pre-exposure prophylaxis (PrEP)

Ref. no.	Short name	Indicator definition	Numerator	Denominator
PRV.2 ●	Total PrEP recipients	Number of people who received PrEP at least once during the reporting period	Number of people prescribed or dispensed any form of PrEP at least once during the reporting period. Individuals prescribed different products or regimens at different times during the reporting period should be counted only once	NA
PRV.3 (NEW)	PrEP coverage	% of people prescribed PrEP among those identified as being at elevated risk for HIV acquisition	Number of people prescribed or dispensed any form of PrEP at least once during the reporting period. Individuals prescribed different products or regimens at different times during the reporting period should be counted only once	a) **Programme/service provider level:** number of people who received a negative HIV test during the reporting period and identified as being at elevated risk for HIV acquisition (includes people requesting/receiving any HIV prevention intervention, people from key populations, people with known risk factors or assessed as being at risk of HIV acquisition) b) **Population level:** population-level estimate of the number of people who would benefit from PrEP, for example, as derived from a PrEP need estimator tool

● Core indicator ● Indicates that indicator is survey-based

Table 2.3 (continued) Priority indicators for HIV prevention

PRV.4 (NEW) ●	Volume of PrEP prescribed	Total volume of PrEP product prescribed	The total sum of the volume of PrEP product prescribed for each PrEP recipient during the reporting period	NA

Post-exposure prophylaxis (PEP)

Ref. no.	Short name	Indicator definition	Numerator	Denominator
PRV.5 (NEW)	Number of PEP recipients	Number of people prescribed PEP during the reporting period	Number of people prescribed PEP during the reporting period	NA
PRV.6 (NEW)	PEP completion	% of PEP recipients completing PEP course	Number of people completing a course of PEP among those starting in the reporting period	Number of people starting PEP during the reporting period, excluding those whose PEP course is due to be completed after the end of the reporting period
PRV.7 (NEW)	HIV in PEP recipients	% of PEP recipients testing HIV-positive three months after PEP was prescribed	Number of people testing positive for HIV three months after receiving PEP during the reporting period	Number of people receiving PEP during observation period. To allow for observation of a 3-month test result, the observation period must be set at least three months prior

Needle–syringe programme (NSP)

Ref. no.	Short name	Indicator definition	Numerator	Denominator
PRV.8 (NEW)	NSP coverage	% of people who inject drugs provided with needles–syringes during the reporting period	Number of people receiving needles–syringes during the reporting period	a) **Programme/service provider level:** number of people who inject drugs who access the service b) **Population level:** population size estimate of people who inject drugs in relevant geographic area
PRV.9 (NEW)	Regular NSP access	% of people who inject drugs accessing a NSP at least once per month during the reporting period	Total number of people receiving needles–syringes at least once per month during the reporting period; either: a) number of people accessing a NSP at least once in each 30-day interval during the reporting period b) number of people accessing an NSP at least once per month on average during the reporting period	a) **Programme/service provider level:** number of people who inject drugs accessing service b) **Population level:** population size estimate of people who inject drugs in relevant geographic area

Table 2.3 (continued) Priority indicators for HIV prevention

PRV.10 ●	Needles–syringes distributed	Number of needles–syringes distributed per year per person who injects drugs	a) number of needles–syringes distributed by NSPs in the reporting period b) number of needles–syringes sold to people who inject drugs by pharmacies or other outlets in the reporting period	a) **Programme/service provider level:** number of people who inject drugs accessing service b) **Population level:** population size estimate of people who inject drugs in relevant geographic area

Opioid agonist maintenance treatment (OAMT)

Ref. no.	Short name	Indicator definition	Numerator	Denominator
PRV.11 ●	OAMT coverage	% of opioid dependent people receiving OAMT at a specified date	Number of people on OAMT at specified census date	a) **Programme/service provider level:** number of opioid dependent people accessing service b) **Population level:** population size estimate of opioid dependent people in relevant geographic area
PRV.12 (NEW)	Total person–years on OAMT	% of person-years of follow-up (PYFU) on OAMT among opioid dependent people	Total PYFU on OAMT during defined reporting period Calculated from the sum of the time on OAMT of each OAMT recipient during the reporting period	a) **Programme/service provider level:** estimated PYFU for all opioid dependent people accessing service during defined reporting period b) **Population level:** estimated PYFU for total population of opioid dependent people in relevant geographic area during defined reporting period
PRV.13 (NEW)	OAMT minimum duration	% of OAMT recipients who received treatment for at least six months	Number of people in cohort retained in OAMT for at least six months	Number of people starting OAMT during defined cohort recruitment period
PRV.14 (NEW)	OAMT minimum dose	% of OAMT recipients receiving a maintenance dose greater than or equal to the recommended minimum dose	Number of people, at a specified date, maintained on methadone or buprenorphine receiving recommended minimum maintenance dose (WHO guidance recommends doses of ≥60 mg of methadone or ≥8 mg of buprenorphine *(43)*)	Number of people receiving maintenance dose of methadone or buprenorphine at a specified date, excluding: a) individuals currently being inducted on OAMT and yet to reach the maintenance dose and b) individuals on reducing doses of OAMT

Table 2.3 (continued) Priority indicators for HIV prevention

Voluntary medical male circumcision (VMMC)

Ref. no.	Short name	Indicator definition	Numerator	Denominator
PRV.15 ●	VMMC scale-up	Total number of voluntary medical male circumcisions (VMMCs) performed according to national standard during the reporting period	Total number of people undergoing VMMC performed according to national standard during the reporting period	NA
PRV.16	VMMC adverse events	(a) Number or (b) % of adverse events during the reporting period	Number of people experiencing at least one moderate or severe adverse event during or following circumcision surgery during the reporting period	a) NA b) Total number of people undergoing VMMC performed according to national standard during the reporting period

HIV testing

Ref. no.	Short name	Indicator definition	Numerator	Denominator
HTS.7 (NEW)	HTS linkage to prevention	Among those testing HIV-negative and identified as being at elevated risk for HIV acquisition	Number of people who receive an HIV prevention intervention within a defined period after receiving a negative HIV test result	Number of people testing negative for HIV in the reporting period and identified as being at elevated risk for HIV acquisition (includes people requesting/receiving any HIV prevention intervention, people from key populations, people with known risk factors or those assessed as being at risk of HIV acquisition)
HTS.8 (NEW)	HIV retesting coverage	% of people testing HIV-negative who tested again within a defined period after their previous test	Number of individuals who tested HIV-negative assessed to be at elevated risk for HIV acquisition who had another HIV test within a defined period after previous test	Number of people assessed as being at elevated risk for HIV acquisition (includes people requesting/receiving any HIV prevention intervention, people from key populations, people with known risk factors or those assessed as being at risk of HIV acquisition) who received an HIV-negative test result in the reporting period

References

1. United Nations General Assembly. Political declaration on HIV and AIDS. On the fast track to accelerating the fight against HIV and to ending the AIDS epidemic by 2030. New York: United Nations; 2016 (https://digitallibrary.un.org/record/833243?ln=es, accessed 24 June 2022).
2. Global AIDS Strategy 2021–2026. End inequalities. End AIDS. Geneva: Joint United Nations Programme on HIV/AIDS (UNAIDS); 2021 (https://www.unaids.org/en/Global-AIDS-Strategy-2021-2026, accessed 24 June 2022).
3. Global AIDS Update 2021. Confronting inequalities: lessons for pandemic responses from 40 years of AIDS. Geneva: United Nations Joint Programme on HIV/AIDS (UNAIDS). (https://www.unaids.org/en/resources/documents/2021/2021-global-aids-update, accessed 23 June 2022).
4. UNAIDS data 2021. Geneva: Joint United Nations Programme on HIV/AIDS (UNAIDS); 2021 (https://www.unaids.org/en/resources/documents/2021/2021_unaids_data, accessed 24 June 2022).
5. AIDSinfo. Global data on HIV epidemiology and response [webpage]. Geneva: Joint United Nations Programme on HIV/AIDS (UNAIDS); 2020 (https://aidsinfo.unaids.org/, accessed 21 April 2021).
6. Key populations atlas [website]. Geneva: Joint United Nations Programme on HIV/AIDS (UNAIDS); 2022 (https://kpatlas.unaids.org/dashboard, accessed 24 June 2022).
7. Addressing a blind spot in the response to HIV — reaching out to men and boys. Geneva: Joint United Nations Programme on HIV/AIDS (UNAIDS). (https://www.unaids.org/en/resources/documents/2017/blind_spot, accessed 24 June 2022).
8. Grimsrud A, Ameyan W, Ayieko J, Shewchuk T. Shifting the narrative: from "the missing men" to "we are missing the men". J Int AIDS Soc. 2020;23:e25526. doi: https://doi.org/10.1002/jia2.25526.
9. Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach. Geneva: World Health Organization; 2021 (https://apps.who.int/iris/handle/10665/342899, accessed 24 June 2022).
10. Consolidated guidelines on HIV, viral hepatitis and STI prevention, diagnosis, treatment and care for key populations. Geneva: World Health Organisation; 2022.
11. Bärnighausen K, Geldsetzer P, Matse S, Hettema A, Hughey AB, Dlamini P et al. Qualitative accounts of PrEP discontinuation from the general population in Eswatini. Cult Health Sex. 2021;23:1198-214.
12. Hill LM, Maseko B, Chagomerana M, Hosseinipour MC, Bekker LG, Pettifor A et al. HIV risk, risk perception, and PrEP interest among adolescent girls and young women in Lilongwe, Malawi: operationalizing the PrEP cascade. J Int AIDS Soc. 2020;23:e25502.
13. Price JT, Rosenberg NE, Vansia D, Phanga T, Bhushan NL, Maseko B et al. Predictors of HIV, HIV risk perception, and HIV worry among adolescent girls and young women in Lilongwe, Malawi. J Acquir Immune Defic Syndr. 2018;77:53.
14. Improving men's uptake of HIV testing and linkage to services: policy brief. Geneva: World Health Organization; 2021 (https://www.who.int/publications/i/item/9789240018938, accessed 24 June 2022).

15. Monitoring HIV impact using population-based surveys. Geneva: Joint United Nations Programme on HIV/AIDS (UNAIDS); 2015 (https://www.unaids.org/sites/default/files/media_asset/JC2763_PopulationBasedSurveys_en.pdf, accessed 24 June 2022).

16. World Health Organization, Centers for Disease Control and Prevention, Joint United Nations Programme on HIV/AIDS, FHI 360. Biobehavioral survey guidelines for populations at risk for HIV. Geneva: World Health Organization; 2017 (https://www.who.int/publications/i/item/978-92-4-151301-2, accessed 24 June 2022).

17. Hakim AJ, MacDonald V, Hladik W, Zhao J, Burnett J, Sabin K et al. Gaps and opportunities: measuring the key population cascade through surveys and services to guide the HIV response. J Int AIDS Soc. 2018;21:e25119. doi: https://doi.org/10.1002/jia2.25119.

18. United Nations Office on Drugs and Crime, International Network of People Who Use Drugs, Joint United Nations Programme on HIV/AIDS, United Nations Development Programme, United Nations Population Fund, World Health Organization et al. Implementing comprehensive HIV and HCV programmes with people who inject drugs: practical guidance for collaborative interventions. Vienna: United Nations Office on Drugs and Crime; 2017 (www.unodc.org/documents/hiv-aids/publications/People_who_use_drugs/19-04568_HIV_Prevention_Guide_ebook.pdf, accessed 24 June 2022).

19. United Nations Population Fund, Global Forum on MSM & HIV, United Nations Development Programme, World Health Organization, United States Agency for International Development, World Bank. Implementing comprehensive HIV and STI programmes with men who have sex with men: practical guidance for collaborative interventions. New York: United Nations Population Fund; 2015 (https://www.unfpa.org/publications/implementing-comprehensive-hiv-and-sti-programmes-men-who-have-sex-men, accessed 24 June 2022).

20. United Nations Development Programme, IRGT A Global Network of Transgender Women and HIV, United Nations Population Fund, UCSF Centre of Excellence for Transgender Health, Johns Hopkins Bloomberg School of Public Health, World Health Organization et al. Implementing comprehensive HIV and STI programmes with transgender people: practical guidance for collaborative interventions. New York: United Nations Development Programme; 2016 (https://www.unfpa.org/publications/implementing-comprehensive-hiv-and-sti-programmes-transgender-people-practical, accessed 24 June 2021).

21. World Health Organization, United Nations Population Fund, Joint United Nations Programme on HIV/AIDS, Global Network of Sex Work Projects, World Bank. Implementing comprehensive HIV/STI programmes with sex workers: practical approaches from collaborative interventions. Geneva: World Health Organization; 2013 (https://apps.who.int/iris/handle/10665/90000, accessed 24 June 2022).

22. Making every school a health-promoting school: global standards and indicators for health-promoting schools and systems. Geneva: World Health Organization and the United Nations Educational, Scientific and Cultural Organization; 2021 (https://www.who.int/publications/i/item/9789240025059, accessed 24 June 2022).

23. WHO guideline on school health services. Geneva: World Health Organization; 2021 (https://www.who.int/publications/i/item/9789240029392, accessed 24 June 2022).

24. Consolidated HIV strategic information guidelines: driving impact through programme monitoring and management. Geneva: World Health Organization; 2020 (https://www.who.int/publications/i/item/9789240000735, accessed 24 June 2022).

25. Integration of mental health and HIV interventions. Key considerations. Geneva: Joint United Nations Programme on HIV/AIDS (UNAIDS); 2022 (https://www.unaids.org/en/resources/documents/2022/integration-mental-health-hiv-interventions, accessed 24 June 2022).

26. Bulstra CA, Hontelez JA, Otto M, Stepanova A, Lamontagne E, Yakusik A et al. Integrating HIV services and other health services: A systematic review and meta-analysis. PLoS Med. 2021;18:e1003836.

27. Sexual and reproductive health and rights and HIV: Strengthening systems to reach adolescent girls and young women and promote rights, dignity and autonomy for all. Geneva: Joint United Nations Programme on HIV/AIDS (UNAIDS); 2019 (https://open.unaids.org/sites/default/files/documents/7_UNAIDS%20Case%20Study_SRHR%20and%20HIV.pdf, accessed 24 June 2022).

28. SRA 8: HIV and health services integration. Geneva: Joint United Nations Programme on HIV/AIDS (UNAIDS); 2021 (https://open.unaids.org/sites/default/files/documents/SRA8_SRA%20report_2020.pdf, accessed 24 June 2022).

29. Tool to set and monitor targets for HIV prevention, diagnosis, treatment and care for key populations. Geneva: World Health Organization; 2015 (https://apps.who.int/iris/handle/10665/177992, accessed 24 June 2022).

30. Creating HIV prevention cascades: operational guidance on a tool for monitoring programmes. Geneva: Joint United Nations Programme on HIV/AIDS (UNAIDS); 2021 (https://www.unaids.org/en/resources/documents/2021/20211125_creating-hiv-prevention-cascades, accessed 24 June 2022).

31. Framework for monitoring HIV/STI services for key populations in Latin America and the Caribbean. Washington (DC): Pan American Health Organization; 2019 (https://www.paho.org/en/documents/framework-monitoring-hivsti-services-key-populations-latin-america-and-caribbean-2019, accessed 24 June 2022).

32. Jia KM, Eilerts H, Edun O, Lam K, Howes A, Thomas ML et al. Risk scores for predicting HIV incidence among adult heterosexual populations in sub-Saharan Africa: a systematic review and meta-analysis. J Int AIDS Soc. 2022;25:e25861.

33. Stelzle D, Godfrey-Faussett P, Jia C, Amiesimaka O, Mahy M, Castor D et al. Estimating HIV pre-exposure prophylaxis need and impact in Malawi, Mozambique and Zambia: A geospatial and risk-based analysis. PLoS Med. 2021;18:e1003482.

34. Ayton SG, Pavlicova M, Abdool Karim Q. Identification of adolescent girls and young women for targeted HIV prevention: a new risk scoring tool in KwaZulu Natal, South Africa. Sci Rep. 2020;10:1-10.

35. Smith DK, Pals SL, Herbst JH, Shinde S, Carey JW. Development of a clinical screening index predictive of incident HIV infection among men who have sex with men in the United States. J Acquir Immune Defic Syndr. 2012;60:421-7.

36. Baeten JM, Heffron R, Kidoguchi L, Mugo NR, Katabira E, Bukusi EA et al. Integrated delivery of antiretroviral treatment and pre-exposure prophylaxis to HIV-1–serodiscordant couples: a prospective implementation study in Kenya and Uganda. PLoS Med. 2016;13:e1002099.

37. Irungu EM, Heffron R, Mugo N, Ngure K, Katabira E, Bulya N et al. Use of a risk scoring tool to identify higher-risk HIV-1 serodiscordant couples for an antiretroviral-based HIV-1 prevention intervention. BMC Infect Dis. 2016;16:1-6.

38. Kahle EM, Hughes JP, Lingappa JR, John-Stewart G, Celum C, Nakku-Joloba E et al. An empiric risk scoring tool for identifying high-risk heterosexual HIV-1 serodiscordant couples for targeted HIV-1 prevention. J Acquir Immune Defic Syndr. 2013;62:339.

39. Balkus JE, Brown E, Palanee T, Nair G, Gafoor Z, Zhang J et al. An empiric HIV risk scoring tool to predict HIV-1 acquisition in African women. J Acquir Immune Defic Syndr. 2016;72:333.

40. Pintye J, Drake AL, Kinuthia J, Unger JA, Matemo D, Heffron RA et al. A risk assessment tool for identifying pregnant and postpartum women who may benefit from preexposure prophylaxis. Clin Infect Dis. 2017;64:751-8.

41. Peebles K, Palanee-Phillips T, Balkus JE, Beesham I, Makkan H, Deese J et al. Age-specific risk scores do not improve HIV-1 prediction among women in South Africa. J Acquir Immune Defic Syndr. 2020;85:156.

42. Ayala G, Sprague L, van der Merwe LL-A, Thomas RM, Chang J, Arreola S et al. Peer- and community-led responses to HIV: A scoping review. PLoS One. 2021;16:e0260555.

43. Guidelines for the psychosocially assisted pharmacological treatment of opioid dependence. Geneva: World Health Organization; 2009 (https://www.who.int/publications/i/item/9789241547543, accessed 24 June 2022).

CHAPTER 3 – PERSON-CENTRED HIV PATIENT MONITORING FOR TESTING, EARLY DIAGNOSIS AND TREATMENT

3

CHAPTER 3 – PERSON-CENTRED HIV PATIENT MONITORING FOR TESTING, EARLY DIAGNOSIS AND TREATMENT

Key recommendations

NEW 1. Promote the analysis and **use of routinely collected testing data** to optimize HIV testing services, reaching populations and settings with the largest proportion of people living with HIV who do not know their status and supporting early HIV diagnosis.

a) Improve the **monitoring of time to HIV diagnosis** to support rapid ART initiation and engagement in care, thus reducing morbidity and mortality.

UPDATE 2. Use of person-centred patient data is recommended to **continuously assess interruption of HIV treatment to improve re-engagement and retention in care.**

a) Strengthen the routine analysis and use of data to assess treatment interruption and facilitate tracing interventions to support ART re-initiation and re-engagement in care.

b) Longitudinal monitoring of people on ART is recommended, through linkage of data across services via improved referral and follow-up and integrated service delivery.

c) Use standardized and digitalized tools for health facilities and community-delivered services to optimize data collection, reporting and flow of data for linkage and monitoring.

NEW 3. Integrate and strengthen data collection and reporting of **differentiated service delivery** in HIV patient monitoring systems to improve treatment outcomes and programmatic efficiency.

a) Integrate and **strengthen data collection and reporting of differentiated service delivery** within the HIV patient monitoring system, linking to monitoring of community-delivered services while ensuring that health facilities retain overall responsibility for clinical care and follow-up.

b) Monitor the impact of differentiated service delivery on treatment outcomes, including retention, VL suppression and programme efficiencies, for example, reduced clinical visits and staff time.

UPDATE 4. **Data quality and use:** Include routinely scheduled data quality assessments in long-term data quality improvement to strengthen data use and improve HIV treatment outcomes.

a) **Integrate routine assessment of the quality of data on HIV treatment and (VL) testing** with broader, long-term data quality improvement processes to support a systems approach to strengthening data quality and use.

b) **Strengthen the use of data** by supporting enhanced data analysis, frequent feedback to data custodians and users, use of standardized information products, and mentorship and training to improve treatment outcomes and service delivery.

NEW 5. **Drug stock data: Use aggregated, deduplicated individual-level patient treatment data to more accurately inform drug inventory management**,[1] **dispensing, procurement and logistics** at national, district and facility levels, thus reducing drug wastage and stock-outs.

3.1 Introduction

3.1.1 Purpose of person-centred monitoring of HIV testing, treatment and care

HIV patient monitoring encompasses the routine collection, compilation, analysis and use of data on people living with HIV over time and across service delivery points. Its primary purposes are to guide the clinical management of people living with HIV and to ensure the quality and continuity of HIV testing, early diagnosis and access to treatment and care services.

Person-centred monitoring generates data that track the health status of people living with HIV over time and support case management, enable tracking of HIV epidemic trends, measure programme performance across health facilities and support efficient allocation of resources. Because patient monitoring systems inform programme management, they are an integral part of robust HIS and the overall health system in many countries, contributing to the delivery of person-centred comprehensive health services and promoting linkage and integration of services.

In this strategic information guidance, the scope of person-centred HIV patient monitoring has been extended to include HIV testing, recognizing the need for robust monitoring and linkage throughout the entire cascade of HIV care from diagnosis through treatment outcomes and chronic care. In addition, it includes updates to the consolidated framework for HIV strategic information and recommended indicators from WHO's 2020 *Consolidated HIV strategic information guidelines: driving impact through programme monitoring and management (1)* as well as revision and reprioritization of indicators undertaken during the development of these guidelines. These guidelines consolidate and prioritize indicators across the spectrum of health sector HIV services and reflect the key role that individual-level data play in monitoring at all levels.

[1] Drug stocks could include ART, PrEP and drugs for treating opportunistic infections and for opioid agonist maintenance therapy.

3.1.2 Evolution of person-centred HIV patient monitoring

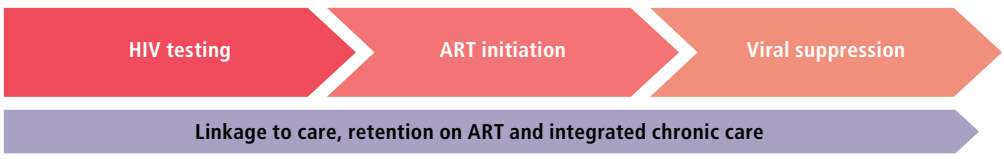
The investments that countries have made in digital HIS, including electronic medical records (EMRs) and the adoption of UIDs, has strengthened person-centred patient monitoring and service delivery. The quality of individual-level data has also improved over time, not only for patient monitoring but also as the underlying data source for aggregate reporting for programme management, case surveillance and global monitoring. This has given rise to the concept of a prioritized minimum dataset across all data use cases, which is central to building stronger, more efficient and more effective HIS in support of the health system response to HIV. Within this framework, strengthening patient monitoring is critical to reflect the flow of service delivery as well as to ensure that key data are collected in a timely manner to enable monitoring of services and improve the use and quality of data.

HIV patient monitoring should be integrated as closely as possible with patient monitoring for other frequently associated communicable diseases, particularly for viral hepatitis, TB and STIs, in all settings where treatment of people living with HIV is initiated or maintained, including maternal, newborn and child health (MNCH) services. Over the long term, countries should also seek to integrate and link HIV patient monitoring systems with the monitoring of individuals receiving care for other chronic non-communicable conditions, such as cardiovascular diseases and diabetes. Important issues related to integration and linkage of HIV patient monitoring with other parts of the health system are discussed in more detail in Chapter 4.

The guidance in this chapter seeks to enable national HIV programmes to update their HIV patient monitoring system to better test and diagnose, link, manage, monitor, retain, trace and, where needed, re-engage the increasing number of people living with HIV who are receiving ART over an extended period along the entire HIV care cascade (Fig. 3.1). In addition, it is intended to support innovations in service delivery, including differentiated service delivery (DSD), which seek to respond to the needs of people living with HIV and expand person-centred care.

This updated guidance also supports the capture of the main elements of HIV testing services and clinical management and the cascade of HIV care, aided by monitoring of the most important clinical and programmatic indicators. It responds to country demand for robust longitudinal monitoring within the context of changes in both digital health and the 2021 HIV clinical and service delivery recommendations *(2, 3)*. These guidelines provide updates to a standardized, simplified and integrated approach to patient monitoring, with the aim of optimizing HIV testing and treatment linkages, retention and clinical outcomes over time. The HIV patient monitoring system also enables reporting on key indicators from the district to subnational to national and global levels, providing timely information for decision-making and optimizing programme and patient outcomes.

Fig. 3.1 The scope of HIV patient monitoring within the 2022 WHO consolidated HIV strategic information guidelines



This chapter consists primarily of an update of the 2017 WHO person-centred HIV patient monitoring and case surveillance guidelines and tools *(3)*, aligned with the recommended priority indicators in the 2020 WHO consolidated HIV strategic information guidelines for programme monitoring and management *(1)*. In addition, these indicators were revised and reprioritized to respond to evolving programme and service delivery monitoring needs. This update is based on an extensive review of newly available WHO guidelines and recommendations relevant to person-centred HIV patient monitoring and data systems. The updates include the following:

- Expansion of the set of 40 priority indicators recommended in the WHO 2020 consolidated strategic information guidelines to 80 indicators, including prevention, for programme monitoring best suited for monitoring and managing the health sector response to HIV.
  - Of the 80 priority indicators recommended in these guidelines, 36 originate from the patient monitoring system and are addressed in this chapter (Fig. 3.2).
  - Twenty-five of the 80 indicators are designated core; of these, three cover HIV testing; five, ART and DSD; two, vertical transmission; two, TB. See Chapter 8.
  - In addition, five indicators included in the priority 80 indicators address TB and HIV and are recommended for countries with a high burden of HIV-related TB.
- Updated WHO guidelines on HIV testing and treatment and VL monitoring, with new clinical and service delivery recommendations *(2, 3)*. The key updates pertaining to patient monitoring system are as follows:
  - *Community-based HIV testing services recommended for key populations and all populations in high HIV burden settings*. Delivery of community-based testing services requires monitoring approaches and tools adapted to models of service delivery outside of health facilities that feed into or are linked to facility monitoring and care.
  - *Retesting of all pregnant women with unknown or HIV-negative status in late pregnancy*. Third trimester testing in high burden settings is now recommended and requires adaptations to enable such monitoring.
  - *Rapid ART initiation should be offered to all people living with HIV, based on confirmed HIV diagnosis and clinical assessment* – defined as treatment starting within seven days from the day of confirmed HIV diagnosis and clinical evaluation, but preferably offered on the same day as confirmed HIV diagnosis if the individual is ready to initiate treatment. Monitoring rapid ART initiation requires updates to the patient monitoring tools and system.
  - *Revised ART regimens and codes*. Updates to patient monitoring tools and the minimum dataset reflect updated recommendations for preferred and alternative first- and second-line ARV regimens. Dolutegravir (DTG) in combination with two nucleoside reverse transcriptase inhibitors (NRTIs) is now recommended as the preferred first- and second-line ARV regimens for children above 30 kg, adolescents, pregnant and breastfeeding women and adults generally. In addition, a raltegravir-based regimen may be used as the preferred first-line regimen for neonates (however, with recent availability of DTG 10 mg formulation, neonates should be transitioned to DTG as soon as possible to minimize selection resistance to integrase inhibitors) *(2)*.
  - *Additional recommendations for DSD*. ART may be offered outside the health facility, and people established on ART should be offered clinical visits and ART refills every 3–6 months (see section 3.7). Adaptations to the patient monitoring system are required to enable monitoring of the unique aspects of DSD, including ensuring linkage and data

flow between community settings and health facilities and tracking individuals lost to follow-up (LTFU). The minimum HIV patient monitoring dataset has been updated; new indicators, introduced; and related patient monitoring tools, updated to enable monitoring of DSD reflecting the new recommendations.

– *Updates to the definition of LTFU from treatment services*. The period defining loss to follow-up was revised in 2020 from 90 days to 28 days or more since last missed appointment (including missed ARV refills in either facility or community settings). This change necessitates updates to patient monitoring tools. Criteria to trigger tracing interventions, a minimum dataset for tracing interventions for those who disengage from HIV care and support for re-engagement with HIV care have been developed to reflect new definitions and programme priorities.

– *Changes to monitoring retention*. Focus shifts towards measuring total attrition from ART (which is calculated differently from retention and focuses on those lost from treatment among people newly initiating ART and those already on ART) for programme monitoring and undertaking interventions to improve retention in HIV care and tracing and re-engaging patients who have discontinued ART. To capture this, updates have been made to patient monitoring activities and tools (see section 3.10.1,Tools for facility-based monitoring of HIV treatment and care and to indicator definitions in Table 3.8.

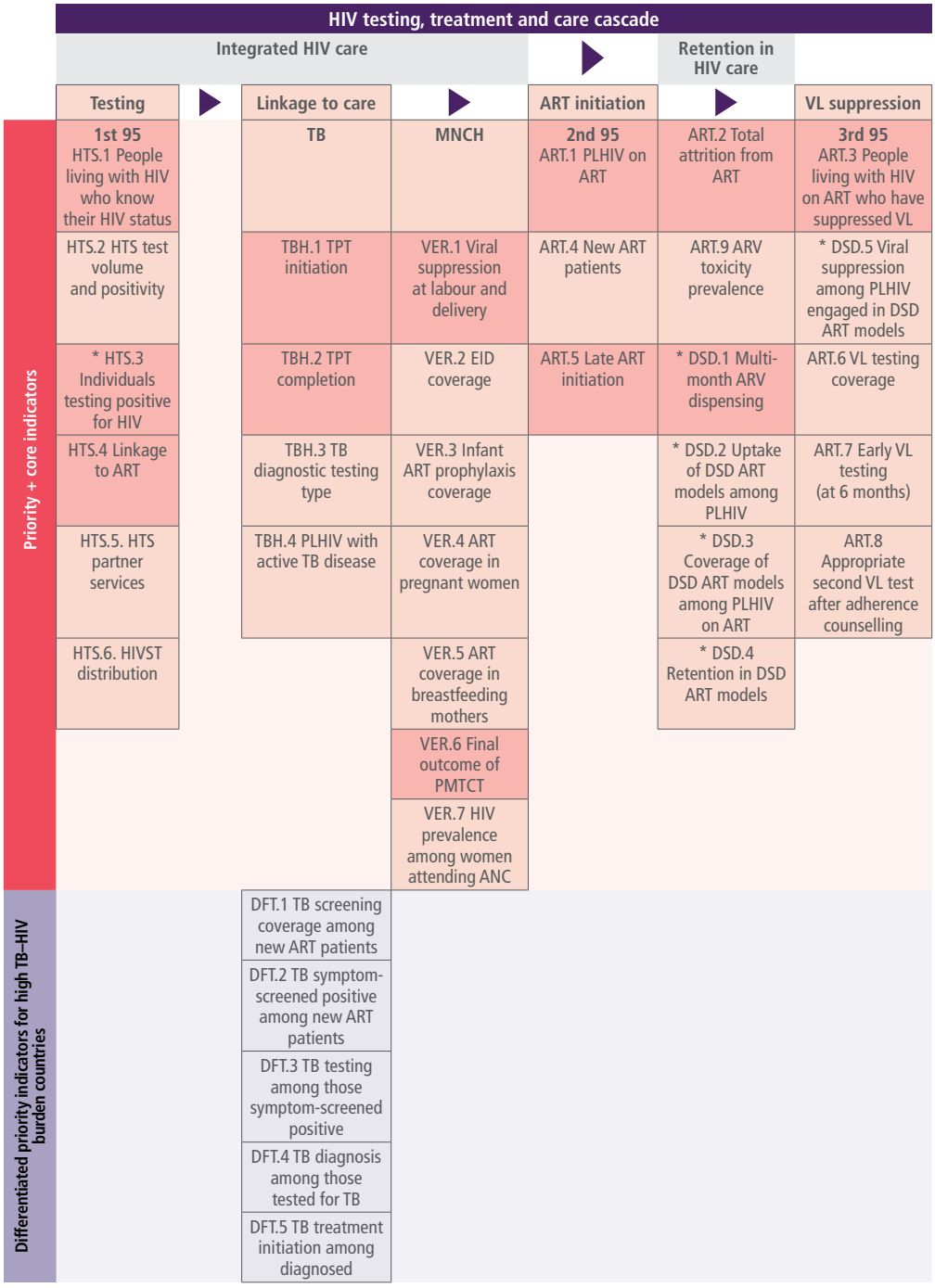
– *Updates to the HIV VL monitoring algorithm*. Routine VL monitoring is recommended at six months after ART initiation (that is, results available at six months, meaning a sample should be collected earlier than six months), 12 months after ART initiation and every 12 months thereafter for people living with HIV established on ART, for purposes of routine monitoring and management, measurement of treatment success and programme evaluation.

– *Monitoring VL testing results is now recommended for all HIV-positive pregnant women* at 34–36 weeks of gestation (or at the latest at delivery) to identify those who may be at risk of treatment failure and/or may deliver infants at higher risk of perinatal transmission.

– *Changing role of CD4 cell count monitoring*. Every patient should be evaluated by means of CD4 cell testing at first-ever presentation to care and, return to care after treatment interruption for the presence of high VL or for assessment of advanced HIV disease. In individuals who are established on ART and living where routine HIV VL monitoring is available, routine CD4 cell testing for monitoring ART response can be stopped, but periodic CD4 testing continues to be necessary for clinical management of people living with HIV who present with signs or symptoms, for identification of advanced HIV disease or when clinically unstable, and for assessment of those who interrupted treatment and are re-engaging in care.

– *Management of co-infections*. The guidelines now recommend systematic screening for TB at each visit among people living with HIV; TB diagnosis with WHO-recommended molecular rapid diagnostic tests; HIV testing among individuals with confirmed or presumptive TB; initiation of ART within two weeks after starting TB treatment regardless of CD4 cell count; testing and management of latent TB; and new, shorter rifamycin-based TB preventive regimens. Also now recommended is a package of interventions including screening, treatment and/or prophylaxis for major opportunistic infections and rapid ART initiation and intensified adherence support interventions for people with advanced disease. Patient monitoring systems should capture implementation of these updates.

Fig. 3.2 Overview of the 36 priority, core and differentiated indicators from the HIV patient monitoring system[a]



* New indicators (introduced in 2022) Core indicators Priority indicators Differentiated priorityindicators for TB/HIV

Abbreviations:
ART = antiretroviral therapy; ARV = antiretroviral; DSD = differentiated service delivery; EID = early infant diagnosis; MNCH = maternal, newborn and child health; PLHIV = people living with HIV; PMTCT = prevention of mother-to-child transmission; TB = tuberculosis; VL = viral load

[a] See Chapter 4 for indicators for viral hepatitis, STIs and cervical cancer.

Box 3.1 Additional WHO HIV indicators that countries can consider including in national indicator sets based on programme needs and context

An additional set of indicators is included in this guidance that countries can consider as a supplement to the 80 priority indicators. Countries with greater investments in specific programme areas or priority populations and/or with more robust HIS may decide to use these additional indicators to refine their national priority sets. These additional indicators are drawn from the 2022 WHO HIV strategic information indicator list; see Web Annex B. Additional indicators.

3.1.3 Application of this guidance

The updated guidance in this chapter seeks particularly to support monitoring of people living with HIV as they move between health facilities over time. WHO recommends the use of an HIV patient card and ART register or electronic versions of these, which remain at the health facility so that the facility retains overall responsibility for patient management and follow-up, with prompt and efficient data flow from community settings where HIV testing and ART services are delivered.

At the facility level, the intention is to facilitate the use of integrated facility-held patient cards, folders or booklets and interlinked patient registers, as well as the use of integrated EMRs (see Chapter 6). Additionally, new indicators are recommended to supporting DSD and the monitoring of models of DSD, as are adaptations to existing patient monitoring tools and the development of new tools for use in community settings.

Intended audiences

Various audiences will use the guidance in this chapter differently, depending on their roles and responsibilities at different levels of the health system and community settings.

Programme staff at the national level, together with partners and other stakeholders, can use this guidance:

- to update and standardize minimum datasets (section 3.9) and tools (section 3.10) so that HIV patient monitoring systems meet national and global reporting requirements;
- to harmonize health data monitoring, use and reporting systems, whether paper-based or electronic, across programme areas, including community-delivered services, and within the broader HIS, to ensure effective linkage and integration of these systems. WHO recommends transitioning to electronic reporting at the appropriate level of the system (see Chapter 6).

At the facility level, health care providers and supervisors can use this guidance:

- to improve HIV patient monitoring, retention and health outcomes;
- to identify key data elements and relevant indicators for HIV testing, effective ART, clinical care and programme management, in line with national and global HIV testing, treatment and care recommendations, to improve supervision, mentoring, quality of care and data quality and use;
- to improve HIV testing and early diagnosis, flow of testing results and knowledge of HIV status and referral for ART initiation and, through tracing interventions and other follow-up, to support re-engagement in care by people who interrupt treatment.

Additionally, at the subnational and national levels, programme managers can use this guide:

- to improve the analysis and use of data to identify weaknesses in service delivery and focus training and mentoring to address gaps and improve quality of care;
- to provide feedback to health facility staff when evaluating programmes and improving data quality and use;
- to ensure improved linkages, retention and outcomes along the HIV cascade of services and increase impact, including reducing mortality.

The guidance in this chapter does not address pharmacy services except for adherence monitoring and ARV toxicity monitoring. The guidance also does not include all data elements needed to provide non-HIV-related TB care or MNCH services. These may be found in the WHO 2013 definitions and reporting framework for TB, updated in 2020 *(4)* and on the WHO website at: https://www.who.int/teams/maternal-newborn-child-adolescent-health-and-ageing/maternal-health.

3.2 HIV testing services, early diagnosis and linkage to treatment

Box 3.2 What's new in HTS relevant to HIV patient monitoring

Facility-based testing

- **Pregnant women and key populations:** All pregnant women should be tested for HIV, syphilis and hepatitis B surface antigen (HBsAg) at least once and as early as possible. In the 2022 WHO *Consolidated guidelines for HIV, viral hepatitis and STI prevention, diagnosis and treatment and care for key populations*, this recommendation was expanded to include key populations. Since 2019 WHO has recommended dual HIV/syphilis rapid diagnostic tests (RDTs) as the first test in HIV testing strategies and algorithms in ANC.
- **High HIV burden settings:** HIV testing should be offered to all populations and in all services (for example, services for STIs, viral hepatitis, TB, children under five, immunization, malnutrition, ANC and all services for key populations) as an efficient and effective way to identify people living with HIV.
- **Low HIV burden settings:** HIV testing should be offered to adults, adolescents and children who present in clinical settings with signs and symptoms or medical conditions that could indicate HIV infection, including TB and STIs (syphilis among adults and adolescents and syphilis, gonorrhoea, chlamydia and hepatitis B for key populations), as well as to HIV-exposed children and symptomatic infants and children, to people from key populations and their partners and to all pregnant women.
- **Key populations:** As of 2019 WHO recommends that HIV testing services should be routinely offered in facility and community settings to all people from key populations (see recommendations for community testing below).
- **Provider-assisted referral/index testing and assisted partner notification** should be offered to people living with HIV and syphilis as part of a comprehensive package of testing and care (recommended in 2016 and updated in 2019).

Box 3.2 (continued) What's new in HTS relevant to HIV patient monitoring

- **Retesting in high HIV burden settings:** Annual retesting is recommended for all sexually active individuals in high HIV burden settings and people who have ongoing HIV-related risks in all settings, including people from key populations, country- or epidemic-specific risk groups, for example, men and adolescent girls and young women in southern Africa and people with a known HIV-positive partner.
- **Retesting in certain populations:** In certain situations individuals who have been tested for HIV in the past can be retested. These include:
  - individuals presenting with a diagnosis of, or receiving treatment for, STIs or viral hepatitis
  - individuals with a confirmed or presumptive TB diagnosis
  - outpatients presenting with clinical conditions or symptoms indicative of HIV
  - individuals with recent HIV risk exposure
  - individuals in a serodiscordant relationship
  - pregnant and postpartum women (see section 3.5).

HIV self-testing

- HIV self-testing should be offered as one approach to HIV testing (recommended in 2016 and updated in 2019).

Community-based testing

- **High HIV burden settings:** WHO recommends community-based HIV testing services, with linkage to prevention, care and treatment services, in addition to routinely offering facility-based testing for all populations.
- **Key populations:** WHO recommends community-based HIV and syphilis testing services, with linkage to prevention, care and treatment, in addition to facility-based testing, for key populations.

Social network-based approaches

- Social network-based approaches can be offered as an HIV testing approach for key populations as part of a comprehensive package of care and prevention.

In light of these WHO HTS recommendations, HIV patient monitoring tools and EMR systems, where the latter are in use, should be updated with linkage and referral between facilities, and community testing services strengthened.

Sources: Consolidated guidelines on HIV testing services for a changing epidemic. Geneva: WHO; 2019; Consolidated guidelines on HIV prevention, testing, treatment and service delivery. Geneva: WHO; 2021; and Consolidated guidelines on HIV, viral hepatitis and STI prevention, diagnosis, treatment and care for key populations. Geneva: WHO; 2016.

3.2.1 Purposes of monitoring testing

Understanding HIV testing history, patterns of testing, retesting and test results is necessary to guide the provision of support and clinical care to clients. Patient monitoring systems, whether paper-based or electronic, can facilitate effective clinical management and also generate data for programme monitoring. To support collection of comprehensive client data and support linkage, HIV programmes should promote person-centred HIV patient monitoring that includes all feasible and appropriate prevention, HTS and ART service delivery points.

> HIV programmes should promote person-centred HIV patient monitoring that includes all prevention, HTS and ART service delivery points.

In the context of the WHO HIV testing recommendations summarized in Box 3.2, HTS includes pre-test information, HIV testing and diagnosis, post-test counselling when applicable, re-testing and referral and linkage to prevention, care and treatment services. A key objective of these guidelines is to encourage greater national and global commitment to implementing effective and efficient HTS as a vital element of the national and global HIV response, essential to achieving and maintaining low HIV incidence.

Although many countries have scaled up HIV testing services, the mark of an effective HTS system is a focus on population outcomes, such as:

1. increasing the proportion of people living with HIV who know their status (the first "95" of the 95–95–95 goals, or indicator *HTS.1. People living with HIV who know their HIV status*);
2. ensuring that people diagnosed with HIV are linked to treatment (indicator *HTS.4. Linkage to ART*) and
3. optimizing linkage to prevention services among HIV-negative persons at substantial risk of infection (indicators *HTS.7. HTS linkage to prevention and HTS.8. HIV retesting coverage*, described in Chapter 2).

Strategic information for HTS can be collected and analysed using a combination of patient monitoring and routine programme-based data for both patient management and programme monitoring purposes. To improve patient care and service delivery, standard approaches to collecting and reporting data are needed across a wide variety of testing settings and levels of health care facilities, including where HTS services are integrated into other clinical contexts (for example, ANC, family planning, TB clinics).

Among the 80 national HIV priority indicators recommended in these guidelines, six HIV testing indicators are drawn from the HIV patient monitoring system. Table 3.1 summarizes these six HTS indicators (see also Chapter 8).

Testing is promoted for different reasons according to epidemiological context and individual preferences and needs. Its purpose may be to confirm a clinical diagnosis, or it may be offered through routine testing of selected populations such as key populations, in ANC and STI clinics or to contacts of index clients to optimize case finding. Understanding to whom testing is promoted in different testing contexts is critical to interpretation of the HTS indicators and has important implications for the collection, aggregation and analysis of data. Community-based testing and self-testing are important parts of the HTS service mix and should be included when assessing overall testing uptake, coverage and linkage to treatment. Data on HIV testing uptake might come from the logistics and information management system as well as from retailers and vendors for HIV-self testing.

Finally, retesting is critical to ascertain whether people enrolled in prevention programmes remain HIV-negative and, when seroconversion is identified, that they are rapidly linked to ART. These various modes of testing are captured as disaggregation variables recommended for various testing and linkage indicators.

Table 3.1 Priority indictors for HIV testing

Ref. no.	Short name	Indicator definition	Numerator	Denominator
HTS.1 ●	People living with HIV who know their HIV status (first 95)	Number and % of people living with HIV who know their HIV status	Number of people living with HIV who have received their diagnosis and are still alive	Estimated number of people living with HIV
HTS.2	HTS test volume and positivity	Number of HIV tests performed (volume) and the % of HIV-positive results returned to people (positivity)	Number of tests conducted in which a new HIV-positive result or diagnosis was returned to a person during the reporting period (positivity)	Number of tests performed where results were returned to a person during the reporting period (testing volume)
HTS.3 (NEW) ●	People testing positive for HIV	% testing positive among people who received an HIV test in the reporting period[a]	Number of people who test HIV-positive in the reporting period and have results returned to them	Number of people receiving an HIV test in the reporting period
HTS.4 ●	Linkage to ART	% of people newly diagnosed with HIV initiated on ART	Number of people newly diagnosed with HIV and started on ART during the reporting period	Number of people newly diagnosed with HIV during the reporting period
HTS.5	HTS partner services	Number of people who were identified and tested using partner testing services and who received their results	For the general population: Number of elicited partners and other contacts[b] of people diagnosed with HIV who received HTS For key populations: Number of elicited contacts of members of key populations who received HTS	NA
HTS.6	HIVST distribution	Total number of HIV self-test (HIVST) kits distributed during the reporting period	Number of individual HIVST kits distributed	NA

● Core indicator

[a] HIV diagnosis is not based on a single test but rather on application of a full testing algorithm according to national guidelines.

[b] Contacts are defined as current or past sexual partner(s), biological children/parents (if index case is a child) or anyone with whom a needle was shared. Biological children should include only children of an HIV-positive mother. Children of male-index clients (fathers) should be included only when the biological mother is HIV-positive, she is deceased or her HIV status is not known or not documented. Conversely, if the index client is the child, his/her mother should be tested, and, if the mother is HIV-positive or deceased, the father should be tested as well. In addition, all biologic siblings of the index child should be tested.

3.3 Key considerations for monitoring HTS and linkage

3.3.1 Increasing number of people living with HIV who know their status

As HIV testing and treatment expands, there is a greater need to focus testing services so as to reach individuals most at risk of acquiring HIV and to support access to HIV prevention and treatment services, in the process achieving the first 95 (testing) target. However, as the proportion of people living with HIV who are aware of their HIV serologic status increases, the testing yield (the percentage testing positive) diminishes, and reaching at-risk populations becomes more challenging. The analysis and use of routine testing data are critical to selecting and optimizing implementation of HTS delivery to reach populations and geographical settings with the largest proportion of people living with HIV who do not know their status.

Patient monitoring data that use some form of UID across testing, care and treatment services enable longitudinal tracking of people living with HIV along the continuum of care from diagnosis through enrolment in care, uptake of and retention on treatment to VL testing, treatment and viral suppression. This allows person-centred monitoring that benefits the people receiving services and enables programmes to differentiate individuals, avoiding duplication and double-counting. This is particularly important in the context of high rates of retesting, including among those previously on ART who retest as they re-engage in care, as individuals may be reported multiple times and/or from multiple facilities, which can lead to overestimates of the number of diagnosed individuals.

To assess gaps in testing in various settings, contexts and populations and so better target service delivery, the indicator HTS.2. HTS test volume and positivity is recommended within the set of 80 priority indicators recommended. In addition, with a view to strengthening person-centred monitoring, the new core indicator HTS.3. Individuals testing positive for HIV measures the proportion of individuals diagnosed as distinguished from the number of positive tests.

3.3.2 Early HIV diagnosis

Early diagnosis is key to treatment success, improved patient outcomes and reduced onward HIV transmission. New diagnoses likely reflect a mix of those newly identified with HIV infection, those previously diagnosed but not linked to care and those previously diagnosed but disengaged from HIV treatment and care services. Monitoring CD4 count and disease stage at diagnosis is important to identify late diagnoses, as well as people with advanced HIV disease, for effective management.

Early diagnosis enables early linkage to care and rapid ART initiation. Expanding testing services outside of health facilities is critical for reaching undiagnosed at-risk individuals and supporting early diagnosis. HIV self-testing and social network-based and community-based approaches *(5)* to HTS are effective strategies for reaching such populations but must be accompanied by timely linkage to treatment and care services. Community-based testing provides an important source of information on subpopulations with higher levels of HIV positivity than background levels. However, depending on how closely community-based testing venues are integrated with HIV treatment and care services, capturing information on linkage-to-care from community testing may be challenging. Addressing this requires ensuring the flow and use of data between community-delivered services and health facilities through harmonized and standardized data collection, mapping of community service delivery, use of client UIDs, interoperable community and facility data systems and linkage through EMR systems as well as linkage registers. In addition, community-led monitoring of services contributes important data on access, coverage and quality of testing services.

3.3.3 Linkage to treatment and care

Linkage to treatment and care is the first step toward onward services, including timely initiation of ART as well as access to interventions to prevent the further transmission of HIV, to prevent other infections and to manage co-morbidities. Linkage to treatment and care is essential to achieve programmatic impact and effective patient management and care. Delays in ART linkage are associated with lower levels of viral suppression, higher likelihood of viral resistance and increased HIV morbidity, mortality and transmission rates *(5-8)*.

Improving data use, together with the use of UIDs, is key to strengthening linkage to treatment and care services following diagnosis. Linkage to care also includes relinking people who know their HIV-positive status but disengage from care and who need to be supported to re-engage and initiate treatment. People in this group might include: *(1)* people diagnosed with HIV before the "treat all" policy era and who never started treatment; *(2)* people who were offered ART but were not yet ready to start; and *(3)* people who started ART but later discontinued. Sometimes, these individuals need to retest to relink to care and initiate or (reinitiate) ART. When people present for testing, providers cannot always identify who already knows their status or who was previously engaged in care but may have transferred to another facility or was LTFU. For these individuals, linkage from HTS sites can be critical to initiating or re-initiating treatment, and using data to support this re-engagement is increasingly important both for patient care and for successful achievement of the first 95 target.

Linkage to treatment and care is captured by the core indicator HTS.4, which is defined as the proportion of newly diagnosed individuals who initiate ART. Disaggregated reporting of this indicator by time since diagnosis (for example, 28 days or 90 days) and timing of ART initiation provides an indication of the quality of care with respect to national guidelines on when treatment should be started and enables monitoring of rapid ART initiation (within seven days of diagnosis). Programmes wishing to look at linkage to ART for non-recent diagnoses – for example, in the last six months – can do so by choosing the desired time period since diagnosis in the disaggregation. Coupled with ART coverage, this indicator can give programmes an indication of their ability to reach and link diagnosed individuals with treatment and care services.

HTS partner services/provider-assisted referral

Partner HTS services, also known as provider-assisted referral, are an effective way to identify additional people living with HIV *(9)*. Partners of diagnosed individuals who test positive can be linked to treatment services, while those who test negative can be linked to prevention services. With this approach, the provider contacts partners by telephone, email or in person to offer HTS. Contact and/or partner notification and testing should be voluntary and provided with supportive services. It is important to ensure that the index partner's consent is obtained before contacting partners and that data confidentiality is ensured.

The indicator HTS.5 measures the number of HIV-negative people or people of unknown status who were identified and tested using partner testing services and received their results. This indicator represents a type of service cascade, with the number of partners or contacts receiving HTS measuring the final step in the cascade of services. Drop-off along the cascade can be measured by the percentage accepting services from among those offered partner/contact services as well as the number of partners/contacts receiving testing from among those whose information is obtained from index cases or key population members, taking into account partners who are HIV-positive and already aware of their status.

The following additional cascade data can be collected to support interpretation of this indicator (included in the recommended minimum dataset for HIV testing) for more in-depth monitoring:

- number of people diagnosed with HIV (index cases) offered partner/contact testing
- number of people diagnosed with HIV (index cases) accepting partner/contact testing
- number of HIV-negative or unknown-status contacts/partners of people living with HIV whose information is elicited from people diagnosed with HIV (index cases).

For key populations the following additional cascade data can be collected:

- number of key population members offered social network-based/partner services
- number of key population members accepting social network-based/partner services
- number of contacts of key population members elicited.

Community testing and self-testing

HIV self-testing (HIVST) and community-based services, including outreach HTS provided by health care workers and by communities, are increasingly expanding access and coverage of HIV testing among hard-to-reach groups at high risk of acquiring HIV. Community-based HTS can be delivered in many ways and in many different settings and venues. These include HTS at fixed locations in the community and at limited-time events, places of worship, workplaces and educational establishments, sometimes with the use of mobile vans. Community-based HTS also can be delivered at peoples' homes, usually referred to as home-based HTS. Community-based HTS can also be conducted by trained lay providers and peers using RDTs and the test for triage strategy *(5)*.

Data from community testing services can complement and improve linkage to facility-based testing. Community-based venues may focus on providing services for people from key populations. Data from community testing services provide important information making possible improved follow-up and targeting of services. The 2020 HIV strategic information guidelines recommend an indicator on HIV self-test kit distribution in both facilities and communities for both prevention and linkage to treatment which has been retained in this guidance.

For HIVST all reactive results should be followed by further testing by a trained provider to confirm HIV status *(10)*. In standard facility-based HTS or when HIVST is offered in a facility or supervised by a provider in the community or online, appropriate linkage can be provided in a single visit or testing session. However, for many HIVST models, HIVST use and linkage are not likely to follow immediately after HIVST kit distribution or to take place in the same location. This leads to challenges for routine data collection to track the progression from HIVST kit distribution through use, initial test result, confirmatory testing and linkage. For HIVST, depending on context, it may be feasible and desirable to collect data at the facility level from testing registers, either by adding extra data elements in the HTS register (see Web Annex C for an example of an HTS register from Western Cape, South Africa) or by using a dedicated HIVST distribution register; see Web Annex D) or electronic equivalents recording the numbers and types of HIVST kits distributed, population groups receiving HIVST kits and prior HIVST use.

Additional data fields can be considered for HIVST follow-up services such as confirmatory testing after a reactive HIVST result and linkages to treatment or care. The decision to add fields should weigh feasibility and the demands on health care providers to collect and report data. Some sites use site-level HIVST commodity consumption forms or registers to document the number of tests used and the numbers of positive and negative results over a period of time, as well as to monitor HIVST.

As with any other HTS or site registers, it is important to ensure the confidentiality of data and clients' identities. In most instances facilities or community testing sites may collect client identifying information to facilitate client follow-up and/or to calculate the number of unique individuals receiving HIVST kits or community testing. For the client, providing such information should be optional; a requirement may deter some clients, particularly members of key populations, from obtaining HIVST kits or opting for community testing. Individual follow-up of all clients may not be necessary or feasible in many settings. Data for follow-up should not be collected if follow-up is not undertaken.

HTS and linkage for key populations

HIV testing services for key populations are an important part of HIV prevention and key to ensuring early diagnosis and linkage to care. HIV testing services should be routinely offered to all key populations both in the community and in facility-based settings. To support such services, careful use and sharing of selected data is important to promote linkage across service delivery areas and from community sites to facilities. However, collecting data on key populations poses certain challenges. Ensuring data confidentiality and security of testing data is essential. This is particularly the case when information is linked or shared across service providers and programmes and when the information is sensitive, such as HIV status or key population status or other stigmatized or criminalized behaviours or characteristics. Partner services, including partner testing and notification and social network-based approaches, must also actively ensure confidentiality of client and partner data as well as personal and medical information. Policies, regulations, standard operating procedures and technical measures to protect confidentiality must be in place at all levels of the health information system, including community settings.

Client confidentiality and data protection are also important considerations when using UIDs. For this reason, use of national identity numbers in HIV testing services is discouraged. Programme-based or other types of anonymous UIDs can be considered instead (see Chapter 6). In settings with robust systems for ensuring data security and confidentially, testing data for key populations collected by community service providers represent strong sources of data, with community service organizations leading the way in the sensitive collection and use of data to support integrated service delivery. See section 3.8 for further considerations when monitoring treatment services and outcomes in key populations.

The survey-based indicator HTS.9. People from key populations who know their status, is recommended to monitor access and coverage of testing services in these groups. This indicator is measured by representative surveys of key populations – for example, biobehavioural surveys (BBS) or HIV sentinel sero-surveillance surveys (HSS+) (see Chapter 8).

3.3.4 Standardized data collection tools for HTS

Annexes provide examples of countries' standardized data collection tools for HTS. These include an HTS register (Web Annex C), digital scan forms that include an HTS initial screening register (Web Annex F), an HTS confirmatory register (Web Annex E) and an HIVST distribution register (Web Annex D) from Malawi.

3.3.5 Minimum dataset

Data collection practices and completeness of records may vary across settings and testing approaches. Where possible, HIV testing information should be collected in a standardized manner across all service sites, including at the facility and community levels. At a minimum the following information should be recorded:

- HIV test date
- HIV test result
- date of diagnosis
- date that client received the result
- linkage to care, where feasible and appropriate.

For details see Web Annex A. Minimum dataset for HIV testing, which includes the above data elements for HTS.

3.4 ART initiation, retention and viral suppression

Box 3.3 What's new in HIV treatment relevant to HIV patient monitoring

- **Rapid initiation and same-day start of ART:** Since 2017 WHO has recommended that ART should be offered to all people living with HIV following a confirmed HIV diagnosis and clinical assessment within seven days of diagnosis and preferably on the same day as confirmed HIV diagnosis, for people who are ready to start ART *(11)*. Patient monitoring tools and, where in use, EMR systems should be updated to monitor rapid treatment initiation.
- **Updates to WHO recommendations for preferred and alternative first-, second- and third-line ART regimens for neonates, infants, children, adolescents and adults including pregnant and breastfeeding women** *(2)*: These updates require updates to existing drug regimens and codes in patient monitoring tools, EMR systems and the minimum dataset for HIV treatment.
- **Revised HIV VL monitoring algorithm:** WHO recommends routine VL monitoring at six and 12 months after ART initiation, and then every 12 months thereafter, and CD4 cell count testing at first-ever presentation to care and then every six months until established on ART *(2)*. CD4 count monitoring is also necessary, when clinically indicated, for assessment for advanced HIV disease and return to care during re-engagement. HIV patient monitoring tools and EMR systems should be revised to capture these updates.
- **New indicator on early VL testing:** In 2021 WHO recommended review of a VL test result by six months after treatment initiation to promote early ART adherence and VL suppression *(2)*. Patient monitoring tools should be updated to capture early VL testing.

Box 3.3 (continued) What's new in HIV treatment relevant to HIV patient monitoring

- **Retention:** In 2020 WHO recommended the modified indicator ART.2. Total attrition from ART, to measure progress towards retention on ART for purposes of programme management *(1)*. Box 3.5 provides further clarification of this indicator.
- **Revised LTFU definition:** In 2020 the criterion defining LTFU was reduced from 90 or more days to 28 or more days since the last missed appointment (including missed ARV refills in either facility or community settings) *(1)*. Patient monitoring tools and systems used for tracking LTFU (including EMR and appointment systems) should be updated with the revised definition.
- **Updated treatment service delivery recommendations:** Updated recommendations provide for ART initiation outside health facilities, with clinic visits at three to six month intervals, and ARV dispensing for individuals established on ART as well as implementation of tracing interventions for people living with HIV who disengage from care. Monitoring these recommendations requires updates to HIV patient monitoring tools, including those adapted for community-delivered ART services, and development of indicators for differentiated service delivery, including for multi-month ARV dispensing, among others, and criteria for triggering tracing interventions and patient recall.
- **Updates to ARV toxicity monitoring:** ARV toxicity indicators were revised in 2020 with updates to capture emerging signals observed with introduction of new ARVs, including weight gain and cardiometabolic toxicities. An additional indicator for adverse pregnancy outcomes monitors low birth weight, stillbirths and miscarriages, preterm births and congenital abnormalities related to exposure to ARVs in pregnancy *(1)*. Patient monitoring tools should also be updated to capture emerging toxicities.

3.4.1 What to monitor and relevant treatment indicators

In the context of current WHO "treat all" recommendations, it remains critical to monitor people living with HIV who receive ART over time as they move between health facilities and access care at different service delivery points. Priority indicators for HIV treatment focus on monitoring the treatment cascade from ART initiation and/or re-entry into treatment through to treatment outcomes that include retention, VL suppression, treatment discontinuation, ARV toxicity, LTFU and death *(1)* (see Table 3.2 and Chapter 8).

All the indicators shown in Table 3.2 are drawn from the HIV patient monitoring system (except the denominator for indicator ART.1). The first two indicators focus on ART coverage to measure progress towards the second 95 target and to count people who initiate ART for HIV and are retained on treatment (ART.1), while causes of attrition, including death, stopping treatment and LTFU, are characterized and monitored at the programme level through ART.2, the indicator on ART attrition. The latter informs mitigation efforts to promote retention. Box 3.4 summarizes some key considerations for measuring indicator ART.1, while Box 3.5 clarifies indicator ART.2.

Table 3.2 Priority indicators for HIV treatment and care

Ref. no.	Short name	Indicator definition	Numerator	Denominator
ART.1 ●	People living with HIV on ART	Number and % of people on ART among all people living with HIV at the end of the reporting period	Number of people on ART at the end of the reporting period (HIV patient monitoring data from, for example, ART registers, patient records or EMR). For key populations survey data may be required.	For calculation of ART coverage: 1. To determine treatment coverage: estimated number of people living with HIV (from models, such as Spectrum AIM) 2. To gauge progress toward the second 95 target: number of people living with HIV who know their HIV status (from surveys or models)
ART.2 (updated) ●	Total attrition from ART[a]	Number and % of people living with HIV on ART at the end of the last reporting period and those newly initiating ART during the current reporting period who were not on ART at the end of the current reporting period	Number of people living with HIV reported on ART at the end of the last reporting period *plus* Number of people living with HIV newly initiated on ART during the current reporting period *minus* Total number of people living with HIV on ART at the end of the current reporting period	For calculation of attrition rate: Number of people reported on ART at the end of the last reporting period *plus* those newly initiated on ART during the current reporting period
ART.3 ●	People living with HIV on ART who have suppressed VL[b]	% of people living with HIV on ART (for at least six months) who have virological suppression	Number of people living with HIV on ART for at least six months and with at least one routine VL test result who have virological suppression (<1000 copies/mL[c]) during the reporting period	Number of people living with HIV on ART at least six months with at least one routine VL result in a medical or laboratory record during the reporting period, to monitor progress towards the third 95 target. In addition, this can also be presented as the number with suppressed VL among all people living with HIV to calculate population-level viral suppression.
ART.4	New ART patients	Number of people living with HIV who initiated ART	Number of people living with HIV who initiated ART in accordance with national treatment guidelines during the reporting period	NA

Table 3.2 (continued) Priority indicators for HIV treatment and care

Ref. no.	Short name	Indicator definition	Numerator	Denominator
ART.5 ●	Late ART initiation	% of people living with HIV who initiate ART with a CD4 count of <200 cells/mm^3	Number of people living with HIV initiating ART during the reporting period with a baseline CD4 count of <200 cells/mm^3	Number of people living with HIV initiating ART during the reporting period who have a baseline CD4 cell count
ART.6	VL testing coverage	% of people living with HIV on ART (for at least six months) with VL test results	Number of people living with HIV on ART with at least one routine VL test result during the reporting period	Number of people living with HIV on ART for at least six months.
ART.7	Early VL testing (at six months)	Number and % of people living with HIV on ART who had a VL result reviewed by six months after initiation of ART[d]	Number of people living with HIV on ART who were eligible for VL monitoring at six months after initiation of ART during the reporting period and who had a VL test performed and result reviewed by six months after ART initiation	Number of people living with HIV on ART eligible for VL monitoring at six months after initiation of ART during the reporting period
ART.8	Appropriate second VL test after adherence counselling	% of people living with HIV receiving ART with VL ≥1000 copies/mL who received a follow-up VL test within three months	Number of people living with HIV on ART who received a follow-up VL test three months after a VL test result of ≥1000 copies/mL during the reporting period[e]	Number of people living with HIV on ART with VL ≥1000 copies/mL during the reporting period
ART.9	ARV toxicity prevalence	% of ART patients with treatment-limiting ARV toxicity[f]	Number of ART patients who have stopped treatment or switched regimen due to toxicity in the reporting period	Number of ART patients in the reporting period

● Core indicator

Abbreviations: ART = antiretroviral therapy; NA = not applicable; PLHIV = people living with HIV; VL = viral load

[a] Numerator updated for clarity. However, calculation of the indicator and what it measures remain unchanged.

[b] This indicator must be interpreted along with VL testing coverage to assess the potential for bias, that is, whether VL testing occurs only in a particular subset of people receiving ART.

[c] WHO recommends the following thresholds to distinguish between treatment failure (>1000 copies/mL) and undetectable levels (not detected by assay or sample type used) *(2)*.

[d] It important that patient monitoring systems can identify VL tests conducted at six months after ART initiation and that this is taken into account in HIV surveillance so as not to disrupt surveillance of population-level VL.

[e] In 2021 the WHO recommendation on timing of second VL test was updated from six months to three months in line with updates to the algorithm for treatment monitoring.

[f] "Treatment-limiting toxicity" is defined as a serious adverse drug reaction that results in drug discontinuation or substitution. In addition, any reaction that leads to treatment interruption or requires changing the drug or regimen because of an adverse drug reaction is also considered a serious adverse drug reaction.

Box 3.4 Considerations for measuring the number of people living with HIV on ART (ART.1)

- People on ART who initiated or transferred in during the reporting period should be counted.
- People on ART who pick up three or more months of ARV drugs at one visit (that is, multi-month ARV dispensing) should also be counted, as long as they have received enough ARVs to last at least to the end of the reporting period.
- If it is determined that an individual has died, been LTFU or transferred out to another facility, they should immediately be removed from the ART.1 indicator.

Box 3.5 Updates to the indicator ART.2. Total attrition from ART: simplification to support country adoption

Since the release of the 2020 HIV strategic information guidelines, when the ART retention indicator was modified to measure attrition from ART, this indicator has been revised for clarity following review by technical partners and experts. As described in the table below, the numerator for this indicator has been updated to simplify and support the operationalization. The conceptualization and overall calculation of this indicator, as far as measuring attrition due to death, LTFU or stopping treatment among individuals previously on treatment and those newly initiating treatment, remains unchanged, however.

Components description	
2020 numerator calculation	Revised 2022 numerator calculation
Attrition = Number of people living with HIV reported on ART at the end of the last reporting period who were not on treatment at the end of the current reporting period (including those who died, stopped treatment or were LTFU) **plus** Number of people living with HIV newly initiated on ART during the current reporting period who were not on treatment at the end of the current reporting period (including those who died, stopped treatment or were LTFU)	Attrition = (Total number on ART at the end of the last reporting period) **plus** (total number newly initiated on ART during the current reporting period) **minus** (Total on ART at the end of the current reporting period)
Denominator (for calculation of attrition rate) – no change	
Number of people reported on ART at the end of the last reporting period *plus* number newly initiated on ART during the current reporting period	
Calculation of indicator (attrition rate) – no change	
Numerator/denominator	

WHO welcomes further feedback from countries and technical partners on their experience of adopting and using this indicator, including feedback on feasibility and implementation considerations.

3.4.2 Monitoring ART initiation, late initiation and clinical management

ART initiation should follow the overarching principles of providing person-centred care. Person-centred care should be focused and organized around the health needs, preferences and expectations of people and communities. Likewise, patient monitoring should also be person-centred and enable longitudinal monitoring of people living with HIV as they access HIV treatment and care services and, where relevant, re-engage in care and reinitiate treatment. ART initiation is captured by the indicators ART.4. New ART patients and ART.5. Late ARV initiation.

Since 2017 WHO has recommended rapid initiation of ART, within seven days of diagnosis, and offering ART initiation on the same day to people who are ready to start *(11)*. Table 3.3 summarizes the WHO recommendations on when to start ART, highlighting the implications from a patient monitoring perspective vis-à-vis which populations are eligible for rapid ART initiation.

Table 3.3 Recommended timing of ART initiation among people living with HIV

Population or clinical status	Timing of ART initiation
Adults, adolescents and children living with HIV with no signs and symptoms of TB	Rapid ART initiation on the same day should be offered to all people living with HIV following a confirmed HIV diagnosis and clinical assessment.
Adults, adolescents and children living with HIV with suspected TB	Rapid ART initiation should be offered to all PLHIV following a confirmed HIV diagnosis and clinical assessment and to people living with HIV with signs and symptoms suggesting TB. Except in cases of central nervous system disease (meningitis), initiate ART while rapidly investigating for TB, with close follow-up within seven days to initiate TB treatment if TB is confirmed.
Adults, adolescents and children being treated for HIV-associated TB	ART should be started as soon as possible and within two weeks of initiating TB treatment, regardless of CD4 cell count, among people living with HIV.
Adults, adolescents and children being treated for HIV-associated TB meningitis (diagnosed either clinically or with a confirmed laboratory test)	ART should be delayed at least four weeks (and initiated within eight weeks) after treatment for TB meningitis is initiated. Corticosteroids should be considered adjuvant treatment for TB meningitis.
PLHIV who are diagnosed with TB but not receiving ART or treatment for TB	TB treatment should be initiated first, followed by ART as soon as possible and within the first two weeks of TB treatment.

Table 3.3 (continued) Recommended timing of ART initiation among people living with HIV

Population or clinical status	Timing of ART initiation
PLHIV with cryptococcal meningitis	Immediate ART initiation is not recommended for adults, adolescents and children living with HIV who have cryptococcal meningitis because of the risk of increased mortality and should be deferred by 4–6 weeks from the initiation of antifungal treatment. Thus, ART should be initiated between 4–6 weeks after undergoing antifungal treatment.
PLHIV with histoplasmosis infection	ART should be initiated as soon as possible among people with disseminated histoplasmosis for whom central nervous system involvement is not suspected or proven.

Abbreviations: ART = antiretroviral therapy; PLHIV = people living with HIV; TB = tuberculosis
Source: WHO, 2021 *(2)*.

Late initiation of ART is a risk factor for treatment failure and, therefore, important to monitor and recommended as a key treatment indicator (ART.5). In the era of the "treat all" policy, late initiation on ART most likely reflects treatment interruption and disengagement from HIV care in facilities or community ART services as well as potential challenges with linkage to care.

Among children living with HIV, late diagnosis is associated with children not being identified as at risk of HIV infection and, therefore, not accessing testing. In addition, among children who are in care and are known to be exposed to HIV, there are often delays in the infant diagnosis cascade. These delays include those associated with provider factors, such as availability of infant testing and laboratory delays in returning results to clients, and client factors that include failure to return for testing and other attrition along the care continuum. Beyond late diagnosis, ART initiation is often delayed among children due to social factors and the fact that they are dependent on an adult caregiver for ART. Delays often are due to the unavailability of the caregiver and/or the caregiver not being ready to give ART. Therefore, it will be important not only to record access to testing and age at initiation of ART but also turnaround time of results and time from diagnosis to initiation of ART. Monitoring the following can help understand the issues driving late ART initiation in children:

- postnatal attendance in MNCH services
- the number of identified infants and young children exposed to HIV, disaggregated by time of identification
- coverage of early infant diagnosis (EID)
- continuity along the early infant diagnosis cascade to final diagnosis
- age at diagnosis and ART initiation (which requires disaggregation by detailed age groups, for example, by five-year age bands, of testing and treatment indicators including treatment outcomes such as VL suppression).

3.4.3 Monitoring treatment outcomes

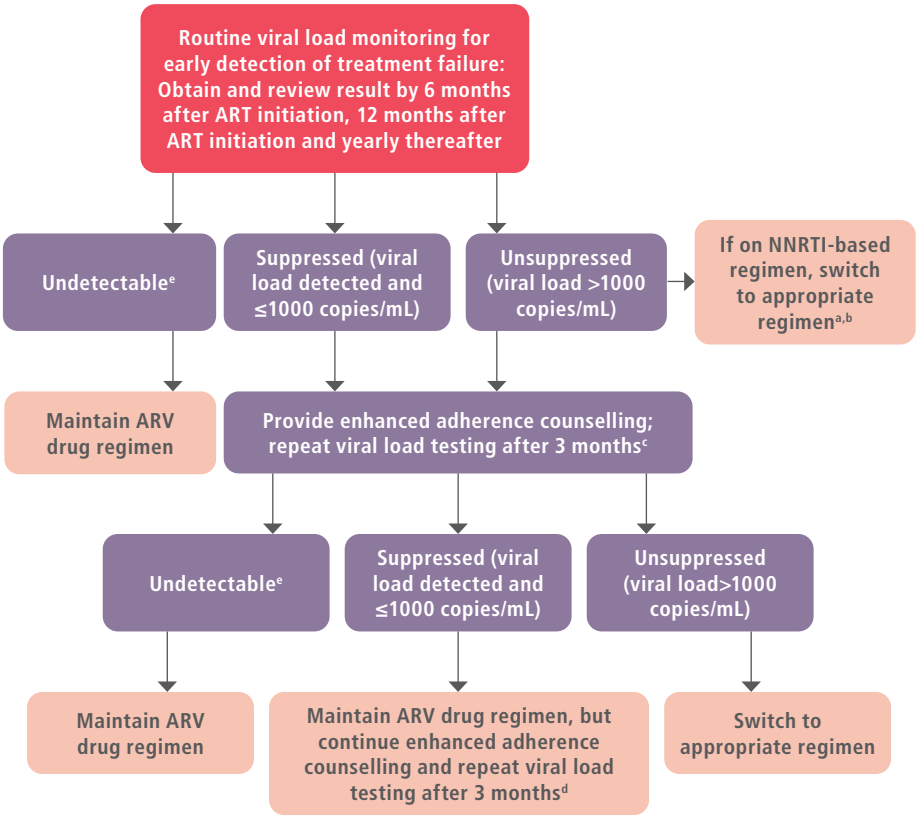
Viral suppression

A number of updates have been made to the treatment monitoring algorithm. First, the initial VL test should be collected and tested, and the result should be reviewed, by the time of the six-month visit after ART initiation. The timing of subsequent VL monitoring tests remains the same (12 months after ART initiation and yearly thereafter). Second, for patients with an unsuppressed VL, a second VL test should be performed three months after the initial elevated VL (measured by indicator ART.8. Appropriate second VL test after adherence counselling), with enhanced adherence counselling provided between tests. Further, WHO's consolidated HIV guidelines attempt to distinguish between treatment failure (>1000 copies/mL) and undetectable[1] thresholds. People living with HIV on ART with a detectable VL but virally suppressed should be monitored more closely (similar to those with >1000 copies/mL); however, treatment switch should be considered more carefully, particularly for those on DTG-based regimens (Fig. 3.3).

Monitoring of viral suppression and undetectability is critical for the health and well-being of people living with HIV as well as to gauge the quality of a treatment programme. Using these data – not only programmatically but, more importantly, clinically – remains a key issue, as does addressing data quality challenges (particularly timeliness and completeness) (see Box 3.32 for a summary of VL data checks that can be routinely implemented). All VL tests warrant follow-up action: A person living with HIV whose VL is undetectable could be considered for DSD or, if already in such a programme, should be commended for achieving and maintaining their target VL. A person living with HIV who has detectable viremia should receive appropriate follow-up care, including enhanced adherence counselling, VL testing and, if appropriate, a change of treatment. Increasing the number and proportion of people living with HIV who have undetectable VLs can transform patient health and care, strengthening a person-centred approach, minimizing transmission and decreasing morbidity and mortality.

[1] Not detected by assay or sample type used

Fig. 3.3 HIV treatment monitoring algorithm



Adherence counselling should be provided at all visits to ensure that viral suppression is maintained or given priority throughout care.

[a] Switch after a single elevated viral load should be considered if treatment experience is likely.

[b] A second viral load test may be considered before regimen switch if DTG-based regimens are unavailable and the results of a viral load test can be returned and acted on rapidly.

[c] Conduct same-day testing using point-of-care viral load testing for a repeat viral load test, where available, to expedite the return of results. If not available, viral load specimens and results for a repeat viral load test should be given priority across the laboratory referral process (including specimen collection, testing and return of results).

[d] Consider therapy switch for those receiving NNRTI-based regimens and based on clinical considerations and no adherence concerns.

[e] Not detected by assay or sample type used. This is updated from<50copies/mL.

Source: WHO, 2021 *(12)*

3.4.4 ART retention/attrition

The main function of an ART programme, after initiation, is to support retention in treatment and adherence in order to achieve viral suppression and so reduce mortality. Long-term retention in care is a key challenge, with impacts on patient health, the emergence of HIV drug resistance and onward transmission of HIV. Programmatic data from sub-Saharan Africa indicate that, five years after initiating ART, nearly one fifth (19%) of patients had stopped ART and 15–20% had died *(13, 14)*.

Monitoring ART attrition (indicator ART.2) is, therefore, critical. It involves determining the number and percentage of people living with HIV who are currently on ART, based on numbers of people living with HIV newly initiated on ART and attrition among those previously or newly reported to be on ART (see Box 3.5 for updates to indicator ART.2. Total attrition from ART and Table 3.2 for indicator definition and calculation). This requires assessment of outcome categories, including LTFU, death and stopping treatment, at the patient and facility levels. "Silent transfers" of people living with HIV on ART from one facility to another without formal transfer documentation continues to have an important influence on ART attrition rates, as these individuals are classified as LTFU when they are in fact not. Patient monitoring systems that allow longitudinal person-centred monitoring with the use of UIDs support the sharing of information between facilities and enable tracking between facilities of people living with HIV on ART as well as better measurement and understanding of retention.

Routine analysis of ART attrition data at the facility and subnational levels and by priority population should be conducted to identify and address gaps in the HIV care cascade that contribute to late presentation for care, loss to follow-up and other challenges arising from ART clients moving into out of and among health facilities. In addition, these data should be analysed to identify facilities that need support and the reasons for retention problems, including health system issues (long waiting times, quality of service), sociodemographic issues and client- and treatment-related factors (for example, ARV toxicity). These should be assessed and observations used to inform improvements in treatment programmes.

3.4.5 Loss to follow-up

Loss to follow-up generally refers to the unknown outcomes of people living with HIV who have not returned to a facility/community ART site for their HIV care or to collect their ARV drugs. Individuals who are LTFU are often interpreted as being out of care. However, instead most patients are undocumented "silent" transfers, those who have died and those who have discontinued treatment. Strengthening linkage and data flow between facilities and community service delivery sites and the use of data to track patients and support re-engagement in care is important for improved patient management and more accurate measurement of the real outcomes of individuals classified as LTFU. In addition, assessing the reasons that patients are LTFU is important so as to address gaps in service delivery and care.

Loss to follow-up and implementation of tracing interventions are monitored through the HIV patient card (Web Annex H), the ART register (Web Annex K) and the ART cohort report (Web Annex M). Notably, the definition of LTFU has been reduced from 90 days or more to 28 days or more since the last missed appointment, including missed ARV refills in either facility or community settings to account for DSD. This change is intended to improve treatment outcomes and patient care by supporting timely identification of LTFU and re-engagement into care. In the context of DSD, where patients have less frequent clinic interactions, it is important that patient monitoring systems are updated to distinguish between individuals who are LTFU and those enrolled in DSD care models (see section 3.7).

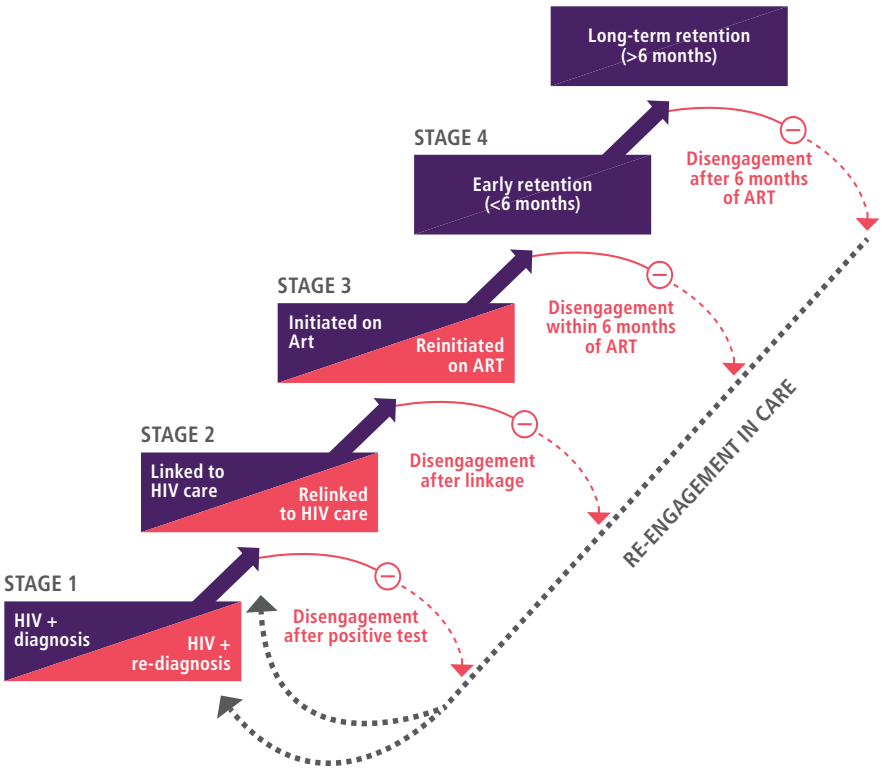
Data collected from patient monitoring, including the HIV card and ART register, serve as the primary data source for treatment indicators and outcomes such as retention and LTFU. At the facility level, longitudinal cohort analysis of these data enables assessment of short-, medium- and/or long-term patient outcomes and the performance of the ART programme. A standardized cohort report (Web Annex M) is available to facilitate such analysis.

Treatment interruption/discontinuation and ART re-initiation

Treatment interruption or discontinuation may result in viral rebound, immune decompensation and/or clinical progression *(15, 16)*. Therefore, it is important to address. Individuals may stop their ART for a variety of reasons, sometimes but not always in discussion with health care providers. There may be overlap between the "LFTU" and "stopped ART" categories since people living with HIV who stop treatment without notifying facility staff/community ART providers are classified as LTFU. This is captured in the patient monitoring tools (Web Annexes H, K and M).

Typically, the HIV care cascade has been represented as a linear, unidirectional continuum of care. However, many people living with HIV start and stop ART numerous times over their lifetimes. More recently, a cycle of engagement and re-engagement in services, termed the "revolving door of HIV care" (see Fig. 3.4), has been proposed *(17)*. This dynamic HIV care cascade recognizes that engaging and re-engaging in care is not a final state, but rather it is cyclical. This concept is critical for understanding, monitoring and addressing treatment interruption.

Fig. 3.4 Cyclical cascade of HIV care



Source: Ehrenranz et al., 2021 *(17)*

Strengthening the use of data to facilitate the tracing of clients and support re-engagement in care is important for addressing treatment interruption and supporting ART re-initiation. Section 3.7, Monitoring HIV service delivery for HIV treatment and care, provides details on monitoring such interventions, including suggested criteria to trigger tracing efforts and a minimum dataset for monitoring, tracking and re-engagement interventions.

Additionally, monitoring ART initiation alongside treatment interruption is important as people living with HIV re-engage in HIV services. To enable this, the HIV care and treatment patient card has been updated to enable monitoring of prior ARV exposure, including regimens and dates of starting and restarting treatment (Web Annex H).

3.4.6 Advanced HIV disease

Advanced HIV disease in adults and adolescents is defined by a CD4 cell count of less than 200 cells/mm^3 and/or WHO clinical stage 3 or 4 disease *(2)*. All children younger than five years of age living with HIV are considered to have advanced HIV disease. People with advanced HIV disease are at greater risk of mortality and require closer follow-up during the initial period of ART to monitor the response to treatment and to identify signs and symptoms of possible immune reconstitution inflammatory syndrome and other adverse events. Individuals with advanced HIV disease could be those who recently received an HIV diagnosis (that is, ART naive) or individuals re-entering care. The proportions of these may vary from one HIV programme to another *(18)*. In some settings the term "late presenters" is used to describe individuals with advanced HIV disease. To avoid development of life-threatening complications, those whose CD4 count indicates advanced HIV disease should be rapidly traced by telephone or through home visits. So should those who are missing appointments. This is particularly important as individuals with advanced HIV disease have much greater risk of mortality due to greatly compromised immune systems. The main causes of this mortality are TB, cryptococcal disease, severe bacterial infections and viral and other invasive fungal infections. Therefore, it is critical that health care providers quickly recognize these individuals at diagnosis (that is, those with CD4 cell counts <200 cells/mm^3) and provide timely interventions for diagnosis and management of co-infections *(2)*. In many LMICs, life-threatening opportunistic infections go undiagnosed due to lack of diagnostic tools and, thus, remain a significant barrier to achieving the 2030 target of zero AIDS-related deaths.

To reduce AIDS-related deaths, WHO recommends a package of care for advanced HIV disease *(11)*. This package includes recommendations for the use of diagnostic tests, prophylaxis, treatments and adapted adherence counselling. Table 3.4 summarizes the package.

With the addition of several recommended screening tools, the tools for treatment monitoring remain the same in individuals with advanced HIV disease as in all other people living with HIV. These include the CD4 cell count assessment (lab-based or POC semi-quantitative) at HIV diagnosis, cryptococcal antigen test and histoplasmosis antigen test. They also include screening for TB with a WHO-recommended algorithm, diagnosing TB with a molecular WHO-recommended rapid diagnostic test and the lateral flow urine lipoarabinomannan assay (LF-LAM) in outpatient individuals with a CD4 count of <100 cell/mm^3 *(19)*. It is based on this stratification that individuals with advanced HIV disease can be linked to appropriate differentiated care, to community- or facility-based management, as well as to management of co-morbidities such as TB or cryptococcal disease.

Table 3.4 WHO-recommended package of care for advanced HIV disease

	Intervention	CD4 cell count	Adults	Adolescents	Children <10 years
Screening and diagnosis	Screening tools for TB disease for adults and adolescents: WHO-recommended four-symptom screen, chest X-ray, C-reactive protein test, molecular WHO-recommended RDT for TB, alone or in combination Screening tools for TB disease among children: symptom screening for children living with HIV	Any	Yes	Yes	Yes (symptom-screen only)
	Molecular WHO-recommended RDT as the first test for pulmonary TB diagnosis among those who screen positive for TB and investigations for extrapulmonary TB as applicable; chest X-ray may also be used to support investigations	Any	Yes	Yes	Yes
	LF-LAM to assist TB diagnosis among people with symptoms and signs of TB	≤200 cells/mm^3 (inpatient) ≤100 cells/mm^3 (outpatient) Or any CD4 count if symptoms or seriously ill	Yes	Yes	Yes
	Cryptococcal antigen screening	Recommended for <100 cells/mm^3 and considered for < 200 cells/mm^3	Yes	Yes	No

Table 3.4 (continued) WHO-recommended package of care for advanced HIV disease

	Intervention	CD4 cell count	Adults	Adolescents	Children <10 years
Prophylaxis and pre-emptive treatment	Co-trimoxazole prophylaxis	<350 cells/mm³ or clinical stage 3 or 4 Any CD4 count in settings with high prevalence of malaria or severe bacterial infections	Yes	Yes	Yes
	TB preventive treatment	Any	Yes	Yes	Yes
	Fluconazole pre-emptive therapy for cryptococcal antigen-positive people without evidence of meningitis	<100 cells/mm³	Yes	Yes	Not applicable (screening not advised)
ART initiation	Rapid ART initiation[b]	Any	Yes	Yes	Yes
	Defer initiation if clinical symptoms suggest meningitis (TB or cryptococcal)	Any	Yes	Yes	Yes
Adapted adherence support	Tailored counselling to ensure optimal adherence to the advanced HIV disease package, including home visits if feasible	<200 cells/mm³	Yes	Yes	Yes

Source: WHO, 2021 *(2)*

Abbreviations: ART = antiretroviral treatment; LF-LAM = lateral flow urine lipoarabinomannan assay; RDT = rapid diagnostic test; TB = tuberculosis

[a] TB preventive treatment should be provided in accordance with current WHO guidance.

[b] People receiving a positive WHO four-symptom screen should initiate ART while being evaluated for TB if clinical signs and symptoms of meningitis are absent.

It is important to ensure timely linkage and data flow of diagnostic tests and results, including linking POC tests undertaken to screen for advanced HIV disease with patient records or EMR, where in use, so that results are available for appropriate patient management and care. Further, the development of estimates of the number of individuals with advanced HIV disease within the context of an HIV programme is important to inform programme planning to ensure that the required resources for advanced HIV disease care are available. Other important considerations include assessment of the functional status of an individual with advanced HIV disease and early recognition and linkage to care for those who are seriously ill. Monitoring for immune reconstitution inflammatory syndrome, adverse reactions occurring from management of opportunistic infections and ARV toxicity also is critical.

3.4.7 ARV toxicity monitoring

As ART scale-up continues, with earlier and more prolonged exposure to treatment, and with the transition to new ARVs among all age groups including pregnant and breastfeeding women, monitoring the safety of ARV drugs has become a critical component of HIV treatment and prevention programmes. Newer ARVs have more favourable toxicity profiles and provide an opportunity to standardize and optimize HIV treatment. Still, ARV-associated toxicities are among the most common reasons reported for ART non-adherence, treatment discontinuation or drug substitution. In this context WHO recommends that countries consider a combination of approaches to monitor ARV drug toxicity and promote patient safety, including surveillance of drug safety in pregnancy and active and routine toxicity monitoring in all populations, including adults, adolescents and children *(20)*.

ARV toxicity monitoring provides data on the incidence, clinical significance and type of serious treatment-limiting ARV toxicities as well as on their impact on patient outcomes. This information can inform guidance to prevent and limit the severity of drug toxicity and help to optimize patient management, including retention and viral suppression on treatment.

ARV drug toxicity monitoring – a priority indicator for routine monitoring of the health sector response to HIV

The ARV drug toxicity indicator (ART.9) is included among the 80 priority HIV indicators recommended in these guidelines (see Table 3.2 for indicator definition). In addition, the 2020 WHO strategic information guidelines also recommend collecting information on programmatic reasons for switching ART regimens or treatment interruption, defined as the percentage of people receiving ART who switch or stop their ARV drug regimen *(1)*.

New indicators for routine monitoring of adverse pregnancy outcomes related to exposure to ARV drugs

Four indicators are now recommended as part of HIV programme management and monitoring to monitor adverse pregnancy outcomes related to exposure to ARV drugs *(1)* (Box 3.6). These indicators were recommended in 2020 to enable more comprehensive monitoring of the safety of ARV drugs in pregnancy.

Box 3.6 Adverse pregnancy outcome indicators recommended as additional indicators to support programmatic transition to new ARV regimens

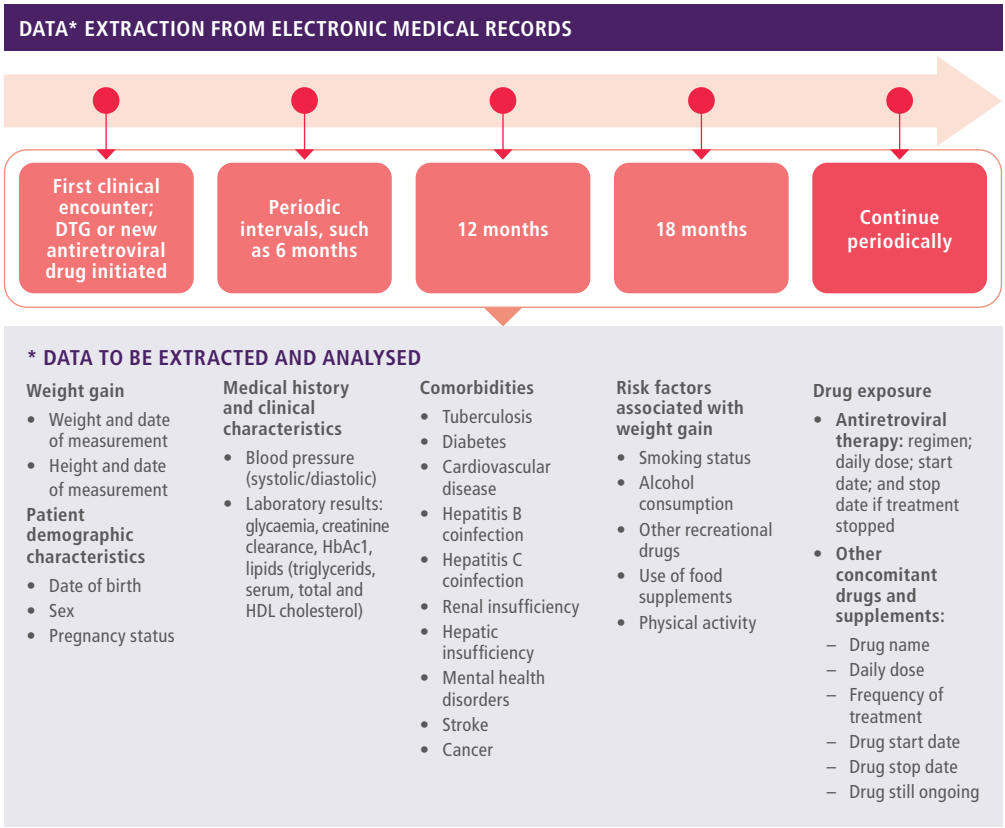
- proportion of low birth weight (<2.5 kg) deliveries among HIV-positive women
- proportion of stillbirths/miscarriages among HIV-positive women
- proportion of preterm deliveries (<37 weeks gestation) among HIV-positive women
- proportion of HIV-positive women with conception and 1st trimester (<14 gestation weeks) ART exposure with a major external congenital anomaly.

A higher than expected rate of adverse pregnancy outcomes on these indicators suggests the need for more formal assessment through, for example, birth defect surveillance or pregnancy registries *(21)*.

Longitudinal monitoring recommended to address emerging concerns and risk factors related to ARV drug toxicity

In 2020 WHO recommended that countries implement longitudinal monitoring of people living with HIV to assess changes in body weight or body mass index, to screen for risk factors for ARV toxicity and to assess the impact of ARVs on metabolic comorbidities, cardiovascular disease and maternal and pregnancy outcomes *(20)*. Longitudinal monitoring complements adverse drug reaction reporting by using clinical data from HIV patient monitoring systems to detect patterns in adverse drug reactions or risk factors that emerge over time. Fig. 3.5 illustrates the key data elements and the approach to longitudinal monitoring of weight gain and other clinical risk factors associated with ARV drug use. This approach is feasible in countries and contexts where EMR are used and data can be extracted, anonymized and analysed periodically at selected sites to inform clinical practice at the national level.

Fig. 3.5 Longitudinal monitoring of adverse drug reactions and clinical characteristics among people receiving ARV drugs



HbAc1: glycated haemoglobin.

Source: WHO, 2020 *(20)*

3.4.8 Early warning indicators of HIV drug resistance

The early warning indicators (EWIs) are a set of standard quality-of-care indicators used to assess whether ART programmes deliver services of sufficient quality to minimize the emergence of HIV drug resistance. The EWIs use standardized definitions that have evolved over time as programmes mature and public health actions are refined (Table 3.5). Monitoring EWIs is useful to identify gaps in service delivery that can be corrected at the clinic or programme level to minimize the risk of resistance as well as to optimize overall programme performance. Findings from EWI monitoring can be used to identify the clinics most in need of support or resources and to address the most pressing gaps in service delivery.

Many factors are associated with the emergence of HIV drug resistance or viral non-suppression. These include viral factors (for example, subtype, replication capacity and pre-existing polymorphisms) and drug-related factors (for example, drug potency, pharmacokinetics, drug–drug interactions, drug tolerability and genetic barriers to selection of resistance). There are also programmatic factors (for example, adherence, drug stock-outs, attrition of individuals from ART and the use of viral load testing to identify people with virological failure, followed by prompt switch of regimen, if indicated).

Although viral and drug-related factors are often beyond the control of public health or programme action, the monitoring of programme factors associated with HIV drug resistance can alert ART programmes to situations that may favour the emergence of HIV drug resistance or virological failure at the population level.

Table 3.5 WHO-recommended quality-of-care indicators: EWIs of HIV drug resistance

Ref. no.	Short name	Indicator definition	Performance strata Green: good Amber: fair Red: poor
ART.2	Total attrition from ART	Number and % of people living with HIV reported on ART at the end of the last reporting period and those newly initiating ART during the current reporting period who were not on ART at the end of the current reporting period	Green: <15% Amber: 15–25% Red: >25%
ART.3	People living with HIV on ART who have suppressed VL	% of people living with HIV on ART (for at least six months) who have viral suppression (for the purpose of monitoring, defined as VL <1000 copies/mL)	Green: ≥90% Amber: 80 to <90% Red: <80%
ART.6	VL testing coverage	% of people living with HIV on ART (for at least six months) with VL test results	Green: >95% Amber: 85–95% Red: <85%
ART.8	Appropriate second VL test after adherence counselling	% of people living with HIV on ART with VL ≥1000 copies/mL who received a follow-up VL test within three months	Green: ≥90% Red: <90%
ART.12[a]	ARV medicine stock-out	% of months with any day(s) of stock-out of any routinely dispensed ARV drug during the reporting period (12 months)[a]	Green: 0% Red: >0%
ART.13[a,b]	ART adherence proxy (ARV drug refills)	% of people receiving ART who pick-up all prescribed ARV drugs on time (no more than two days late at the first drug pickup after a defined baseline pickup)	Green: >90% Amber: 80–90% Red: <80%
ART.14[a]	Appropriate switch to second-line ART	% of people with confirmed VL ≥1000 copies/mL who switch to second-line ART within 90 days of a confirmatory VL test result of ≥1000 copies/mL. (In the case of individuals taking NNRTI-based ART, appropriate switch is defined as switch of regimen within 90 days of the first VL test result of ≥1000 copies/mL).	Green: 100% Red: <100%

[a] Designated an additional indicator that programmes can consider including in their national indicator sets.

[b] The 2020 WHO *Consolidated HIV strategic information guidelines (1)* describe the indicator ART adherence proxy (ARV drug refills) as a programmatic indicator as follows: % of ART sites that had stock-outs of any ARV drugs during the reporting period.

Use of standardized indicator definitions and targets allows ART sites to be classified into one of three performance strata: green (excellent performance, achieving the desired level); amber (fair performance, not yet at desired level); and red (poor performance, below the desired level) (Table 3.5).

These stratified EWI targets provide clinic-specific and programme-level benchmarks against which to assess performance, and they help to identify areas with the greatest need for additional resources to close gaps in service delivery. ART site or programme performance below the desired targets prompts investigation and implementation of programmatic and/or public health actions to improve the quality of ART service delivery, which could contribute to the emergence of HIV drug resistance (Box 3.7).

Additionally, exploring differences in performance between ART sites can lead to documentation and sharing of best practices. The WHO *Global action plan on HIV drug resistance 2017–2021 (22)* provides examples of public health actions that respond to suboptimal performance evidenced by quality-of-care indicators. These include:

- implementing interventions to improve ART adherence, which is linked to improved suppression of VLs;
- advocating high levels of coverage for VL testing;
- implementing a process to ensure a prompt switch to second-line ART when indicated;
- strengthening communication and integration between pharmacy and clinic records to identify people at risk of HIV drug resistance due to missed pill pickups; and
- supporting and strengthening supply chain management.

Annual monitoring of EWIs allows for measurement of degrees of improvement or decline over time, both within and between ART sites. The EWIs are fully integrated into these consolidated HIV SI guidelines.

Box 3.7 WHO recommendations for use of EWIs

- EWIs should be reported on a census of patients (as with all key indicators) where resources and data quality are adequate; where they are not, EWIs are reported on a nationally representative sample of patients (by facility).
- EWIs should be collected at the facility level at the same time that data quality assessments are conducted (see section 3.11), or they may be collected and reported separately by clinics, depending on the country situation.
- Resources should be directed at verifying, strengthening and using the routine patient monitoring systems and processes rather than creating parallel ones for EWI data collection and reporting.
- Except for "ART adherence proxy" (ART.13), which cannot be generated through data quality assessments, use of the WHO EWI data abstraction tool, while encouraged since it supports data verification and validation, is optional and is not strictly required to collect and report routinely on EWIs.
- The ART cohort report, which is the source for EWIs ART.2, ART.3, ART.6, ART.8, ART.12 and ART.14, is validated during data quality assessments by reviewing the ART register and then HIV patient cards as necessary.
- Gaps in data quality should be addressed and followed up in a timely manner. Any weaknesses in data reported from the patient monitoring system should be noted, to the extent possible, to facilitate interpretation of indicators (for example, % missing data).
- Gaps in clinic and programme performance should prompt appropriate and focused investigation.

For a complete picture of facility and programme functioning, EWIs should be reported from all ART sites in a country (a census of facilities). However, EWI monitoring may be carried out initially through random primary sampling of ART sites and then progressively scaled up to include all facilities. Use of representative primary facility sampling allows countries to calculate an aggregated national prevalence estimate for each EWI. In addition, this method can incorporate information from facilities with conveniently available data (for example, sites with data readily available from electronic health information systems or easily exploitable paper-based records) without sacrificing representativeness. While this primary sampling method does not apply more broadly to the key indicators presented in this guidance, the secondary method for sampling patient records at the facility level does apply. Web Annex G provides detail on the overall recommended primary (clinic) and secondary (patient record) sampling methods for EWIs.

Detailed instructions on how to collect EWIs using the routine patient monitoring system also can be found in WHO's EWI data abstraction tool in Microsoft Excel format which facilitates data abstraction and automatically assigns the appropriate classification (green, amber and red) to the facility for a given indicator. The tool keeps track of complete entries and reports a score in grey if ≥30% of the information is missing. This tool is available at the WHO HIV drug resistance website: https://www.who.int/teams/global-hiv-hepatitis-and-stis-programmes/hiv/treatment/hiv-drug-resistance/prevention. Although this tool is not required to collect and report data on EWIs, with the exception of the adherence proxy (on-time pill pick-up), it does support data verification and validation (see Box 3.7), it aggregates all facility-specific data into one national report and provides the facility and the national programme with an at-a-glance colour-coded performance report. Countries should make every effort to harmonize the collection and reporting of these indicators by validating (through data quality assessments (DQAs)), strengthening and using the routine patient monitoring system rather than creating parallel systems.

3.4.9 Monitoring considerations for paediatric populations

Monitoring for children includes general and HIV-specific monitoring. Age disaggregation (five-year intervals) is important, as interventions may depend on age.

Key general child health monitoring includes:

- growth monitoring (weight, height and mid-upper arm circumference measurements)
- developmental assessments to determine achievement of motor, sensory, cognition, communication, behaviour, social and adaptive skills
- immunizations based on country-specific immunization schedules
- infant feeding practices in the context of HIV. (WHO infant feeding guidelines recommend that mothers who are living with HIV, receiving ART and have suppressed VLs can breastfeed their infants up to two years of age, with exclusive breastfeeding in the first six months *(2)*.)

All of the above are included in the HIV patient card (see Web Annex H).

Key paediatric indicators to monitor, in addition to the 80 priority HIV indicators, include:

- immunization coverage, especially first-dose diphtheria–pertussis–tetanus (DPT1) coverage, as this is a key time point for other interventions for HIV exposed infants
- breastfeeding (exclusive breastfeeding and duration of breastfeeding)
- nutritional status
- coverage of nurturing care interventions.

Infants and young children exposed to HIV may be identified early, if the mother is receiving services for prevention of vertical transmission, or late, if the child is identified outside the cascade of interventions for prevention of vertical transmission.

- Infants identified as exposed during pregnancy or immediately postpartum may be classified as high or low risk for HIV transmission depending on prevailing conditions – for example, mother on ART and maternal VL suppressed during pregnancy and delivery. These infants will receive postnatal prophylaxis (single ARV for six weeks if low risk or dual ARVs for six weeks followed by dual or single ARVs for an additional six weeks if high risk). If the risk of transmission remains high during breastfeeding, postnatal prophylaxis may be extended or prolonged beyond 12 weeks *(2)*.
- Infants identified as exposed to HIV late, especially if their mothers are not on ART or virally suppressed and/or suspected to already have been infected, may receive presumptive treatment with triple combination ARVs. If HIV infection is ruled out, postnatal prophylaxis is provided as for high-risk infants up to 12 weeks. If HIV infection is confirmed, the presumptive treatment is transitioned to recommended first-line ART as per WHO 2021 HIV prevention, testing, treatment and care guidelines *(2)*.

Key indicators to monitor are:

- postnatal prophylaxis coverage (the numerator is defined as HIV-exposed infants provided with postnatal prophylaxis, but the denominator is described differently in different settings, as the number of HIV-exposed infants identified or the number of women in need of prevention of mother-to-child transmission (PMTCT) or women infected with HIV. The coverage is anticipated to be much lower if the estimated number of HIV-exposed infants is the denominator);
- co-trimoxazole coverage;
- the timing, duration and number of infants acquiring HIV through vertical transmission, disaggregated for the timing of transmission;
- ANC and postnatal care (PNC) attendance;
- maternal HIV testing and re-testing coverage;
- maternal ART coverage during pregnancy and breastfeeding;
- maternal viral suppression during pregnancy and breastfeeding.

ART for children living with HIV

Based on the new guidelines for optimization of ART for children, treatment optimization status will be key for monitoring children, as paediatric DTG is still not widely available *(1)*. It will be important to monitor transition to optimized regimens (to DTG-based regimens for children >20 kg and to lopinavir/ritonavir (LPVr) or DTG for children <20 kg). As DTG becomes more available, transition to paediatric DTG for children previously optimized to LPVr should also be monitored. Treatment monitoring should follow the WHO recommended VL algorithm *(1)*. Access to psychosocial support for adherence should also be monitored. Treatment

guidelines also recommend optimized second-line regimens, which may be either DTG-based or protease inhibitor (PI) based. However, delayed switch to second-line regimens may lead to increased morbidity and mortality. The following data elements are recommended to monitor transition to optimized regimens for children:

- number/percentage of children >20 kg on DTG-based regimens
- number/percentage of children <20 kg, disaggregated by either LPVr or DTG
- children receiving VL test at six months after initiation of ART and then annually
- children receiving TB prophylaxis (based on the regimen in the country guidelines)
- co-trimoxazole prophylaxis coverage
- children receiving multi-month ARV dispensing, disaggregated by age and duration of dispensing
- rates of VL suppression, disaggregated by age
- number of children receiving psychosocial support
- ART attrition
- number of children on second-line ART and percentage of children eligible for second-line regimen who are on an optimized second-line regimen.

In addition, as children transition into adolescent and adult care, longitudinal monitoring, with linkage and flow of data including patient records, is important to ensure person-centred care over the life course.

3.5 Monitoring vertical transmission

Box 3.8 What's new in monitoring vertical transmission?

- A focus on strengthening monitoring of the PMTCT cascade for prevention of mother-to-child transmission (PMTCT) across multiple service delivery points and extended follow-up to improve tracking throughout the entire exposure period;
- Increased emphasis on elimination of vertical transmission of HIV to reduce new infections in infants/young children as well as improve maternal health; this is accompanied by monitoring of HIV vertical transmission that focuses on cascade outcomes such as viral suppression (see below) and early infant diagnosis and tracking service milestones at time points linked to the vertical transmission risk period.
- A priority indicator on VL suppression at labour and delivery (VER.1), introduced in 2020 to enable monitoring of the health of pregnant and breastfeeding women living with HIV as well as risk of vertical transmission from women to their infants or young children.

In 2021 WHO released guidelines that included updates to recommendations on treatment and VL monitoring for all populations, including pregnant and breastfeeding women *(2)*, as well as, in 2020, indicators for monitoring vertical transmission of HIV *(1)*. Elimination of mother-to-child transmission of HBV has also been adopted to promote service integration and triple elimination of vertical transmission of HIV, syphilis and HBV *(23, 24)*. In addition, with new infections during pregnancy and breastfeeding an increasing concern, retesting for HIV of all pregnant women with unknown or HIV-negative status in late pregnancy, at a third trimester visit is also recommended in high burden settings. One additional retest during pregnancy (at 14 weeks, six months or nine-months) can also be considered for those at high ongoing risk in such settings *(5)*. In line with this recommendation, an additional indicator (VER.8) was introduced in 2020 to enable monitoring of implementation (see Web Annex B). Additional indicators are designated indicators that countries can consider to refine their national priority sets and track in more depth efforts to strengthen services in specific programme areas.

Table 3.6 Priority indicators for vertical transmission and updates

Ref. no.	Short name	Indicator definition	Numerator	Denominator	Updates
VER.1 ●	Viral suppression at labour and delivery	% of HIV-positive pregnant women who are virally suppressed at labour and delivery	Number of HIV-positive pregnant women on ART during pregnancy and delivering at a facility during the reporting period who were virally suppressed (<1000 copies/mL) at delivery	Number of HIV-positive pregnant women on ART during pregnancy who deliver at a facility during the reporting period and had a viral load test during delivery, or the estimated total number of pregnant women living with HIV.	**New indicator** in 2020
VER.2	Early infant diagnosis (EID) coverage	% of HIV-exposed infants who receive a virological test for HIV within two months (and 12 months) of birth	Number of HIV-exposed infants born during the reporting period who received a virological HIV test within two months (and 12 months) of birth	Estimated number of HIV-positive women who delivered during the reporting period	**Retained indicator.** Additional disaggregation to include % of HIV-exposed infants who receive a virological test for HIV at *12 months* of age (previously only within 2 months). This enables disaggregation by age of infants <2 months and 2–12 months.

Table 3.6 (continued) Priority indicators for vertical transmission and updates

Ref. no.	Short name	Indicator definition	Numerator	Denominator	Updates
VER.3	Infant ARV prophylaxis coverage	% of HIV-exposed infants who initiated ARV prophylaxis	Number of HIV-exposed infants born within the past 12 months who were started on ARV prophylaxis at birth	**a) Programme-based / service delivery denominator:** Number of HIV-positive women who delivered in a facility within the past 12 months **b) Population-based denominator:** Number of HIV-positive women who delivered within the past 12 months	**Retained indicator.** No changes.
VER.4	ART coverage in pregnant women	% of HIV-positive pregnant women who received ART during pregnancy and/or at labour and delivery	Number of HIV-positive pregnant women who delivered during the reporting period and received ART during pregnancy and/or at labour and delivery	**a) Programme-based / service delivery denominator:** Number of HIV-positive pregnant women who delivered during the reporting period and attended ANC or had a facility-based delivery **b) Population-based denominator:** Number of HIV-positive pregnant women who delivered during the reporting period	**Modified indicator.** Updates the numerator to specify that this includes women who delivered in the reporting period and received ART in labour and delivery as well as pregnancy
VER.5	ART coverage in breastfeeding mothers	% of HIV-exposed breastfeeding infants whose mothers are receiving ART at 12 (and 24 months) postpartum	Number of HIV-exposed breastfeeding infants whose mothers are receiving ART at 12 months (and 24 months[a]) postpartum	Number of HIV-exposed infants attending MNCH services for a 12-month visit (and 24-month visit or first visit after the end of breastfeeding)	**Modified indicator.** Time period for measuring ART coverage updated from 3 and 12 months to 12 and 24 months postpartum

Table 3.6 (continued) Priority indicators for vertical transmission and updates

Ref. no.	Short name	Indicator definition	Numerator	Denominator	Updates
VER.6 ●	Final outcome of PMTCT	% of HIV-exposed infants whose final HIV outcome status is known	Number of HIV-exposed infants born within the past 12 months (or 24 months in breastfeeding settings) who have known final HIV outcome status	**a) Programme-based / service delivery denominator:** Number of HIV-exposed infants who were born within the 12 months (or 24 months in breastfeeding settings) prior to the reporting period and registered in the birth cohort **b) Population-based denominator:** Estimated number of HIV-positive women who delivered within the past 12 months (or 24 months in breastfeeding settings)	**Modified indicator.** Time period for the numerator and denominator for this indicator updated as follows: **Updated numerator:** HIV-exposed infants born within the past 12 months (or 24 months in breastfeeding settings) with known final outcome status (previously HIV-exposed infants ages 18 months or 3 months after breastfeeding) **Updated programme-based / service delivery denominator:** Number of HIV-exposed infants who were born within the 12 months (or 24 months in breastfeeding settings) prior to the reporting period and registered in the birth cohort (previously HIV-exposed infants ages 18 months or 3 months after breastfeeding). For example, for the reporting period January to December 2021, the denominator would be the number of HIV-exposed infants born between January and December 2020 in non-breastfeeding settings and between January and December 2019 in breastfeeding settings.

Table 3.6 (continued) Priority indicators for vertical transmission and updates

Ref. no.	Short name	Indicator definition	Numerator	Denominator	Updates
VER.7 (NEW)	HIV prevalence among women attending ANC	% of pregnant women who are HIV - positive at the time of their first test during the current pregnancy	Number of ANC attendees who tested positive at their first test during the current pregnancy *plus* number of ANC attendees known to be HIV-positive before first ANC visit	Number of ANC attendees receiving their first HIV test during pregnancy *plus* number of ANC attendees known to be HIV-positive before first ANC visit	**New indicator** introduced in 2022 for HIV surveillance

● Core indicator

[a] Or a timeframe matched to median duration of breastfeeding in the country.

HIV testing at antenatal clinics is used for surveillance in most countries. To ensure that surveillance measures are accurate, only the outcomes of the first test during each pregnancy are used in those systems. It is critical that second and third tests during a pregnancy are identified as such, to avoid their use when calculating ANC prevalence.

Other recommendations relevant to monitoring the care of pregnant and breastfeeding women include recommendations for DSD (see section 3.7). These updates collectively necessitate changes to HIV patient monitoring for pregnant and breastfeeding women and their infants, including updates to tools and indicators. These are described below and in relevant sections and annexes for HIV testing and DSD (sections 3.3 and 3.7).

3.5.1 Conceptual framework for preventing vertical transmission

Monitoring of PMTCT services needs to follow the cascade across multiple service delivery points and over a prolonged period, for both mother and child' from primary prevention and access to comprehensive sexual and reproductive health services to diagnosing and treating HIV-positive mothers and retaining them on ART, ensuring safe delivery and optimizing infant feeding practices to, finally, tracking exposed infants and young children throughout the exposure period to ensure early diagnosis and treatment of those who become infected.

3.5.2 Following the cascade across multiple service delivery points and over prolonged periods

Tools to collect data must reflect the patient care workflows of these different service delivery points and possibly different health facilities and be able to track mother–baby pairs from one such point to another. The patient monitoring system for vertical transmission relies on robust systems for assigning UIDs to link records of the mother or the mother–baby pair, integrating HIV information into existing MNCH cards or using electronic health information systems to facilitate this process. Therefore, it is important to integrate PMTCT and paediatric HIV care and treatment services with MNCH care and to ensure that patient monitoring systems for HIV and other MNCH care are also integrated. The HIV patient monitoring system can support this integration in various ways, for example, by promoting the early provision of PMTCT interventions by recording the pregnancy or family planning status of women of childbearing age at each visit, strengthening monitoring of the outcomes of the PMTCT cascade and capturing cross-referrals to and from MNCH services.

3.5.3 Monitoring key outcomes towards elimination of vertical transmission

The vertical transmission indicators recommended in this guidance reflect important updates to definitions and disaggregation for tracking progress and managing PMTCT programmes across the array of services offered (Table 3.6). The indicators for monitoring vertical transmission were updated in 2020 to focus on outcomes such as viral suppression and early infant diagnosis in addition to intermediate outcomes such as ART coverage in pregnancy and breastfeeding and infant ARV prophylaxis. Seven indicators are designated as national priority indicators, linked to critical time points in the vertical transmission risk period. This prioritization is intended to assist countries in focusing resources on strengthening the data sources, data collection tools (in this case HIV patient monitoring tools) and data quality assurance mechanisms to enable data use for both patient care and programme management. These changes are reflected in the updated annexes to the patient monitoring tools (Web Annex H, HIV care card; Web Annex K, ART register) and the minimum dataset for HIV (Web Annex A).

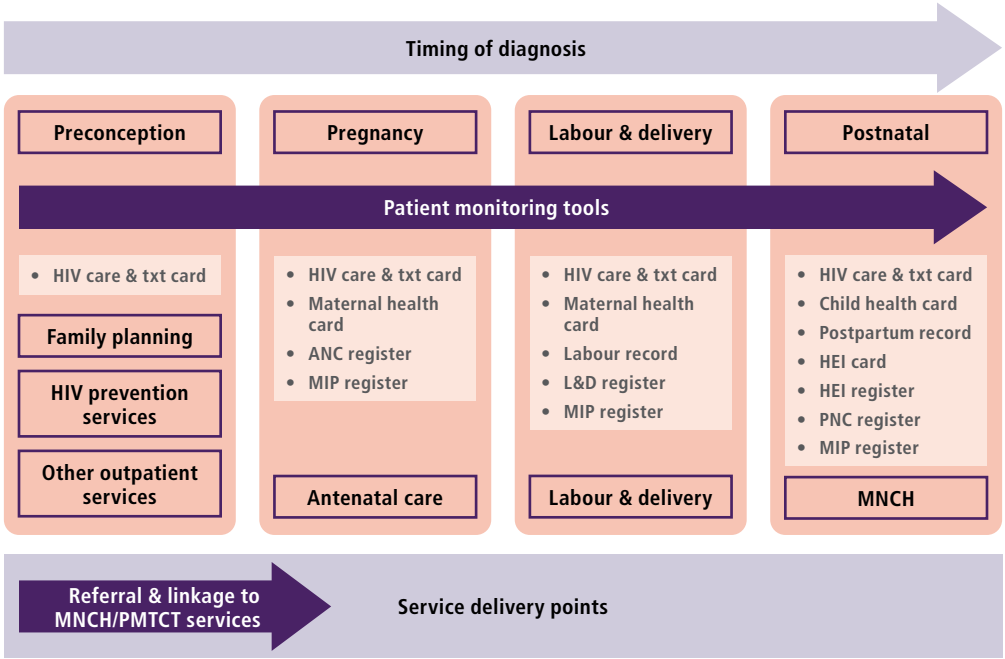
A new indicator, VER.1, was introduced in 2020 on viral suppression at labour and delivery and added as one of the key 2025 targets of the 2021 UN political declaration on HIV and AIDS *(25)*. This indicator provides important information for monitoring the health of pregnant and breastfeeding women living with HIV as well as risk of vertical transmission. It reflects updates to the 2021 WHO HIV clinical recommendations (see Box 3.8).

Table 3.6 summarizes the seven priority indicators for vertical transmission and updates to the indicators since release of the 2017 WHO guidelines for person-centred HIV patient monitoring and case surveillance. For full indicator definitions, see Chapter 8.

Monitoring of the vertical transmission indicators relies on consistently capturing key data elements using a range of patient monitoring tools that reflect patient flow across an array of service delivery points (for example, at MNCH/ANC and at a separate ART clinic at the same or a different site). The availability of data for indicator VER.6. Final PMTCT outcome status is especially challenging in some settings, particularly where many women do not return to facilities after delivery.

Pregnant and breastfeeding women can interact with different service delivery points in a variety of scenarios, which has implications for monitoring service delivery and outcomes. These include a woman who has either already been identified as living with HIV (and is or is not enrolled in HIV care) and then becomes pregnant or is identified as living with HIV during antenatal care (ANC), labour and delivery, or postnatal follow-up. If the woman is already enrolled in HIV care (and on ART) and becomes pregnant, it is crucial that she is referred to MNCH/PMTCT services, either at her current facility or elsewhere, for appropriate pregnancy related care, and to record this on her HIV patient card or equivalent EMR. If the woman is given a special PMTCT or ANC or other UID number, it should also be recorded, to facilitate reconciliation of data. Women who are confirmed as living with HIV in MNCH settings should be enrolled in HIV care directly with a HIV patient card or equivalent EMR and immediately entered into the ART register once started on ART. Fig. 3.6 summarizes the key patient monitoring tools that may be used to track service delivery and key outcomes across service delivery settings and according to where and when a woman is diagnosed.

Fig. 3.6 Summary of key patient monitoring tools to monitor the PMTCT cascade across a range of service delivery settings



Abbreviations: ANC = antenatal care; ART = antiretroviral therapy; HEI = HIV-exposed infant; L&D = labour and delivery; MIP = mother–infant pair; MNCH = maternal, newborn and child health; PNC = postnatal care; txt = treatment

3.5.4 Follow-up of the mother–infant pair

Strengthening follow-up of mother–infant pairs, from ANC, labour and delivery (maternity) and postpartum maternal visits to child health clinics and ART services, remains critical for elimination of vertical transmission and improved maternal and child health outcomes. A mother–infant pair register can be used for this (see Box 3.9). Monitoring tools should capture the full spectrum of care that HIV-exposed infants should receive, that is, ARV and co-trimoxazole preventive therapy, timely HIV nucleic acid testing, appropriate infant-feeding practices, testing for final outcome status, and ART if diagnosed HIV-positive. Also, recording the mother's UID number, where in use, on the infant's record supports linkage and follow-up of mother–infant pairs.

All care is monitored through the mother's HIV patient card. This is critical to support her adherence, retention and VL suppression throughout the vertical transmission risk period. However, once an infant is confirmed HIV-positive, a separate card or equivalent EMR should be created, and the child should receive a UID number.

HIV data elements integrated into the following generic MNCH tools facilitate monitoring the full cascade of care of the mother living with HIV and her HIV-exposed infant/young child in MNCH settings (see Box 3.10). The list of data elements has been updated in this guidance to reflect updates in recommendations, including inclusion of VL testing during pregnancy and/or at delivery, hepatitis B ANC screening and administration of birth-dose hepatitis B vaccine. Additional data elements relevant to MNCH care specifically are listed in Web Annex A (Minimum dataset for HIV, ANC, labour, postpartum and HIV-exposed infant follow-up) and are drawn from the following tools:

- maternal health card
- ANC, labour and delivery, and PNC registers
- labour and postpartum records
- child health card.

Box 3.9 Key considerations for using mother–infant pair registers

An HIV-exposed infants register should be used to follow the entire cascade of care through to the final outcome of the exposed infant/young child. In some settings it may be possible to use a longitudinal mother–infant pair register to capture the range of PMTCT interventions specifically for mothers living with HIV and their exposed infants (see Appendix 3 in the 2015 IATT Option B/B+ M&E Framework *(26)*). This option may be particularly practical in settings:

- with lower prevalence (for example, <10%)
- with concentrated epidemics
- where MNCH and HIV service delivery occurs in the same facility or site
- where services not being provided in the same place but with provisions for updating the register (for facilities with paper-based reporting systems)
- where linked electronic information systems are in use and so it may be feasible to conduct longitudinal follow-up of mother–infant pairs.

WHO recommends organizing the mother–infant pair register by expected date of delivery, rather than ANC registration date, so that infant outcomes are obtainable by rough birth cohort. With either option, mothers on ART would still be captured in an ART register wherever it is provided. Recording patient or UID numbers for ART, ANC and HIV-exposed infants in the relevant HIV and MNCH patient monitoring tools can help to link the mother–infant pair to care.

Box 3.10 Data elements relevant for HIV care and treatment of pregnant and postpartum women and their infants/young children

ANC elements

- name, date of birth, age, marital status
- address
- patient clinic ID number/UID number
- ANC registration number
- **first ANC visit date***
- district
- health facility
- estimated due date (EDD)
- HIV status at enrolment
- date positive HIV test confirmed OR HIV test date, HIV test result for first test during the pregnancy
- partner's HIV test result
- date enrolled in HIV care
- **ART status at enrolment***
- date started ART
- ARV regimen (date and dose dispensed)
- visit date
- weight
- CD4 count (date of sample collection and date of results)
- **HIV VL (date and results)***
- CPT (dates started and completed, dose (mg), number of days dispensed)
- reproductive/family planning choice
- TB status
- TB preventive therapy (dates started and completed)

Box 3.10 (continued) Data elements relevant for HIV care and treatment of pregnant and postpartum women and their infants/young children

- infant-feeding counselling
- ART adherence counselling
- ART adherence
- syphilis test date
- syphilis test results
- syphilis treatment
- **HBsAg test date***
- **HBsAg test results***
- **HBV prophylaxis start date for those eligible***

Labour and delivery, postpartum elements

- HIV status at admission
- date positive HIV test or retest confirmed OR HIV test date, HIV test result
- date started ART
- ARV regimen
- infant-feeding counselling
- infant-feeding choice/practice
- infant ARV prophylaxis (date and drug(s) dispensed)
- reproductive/family planning choice
- referred to HIV care (if applicable)
- TB status
- TB preventive therapy (dates started and completed)
- **HIV VL date and results***

Child health card data elements

- maternal HIV status
- maternal syphilis test date and results
- maternal syphilis treatment and date
- infant date of birth
- infant-feeding counselling (and date)
- infant-feeding choice/practice (and date recorded)
- maternal ART (start date, ARV regimen)

Box 3.10 (continued) Data elements relevant for HIV care and treatment of pregnant and postpartum women and their infants/young children

- infant ARV prophylaxis (date and drug(s) dispensed)
- infant age in weeks/months when tested and date
- infant HIV test type
- infant HIV test result
- infant syphilis treatment if indicated and date
- infant age in weeks/months when started on CTX
- infant final outcome status
- date infant enrolled in HIV care
- infant UID
- infant ART start date
- TB status
- TB preventive therapy (dates started and completed)
- **maternal HBsAg test date and result***
- **HBV birth dose (date)***

HIV-exposed infants register data elements

- date of birth (delivery)
- HIV-exposed infant registration number
- mother's UID
- exposed infant's name
- mother's ART start date
- maternal ART at 3, 12 and 24 months postpartum (Y/N)
- HIV-exposed infant ARV prophylaxis (date and drug(s) dispensed)
- infant-feeding practice at 3 months (DTP3 visit)
- age in weeks/months when started on CPT
- TB status
- TB preventive therapy (dates started and completed)
- infant HIV test sample collection date
- age in weeks/months when tested
- HIV test type
- infant HIV test result
- date HIV test result given

Box 3.10 (continued) Data elements relevant for HIV care and treatment of pregnant and postpartum women and their infants/young children

- **age in months when additional infant HIV test(s) is/are done and date***
- final outcome status of HIV-exposed infant (at 12 months in non-breastfeeding settings and 24 months in breastfeeding setting)
- date enrolled in HIV care
- infant UID
- ART start date.

* Asterisk and bold type Indicate updates since the 2017 WHO Consolidated guidelines on person-centred HIV patient monitoring and case surveillance *(27)*. Note that the majority of data elements, particularly demographic variables, need be recorded/entered only once. See Web Annex A, Minimum dataset for HIV, for further details of each data element.

3.6 Monitoring TB/HIV

Box 3.11 What is new in TB–HIV patient monitoring in 2020

- Updates to the TB–HIV indicators on TB preventive treatment (TPT) initiation and completion; TB diagnostic testing with molecular WHO-approved rapid diagnostics among people living with HIV; and TB burden among new ART patients
- Updated TPT regimens, including 6H and shorter rifamycin-based regimens
- Five additional indicators reflecting the TB screening and diagnostic cascade, which are recommended for countries that are a priority for high-burden TB–HIV.

High comorbidity and mortality due to HIV-associated TB require an integrated approach to service delivery as well as patient monitoring. WHO has recommended 12 collaborative TB–HIV activities since 2004 *(28)*.

WHO has introduced a number of new recommendations to address HIV-associated TB that have relevance for recording and reporting. These include the following:

- additional TB screening tools for ruling in and for ruling out TB disease that are to be used in addition to the WHO-recommended four-symptom screen; these include, as feasible, chest X-ray, C-reactive protein and molecular WHO-approved rapid diagnostics *(29)*;
- A broader range of options for TPT, including 6H and shorter rifamycin-based regimens *(2)*;
- Initiation of ART within two weeks of starting TB treatment for all people living with HIV, regardless of CD4 cell count *(2)*.

TB/HIV collaborative activities are monitored nationally and globally. They are described in the 2015 WHO *Guide to monitoring and evaluation for collaborative TB/HIV activities (30)* and the 2020 *Consolidated HIV strategic information guidelines (1)*. The HIV patient monitoring system captures several of these indicators.

3.6.1 TB in people living with HIV captured in the HIV patient monitoring system

Services to reduce the burden of TB among people living with HIV, which are measured and reported from the HIV patient monitoring system, include initiation of ART, intensified case-finding, TPT and infection control *(28)*. The 2020 *Consolidated HIV strategic information guidelines* include TPT completion as a national core indicator as well as key indicators to capture the TB diagnostic and care cascade for high TB–HIV burden countries. Box 3.12 presents important interventions that can be measured using the HIV patient monitoring system.

Box 3.12 TB–HIV indicators

National core

- TPT initiation (TBH.1. Number and % of eligible people living with HIV on ART who initiated TPT)
- TPT completion (TBH.2. Number and % of people living with HIV on ART who completed a course of TPT among those who initiated TPT).

National priority

- TB diagnostic testing type (TBH.3. % of people living with HIV with TB symptoms who receive a rapid molecular test, for example, Xpert MTB/RIF, as a first test for diagnosis of TB)
- People living with HIV with active TB disease (TBH.4. % of people living with HIV newly initiated on ART who have active TB disease).

For high TB–HIV burden countries *(31)*

- DFT.1. TB screening coverage among new ART patients
- DFT.2. TB symptom-screened positive[1] among new ART patients
- DFT.3. TB testing among those symptom-screened positive[2]
- DFT.4. TB diagnosis among those tested for TB
- DFT.5. TB treatment initiation among diagnosed.

See Chapter 8 for definitions of the above indicators.

[1] In 2021 WHO released new recommendations on tools for TB screening among PLHIV, in addition to the WHO-recommended four-symptom screen. Additional tools for ruling in and ruling out TB disease include C-reactive protein, chest X-ray and molecular WHO-recommended rapid diagnostics.

[2] Appropriate diagnostic TB tests include molecular WHO-recommended rapid diagnostic test for TB; LF-LAM for TB; microscopy-sputum acid-fast bacilli (AFB) examination (alone) and sputum culture for TB.

3.6.2 HIV in presumptive and diagnosed TB patients captured in the TB patient monitoring system

The TB definitions and reporting framework with integrated HIV recording and reporting requirements have been developed and updated previously by WHO *(4)*. These guidelines provide, in addition, a list of supplementary recommended HIV data elements to be included in programme-specific TB monitoring tools.

Monitoring of HIV among TB patients is based on a standardized TB patient treatment card and registers and reports using globally standardized definitions *(4)*. Although forms and registers may vary slightly between countries, the core data collected and definitions are quite consistent. The reporting unit is the TB basic management unit (BMU), and summary reports on programme performance are usually produced quarterly by the clinical team and district coordinator/programme managers. Increasingly, countries are moving from paper-based recording and reporting to electronic data systems, for example, District Health Information Software (DHIS-2). Similarly, digital apps such as the Prevent TB App[1] can be used to aid real-time capture of data and cross-programme collaboration.

Services provided to reduce the burden of HIV in patients with presumptive or diagnosed TB, which are measured and monitored by the TB programme, include the following:

- CPT among TB patients
- new and relapse TB patients tested for HIV at the time of TB diagnosis or with known HIV status at the time of TB diagnosis
- new and relapse TB patients with an HIV-positive test result
- HIV-positive new and relapse TB patients started or continued on ART.

The numerator and denominator for ART started among TB patients require reconciliation with ART and TB registers to ensure that data on all patients are captured and not duplicated. Indicators for HIV testing, HIV prevalence among TB patients, TB treatment outcomes, including mortality among HIV-positive TB patients, are national TB–HIV indicators collected specifically from TB programme records and, therefore, not included in this guidance.

3.6.3 Coordination of care, treatment and patient monitoring

Robust mechanisms for effective coordination, referral and communication between TB and HIV services should be established to ensure effective care and treatment of both diseases. Electronic data systems can facilitate integrated patient monitoring, which captures information on how well HIV prevention, diagnosis and care or referral for HIV care take place within TB programmes, and how well TB screening, prevention and treatment are carried out in HIV care/ART programmes. Some of the core indicators require data collection and reconciliation by the national HIV and TB programmes in tandem. HIV and TB clinics may be co-located (in the same building or next door to each other), which facilitates cross-referral, co-treatment and reconciliation of patient cards and registers. For example, patients who are tested for TB may receive results from the TB clinic and may walk over with the results to their clinical worker in the HIV clinic, who in turn records the results in the HIV patient card.

[1] To access the WHO Prevent TB mobile app, see: https://www.who.int/activities/preventing-tb.

Box 3.13 Data source and elements for joint management of HIV-associated TB

An HIV patient card or electronic equivalent should be started for all patients who test HIV-positive at TB clinics, and once started on ART, the patient should be entered in an ART register in that setting or electronic record equivalents

In settings with high TB–HIV comorbidity, integrated patient records (either a patient folder with separate HIV and TB cards or a single patient record that captures information on both diseases) can simplify patient care, monitoring and management, especially when carried out by the same health worker.

Table 3.7 summarizes the data sources and data elements required for monitoring the joint management of HIV-associated TB. Box 3.14 lists additional HIV data elements recommended for inclusion in the TB patient monitoring tools.

Table 3.7 Data source and elements for joint management of HIV-associated TB

HIV patient card and ART register (Web Annexes H and K)		
Data source	**Data element**	**Details codes**
HIV patient card	Status at start of ART	• confirmed TB • on TB treatment • TB-exposed infant
	TB status	• assessment not done • no signs or symptoms of TB[a] • presumptive TB • unconfirmed/confirmed TB • type of TB • TB/MDR-TB Rx (record month and year of starting TB/MDR-TB treatment and registration number)
	TB preventive treatment	• start/complete dates
	TPT regimen	• isoniazid/shorter rifamycin-based regimen
	Other medicines dispensed	• record TB/MDR-TB treatment regimen
	Investigations	Investigation and results from one or more of the following: • molecular WHO-recommended rapid diagnostic test (mWRD), for example, Xpert MTB/RIF • LF-LAM • TB sputum microscopy • chest x-ray

Table 3.7 (continued) Data source and elements for joint management of HIV-associated TB

ART register (page 1)	TB confirmation	• active TB at start of ART
	TB prevention	• TPT start and complete (month/year)
	TPT regimen	• isoniazid/shorter rifamycin-based regimen
	TB/DR-TB treatment	• TB treatment start (month/year) and TB registration number
Tuberculosis records and registers (WHO 2006,[b] 2013[c])		
Data source	**Data element**	**Details codes**
Request form for examination of biological specimen for TB	HIV infection	Yes, No, Unknown
Register of TB suspects (presumptive TB)	Result of HIV test	Positive, Negative, Indeterminate, Not done
Laboratory register for smear microscopy and mWRD	HIV infection	Yes, No, Unknown
Laboratory register for culture, mWRD and drug susceptibility testing	HIV infection	Yes, No, Unknown
TB treatment card	HIV test	Date, result (Positive, Negative, Indeterminate, Not done)
	CPT start	Date
	ART start	Date
Basic management unit TB register/ Second-line TB treatment register	HIV infection	Yes, No, Unknown
	CPT start	Yes, No
	ART start	Yes, No
Quarterly report on TB case registration in the basic management unit	Patients tested for HIV at the time of TB diagnosis or with known HIV status at the time of TB diagnosis (all new and relapse TB cases)	TB patients tested for HIV at the time of TB diagnosis or with known HIV status at the time of TB diagnosis HIV-positive TB patients HIV-positive TB patients on ART HIV-positive TB patients on CPT

Table 3.7 (continued) Data source and elements for joint management of HIV-associated TB

Quarterly report on TB treatment outcomes in the basic management unit	HIV-positive TB patients (all new and relapse TB cases)	Number of cases registered, number cured, treatment completed, treatment failed, died, LTFU, not evaluated HIV-positive TB patients HIV-positive TB patients on ART
Combined annual report on treatment outcomes for basic TB and for RR-TB/MDR-TB	Treatment outcome in HIV-positive, new and relapse TB cases, and RR-TB/MDR-TB cases	Number of cases registered/started on TB treatment, number cured, treatment completed, treatment failed, died, LTFU, not evaluated

Abbreviations: ART= antiretroviral therapy; CPT= co-trimoxazole preventive therapy; LF-LAM= lateral flow urine lipoarabinomannan assay; MDR= multidrug resistant; mWRD= molecular WHO-approved rapid diagnostic test; RR= rifampicin-resistant.

[a] New recommendations on tools for TB screening among people living with HIV, in addition to the WHO-recommended four-symptom screen, were released in 2021. Additional tools for ruling in and ruling out TB disease include C-Reactive Protein, chest X-ray and molecular WHO-recommended rapid diagnostics.

[b] WHO, 2006 *(32)*.

[c] WHO, 2013 *(4)*.

Box 3.14 Additional HIV data elements recommended for inclusion in the TB treatment card and registers

- UID number
- Patient's clinic ID number
- ANC number
- CD4 cell count (date sent, results)
- HIV VL (date sent, results)
- ARV regimen (date and dose dispensed).

3.7 Monitoring service delivery for HIV treatment and care

3.7.1 Introduction

In 2021 WHO released updated recommendations on treatment and care service delivery for people living with HIV *(3)* with a series of recommendations and good practice statements intended to promote continued improvements in access to ART, to simplify care delivery for providers and end users and to support return to care for those who have disengaged (Box 3.15). These recommendations include approaches for DSD of HIV treatment, recognizing the diverse needs of people living with HIV and adapting accordingly how HIV services are provided.

This section presents eight key WHO 2021 recommendations for service delivery that contribute to the implementation of DSD models. It focusses on monitoring DSD for HIV treatment in a public health approach that uses simplified and standardized ART to support the decentralization of care, task sharing, community delivery and more efficient procurement and supply management *(3)*.

3.7.2 Overview of DSD

DSD is a person-centred approach that simplifies and adapts HIV services across the care and treatment cascade to reflect the needs and preferences of people living with HIV or vulnerable to infection. At the same time, it optimizes the use of available health system resources. "DSD seeks to create efficiencies in HIV service delivery to achieve programme expansion, while ensuring that care meets the diversity of patient needs" *(33)*. It entails programmatic shifts in the way services are targeted and delivered, focusing on four building blocks:

1. *what* – the type of services delivered
2. *where* – the location of service delivery (health facility or the community)
3. *who* – client eligibility criteria/specific populations or type of health service provider
4. *when* – the frequency of services such as clinical visits, ARV refills and psychosocial support.

DSD for HIV treatment can be classified into four categories: 1) group models managed by health care workers; 2) group models managed by clients; 3) individual models based at facilities; and 4) individual models not based at facilities.

Within these four general categories, many adaptations can be made to provide person-centred health services that meet the distinct and evolving needs of specific populations – for example, those receiving second- or third-line regimens, those with controlled comorbidities, key populations, pregnant and breastfeeding women, children and adolescents. In addition, adaptations can help to address contexts where service delivery is disrupted or must be adapted, for example, in the context of the COVID-19 pandemic. Whatever the specific permutations of the model, it is important to monitor DSD implementation in order to assess needs and opportunities for further adaptations to continue improving patient outcomes and programme efficiencies.

Box 3.15 WHO 2021 service delivery recommendations

- ART initiation may be offered outside the health facility *(new, conditional)*.
- People established on ART should be offered clinical visits every 3–6 months, preferably every six months if feasible *(update, strong)*. [Box 3.16 lists criteria for determining whether a person is established on ART.]
- People established on ART should be offered refills of ART lasting 3–6 months, preferably six months if feasible *(update, strong)*.
- HIV programmes should implement interventions to trace people who have disengaged from care and provide support for re-engagement *(new, strong)*.
- Sexual and reproductive health services, including contraception, may be integrated with HIV services *(update, conditional)*.
- Diabetes and hypertension care may be integrated with HIV services *(new, conditional)*.
- Psychosocial interventions should be provided to all adolescents and young adults living with HIV *(new, strong)*.
- Task sharing of specimen collection and point-of-care testing with non-laboratory personnel should be implemented when professional staffing capacity is limited *(update, strong)*.

Source: WHO, 2021 *(3)*

Box 3.16 WHO criteria for determining whether a person is established on ART

To support implementation of these recommendations, WHO has developed the following criteria for determining whether a person has been successfully established on ART:

- receiving ART for at least six months;
- no current illness, which does not include well-controlled chronic health conditions;
- good understanding of lifelong adherence: adequate adherence counselling provided; and
- evidence of treatment success: at least one suppressed VL result within the past six months. (If VL is not available: CD4 cell count >200 cells/mm^3 or weight gain, absence of symptoms and of concurrent infections; for children 3–5 years, CD4 cell count >350 cells/mm^3.)

Monitoring for DSD also needs to include the 2016 WHO recommendations that address community support to improve retention in care and task shifting for initiating and maintaining ART in community settings (Box 3.17). For guidance on quality standards for differentiated ART service delivery, see *Quality standards for less-intensive differentiated ART models* (2019), developed by ICAP at the Columbia University CQUIN Project HIV Learning Network *(34)*.

Box 3.17 2016 WHO DSD recommendations on community support to improve retention and task sharing for initiating and maintaining ART

Programmes should provide community support for people living with HIV to improve retention in HIV care *(strong recommendation, low-certainty evidence).*

The following community-level interventions have demonstrated benefit in improving retention in care:

- a package of community-based interventions[1] *(children: low-certainty evidence; adults: very low-certainty evidence);*
- adherence clubs[2] *(moderate-certainty evidence)* and extra care for high-risk people *(very low-certainty evidence).*

Task sharing for initiating and maintaining ART

- **Trained and supervised community health workers can dispense ART between regular clinical visits** *(strong recommendation, moderate-certainty evidence).*
- **Trained and supervised lay health care providers can distribute ART** *(strong recommendation, low-certainty evidence).*

[1] Patient advocates, treatment and peer support interventions providing adherence and psychosocial support in the community.

[2] Peer support, distribution of ARV drugs and assessment by non-clinical or lay health care providers.

Source: WHO, 2016 *(35)*

3.7.3 Monitoring DSD

Patient monitoring systems must provide accurate and timely data on the diverse services and delivery models for DSD. Doing this requires adaptation of patient monitoring systems and tools and the introduction of indicators to monitor the unique aspects of DSD *(36, 37)*. Updates have been made to the HIV treatment and care patient card (see Web Annex H), ART register (Web Annex K), HIV cross sectional report (Web Annex L) and ART cohort report (Web Annex M) to enable monitoring of patients engaged in differentiated ART models.

The patient monitoring system should capture key information irrespective of where services are delivered. The health facility linked to the DSD provider should retain overall responsibility for clinical care and follow-up of clients. Data from community ART sites (for example, community ART groups (CAGs) and distribution points) should be promptly entered into facility-based patient monitoring systems. This is critical to avoid establishing parallel reporting systems and to ensure linkage and flow of data to improve patient management and care. Data from all community ART delivery models should be reviewed routinely at the facility level (and

higher) to improve services as well as data quality. Similarly, it is important to ensure that data are shared between public and private DSD delivery points, including ARV refill and real-time tracking of missed appointments *(38)*.

Critically, facility-based patient monitoring remains the main data system and should be adapted to identify and respond to missed appointments for clients engaged in DSD ensuring efficient flow of people and data at health facilities. If UIDs are used for clients initiating ART in community settings, ideally the health facility should issue the identifier and retain responsibility for confidentiality and security.

Another key consideration with the scale-up of DSD is interoperability between systems, including HIV patient monitoring (EMR/paper-based), community health information, logistics information management and supply and laboratory information systems, to harmonize appointment dates and facilitate timely tracking for missed medication pick-up appointments and pharmacy dispensing and to minimize disruptions in drug supply.

Given the multitude of DSD models adapted to different contexts and populations and the evolving nature of DSD implementation, this section provides overall guidance, including key indicators, data elements and sample tools as well as key considerations, to help countries design and implement DSD monitoring approaches applicable to their context and setting.

3.7.4 Key DSD indicators

Table 3.8 summarizes key indicators, drawn from the HIV patient monitoring system, recommended to monitor the coverage, uptake and clinical outcomes of DSD. These indicators do not, however, represent the entire range of DSD indicators required for programme monitoring and management. For this, countries should consider a wider range of indicators including the experience or satisfaction of clients and health care workers, facility uptake of DSD, efficiency of DSD services in terms of service delivery cost to facilities, out-of-pocket costs to clients, drug wastage, clinical consultation times, case load of health workers and time spent by clients engaged in DSD models, among others. WHO will issue further guidance that will cover M&E of these additional aspects of DSD. For an M&E framework for DSD developed by ICAP and the HIV Coverage and Quality Network M&E community of practice, see: http://cquin.icap.columbia.edu/wp-content/uploads/2017/11/CQUIN-ME-Framework_2018-1.pdf.

3.7.5 Multi-month ARV dispensing

This key indicator, DSD.1, multi-month ARV dispensing is recommended by WHO, the United States President's Emergency Plan for AIDS Relief (PEPFAR) and UNAIDS and is now included as a Global AIDS Monitoring (GAM) indicator. This is recommended as the minimum indicator for monitoring when DSD ART is rolled out in countries. As DSD implementation is expanded, five core indicators are recommended to track progress and patient outcomes for established programmes (Table 3.8 and Chapter 8).

Some key considerations for implementation of multi month ARV dispensing and resulting monitoring include:

- streamlining appointments for ARV drug pick-ups and clinical appointments, where possible, to alleviate burden on clients;
- aligning multi-month dispensing of prophylaxis and treatment for other co-infections and comorbidities, such as TB and chronic diseases, with ARV multi-month dispensing (depending on national guidelines for other disease areas).

Table 3.8 Priority indicators for DSD

Ref. no.	Short name	Indicator definition	Numerator	Denominator
DSD.1 ●	Multi-month ARV dispensing	% of people living with HIV and currently on ART who are receiving multi-month dispensing of ARV medicine during the reporting period	Number of people living with HIV and currently on ART who received 3–5 or ≥6 months of ARV medicine at their most recent ARV medicine pick-up	Number of people living with HIV and currently on ART
DSD.2	Uptake of DSD ART models among people living with HIV	% of people newly enrolled in DSD ART models among those eligible	Number of people on ART *newly* enrolled in DSD ART models during the reporting period	Number of people on ART *newly* eligible[a] for DSD ART models during the reporting period. For facilities with electronic health information systems, it is possible to measure uptake as a proportion of all people living with HIV eligible for DSD. No denominator for facilities with paper-based reporting systems
DSD.3	Coverage of DSD ART models among people living with HIV on ART	% of people living with HIV enrolled in DSD ART models among those eligible for DSD ART (for facilities with electronic HIS) or among people living with HIV currently on ART (facilities with paper-based systems) during the reporting period	Number of people living with HIV enrolled in DSD ART models during the reporting period	**Facilities with electronic health information systems** Number of people living with HIV on ART eligible for DSD ART models during the reporting period **Facilities with paper-based systems** Number of people living with HIV receiving ART at the end of the reporting period

Table 3.8 (continued) Priority indicators for DSD

Ref. no.	Short name	Indicator definition	Numerator	Denominator
DSD.4	Retention in DSD ART models	% of people retained in DSD ART models during the reporting period	Number of people on ART known to be on treatment 12 months after enrolling in a DSD ART model[b] (also at 24, 36, 48, 60 months, etc. after enrolment in the model)	Number of people on ART enrolled in a DSD ART model 12 months ago, excluding individuals who transferred out (also 24, 36, 48, 60 months ago, etc.)
DSD.5	Viral suppression among people living with HIV engaged in DSD ART models	% of people living with HIV engaged in DSD ART models who have virological suppression	Number of people enrolled in a DSD ART model with at least one routine VL test during the reporting period who have virological suppression (<1000 copies/mL) at 6 and 12 months after ART initiation and yearly thereafter (that is, at 24, 36, 48 and 60 months after ART initiation)	Number of people enrolled in a DSD ART model with at least one routine VL result in a medical or laboratory record during the reporting period

● Core indicator

[a] Eligibility for DSD ART as defined in national guidelines.

[b] Includes all people living with HIV on ART receiving DSD ART regardless of whether they switch models or there is a reduction in ARV drugs dispensed.

Abbreviations: ART = antiretroviral treatment; ARV = antiretroviral; DSD = differentiated service delivery; VL = viral load

Source: Adapted from ICAP at the Columbia University CQUIN Project HIV Learning Network, 2018 *(39)*

Uptake and coverage of DSD ART services

Indicators DSD.2 and DSD.3 track the rollout and implementation of DSD. Assessing uptake of DSD ART (indicator DSD.2) is especially relevant in the early stages of implementation and less critical for more mature programmes. The indicator on coverage of DSD ART models (indicator DSD.3), which assesses whether eligible people living with HIV on ART are receiving DSD, is an important indicator for all programmes, including mature DSD programmes. It may be useful to monitor, in addition to the five recommended DSD indicators, the implementation of the eligibility criteria for DSD ART to ensure that people living with HIV on ART are offered DSD ART if eligible and not if ineligible, according to national guidelines.

3.7.6 Clinical outcomes among people living with HIV enrolled in DSD ART models

Assessment of key clinical outcomes among people receiving differentiated ART can be used to evaluate the impact of DSD models. Outcomes such as ART retention (indicator DSD.4) and viral suppression (indicator DSD.5) can be compared before and after implementation of DSD. The retention period would be defined for a relevant period (for example, 12 or 24 months after ART initiation).

As various DSD models are implemented, conducting periodic assessments of patients' clinical outcomes enrolled in DSD ART models is recommended. Adapted quarterly ART cohort reports (Web Annex M) for clients engaged in DSD models can also be used to calculate ART retention outcomes and VL suppression. It is important to ensure that people enrolled in DSD are included in ART cohort monitoring and that measures are in place to prevent both double counting and undercounting to assure accurate drug supply management and programme monitoring.

If resources allow, annual or biannual review of medical records to assess retention of individuals enrolled in DSD models can supplement routine review of clinical outcomes. For all people living with HIV on ART, it is important to continuously assess treatment interruption and loss to follow-up. This means identifying individuals with no clinical contact for 28 days since last scheduled appointment/expected clinical contact (which in the context of DSD ART could be, for example, after seven months for those receiving 6-month ARV drug dispensing and clinical visits). See section below on tracing interventions to identify people who interrupt treatment and support their re-engagement in care.

As DSD models of care aim to enhance coverage, efficiency and quality of care, additional M&E approaches may be useful – for example, surveys of patient satisfaction and provider satisfaction, assessment of providers' patient load and productivity and cost-effectiveness evaluations of DSD models. Findings from these assessments may be used to track progress in implementation of key DSD elements (for example, establishment of specific DSD models, roles and responsibilities in ART distribution, use of patient monitoring tools) within facilities and may be linked with patient clinical data to identify trends in treatment outcomes as uptake of DSD increases.

For all DSD indicators, disaggregation by age, gender and key population status is recommended, as adults, adolescents, children above age five years, pregnant and breastfeeding women and members of key populations all are eligible for differentiated ART treatment and care services. Thus, it is important to monitor access and coverage of DSD models within these groups to identify service delivery gaps. At the programme level, the various models for specific populations may need monitoring and adaptation if they are not yielding the expected outcomes for a specific group. Monitoring patient outcomes by DSD model or category may be useful to identify which populations to target for DSD and inform programme investment decisions. However, it is not advisable to use outcomes disaggregated by model to directly evaluate the effectiveness of different DSD ART models, since enrolment is self-selected and limited to patients who are eligible.

3.7.7 Tracing interventions to identify people who interrupt treatment and support re-engagement in care

Implementing tracing interventions to identify individuals who have disengaged from care and provide them with support for re-engagement is among the key WHO 2021 HIV treatment and service delivery recommendations *(3)*. Individuals receiving DSD will visit a clinic as infrequently as every six months up to a year. At present, facilities often initiate tracing of patients who have missed appointments (and not picked up ART) or who have not visited a clinic within a certain period of time (for example, three months). To detect missed clinic visits among clients receiving DSD, reported ART pick-up dates will need to be incorporated into existing tools, including ART registers, patient cards/folders and EMR systems. This requires integration of services, including TB–HIV and maternal and child health. If the same health care worker is not providing multiple services, appointments need to be scheduled to coincide, as people may be accessing care at different service delivery points.

Criteria defining disengagement from care depend on information on missed ART pick-up (or a missed appointment, which should coincide with the ART pick-up date) and account for expected gaps between ART refill visits. With appropriate procedures in place to identify people who disengage from DSD care, standard procedures for tracing may be conducted, and, subsequently, some people may be classified as LTFU.

Suggested criteria that can be used to trigger tracking interventions, such as telephone recall and home visits, include:

- appointment missed by >7 days or no ARV drugs in hand for >7days
- HIV diagnosis but not initiated on ART
- TB diagnosis but not on TB treatment
- pregnant women without a VL test result
- two consecutive high VL test results (>1000 copies/mL)
- VL test required (based on VL monitoring algorithm)
- TB conversion test required
- TB treatment failure, did not restart TB treatment.

The minimum dataset or data elements presented in Box 3.18 can be adapted for country use to monitor tracing and patient recall interventions that support re-engagement in HIV treatment and care services.

Box 3.18 Key data elements to collect for tracing and patient recall interventions

Outcome values (select one):

- home visit (successful)
- home visit (unsuccessful)
- telephone call (successful)
- telephone call (unsuccessful)
- recall cancelled.

Recall details values (select one):

- date of agreed return (provided by client)
- telephone number incorrect
- address incomplete or incorrect
- client does not want to come back to health facility
- client does not want to be called again
- client requests no home visits.

3.7.8 Key data elements to monitor for DSD ART

DSD care elements should be integrated into existing patient monitoring tools and EMR systems in line with updates to HIV treatment and care service delivery recommendations. Updates have been made to the HIV care and treatment patient card (see Web Annex H) to capture ART initiation outside health facilities and enrolment in DSD ART models as well as delivery of community-based interventions to improve retention and psychosocial interventions for adolescents and young adults living with HIV. The minimum dataset for HIV treatment (Web Annex A) has also been updated to include key data elements related to DSD ART.

It is important to monitor CD4 cell count at first clinical presentation and at the return-to-care visit after treatment interruption to assess for advanced HIV disease as well as factors such as high VL, adherence challenges and opportunistic infections. These individuals may need more clinical follow-up and, thus, may not be eligible for DSD ART models. Similarly, to assess DSD eligibility upon re-engagement, it is important to differentiate between new ARV-naive people living with HIV who initiate treatment late and those who disengage from care.

DSD eligibility criteria (see Box 3.16) should be added to existing patient monitoring tools. Monitoring demographic, clinical, laboratory, adherence and psychosocial criteria will enable assessment and recording of eligibility classification for DSD. In addition, it is important to monitor which DSD elements are being provided (for example, ART refills, clinical monitoring, adherence support) and where (community, clinic, pharmacy, laboratory). Patient monitoring tools/EMRs should capture ARV drug pick-up date, supply of ART and other services provided – for example, psychosocial support, adherence counselling or laboratory testing.

Box 3.18 includes key data elements to include in HIV treatment and care cards/folders and EMRs to enable monitoring of DSD ART (see updates to Web Annex H). These are not yet routinely captured in patient medical records or EMR systems and, thus, in many settings may require their updating. DSD models are constantly evolving and being adapted. Patient monitoring tools and EMR systems need continual, flexible adaptations accordingly.

Facilities using exclusively paper records will need to rely on revised ART registers – or new registers specifically for DSD models – to monitor uptake and outcomes under DSD. Registers/EMRs may be revised to include the data elements for each DSD client (Box 3.19). Since many of these items will change over time, this information should be organized by time (for example, monthly) since first initiation of DSD services.

Box 3.19 Key DSD elements for periodic recording in HIV patient monitoring for each recipient of care

- date of DSD eligibility assessment
- patient DSD eligibility classification: established on ART/not established, and eligible/ineligible for DSD (if not eligible, record the reason – for example, VL test result >1000 copies/mL)
- DSD start date
- DSD model (for example, fast-track ART refills, facility adherence club, CAG, and virtual approaches, such as, teleconsultations, drug ARV pick-up from vending machines/automated dispensing machines)
- group ID (applicable for individuals in group DSD models only)
- ART pick-up dates and quantity dispensed
- type of other medication picked up at the same time as ARVs (for example, TB preventive treatment) and date
- HIV clinic visit dates
- VL test result and date
- additional information, such as adherence monitoring and development of symptoms
- whether or not client is still receiving DSD services
- whether client is switched between DSD models and reason for switch
- reasons for exclusion from DSD model, such as pregnancy, development of opportunistic infection, increased VL, health care worker's concern, adverse drug reaction or patient preference. (The exclusion can be temporary until the situation is resolved; a new assessment should take place within a specified time according to national guidelines/protocols.)

Source: Adapted from Columbia University, ICAP, 2017 *(33)*

3.7.9 Monitoring considerations for community ART services

Key monitoring considerations related to the initiation and delivery of ART outside of health facilities and other aspects of community DSD include the following:

- **Development, use and storage of facility and community tools.** The HIV patient card/folder, the paper or e-register should remain at the facility. Since patient monitoring tools are not available at the point of service delivery for community-based DSD models, monitoring tools for community-delivered ART services will need to be developed and implemented. See Web Annex I for an example of a community ART tool and Box 3.20 for existing tools that countries can adapt. Ideally, these should be simple, user-friendly tools that enable tracking of DSD ART services and follow-up of clients as needed.
- **Data confidentiality and security issues** regarding the use of tools and storage of data in community settings is an important consideration. For paper-based systems cross-sectional tools that utilize numeric codes or other identifiers that avoid the unintended disclosure of HIV status may be more appropriate than the use of identifiers based on personal information. Both paper-based and electronic reports should be stored securely or transmitted immediately to the health facility. For the collection and submission of longitudinal information on clients to health facilities, electronic tools, including secure tablets and mobile applications if feasible, are advisable.
- **Data flow** between community-delivered services and health facilities is essential for effective patient management and care. Data from community ART tools need to be abstracted and transmitted to health facilities in as close to real time as possible for transcription and entry into the HIV patient monitoring system at the facility level. This includes updating HIV treatment and care cards/folders and EMR where in use.
- **Data quality.** Introducing new tools, roles and responsibilities, including peer and client data collection, data flow (for data collected in the community) and reporting requirements under DSD may confer the risk of errors, missing data, and delayed data submission. Conventional data quality improvement strategies may be adapted to the new tools and monitoring approaches implemented under DSD. These involve identifying data elements to assess, sampling records, comparing values across paper and/or electronic data elements and re-counting aggregate tallies. Joint community and facility data quality assessments should be conducted. Adapted data quality assessments should build on the full set of patient monitoring tools used to collect data on individuals receiving DSD (that is, registers and forms). Data quality improvement activities may be incorporated into activities that assess both the quality of care and data for DSD services.

Box 3.20 Examples of existing DSD ART tools

1. *ART distribution form for stable patients* (Kenya)
   https://cquin.icap.columbia.edu/resources/art-distribution-form-for-stable-patients/
2. *Health facility's devolvement monthly summary form* (Nigeria)
   https://static1.squarespace.com/static/5a29b53af9a61e9d04a1cb10/t/5ea05633aec2a673e8787ebb/1587566132567/Health+Facility+Clients%27+Devolvement+Monthly+Summary+Form.pdf
3. *Health facility devolvement & monitoring register* (Nigeria)
   https://static1.squarespace.com/static/5a29b53af9a61e9d04a1cb10/t/5ea0564dd801be771a23e1bd/1587566158417/Health+Facility+Devolvement+%26+Monitoring+Register+.pdf
4. *Community ART group register* (Médecins Sans Frontières)
   https://cquin.icap.columbia.edu/resources/cag-register/
5. *CAG group monitoring form* (Zimbabwe)
   https://cquin.icap.columbia.edu/resources/cag-group-monitoring-form/
6. *CAG toolkit* (Malawi)
   https://differentiatedservicedelivery.org/Portals/0/adam/Content/JFcbS1YfeE2vTpDmKoJqvA/File/CAG.Toolkit.Malawi.2015.web.4%20(1).pdf
7. *Community ART distribution assessment form* (Kenya)
   https://cquin.icap.columbia.edu/resources/kenya-community-art-distribution-assessment-form/
8. *ART adherence club report and toolkit* (Médecins Sans Frontières)
   https://www.msf.org.za/about-us/publications/reports/art-adherence-club-report-and-toolkit
9. *Operational and service delivery manual for HIV prevention, care and treatment, Appendix 6: M&E forms for ART clubs and CAGs* (Zimbabwe)
   https://www.differentiatedservicedelivery.org/Portals/0/adam/Content/JAOEkYYIREyKQ6R637vBmA/File/Zimbabwe_OSDM_webrevised_2017.pdf
10. *Adherence club register template* (International AIDS Society)
    https://www.differentiatedservicedelivery.org/Portals/0/adam/Content/U_zTjQQkAUm4QjpgBeWxYg/File/Adherence-Club_Register.pdf
11. *EpiC decentralized drug distribution mobile application: overview and technical architecture guide* (FHI360)
    https://www.fhi360.org/sites/default/files/media/documents/ddd-overview-technical-guide.pdf

Box 3.21 describes the adaptations and process that Mozambique underwent to enable and strengthen monitoring of DSD to improve implementation and patient care.

Box 3.21 Strengthening the HIV patient monitoring system, tools, indicators and activities to support the implementation and monitoring of DSD in Mozambique

In 2018 the Ministry of Health of Mozambique developed and began implementation of the national DSD guideline in all facilities with differentiated prevention, testing and ART services. This was further strengthened in 2020 when 3-monthly ARV drug dispensing was scaled up to all facilities, 6-monthly ARV drug dispensing was adopted, and one-stop models for service delivery and community drug dispensing were implemented. Led by the Ministry of Health with support and engagement of local and international partners, Mozambique is currently implementing more than 10 different DSD models of care, for established and unestablished ART patients. This includes people on ART who are eligible and enrolled in more than one model of care.

Registration of DSD in primary patient monitoring tools

Mozambique is using a paper-based tool (known as a master card) for HIV patient monitoring. The card has limited space to capture patient data related to DSD. To overcome this challenge, the country standardized the registration of DSD services in the master card:

1. The various DSD models were coded as follows (two to four characters per model).

Model	Code
Fast track	FR
3-months drug dispensing	DT
6-months drug dispensing	DS
Community adherence groups	GA
Family approach	AF
Adherence clubs	CA
Community drug dispensing through APE	DCA
Community drug dispensing through providers	DCP
Community drug dispensing through mobile brigades	BM
Community drug dispensing through mobile clinics	CM
Extended hours	EH
One-stop model – TB/HIV	TB
One-stop model – MCH	SMI
One-stop model – clinical cabinet[a]	CT
One-stop model – AYFS	SAAJ
ART dispensing at private pharmacies	DD
HIV advanced disease package	DAH

Abbreviations: APE = multiuse, elementary agents (community health workers); MCH = maternal and child health; AYFS = adolescent- and youth-friendly services

[a] Outpatient clinic offering consultation, laboratory and pharmacy services in one area

Box 3.21 (continued) Strengthening the HIV patient monitoring system, tools, indicators and activities to support the implementation and monitoring of DSD in Mozambique

2. For people living with HIV on ART enrolled in only one model, the respective code is recorded.
3. For people living with HIV on ART enrolled in two models, the respective codes are recorded and separated by a slash (/).
4. For people living with HIV on ART enrolled in three or more models, the registration of the following models is prioritized:
   a) multi-month drug dispensing (3-monthly or 6-monthly)
   b) community drug dispensing
   c) dispensing of ART at private pharmacies
   d) family approach.

The Ministry of Health prioritized the first four models due to their impact on planning and management of ART services.

DSD data reporting, review and use

Supported by PEPFAR, Mozambique is implementing an EMR system in high volume health facilities, which cover more than 80% of the people living with HIV on ART. In these health facilities, the data captured in the paper master card by the health care provider is entered daily into the EMR. The EMR contains the same data elements as the master card. There is a standard report in the EMR that contains the main DSD indicators adopted by the country, which include the following:

- percentage of clients enrolled in DSD among eligible clients and
- percentage of eligible clients enrolled in at least one DSD model of care.

These indicators are disaggregated by:

- province, district, health facility
- age
- type of DSD model.

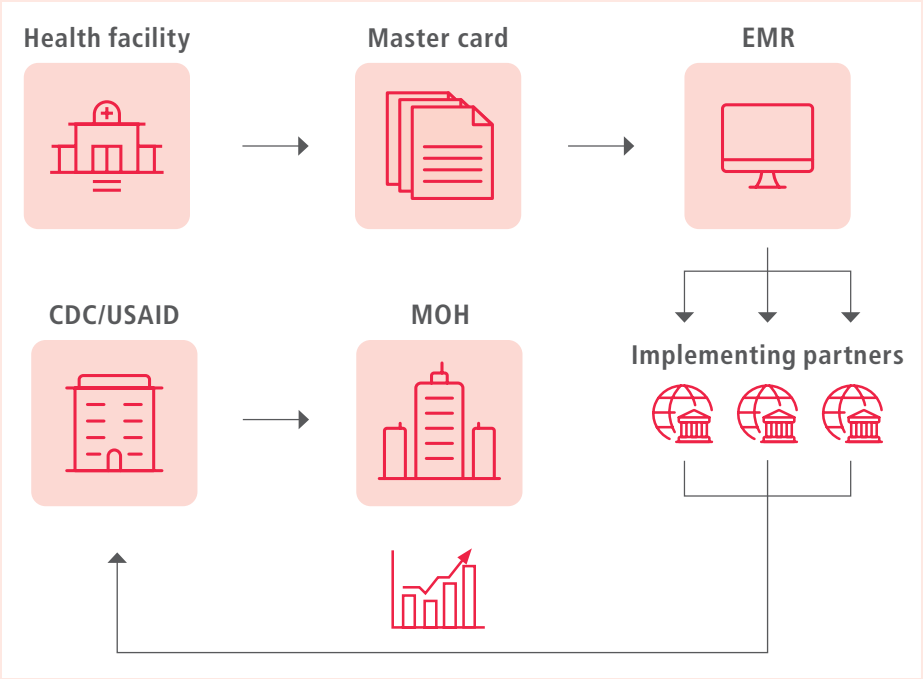
The report is shared monthly with the Ministry of Health and implementing partners to review performance and improve service delivery.

The first indicator (DSD coverage of eligible people living with HIV on ART) assesses, among all eligible clients, how many are enrolled in DSD for established clients (limited to the following DSD models: fast-track, 3- and 6-monthly dispensing of ARV drugs, CAG, ART dispensing at private pharmacies and community drug dispensing). Eligible clients are defined as people living with HIV on ART for more than six months, with suppressed VL and good adherence on ART (excluding pregnant and breastfeeding women).

The second indicator (% of eligible clients enrolled in at least one DSD model) assesses, among all people living with HIV on ART, how many are enrolled in DSD, regardless of the model type.

Fig. 3.7 summarizes the data flow for these key indicators from the health facility level to the Ministry of Health and the tools used to collect and transmit data.

Fig. 3.7 Data flow from the health facility to the MoH, Mozambique



Abbreviations: CDC/USAID = Centers for Disease Control and Prevention/United States Agency for International Development; EMR = electronic medical record; MOH = Ministry of Health
Source: Ministry of Health of Mozambique

DSD performance review

In 2021 the country conducted the first DSD data performance review, with support from the ICAP CQUIN network and the CQUIN DSD performance review toolkit *(40)*. The DSD performance review had the following objectives:

- determine the health facility coverage of DSD
- determine client coverage of DSD
- assess the quality of services provided to people living with HIV enrolled in DSD
- assess the impact of DSD on retention and VL suppression
- understand clients' and providers' perception of DSD services.

Quantitative data from registration tools and patient medical records and qualitative data (interviews of providers and recipients of care) were collected to enable more in-depth assessment of DSD implementation. The data were collected from a sample of 17 health facilities by local staff (trained by the MOH) and supervised by members of the care and treatment technical working group.

Box 3.21 (continued) Strengthening the HIV patient monitoring system, tools, indicators and activities to support the implementation and monitoring of DSD in Mozambique

To be representative, health facilities from the three regions in the country (North, Center and South), from rural and urban areas and of low, mid and high-volume ART sites were selected. Data were collected through paper-based tools. Quantitative data were analysed using Microsoft Excel. A DSD performance review meeting was subsequently conducted with representatives of all provinces and all sampled health facilities to present and discuss the data. The MOH plans to conduct the DSD data performance review yearly to complement routine monitoring of DSD services.

National quality improvement guideline

DSD data is also being reported through the National Guideline for Quality Improvement, an approach that uses iterative plan-do-study-act (PDSA) cycles for problem-solving to improve services. Yearly, the health facilities collect and analyse data and then develop action plans to improve the areas with poor performance. In this strategy the following indicators are collected and assessed:

- **uptake:** percentage of people living with HIV on ART who had a clinical consultation in the period, are eligible and are enrolled in DSD;
- **quality:** percentage of people living with HIV on ART who had a clinical consultation in the period, who became ineligible and were removed from DSD models of care;
- **quality:** percentage of people living with HIV on ART enrolled on DSD who had a VL result;
- **impact:** percentage of people living with HIV on ART enrolled on DSD with suppressed VL.

Source: Ministry of Health, Mozambique, 2022

3.8 Key populations

For monitoring for key populations, WHO recommends the following: All patient monitoring systems should be governed by frameworks and regulations for data protection and confidentiality. Individual-level information related to key populations and behaviours that might be criminalized or stigmatized should not be included in ART registers or reported up to subnational or national data management units. Information about behaviours, comorbidities or other medications dispensed, and referrals for prevention services may be noted in clinical records such as the HIV patient card only if that information is clinically useful. Importantly, all client data must be kept secure and confidential. Clients should be assured that medical records are secure and confidential.

3.8.1 Background

Data relating to an individual's behaviours can be important for patient management and programme monitoring. However, in many settings consensual same-sex sexual activity, sex work, cross-dressing or drug use are stigmatized and even criminalized.

Collecting identifiable information linked to these behaviours from people receiving ART raises the potential for negative consequences both for individual clients and for providers delivering HIV services. These consequences may include the following:

1. Data related to criminalized behaviours can be used by law enforcement officers and others to identify clients for questioning, detention or arrest.
2. Awareness among clients that information on criminalized behaviours is being recorded can result in under-reporting of risk behaviours and even avoidance of that health service.
3. Clients can be discriminated against by health care workers and other service providers based on their behaviour or identity.

It is also worth noting that behavioural risk factors are fluid over a person's lifetime. For example, individuals may have acquired HIV because they used contaminated needles or had unprotected sex in the past, but they do not do so currently. Accordingly, identifying a person as a member of a key population community at one point in time may not be meaningful or useful for future patient management or programme monitoring.

3.8.2 Considerations for patient management

While HIV prevention services can be provided without the need to collect personally identifying information and using anonymous UID codes to allow longitudinal monitoring, in most settings it is required that individuals receiving HIV treatment are identified.

Because of the sensitivities around information that might indicate an individual's engagement in stigmatized or criminalized behaviours or their key population status, only information that is clinically relevant should be included in clinical records where individuals are personally identified. Clinical information such as alcohol or other drug dependence, concomitant medications (including opioid agonist maintenance therapy (OAMT) and hormone therapy) and sexual risk behaviour has relevance to clinical care and can be included in secure clinic records. In addition, in facilities or contexts where there may be concerns of stigma, there may be limited value in collecting data on stigmatized behaviours, as individuals are unlikely to report those behaviours in such circumstances.

Important clinical information related to key populations that could be recorded on the HIV patient card provided in Web Annex H includes whether the patient is also receiving OAMT or hormone therapy at the ART clinic (under *Other dispensed medicines*) or elsewhere (under *Concomitant medications*) or that alcohol/substance use is a reason for non-adherence (under *ART why missed doses*).

Counselling, support or education on these and other relevant interventions (for example, testing partners, couples counselling, pre-or post-exposure prophylaxis for partners of those receiving ART) may be addressed and recorded on the back of the HIV patient card by counsellors, clinicians or other health workers.

3.8.3 Considerations for programme monitoring

ART registers can be accessed by a variety of facility staff and other staff and so may be difficult to keep confidential. For this reason, ART registers are not appropriate for the collection of data related to key population status. Ensuring sufficient ART coverage among key populations living with HIV, however, is critical for a successful HIV response.

Routine programme data reported up to subnational and national data management units should not include the key population category or risk behaviour if this information can be linked to an individual. HIV programme monitoring specific to key populations can be achieved

through community-based surveys (such as bio-behavioural surveys) and other special surveys to provide estimates of ART coverage and viral suppression (see Chapter 8), for definition of survey indicator ART.10. People from key populations living with HIV on ART). It is also possible to use de-identified case surveillance data, disaggregated by probable transmission route collected at diagnosis, as a proxy for key population group, to measure the impact of HIV programmes on certain key populations and allow estimation of the number and proportion of people from key populations covered at different points in the HIV care cascade. In addition, methods to use routine data have been applied, where there are robust protective policies and frameworks to protect individuals and their information. This will be the focus of subsequent technical review and WHO guidance, as there are many issues to take into account, including security, confidentiality and sources of bias.

In some settings, where key population-specific programmes have referred HIV-positive people from key populations to health services for HIV treatment and care, these programmes may keep a record of referred individuals. These programmes may then be able to review the ART register to identify whether referral was completed and if these individuals received ART, provided there are safeguards and measures in place to adequately protect the identity of clients and ensure confidentiality. This can be a useful approach to monitoring successful linkage to care and treatment uptake among members of key populations (see Box 3.22).

Box 3.22 Following people from key populations along the HIV treatment cascade in Malawi

The *Meeting Targets and Maintaining Epidemic Control (EpiC) Programme* in Malawi supports the provision of HIV services for people from key populations. When a client is referred from an EpiC key population programme to a public health facility for HIV treatment and care, the EpiC worker completes a referral ticket in triplicate. Two of these referral tickets are provided to the client, and the EpiC programme keeps one.

When the client attends the referral, the health care provider at that facility signs both referral tickets and indicates the service received (for example, ART prescribed) and the UID that will be used to identify the client in the facility register. One ticket is then deposited in a referral ticket box at the facility, and the other is given back to the client to return when they next attend the EpiC programme (for example, to access a drop-in centre).

Twice each month clinicians or accredited M&E officers from the EpiC programme go to each public health facility and collect the referral tickets that have been deposited in the referral box, allowing them to ascertain which referrals from the EpiC programme have been completed. Then, they review the ART registers of the public health facility and are able to identify the key population clients and track retention in care, adherence to ART and VL suppression. These individual-level data on HIV treatment and care are then added to the client's EpiC programme record. Thus, the EpiC programme is able to use this information to monitor HIV treatment outcomes among the programme's key population clients and to generate HIV testing, treatment and care cascades. At no time is the client's key population status disclosed or recorded in public health facility ART registers or the HIV patient card.

The system has a level of redundancy built into it to increase the likelihood that the client can be tracked from the EpiC programme and through the public health facility.

Source: EpiC programme, Malawi, 2022

3.8.4 Considerations when collecting data about gender

Trans and gender diverse people is an umbrella term for people whose gender identity and expression do not conform to the norms and expectations traditionally associated with the sex assigned to them at birth. Since gender is described differently in different countries and cultures, gender identity categories include male, female and other, where other includes trans and gender diverse people including those who choose an identity other than male or female.

In settings where being trans or gender diverse is highly stigmatized or penalized, and to increase client safety, it is acceptable to include only two categories (male or female) for gender on facility records. In other settings consideration should be given to including the following two questions when recording gender on clinical records. The answers will allow better patient management and disaggregation of data by variously gendered groups:

1. Gender

- male
- female
- other (includes trans and gender diverse people who choose an identity other than male or female).

2. Sex assigned at birth

- male
- female
- other.

3.9 Minimum dataset and key definitions for HIV patient monitoring

3.9.1 Minimum dataset

The minimum dataset contains core demographic, clinical and laboratory data. Each data element has a standardized definition and prescribed coding categories. The minimum dataset comprehensively assesses all people living with HIV tested and receiving HIV care. The primary purpose is to standardize patient information with a simplified and harmonized set of essential data elements relevant to core patient management and programme monitoring. Standardization also enables programme staff to compare data across populations, time, geographical areas and settings, and provides data for clinical teams to monitor quality of care longitudinally and along the cascade of HIV services.

Box 3.23 highlights the new elements in the 2022 WHO minimum dataset for HIV testing and treatment, which reflect the latest WHO HIV testing, ARV treatment, service delivery and strategic information recommendations. Web Annex A lists the minimum data elements, including a definition and purpose for each, and describes how the data can be used to improve individual patient care and programme monitoring. The data elements are aligned and linked to the WHO 2022 priority indicators for HIV testing and treatment. Programmes may choose to collect additional information depending on local need and context. Table 3.9 presents key terms and definitions for HIV patient monitoring.

Box 3.23 What is new in the WHO minimum dataset for HIV testing and treatment

HIV enrolment and testing data

- updates to status at enrolment to reflect differentiated service delivery eligibility
- updates to relevant chronic conditions (previously relevant medical conditions).

Treatment and drug prophylaxis data

- updates to newly recommended ARV regimens and codes (for adults, including pregnant and breastfeeding women, adolescents, children and infants)
- updates to ARV treatment-limiting toxicities/adverse drug reactions
- updates to follow-up status codes and definitions
- addition of ART initiation site to capture ART initiation outside health facilities
- addition of DSD ART eligibility, enrolment and DSD ART models of care received
- addition of timing of ART initiation to monitor rapid ART initiation (within seven days of diagnosis) and reasons for delayed ART initiation
- updates to enable tracking of tracing interventions for individuals who disengage from care and to identify people living with HIV re-engaging in care
- addition of monitoring of fluconazole prophylaxis for people living with HIV with advanced HIV disease
- update to TPT drug regimens.

Laboratory data

- updates to VL and CD4 monitoring recommendations
- revisions to recommended investigations (for example, for TB, hepatitis and others).

Clinical data

- updates to the list of comorbidities and co-infections
- addition of data elements to monitor advanced HIV disease
- addition of WHO functional status for monitoring the functionality of people living with HIV with advanced HIV disease
- addition of childhood immunizations and updates to adult immunizations
- addition of data elements to enable monitoring of developmental disorders in children.

Box 3.23 (continued) What is new in the WHO minimum dataset for HIV testing and treatment

ANC and labour and delivery data

- update to pregnancy outcomes to enable monitoring of adverse pregnancy outcomes associated with ARV exposure, including preterm delivery, low birth weight, miscarriage and still birth and congenital abnormalities.

Follow-up education, support and preparation for ART

- addition of data elements to enable monitoring of tailored adherence counselling for people with advanced HIV disease and enhanced counselling for people living with HIV with unsuppressed VL.

Table 3.9 Key terms and definitions used in this guidance for HIV patient monitoring

Term	Definition
Newly enrolled in HIV care	Enrolment takes place when a person with a confirmed HIV diagnosis presents to a facility or community ART site where HIV care is provided and a patient card, file or chart or electronic equivalent is opened for the first time. This could be at an HIV care/ART, MNCH or TB clinic or a community ART site. **WHO recommends** that all eligible clients be enrolled in HIV care at their first facility visit following an HIV-positive diagnosis. Enrolment may take place in the same facility or in a community setting. **WHO recommends** rapid ART initiation, within seven days of a positive test result. However, in situations where ART is not started on the same day as enrolment (for example, due to treatment of existing opportunistic infections/advanced HIV disease or the need for adherence or psychosocial counselling), this definition assumes that enrolment is followed by promptly starting ART for all people living with HIV, regardless of CD4 cell count, when the patient is able to start according to WHO recommendations (see definition of ART START below). For patients who may have received prior ART, "newly enrolled" includes treatment-experienced patients with or without clinical records who received ART from sources outside the system. This includes, for example, patients seen by a private practitioner and patients who buy drugs themselves or are sent drugs. It also includes patients who have taken PrEP or short-course ARV prophylaxis for PMTCT and have not been counted as newly enrolled in a nationally monitored system. If a facility receives a treatment-experienced patient without records who was previously treated at a facility that reports to the national programme (and, therefore, was reported as newly enrolled once before), an attempt should be made to retrieve the records and confirm that the patient was previously on treatment. Similarly, for patients who initiate ART in community settings, an attempt should be made to access records/key HIV treatment and care information to confirm that the patient was on treatment and to transfer key clinical and treatment information. Newly enrolled patients do not include those who have been referred or transferred in with documentation (that is, referral/transfer slip or patient records).

Table 3.9 (continued) Key terms and definitions used in this guidance for HIV patient monitoring

Term	Definition
Retention in care/ART attrition	This includes individuals who are enrolled in HIV care and routinely attend these services as appropriate to their need. This excludes people who have died or were LTFU, but it includes those who started ART and subsequently stopped ART for any number of reasons (see definition below). In practice, retention is used to describe a cohort of people living with HIV who are alive and receiving routine HIV care, including ART, at a specific time point after enrolment in HIV care or starting ART. Retention is measured by indicator ART.2. Total attrition from ART. Understanding retention is central to understanding net progress towards reaching the second 95 target.
TRANSFER IN	There are four types of transfer patients, but only one (the first one) is categorized as "transfer in" on ART: 1. This type of transfer refers to an individual who has been receiving ART at one site in the country or system and transfers (changes primary location where receiving HIV care/ART) to another facility or community setting in the same system with records (or at a minimum, knowledge of ARV regimen and ART start date). The individual may be on ART at the time of transfer or have stopped ART. This type of patient is the only type to be classified as "transfer in". On the front of the HIV patient card, status at enrolment will be "Transfer in: on ART or Tx failure/interruption" with: date and "ART transfer in from… ARV regimen…Last VL date and result…" recorded, as well as any subsequent regimen changes (substitutions/switches/interruptions). Most importantly, transfer in patients are entered into the ART register by their original ART start group (cohort month/year) after a line has been drawn to differentiate them from those who started ART at the receiving facility/site (note transfer in in the margin). Additionally, these individuals are not included in the cumulative number ever started on ART at the facility/site (see definition below), as they were already recorded as "ever started ART" at another facility/site in the system. 2. This type of transfer refers to an individual who has received ART from sources outside of the system or one who has received ARVs within the system but who has no records or knowledge of ARV regimen or ART start date. This individual will be classified as having received "Earlier ARVs not transfer in" and will be "newly enrolled" in HIV care (see below). 3. This type of transfer refers to an individual with records who has not yet started on ART who transfers between facilities or from a community service delivery organization to a health facility. This individual will have an existing "enrolled in HIV care" date and have the "HIV care transfer in from" box checked and completed. For status at enrolment, this patient will be recorded as "Transfer in: naive". 4. This type of transfer refers to an individual without records who has not yet started on ART who transfers between facilities or from a community service delivery organization to a health facility. This individual will be classified as "newly enrolled in HIV care having no prior ARVs" and may be double counted as newly enrolled in HIV care. These categories apply whether the patient is transferring between HIV services at different health facilities and from MNCH or TB services into HIV services or vice versa.
START	Refers to the date on which a patient in the system begins the first, original ART regimen (or it documents the date that a patient started in any programme or under care of another practitioner, if that date is known). For example, if a patient starts ART at clinic A and then transfers to clinic B, clinic A will record the patient as having started ART; clinic B will copy the start date which precedes their first encounter date at Clinic B into Clinic B's patient records. This is the same as cohort month/year which is reordered in the ART register and cohort report or electronic equivalent.

Table 3.9 (continued) Key terms and definitions used in this guidance for HIV patient monitoring

Term	Definition
STOP	Refers to the date on which a patient intentionally stops an ART regimen (usually but not always in discussion with the clinical team). Stopping ARTs can be patient- or clinician-motivated. It refers to people no longer on ART but still in care.
RESTART	The date on which a patient who had previously stopped ART restarts, regardless of regimen. Operationally, people living with HIV who restart ART after an interruption of three months or more are deemed to be restarting treatment *(41)*.
LOST TO FOLLOW-UP (LTFU)	This includes patients who have not been seen at the facility/community service delivery site for 28 days or more since the last missed appointment (including missed ARV refills in either facility or community settings). When reporting, a one-month grace period should be allowed before concluding that a patient is actually LTFU. However, with the implementation of DSD, these periods should be reconsidered, with an effort to ensure that patients engaged in DSD models are not included in the list of patients LTFU. While this is a practical definition of LTFU for reporting purposes, normally most clients who do not present by one month of last missed appointment are unlikely to return thereafter. Therefore, for patient management, the facility should make every effort to contact patients (by phone or via a community health worker) as soon as they miss an appointment, rather than waiting for the prescribed 28 days. This is particularly important when patients receiving DSD are routinely seen every three to six months (a patient may not have been seen for up to seven months if the facility adheres to the waiting period before attempting contact). LTFU is an ambiguous outcome that may often include patients who have self-transferred (without proper documentation or referral from their original primary care facility/community ART site) or who have died. "Transfer out" and "dead" are two concrete outcomes that are also collected, and it is important to understand what actually happened to the LTFU patient to improve both clinical and reporting outcomes.
TRANSFER OUT	This refers to the date on which a person who has been receiving ART at one facility/community ART site transfers out of that facility/site.
DEAD	A person who died at any time after being enrolled in HIV care.
SUBSTITUTE	Substitution of ARV drugs within first-, second- or third-line regimens, with date and reason.
SWITCH	Switch from first-line to second-line regimens or from second-line to third-line regimens, with date and reason.
Cumulative ever-started on ART	Number of people who have ever started ART as "new" at the facility. This should NOT include people who transfer in, but it should include those who subsequently transferred out or were categorized as dead, LTFU or stop.
People living with HIV on ART	A cross-sectional indication of people living with HIV who are currently on ART at a given site, including individuals who transfer in. The numerator excludes individuals who transfer out or are categorized as dead, LTFU or stop (national indicator ART.1), thus informing the calculation of attrition during the reporting period.
Cohort	Group of people living with HIV who start ART in a given month (or quarter) and year, whose status is followed over time using the ART register.

Table 3.9 (continued) Key terms and definitions used in this guidance for HIV patient monitoring

Term	Definition
Net current cohort (cohort analysis report)	People living with HIV in each cohort for whom the facility/site is currently responsible, consisting of those who started on ART at the facility/site in a given month/quarter and year, minus those who have since transferred out, plus those who have since transferred in.
Final outcome status of PMTCT	The final HIV outcome status of HIV-exposed infants born in the past 12 months (or 24 months in breastfeeding settings), based on either HIV virological testing (that is, polymerase chain reaction (PCR)) or rapid antibody testing, including: • HIV-positive • HIV-negative and no longer breastfed (national indicator VER.6. Final outcome of PMTCT).

Abbreviations: ART = antiretroviral treatment; ARV = antiretroviral; DSD = differentiated service delivery; LTFU = lost to follow-up; MNCH = maternal, newborn and child health; PMTCT = prevention of mother-to-child transmission; TB = tuberculosis

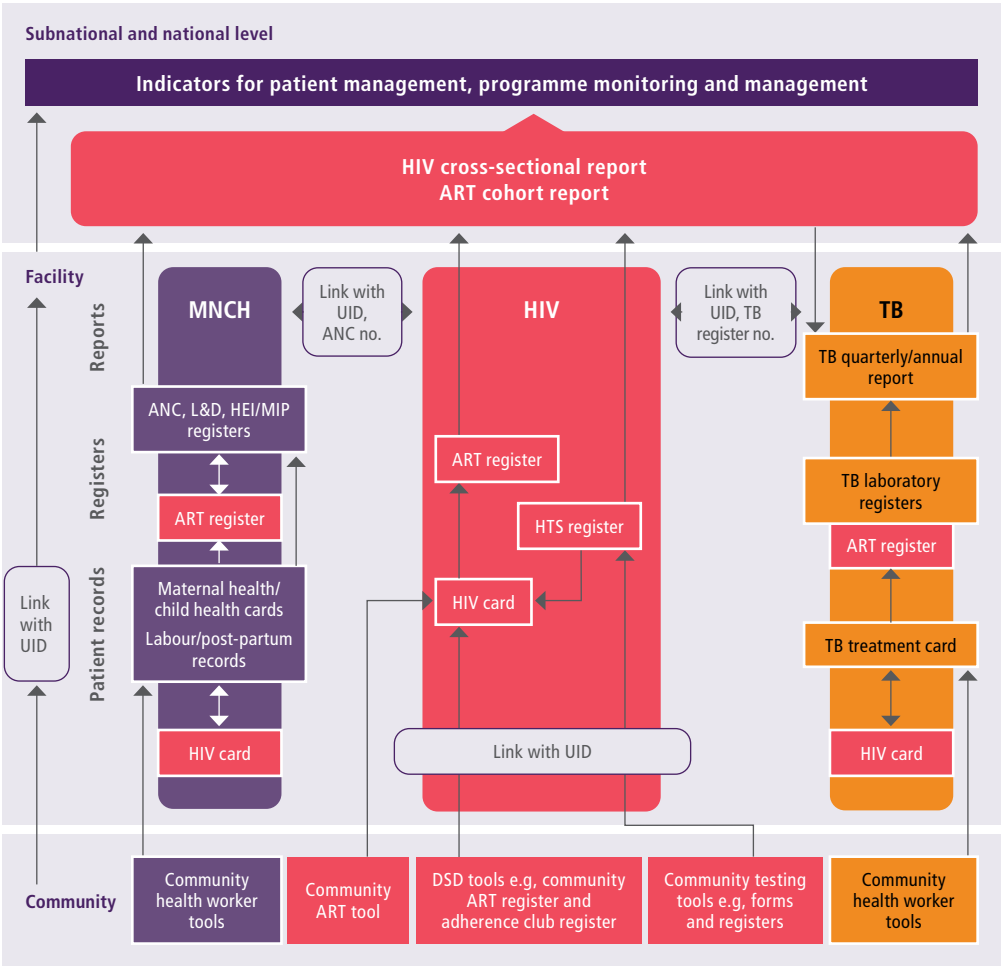
3.10 Standardized data collection and reporting tools for HIV patient testing, treatment and care

Box 3.24 Standardized data collection and reporting tools: WHO recommendations

- Health workers should create an HIV treatment and care patient card or EMR for every person who is confirmed HIV-positive and subsequently record care, regardless of the entry point (that is, HIV, MNCH, TB service).
- ART registers or electronic equivalents should be kept and used at all sites where ART is provided.
- Community ART providers engaged in ART delivery should routinely monitor and report on a minimum key set of data in a simple, standardized way.

Fig. 3.8 provides an overview of the HIV patient monitoring systems and data collection tools required for ART delivery in HIV, MNCH and TB settings. The transfer/referral form (Web Annex J) is used to facilitate continuity of patient care between sites that provide HIV care and treatment, including between community ART sites and health facilities. The generic HIV patient monitoring tools provided in this guidance are shown in red. MNCH-specific tools are shown in purple, and TB-specific tools are shown in yellow. Additionally, there could be monitoring tools for other diseases or conditions that interlink with or can be integrated into the system (for example, patient cards and registers for noncommunicable diseases).

Fig. 3.8 Standardized HIV patient monitoring system and linkages by service delivery area and level



Abbreviations: ANC = antenatal care; ART = antiretroviral treatment; HEI = HIV-exposed infant; HTS = HIV testing services; L&D = labour and delivery; MIP = mother–infant pair; MNCH = maternal, newborn and child health; PMTCT = prevention of mother-to-child transmission; PrEP = pre-exposure prophylaxis; TB = tuberculosis; UID = unique identifier

3.10.1 Tools for facility-based monitoring of HIV treatment and care

The HIV patient monitoring system is designed to capture and retain data on all people with a confirmed HIV diagnosis and follow them through the cascade of HIV care services, from diagnosis and ART initiation to sustained viral suppression. Patient monitoring tools should culminate in reports that are acted on. Each report should list the suggested name of who at each level should act on the outcomes of the report, how and by when. For guidance on data use, see section 3.11 on improving the quality and use of individual-level data.

A health care worker takes the following steps to start an HIV patient card:

1. The health care worker fills in a card for each person who enters into care (is diagnosed), regardless of entry point (that is, HIV care, MNCH service, TB care or community ART site). In an integrated care setting, the individual will receive HIV care and treatment at the same facility for life (for example, at ANC if the individual started there). In settings where EMRs are in use, information may be directly entered into the electronic health information system either at the same time that the patient card is created or retrospectively. In a non-integrated care setting, this card would ideally move with people living with HIV as they transfer between service delivery points. For example, a woman starts ART at the ANC clinic and transfers to the ART clinic postpartum with the same HIV patient card (the two clinics may be housed at the same facility or at different facilities).
2. The health care worker assigns a UID. This is different from a patient's clinic ID and may or may not be unique to HIV care. An existing health, national or other ID may be used when available, if it is unique to the individual and strong data protection procedures are in place. (See Chapter 6 for further guidance and recommendations on UIDs.)
3. Health care workers record information on the card or electronic equivalent to monitor clinical care over time, allowing different health workers, including supervisors and clinical mentors, to follow up on subsequent visits. The HIV patient card is the primary data source for the other tools in the HIV patient monitoring system and covers the entire HIV-specific minimum dataset. In some settings the facility-based HIV patient card may be referred to as a patient record or file; it can be paper-based or an EMR. The card includes links to other services that a person may be receiving at the same time, as well as specific patient records and registers, for example, for the MNCH register (see section 3.5) and for the TB register (see section 3.6). Other linked information may include the following:

- sexual and reproductive health and family planning choices, including current pregnancy status
- ANC number
- child vaccinations
- tests for STIs and their results
- nutritional support and infant feeding practices, including current breastfeeding status
- HIV-exposed infant status, including name, date of birth, co-trimoxazole prophylaxis, HIV test type, result and final outcome status (and UID if confirmed HIV-positive).

The HIV patient card consists of three sections. Web Annex H provides a model of a generic HIV patient card. The card has been revised to reflect updates to WHO HIV clinical and strategic information recommendations (Box 3.25).

The front page of the card summarizes demographic, family, HIV care and ART information. This information is generally completed once and updated as needed (for example, when assessing DSD eligibility). The second section is the clinical encounter page. Each row covers one clinical visit, with the first row being the baseline visit. When this page is full, blank photocopies can be inserted or stapled to the card. The health worker should check and record the information outlined in each of the columns during each clinical visit, using the code boxes below the visit rows as a guide. The third section is a summary of patient education and counselling, including adherence support, which should be completed as necessary. This section may be completed by the same health worker who completes the encounter form or by a counsellor/educator in the clinic. However, it is important to prioritize which points are covered during each visit and to write succinctly and legibly to enable follow-up. There are seven rows; again, a blank photocopied sheet may be inserted or attached once these rows are filled.

Box 3.25 What is new on the HIV patient card

- ART initiation site updated to include community settings
- Monitoring of rapid ART initiation (within seven days of diagnosis)
- Addition of eligibility for DSD, date of eligibility assessment and type of DSD model(s) clients engaged in
- Tracking of tracing interventions for people living with HIV who disengage from care
- Monitoring of people living with HIV with advanced HIV disease
- Monitoring of psychosocial interventions provided to adolescents and young adults
- Monitoring of tailored adherence support for people living with HIV with advanced HIV disease and enhanced adherence counselling for people living with HIV with unsuppressed VL
- Reason for non-rapid initiation (within 7 days)/same day start of ART
- Addition of weight gain to "codes for ARV treatment-limiting toxicity"
- Updates to comorbidities and co-infections
- Codes for TPT updated
- Type of TB diagnostic test updated to reflect range of molecular WHO-approved rapid diagnostic TB tests
- Updates to adult and child immunizations
- Removal of data elements tracking home-based care.

3.10.2 HIV transfer or referral form

To the extent possible, if a person is referred from or transfers from another facility or community ART site for care and treatment, key information should be recorded and sent with the patient for continuity of care, retention on ART and maintenance of viral suppression, as well as to avoid duplication in record-keeping and reporting. The generic HIV care referral form includes information taken primarily from the front of the HIV patient card and comes with a "counter-referral" section that can be cut off and sent back to the referring facility so that it is notified of a successful referral or transfer. Web Annex J provides a model referral form updated to include referrals to and from community ART sites and facilities.

3.10.3 ART register

Box 3.26 ART register: WHO recommendation

All people living with HIV who initiate treatment should be entered into a longitudinal ART register or electronic equivalent when they start ART, preferably within seven days of diagnosis.

The ART register:

- contains a subset of key information from the HIV patient card/folder in certain settings;
- is organized by the month and year (cohort) in which the patient starts ART, regardless of where started;
- records the follow-up of patients on ART over time, including CD4 count and VL and enrolment in DSD;
- is used to aggregate data into the ART cohort report and the HIV cross-sectional report.

WHO recommends that ART registers in paper or electronic form be kept wherever people living with HIV receive treatment and also use of HIV patient cards for integrated service delivery, including at ANC or TB clinics. This facilitates data reconciliation for certain TB–HIV and HIV/MNCH indicators by grouping all people on ART in one place. It also allows for the longitudinal follow-up of cohorts of pregnant and postpartum patients. (In general, MNCH service registers are cross-sectional and, thus, cannot be used for longitudinal follow-up.) Due to its design, the ART register can be used to observe patient outcomes at a glance at various points during treatment, with reference to specific patient cards or EMRs to better understand what has happened (for example, patient recorded as dead three months after ART start). Web Annex K provides a generic ART register and a list of patients who cannot or will not start ART soon after HIV diagnosis, with reasons for the delay. The updated generic ART register contains 20 rows – one row per patient. Each row is divided into two sub-rows (white and grey). The first page of the register is used to record information once (demographics, status at start of ART, key co-treatments, pregnancies, regimen substitutions and switches) and then is updated as necessary. Pages 2–6 are for the monthly follow-up of people on ART, starting at month 0 (the month in which the individual started ART) and continuing through 10 years (120 months). At each month the follow-up status of the patient (on ART [regimen code]; STOP [and reason]; LTFU; transfer out (TO) [and to where]; DEAD) is recorded in the top (white) row, and the current pregnancy or breastfeeding status (for women of reproductive age) and/or enrolment in DSD ART models is recorded in the bottom (grey) row. In addition, CD4 cell count and VL test dates and results are recorded at key points (6, 12, 24 months, etc.). Like VL, CD4 cell count could be recorded at key points.

Box 3.27 What is new in the ART register

- Updated drug regimen codes to reflect newly recommended ARVs and regimens for adults, adolescents, children and infants
- Enrolment in DSD models for ART included in the follow-up status to enable tracking of enrolled clients
- Treatment-limiting toxicities updated to include weight gain
- Codes for TPT updated
- Addition of column for tracking receipt of fluconazole prophylaxis for people with advanced HIV disease.

3.10.4 Cross-sectional and cohort reports

Two reports aggregate data from the ART register:

- The cross-sectional report tallies the cumulative and current numbers of people living with HIV in care and on ART, disaggregated by age and sex quarterly to annually.
- The cohort report records outcomes of groups of people living with HIV who started ART in the same month and year at 6, 12, 24 months, etc., after ART initiation.

Cross-sectional report

The cross-sectional report provides a snapshot of patients' status at one point in time. The number of people living with HIV who have started treatment (key indicator ART.4 New ART patients) during a defined reporting period such as one quarter or year is a useful cross-sectional indicator to monitor uptake of services over time and plan accordingly.

Similarly, data on people living with HIV who initiate ART late (key additional indicator ART.5 Late ART initiation) may guide better targeting of resources or outreach. The current number of people living with HIV on ART (key indicator ART.1 people living with HIV on ART) (as of a defined period such as the last quarter in a given year and on what treatment regimen) can be useful for monitoring actual patient caseload and can contribute to drug supply management at the health facility. Of those clients, the number of people on ART who are virally suppressed (key indicator ART.3 people living with HIV who have suppressed VL), regardless of length of treatment, can provide insight into the population-based VL, whereas the proportion of people on ART for at least six months receiving VL test results (key additional indicator ART.6 VL testing coverage) measures the uptake of routine HIV VL monitoring. These numbers can be disaggregated by age, sex, breastfeeding and pregnancy status to assess how equitable service distribution is at each level of the health system.

The cross-sectional report also provides indicators from other service delivery points, such as the following:

- TB – key indicators TBH.4 people living with HIV living with active TB disease and TBH.1 TPT initiation;
- Hepatitis – key indicator HEP.2 HCV test coverage;
- MNCH – key indicators STI.1 Syphilis testing coverage disaggregated by ANC, STI.3 Syphilis treatment coverage (ANC), VER.9 HIV testing among pregnant women, VER.1 Viral suppression at labour and delivery, VER.4 ART coverage in pregnant women, VER.2 Coverage of early infant diagnosis, VER.3 Coverage of infant ARV prophylaxis and VER.11 CTX coverage of exposed infants.
- DSD – people living with HIV eligible for DSD and enrolled in DSD during the reporting period who are receiving DSD (DSD.3).

In the revised cross-sectional report (Web Annex L,) total ART attrition has been added to enable calculation of the national priority indicator on total attrition from ART (ART.2) at the aggregate level.

For community-delivered ART services, community organizations, health workers and client/peer groups should report the number of people initiated on ART and receiving ART periodically according to national reporting requirements so that that these data can be incorporated into the facility cross-sectional and cohort reports.

Cohort analysis report

The cohort analysis report aggregates data by when people living with HIV started ART (month/year). This allows for tracking important and useful indicators along the HIV cascade of care and treatment, including whether or not people living with HIV are still alive and on ART after six months and one, two, three or more years from the start of ART (which includes deaths, stopping ART and LTFU). Also included are key additional indicator VER.10 ART retention PMTCT; how many have died or been LTFU; how many have transferred out or stopped ART (but are still in care); how many have substituted or switched regimens; and how many have a suppressed VL (key indicator ART.3 people living with HIV on ART who have suppressed VL (regardless of ART start date). Where there are electronic health information systems, it may be possible to report on viral suppression and 12-month retention to assess clinical outcomes in people living with HIV engaged in DSD ART (see revised cohort report, Web Annex M).

These cohort data are critical for patient and programme monitoring and facilitate health workers' follow-up on negative outcomes such as large numbers of people on ART who are LTFU, have died, have switched regimens or are not virally suppressed over the long term.

Cohort analysis is useful for examining trends over time. For example, it allows facilities to understand if deaths are happening early or late in the course of treatment; if loss to follow-up increases over time between cohorts; and when switches to second- and third-line regimens are taking place. As with the cross-sectional report, information in the cohort report can be disaggregated by sex, age and pregnancy/breastfeeding status to determine how different populations are progressing on treatment (for example, whether men are more likely to be LTFU than women, or whether younger adults are alive and on ART at different time points than older adults).

Both the cross-sectional and cohort reports use the ART register as their data source. While the cohort analysis report is conceptually more challenging, in practice it is easier to compile, as it tallies data in the same column (month 12) for every cohort in the register. By comparison, the cross-sectional report tallies data in many different columns based on when the patient started ART (for example, for a December 2021 report, December 2021 might be the baseline (month 0) for some cohorts, month 5 for those starting in July 2021, or month 9 for those starting in March 2021). Web Annex L provides a generic HIV cross-sectional report. Web Annex M provides an example of an ART cohort report.

Box 3.28 What is new in the cross-sectional and cohort reports

Cross-sectional report

- Inclusion of tally of patients eligible for and enrolled in DSD ART models
- Addition of data elements to enable assessment of ART attrition (patients LTFU, died and stopped ART) to enable calculation of new indicator ART.2. Total ART attrition
- Updates to timing of VL test as per the VL monitoring algorithm recommended by WHO
- Different periodicity of reporting (monthly subnationally, quarterly nationally).

Cohort report

- LTFU defined as 28 days or more since last missed appointment (including missed ARV refills in either facility or community setting)
- Updates to timing of VL test as per the VL monitoring algorithm recommended by WHO
- Inclusion of people living with HIV receiving DSD ART models and key clinical outcomes (VL suppression and retention on ART) at 12, 24, 36 months, etc.

3.10.5 Other recommended tools to facilitate HIV patient monitoring

WHO recommends additional tools to facilitate patient monitoring, including monitoring ART adherence from pharmacy records (Box 3.29).

Box 3.29 Other WHO-recommended tools for HIV patient monitoring

- Appointment book in health facilities with paper reporting, for tracking patients who miss scheduled visits or drug pick-ups
- List of recommended data elements for monitoring adherence in people on ART from a pharmacy record:
  - date of pick-up
  - number of days for which ARV drugs were dispensed
  - ARV regimen dispensed.

3.10.6 Tools for community - delivered treatment and care services

Community-based ART patient monitoring tool

Under the DSD guidelines recommended by WHO in 2021, clients may initiate ART outside health facilities and clients established on ART may have less frequent clinical visits and medication pick-up, and they may access more decentralized service delivery points, including community-based services *(3)*. To accommodate larger numbers of people enrolled in HIV care programmes, WHO also recommends task shifting to allow clinical settings to focus on individuals who are initiating treatment or who are unwell and to delegate the monitoring of patients established on ART to supervised lay providers.

Community ART service providers can play a pivotal role by:

- providing a link between clients and health facility services (for example, HIV testing, counselling and referral, HIV care and treatment, MNCH and TB care) through referral to and follow-up with facilities;
- picking up and distributing medications to people on ART in their homes or communities;
- providing psychosocial and adherence monitoring and support and follow-up of clients; and
- linking clients with community-based support groups and organizations.

Given the breadth of activities in which community health care workers/community service delivery providers, including community ART groups, may engage, it is important that they are able to routinely monitor and report on a key minimum set of actions in a simple and standardized way. Patient monitoring can play a key role in DSD and linking between community and facility health workers. While community health care workers/community service delivery providers may monitor clients using their own tool, the information that is collected should always be reconciled with the facility-based ART register or electronic equivalent, which is the main aggregation tool for any cross-sectional and cohort report. This can be done on a monthly or quarterly basis (for example, whenever community health care workers/community service delivery providers have meetings at the facility) to ensure that the follow-up status of each client is up to date (that is, treatment regimen, stopping, died, LTFU, transferred out). If community health care workers/community service delivery providers are picking up and distributing ARVs to clients in the community, their tool should be reconciled with the pharmacy dispensing records.

It is important that community health workers and community service providers can routinely monitor and report on a key minimum set of actions in a simple and standardized way.

Box 3.30 What is new in the community ART monitoring tool

These guidelines include a generic community-based patient monitoring tool for differentiated ART service delivery for use by community health workers who provide or support HIV care and treatment in the community, outside the health facility (Web Annex I). Recommended data elements for such a tool are shown in Box 3.31.

Box 3.31 Recommended HIV data elements for a community DSD ART data collection tool

- site ART initiated
- name and district of referral facility
- community ART group number (where relevant)
- UID
- name
- sex
- date of birth
- telephone number
- address, including village and district
- visit date
- date of ART initiation
- ARV regimen (including any changes) – dates dispensed – number of pills dispensed, date of next refill
- TB symptoms (current cough, fever, weight loss, night sweats): Yes/No
- any missed doses of ARVs
- reasons for missed doses (non-adherence)
- other problems (ankle swelling, puffiness of the face, breathlessness, diarrhoea >2 weeks, severe headache
- transfer out (date, to where)
- moved out of community health care worker's/CAG catchment area (date, new address)
- dead (date)
- treatment interruption (dates and reasons)
- pregnancy status.

Integration and linkage

It is essential that HIV services are linked and integrated with other services to ensure comprehensive patient management over time. This requires integration of patient monitoring tools. Those included in this guidance support monitoring integration with maternal and child care (see section 3.5) as well as TB screening and treatment services (see section 3.6). Further aspects of linkage and integration through patient monitoring of HIV and other services are detailed in Chapter 4.

3.11 Improving the quality and use of individual-level data to strengthen HIV patient monitoring and care

3.11.1 Importance of strengthening the quality of individual-level HIV patient monitoring data

Good-quality individual-level data are important to ensure that health care providers make well-informed decisions for improved HIV patient management. As countries move towards the UN Political Declaration 95–95–95 targets for HIV treatment and care, it is now more important than ever to collect and report accurate data in real time to understand where gaps in service delivery remain and ensure the use of data to improve quality of care and patient outcomes.

Data quality assessments need to become an institutionalized part of the data management cycle.

Efforts should be made to ensure that data quality assessments are not singular events implemented on an ad hoc basis. Rather, these activities need to become institutionalized as part of the entire data management cycle. Once achieved, data quality helps to ensure that limited resources are used effectively, progress toward established targets is accurately monitored, measured and reported; and decisions are based on strong evidence. Data should be used to strengthen health care at all levels of the health service from facility to district to subnational and national levels.

Data quality assessment (DQA) is a key component of data quality improvement (DQI) processes. DQA determines which types of data need improvement and the relative strengths and weaknesses of data management and reporting systems. It also determines the reliability of information and, thus, supports the accurate measurement of service delivery. Data quality is a multidimensional concept that has a number of attributes that can be assessed (Table 3.10). Different DQA methods assess different data quality attributes *(42)*.

Table 3.10 Data quality dimensions

Components	Description
Accuracy and validity	The data collated must be accurate and match the source data. Documentation should correctly reflect events or results.
Reliability	Data should yield the same results on repeated collection, processing, storing and display of information. Data elements should be consistent across different data sources, for example, paper versus electronic or laboratory information systems versus patient monitoring systems.
Completeness	All required data should be present, and the patient/health record should contain all pertinent data elements, with complete and appropriate documentation.
Timeliness	Data are recorded at the time of observation where possible. Delaying documentation could lead to omission of information or recording errors, and, most importantly, data are not available when needed to guide patient management and care.
Accessibility	All necessary data are available to authorized persons when and where needed. The value of accurately recorded data is lost if it is not accessible.
Relevance	Information is pertinent and useful and reflects activities and achievements. Data should be collected only if it will have a specific use for patient care or programme management and outcome monitoring.
Confidentiality and data security	Patient monitoring systems must be governed by frameworks and regulations for data protection and confidentiality. The data should be used only for purposes related to patient and programme management. Data should not be used for discrimination or criminalization.

Source: adapted from WHO, 2003 *(43)* and Chen et al., 2014 *(42)*.

Data quality improvement

A systems approach to improving data quality involves developing a data quality improvement (DQI) strategy. Efforts to ensure DQI are not limited to data quality assessment/assurance exercises, but a wide range of routine activities integrated as part of strengthening health information systems are critical. This entails building data systems and human resource capacity – strengthening the health system holistically – as well as taking actions to understand and address underlying systematic issues contributing to data quality challenges.

Countries should develop or update their strategies for improving both data quality and use, linking assessments of data quality with remedial actions, including training, supportive supervision and mentoring, as indicted. If errors are identified in data, these should be corrected at the point of service delivery in the HIV patient monitoring system. Smart design of patient monitoring tools can improve data quality and reduce the time that health care professionals and administrative/clerical staff spend on reporting tasks. Periodic review of these tools is also important to ensure that they are consistent with current guidelines, indicator definitions and patient and data flow. Development of job aides, standard operating procedures and appropriate site-level orientation for data clerks and health care workers involved in recording and entering patient monitoring data can improve data quality and standardize data entry and reporting.

In addition, periodic monitoring of data completeness, including labelling patient records with prompts to health care workers to follow up and address incomplete data at consecutive clinic visits, is also important. Incomplete data continues to be a significant data quality challenge in many contexts; it affects patient care and management as well as the accuracy and interpretation of programme indicators and appropriate resource allocation. Box 3.32 summarizes data checks, applicable to any data element, that can ensure the quality of data. The example provided is for HIV VL testing data.

Box 3.32 Viral load data checks

VL data checks should be routinely conducted to improve data quality, strengthen the lab–clinic interface and support both patient and programme management.

To conduct VL data checks, the laboratory's central database/laboratory information systems should be queried by site for the number of samples processed, rejected and pending and these numbers compared with site-reported data for VL results received and documented in the VL sample collection logbook/tracking log. Likewise, the central database/laboratory information management and supply system may be used to generate a line list of high VL clients (aggregate number or by unique ART number) per site for a specific time period (at a minimum, monthly) and checked for agreement with the facility VL sample collection logbook/tracking log, high VL register and facility-level EMR-generated data on VL results received. As another option, or in facilities without EMRs, patient files may be randomly selected to verify results availability and proper documentation (for example, accurate date of VL sample collection and result).

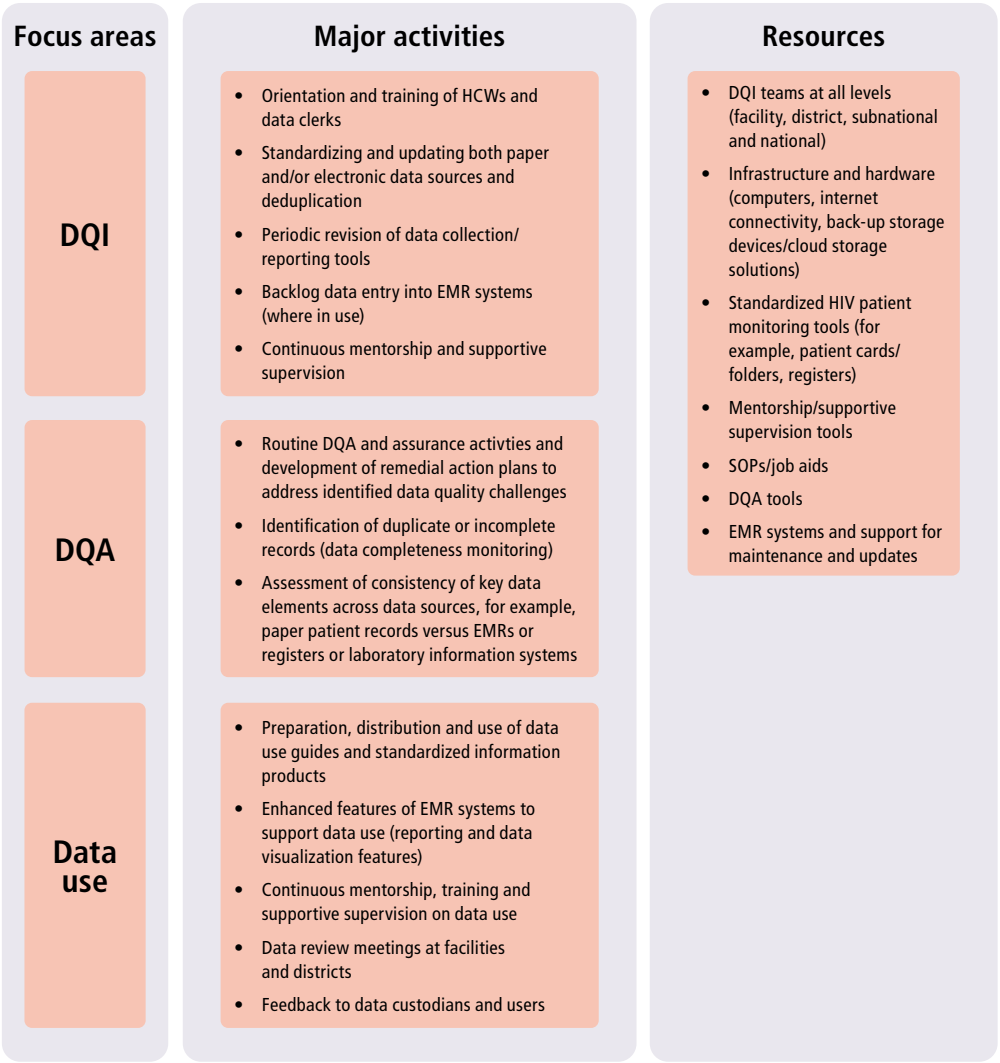
High VL results from a central database/laboratory information management and supply system should be checked against the facility's high VL registers for the same period, and the site's high VL cascade reviewed to see how many individuals have received enhanced adherence counselling (one/two/three sessions), to assess the timeliness of receipt of VL results and subsequent expected actions (repeat VL measurement, multidisciplinary review for virologic failures, potential ART regimen change and repeat VL after regimen switch).

POC testing for VL has been deployed in many countries for priority subpopulations such as children, adolescents, pregnant or breastfeeding women and patients with prior high VL to improve VL testing access and results turn-around time. The scale-up of POC testing platforms has presented unique challenges for data availability, as POC testing platforms do not always communicate with conventional laboratory-based information systems. Data quality checks to ensure the transfer, availability and completeness of all VL data from different settings are critical for programme monitoring.

Frequent onsite follow-up, mentorship, supportive supervision and use of standardized tools for patient monitoring and reporting have improved both data use and data quality in many settings. Close follow-up and intensive supportive supervision are needed for long-term sustainability and support for DQI. In addition, establishing DQI teams within health facilities and engaging a range of stakeholders at all levels (for example, through DQI communities of practice or technical working groups) can help improve accountability, secure stakeholders' buy-in and support learning and sharing of best practices, thereby strengthening implementation of data use and DQI activities.

Collectively, these activities form the building blocks for strategies for long-term DQI and will be context-specific, depending on data collection systems in use, M&E processes, available resources, existing supportive supervision and quality improvement processes, among other factors. Fig. 3.9 presents an example of a DQI and use framework.

Fig. 3.9 Example data quality improvement and use framework



Abbreviations: DQA = data quality assessment; DQI = data quality improvement; EMR = electronic medical record; HCW = health care worker; SOP = standard operating procedure

Source: adapted from PEPFAR. Ethiopia data improvement and use initiative campaign, 2019

Integrated approach to DQI

DQI activities should be well integrated into existing service delivery and quality management and improvement structures. Leveraging existing continuous quality improvement (CQI) management processes to better support data quality improvement will ensure continuity of activities and minimize the additional resources required for DQI.

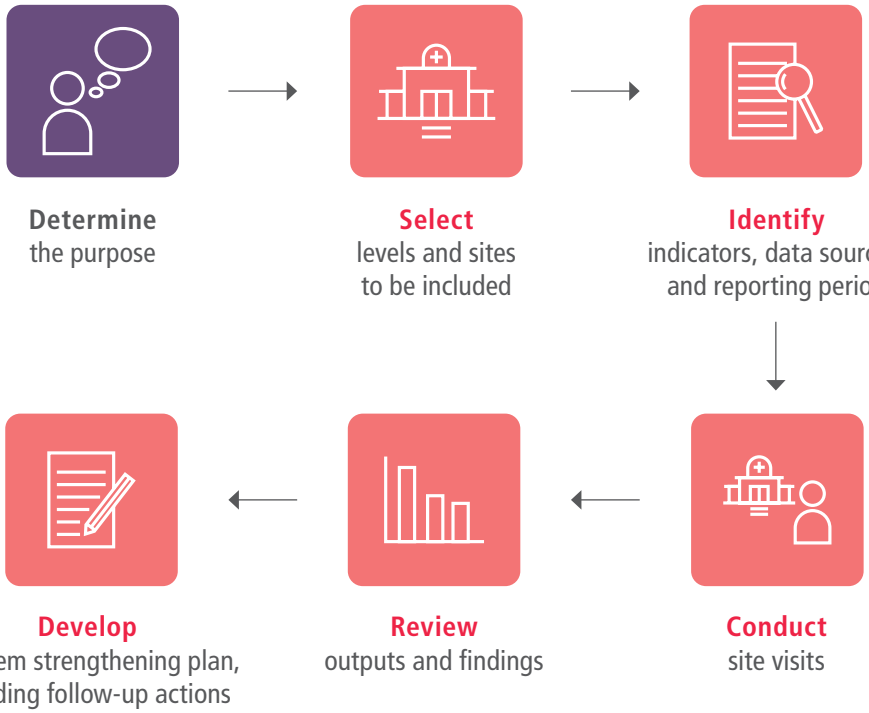
CQI relies heavily on performance measurement and analysis to improve service delivery, which in turn is underpinned by accurate, valid and complete data. Specifically, quality improvement in HIV patient monitoring systems is directed toward achieving better health outcomes, including effective linkage to ART initiation after diagnosis, retention on ART and VL suppression. These all rely on accurate, timely and complete data for measurement and appropriate clinical follow-up.

Available DQA tools

Countries should establish DQA and assurance processes for key HIV indicators and individual-level patient monitoring data to ensure consistency, accuracy, completeness and timeliness. Key HIV indicators should undergo routine DQAs in alignment with the national reporting requirements. Strengthening data quality and use along the entire cascade of HIV services is essential for ensuring quality and continuity of HIV care. As such, data quality assurance activities should target indicators of programmatic priority, preferably integrating HIV testing, treatment and VL testing data to improve service quality and treatment outcomes.

In 2018, to support DQI, WHO, together with UNAIDS, PEPFAR and The Global Fund, developed a joint DQA tool to harmonize and consolidate the approaches taken to review, assess and validate the reported number of people living with HIV receiving ART (the second "95" of the 95–95–95 targets) *(44)*. These reviews focussed on national-level aggregated data as well as the patient monitoring system generating these data. The process ensured that the health ministry led the overall process and the remedial actions and that all stakeholders had defined roles in support of this review. A second module was published in 2020 to enable routine assessment of VL measurement data (the third "95" of the 95–95–95 targets) combined with service delivery and quality assessments of VL monitoring *(45)*. Both tools include data completeness and consistency checks as well as verification of the indicators for ART numbers and VL suppression and supportive actions to strengthen the HIV patient monitoring system. Fig. 3.10 depicts the recommended steps for data quality assessment and assurance activities for key HIV indicators and data elements.

Fig. 3.10 Steps for implementing routine HIV data quality assurance activities at health facilities



Source: WHO, 2020 *(45)*

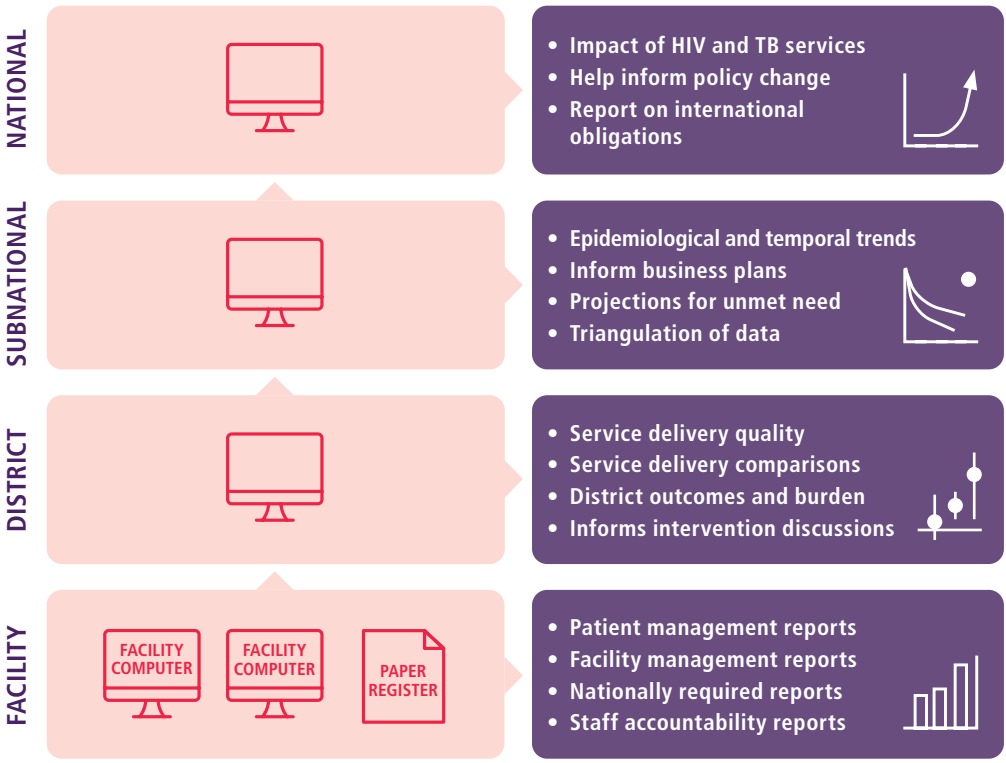
Additional tools for assessing data quality, including at the aggregate level, include the WHO, The Global Fund and GAVI health sector-wide framework for data quality review, which can be used at both facility and national levels[1] and the UNAIDS Naomi model, which can generate modelled estimates of key indicators, including ART coverage. Estimates of HIV indicators generated by the Naomi model are synthesized from a range of data sources at the district level, which creates a feedback loop to improve the quality of model inputs (including routine HIV service delivery data) and outputs (modelled HIV indicators at the subnational level) *(46)*.

3.11.2 Data use for improved service delivery

DQI is ultimately useful only if accompanied by enhanced data use to improve service delivery and health outcomes. Using data at the level of collection improves clinical care and management, strengthens the health service and improves the quality of the data. (See Box 3.33 for a country example of strengthening data use to improve HIV patient management and monitoring.) Enhanced data analysis and use can provide additional information to correct quality of care issues and to better understand service delivery gaps as well as to improve programme management and surveillance and to inform polices (Fig. 3.11).

[1] The data quality review methodology is available in a toolkit from WHO at: https://www.who.int/healthinfo/tools_data_analysis/en/.

Fig. 3.11 Examples of data use at different levels



Source: University of Cape Town, 2021

Data can be used in a number of ways to improve patient care. Some key examples of data use and activities to encourage enhanced data utilization for patient management include the following:

Frequent feedback to data custodians and users. Feedback to individuals associated with the collection, collation and reporting of data is critical to improve both data quality and use. Frequently, health care providers or clerical staff collect data and report upwards without seeing the value of the data they collect. To promote data use in health facilities, opportunities need to be created to review and discuss the data collected. Regular meetings with consistent feedback to facility staff (clinical and non-clinical) on the interpretation of the data and implications for patient care and management are critical. Depending on the context and the tools available, data use can be facilitated by analysis tools such as dashboards to support data visualization and by sharing performance reports and other information products (see next paragraph). Standardized information products have been successfully employed in a range of settings to facilitate and encourage the use of data for improved patient management and service delivery *(47)*.

Standardized information products. Standardized information products should be developed that communicate key messages from the data and allow data visualization at the service delivery level. These products should contain brief written feedback to explain key messages from dashboards, tables and bar charts, for example, to support the development of follow-up actions. The products should be pilot-tested to ensure that the intended audience, namely health care providers and facility staff engaged in data entry and reporting, find them

useful and understandable. Additional information products for specific uses/circumstances, with additional analysis and display of different data, can be developed as needed to complement standardized information products.

Training, mentorship and supportive supervision. To improve data use at different levels, data users should understand the information being collected and generated and understand the source documents. They should possess the basic skills to analyse and interpret the data effectively. Supportive supervision entails regular "in situ" visits to health facilities. Regular district meetings with representatives of each facility can be held to showcase each other's data and share implementation successes and challenges. In a similar vein, less frequent meetings can be held at subnational levels comparing the various districts' achievements in meeting health goals.

Training on data analysis, visualization and use is important for health care providers, facility managers and personnel involved in data entry, management and demand and use at the facility level. Patient monitoring data can also guide the design of training and capacity-building activities by identifying areas in which facilities are performing well as well as areas of weakness. For example, during trainings facilities with low LTFU rates can share their practices and experiences on how they achieve and maintain these low rates. Conversely, patient monitoring data can be used to focus training on areas with identified service delivery gaps. For instance, health facilities with low rates of VL suppression can be targeted for additional on-site support and mentoring that focuses on managing people on ART with high VL. Mentorship from subnational levels of the health system to health facilities on use of data, including EMR reports and tools, if relevant, to improve clinical management, service delivery and client tracing may also be employed to support data use.

Monthly/periodic facility data review meetings. Every meeting at all health system levels can start, for example, with a short presentation of recent data and trends. Such opportunities for performance review support information sharing and encourage health care providers to examine the data and reflect on gaps and weaknesses and how to address them. Data staff can report service delivery data and patient alerts at clinical meetings to encourage discussions on:

- strengths and weaknesses in service delivery at the site
- possible interventions for poor outcomes
- data that need to be captured but that health care providers are not recording or that are often incomplete
- data backlog or storage issues
- mentoring needs.

To support the above, health facilities should commit to a schedule of action reports with clear guidance on who extracts the data, who takes action, who checks completion and clears data reports. Patient monitoring tools should culminate in reports that are actionable, so that each report suggests who at each sublevel should take action, how and by when. This will help to ensure that data are available at the right level and that roles and responsibilities for follow-up are clearly identified on data reports.

Analysis of LFTU data to support client tracing. Clients recorded and reported as LTFU are generally a combination of unidentified deaths, unrecorded transfers and individuals truly LTFU. This information can help in determining treatment outcomes as well as support client tracing efforts. Analysis of patient monitoring data on LTFU clients should be performed routinely to understand these patient losses and support re-engagement in care. Records should be corrected with this additional information to improve service delivery, including adherence and

retention, and to better inform reporting of programme results. Data can be used to trigger patient recall through telephone follow-up and home visits. For instance, periodic review of patients who have missed an appointment by more than seven days or do not have ARV drugs for more than seven days can identify patients for recall, tracing interventions and support for re-engagement. Sites also should review these data to understand what actions could be taken at the facility to improve engagement and the experience of clients.

Attention to LTFU is particularly important in the context of the scale-up of DSD models, such as multi-month dispensing, where tracking the follow-up status of patients is critical. Routine and timely data reviews at the site, district and national levels can provide information on transfer-in and transfer-out issues and explain data quality issues.

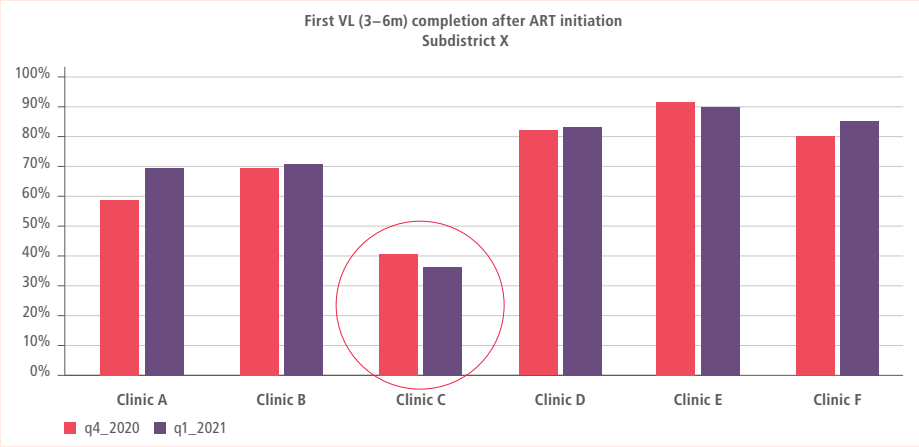
Additional tools and resource materials on data use and demand developed by Measure Evaluation can be found at: https://www.measureevaluation.org/our-work/data-demand-and-use/data-demand-and-use-publications.html.

Box 3.33 Data use to improve service delivery and patient monitoring in Cape Town, South Africa

Subdistrict meetings in a large Cape Town metro subdistrict are organized quarterly, aggregated reports from the patient monitoring system are reviewed, and the data are used to improve service delivery. Challenges and successes in the performance of individual clinics are highlighted and possible reasons are addressed by sharing experiences and developing recommendations. A case example of the process follows:

1. Using aggregate patient monitoring data, the district identified challenges at individual clinics. For example, completion rates of early HIV VL testing (3–6 months after ART initiation) were compared across facilities. Review of these data revealed that Clinic C had performed below average for two quarters (Fig. 3.12). Reasons for these performance issues needed to be addressed at the clinic, using a line list of patients to review individual records.

Fig. 3.12 Completion of first VL test after ART initiation by clinic in one subdistrict, quarter 4, 2020 and quarter 1, 2021



Source: University of Cape Town, 2021

Box 3.33 (continued) Data use to improve service delivery and patient monitoring in Cape Town, South Africa

2. Using individual-level patient monitoring data, Clinic C investigated possible reasons for performance issues. Clinic management meetings were held, and the clinic staff (clinical, clerical, and patient-support) discussed reasons for low early VL testing coverage. The first step was to investigate whether this was a data issue or a clinical/patient management issue. This entailed several steps, and in each case a person was responsible for collecting the information. The steps in the process were these:
    - extracting a line list of all people initiated on ART in the first quarter of 2021;
    - extracting VL test dates and results from the laboratory information management system;
    - retrieving the patient folders and comparing "ART initiation" dates and presence or absence of VLs test results with the patient line list;
    - entering these data into a spreadsheet and analysing it after removing deaths, losses to care and transfers out.

Findings

Both data errors and VL test opportunities missed by clinicians contributed to the low early VL testing coverage. The following specific data issues were identified:

- Patient folders were missing.
- Discrepancies were noted in ART initiation dates between the patient folders and the EMRs.
- HIV VL samples were taken, but outside the appropriate time window, that is, not following the national guidelines for treatment monitoring.
- HIV VL samples were taken, but the results were not transcribed onto the clinic stationary (that is, patient monitoring tools).

However, most of the missed VL tests were due to clinicians overlooking the opportunity for a VL test for various reasons (for example, time constraints, high burden of patients).

At the next clinic meeting, the head clinician made the following recommendations for improving early VL testing coverage:

Clinicians

- ongoing in-house training
- ensuring the correct use of patient monitoring stationery/tools
- regular audits (using WHO or other audit survey tools)
- avoiding postponing taking blood samples at next visit. Clinicians were advised that, if they are short on time during clinical visits, they ask other clinical staff to assist and ensure that a VL test is performed.

Box 3.33 (continued) Data use to improve service delivery and patient monitoring in Cape Town, South Africa

Clerical staff

- daily organizing of patient folders
- printing test results as patients arrive for their visit if there is no hard copy in the patient's folder
- daily capturing and filing of test results, including VL.

Counsellors

- checking patient folders systematically and referring for VL testing if appropriate timing.

3.12 Adaption and implementation of the HIV patient monitoring system

3.12.1 Introduction

This section provides guidance on steps for adapting and implementing all or part of the HIV patient monitoring system outlined in this document. It includes recommendations for coordinating across programmes and services and for the transition from a previous version of the patient monitoring system to an updated one. It lays out requirements for a patient monitoring system that can be applied to any system along the paper-to-electronic continuum. The generic tools and accompanying recommendations in this guidance should be adapted and customized to fit the specific setting of each country and programme. To provide essential, quality patient care, it is crucial to meet the minimum requirements.

3.12.2 Steps for country adaptation of the guidance

The generic HIV patient monitoring system is designed to support both integrated service delivery at the facility level and facilities and community ART and testing sites where services remain separate but need to be closely linked. "Integration" refers to HIV services included in the same visit (by the same health worker or within a clinical team) along with ANC, labour and delivery, postpartum and new born care and with TB and other acute and chronic care services. While not providing a detailed methodology, Table 3.11 shows the recommended actions to take (not necessarily in the order shown) to adapt and operationalize the generic HIV patient monitoring system. Where a previous version of the system has already been implemented, these steps may be less involved. Before and during these 16 steps, it is important to also keep in mind a few special considerations:

- **Service delivery model.** The extent to which services are integrated – whether fully, partially or not at all – will affect where and how the HIV patient monitoring tools will be used (see also level of health system).

- **Type of HIV epidemic.** The minimum dataset for HIV testing and treatment (Web Annex A) and indicators (Chapter 8) presented in this guidance mainly reflect high HIV burden settings (with some exceptions).
- **Level of health system.** This is the first point of contact with the patient. As with the type of service delivery model, linking records for referral (and transfer) of clients is critical so that they receive an uninterrupted continuum of care, and the primary care facility/community ART/testing site in the context of DSD remains the client's first point of contact. Additionally, careful monitoring of transferred clients (using a standardized referral form (Web Annex J) and confirming receipt of the patient) reduces the potential for double reporting. The community ART monitoring tool (Web Annex I) may also have to be adapted, depending on whether, and what kind of, activities are being carried out by community service delivery organizations.
- **Adoption of DSD.** This will affect the patient monitoring tools and system, which will need to be adapted to monitor and account for the unique aspects of DSD, including linkage and referral as well as data flow between community service delivery sites and health facilities.
- **Stage of transition from paper to electronic system and digital health.** This will influence how tools are adapted. Revised paper tools will be printed and distributed, whereas electronic systems will be reconfigured, with appropriate links to the HIS and other data systems and adhering to set data standards (see Chapter 6).

Table 3.11 Sixteen recommended steps to adapt the revised HIV patient monitoring system

Action	Description
1. Health ministry leads technical work group	The health ministry forms a technical work group to lead review of the existing HIV patient monitoring system, strengthening of a harmonized national system and potential revision. This technical working group will carry out the actions listed in this table.
2. Stakeholders meet	The technical working group gathers key stakeholders to discuss revision of the current HIV patient monitoring system. Bring in new actors (from chronic and communicable disease programmes, digital health, implementing partners) as necessary, depending on the scope of integration and intended linkages of the revised HIV patient monitoring system.
3. Inventory current tools	Make an inventory of existing tools for HIV, MNCH and TB (and any other integrated or linked programme) and identify potential gaps.
4. Define indicators and minimum dataset	Discuss the changes in the recommended key indicators and the minimum dataset; determine which to add to the current HIS.
5. Identify the system and tools for data collection	Discuss whether the existing system and tools are adequate (with the addition of data elements) for the recommended revised HIV patient monitoring system; add/adapt or remove tools as necessary.
6. Review the digital health ecosystem	Discuss whether the existing paper-to-electronic pathway is adequate and make changes as needed. Review issues of interoperability, use of UIDs (if not already in use) and data security and governance issues (see Chapter 6).

Table 3.11 (continued) Sixteen recommended steps to adapt the revised HIV patient monitoring system

Action	Description
7. Adapt generic tools based on national guidelines	Adapt existing tools based on guidelines, changes in country needs, special settings or different epidemics, and stakeholder discussions.
8. Develop stakeholder consensus	Obtain consensus from key stakeholders for all revisions.
9. Identify supervision structure	Confirm supervision structure if already existing. If none exists, plan who will carry out, supervise and support patient monitoring at community, facility, district, subnational and national levels, including for periodic review of the revised patient monitoring system.
10. Develop training materials and conduct training	Adapt existing (or develop new) training materials to prepare staff at all levels for the use of the revised patient monitoring tools; then, train and retrain as necessary.
11. Plan for follow-up after training	Plan for systematic follow-up after training and supportive supervision to ensure that revisions to the system are being adequately implemented.
12. Consider human resources	Make an inventory of current staff members who carry out patient monitoring activities at each level of the overall system. Identify and plan to fill any gaps and retrain on the revised system accordingly (see section 3.12.3).
13. Consider infrastructure	Make an inventory of infrastructure needs for the revised patient monitoring system (including for electronic systems) and plan to obtain required items to ensure a functioning HIV patient monitoring system (see section 3.12.4).
14. Review data quality and use	Review data quality and use guidelines/SOPs, if existing; if not, develop and implement them based on these guidelines (see section 3.11 on improving the quality and use of individual-level data to strengthen HIV patient monitoring and care).
15. Coordinate across programmes and partners	Expand coordination across disease programmes and implementing partners as necessary, depending on the revised HIV patient monitoring system (see Box 3.34).
16. Assure sustainability	Include patient monitoring in programme budgets, funding proposals, strategic planning and policy documents to ensure sustainability and continuing improvement of the revised patient monitoring system.

Box 3.34 Integration, collaboration and partnership

A successful HIV patient monitoring system is founded on the collaborative work and cooperation of various health sector partners. These include the following:

HIV programmes

A standardized minimum dataset should be the foundation of any national HIV patient monitoring system (Web Annex A). This should define the data collected from any system, whether paper-based or along the paper-to-electronic continuum. Sites with greater resources may collect more data. Standardized tools facilitate supervision, aggregation and transfer of clients between facilities and community service delivery sites. The HIV patient monitoring system is a key component of any national HIS. The individual data elements should be standardized and well-defined (data exchange standards set up), and, similarly, the indicators that they feed into should be clearly defined. Also, electronic systems should be harmonized. At a minimum, the HIS should include the priority national HIV indicators and adhere to data standards. The patient monitoring system will contribute to many of these. Given that HIV services have strong links to MNCH and TB programmes, it is important to ensure that the relevant data elements are harmonized across programmes (for example, numbers of pregnant women receiving ART may come from both ANC clinics and HIV clinics). This is true also for other programmes, such as STIs, viral hepatitis and cervical cancer, among others (see Chapter 4).

National programmes

With the scale-up of ART, HIV is now among a number of treatable chronic diseases that require longitudinal patient follow-up. Collaboration between related national programmes is important for the success of the HIV programme. This includes TB, MNCH, sexual and reproductive health, STIs, other communicable and chronic disease programmes, as well as strategic information units or the HIS. Recommended activities include:

- using HIV patient cards and ART registers, or electronic equivalents, including integrated EMRs, at TB and MNCH sites;
- including an HIV patient card in an integrated health facility patient folder or integrating HIV patient monitoring information into the patient card (see Web Annex H);
- reconciling programme registers to avoid double-counting;
- integrating service delivery at the facility (for example, a pregnant HIV-positive woman can receive ANC and HIV care at the same place);
- integrating HIV data into other programme records;
- integrating HIV data into the HIS;
- standardizing HIV indicators across programme areas;
- adopting/rolling out UIDs to enable tracking of clients longitudinally across multiple service delivery areas.

Box 3.34 (continued) Integration, collaboration and partnership

Other institutions

Collaboration between the HIV programme and nongovernmental institutions can facilitate access to resources to improve patient and programme monitoring and so improve patient care. Such collaboration can be both in the country (for example, country offices of UN organizations, community-based organizations, faith-based organizations, implementing partners, private sector providers, teaching institutions) and international (for example, foundations, donors, universities). Internal institutions may collaborate through involvement in relevant (technical or otherwise) working groups to broaden the range of available support.

3.12.3 Human resources and capacity-building

Patient monitoring requires the participation of a wide range of staff with overlapping responsibilities. Shifting tasks to lower-level cadres and even lay providers can increase what the programme can accomplish. Table 3.12 suggests a breakdown of different roles and responsibilities among staff members. In the case of electronic systems, "EMR" may replace "patient record" and "electronic register" may replace "register", but staff responsibilities will remain the same. Once the roles and responsibilities of each staff member have been identified, it is important to provide the necessary training and follow-up so that all patient monitoring activities are carried out correctly and efficiently. Box 3.35 outlines special considerations for strengthening human resources for patient monitoring, including training, clinical mentoring and supervision.

Table 3.12 Suggested staff roles and responsibilities for HIV patient monitoring

Staff	Roles and responsibilities for patient monitoring
District health management teams and HIS/M&E focal point	• Supervise the monitoring system to ensure quality of care and data. • Discuss data and how to use data to improve patient care and service delivery. • Integrate patient monitoring into clinical mentoring and supervision visits (at least once a quarter). • Carry out periodic review of the patient monitoring system. • Assist staff with analysis and compilation of data for routine reporting and improved data use for patient management. • Provide feedback from previous reports, data quality assurance activities and other data analyses or evaluations. • Provide on-the-spot training of health centre staff to support patient monitoring, data use and data quality. • Provide supportive supervision for documentation and data management to achieve quality patient monitoring. • Link the health centre and the national level to ensure that all patient monitoring needs are met (for example, adequate staff, tools and other resources) and to communicate any changes to national standards or norms.

Table 3.12 (continued) Suggested staff roles and responsibilities for HIV patient monitoring

Staff	Roles and responsibilities for patient monitoring
Health facility in-charge	• Be familiar with the existing patient monitoring tools (both paper and electronic), how they fit into the overall patient flow of the health facility (and community links) and how data collected by these tools should be used to improve patient management. • Be alert to any stock-out and restock as necessary. • Ensure that all staff members who are designated to carry out any element of patient monitoring are adequately trained. • Validate and analyse the final monthly/quarterly/annual report before it is transmitted to the next administrative level. • Ensure that the clinical mentor(s) and supervisor(s) address the patient monitoring system during their routine visits. • Build a strong relationship with the district health management team. • Provide helpful feedback to staff based on feedback received from the district or higher level or one's own observations. • Be familiar with the minimum dataset and core indicators and how to report and analyse them. • Keep up to date with any changes to the patient monitoring system and ensure that the health centre adheres to national standards.
Triage worker, receptionist or data clerk	• Maintain an appointment book/system and flag missed appointments. • Start or retrieve patient records. • Record patient data in the patient record (or register, depending on the HIV service provided). • Generate a list of patients LTFU that should be traced.
ART aid, lay counsellor or professional counsellor	• Record patient data in the patient record (or register, depending on the HIV service provided) and use data to support follow-up by, for example, tracing activities or identifying patients that may need follow-up clinical visits, ARV drug refills, laboratory tests and referrals.
Nurse, clinical officer or other clinician	• Record patient data in the patient record (or register, depending on the HIV service provided) or equivalent electronic tools, for example, EMR. • Record data on the patient-held card, or book or health passport (if used) or equivalent electronic tools, for example, EMR. • Tally data and fill in routine reports. • Conduct patient reviews with the clinical team (using longitudinal records) and use data to discuss patient management and strategies/interventions to improve clinical outcomes. • Review routine HIV programme reports to track progress. • Review registers to assess the quality of HIV services. • Review the quality of HIV patient records and registers with the clinical or district supportive supervision team. If a data clerk, administrator or other staff member is not available: transcribe data from patient records to registers.

Table 3.12 (continued) Suggested staff roles and responsibilities for HIV patient monitoring

Staff	Roles and responsibilities for patient monitoring
Data clerk or administrative or other staff member responsible for data entry, management and reporting	• Report on key HIV testing, treatment and care performance data at monthly clinical meetings, with head-clinician facilitating the discussion that follows; discuss issues such as missing data, how health care providers can improve data quality. • Organize and manage patient records and registers. • Transcribe data from patient records to registers. • Enter patient data into the database/EMR (if used). • Tally data and fill in routine reports. • Review registers to assess the quality of HIV services and data. • Review the data quality of HIV patient records and registers with the clinical or district supportive supervision team.
Community health worker/ service provider	• Initiate HIV testing and counselling and ART initiation in the community. • Monitor adherence and drug pick-up. • Follow up and trace individuals LTFU. • Record patient data in the community ART tool (or register, depending on the HIV service provided) or equivalent electronic tools, for example, EMR. Use the data to identify which clients need to be followed up or require referral or follow-up clinical visits, including laboratory tests or need ARV drug refills. • Organize and manage patient records and registers. • Transcribe data from patient records to registers. • Enter patient data into the database/EMR (if used). • Tally data and fill in routine reports. • Transmit and report data to nearby health facility and or national reporting system. • Review community patient monitoring tools to assess the quality of HIV services and data. • Review the quality of HIV patient records and registers with the clinical or district supportive supervision team/partners where relevant.
External clinical mentors and supportive supervisors (for example, from district team)	• Review the data quality of HIV patient records and registers with the clinical or district supportive supervision team. • Provide supportive advice and recommendations to help improve clinical care and monitoring and to improve data use.
Pharmacist, pharmacy technician/assistant	• Dispense drugs. • Manage drug-related toxicity and report adverse drug reactions. • Provide adherence counselling and monitoring. • Enter/record ARV dispensing into pharmacy records.
Facility-based lay provider	• Enrol patients, fill demographic information in the cards; transfer information to registers. • Provide adherence counselling, treatment literacy and education for patients. • Assess adherence (by pill counts). • Track patients LTFU.

Box 3.35 Recommendations for strengthening human resource development

Training

- Use patient monitoring data to design and inform training, identifying areas of weakness as well as strong performance.
- Integrate training into pre-service education.
- Integrate in-service and ongoing training.
- Support trainees.
- Ensure that staff trained in medical, nursing, pharmacy or other degree programmes take refresher courses or continuing education.
- Take advantage of opportunities outside of formal training, such as review of cases, experience sharing, clinical mentoring, educational presentations, conferences and cross-site visits.

Clinical mentoring and supportive supervision

A clinical mentor:

- is a clinician with experience and expertise who provides ongoing training and advice to clinical providers with less experience or expertise to improve their capacity, motivation and confidence;
- helps less experienced providers develop skills and experience, grow professionally and provide better care, and supports them in their personal and professional growth;
- meets regularly with providers to review clinical cases, answer questions, solve problems, provide feedback and assist with case management;
- is formally assigned to a staff member or can volunteer based on personal interest;
- may be a clinical provider from the district hospital, mentoring through visits and ongoing long-distance exchanges. These visits should include the following components related to patient monitoring:
  - observation of case management and reinforcement of a staff member's skills
  - review of HIV patient cards and ART registers or electronic equivalents
  - clinical case review
  - clinical team meeting
  - documentation of each visit (including recommendations).

Box 3.35 (continued) Recommendations for strengthening human resource development

The health centre clinical team should prepare for these visits by selecting cases for review (such as cases of people recently initiated on ART, as well as routine, challenging or difficult cases, or deaths). In some instances, inviting the client back to the clinic when the clinical mentor will be there can facilitate consultation and avoid referral.

- integration of the recommendations of mentoring into quality management/ improvement activities at the health centre.

Supervision

- is making sure that staff members have the training, mentoring, guidelines, tools, equipment, supplies and working conditions that they need to perform their jobs effectively;
- can take place at the community ART site, at the primary health centre or at a higher-level facility such as the district hospital;
- can help ensure that each staff member is providing adequate services, is following health ministry procedures and policies and supports data use to improve clinical management and outcomes;
- should be regular, compassionate, helpful, adaptable and should focus on assisting junior staff to achieve goals, identify problems and challenges and jointly find solutions to problems;
- can be done with a supervisory checklist that acts as a reminder and follow-up of the key components of a supervisory visit.

3.12.4 Transitioning to digital health systems

Over time many HIV high burden countries have transitioned from paper-based systems towards the use of electronic information systems, including EMRs. This transition is driven by (a) the increasing difficulty of accurately and reliably retrieving data from a paper-based patient record system, (b) the time and effort required to maintain a paper-based system as the volume of data increases, (c) the need to support integration and linkage across different service delivery areas and sites over time, and d) increasing investments and adoption of digital health innovations by both countries and partners. For instance, a variety of EMR systems have been rolled out to support HIV patient monitoring and management. Although many countries have begun this transition to digital systems, in many settings coverage across all facilities is far from optimal. As a result, some countries may need to continue to use data from aggregate systems to report on HIV programme performance. Chapter 6 offers guidance on transitioning to EMRs, as well as issues concerning UIDs, interoperability of data systems and data security and confidentiality.

Improving national and global reporting

Establishing good-quality individual-level data is the first step to improving reporting and data use at any level. This means accurate patient-level data from the HIV patient monitoring system, which is entered in the HIV patient card or directly into an EMR. It also means that there are data quality checks at each step of transcription or aggregation (see section 3.11).

References

1. Consolidated HIV strategic information guidelines: driving impact through programme monitoring and management. Geneva: World Health Organization; 2020 (https://www.who.int/publications/i/item/9789240000735, accessed 24 June 2022).
2. Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach. Geneva: World Health Organization; 2021 (https://www.who.int/publications/i/item/9789240031593, accessed 23 June 2022).
3. Updated recommendations on service delivery for the treatment and care of people living with HIV. Geneva: World Health Organization; 2021 (https://www.who.int/publications/i/item/9789240023581, accessed 27 June 2021).
4. Definitions and reporting framework for tuberculosis – 2013 revision. Geneva: World Health Organization; 2013 (https://www.who.int/publications/i/item/9789241505345, accessed 4 July 2022).
5. Consolidated guidelines on HIV testing services. Geneva: World Health Organization; 2019 (https://www.who.int/publications/i/item/978-92-4-155058-1, accessed 23 June 2022).
6. Nakagawa F, Lodwick RK, Smith CJ, Smith R, Cambiano V, Lundgren JD et al. Projected life expectancy of people with HIV according to timing of diagnosis. AIDS. 2012;26:335-43.
7. Siedner MJ, Ng CK, Bassett IV, Katz IT, Bangsberg DR, Tsai AC. Trends in CD4 count at presentation to care and treatment initiation in sub-Saharan Africa, 2002–2013: a meta-analysis. Clin Infect Dis. 2015;60:1120-7.
8. Wanyenze RK, Hahn JA, Liechty CA, Ragland K, Ronald A, Mayanja-Kizza H et al. Linkage to HIV care and survival following inpatient HIV counseling and testing. AIDS Behav. 2011;15:751-60.
9. Dalal S, Johnson C, Fonner V, Kennedy CE, Siegfried N, Figueroa C et al. Improving HIV test uptake and case finding with assisted partner notification services. AIDS. 2017;31:1867.
10. Policy brief: WHO recommends HIV self-testing – evidence update and considerations for success. Geneva: World Health Organization; 2019 (https://apps.who.int/iris/bitstream/handle/10665/329968/WHO-CDS-HIV-19.36-eng.pdf?sequence=1&isAllowed=y, accessed 17 February 2022).
11. Guidelines for managing advanced HIV disease and rapid initiation of antiretroviral therapy. Geneva: World Health Organization; 2017 (https://www.who.int/publications/i/item/9789241550062, accessed 27 September 2021).
12. WHO updated recommendations on HIV prevention, infant diagnosis, antiretroviral initiation and monitoring. Geneva: World Health Organization; 2021 (https://www.who.int/publications/i/item/9789240022232, accessed 4 July 2022).
13. Chammartin F, Ostinelli CHD, Anastos K, Jaquet A, Brazier E, Brown S et al. International epidemiology databases to evaluate AIDS (IeDEA) in sub-Saharan Africa, 2012–2019. BMJ Open. 2020;10:e035246.
14. Haas AD, Zaniewski E, Anderegg N, Ford N, Fox MP, Vinikoor M et al. Retention and mortality on antiretroviral therapy in sub-Saharan Africa: collaborative analyses of HIV treatment programmes. J Int AIDS Soc. 2018;21:e25084.
15. Holkmann Olsen C, Mocroft A, Kirk O, Vella S, Blaxhult A, Clumeck N et al. Interruption of combination antiretroviral therapy and risk of clinical disease progression to AIDS or death. HIV Med. 2007;8:96-104.

16. Kousignian I, Abgrall S, Grabar S, Mahamat A, Teicher E, Rouveix E et al. Maintaining antiretroviral therapy reduces the risk of AIDS-defining events in patients with uncontrolled viral replication and profound immunodeficiency. Clin Infect Dis. 2008;46:296-304.

17. Ehrenkranz P, Rosen S, Boulle A, Eaton JW, Ford N, Fox MP et al. The revolving door of HIV care: Revising the service delivery cascade to achieve the UNAIDS 95-95-95 goals. PLoS Med. 2021;18:e1003651. doi: 10.1371/journal.pmed.1003651

18. Osler M, Hilderbrand K, Goemaere E, Ford N, Smith M, Meintjes G et al. The continuing burden of advanced HIV disease over 10 years of increasing antiretroviral therapy coverage in South Africa. Clin Infect Dis. 2018;66:S118-S25.

19. Consolidated guidelines on tuberculosis. Module 3: Diagnosis - rapid diagnostics for tuberculosis detection Geneva: World Health Organization; 2020 (https://www.who.int/publications-detail-redirect/9789240029415, accessed 27 September 2021).

20. Technical brief: Surveillance of antiretroviral toxicity: global HIV, hepatitis and STIs programme: what's new in person-centred HIV patient and antiretroviral drug toxicity monitoring. Geneva: World Health Organization; 2020 (https://www.who.int/publications/i/item/9789240007901, accessed 9 November 2021).

21. Transition to new antiretroviral drugs in HIV programmes: clinical and programmatic considerations. Geneva: World Health Organization; 2017 (http://apps.who.int/iris/bitstream/handle/10665/255888/WHO-HIV-2017.20-eng.pdf?sequence=1, accessed 9 November 2021).

22. Global Action plan on HIV drug resistance 2017-2021. Geneva: World Health Organization; 2017 (https://www.who.int/publications/i/item/978-92-4-151284-8, accessed 12 July 2022).

23. Global guidance on criteria and processes for validation: elimination of mother-to-child transmission of HIV and syphilis. Geneva: World Health Organization; 2021 (https://www.who.int/publications/i/item/9789240039360, accessed 4 July 2022).

24. Prevention of mother-to-child transmission of hepatitis B virus: guidelines on antiviral prophylaxis in pregnancy. Geneva: World Health Organization; 2020 (https://www.who.int/publications/i/item/978-92-4-000270-8, accessed 31 August 2021).

25. Ending inequalities and getting on track to end AIDS by 2020. A summary of the commitments and targets within the United Nations General Assembly's 2021 Political Declaration on HIV and AIDS. Geneva: Joint United Nations Programme on HIV/AIDS (UNAIDS); 2021 (https://www.unaids.org/sites/default/files/media_asset/2021-political-declaration_summary-10-targets_en.pdf, accessed 1 April 2022).

26. Monitoring and evaluation framework for antiretroviral treatment for pregnant and breastfeeding women living with HIV and their infants – IATT Option B/B+ M&E framework. New York: Inter-agency Task Team on the Prevention and Treatment of HIV Infection in Pregnant Women, Mothers and Children; 2015 (https://www.childrenandaids.org/sites/default/files/2017-05/IATT-Framework-Monitoring-Evaluation-Framework-for-ART-Treat.pdf, accessed 4 July 2022).

27. Consolidated guidelines on person-centred HIV patient monitoring and case surveillance. Geneva: World Health Organization; 2017 (https://www.who.int/publications/i/item/978-92-4-151263-3, accessed 11 July 2022).

28. WHO policy on collaborative TB/HIV activities: guidelines for national programmes and other stakeholders. Geneva: World Health Organization; 2012 (https://apps.who.int/iris/handle/10665/44789, accessed 4 July 2022).

29. WHO consolidated guidelines on tuberculosis. Module 2: Screening – systematic screening for tuberculosis disease Geneva: World Health Organization; 2021 (www.who.int/publications/i/item/9789240022676, accessed 23 December 2021).

30. A guide to monitoring and evaluation for collaborative TB/HIV activities. Geneva: World Health Organization; 2015 (https://www.who.int/publications/i/item/9789241508278, accessed 23 December 2021).

31. WHO global lists of high burden countries for tuberculosis (TB), TB/HIV and multidrug/rifampicin-resistant TB (MDR/RR-TB), 2021–2025: background document. Geneva: World Health Organization; 2021 (https://apps.who.int/iris/handle/10665/341980, accessed 4 July 2022).

32. Revised TB recording and reporting forms and registers – version 2006. Geneva: World Health Organization; 2006 (http://apps.who.int/iris/bitstream/10665/69608/1/WHO_HTM_TB_2006.373_eng.pdf?ua=1, accessed 7 July 2022).

33. ICAP approach to differentiated service delivery. New York: ICAP at Columbia University; 2017 (https://cquin.icap.columbia.edu/resources/icap-approach-to-differentiated-service-delivery/, accessed 4 July 2022).

34. Quality standards for less-intensive differentiated ART models. New York: Columbia University, ICAP. The CQUIN Project HIV Learning Network; 2019 (https://cquin.icap.columbia.edu/wp-content/uploads/2021/06/CQUIN-DART-Standards_August-2019_FINAL.pdf, accessed 4 July 2022).

35. Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infections: recommendations for a public health approach. Geneva: World Health Organization; 2016 (https://www.who.int/publications/i/item/9789241549684, accessed 26 June 2022).

36. Ehrenkranz PD, Calleja JM, El-Sadr W, Fakoya AO, Ford N, Grimsrud A et al. A pragmatic approach to monitor and evaluate implementation and impact of differentiated ART delivery for global and national stakeholders. J Int AIDS Soc. 2018;21:e25080.

37. Reidy WJ, Rabkin M, Syowai M, Schaaf A, El-Sadr WM. Patient-level and program-level monitoring and evaluation of differentiated service delivery for HIV: a pragmatic and parsimonious approach is needed. AIDS. 2018;32:399.

38. Decentralized distribution of antiretroviral therapy through the private sector strategic guide for scale up. Research Triangle Park: FHI360; 2019 (https://www.fhi360.org/sites/default/files/media/documents/epic-project-strategic-guide-scale-up.pdf, accessed 4 July 2022).

39. M&E framework for monitoring of differentiated ART services New York: ICAP CQUIN HIV Learning Network; 2018 (https://cquin.icap.columbia.edu/news/cquin-framework-helps-countries-improve-monitoring-and-evaluation-of-differentiated-service-delivery/, accessed 7 July 2022).

40. CQUIN DSD performance review toolkit. New York: Columbia University, ICAP; 2020 (https://cquin.icap.columbia.edu/wp-content/uploads/2020/12/DSD-Performance-Review-Toolkit-Print-v1.pdf, accessed 4 July 2022).

41. Surveillance of HIV drug resistance in populations initiating antiretroviral therapy (pre-treatment HIV drug resistance). Geneva: World Health Organization; 2014 (https://apps.who.int/iris/bitstream/handle/10665/112802/9789241507196_eng.pdf?sequence=1, accessed 23 December 2021).

42. Chen H, Hailey D, Wang N, Yu P. A review of data quality assessment methods for public health information systems. Int J Environ Res Publ Health. 2014;11:5170-207.

43. Improving data quality. A guide for developing countries. Geneva: World Health Organization; 2003 (https://apps.who.int/iris/bitstream/handle/10665/206974/9290610506_eng.pdf?sequence=1&isAllowed=y, accessed 6 June 2022).

44. Data quality assessment of national and partner HIV treatment and patient monitoring data and systems implementation tool. Geneva: World Health Organization; 2018 (https://apps.who.int/iris/handle/10665/274287, accessed 26 June 2022).

45. Module for assessing and strengthening the quality of viral load testing and HIV patient monitoring systems. Geneva: World Health Organization; 2020 (https://apps.who.int/iris/bitstream/handle/10665/206974/9290610506_eng.pdf?sequence=1&isAllowed=y, accessed 17 October 2022).

46. Eaton JW, Dwyer-Lindgren L, Gutreuter S, O'Driscoll M, Stevens O, Bajaj S et al. Naomi: a new modelling tool for estimating HIV epidemic indicators at the district level in sub-Saharan Africa. J Int AIDS Soc. 2021;24:e25788.

47. Information products to drive decision making: how to promote the use of routine data throughout a health system. Washington (DC): Measure Evaluation; 2018 (https://www.measureevaluation.org/resources/publications/sr-17-145-en.html, accessed 18 December 2021).

CHAPTER 4 – INTEGRATING RELATED INFECTIONS INTO HIV SURVEILLANCE SYSTEMS

4

CHAPTER 4 – INTEGRATING RELATED INFECTIONS INTO HIV SURVEILLANCE SYSTEMS

Key recommendations

NEW 1. **Person-centred data should** support the improved health and quality of life of people over their lifetimes, with **routine HIV systems monitoring related infections** such as TB, STIs, hepatitis B and C, pre-invasive cervical disease and cancer and noncommunicable diseases.

NEW 2. **STI testing and treatment** should be measured as part of HIV prevention, testing and treatment programmes.

NEW 3. A recent record of **STI symptoms, diagnoses or treatment should be recorded** in HIV data systems and included as a key event to trigger HIV testing and prevention services.

NEW 4. **Hepatitis B and C testing and treatment services** should be provided and measured as part of HIV prevention, testing and treatment programmes among people living with HIV and priority populations, including people who inject or use drugs, sex workers, men who have sex with men and people in prisons and other closed settings.

NEW 5. **Screening and treatment for cervical cancer** is recommended and should be recorded in routine HIV reporting systems that monitor services received by women living with HIV.

4.1 Introduction

The modes of transmission and epidemiology of a number of STIs and bloodborne infections such as viral hepatitis are similar to those of HIV, with overlapping risk profiles. Interventions to prevent, diagnose and treat these infections are often delivered through integrated or closely linked services. As countries move toward operationalizing the wider use of individual-level data, these data systems will become an important tool for ensuring effective, high-quality services across not only the HIV cascade but also for the prevention, diagnosis and treatment of other related infections. Better integration of health services across diseases also will advance the goals of universal health coverage *(1)*.

This section covers the data elements and indicators needed for monitoring STIs, hepatitis and pre-invasive cervical disease and cervical cancer in HIV surveillance systems. Of the infections that are related to HIV, these have been chosen as important for any country implementing HIV prevention and treatment programmes because of their shared modes of transmission, elevated risk of acquiring HIV, and their substantial burden *(2-7)*. A better understanding of clinical service use and health outcomes for each of these infections can help to improve the health of people living with HIV and people at risk of HIV infection and also reduce transmission to partners. TB, another important infection associated with HIV, is discussed in Chapter 3. Each of the three priority areas – STIs, viral hepatitis, and cervical disease and cervical cancer – are described briefly below and in subsequent separate sections in this chapter. The data elements and indicators discussed here for HIV surveillance systems are a subset of those needed for comprehensive STI, viral hepatitis or cervical cancer surveillance, which must cover a broader population than people living with HIV or people at elevated risk for HIV acquisition.

> The data elements and indicators covered in this section for inclusion in HIV surveillance systems are a subset of what is needed for comprehensive STI, viral hepatitis or cervical cancer surveillance.

Surveillance for incident STIs can serve as both an early warning of the potential of HIV infection in a particular population and an indication of ongoing high-risk sexual activity that may need intensified programme interventions. At the same time, data used for HIV prevention and treatment programme monitoring, such as size estimates of key populations and behavioural survey findings, are useful for informing STI control activities.

An estimated 5–25% of people living with HIV worldwide also have chronic hepatitis B and/or hepatitis C infections. HIV co-infection increases the severity of infections with HBV and HCV and, in the absence of ART, may increase the risk of death due to cirrhosis, hepatocellular carcinoma and other liver-related mortality, and may reduce the response to hepatitis C treatment. Preventing HIV and viral hepatitis are a joint priority for programmes serving key population groups such as people who inject drugs.

Testing and treatment services for HBV, HCV and HIV infections can use similar programmatic and delivery approaches. Facilitating better data linkage between viral hepatitis and HIV interventions will improve the impact and efficiency of both programmes.

Worldwide, an estimated 5% of all cervical cancer cases are attributable to HIV, and women living with HIV have a six-fold higher risk of cervical cancer than women who are not infected with HIV *(6)*. An estimated 85% of women with both cervical cancer and HIV live in sub-Saharan Africa, underscoring the major contribution of HIV to the cervical cancer burden in the region, contributing to the geographic disparities seen in cervical cancer burden *(6, 8)*. New WHO guidelines released in 2021 on screening and treatment to prevent cervical cancer include recommendations for women living with HIV *(9)*. WHO suggests that women living with HIV be offered cervical cancer screening as part of standard HIV care, and that women who have screened positive for cervical pre-cancer or cancer be treated or managed adequately *(10)*.

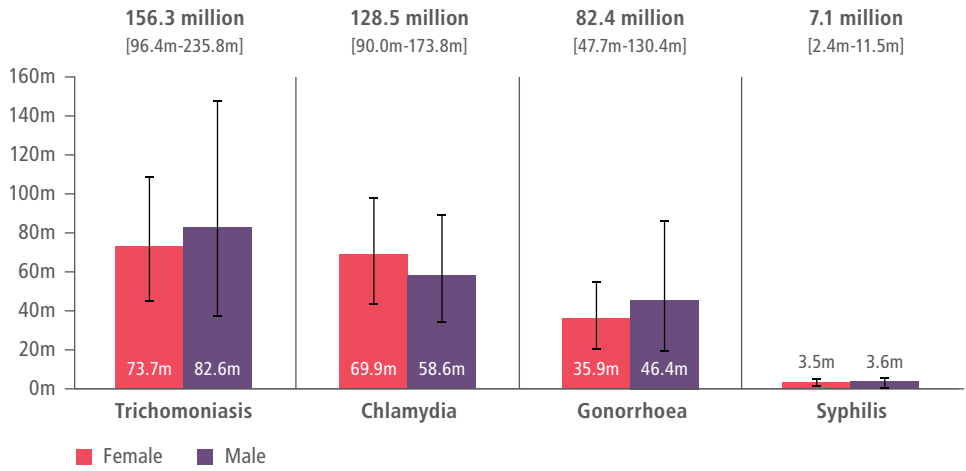
These 2022 consolidated HIV strategic information guidelines seek to strengthen programmes' ability to identify and close gaps in service access, coverage and quality through better integration of STIs, viral hepatitis and cervical cancer screening and treatment data with person-centred HIV surveillance systems. They include a suggested minimum dataset for each area (STIs, hepatitis and cervical cancer) and related indicators for inclusion in HIV prevention and treatment programmes. This minimum dataset, including a date associated with each event and a robust UID standard that can link a single patient's experience across infections, care, time and geographical locations, can provide granular information at facility, subnational and national levels to prioritize prevention and treatment interventions and to inform decision-making on how to best allocate and optimize use of resources.

4.2 Sexually transmitted infections

4.2.1 Background and rationale

More than one million curable STIs are acquired every day worldwide, primarily caused by *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Treponema pallidum* (syphilis) and *Trichomonas vaginalis* (Fig. 4.1). In addition, more than one in every seven women are estimated to be infected with human papillomavirus (HPV) which causes cervical cancer, and more than 500 million people have genital herpes simplex virus (HSV) infection *(11, 12)*. Population groups that are especially vulnerable to STIs include sex workers and their clients, men who have sex with men, trans and gender diverse people, adolescents and young adults, mobile populations and people affected by conflict and civil unrest.

Fig. 4.1 Estimated new cases of four curable STIs among adults (15–49 years old), by sex, 2020



Source: WHO, 2021 *(13)*

GHSS 2022–2030

The Global Health Sector Strategy (GHSS) on HIV, Hepatitis and STIs calls for ending STIs as public health concerns by 2030. It includes the following global impact targets for 2030 *(14)*:

- Number of new cases of syphilis, gonorrhoea, chlamydia and trichomoniasis among people 15 to 49 years old in 2030 of less than 150 million, a 60% decline from 2020;
- Number of new cases of syphilis among people 15 to 49 years old in 2030 of 0.7 million, a 90% decline from 2020;
- Number of new cases of gonorrhoea among people 15 to 49 years old in 2030 of 8.2 million, a 90% decline from 2020;
- Congenital syphilis cases in 2030 of less than 50 per 100 000 live births per year, an 88% decline from 2020.

STIs and HIV infection

Meeting these STI impact targets will require a significant scale-up in the resources for STI prevention and treatment and the investment in new prevention, diagnostic and treatment technologies. Also, there will be a need to strengthen the capacity of national health systems to collect and analyse STI data in a timely manner to inform health polices, treatment guidelines and resource allocation. This need includes collecting data on case reports of symptomatic infections, data on individuals tested for STIs, prevalence surveys, etiological assessment of STI syndromes and monitoring of gonococcal antimicrobial resistance.

Diagnosing and treating STIs are an integral component of HIV prevention and treatment services, and STI surveillance is a key component of HIV epidemic control and programme management. The sexual behaviours that put people at risk for HIV (for example, not using condoms and having non-regular or multiple sex partners) also put them at risk for acquiring other STIs. Surveillance for incident STIs (for example, urethral discharge and gonorrhoea in men and primary and secondary syphilis) can serve as both an early warning of the epidemic potential of HIV via sexual transmission in a particular population and an indication of ongoing high-risk sexual activity that may need intensified programme interventions.

There is a high co-prevalence of HIV and the other STIs, particularly in vulnerable populations, and many of these infections, especially among women, are asymptomatic. A systematic review estimated that the median prevalence of STIs among people living with HIV was 12.4% and STI prevalence was greatest at the time of HIV diagnosis *(15)*. Various STIs also are common among individuals who identify themselves as concerned about acquiring HIV. A systematic review of individuals prior to starting PrEP reported a pooled prevalence of 23.9% for a compositive indicator of chlamydia, gonorrhoea and early syphilis and documented that STI incidence was high among persistent users of PrEP *(16)*.

Substantial evidence indicates that STIs increase HIV transmissibility and the risk of acquiring HIV by as much as 2–3 times in some populations *(2, 5, 7, 17, 18)*. The increased transmissibility may result from STI sores or inflammation allowing infection that might otherwise have been stopped by intact skin and from increased HIV shedding among people with HIV who have urethritis or a genital ulcer or are infected with *N. gonorrhoeae (19)*. Genital herpes (HSV-2) almost triples the risk of acquiring HIV for both men and women *(17, 18)*. Also, HIV increases the infectiousness and severity of STIs *(4, 20)*, and a recent study has documented that HIV and syphilis co-infection can have an adverse impact on immune recovery and antiretroviral effectiveness *(21)*.

Prompt diagnosis and treatment of STIs can contribute to reducing HIV transmission to others. In addition, individuals seeking testing or treatment for STIs constitute a population at increased risk for HIV and provide an opportunity for HIV screening. Furthermore, providing STI services to people living with HIV is part of a holistic and comprehensive approach to sexual and reproductive health and rights for people living with HIV. Box 4.1 provides an overview of WHO recommendations on STI screening and treatment.

Box 4.1 WHO recommendations on STI screening and treatment

For men who have sex with men and for trans and gender diverse people (2011)

- Offering periodic testing for asymptomatic urethral and rectal *N. gonorrhoeae* and *C. trachomatis* infections using a molecular assay is suggested over not offering such testing for men who have sex with men and trans and gender diverse people. *(conditional recommendation, low-certainty evidence)*
- Offering periodic serological testing for asymptomatic syphilis infection to men who have sex with men and trans and gender diverse people is strongly recommended over not offering such screening. *(strong recommendation, moderate-certainty evidence)*

For sex workers and their clients in low- and middle-income countries (2012)

- WHO suggests offering periodic screening for asymptomatic sexually transmitted infections to female sex workers. *(conditional recommendation, low-certainty evidence)*

For pregnant women (2017)

- The WHO STI guideline recommends screening all pregnant women for syphilis during the first antenatal care visit. *(strong recommendation, moderate-certainty evidence)*

Box 4.1 (continued) WHO recommendations on STI screening and treatment

For the management of symptomatic sexually transmitted infections (2021)

- For people with symptom of urethral discharge from the penis, WHO recommends basing management on the results of quality-assured molecular assays. However, in settings with limited or no molecular tests or laboratory capacity, WHO recommends syndromic treatment to ensure treatment on the day of the visit. *(strong recommendation, moderate-certainty evidence)*
- For people with symptom of vaginal discharge, WHO recommends treatment for *N. gonorrhoeae* and/or *C. trachomatis* and/or *T. vaginalis* on the same visit. WHO suggests treatment based on the results of quality-assured molecular assays for *N. gonorrhoeae* and/or *C. trachomatis* and/or *T. vaginalis*. In settings in which treatment in the same visit based on the results of molecular assay is not feasible or that have limited or no molecular testing, WHO suggests treatment based on testing with quality-assured rapid POC tests or on syndromic diagnosis. *(strong recommendation, moderate-certainty evidence)*
- For sexually active women who present with lower abdominal pain, WHO suggests assessing for pelvic inflammatory disease and treating syndromically. *(conditional recommendation, low-certainty evidence)*
- For people who present with genital ulcers (including anorectal ulcers), WHO recommends treatment based on quality-assured molecular assays of the ulcer. However, in settings with limited or no molecular tests or laboratory capacity, WHO recommends syndromic treatment to ensure treatment on the day of the visit. *(strong recommendation, moderate-certainty evidence)*
- For people with symptom of anorectal discharge and report receptive anal sex, WHO recommends management based on the results of quality-assured molecular assays. However, in settings with limited or no molecular tests or laboratory capacity, WHO recommends syndromic treatment to ensure treatment on the day of the visit. *(strong recommendation, moderate-certainty evidence)*

Sources:

- Guidelines: prevention and treatment of HIV and other sexually transmitted infections among men who have sex with men and transgender populations: recommendations for a public health approach. Geneva: World Health Organization; 2011 *(22)*.
- Prevention and treatment of HIV and other sexually transmitted infections for sex workers in low- and middle-income countries: recommendations for a public health approach. Geneva: World Health Organization; 2012 *(23)*.
- WHO guideline on syphilis screening and treatment for pregnant women. Geneva: World Health Organization: 2017 *(24)*.
- Guidelines for the management of symptomatic sexually transmitted infections. Geneva: World Health Organization; 2021 *(25)*.

4.2.2 Minimum dataset for STIs

Table 4.1 presents a minimum set of data elements for monitoring STIs in individuals using HIV prevention services and people living with HIV. The data elements cover information on both clinical diagnosis and testing. The lack of low-cost reliable POC tests for STIs apart from syphilis means that in many parts of the world individuals are treated for STIs based on symptoms. For individuals treated based on symptoms, clear and consistent case definitions are critical if the data are to be used for monitoring appropriate treatment.

STI data may be collected and reported from different HIV programmes – for example, HIV prevention services including community outreach programmes; HIV testing, care and treatment clinics; and key population programmes.

Table 4.1 Recommended minimum dataset for STIs

Topic area	Data element	Details
Testing and diagnosis	Date of clinic visit for STI	
	Syndrome/STI diagnosed	Collect data on STI diagnosed; or, if diagnosis based on symptoms, for each of the following syndromes separately: urethral discharge syndrome, vaginal discharge syndrome, lower abdominal pain, genital ulcer disease syndrome, anorectal discharge
	Date of STI test	
	STI tested for	Collect data separately for each STI tested (for example, syphilis, gonorrhoea, chlamydia)
	Sample tested	Sample collected (for example, blood, urine, endocervical swab) and, for gonorrhoea and chlamydia, the anatomic site(s)
	STI test used	
	STI test result	
	Date of STI confirmatory test	
	Confirmatory test used	
	STI confirmatory test result	
Treatment	Date STI treatment prescribed	
	STI treatment prescribed	
	Date STI treatment dispensed (if available)	
	STI treatment dispensed (if available)	

4.2.3 Priority indicators for STIs

Table 4.2 presents a set of priority STI indicators for inclusion in HIV prevention or treatment surveillance systems (details and metadata can be found in Chapter 8). These indicators are a subset of the indicators for national monitoring of STIs and reflect guidelines for HIV prevention and treatment programmes. They complement the collection of STI-related data through routine surveillance and special studies, including prevalence surveys, etiological assessments of STI syndromes and monitoring of gonococcal antimicrobial resistance.

The indicators focus on STI syndromes, syphilis and gonorrhoea. In countries or regions where data are collected on other STIs, such as chlamydia, trichomoniasis and human T-lymphotropic virus type 1 (HTLV-1), similar indicators should also be considered. In addition, in some countries one or more of these indicators may not be appropriate or practical. (For example, the indicators on STI syndromes will not be relevant to countries where STI diagnosis is based on aetiology.)

The denominator for these proposed indicators is the number of people using the service. This could be people using HIV treatment services or individuals attending STI clinics, PrEP services, key population services, HIV testing services or antenatal care (ANC) clinics (Table 4.2).

The 2020 Consolidated HIV strategic information guidelines *(26)* included two syphilis indicators in the Top 40 indicators – syphilis screening coverage in ANC and syphilis treatment coverage in ANC. Both of these important indicators are incorporated under the new STI indicators STI.1 and STI.3.

Table 4.2 Priority indicators for STIs

Ref. no.	Short name	Indicator definition	Numerator	Denominator
STI.1 (NEW) ●	Syphilis testing coverage	% of people tested for syphilis during the reporting period	Number of people tested for syphilis during the reporting period	Number of people attending HIV treatment or prevention services during the reporting period[a]
STI.2 (NEW)	Syphilis test positivity	% of people who tested positive for syphilis during the reporting period	Number of people who tested positive for syphilis during the reporting period (tested positive on both nontreponemal and treponemal tests or tested positive on either nontreponemal or treponemal test)	Number of people tested for syphilis during the reporting period
STI.3 (NEW)	Syphilis treatment coverage	% of people tested positive for syphilis who were treated based on national guidelines in the reporting period	Number of people who tested positive for syphilis and were treated based on national guidelines in the reporting period	Number of people who tested positive for syphilis during reporting period[b]

Table 4.2 (continued) Priority indicators for STIs

Ref. no.	Short name	Indicator definition	Numerator	Denominator
STI.4 (NEW) ●	Gonorrhoea testing coverage	% of people tested for gonorrhoea during the reporting period	Number of people tested for gonorrhoea (using a molecular test, culture or POC test) during the reporting period	Number of people attending HIV treatment or prevention services during the reporting period[a]
STI.5 (NEW)	Gonorrhoea test positivity	% of people who tested positive for gonorrhoea during the reporting period	Number of people who tested positive for gonorrhoea during the reporting period	Number of people tested for gonorrhoea (using a molecular test, culture or POC test) during the reporting period
STI.6 (NEW)	Gonorrhoea treatment coverage	% of people tested positive for gonorrhoea who were treated based on national guidelines during the reporting period	Number of people who tested positive for gonorrhoea and were treated based on national guidelines during the reporting period	Number of people who tested positive for gonorrhoea (using a molecular test, culture or POC test) during the reporting period
STI.7 (NEW)	Presence of STI syndrome	% of people diagnosed with a particular STI syndrome during the reporting period[c]	Number of people diagnosed with a particular STI syndrome during the reporting period	Number of people attending HIV treatment or prevention services during the reporting period
STI.8 (NEW)	Repeat diagnosis of STI syndrome	% of people diagnosed with a particular STI syndrome who were diagnosed with the same STI syndrome two or more times during the reporting period[c]	Number of people who were diagnosed with a particular STI syndrome two or more times during the reporting period	Number of people diagnosed with a particular STI syndrome during the reporting period

● Core indicator

[a] All unique individuals who have accessed an HIV service (including individuals attending STI clinics, PrEP services, key population services, HIV testing services, ANC clinics or HIV treatment). These indicators should be disaggregated by service type.

[b] Denominator to reflect country guidelines. For some countries treatment may be offered to those who are suspected of having syphilis, while in others only those who test positive on both non-treponemal and treponemal test are treated.

[c] WHO has treatment guidelines for the management of symptomatic infections related to five syndromes: urethral discharge syndrome, vaginal discharge syndrome, lower abdominal pain, genital ulcer disease syndrome and anorectal discharge *(25)*.

4.3 Viral hepatitis

4.3.1 Background and rationale

Viral hepatitis burden

Hepatitis B and C viral infections account for a significant global disease burden and high mortality from cirrhosis and hepatocellular cancer. In 2019 WHO estimated that, worldwide, 296 million people were living with chronic HBV infection and 58 million people, with HCV infection, together causing over one million deaths annually *(13)*. The greatest burden of viral hepatitis infection is concentrated by geography and population, with 80% of the global burden of HCV infection in the 10 most severely affected countries *(13)*. People in economically disadvantaged regions, displaced people and migrants, and rural populations are more severely affected. Further, injecting drug use is a major contributor to the HCV epidemic globally. Other affected populations include health care workers exposed through needle-stick injuries, people in prisons and other closed settings and men who have sex with men.

Viral hepatitis and HIV infection

HIV, HBV and HCV infections can be prevented with interventions to reduce mother-to-child transmission, blood safety measures, standard universal precautions in health care and other settings, safer sex, and harm reduction interventions for people who inject drugs *(27)*.

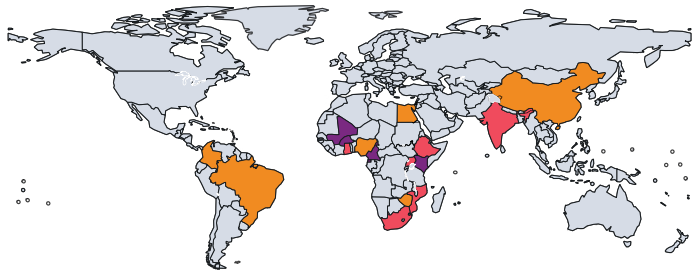
Globally, 2.7 million people living with HIV are coinfected with HBV and 2.3 million people living with HIV are coinfected with HCV *(28, 29)* (Fig. 4.2). HCV prevalence among people living with HIV is estimated at 6.2% and is highest among people who inject drugs (82.4%), followed by men who have sex with men (6.4%) *(30, 31)*. HBV prevalence among people living with HIV is 7.4% and is similar across different population groups *(28)*. In the absence of treatment, people living with HIV and co-infected with viral hepatitis have accelerated progression to HBV- and/or HCV-associated liver diseases, hepatocellular cancer and death *(32-37)*. Pregnant women living with HIV have twice the risk of vertical transmission of HBV *(38, 39)*.

Key and vulnerable populations coinfected with HIV and viral hepatitis are at higher risk of disease progression, as they may have more limited access to health services and face stigma and discrimination because of socioeconomic status, sexual behaviours or use of injection drugs. A number of factors can influence whether people are at elevated risk for acquiring HIV, HBV and HCV, the most important of which are their own, or their partners', sexual and drug using behaviour, in addition to the prevalence of unsuppressed HIV infection in the setting where they live or may be potentially exposed. Therefore, in settings and populations where individuals are at substantial risk of both viral hepatitis and HIV, a comprehensive, person-centred approach will ensure that individuals identified as at high risk and receiving HIV prevention services also receive hepatitis screening. Similarly, people living with HIV already receiving HIV care will particularly benefit from hepatitis screening and referral and/or treatment for viral hepatitis.

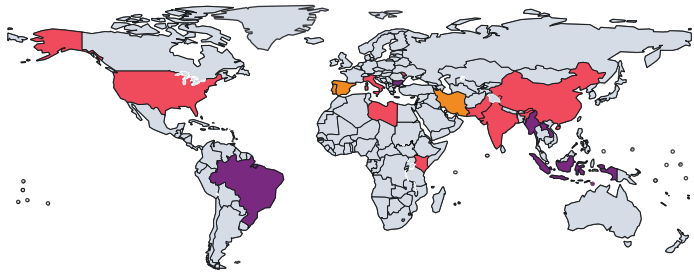
HIV, HBV and HCV infections can be prevented with interventions to reduce vertical transmission, blood safety measures, standard universal precautions in health care and other settings, safer sex, and harm reduction interventions for people who inject drugs.

Fig. 4.2 Prevalence of hepatitis B surface antigen (HBsAg) among various populations living with HIV

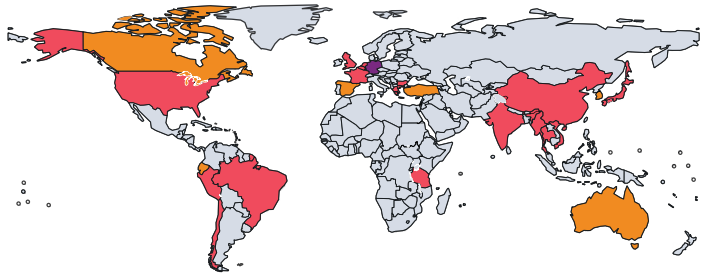
(A) General population



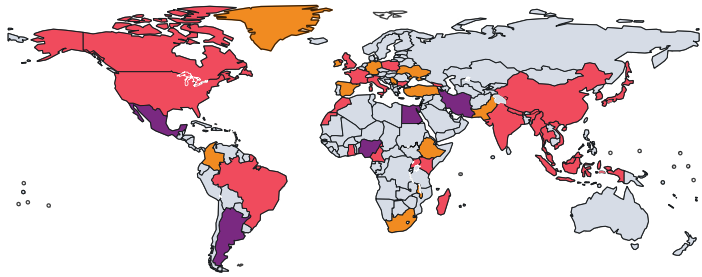
(B) People who inject drugs



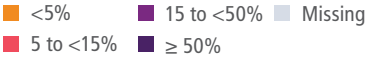
(C) Men who have sex with men



(D) Other populations at elevated risk of HIV



Prevalence % (HBsAg+)



Source: Platt et al., 2020 *(28)*

GHSS 2022–2030 on viral hepatitis

In 2016 WHO developed the GHSS on viral hepatitis 2016–2021, with the ambitious goal to eliminate viral hepatitis as a public health threat by 2030.

Building on the achievements and lessons learned under the 2016–2021 GHSS, the 2022–2030 GHSS seek to achieve the following viral hepatitis impact targets by 2030 as compared with the baselines of 2020:

- prevalence of HBsAg reduced from 0.94% to 0.1% among children ages ≤5 years;
- annual new HBV infections reduced from 1.5 million cases to 170 000 cases (from 20 per 100 000 to 2 per 100 000);
- annual new HCV infections reduced from 1.575 million cases to 350 000 cases (from 20 per 100 000 to 5 per 100 000);
- annual new HCV infections among people who inject drugs reduced from 8 per 100 to 2 per 100 people who inject drugs;
- annual deaths from HBV reduced from 820 000 to 310 000 (from 10 per 100 000 to 4 per 100 000);
- annual deaths from HCV reduced from 290 000 to 140 000 (from 5 per 100 000 to 2 per 100 000).

The global targets outlined in the 2022–2030 GHSS provide a guide for national targets to be set by each country. They advocate a person-centred response through combined and shared approaches across the three diseases, HIV, STIs and viral hepatitis. Therefore, it is necessary for all HIV programmes to record and report hepatitis indicators. The strategies also advocate equitable progress across all populations within countries to ensure that those most affected and with elevated risk are not left behind. Data disaggregated by age, sex and other population characteristics are needed to identify inequalities between subpopulations and to track trends. Person-centred monitoring through routine HIS is key to ensuring the quality of hepatitis care and monitoring the hepatitis care (HBV) or cure (HCV) cascade among individuals receiving HIV treatment and those receiving HIV prevention services.

4.3.2 Minimum dataset for viral hepatitis

Table 4.3 presents a minimum set of data elements specifically on testing and treatment of viral hepatitis to be routinely collected and reported in HIV programmes. Viral hepatitis data may be collected and reported from different HIV programmes, that is, HIV prevention services, including community outreach programmes, HIV testing, care and treatment clinics and key population programmes. Because viral hepatitis data will include people living with HIV as well as individuals receiving HIV testing or prevention services who may have either unknown HIV status or test HIV-negative, disaggregating by HIV status is critical.

Table 4.3. Recommended minimum dataset for viral hepatitis

Topic area	Data element
Testing and diagnosis	HBV test date
	HBV test result (HBsAg)
	HCV test date
	HCV test result (HCV antibody, HCV RNA or HCV core antigen)
Treatment initiation and continuation	HBV treatment initiation date
	HBV regimen prescribed
	HCV treatment initiation date
	HCV treatment regimen prescribed
Monitoring of treatment effectiveness	HCV viral suppression test date
	HCV suppression test result

4.3.3 Priority indicators for viral hepatitis

Table 4.4 presents the proposed HBV and HCV indicators to be collected and reported routinely within all HIV programmes.

The indicators are based on the 10 core indicators of the M&E framework for viral hepatitis *(40)* as well as the targets for the elimination of viral hepatitis *(41)*. Also, data collected from these indicators complement other requirements for Member States to report to WHO. These include the Global AIDS Monitoring (GAM) and the Global Reporting System for Hepatitis (GRSH) as well as the indicators for validation of viral hepatitis elimination.

Table 4.4 Priority indicators for viral hepatitis

Ref. no.	Short name	Indicator definition	Numerator	Denominator
HEP.1 (NEW) ●	HBV test coverage[a]	% of people who were tested for hepatitis B surface antigen (HBsAg) during the reporting period	Number of people tested for HBsAg during the reporting period	Number of people attending HIV treatment or prevention services during the reporting period
HEP.2 (NEW) ●	HCV test coverage[a]	% of people who were tested for HCV (HCV antibody, HCV RNA or HCV core antigen) during the reporting period	Number of people tested for HCV during the reporting period	Number of people attending HIV treatment or prevention services during the reporting period

Table 4.4 (continued) Priority indicators for viral hepatitis

Ref. no.	Short name	Indicator definition	Numerator	Denominator
HEP.3 (NEW)	HBsAg positivity[a]	% of people who were tested for HBsAg and had a positive HBsAg test result during the reporting period	Number of people who tested positive for HBsAg during the reporting period	Number of people who were tested for HBsAg during the reporting period
HEP.4 (NEW)	HCV positivity[a]	% of people with a positive HCV test result (HCV antibody, HCV RNA (PCR) or HCV core antigen) during the reporting period	Number of people newly[b] identified with a positive HCV test result (HCV antibody HCV RNA (PCR) or HCV core antigen) during the reporting period	Number of people who were tested for HCV during the reporting period
HEP.5 (NEW)	HBV treatment among people living with HIV	% of people living with HIV and diagnosed with HBV infection who are on TDF-based ART	Number of people newly started on HBV treatment (TDF) during the reporting period + Number of people living with HIV who are already on TDF-based ART	Number of people living with HIV who were diagnosed with HBV
HEP.6 (NEW)	HCV treatment among people living with HIV	% of people living with HIV and diagnosed with HCV infection who initiated HCV treatment (direct acting antivirals) during the reporting period	Number of people living with HIV newly started on HCV treatment during the reporting period	Number of people living with HIV who were diagnosed with HCV during the reporting period
HEP.7 (NEW)	HCV cured among people living with HIV	% of people living with HIV and co-infected with HCV who were confirmed to be cured of HCV among those who completed treatment during the reporting period	Number of people living with HIV diagnosed with HCV infection who have completed HCV treatment and had a sustained virological response (SVR)	Number of people living with HIV and co-infected with HCV who completed HCV treatment and were assessed for SVR

● Core indicator

Abbreviations: HBV = hepatitis B virus; HBsAg = hepatitis B surface antigen; HCV = hepatitis C virus; HIV = human immunodeficiency virus; SVR = sustained virological response; PCR = polymerase chain reaction; RNA = ribonucleic acid; TDF = tenofovir

[a] Includes testing of HCV (HCV antibody, HCV RNA (PCR) or HCV core antigen) and HBV (HBsAg) among pregnant women seeking ANC services as well persons at high risk receiving HIV prevention services such as PrEP, harm reduction services and services for prisoners

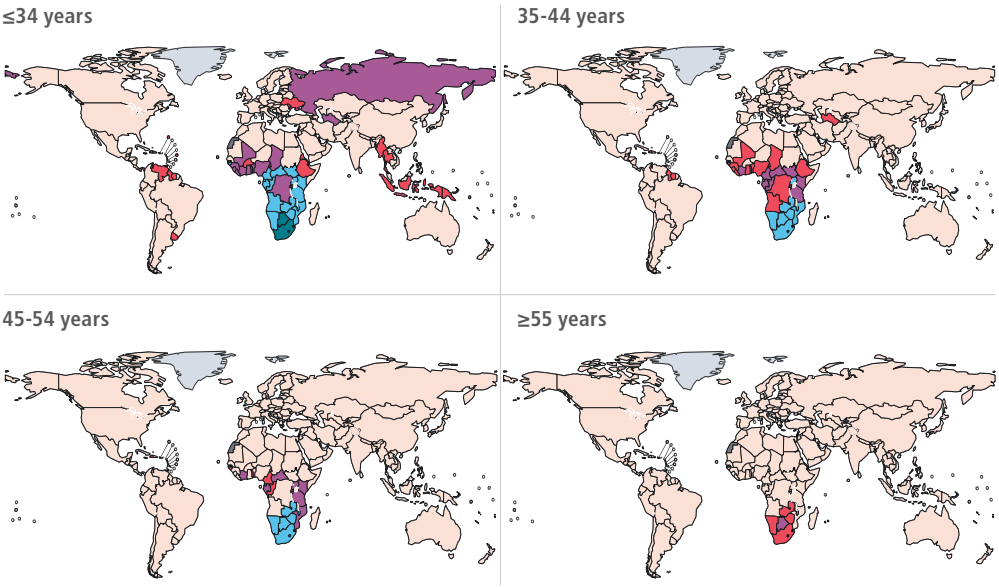
[b] Among persons tested regularly at short time intervals, seroconversion to anti-HCV suggests a recent HCV infection. Seroconversion to anti-HCV should be followed by a reflex RNA test (when available).

4.4 Cervical cancer

4.4.1 Background and rationale

Women living with HIV have a six-fold higher risk of cervical cancer than women without HIV *(6)*, and cervical cancer is classified as an AIDS-defining condition *(42)*. This higher risk starts with an increased risk of acquiring HPV infection, lower chances of regression of pre-cancerous lesions, more rapid progression to cancer and higher rates of recurrence following treatment *(43-45)*. ART has led to steep declines in AIDS-related mortality and has increased life expectancy, with over 19 million women estimated to be living with HIV worldwide in 2019 *(46)*. The proportion of women living with HIV among patients with cervical cancer varies widely by region due to the varying prevalence of HIV (Fig. 4.3). In areas with high HIV prevalence, the fraction of cervical cancer attributable to HIV is high – 40% or more in nine countries in southern Africa, compared with <5% in 122 countries with lower HIV prevalence *(6)*. Cervical cancer is diagnosed at a younger average age in women living with HIV than in HIV-negative women *(3)*.

Fig. 4.3 HIV-attributable fraction in cervical cancer in 2020, by age group



Source: Ibrahim Khalil et al., 2022 *(3)*

The WHO *Global strategy to accelerate the elimination of cervical cancer as a public health problem* includes the following global targets for 2030 *(47)*:

- 90% of girls are fully vaccinated with HPV vaccine by age 15 years;
- 70% of women are screened with a high-performance test by 35 years of age and again by 45 years of age;
- 90% of women identified with cervical disease are treated (90% of women with precancer treated and 90% of women with invasive cancer managed).

Since the countries with high HIV burden have some of the highest cervical cancer rates, a greater effort will be needed to achieve cervical cancer elimination in these settings.

As part of the efforts to achieve these targets for the elimination of cervical cancer, WHO has published a new edition of its guideline on screening and treatment to prevent cervical cancer. It includes 16 new and updated recommendations and good practice statements for women living with HIV *(9)*. The guidance was developed to update the existing WHO recommendations on screening and treatment, including guidance on diagnostic tests, and to simplify the algorithms, while ensuring that the recommendations are feasible and acceptable both for the health workers providing screening and treatment services and for women, the users of those services. In terms of the applicability of the information presented (including the recommendations), the general use of the word "women" should be read as being inclusive of transgender men and non-binary and intersex individuals who have a cervix, while keeping in mind that the majority of the available evidence is based on populations identified in studies as "women".

WHO suggests using the following strategy for cervical cancer prevention among women living with HIV: HPV DNA detection in a screen, triage and treat approach starting at the age of 25 years with regular screening every 3 to 5 years *(9)*.

The new and updated WHO recommendations are intended to support countries' scale-up of access to and uptake of cervical cancer screening and treatment with quality modern technologies and, thereby, to reduce cervical cancer disease and deaths. All programmes should ensure that:

- Women living with HIV are offered cervical cancer screening as part of standard HIV care.
- Women who have screened positive for cervical pre-cancer or cancer are treated or managed adequately.
- Screening registries and call-and-recall efforts are made to encourage women to return for treatment and follow-up.
- Strong links for cross-referral are established at all levels of the health system between HIV and cervical cancer services.

In all HIV epidemic contexts, strategies are needed across health system building blocks to improve the accessibility, acceptability, affordability, uptake, equitable coverage, quality, effectiveness and efficiency of services for women living with HIV – not only services for cervical cancer control but also the range of other health services important to women. Barriers to such services undermine the sexual and reproductive health and rights of women living with HIV.

Cervical cancer screening and treatment should be provided to transgender men, non-binary, gender-fluid and intersex individuals who have a cervix. More data on cervical cancer screening and treatment are needed for these populations, including for those living with HIV. WHO recognizes the need for health care systems, including screening and treatment services for cervical pre-cancer and cancer, to be more inclusive of trans and gender diverse people. This may require additional training and sensitization of health workers and programme managers. Also, public health authorities should prioritize these groups of people for increasing awareness of, access to and uptake of cervical cancer screening and treatment.

4.4.2 Minimum dataset for cervical cancer

A standardized minimum set of reportable data elements is needed to measure cervical screening among women living with HIV and to monitor treatment for cervical pre-cancer and for management of invasive cancer as appropriate (Table 4.5). Minimizing loss to treatment among women screened positive for cervical pre-cancer, and proper management for invasive cancer when it is identified, are important for reducing cervical cancer morbidity and mortality.

Patient registers or electronic medical records for individuals receiving ART can serve as the main source of information on who should be screened for cervical cancer. Data elements for cervical cancer screening can be added to these records and forms for reporting key data elements forward. In many situations cervical cancer screening may occur at a different health facility from the one where treatment is provided for those who screen positive, requiring referral. Therefore, laboratory, pharmacy, and medical records from other services (for example, cancer services) may need to be compiled in order to complete the required fields.

Table 4.5 Recommended minimum dataset for cervical cancer screening and treatment among women living with HIV

Area	Data element	Details
HPV vaccination	Age at last HPV vaccine dose received	Number of last dose (1, 2 or 3)[a]
Primary screening	Cervical cancer screening test date	
	Lifetime screening test number	First in lifetime, second in lifetime, etc.
	Screening test used	HPV DNA testing (including genotyping where done), visual inspection with acetic acid, cytology, other
	Screening test result	Description of test results will depend on the screening test used (for example, positive/negative or high-risk type positive for HPV DNA testing, etc. or suspected for invasive cancer)
Triage testing	Triage test date	
	Triage test used	HPV 16/18 genotyping, visual inspection with acetic acid, colposcopy, cytology followed by colposcopy, other
	Triage test result	Positive or negative triage screening test result

[a] HPV vaccine series is either a 2- or 3-dose schedule for women living with HIV. HPV vaccination is included in the WHO ART treatment card and may be based on either self-report or documented vaccine delivery.

Table 4.5 (continued) Recommended minimum dataset for cervical cancer screening and treatment among women living with HIV

Area	Data element	Details
Diagnosis	Date of diagnosis	
	Histopathology/colposcopy result	Histopathology result (negative, CIN1–3, cancer) or colposcopy result (negative, positive minor/major, suspected cancer)
	Diagnosis	Pre-invasive cervical disease, invasive cervical cancer
	Cervical cancer stage at diagnosis	Stage 0, I, II, III, IV
Pre-invasive cervical disease treatment	Pre-invasive cervical disease treatment date	
	Pre-invasive cervical disease treatment method	Thermal ablation, cryotherapy and excision treatment including Large Loop Excision of the Transformation Zone therapy (LLETZ) type 1–3
	Pre-invasive cervical disease treatment follow-up date	
	Post-treatment follow-up test	HPV DNA testing (including genotyping where done), visual inspection with acetic acid, cytology, other options including triage testing
	Post-treatment follow-up result	Description of test results will depend on the test used (for example, positive/negative or high-risk type positive for HPV DNA testing, or suspected for invasive cancer)
Invasive cervical cancer	Invasive cancer treatment date	
	Treatment method	For example, surgery, radiotherapy, chemotherapy
	Treatment outcome	Depends on treatment provided
	Follow-up treatment(s) date(s)	
	Secondary/other cancers diagnosed	
	Cancers at other sites (HPV- and non-HPV related)	
Death	Date of death	
	Cause of death	

4.4.3 Priority indicators for cervical cancer

The four priority indicators in Table 4.6 were selected based on their importance for measuring programmatic progress in increasing cervical screening and treatment for women living with HIV *(47)*. These indicators are aligned with WHO's guideline for screening and treatment of cervical pre-cancerous lesions for cervical cancer prevention *(9)*, the noncommunicable disease primary care facility-based patient and programme monitoring framework and indicators on cervical cancer screening and the *Global strategy to accelerate the elimination of cervical cancer as a public health problem (47)*. Standard disaggregations of 5-year age bands from the age of 20 should be included. WHO recommends starting cervical cancer screening at age 25 years for women living with HIV, but some women may be screened earlier and it is important to capture this. Gender categories should include all gender diverse people with a female reproductive system such as transgender men and gender diverse individuals who have a cervix, while maintaining policy-protected confidentiality and privacy for these data to prevent their misuse. These data should never be shared with law enforcement or any individual or group outside the health sector. Where safety and legal/policy protections may not be in place, gender disaggregation may be excluded. Chapter 6 addresses privacy, confidentiality and the protections needed for key populations and other vulnerable groups.

Chapter 8 provides full metadata for the priority indicators. Additional indicators can be used to supplement those in the recommended priority set of indicators (see Web Annex B).

Table 4.6. Priority indicators for cervical cancer screening and treatment among women[a] living with HIV

Ref. no.	Short name	Indicator definition	Numerator	Denominator
CCA.1 (NEW) ●	Cervical cancer screening	Number of women living with HIV who were screened for cervical cancer using any screening test	Number of women living with HIV who were screened for cervical cancer using any screening test (HPV DNA test, visual inspection with acetic acid, cytology, other)	NA
CCA.2 (NEW) ●	Pre-invasive cervical disease treatment	% of women living with HIV who screened positive for pre-invasive cervical disease and received treatment for it	Number of women living with HIV who received treatment after screening positive for pre-invasive cervical disease and were deemed eligible for treatment	Number of women living with HIV who screened positive for pre-invasive cervical disease
CCA.3 (NEW)	Invasive cervical cancer treatment	% of women living with HIV diagnosed with invasive cancer who were treated	Number of women living with HIV who received treatment after being diagnosed with invasive cervical cancer	Number of women living with HIV who were diagnosed with invasive cervical cancer
CCA.4 (NEW)	Cervical cancer survival	Crude probability of surviving 1 year after a diagnosis of cervical cancer	Number of women living with HIV still alive 12 months after receiving a diagnosis of invasive cervical cancer	Number of women living with HIV who received a diagnosis of invasive cervical cancer within a 12-month cohort observation period

● Core indicator

Abbreviations: DNA = deoxyribonucleic acid; HIV = human immunodeficiency virus; HPV = human papilloma virus; NA = Not Applicable

[a] To be concise and facilitate readability, the term "women" is used, noting that that all gender diverse people with a female reproductive system are at risk for cervical cancer and should receive screening and treatment services. Most of the available evidence on cervical cancer is based on study populations of cisgender women. All individuals have the right to equality and non-discrimination in sexual and reproductive health care.

References

1. Tracking universal health coverage: 2021 Global Monitoring Report (Conference edition). Geneva and Washington (DC): World Health Organization and World Bank; 2021 (https://www.who.int/publications/i/item/9789240040618, accessed 23 June 2022).
2. Fleming DT, Wasserheit JN. From epidemiological synergy to public health policy and practice: the contribution of other sexually transmitted diseases to sexual transmission of HIV infection. Sex Transm Infect. 1999;75:3-17. doi: 10.1136/sti.75.1.3
3. Ibrahim Khalil A, Mpunga T, Wei F, Baussano I, de Martel C, Bray F et al. Age-specific burden of cervical cancer associated with HIV: A global analysis with a focus on sub-Saharan Africa. Int J Cancer. 2022;150:761-72. doi: 10.1002/ijc.33841
4. Jones J, Weiss K, Mermin J. Proportion of incident human immunodeficiency virus cases among men who have sex with men attributable to gonorrhea and chlamydia. Sex Transm Dis. 2019;46:357-63.
5. Sexton J, Garnett G, Rottingen JA. Metaanalysis and metaregression in interpreting study variability in the impact of sexually transmitted diseases on susceptibility to HIV infection. Sex Transm Dis. 2005;32:351-7. doi: 10.1097/01.olq.0000154504.54686.d1
6. Stelzle D, Tanaka LF, Lee KK, Khalil AI, Baussano I, Shah AS et al. Estimates of the global burden of cervical cancer associated with HIV. Lancet Glob Health. 2020;9:e161-e9.
7. Wu MY, Gong HZ, Hu KR, Zheng H-y, Wan X, Li J. Effect of syphilis infection on HIV acquisition: a systematic review and meta-analysis. Sex Transm Infect. 2021;97:525-33.
8. Arbyn M, Weiderpass E, Bruni L, de Sanjosé S, Saraiya M, Ferlay J et al. Estimates of incidence and mortality of cervical cancer in 2018: a worldwide analysis. The Lancet Global Health. 2020;8:e191-e203.
9. WHO guideline for screening and treatment of cervical pre-cancerous lesions for cervical cancer prevention, second edition. Geneva: World Health Organization; 2021 (https://www.who.int/publications/i/item/9789240030824, accessed 24 June 2022).
10. New WHO recommendations on screening and treatment to prevent cervical cancer among women living with HIV: policy brief. Geneva: World Health Organization; 2021 (https://www.who.int/publications/i/item/9789240030961, accessed 24 June 2022).
11. de Sanjosé S, Diaz M, Castellsagué X, Clifford G, Bruni L, Muñoz N et al. Worldwide prevalence and genotype distribution of cervical human papillomavirus DNA in women with normal cytology: a meta-analysis. Lancet Infect Dis. 2007;7:453-9. doi: 10.1016/s1473-3099(07)70158-5
12. Looker KJ, Welton NJ, Sabin KM, Dalal S, Vickerman P, Turner KM et al. Global and regional estimates of the contribution of herpes simplex virus type 2 infection to HIV incidence: a population attributable fraction analysis using published epidemiological data. Lancet Infect Dis. 2020;20:240-9.
13. Global progress report on HIV, viral hepatitis and sexually transmitted infections, 2021. Accountability for the global health sector strategies 2016–2021: actions for impact. Geneva: World Health Organization; 2021 (https://www.who.int/publications/i/item/9789240027077, accessed 24 June 2022).
14. Global health sector strategies on, respectively, HIV, viral hepatitis and sexually transmitted infections for the period 2022-2030. Geneva: World Health Organization; 2022 (https://www.who.int/teams/global-hiv-hepatitis-and-stis-programmes/strategies/global-health-sector-strategies, accessed 4 July 2022).

15. Kalichman SC, Pellowski J, Turner C. Prevalence of sexually transmitted co-infections in people living with HIV/AIDS: systematic review with implications for using HIV treatments for prevention. Sex Transm Infect. 2011;87:183-90.

16. Ong JJ, Baggaley RC, Wi TE, Tucker JD, Fu H, Smith MK et al. Global epidemiologic characteristics of sexually transmitted infections among individuals using preexposure prophylaxis for the prevention of HIV infection: a systematic review and meta-analysis. JAMA Netw Open. 2019;2:e1917134-e.

17. Glynn JR, Biraro S, Weiss HA. Herpes simplex virus type 2: a key role in HIV incidence. AIDS. 2009;23:1595-8.

18. Looker KJ, Elmes JA, Gottlieb SL, Schiffer JT, Vickerman P, Turner KM et al. Effect of HSV-2 infection on subsequent HIV acquisition: an updated systematic review and meta-analysis. Lancet Infect Dis. 2017;17:1303-16.

19. Cohen MS, Hoffman IF, Royce RA, Kazembe P, Dyer JR, Daly CC et al. Reduction of concentration of HIV-1 in semen after treatment of urethritis: implications for prevention of sexual transmission of HIV-1. AIDSCAP Malawi Research Group. Lancet. 1997;349:1868-73. doi: 10.1016/s0140-6736(97)02190-9

20. Naresh A, Beigi R, Woc-Colburn L, Salata RA. The bidirectional interactions of human immunodeficiency virus-1 and sexually transmitted infections: a review. Infect Dis Clin Pract. 2009;17:362-73. doi: 10.1097/IPC.0b013e3181aba461

21. Fan L, Yu A, Zhang D, Wang Z, Ma P. Consequences of HIV/syphilis co-infection on HIV viral load and immune response to antiretroviral therapy. Infect Drug Resist. 2021;14:2851-62. doi: 10.2147/idr.S320648

22. Prevention and treatment of HIV and other sexually transmitted infections among men who have sex with men and transgender people: recommendations for a public health approach. Geneva: World Health Organization; 2011 (https://www.who.int/publications/i/item/9789241501750, accessed 23 June 2022).

23. Prevention and treatment of HIV and other sexually transmitted infections for sex workers in low- and middle-income countries: recommendations for a public health approach. Geneva: World Health Organization; 2012 (https://apps.who.int/iris/handle/10665/77745, accessed 24 June 2022).

24. WHO guideline on syphilis screening and treatment for pregnant women. Geneva: World Health Organization; 2017 (https://www.who.int/publications/i/item/9789241550093, accessed 24 June 2022).

25. Guidelines for the management of symptomatic sexually transmitted infections. Geneva: World Health Organization; 2021 (https://www.who.int/publications/i/item/9789240024168, accessed 24 June 2022).

26. Consolidated HIV strategic information guidelines: driving impact through programme monitoring and management. Geneva: World Health Organization; 2020 (https://www.who.int/publications/i/item/9789240000735, accessed 24 June 2022).

27. Hutin Y, Low-Beer D, Bergeri I, Hess S, Garcia-Calleja JM, Hayashi C et al. Viral hepatitis strategic information to achieve elimination by 2030: key elements for HIV program managers. JMIR Public Health Surveill. 2017;3:e91. doi: 10.2196/publichealth.7370

28. Platt L, French CE, McGowan CR, Sabin K, Gower E, Trickey A et al. Prevalence and burden of HBV co-infection among people living with HIV: A global systematic review and meta-analysis. J Viral Hepat. 2020;27:294-315. doi: 10.1111/jvh.13217

29. Platt L, Easterbrook P, Gower E, McDonald B, Sabin K, McGowan C et al. Prevalence and burden of HCV co-infection in people living with HIV: a global systematic review and meta-analysis. Lancet Infect Dis. 2016;16:797-808. doi: 10.1016/s1473-3099(15)00485-5

30. Global hepatitis report 2017. Geneva: World Health Organization; 2017 (https://apps.who.int/iris/handle/10665/255016, accessed 24 June 2022).

31. Jin F, Dore GJ, Matthews G, Luhmann N, Macdonald V, Bajis S et al. Prevalence and incidence of hepatitis C virus infection in men who have sex with men: a systematic review and meta-analysis. Lancet Gastroenterol Hepatol. 2021;6:39-56. doi: 10.1016/s2468-1253(20)30303-4

32. Thomas DL, Astemborski J, Rai RM, Anania FA, Schaeffer M, Galai N et al. The natural history of hepatitis C virus infection: host, viral, and environmental factors. JAMA. 2000;284:450-6. doi: 10.1001/jama.284.4.450

33. Shepard CW, Finelli L, Alter MJ. Global epidemiology of hepatitis C virus infection. Lancet Infect Dis. 2005;5:558-67. doi: 10.1016/s1473-3099(05)70216-4

34. Valle Tovo C, Alves de Mattos A, Ribeiro de Souza A, Ferrari de Oliveira Rigo J, Lerias de Almeida PR, Galperim B et al. Impact of human immunodeficiency virus infection in patients infected with the hepatitis C virus. Liver Int. 2007;27:40-6. doi: 10.1111/j.1478-3231.2006.01344.x

35. Sulkowski MS. Viral hepatitis and HIV coinfection. J Hepatol. 2008;48:353-67. doi: 10.1016/j.jhep.2007.11.009

36. Thio CL. Hepatitis B and human immunodeficiency virus coinfection. Hepatol. 2009;49:S138-45. doi: 10.1002/hep.22883

37. Easterbrook P, Sands A, Harmanci H. Challenges and priorities in the management of HIV/HBV and HIV/HCV coinfection in resource-limited settings. Semin Liver Dis. 2012;32:147-57. doi: 10.1055/s-0032-1316476

38. Floreani A. Hepatitis C and pregnancy. World J Gastroenterol. 2013;19:6714-20. doi: 10.3748/wjg.v19.i40.6714

39. Benova L, Mohamoud YA, Calvert C, Abu-Raddad LJ. Vertical transmission of hepatitis C virus: systematic review and meta-analysis. Clin Infect Dis. 2014;59:765-73. doi: 10.1093/cid/ciu447

40. Monitoring and evaluation for viral hepatitis B and C: recommended indicators and framework. Geneva: World Health Organization; 2016 (https://apps.who.int/iris/handle/10665/204790, accessed 24 June 2022).

41. Interim guidance for country validation of viral hepatitis elimination. Geneva: World Health Organization; 2021 (https://www.who.int/publications/i/item/9789240028395, accessed 24 June 2022).

42. WHO case definitions of HIV for surveillance and revised clinical staging and immunological classification of HIV-related disease in adults and children. Geneva: World Health Organization; 2007 (https://apps.who.int/iris/handle/10665/43699, accessed 23 June 2022).

43. Liu G, Sharma M, Tan N, Barnabas RV. HIV-positive women have higher risk of human papilloma virus infection, precancerous lesions, and cervical cancer. AIDS. 2018;32:795-808.

44. Massad LS, Xie X, Burk R, Keller MJ, Minkoff H, D'Souza G et al. Long-term cumulative detection of human papillomavirus among HIV seropositive women. AIDS (London, England). 2014;28:2601.

45. Debeaudrap P, Sobngwi J, Tebeu P-M, Clifford GM. Residual or recurrent precancerous lesions after treatment of cervical lesions in human immunodeficiency virus-infected women: a systematic review and meta-analysis of treatment failure. Clinical Infectious Diseases. 2019;69:1555-65.

46. AIDSinfo. Global data on HIV epidemiology and response [webpage]. Geneva: Joint United Nations Programme on HIV/AIDS (UNAIDS); 2020 (https://aidsinfo.unaids.org/, accessed 21 April 2021).

47. Global strategy to accelerate the elimination of cervical cancer as a public health problem. Geneva: World Health Organization; 2020 (https://www.who.int/publications/i/item/9789240014107, accessed 24 June 2022).

CHAPTER 5 – HARNESSING THE STRENGTH OF ROUTINE DATA FOR HIV SURVEILLANCE

5

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Key recommendations

NEW 1. It is recommended that national health information systems **include and strengthen individual-level HIV surveillance** that:

a) routinely links individual data on HIV prevention, diagnosis and treatment over time as people move between facilities and locations

b) provides granular, subnational strategic information for public health action.

NEW 2. **Collection of a minimum dataset of routine clinical health information** is recommended for national surveillance to monitor and guide the HIV response and support measurement of incidence:

a) Methods using person-centred data, including back-calculation and retesting, should be considered together with data from other sources and modelling to improve incidence measurement.

NEW 3. **A CD4 test conducted at HIV diagnosis** is recommended for use in clinical staging, providing clinical information on entry or re-entry to care and estimating HIV incidence.

NEW 4. **Mortality and causes of death (AIDS-related and non-AIDS-related) should be reported** for all people registered in routine HIV information systems. Vital registration records should be consulted to measure the overall burden of AIDS mortality, including as a proportion of total deaths.

NEW 5. **Expanding and strengthening HIV case surveillance** systems that use simple electronic interfaces and built-in validation mechanisms is recommended in order to better capture new HIV diagnoses and risk factors for HIV acquisition.

5.1 Introduction

5.1.1 Harnessing routine data to track the epidemic and guide the response

Several indicators are important for tracking the course of the HIV epidemic and progress of the response. Impact indicators that measure trends in HIV incidence, all-cause and AIDS-related mortality among persons with HIV, and outcomes such as ART coverage and viral suppression have been critical in identifying service gaps and for prioritizing commitments of resources and services *(1, 2)*. Typically, these indicators come from a mix of nationally representative surveys and programmatic data on the number of individuals who have received services, which can be synthesized with mathematical modelling *(1)*. With the increase in digitization of health information systems around the world, and their growing penetration in all settings, the use of person-centred data captured in routine national health information systems has growing importance. This chapter focuses on HIV incidence and prevalence estimation, as well as mortality measurement, and describes how routine health information data can be used to track HIV infections and guide the HIV response.

Estimates of HIV incidence and mortality are critical to understanding shifting epidemiologic trends and to guiding the programmatic response, particularly in light of the growing need for focused age, gender, geographic and other demographic prioritizations for service delivery (for example, by key population, ethnicity or immigration status). Epidemiologic research conducted through national surveys, clinical trials and cohort studies has shown that HIV incidence varies considerably between and within different geographic areas and population groups in a country *(3, 4)*. Similarly, variations in mortality statistics among people living with HIV can assist in identifying populations with delayed access to ART and important co-morbidities and other factors that require programme response. Regular, reliable routine surveillance data that inform HIV incidence, prevalence and mortality will enhance timely decision-making and the overall national response.

HIV incidence

Tracking HIV incidence is essential to making progress toward the fast-track goal of reducing new HIV infections among adults to <200 000 per year and, thus, ending the AIDS epidemic as a global health threat by 2030 *(5)*. HIV incidence, which is the rate of new infections occurring in a susceptible (or uninfected) population, is the fundamental measure of the current state of the epidemic *(6)*. Tracking the incidence of new infections over time helps to prioritize interventions to subpopulations at greatest risk of HIV acquisition, to assess where control measures are working and to anticipate future health care needs. HIV incidence is the indicator used to measure progress toward the target of Sustainable Development Goal (SDG) 3, ending the AIDS epidemic *(7)*.

HIV incidence is a fundamental measure of the current state of the epidemic and is critical to guiding the programmatic response.

HIV incidence can be measured directly, for example through longitudinal follow-up studies, or indirectly, for example through modelling to calculate incidence from changes in prevalence data. Direct and indirect methods have different advantages and challenges. Direct measurements are prone to biases arising from sampling, whereas indirect estimates rely on assumptions about prevalence, mortality, migration and, for some methods, reasons for HIV testing. Many countries rely on national-level mathematical models and population-based cross-sectional studies for HIV incidence estimation and for reporting at the national level toward the SDG. Ideally, information from multiple sources should be used together to create a fuller epidemiological picture of HIV incidence and prevalence in a given population or setting.

Common methods used for measuring HIV incidence and prevalence include:

- **Population-based surveys** typically are nationally representative cross-sectional household surveys that are large enough to estimate HIV incidence with precision and describe epidemiologic patterns among different subpopulations. If repeated, such surveys can describe trends over time. Measuring HIV prevalence or HIV incidence in a household survey is recommended only if the HIV prevalence among adults is greater than 2%. Thus, they are appropriate only in high burden countries *(8)*. Bio-behavioural surveys (BBS) are particular study designs that can provide specific population-level estimates of the burden of HIV disease and HIV-related risk factors for key populations along with estimates of the coverage of prevention and treatment services that they receive *(9)*. Currently, these different survey types are the standard sources of data for calculating HIV prevalence and, in high burden countries, HIV incidence. Due to their substantial cost and the logistical effort required, they are usually conducted at intervals of 3–5 years. Examples include the BBS, Demographic and Health Surveys (DHS), AIDS Indicator Surveys (AIS) and Population-based HIV Impact Assessments (PHIA).
- **Cohort studies** follow individuals over time to determine the number of new HIV infections that occur, enabling the calculation of HIV prevalence and incidence among the population being studied. Prospective cohort studies require substantial time and resources but can provide a wealth of information on risk factors for HIV and the impact of embedded interventions. The populations enrolled in cohort studies tend to be selected based on geography or convenience and so are often not representative of the general population. Therefore, although they can provide information on risk factors that clearly indicate causation, the results, depending on the study design, may have limited generalizability. The Rakai Community Cohort in Uganda *(10)* and the Manicaland General Population Cohort *(11)*, both studies that have run since the 1990s, are two examples; the ALPHA network is a collaboration across 10 such studies *(12)*.
- **Mathematical models** incorporate data from multiple sources, such as population-based surveys, demographic projections and routine data on HIV prevalence at ANC clinics, case surveillance, the number of people receiving ART, mortality or key population surveys. Models can be designed to provide comparable measures of HIV incidence over time and assess the impacts of HIV interventions. Models such as the UNAIDS-supported Spectrum package of models and software application tools *(13-16)* can be used to estimate new infections by age and sex, AIDS-related mortality, the number of child infections, treatment needs and other indicators in support of impact measurement and national priority setting. Some models have been developed to incorporate case surveillance and vital registration data *(14, 15)*. Other tools include the Optima HIV model *(17)* and the AIDS Epidemic Model (AEM) (also part of the Spectrum package), which focuses on the primary subpopulations and transmission modes driving concentrated HIV epidemics *(18)*. The key data needed to generate these estimates are demographic projections, HIV prevalence and historical data on the numbers of people receiving ART, and the numbers of pregnant women receiving antiretrovirals to prevent vertical HIV transmission.

- **Routine HIV testing and surveillance data** can contribute to better estimates of HIV prevalence and incidence at finer levels of geographic and subpopulation granularity. Data routinely collected through testing platforms, including CD4 count at diagnosis and testing history, can be used to develop multi-state back-calculation models and demographic and epidemiological simulation tools to estimate HIV incidence *(14, 19-21)*. Other approaches include utilizing laboratory tests (such as the limiting-antigen avidity assay) to distinguish recent from long-standing HIV infection *(22)* and longitudinal data from people or groups who are retested frequently, such as key populations.

While the availability and quality of HIV data are improving in most settings, and despite the increased need to better understand the determinants of HIV acquisition and transmission dynamics, our understanding of HIV incidence trends generally remains poor. Among key population groups in high burden settings, estimates of incidence, particularly direct estimates, are almost non-existent. The lack of incidence data on key populations can impede effective budgeting and programming for these groups.

Mortality

Accurate information on deaths among people living with HIV is critical to understanding the impact of HIV programmes and to inform methods of HIV prevalence and incidence estimation. The under-reporting of deaths among persons diagnosed with HIV and potential misclassification of the cause of death can result in overestimation of loss to follow-up *(23)*. Such misclassification has consequences for programme planning. Estimates of key population-specific mortality are particularly difficult to obtain in resource-limited settings and urgently need improvement.

Deaths among people living with HIV may be recorded and reported directly by clinics when the death of a patient is known, but in many instances this information is either missing or unknown. In an HIV information system, such as case surveillance, death records from reporting sites can be supplemented or confirmed by national death registration. There are several approaches to better enumerate deaths among people living with HIV and AIDS-related deaths in the population by cross-referencing other data sources where deaths are recorded. Where available, data files including deaths where HIV and/or AIDS were recorded on the death certificate, or where cause(s) of death would be unusual in a non-HIV-infected individual (for example, Kaposi's sarcoma or Pneumocystis pneumonia), may be linked using unique personal identifiers (for example, civil identification numbers, national health identifiers, master patient indexes or bespoke matching algorithms based on existing patient identifying information). In some settings there may also be the option to compare routine HIV data records with national death files listing all deaths in persons under age 60 years occurring within a calendar year. (Globally, death rates are highest among adults ages 60 years and above.) Recording of deaths is likely to be more accurate in countries where logging deaths with a national registry system is a legal requirement. In resource-constrained settings, HIV-specific verbal autopsy methods may be considered to improve death reporting among people living with HIV. Such methods have proved efficient in identifying HIV-related mortality in several African countries and among different cohorts *(24)*.

Considerations for key populations

Five key populations – men who have sex with men, people who inject drugs, sex workers and trans and gender diverse people, and people in prisons and other closed settings – are disproportionately affected by HIV and in almost every setting have a higher prevalence and incidence than people not in these groups *(2)*. Therefore, measuring HIV incidence and prevalence and the coverage of prevention and treatment services in these populations is essential for HIV control in all settings. Also, key populations face criminalization, stigma, discrimination and violence, which increase their vulnerability to HIV and often result in barriers to accessing services. Therefore, estimating HIV prevalence and incidence among key populations will usually require complex BBS designs where a known sampling frame is not available. In some settings other approaches have been used, such as the United Kingdom multi-parameter estimation synthesis model. This model uses national census, surveillance and survey data to provide a robust sampling frame for estimating diagnosed and undiagnosed HIV prevalence and disaggregating these estimates by exposure groups (key populations) *(25, 26)*.

In health services provided to the general population, key population clients may not disclose HIV-related risk factors. This can make it difficult to disaggregate key population data in routine service statistics and likely underestimates numbers. However, some facilities cater specifically to key populations; in these settings patients/clients may be more comfortable discussing behavioural risk factors for HIV. Asking simple questions about risk factors for HIV as part of clinical encounters can be helpful (see Chapter 2 for details); this approach has been used in the Latin America region to measure progress and outcomes among key populations *(27)*. Although it may not cover all key population members who use services, this information can make an important contribution to understanding the HIV response for key populations. Several HIV prevention interventions are relevant only for key populations, such as harm reduction interventions for people who inject drugs. However, most HIV prevention and treatment interventions are designed for all individuals who need them, many of whom are not part of key populations. Therefore, where possible, and where safety and confidentiality are assured, data elements and indicators should be disaggregated for each key population group. At a minimum, in settings where it is safe to do so, or where anonymized case reporting systems are in place, capturing the probable route of transmission for all new HIV diagnoses will be important for estimating trends in HIV incidence and prevalence and risk factors.

All individual-level health data, including those of key populations, must be classified as sensitive personal data, or personally identifiable information, that require a high standard of safety and security. All health information systems must have robust data security and confidentiality protocols in place to safeguard data, supported by laws and policies that protect health information. The processing of personal health data must address cybersecurity, trust building, accountability and governance, ethics, equity, capacity building and digital literacy. Where safety and the potential to discourage access to services are a concern, the routine collection of key population information is not advised. Chapter 6 further addresses data security. When determining how best to monitor and evaluate the success of HIV programmes for key populations, countries should consider punitive laws and policies that may be in place and the availability and limitations of different data sources and indicators. Triangulation of programme and survey data can help to gauge the success of programmes addressing HIV among key populations.

5.1.2 Using data from routine HIV surveillance systems

Most countries manage a complex system of individual patient-level data and summed aggregated information based on these data. Patient information systems typically interface (directly, via interoperability, or indirectly, via manual data transfer) with laboratory and pharmacy routine information systems to more efficiently capture essential information for use in routine cascade analyses as well as in data validation and quality assessments *(28)*. Data collected through person-centred monitoring may be aggregated at the facility level before being reported to higher levels of the health system either by manually summing categories of subpopulations receiving services (for example, by age bands or gender) or by automated aggregation from individual-level data. While both approaches may provide reasonably robust estimates of progress against key indicators, manual aggregation does not enable flexibility in interrogating data by time, demographics or risk factors. In addition, because aggregated data cannot subsequently be disaggregated into individual-level data, it is not possible to assess how complete or accurate the data are, and therefore does not enable systematic quality control procedures to ensure internal validity. For example, it is difficult to detect duplicate records, resulting in overestimation of the number of people diagnosed with HIV and an incorrect assessment of the testing and treatment cascade at the facility level. At the national level, the inability to deduplicate numbers on ART or other indicators may result in incorrect estimates of progress toward the 95–95–95 Political Declaration targets *(29)*.

Expanding and interlinking existing HIV information systems to routinely capture and link individual data over time will improve data quality, simplify reporting and provide actionable data at granular subnational levels *(30)*. Implementing person-centred monitoring involves the progressive transition from name- and paper-based individual records and registers maintained at health facilities, to an electronic individual record coded with a unique identifier. UIDs are an important functional requirement to link and deduplicate patient data, as are policies for including HIV as a notifiable condition for the reporting of HIV cases and sentinel events *(31)*. Policies and laws are also important to protect the data security, privacy, and confidentiality of HIV information.

Strengthened HIV surveillance systems involve the reporting of HIV diagnoses and AIDS cases through a standardized reporting system, with additional data elements that can include sentinel paediatric or pregnancy-related events, related infections or death and more specific data elements such as the probable route of HIV acquisition that enable the understanding of the distribution of new HIV infections. As with other infectious diseases, surveillance of HIV requires a human rights-based, ethical, legal and policy framework (described in more detail in Chapter 6), standardized case definitions for adults and children, reporting procedures and documents, a data management system, security and confidentiality requirements and data analysis and dissemination plans.

5.2 Methods for estimating HIV incidence and prevalence using routine data

To promote sustainable and efficient surveillance platforms to guide HIV prevention, testing and treatment efforts, it is essential to strengthen the demand, supply, analysis and use of routine HIV programme or service data. To demonstrate the utility of routine programmatic surveillance data to guide the global, national and subnational response, and to inform models such as Spectrum, the methods in this guidance focus on approaches to measuring HIV incidence and prevalence. These methods utilize individual-level data (either paper-based or, preferably, electronic) that are routinely collected through regular clinical procedures from service delivery platforms for prevention, testing and treatment, national registries and/or programme-driven community and client surveys. As seroconversion rates (rate of conversion within a given population from an HIV-negative antibody test result to a positive test result) are at times used as a proxy for sero-incidence *(32)*, the methods for estimating this measure are also described. The methods described here are:

1. CD4/AIDS back-calculation
2. retesting
3. recency testing
4. routine antenatal HIV testing
5. age-specific HIV prevalence
6. phylogenetics
7. inclusion of routine data in modelling.

5.2.1 CD4/AIDS back-calculation

Background

Back-calculation is a widely used method to estimate the number of newly acquired HIV infections over time, or HIV incidence, from observed longitudinal data on HIV or AIDS diagnoses *(19-21, 33)*. The principle underlying back-calculation is that, if the evolution of a biomarker (for instance, CD4 cell counts) during untreated HIV infection is well characterized, levels of that biomarker at the time of diagnosis can be used to estimate, or back-calculate, the time since acquiring the HIV infection. In settings with concentrated HIV epidemics, back-calculation is often the only method available for estimating HIV incidence.

Originally, back-calculation was based on the observed number of AIDS diagnoses and the known incubation period of AIDS (the time distribution from infection to AIDS-related clinical symptoms in the absence of treatment). Since efficacious ART has become available, back-calculation methods mainly use data on HIV diagnoses (although information on whether or not there was a concurrent AIDS-defining event at the time of HIV diagnosis can still be used). An advantage of using HIV diagnoses is that the time to HIV diagnosis is generally much shorter than the time to AIDS, which allows for more precision when estimating the HIV incidence curve.

CD4 cell counts at diagnosis are the most important biomarker used for back-calculation, and they are often available as routinely collected data for new diagnoses. Most people with HIV who are not yet treated experience a steady decline in CD4 cell counts. The rate at which CD4 counts decrease over time is known from cohorts of people with a known date of HIV seroconversion *(34)*. The rate of decline also depends on factors such as age, gender, ethnicity and HIV viral load.

Operationalizing CD4 back-calculation in routine surveillance

When an individual is diagnosed with HIV and has a CD4 cell count measurement, the time since acquiring HIV can be estimated using the known distribution of times to reach this CD4 count level. The lower the CD4 cell count, the more likely it is that the infection was acquired longer ago. Importantly, the CD4 cell count measurement must be done before start of treatment, as, after treatment has started, CD4 counts are likely to increase. Box 5.1 presents a case study of the back-calculation method used in Brazil.

In order to estimate HIV incidence, back-calculation methods need additional information on the proportion of people with HIV who have not yet been diagnosed. The size of the undiagnosed population can be estimated with mathematical and/or statistical methods that calculate the probability of remaining undiagnosed as a function of the time since HIV acquisition *(21, 35, 36)*.

When CD4 counts at diagnosis are not available for everyone diagnosed with HIV, it may still be possible to use CD4-based back-calculation methods. For people without a CD4 count measurement, a CD4 value may be imputed using statistical methods that compare characteristics of people who have a CD4 measurement with those of people without a measurement. These characteristics typically include demographic information, such as age, gender, nationality at birth and location of residence, and clinical information, such as HIV viral load at diagnosis and date of last HIV-negative test. In settings where CD4 cell counts between diagnosis and the start of ART are not available, data from other settings on the rate of CD4 cell count decline over time may be used. Challenges may also arise where retesting of known HIV-positive individuals cannot be deduplicated, as this may bias estimations of the time of infection. Other clinical information such as viral load or the presence of ARVs in blood can be used to differentiate new diagnoses from known HIV-positive individuals who retest for HIV.

Box 5.1 Case study: Estimating HIV incidence and prevalence from routine surveillance data in Brazil

Annually, the Ministry of Health of Brazil updates a linked database with data collected over the last year from the main four information systems related to HIV: SINAN (Notifiable Disease Information System), which gathers information related to mandatory notifiable diseases, including HIV and AIDS cases; SIM (Mortality Information System), which includes all causes of deaths throughout the country, including AIDS deaths; SISCEL (Laboratory Test Control System), which registers HIV viral load and CD4 counts performed by public laboratories nationwide; and SICLOM (System for Logistic Control of ARV Drugs), which compiles information related to all people on ART in the country, from both public and private providers, and includes ARV stock control and distribution. The resulting HIV integrated information system (HIV-IS) is used for both patient monitoring and case surveillance.

To estimate HIV incidence, a back-calculation method is based on the first CD4 count among ART-naïve people living with HIV, as reported in the HIV-IS *(20, 37)*. In 2021 the model was adapted to estimate HIV incidence at granular levels, including region of residence, age group and sex *(38)*.

The first HIV detection date among all databases that comprise the HIV-IS is assumed to be the date of HIV diagnosis. In the first step, for each treatment-naïve case of HIV infection reported to SISCEL, the Brazilian CD4 depletion model is used to estimate the time between infection and the first CD4 count and the time between HIV infection and diagnosis. In the next step, for all cases without CD4 count information, the time between HIV infection and diagnosis is estimated by using a multiple imputation procedure based on the SINAN notification criterion (AIDS or HIV) *(38)*.

HIV incidence is calculated as the upper limit of the cumulative sum of people living with HIV reported to the HIV-IS in the same year of infection, in the year following infection, two years after infection and so on.

However, as the estimated HIV incidence loses accuracy when the number of observations is small *(20)*, the number of HIV cases diagnosed within the first year of infection was used to derive estimates in recent years. First, a regression model was used to predict the proportion of cases reported within the first year of HIV infection. Then, the HIV incidence estimate for the last five years was given by the ratio of the number of newly infected individuals diagnosed within the first year of HIV infection and the predicted proportion *(38)*.

In 2018 the average time between HIV infection and diagnosis was around three years (3.4 among males and 3.0 among females). In this same year, the number of new HIV infections in Brazil was estimated as 48 500 (95% CI: 45 300–57 500), representing an HIV incidence rate of 29 cases per 100 000 inhabitants.

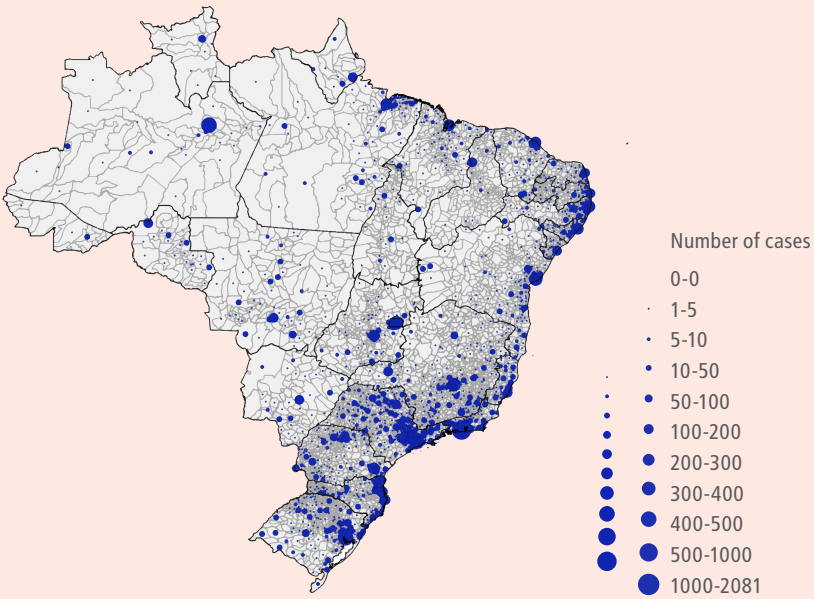
The approach is applicable at granular levels to all countries that monitor patients' clinical information (CD4 count and ART). The current procedure is a simplification of previous models *(20, 37)*, as it uses the number of HIV cases diagnosed within the first year of infection to generate estimates for recent years.

Box 5.1 (continued) Case study: Estimating HIV incidence and prevalence from routine surveillance data in Brazil

Analysis of progress indicators shows an increase in the proportion of people diagnosed within the first year of infection, a decrease in the average time from infection to diagnosis and improvements in the proportion of cases starting ART less than one year after HIV infection. Additionally, the results by age group and sex show that the youngest group of men (15–24 years of age) was the only group with a significant increase in HIV incidence between 2000 to 2018. The highest percentage of undiagnosed incident cases from 2010 to 2018 also was found in this group *(38)*.

At subnational levels the map (Fig. 5.1) shows the Brazilian epidemic is still concentrated in the largest cities, such as São Paulo, Rio de Janeiro and Manaus.

Fig. 5.1 Number of new HIV cases by municipality, Brazil, 2019.



Source: Ministry of Health, Brazil.

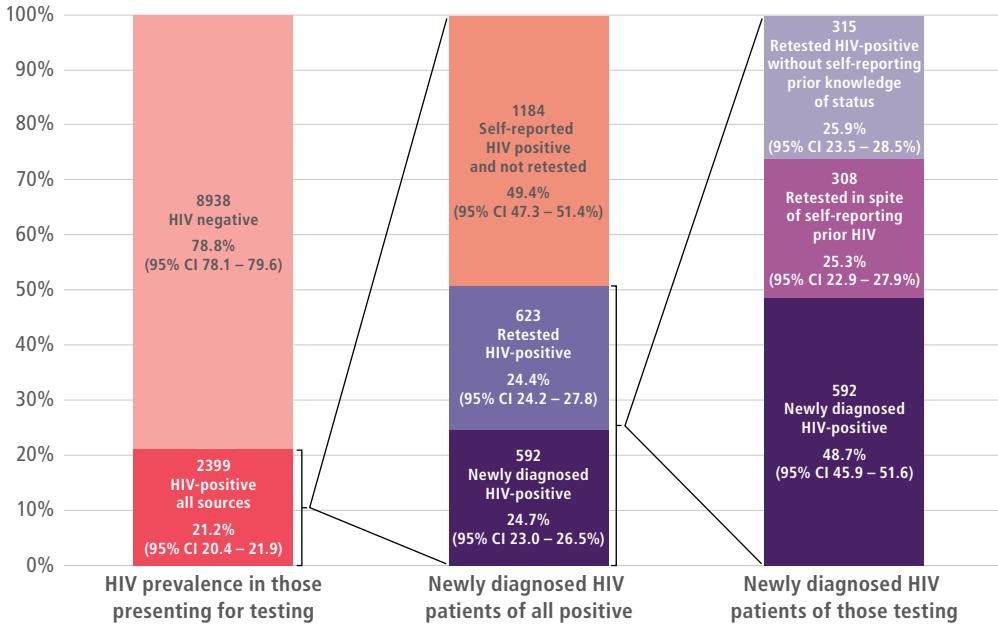
5.2.2 Retesting

Background

Retesting for HIV can play an important part in sustaining prevention activities, particularly in high burden settings, as it provides opportunities to engage or re-engage people testing HIV-negative *(39)* and facilitates re-linkage to HIV care among those who are HIV-positive *(40)*. Frequent retesting among priority groups such as key populations, for whom testing at least annually is recommended *(41)*, can help promote earlier diagnosis among people who have acquired HIV since their last negative test.

The decision to retest has been reported as linked to a person's awareness of HIV status, female gender, knowing someone living with HIV, recognition of continuing elevated risk of HIV acquisition and the use of opt-out HIV testing approaches *(42, 43)*. Some individuals with known HIV-positive status also retest, including those already on treatment *(44)*. The reasons for non-disclosure of HIV-positive status and undergoing retesting may include stigma, discrimination, denial or a lack of understanding of an HIV diagnosis; these and other factors need further research to be better understood.

Fig. 5.2 HIV test positivity by prior testing status based on individual-level data in Western Cape Province, South Africa



Source: Jacob et al., 2020 *(44)*

Retesting as an intervention

Although people who test multiple times for HIV are less likely than first-time testers to be HIV-infected *(43, 45)*, retesting will continue to identify new infections, thereby reducing the potential for missed or delayed opportunities for diagnosis *(40, 43, 45)*. By reducing the period between infection to diagnosis, the risk of disease progression and associated morbidity and mortality will be reduced. As retesting will be associated with declining HIV test positivity *(45)*, where the HIV test positivity rate is used as a programme indicator, it is important to monitor changing testing patterns and to consider their influence carefully when interpreting declining HIV test positivity rates.

Among persons testing HIV-positive, median CD4 count has been shown to be higher among people retesting for HIV than among first-time testers *(43)*. Significant reductions in HIV diagnoses among gay and bisexual men in London, United Kingdom, prior to the scale-up of PrEP, have been attributed to a combination of reducing community viral load by facilitating frequent retesting and prompt treatment initiation following an HIV diagnosis *(46, 47)*.

Recognizing that a person's care pathway following an HIV diagnosis often includes periods of disengagement, disruptions and transitions *(48)*, retesting of people previously diagnosed with HIV can facilitate a person's re-entry into care, thereby reducing their risk of advanced HIV disease and/or a high viral load. To better reflect the actual experiences of people living with diagnosed HIV, a new non-linear "cyclical" cascade has been proposed, the key to which is capturing longitudinal routine testing data (see Chapter 3, Fig. 3.4). There is evidence that a substantial proportion of people categorized as newly diagnosed with HIV in fact have previously been diagnosed HIV-positive *(44)*. Capturing longitudinal testing data can help identify and address duplicate positive results, thereby improving the accuracy of estimates of HIV diagnoses, prevalence and incidence.

Capturing longitudinal testing data can help identify and address duplicate positive results.

Operationalizing retesting data in routine surveillance

It is important to routinely collect reliable and comparable data on testing frequency, particularly among populations at risk for HIV acquisition. Strategies for achieving this include validating self-reports with medical record reviews, linking information across sites, more frequently asking patients about their testing history to improve recall and incorporating additional data sources into surveillance systems, including pharmacy and self-testing data *(49)*.

Accurately monitoring retesting at the individual and population levels requires data systems that track individuals over time and space and that provide strategic information based on deduplicated individual-level records. Individual-level data can be leveraged from multiple systems by referencing records using unique personal identifiers that work across multiple health services (see Chapter 6). Such unique identifiers include civil identification numbers, national health identifiers or identifiers used within master patient indexes (a database used by multiple locations to consistently maintain information on each registered patient), or developing bespoke matching algorithms to compare records based on existing patient identifying information *(50)*. Deterministic or probabilistic methods may be employed to cross-check these identifiers. Probabilistic methods, such as POC interactive record linkage (PIRL), have already been employed successfully in high burden settings *(51)*. National technical and legal protections for unique identifiers should be adopted (see Chapter 6), and health care data should not be linked to immigration and police systems, which might discourage individuals in stigmatized groups from seeking health care services.

Retesting in sustainable prevention initiatives and self-testing increases access to testing where routine contact with health services is limited. These observations have motivated efforts to better understand retesting in the context of self-testing. In KwaZulu-Natal, South Africa, in-depth interviews and telephone follow-up interviews were conducted among people presenting for HIV testing services. The study found that the likelihood of self-retesting was influenced by a person's desire to know their HIV status and by their risk exposure. The study's authors argue that self-testing has potential as an additional retesting tool but is currently limited by lack of affordability and accessibility *(42)*. Further exploration is needed of whether and how self-reported data on HIV self-retesting could be incorporated into retesting analyses.

Estimation of seroconversion rates and incidence

Longitudinal HIV testing data, as generated through nonexperimental or observational study designs (for example, cohort studies), has long been used to estimate HIV incidence. More recently, individual longitudinal testing data collected across multiple health services have been used to identify people who sero-convert (an HIV-positive test after at least one HIV-negative test), thus aiding in the estimation and interpretation of HIV incidence patterns *(45)*.

To support incidence estimation using routine testing data, better insights are needed into the potential biases and limitations (biases and limitations that often also affect other data collection methods), and how these may vary by time and location *(52, 53)*. For example, biases may arise if these HIV testing data are not representative – for example, if people who do not access routine health services are more at risk of HIV infection than those who do access services, or vice versa *(52, 54)*.

In Lesotho routinely collected data from HIV testing sites were analysed to identify persons retesting (an initial HIV test and at least one subsequent documented HIV test) and identify HIV seroconversion among these people. Predictors of re-testing were found to include being male, being tested as a couple and being aware of a partner's recent testing behaviour. Among re-testers who seroconverted, predictors included having less than a high school education and being female *(55)*.

In Zimbabwe sociodemographic information collected through the national sex work programme at first visit and then longitudinal data on programme engagement (including repeat HIV testing) have been used to calculate HIV seroconversion rates *(54)*. Based on seroconversion dates estimated as the midpoint between first positive test and last HIV-negative test, incidence was reported to be lower among women over age 35 and in women who tested for HIV during the six months before their first visit to the programme. Utilizing these same data, there is ongoing work to assess differences in seroconversion rates as calculated using four different ways to assign date of seroconversion between a woman's last HIV-negative and first HIV-positive test results. These four ways are randomly generated, midpoint, two weeks before an HIV-positive test and two weeks after the last HIV-negative test. Individuals contribute time at risk from their first visit until these various imputed dates of seroconversion, which is information that can aid in the estimation of HIV incidence.

Osmond's algorithm approach

A serological approach that uses data from multiple tests to estimate HIV incidence based on a seroconversion date midway between last negative and first positive test results has been compared with an alternative behavioural midpoint seroconversion approach. Based on Osmond's algorithm *(56)* for behavioural imputation, the alternative approach estimated seroconversion in a group of young men who have sex with men in Bangkok as taking place

midway between reported age of first anal intercourse and first HIV-positive test result. The incidence estimates arising from using the behavioural imputation and the serological approaches were in good agreement in this self-selected group of volunteers at risk for HIV infection, at 7.0 and 7.4 per 100 person–years, respectively *(57)*.

5.2.3 Recency assays

A primary outcome of interest in routine surveillance is HIV status. Beyond knowing whether a person is either HIV-negative or positive, it can also be useful to ascertain, among those testing HIV-positive, whether they were likely to have been infected recently. In population-based surveys, recency assays can be used to accurately estimate HIV incidence. In routine programmatic settings the individuals who attend HIV testing do so in a non-random manner (depending on such motivations as their perceived risk for HIV) and are not representative of the population. Therefore, recency testing in routine programmatic settings is best done in groups with a high level of HIV status ascertainment and who are tested for HIV for reasons unrelated to perceived high HIV risk (such as pregnant women attending ANC), and results should be reported as among specific population groups. WHO does not recommend the use of recency testing data for the clinical management of individuals or their partners, as there is currently insufficient evidence of their clinical utility. For routine HIV surveillance, understanding where and among which groups of people new or recent infections are occurring can be useful if the potential biases with programmatic data can be addressed. WHO and UNAIDS are releasing updated guidance on when and how to use recency assays for HIV surveillance in 2022, detailing best practices based on the available evidence *(58)*.

Background

Recency assays distinguish recent from long-standing HIV infection in an individual using one or more biomarkers, typically by measuring the evolution of the immune response following initial infection *(22, 58)*. Historically, a number of laboratory-based assays, such as the limiting antigen avidity assay (LAg), that measure HIV-1 antibody strength have been developed to distinguish recent from long-term HIV infection through the testing of plasma or dried-blood-spot blood specimens *(59)*. In addition, POC rapid tests for recent infection (RTRI) are being used *(60, 61)*. Each recency assay has different properties, and the assumptions made about those properties will influence incidence estimates. This is true for assays with the same name that are produced by different manufacturers. For this reason, when incidence results are being reported, it is important to report the details of which assay(s) were used in the recent infection testing algorithm (RITA) (including manufacturer), which cut-offs were applied and which values of the time cut-off for recency classification, the mean duration of recent infection (MDRI) and the false recent ratio (FRR) were used in the analysis. In addition, it is critical to describe which additional biomarkers were used in the algorithm to remove false recent infections.

Identifying "recent" infections – that is, infections acquired within the previous year – offers the potential for identifying particular age, gender or geographic clusters and factors associated with recent HIV infections in a defined population. However, interpreting this distribution to identify areas for programmatic focus is meaningful only if the geographic areas or demographic groups being compared have an equal chance of being represented in HIV testing data. Household surveys achieve this geographic representation through cluster-based sampling. Most programmatic data, however, will not meet the requirement of an equal chance of representation across geographic areas. Use of voluntary HIV testing services will vary depending on an individual's perceived risk of HIV acquisition. This is likely to vary by

geographic area, education level, access to testing and many other variables, resulting in an unequal chance of being tested for HIV and, subsequently, testing for HIV recency. Therefore, HIV incidence can be estimated accurately from recency assays only when data are collected through population-based surveys or when the results are ascribed to specific populations (such as women attending antenatal clinics or military recruits) and when appropriate MDRI and FRR estimates are included in the calculations *(58)*. Considerations for estimating incidence among the ANC population are described below under method 4 in section 5.2.4.

Performance and interpretation

Two main parameters influence the performance of the laboratory-based and RTRI assays. These are the MDRI and the FRR. MDRI is the average time spent infected within a "recent" period after infection, and the FRR is the probability that someone infected for longer than this "recent" period has a false-recent result *(62)*. All assays have an FRR greater than zero. A false recent measure may occur because of differences in individual immune responses, variable assay performance across differing HIV-1 subtypes and populations with naturally low viral loads, undocumented prior or current ART use and/or advanced HIV disease *(63)*. A high FRR can lead to biased HIV incidence estimates if it is not addressed through statistical adjustment or selective exclusion of specimens.

All recency assays and RITAs will misclassify some individuals with longstanding infection as recently infected. To support interpretation of recency tests, laboratory-based or RTRI results should be incorporated into a RITA that includes additional clinical information to classify an HIV infection *(63-65)*. This additional information should include, at a minimum, viral load and can also include automatic classification as a long-standing infection as a result of a prior HIV diagnosis or exposure to ART. A pilot study in Kenya and Zimbabwe demonstrated the feasibility of integrating recency testing into routine programme activities and identifying recently acquired infections among persons testing HIV-positive *(63)*. The study demonstrated the utility at the population level of characterizing new infections as recent or long-standing, but also highlighted the importance of interpreting recency assay results as part of a RITA.

The inclusion of information on testing history, viral load and ART exposure can improve the positive predictive value of recent infection testing by removing cases that would otherwise be misclassified. Information on testing history can be self-reported or obtained by linking recency samples to a person's clinical record. Viral load testing can be conducted in conjunction with the recency assay, and ART exposure can be ascertained from self-reports, linking to the clinical record and/or quantified testing for ARVs or metabolites in the blood using a robust simultaneous liquid chromatography/tandem mass spectrometry method *(66)*.

The non-random nature by which people come to HIV testing programmes requires special attention to reduce the effect of systematic biases on the accuracy of estimates derived from the use of recency assays from HIV testing services. From a surveillance perspective, the anonymous testing of all samples from individuals newly diagnosed with HIV can be feasible, since results of recency tests would not be returned to individuals. This would reduce the selection bias associated with individual consent, but it would not eliminate the bias associated with self-selection for HIV testing.

Incorporating recency testing into routine surveillance

In addition to test accuracy, data quality and interpretation, a number of factors should be considered when incorporating recency testing into routine surveillance. Health care staff will require training in the performance of the assay, client flows may require modification, and close monitoring of collection, transportation, storage and testing procedures will be needed to ensure that the assay manufacturer's instructions are followed *(67)*. Health systems and data visualization tools will need to be developed or revised to incorporate recency

data alongside available sociodemographic and risk information. Where possible, recency testing data can be incorporated into a national HIV case surveillance system *(68)*. To support the operationalization of a laboratory-based assay, it is helpful to develop a network of laboratories and expertise across which training can be conducted, problems can be discussed as they arise, and advice and support shared *(69)*. It may also be helpful for testing laboratories to participate in an external quality assurance scheme *(67, 70)*.

While recency testing can be used in HIV surveillance, there is currently insufficient evidence on the benefit to the individual beyond an HIV diagnosis, since all individuals testing HIV-positive should be offered treatment and partner services *(71)*. Many challenges present themselves in routinely returning results to those who test: the need for multiple test results to satisfy a RITA, delays in laboratory testing and/or linkage to clinical records, difficulties in aligning clinic visits, and participants opting not to receive test results *(69)*. Furthermore, there is no known individual benefit for recency testing, and these tests are not WHO-prequalified as diagnostic tests. Therefore, WHO does not recommend the use of recency testing for clinical management of HIV-positive individuals or their partners. Such clinical management that would not be recommended would include the return of recency test results to patients, counselling messages about recent infection results, prioritizing ART initiation and additional services based on recency results and prioritizing or altering partner services and index testing based on recency results.

> WHO does **not** recommend recency testing for clinical management of individuals or their partners.

Incidence estimation

A number of indicators for utilizing recency assays in incidence estimation have been identified *(22, 72, 73)*, including interpreting the proportion of recent infections among new diagnoses (HIV-positive tests) or the proportion of recent infections among people at risk of acquiring HIV (HIV-negative tests and recent infections) as surrogate measures of HIV incidence. However, some of these simple proportion indicators have been shown to be questionable proxies for HIV incidence *(73)*. When calculating a proportion-based indicator of recency from case surveillance or HIV testing service data, the "proportion recent" should be calculated as the number of recent infections divided by the total number of people at risk for HIV (those testing recent + those testing HIV-negative), not a denominator of the total number of people newly diagnosed with HIV. In Côte d'Ivoire, Malawi and Mozambique, modelling of HIV testing behaviours showed that the proportion of adults recently infected among those at risk of HIV acquisition more accurately identified trends in HIV incidence than the proportion among HIV-positive tests *(73)*.

To improve the accuracy of incidence estimates derived from recency testing, there are a number of factors to consider. An important consideration is the FRR, as the misclassification of chronic infections as recent infections will affect estimates. Assay-based incidence estimates can achieve high precision if the FRR is estimated to be close to zero *(74)*. However, if the estimated FRR used in the calculation is lower than the true ratio of false recent results, that will lead to overstating the precision of incidence findings. MDRI is also an important consideration. Shorter MDRIs and lower FRRs result in higher incidence estimates *(75)*. Several tools are available for recency-based incidence estimation, including the R package "inctools", an extension of the Kasanjee et al. *(75)* method for estimating incidence using cross-sectional assays, and the Assay-Based Incidence Estimation toolbox version 3 *(76)*. Other important factors to consider when using recency data are whether testing rates are uniform or changing, HIV testing history (particularly important where there is differential testing by HIV status), sample size, population characteristics and potential selection biases (which may be reduced by increasing the proportion of people testing HIV-positive who are included in recency testing).

Given the necessity for multiple test results to satisfy a RITA, the need to carefully consider the denominators used when calculating recency proportions, and the impact of differing testing rates between population groups or over time, the utility of using recency assays to describe the distribution and trends of recent infections should be compared with that of other direct and indirect surveillance methods for estimating HIV incidence.

5.2.4 Routine antenatal HIV testing

Background

Early in the global HIV/AIDS pandemic, pregnant women attending ANC were identified as an ideal sentinel population through which to monitor population-wide HIV trends *(77)* because women become pregnant and present for health screening at ANC for reasons unrelated to HIV risk factors or disease. Therefore, measures of HIV prevalence among pregnant women were considered more representative of population-wide HIV levels than HIV prevalence among other sentinel populations such as, for example, clients at STI clinics or hospital inpatients, who are disproportionately affected by HIV/AIDS.

Following evidence for the effectiveness of ARVs to prevent mother-to-child transmission of HIV and WHO recommendations for "treat all" *(78)*, HIV testing at the first ANC visit is now nearly universal in most countries highly affected by HIV *(78)*. Following WHO guidelines, many countries now implement retesting of women at the final ANC visit or during labour and delivery to identify any seroconversions since initial screening *(39)*. Routinely reported aggregate outcomes typically include:

- the number of new clients attending their first ANC visit during a current pregnancy
- the number of ANC clients who were already diagnosed with HIV and, therefore, were not tested
- the number of ANC clients tested for HIV
- the number ANC clients who tested HIV-positive
- the number already on lifelong ART prior to the first ANC visit
- the number of HIV-positive ANC clients who initiated ART during ANC.

When rates of ANC attendance and HIV testing coverage are high and data are robustly recorded, these indicators provide useful measures for understanding the epidemic. The data elements measure HIV testing coverage at ANC, HIV prevalence among pregnant women attending ANC and ART coverage prior to the first ANC visit. Estimates of HIV prevalence among pregnant women attending ANC must take into consideration women who are already known to be HIV-positive as separate from new HIV diagnoses. Using routine ANC HIV testing data instead of sentinel surveillance data overcomes the lack of representativeness in site selection that hampered interpretation of ANC sentinel surveillance in the past. Compared with ANC sentinel surveys, advantages of routine ANC testing data are:

1. Routine reporting for monitoring HIV service delivery reduces the cost and complexity of implementing a bespoke survey activity.
2. Any surveillance budget spent to improve these data ultimately improves the services to pregnant women.
3. Data are available for nearly all pregnant women, providing granular spatial and temporal information.

Limitations to using routine ANC testing data for surveillance are that they may be susceptible to biases related to incomplete testing of all pregnant women due to changes in testing policy or test kit availability, incomplete reporting by some facilities or reporting errors. Modest but systematic reporting errors can result in biased HIV incidence estimates. Therefore, it is important to consider whether trends and patterns observed among routine ANC testing reflect true epidemiologic changes in HIV among pregnant women and not changes in HIV testing or reporting practices. To address these limitations, combining routine reporting of ANC testing with regular and systematically sampled data quality assurance will provide more robust data for HIV surveillance.

Relating HIV prevalence among pregnant women to population HIV prevalence

Even where routine ANC HIV testing coverage is high, systematic differences between pregnant women and the general population must be accounted for when relating HIV prevalence among pregnant women to population HIV prevalence and trends.

The relative pattern of HIV prevalence among pregnant compared with non-pregnant women varies with age. In mature epidemics HIV prevalence tends to be lower among pregnant women above age 20 than among non-pregnant women, with the relative difference growing with increasing age and older age of sexual debut *(79)*. In contrast, pregnant adolescents, ages 15-19 years, tend to have higher HIV prevalence than non-pregnant adolescents. Lower HIV prevalence among pregnant women than non-pregnant women above age 20 has been related to biological, behavioural and structural factors, including reduced fecundity and higher rates of fetal loss *(80)*, increased risk of widowhood and divorce *(81)*, lower coital frequency and higher secondary abstinence, and structural differences such as higher HIV prevalence among urban populations, who have lower fertility *(82)*.

As HIV incidence declines over time and HIV prevalence shifts to older ages, HIV prevalence among pregnant women may decline more rapidly than prevalence in the general adult population *(79)*. Failing to account for this may result in overstating the level of HIV epidemic decline inferred from routine ANC testing. Age standardizing observed ANC prevalence data accounts partially, but not fully, for differences in prevalence levels and trends among ANC clients compared with the general population *(79, 83)*.

ART availability may reduce the fertility differences between HIV-positive women compared with HIV-negative women. Effective ART may *(1)* ameliorate reduced fecundity of HIV-positive women, *(2)* reduce widowhood, resulting in higher exposure to pregnancy, and *(3)* reduce the risk of vertical transmission, reducing barriers to achieving desired family size. Although data were deemed insufficient, a 2016 systematic review suggested that fertility of women on ART was likely higher than that for untreated HIV-positive women but lower than among HIV-negative women *(84)*; data from Western Cape Province in South Africa identified substantially higher pregnancy rates among women on ART *(85)*. Monitoring fertility among women on ART is important for interpreting trends in ANC prevalence to monitor population HIV trends and could make use of individual-level data.

Considerations for evaluating the robustness of routine ANC testing for surveillance

The key requirement for using routine ANC testing data for surveillance is ensuring confidence that reported HIV prevalence among ANC clients is consistently representative of true HIV prevalence among all pregnant women. This confidence requires meeting several conditions:

- ANC attendance is high and all women are recorded (for example, not missing large private-sector ANC services).
- HIV testing is offered to all pregnant women and not restricted to only higher-risk women or interrupted due to stock-outs of test kits.
- Only the first HIV test result is used to calculate HIV prevalence during a single pregnancy.
- Women who are already known to be HIV-positive and/or are already on ART prior to their first ANC visit during a pregnancy, and, therefore, are not tested for HIV, are recorded and included in routine reporting. All HIV-positive women must be included in both the numerator and denominator when calculating HIV prevalence among pregnant women.

These conditions should be verified through *(1)* auditing of ANC testing and reporting guidelines, reporting systems, registers and data capture forms and *(2)* construction of "ANC testing cascades" to review internal consistency of reported data. Consistency checks include:

1. The number of ANC clients is similar to the expected number of births. A much lower number of recorded ANC clients may indicate incomplete ANC attendance, increasing risk of selection bias. A much higher number may indicate systematic multiple counting of women during the same pregnancy.
2. The number of pregnant women with ascertained HIV status (number tested and number already known positive) is similar to the number of ANC clients. A lower number may indicate incomplete HIV testing, increasing risk of selection or composition bias. A higher number may indicate reporting of multiple HIV tests conducted during the same pregnancy, which suggests systematic retesting of HIV-negative women, which would induce bias.
3. The number of pregnant women already on ART should be less than the number of pregnant women known to be HIV-positive prior to the first ANC visit.
4. The number of pregnant women already on ART and newly initiating ART should be similar to the number of pregnant women known to be HIV-positive and the number who newly tested HIV-positive.

For surveillance purposes, each ANC HIV test and its result should be recorded separately so that women's first HIV test during a pregnancy is separate from retesting during labour and delivery. If retesting results are included together with first ANC HIV test results, this will typically bias HIV prevalence estimates downward and artificially exaggerate apparent HIV prevalence declines. It is good practice to review retesting data as part of ANC testing cascade analyses to confirm whether data conform with HIV programme implementation and to verify that retesting data were not inadvertently reported as part of first ANC HIV test outcomes.

Where the conditions described above are expected to be met, regular and randomly sampled data quality assurance exercises should be conducted to review routine ANC data for their suitability for surveillance and to collect relevant ancillary data. In settings where these conditions are not met, alternatives such as a regular ANC survey protocol can be considered to furnish HIV surveillance data.

Using routine ANC HIV testing to estimate HIV incidence

Several of the methods for calculating HIV incidence and prevalence described in this chapter can be considered among the population of women seeking ANC. Since early in the HIV pandemic, the primary methodology for estimating incidence in settings with generalized HIV epidemics from ANC prevalence has been fitting mathematical models to data on HIV prevalence among pregnant women attending ANC. This includes the UNAIDS-supported Estimation and Projection Package (EPP) in the Spectrum model, used to develop global HIV estimates and projections published annually *(13)*, and other models. A strength of the modelling approach is that models also reflect the systematic differences between prevalence in the ANC population and the general population *(16, 86)*, accounting for the dynamics and potential biases described above. Since 2016 the UNAIDS EPP model has incorporated routine ANC testing prevalence data to inform estimates of national HIV prevalence and incidence trends *(53)*.

There are potential approaches for more direct incidence calculations among the ANC population *(87)*. Routine ANC testing data provide information on HIV prevalence, the number of women newly diagnosed with HIV at their first ANC visit and the number of pregnant women previously diagnosed with HIV. Data on the proportion of undiagnosed people living with HIV, combined with assumptions or auxiliary data about the time since last HIV test or HIV testing rate, can be converted to estimates of HIV incidence *(88)*. However, this methodology for estimating HIV incidence among the ANC population is not suggested and should be used with caution due to substantial underreporting of a previous HIV diagnosis among women attending ANC. Underreporting is evidenced by high levels of viral suppression, indicating likely ARV use, among women recorded as newly diagnosed at ANC. Underreporting of previous diagnosis of status will result in overestimating HIV incidence.

A related approach for incidence estimation from data on new diagnoses is the CD4 back-calculation models described above (section 5.2.1), which use data on CD4 count at diagnosis to estimate how long ago HIV infection occurred. CD4 back-calculation has limited utility among the ANC population and is not recommended because *(1)* CD4 counts systematically change during pregnancy due to haemodilution *(89)* and *(2)* a large proportion of pregnant women are diagnosed prior to ANC and, therefore, CD4 counts among those testing HIV-positive in pregnancy may not be representative.

Another potential approach for estimating incidence among the ANC population is through the use of assays for recent infection that use biomarkers and clinical information such as ARV usage or viral suppression in RITAs *(59)*. While the limitations of recency assays in routine surveillance or programmatic settings remain (such as selection bias and small sample size), their use in ANC settings may have some advantages. Routine HIV testing data from ANC attendees can meet the requirement for representation in settings where the proportion of pregnant women who attend ANC is very high and all attendees are tested for HIV. If these two requirements are met, recency testing matched with the correct algorithm can inform estimates of the geographic distribution of recent HIV infections. Recency data from ANC settings should be analysed separately from those from other populations, and interpretation should be done within the context of women attending ANC. For example, recency results might be reported "among ANC attendees in X region, where 46% of patients are under the age of 25". Failure to specify the population and context may result in inappropriate conclusions about recent infections.

A final potential approach to direct incidence estimation is prospective incidence estimation using retesting of HIV-negative women during ANC *(90, 91)*. Conceptually, the number of women who were HIV-negative at first ANC visit who then test HIV-positive at subsequent ANC visits provides a direct estimate of HIV incidence.

However, incidence derived from ANC retesting should be interpreted cautiously; bias may arise from HIV-positive women having been misclassified as being HIV-negative at their first ANC visit, resulting in incorrect categorization of incident infections. While rapid HIV diagnostic tests are highly accurate and HIV-negative misclassification is rare *(39, 91, 92)*, HIV seroconversion is also a rare event, and, therefore, a small number of HIV-negative misclassifications at the first ANC visit may lead to a substantial upward bias in HIV incidence estimates. Generalization of incidence or risk factors among pregnant women attending ANC to populations other than pregnant women should be done cautiously. Pregnant women are exposed to different levels of HIV risk than non-pregnant women. There is some evidence of increased HIV susceptibility among pregnant women who are exposed to HIV *(93-97)*. However, pregnant women may have reduced behavioural risk during late pregnancy due to less sexual activity and fewer changes in sexual partners over the course of pregnancy, reducing population-level risks of HIV acquisition in pregnancy and postpartum *(98)*.

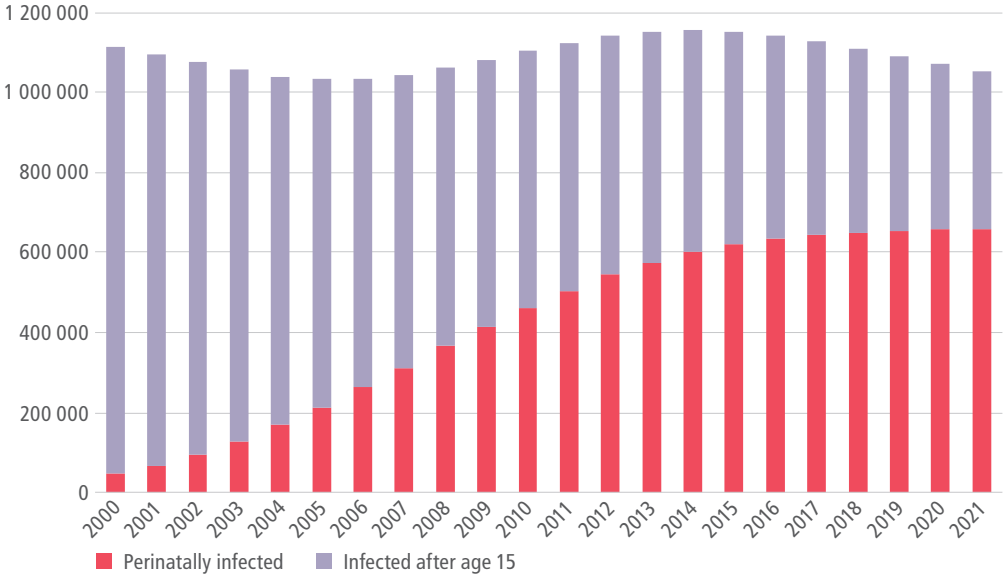
5.2.5 Age-specific HIV prevalence

Demographic methods have been developed to use age-specific cross-sectional HIV prevalence data, and, therefore, changes in HIV prevalence by age, to better understand HIV incidence *(6, 99)*. Methods previously used for estimating HIV incidence from age-specific prevalence data include cumulative incidence methods and survival methods *(99)*. As several assumptions (described below) are required to draw conclusions using these methods *(100)*, they are no longer suggested as a means of estimating or interpreting HIV incidence. They may still provide insights into the plausible limits of HIV incidence or to inform the application of the other methods detailed in this chapter.

To gain insights into HIV incidence using age-specific prevalence estimates, an assumption of stable endemic conditions is needed (that is, that the number of deaths does not exceed the number of new infections). This assumption is likely to hold in countries with widespread ART availability. It is also assumed that age-specific incidence is stable over time, which does not hold in many settings. These assumptions need to be reviewed before such methods are used. A recent analysis of programme-driven survey data collected among adolescent girls (ages 16 to 19 years) who sell sex in Zimbabwe reported a steep rise in HIV prevalence, from 2.1% among those age 16 years to 26.9% among those age 19 *(101)*. Assuming diagnoses in this age group are likely to represent cumulative incidence, and that infections due to vertical transmission were stable across the age group, this steep rise in prevalence was interpreted as being indicative of high HIV incidence among this study population.

Given that rates of risk behaviour and associated HIV incidence and data on excess AIDS-related mortality are likely to vary by age group, estimates of incidence derived from age-specific prevalence may be used as an indication of the plausible limits of HIV incidence *(6, 102)*. In countries with a mature epidemic, the probability that a proportion of infections occurred due to vertical transmission cannot be ruled out (Fig. 5.3). Therefore, interpretation should only be done after estimating the size of the vertically infected population in the adolescent age range. Previous analysis in Zimbabwe, for example, has shown this to be over 50% among the HIV-infected female population ages 15–19 and over 80% among the HIV-infected male population ages 15–19. In settings with growing epidemics, extended dynamic models have been applied *(100)*. These models can be fitted to the available data using maximum likelihood techniques.

Fig. 5.3 Number of adolescents ages 15–19 living with HIV, by timing of infection, global



Source: UNAIDS epidemiological estimates, 2022.

5.2.6 Phylogenetics

In recent years the use of molecular epidemiology to reconstruct viral transmission networks has been recognized widely as a tool for successful interventions to curtail outbreaks of infection. This approach forms an explicit part of the Ending the Epidemic programme in the USA (https://www.cdc.gov/endhiv/index.html). Recent studies published by the Centers for Disease Control and Prevention (CDC) demonstrate the effectiveness of sequence analysis for outbreak monitoring and for the identification of clusters representing recent and rapid transmissions *(103, 104)*. Where HIV Drug Resistance surveillance is in place, phylogenetic analysis of the genotype data generated can add to the repertoire of surveillance activities. In resource-limited settings, however, the availability of HIV drug resistance testing and phylogenetic testing may be limited, and, therefore, its feasibility and scope may be narrower.

Analysis of sequence relatedness allows rapid determination of linkage among incident infections and between them and prevalent cases. For a given incidence, closer linkage between new infections indicates expanding outbreak(s) within the population and so provides information useful for targeting interventions. In addition, where genotyping is performed before ART is started, clusters of transmitted drug resistance indicate treatment failures that may have gone undetected, with implications for the ART regimens that are used.

Phylogenetic analysis brings with it an inherent concern for data security due to the potential to identify individuals associated with transmission events. In all settings where it is considered, all data must be anonymized sufficiently that they cannot be reconstructed to an individual level.

This requires robust security protocols for analysing and reporting phylogenetic data, which should include additional pseudonymization on top of that employed with routine surveillance data. This would ensure that metadata are not automatically linked to the sequences and so would minimize risks of deductive disclosure. Members of key populations are particularly vulnerable to threats from data breaches where information related to HIV clusters and/or criminalized behaviours could be used by law enforcement officers and others. Therefore, if phylogenetic analysis is planned, the applicable legal framework should be considered and data security arrangements should be carefully assessed to ensure that, should the results generated be accessed, it will not be possible to identify individuals. In addition, consultations with the affected community are strongly encouraged.

Tools

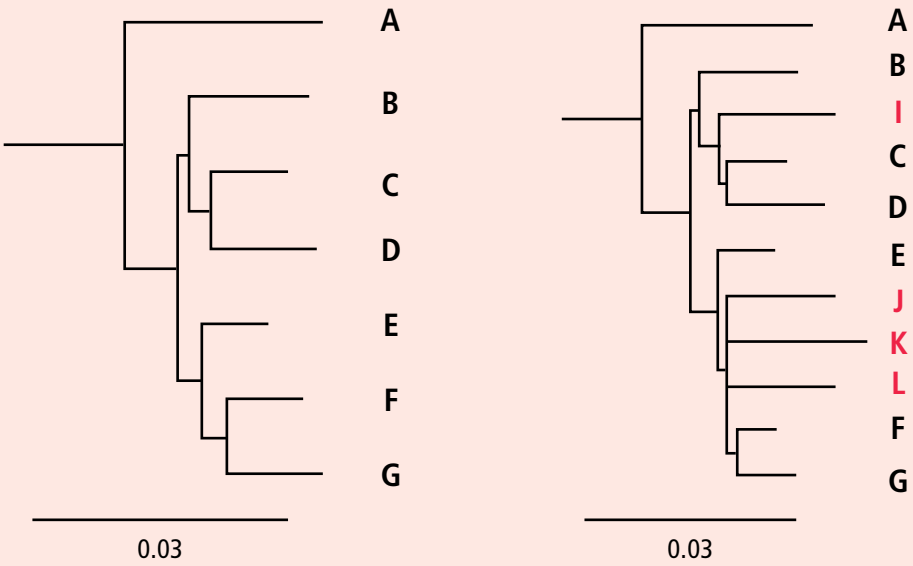
To provide useful interpretations of phylogenies for surveillance, software tools have been developed that can be adapted to the specific setting where they are employed. One such is Cluster Picker (https://hiv.bio.ed.ac.uk/software.html and available from https://github.com/emmahodcroft/cluster-picker-and-cluster-matcher/tree/master/release) *(105)*. This is a graphical user interface-operated tool that will take a phylogeny generated from, for example, IQ-Tree, RaXML or FastTree and output clusters with user-defined characteristics. For surveillance purposes these would typically be sequences that formed a close cluster of HIV, often defined as within a genetic distance of 1.5%. Historic context can be included by expanding the threshold of the relationship, and for this purpose a value of 4.5% is often used. (See Box 5.2 for an example of the use of Cluster Picker to detect an expanding cluster.)

For rapid analysis of large datasets, an alternative tool is available: HIV-TRACE (https://github.com/veg/hivtrace) *(106, 107)*. This tool avoids the need for generating an initial phylogeny, is extremely rapid and can be linked to surveys of large databases, such as the Los Alamos HIV Sequence Database, to reveal linkage outside the surveyed region. It uses the single-linkage algorithm to cluster sequences, which is fast to compute.

Finally, MicrobeTrace is a web-based software package for network analysis made available by the CDC (microbetrace.cdc.gov) *(108)*. Its sequence analytics tool uses the same approach as HIV-TRACE and allows rapid integration, visualization and analysis of data from multiple sources to generate genetic networks. MicrobeTrace can readily be used to discover and display network relationships between patients, and the extensive documentation makes it an intuitive tool to investigate HIV outbreaks that does not require specific bioinformatics skills.

Box 5.1 Phylogenetic surveillance of cluster growth

Clusters that are identified in a particular sample year can be re-evaluated in later years to identify those that are growing and, therefore, represent targets for intervention.



In this figure a cluster of seven individuals identified in the first sample (on the left) is expanded by the addition of four new individuals, I – L, in a sample taken two years later (on the right).

Source: adapted from Ragonnet-Cronin et al., 2013 *(105)*.

5.2.7 Inclusion of routine data in modelling

Using routine data for estimates of HIV incidence and prevalence has several advantages. As these data are routinely collected, few extra resources are needed for measuring incidence and prevalence. Another important advantage of routine data is that estimates can easily be updated over time as additional years of data become available. In settings with HIV epidemics concentrated in key populations, use of routine data can be more challenging due to non-disclosure of HIV risk factors by key population clients. In these cases key population survey data can be used. Where data are available, estimates can be made separately for key populations or for geographic entities such as cities, districts or states. Where key population data are collected, key population organizations and services should be engaged throughout the collection, analysis, use and dissemination of data in order to maintain the trust of communities. For routine data to be of sufficient quality for use in modelling, robust HIV case reporting is needed, as is good quality data on the numbers of people on ART and data from HIV testing among pregnant women in ANC. Each of these can be supplemented by survey data from key populations in concentrated epidemics and from the general population in generalized epidemic settings.

Although routine data on HIV diagnoses can be used to estimate numbers of newly acquired HIV infections and the size of the undiagnosed population, additional data on people accessing HIV treatment and the mortality and migration patterns among individuals with HIV are needed to estimate the number of people living with HIV at a specific time and place *(30, 109)*. Both mortality and out-migration among people with HIV reduce the total number living with HIV, while in-migration of people with HIV increases that number and HIV incidence. Data on mortality and out-migration require surveillance systems with longitudinal follow-up of people diagnosed with HIV and/or information from vital statistics systems. In-migration of people with HIV, in particular transfers of care, may not always be part of routine surveillance data on new HIV diagnoses *(25)*. In addition, assumptions are necessary regarding mortality and migration in the undiagnosed population. Alternatively, other registries on people with HIV may be available, for instance, data on the number of people currently receiving treatment, hospital records on the number receiving care for HIV infection, or data from observational cohorts. The total number of people living with HIV can then be calculated by adding the estimated number with undiagnosed HIV to the number of linked and deduplicated individuals in these registries.

Using routine data to estimate a full incidence curve over the entire duration of a country's epidemic benefits from many years of historical data, but such estimates, including for subnational areas, can still be obtained even if routine data are available only more recently. Methods based on routine data on HIV cases generally give estimates of the number with a newly-acquired infection or the number undiagnosed. To calculate incidence and prevalence per population requires estimates of the population at risk of acquiring HIV, including the general population and for each key population.

Lastly, the accuracy of estimates based on routine data stands or falls with the quality (completeness and accuracy) of the data. Underreporting of HIV and AIDS cases will generally lead to underestimates of incidence and of the size of the undiagnosed population. Analogously, over-reporting may produce estimates that are too high. Over-reporting may take place, for instance, when people who are diagnosed in one district and move to another district are reported twice to the national surveillance system and these data are not identified and deduplicated through data linkage.

Incomplete reporting, where some data items may be missing for a proportion of cases, may also hamper the use of routine data. Although missing information is common, data analyses of routine HIV data often adopt a complete-case approach where, assuming data are missing at random, individual records with missing values are removed *(110)*.

The problem of missing information in routine programmatic data can be mitigated by populating missing variables with information gained through linking individual-level case surveillance and routine data within and between systems over time before it is included in models. Provided that the proportion of cases with incomplete data is small and/or the cases with complete data are representative of all cases, within an archived/analytical version of the live data, individual-level missing values may be imputed based on information previously reported for that individual in the same system or a linked system. For example, if a person with gender not reported has previously had their gender consistently reported, one could consider updating the missing value to that reported. As single imputation methods based on previous reported values, or mean or regression predictors, can result in a loss of precision, use of multiple imputation methods should be considered *(111)*.

5.3 Minimum dataset required for estimating HIV incidence and prevalence

National routine HIV surveillance systems will need to collect a minimum standardized set of reportable data elements (Table 5.1) in order to estimate HIV incidence and prevalence using the methods described above. These data elements include HIV diagnosis date and all immunological testing results such as CD4 count and viral load for individuals newly diagnosed with HIV, as WHO clinical guidelines recommend *(112)*. Surveillance data on HIV case reports should link to databases that may contain laboratory information such as CD4 and viral load test results. At a minimum HIV surveillance programmes should collect the CD4 cell count at time of diagnosis, as recommended by WHO for clinical staging and identification of advanced HIV disease *(112)*. These factors can help determine changes in immune function and viral suppression and to monitor continuity of care. Laboratory tests also can serve as proxies for entering and remaining in care and can aid in distinguishing new diagnoses from retesting of known HIV-positive individuals already on treatment. Also, the probable route of transmission for all new HIV diagnoses is important to understanding the distribution of new HIV infections and estimating trends in HIV incidence, prevalence and risk factors. The probable route of transmission should be recorded only where it is safe to collect or where anonymized case reporting systems are in place. Ensuring completeness of demographic data such as age, gender and other relevant racial, ethnic, geographic or other categories is needed to better track trends in different subpopulations over time.

Many sources can be used to track key or sentinel events and other data elements. Patient registers, hospitals, physicians, TB care and surveillance programmes, ANC clinics, HIV testing services, laboratories and vital statistics registries that include cause of death are all useful sources. In countries that use patient registers, these will likely serve as the main source of information for identifying individuals receiving HIV prevention, treatment and care and for reporting data elements forward. Critically important to enable the calculation of HIV incidence and prevalence from routine data is the ability to distinguish new diagnoses from those who are known HIV-positive; this can be done either through robust individually linked case surveillance or other means such as laboratory testing. In many situations one or more sources may identify a person diagnosed with HIV or receiving prevention or care, but there will not be sufficient information to fully document and report this information. In these circumstances compilation of laboratory, pharmacy and medical records will be needed to complete the required fields.

Table 5.1 Recommended minimum dataset from routine HIV surveillance for use in estimating HIV incidence and prevalence

Area	Data elements	Potential data sources[b]	Use in HIV incidence & prevalence estimation	Potential derived indicators
HIV diagnosis[a]	HIV-positive test: HIV test date HIV test result	HIV testing data (clinical and confirming laboratory results)	Pivotal date from which to estimate incidence and for inclusion in prevalence estimates	Estimated HIV testing coverage (when combined with all other testing data) Reclassification of new diagnoses as long-term infection (with or without ARV exposure)
	Previous HIV-negative (or HIV-positive) test: HIV test date HIV test result	HIV testing data	Date from which some estimates will take a midpoint between this and first diagnosis for incidence estimation The period in which a previous HIV-positive test occurred will determine whether an individual is included in HIV incidence or prevalence calculations	Annualized rate of tests/person/year by key population Previous linkage to HIV prevention services
Initial pretreatment disease assessment	First CD4 test result at HIV diagnosis First CD4 test date Clinical stage at ART start	HIV testing data and/or ART register	Measure of immune function, CD4 back-calculation	Late diagnosis Reclassification of new diagnoses as long-term infection
Initiation of ART	Date started ART (among pregnant women, whether already on ART or ART started during pregnancy)	ART register		Time to ART initiation
Viral suppression	First viral load test result (at diagnosis) First viral load test date	ART register	Measure of immune function	Reclassification of new diagnoses as long-term infection
	Subsequent viral load and CD4 test results and test dates	ART register		Treatment failure
	Any viral load test <1000 per mL	ART register		
Loss to follow-up	>28 days since last appointment	ART register		Implications for viral rebound
Disease progression	Date of first AIDS diagnosis	ART register	Back-calculation of HIV incidence	

Table 5.1 (continued) Recommended minimum dataset from routine HIV surveillance for use in estimating HIV incidence and prevalence

Area	Data elements	Potential data sources[b]	Use in HIV incidence & prevalence estimation	Potential derived indicators
HIV diagnoses among pregnant women	New HIV diagnoses among pregnant women Date of first ANC visit HIV status at first test during current pregnancy (known positive, tested negative, tested positive, not tested) Dates and results of subsequent HIV tests during pregnancy	ART register ANC register/ data	HIV prevalence, incidence in pregnant women	Potential estimation of HIV prevalence in general population New diagnoses in pregnant women not on ART
Vertical transmission	Pregnancy in women living with HIV	ART register ANC register/ data		
	Number of HIV-exposed infants	ART register ANC register/ data	Paediatric HIV prevalence/incidence	
	First infant PCR test result	ART register	Paediatric HIV prevalence/incidence	% of exposed infants who were tested
	Final infant PCR test result	ART register	Paediatric HIV prevalence/incidence	Vertical transmission rate Proportion of children not tested
Death	All-cause mortality	ART register Civil registration and vital statistics (CRVS) system Verbal autopsy Modelled estimates	HIV prevalence	
	AIDS-related death	ART register CRVS system	HIV prevalence	

[a] Recency testing can be considered if conducted routinely in a setting as part of a RITA on all new HIV diagnoses and the conditions described in the section above to address potential sources of bias are met.

[b] Electronic medical records can be used where any of these data elements are recorded.

5.4 Data quality needs for the use of routine data

While routine facility data provide a powerful tool for granular, timely analyses, in different settings integrated data systems with high coverage are at different stages of maturation. Still, in many of these same settings, some form of HIV case reporting and surveillance has been in place for years, either through paper or electronic systems. The quality of routine data (including reliability, completeness, accuracy and timeliness) depends upon how well information is captured by HIS and health service providers, and is cleaned and reviewed by data managers. For example, failure of some facilities to report consistently may appear as drops in programme coverage but may not reflect actual utilization levels. Using data of unknown or low quality may result in flawed analysis and incorrect decisions. Therefore, a systems approach to improving data quality includes establishing and promoting a culture of HIV data quality assessment and use. Such an approach will include developing data quality assurance protocols that ensure the data collected are comprehensive and robust, encouraging responsibility for data quality at the local, subnational and national levels (potentially through the engagement and training of data stewards) and regularly evaluating data quality.

A systems approach to improving data quality includes establishing and promoting a culture of HIV data quality assessment and use.

Assessments of data quality (particularly for completeness and identification of outliers) must be integrated into the steps used to analyse routine facility data *(28, 113)*. With routine programmatic data that are aggregated manually, and without the use of individual-level data or robust HIV case surveillance, there is a risk of counting individuals multiple times if they receive the same services multiple times in a reporting period in the same or different locations. It may be particularly important in HIV incidence calculations to distinguish individuals newly diagnosed with HIV from those who may have tested previously but moved or interrupted treatment. Separate assessments conducted on a sample basis – for example, a client survey to measure the proportion of people tested multiple times in a reporting period – can help to correct for this limitation. Similarly, conducting routine review of ANC prevalence and ART data at the district level is important for the quality of data included in national HIV estimation models *(113)*. For example, tools such as the Naomi reviewer (hivtools.unaids.org) *(114)* can help narrow down the districts with data deduplication issues for ANC or ART data and where further assessments are needed.

As countries expand the use of individual-level routine facility data collection systems as part of an integrated HIS architecture, data quality will improve. The application of robust, user-acceptable unique identifiers enables deduplication of patient records. This, for example, enables assessment of prior ART use to remove apparently new HIV diagnoses that, in fact, were the result of unofficial "silent" transfers from one facility to another. Using performance and outcome standards for monitoring routine surveillance systems is important for improving data quality and use. In the long run, routine health facility data provide a sustainable, timely, granular source of data for monitoring HIV incidence and prevalence and the health sector response to HIV.

References

1. Consolidated HIV strategic information guidelines: driving impact through programme monitoring and management. Geneva: World Health Organization; 2020 (https://www.who.int/publications/i/item/9789240000735, accessed 2 April 2022).
2. Global AIDS Update 2021. Confronting inequalities: lessons for pandemic responses from 40 years of AIDS. Geneva: United Nations Joint Programme on HIV/AIDS (UNAIDS) (https://www.unaids.org/en/resources/documents/2021/2021-global-aids-update, accessed 23 June 2022).
3. Brown K, Williams DB, Kinchen S, Saito S, Radin E, Patel H et al. Status of HIV epidemic control among adolescent girls and young women aged 15-24 years - seven african countries, 2015-2017. MMWR Morb Mortal Wkly Rep. 2018;67:29-32. doi: 10.15585/mmwr.mm6701a6
4. Justman J, Reed JB, Bicego G, Donnell D, Li K, Bock N et al. Swaziland HIV Incidence Measurement Survey (SHIMS): a prospective national cohort study. Lancet HIV. 2017;4:e83-e92. doi: 10.1016/S2352-3018(16)30190-4
5. United Nations General Assembly. Political declaration on HIV and AIDS. On the fast track to accelerating the fight against HIV and to ending the AIDS epidemic by 2030. New York: United Nations; 2016 (https://digitallibrary.un.org/record/833243?ln=es, accessed 24 June 2022).
6. Hallett TB. Estimating the HIV incidence rate: recent and future developments. Curr Opin HIV AIDS. 2011;6:102-7. doi: 10.1097/COH.0b013e328343bfdb
7. Sustainable Development Goals. SDG indicators. Metadata repository [webpage]. New York: United Nations; 2022 (https://unstats.un.org/sdgs/metadata/, accessed 27 May 2022).
8. Monitoring HIV impact using population-based surveys. Geneva: Joint United Nations Programme on HIV/AIDS (UNAIDS); 2015 (https://www.unaids.org/sites/default/files/media_asset/JC2763_PopulationBasedSurveys_en.pdf, accessed 24 June 2022).
9. World Health Organization, Centers for Disease Control and Prevention, Joint United Nations Programme on HIV/AIDS, FHI 360. Biobehavioral survey guidelines for populations at risk for HIV. Geneva: World Health Organization; 2017 (https://www.who.int/publications/i/item/978-92-4-151301-2, accessed 24 June 2022).
10. Grabowski MK, Serwadda DM, Gray RH, Nakigozi G, Kigozi G, Kagaayi J et al. HIV prevention efforts and incidence of HIV in Uganda. N Engl J Med. 2017;377:2154-66. doi: 10.1056/NEJMoa1702150
11. Gregson S, Mugurungi O, Eaton J, Takaruza A, Rhead R, Maswera R et al. Documenting and explaining the HIV decline in east Zimbabwe: the Manicaland General Population Cohort. BMJ Open. 2017;7:e015898. doi: 10.1136/bmjopen-2017-015898
12. ALPHA Network. African Population-based HIV data [website]. London: London School of Hygiene & Tropical Medicine; 2022 (https://alpha.lshtm.ac.uk/#:~:text=The%20ALPHA%20Network%20is%20a,residents%20of%20the%20study%20areas, accessed 26 June 2022).
13. Spectrum suite of policy models [website]. Glastonbury (CT): Avenir Health; 2022 (https://avenirhealth.org/software-spectrum.php, accessed 18 May 2022).
14. Mahiane SG, Eaton JW, Glaubius R, Case KK, Sabin KM, Marsh K. Updates to Spectrum's case surveillance and vital registration tool for HIV estimates and projections. J Int AIDS Soc. 2021;24 Suppl 5:e25777. doi: 10.1002/jia2.25777

15. Mahiane SG, Marsh K, Glaubius R, Eaton JW. Estimating and projecting the number of new HIV diagnoses and incidence in Spectrum's case surveillance and vital registration tool. AIDS. 2019;33 Suppl 3:S245-S53. doi: 10.1097/QAD.0000000000002324

16. Stover J, Glaubius R, Kassanjee R, Dugdale CM. Updates to the Spectrum/AIM model for the UNAIDS 2020 HIV estimates. J Int AIDS Soc. 2021;24 Suppl 5:e25778. doi: 10.1002/jia2.25778

17. Optima Consortium for Decision Science. Melbourne: Optima HIV; 2022 (http://ocds.co/home/about.html, accessed 18 May 2022).

18. Brown T, Peerapatanapokin W. Evolving HIV epidemics: the urgent need to refocus on populations with risk. Curr Opin HIV and AIDS. 2019;14:337.

19. Song R, Hall HI, Green TA, Szwarcwald CL, Pantazis N. Using CD4 data to estimate HIV incidence, prevalence, and percent of undiagnosed infections in the United States. J Acquir Immune Defic Syndr. 2017;74:3-9. doi: 10.1097/QAI.0000000000001151

20. Szwarcwald C, Souza J, Pascom A, Ferreira J. Results from a method for estimating HIV incidence based on the first Cd4 count among treatmentnaïve cases: Brazil, 2004–2013. J AIDS Clin Res. 2016;7:2.

21. van Sighem A, Nakagawa F, De Angelis D, Quinten C, Bezemer D, de Coul EO et al. Estimating HIV incidence, time to diagnosis, and the undiagnosed HIV epidemic using routine surveillance data. Epidemiol. 2015;26:653-60. doi: 10.1097/EDE.0000000000000324

22. Murphy G, Pilcher CD, Keating SM, Kassanjee R, Facente SN, Welte A et al. Moving towards a reliable HIV incidence test - current status, resources available, future directions and challenges ahead. Epidemiol Infect. 2017;145:925-41. doi: 10.1017/S0950268816002910

23. Etoori D, Wringe A, Kabudula CW, Renju J, Rice B, Gomez-Olive FX et al. Misreporting of patient outcomes in the South African National HIV Treatment Database: consequences for programme planning, monitoring, and evaluation. Front Public Health. 2020;8:100. doi: 10.3389/fpubh.2020.00100

24. Bogoch, II, Gomes M, Fuente-Soro L, Varo R, Naniche D, Sacoor C et al. Identifying HIV care continuum gaps with verbal autopsy. Lancet HIV. 2018;5:e65-e7. doi: 10.1016/S2352-3018(18)30007-9

25. Pantazis N, Rosinska M, van Sighem A, Quinten C, Noori T, Burns F et al. Discriminating between premigration and postmigration HIV acquisition using surveillance data. J Acquir Immune Defic Syndr. 2021;88:117-24. doi: 10.1097/QAI.0000000000002745

26. Presanis AM, Kirwan P, Miltz A, Croxford S, Harris R, Heinsbroek E et al. Implications for HIV elimination by 2030 of recent trends in undiagnosed infection in England: an evidence synthesis. arXiv preprint arXiv:191207310. 2019.

27. Framework for monitoring HIV/STI services for key populations in Latin America and the Caribbean. Washington (DC): Pan American Health Organization; 2019 (https://www.paho.org/en/documents/framework-monitoring-hivsti-services-key-populations-latin-america-and-caribbean-2019, accessed 24 June 2022).

28. Data quality assessment of national and partner HIV treatment and patient monitoring data and systems implementation tool. Geneva: World Health Organization; 2018 (https://apps.who.int/iris/handle/10665/274287, accessed 26 June 2022).

29. Prevailing against pandemics by putting people at the centre. Geneva: United Nations Joint Programme on HIV/AIDS (UNAIDS); 2020 (https://www.unaids.org/en/resources/documents/2020/prevailing-against-pandemics, accessed 26 June 2022).

30. Rice BD, Elford J, Yin Z, Delpech VC. A new method to assign country of HIV infection among heterosexuals born abroad and diagnosed with HIV. AIDS. 2012;26:1961-6. doi: 10.1097/QAD.0b013e3283578b80

31. Holmes JR, Dinh TH, Farach N, Manders EJ, Kariuki J, Rosen DH et al. Status of HIV case-based surveillance implementation - 39 U.S. PEPFAR-supported countries, May-July 2019. MMWR Morb Mortal Wkly Rep. 2019;68:1089-95. doi: 10.15585/mmwr.mm6847a2

32. De Schacht C, Hoffman HJ, Mabunda N, Lucas C, Alons CL, Madonela A et al. High rates of HIV seroconversion in pregnant women and low reported levels of HIV testing among male partners in Southern Mozambique: results from a mixed methods study. PLoS One. 2014;9:e115014. doi: 10.1371/journal.pone.0115014

33. Rosinska M, Pantazis N, Janiec J, Pharris A, Amato-Gauci AJ, Quinten C et al. Potential adjustment methodology for missing data and reporting delay in the HIV Surveillance System, European Union/European Economic Area, 2015. Euro Surveill. 2018;23. doi: 10.2807/1560-7917.ES.2018.23.23.1700359

34. Cori A, Pickles M, van Sighem A, Gras L, Bezemer D, Reiss P et al. CD4+ cell dynamics in untreated HIV-1 infection: overall rates, and effects of age, viral load, sex and calendar time. AIDS. 2015;29:2435-46. doi: 10.1097/QAD.0000000000000854

35. Johnson LF, Rehle TM, Jooste S, Bekker LG. Rates of HIV testing and diagnosis in South Africa: successes and challenges. AIDS. 2015;29:1401-9. doi: 10.1097/QAD.0000000000000721

36. Presanis AM, Harris RJ, Kirwan PD, Miltz A, Croxford S, Heinsbroek E et al. Trends in undiagnosed HIV prevalence in England and implications for eliminating HIV transmission by 2030: an evidence synthesis model. Lancet Public Health. 2021;6:e739-e51. doi: 10.1016/S2468-2667(21)00142-0

37. Szwarcwald C, Pascom A, Souza Júnior P. Estimation of the HIV incidence and of the number of people living with HIV/AIDS in Brazil, 2012. J AIDS Clin Res. 2015;6:430.

38. Szwarcwald CL, Souza Júnior PRBd, Pascom ARP, Coelho RdA, Ribeiro RA, Damacena GN et al. HIV incidence estimates by sex and age group in the population aged 15 years or over, Brazil, 1986-2018. Rev Soc Bras Med Trop. 2022;55.

39. What's the 2+1+1? Event-driven oral pre-exposure prophylaxis to prevent HIV for men who have sex with men: update to WHO's recommendation on oral PrEP: Technical brief. Geneva: World Health Organization; 2019 (https://www.who.int/hiv/pub/prep/211/en/, accessed 16 November 2020).

40. Flash CA, Pasalar S, Hemmige V, Davila JA, Hallmark CJ, McNeese M et al. Benefits of a routine opt-out HIV testing and linkage to care program for previously diagnosed patients in publicly funded emergency departments in Houston, TX. J Acquir Immune Defic Syndr. 2015;69 Suppl 1:S8-15. doi: 10.1097/QAI.0000000000000578

41. Consolidated guidelines on HIV, viral hepatitis, and STI prevention, diagnosis, treatment and care for key populations. Geneva: World Health Organization; 2022.

42. Harichund C, Kunene P, Simelane S, Abdool Karim Q, Moshabela M. Repeat HIV testing practices in the era of HIV self-testing among adults in KwaZulu-Natal, South Africa. PLoS One. 2019;14:e0212343. doi: 10.1371/journal.pone.0212343

43. Regan S, Losina E, Chetty S, Giddy J, Walensky RP, Ross D et al. Factors associated with self-reported repeat HIV testing after a negative result in Durban, South Africa. PLoS One. 2013;8:e62362. doi: 10.1371/journal.pone.0062362

44. Jacob N, Rice B, Kalk E, Heekes A, Morgan J, Hargreaves J et al. Utility of digitising point of care HIV test results to accurately measure, and improve performance towards, the UNAIDS 90-90-90 targets. PLoS One. 2020;15:e0235471. doi: 10.1371/journal.pone.0235471

45. Jones HS, Musemburi S, Chinyanganya L, Takaruza A, Chabata S, Matambanadzo P et al. Trends in HIV testing and seroconversion among female sex workers accessing Zimbabwe's national "Sisters" programme: an analysis of individual-level clinic records 2009-2020. Under Review.

46. Brizzi F, Birrell PJ, Kirwan P, Ogaz D, Brown AE, Delpech VC et al. Tracking elimination of HIV transmission in men who have sex with men in England: a modelling study. Lancet HIV. 2021;8:e440-e8. doi: 10.1016/S2352-3018(21)00044-8

47. Nwokolo N, Hill A, McOwan A, Pozniak A. Rapidly declining HIV infection in MSM in central London. Lancet HIV. 2017;4:e482-e3. doi: 10.1016/S2352-3018(17)30181-9

48. Ehrenkranz P, Rosen S, Boulle A, Eaton JW, Ford N, Fox MP et al. The revolving door of HIV care: Revising the service delivery cascade to achieve the UNAIDS 95-95-95 goals. PLoS Med. 2021;18:e1003651. doi: 10.1371/journal.pmed.1003651

49. Paschen-Wolff MM, Restar A, Gandhi AD, Serafino S, Sandfort T. A systematic review of interventions that promote frequent HIV testing. AIDS Behav. 2019;23:860-74. doi: 10.1007/s10461-019-02414-x

50. Rice B, Boulle A, Baral S, Egger M, Mee P, Fearon E et al. Strengthening routine data systems to track the HIV epidemic and guide the response in sub-Saharan Africa. JMIR Public Health Surveill. 2018;4:e36. doi: 10.2196/publichealth.9344

51. Rentsch CT, Kabudula CW, Catlett J, Beckles D, Machemba R, Mtenga B et al. Point-of-contact Interactive record linkage (PIRL): a software tool to prospectively link demographic surveillance and health facility data. Gates Open Res. 2017;1:8. doi: 10.12688/gatesopenres.12751.2

52. Ayoub HH, Awad SF, Abu-Raddad LJ. Use of routine HIV testing data for early detection of emerging HIV epidemics in high-risk subpopulations: a concept demonstration study. Infect Dis Model. 2018;3:373-84. doi: 10.1016/j.idm.2018.10.001

53. Sheng B, Marsh K, Slavkovic AB, Gregson S, Eaton JW, Bao L. Statistical models for incorporating data from routine HIV testing of pregnant women at antenatal clinics into HIV/AIDS epidemic estimates. AIDS. 2017;31 Suppl 1:S87-S94. doi: 10.1097/QAD.0000000000001428

54. Hargreaves JR, Mtetwa S, Davey C, Dirawo J, Chidiya S, Benedikt C et al. Implementation and operational research: cohort analysis of program data to estimate HIV incidence and uptake of HIV-related services among female sex workers in Zimbabwe, 2009-2014. J Acquir Immune Defic Syndr. 2016;72:e1-8. doi: 10.1097/QAI.0000000000000920

55. Grabbe KL, Courtenay-Quirk C, Baughman AL, Djomand G, Pedersen B, Lerotholi M et al. Re-testing and seroconversion among HIV testing and counseling clients in Lesotho. AIDS Educ Prev. 2015;27:350-61. doi: 10.1521/aeap.2015.27.4.350

56. Osmond DH, Page K, Wiley J, Garrett K, Sheppard HW, Moss AR et al. HIV infection in homosexual and bisexual men 18 to 29 years of age: the San Francisco Young Men's Health Study. Am J Public Health. 1994;84:1933-7. doi: 10.2105/ajph.84.12.1933

57. van Griensven F, Mock PA, Benjarattanaporn P, Premsri N, Thienkrua W, Sabin K et al. Estimating recent HIV incidence among young men who have sex with men: Reinvigorating, validating and implementing Osmond's algorithm for behavioral imputation. PLoS One. 2018;13:e0204793. doi: 10.1371/journal.pone.0204793

58. When and how to use recency assays for HIV surveillance, 2022 update. Geneva: World Health Organization; 2022.

59. When and how to use assays for recent infection to estimate HIV incidence at a population level. Geneva: World Health Organization; 2011 (https://apps.who.int/iris/handle/10665/44612, accessed 26 June 2022).

60. Galiwango RM, Ssuuna C, Kaleebu P, Kigozi G, Kagaayi J, Nakigozi G et al. Short communication: alidation of the asante HIV-1 rapid recency assay for detection of recent HIV-1 infections in Uganda. AIDS Res Hum Retroviruses. 2021;37:893-6. doi: 10.1089/AID.2020.0279

61. Grebe E, Facente S, Hampton D, Cheng C, Owen R, Keating S. Asanté™ HIV-1 rapid recency® assay evaluation report (version 1.0): Zenodo; 2019.

62. Jung BH, Rezk NL, Bridges AS, Corbett AH, Kashuba AD. Simultaneous determination of 17 antiretroviral drugs in human plasma for quantitative analysis with liquid chromatography-tandem mass spectrometry. Biomed Chromatogr. 2007;21:1095-104. doi: 10.1002/bmc.865

63. Rice BD, de Wit M, Welty S, Risher K, Cowan FM, Murphy G et al. Can HIV recent infection surveillance help us better understand where primary prevention efforts should be targeted? Results of three pilots integrating a recent infection testing algorithm into routine programme activities in Kenya and Zimbabwe. J Int AIDS Soc. 2020;23 Suppl 3:e25513. doi: 10.1002/jia2.25513

64. Morrison CS, Homan R, Mack N, Seepolmuang P, Averill M, Taylor J et al. Assays for estimating HIV incidence: updated global market assessment and estimated economic value. J Int AIDS Soc. 2017;20. doi: 10.1002/jia2.25018

65. Sempa JB, Welte A, Busch MP, Hall J, Hampton D, Facente SN et al. Performance comparison of the Maxim and Sedia Limiting Antigen Avidity assays for HIV incidence surveillance. PLoS One. 2019;14:e0220345. doi: 10.1371/journal.pone.0220345

66. PEPFAR 2021 country and regional operational plan (COP/ROP) guidance for all PEPFAR countries. Washington (DC): U.S. President's Emergency Plan for AIDS Relief; 2021 (https://www.state.gov/wp-content/uploads/2020/12/PEPFAR-COP21-Guidance-Final.pdf, accessed 26 June 2022).

67. de Wit MM, Rice B, Risher K, Welty S, Waruiru W, Magutshwa S et al. Experiences and lessons learned from the real-world implementation of an HIV recent infection testing algorithm in three routine service-delivery settings in Kenya and Zimbabwe. BMC Health Serv Res. 2021;21:596. doi: 10.1186/s12913-021-06619-6

68. FIND. Diagnosis for all [website] Geneva: FIND; 2022 (https://www.finddx.org, accessed 14 January 2022).

69. Keating SM, Rountree W, Grebe E, Pappas AL, Stone M, Hampton D et al. Development of an international external quality assurance program for HIV-1 incidence using the Limiting Antigen Avidity assay. PLoS One. 2019;14:e0222290. doi: 10.1371/journal.pone.0222290

70. Abdool Karim Q, Macklin R, Gruskin S, Klucking S, Lockett L, Maxwell CJ et al. HIV recency testing: should results be disclosed to individuals tested? J Int AIDS Soc. 2020;23:e25584. doi: 10.1002/jia2.25584

71. TRACE. Tracking with recency assays to control the epidemic [website]. TRACE; 2022 (https://trace-recency.org/, accessed 14 January, 2022).

72. WHO Working Group on HIV Incidence Assays. Estimating HIV incidence using HIV case surveillance. Meeting report, Glion, Switzerland, 10–11 December 2015. Geneva: World Health Organization; 2017 (https://apps.who.int/iris/handle/10665/254867, accessed 26 June 2022).

73. Godin A, Eaton JW, Giguere K, Marsh K, Johnson LF, Jahn A et al. Inferring population HIV incidence trends from surveillance data of recent HIV infection among HIV testing clients. AIDS. 2021;35:2383-8. doi: 10.1097/QAD.0000000000003021

74. Rice B, Wit M, Willis R, Hargreaves J. The feasibility and utility of HIV recent infection testing in a range of routine service-provision contexts. 2019. doi: 10.13140/RG.2.2.21467.39202

75. Kassanjee R, McWalter TA, Barnighausen T, Welte A. A new general biomarker-based incidence estimator. Epidemiol. 2012;23:721-8. doi: 10.1097/EDE.0b013e3182576c07

76. Overview of incidence estimation package inctools [webpage]. 2022 (https://cran.r-project.org/web/packages/inctools/vignettes/Introduction.html, accessed 24 June 2022).

77. Global Programme on AIDS : HIV sentinel surveillance. Geneva: World Health Organization; 1992 (https://apps.who.int/iris/handle/10665/228430, accessed 26 June 2022).

78. Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infections: recommendations for a public health approach. Geneva: World Health Organization; 2016 (https://www.who.int/publications/i/item/9789241549684, accessed 26 June 2022).

79. Eaton JW, Rehle TM, Jooste S, Nkambule R, Kim AA, Mahy M et al. Recent HIV prevalence trends among pregnant women and all women in sub-Saharan Africa: implications for HIV estimates. AIDS. 2014;28:S507.

80. Zaba B, Gregson S. Measuring the impact of HIV on fertility in Africa. AIDS. 1998;12 Suppl 1:S41-50.

81. Terceira N, Gregson S, Zaba B, Mason P. The contribution of HIV to fertility decline in rural Zimbabwe, 1985-2000. Popul Stud. 2003;57:149-64. doi: 10.1080/0032472032000097074

82. Marston M, Zaba B, Eaton JW. The relationship between HIV and fertility in the era of antiretroviral therapy in sub-Saharan Africa: evidence from 49 Demographic and Health Surveys. Trop Med Int Health. 2017;22:1542-50.

83. Johnson LF, Kubjane M, Eaton JW. Challenges in estimating HIV prevalence trends and geographical variation in HIV prevalence using antenatal data: Insights from mathematical modelling. PLoS One. 2020;15:e0242595. doi: 10.1371/journal.pone.0242595

84. Yeatman S, Eaton JW, Beckles Z, Benton L, Gregson S, Zaba B. Impact of ART on the fertility of HIV-positive women in sub-Saharan Africa. Trop Med Int Health. 2016;21:1071-85. doi: 10.1111/tmi.12747

85. Johnson LF, Mutemaringa T, Heekes A, Boulle A. Effect of HIV infection and antiretroviral treatment on pregnancy rates in the Western Cape Province of South Africa. J Infect Dis. 2019;221:1953-62. doi: 10.1093/infdis/jiz362

86. Eaton JW, Brown T, Puckett R, Glaubius R, Mutai K, Bao L et al. The estimation and projection package age-sex model and the r-hybrid model: new tools for estimating hiv incidence trends in sub-Saharan Africa. AIDS. 2019;33:S235.

87. Ortblad KF, Mawandia S, Bakae O, Tau L, Grande M, Mogomotsi GP et al. Using routine programmatic data to measure HIV incidence among pregnant women in Botswana. Popul Health Metr. 2022;20:10. doi: 10.1186/s12963-022-00287-2

88. Fellows IE, Morris M, Birnbaum JK, Dombrowski JC, Buskin S, Bennett A et al. A new method for estimating the number of undiagnosed HIV infected based on HIV testing history, with an application to men who have sex with men in Seattle/King County, WA. PLoS One. 2015;10:e0129551.

89. Heffron R, Donnell D, Kiarie J, Rees H, Ngure K, Mugo N et al. A prospective study of the effect of pregnancy on CD4 counts and plasma HIV-1 RNA concentrations of antiretroviral-naive HIV-1-infected women. J Acquir Immune Defic Syndr. 2014;65:231-6. doi: 10.1097/QAI.0000000000000013

90. Drake AL, Wagner A, Richardson B, John-Stewart G. Incident HIV during pregnancy and postpartum and risk of mother-to-child HIV transmission: a systematic review and meta-analysis. PLoS Med. 2014;11:e1001608.

91. Moodley D, Esterhuizen TM, Pather T, Chetty V, Ngaleka L. High HIV incidence during pregnancy: compelling reason for repeat HIV testing. AIDS. 2009;23:1255-9.

92. Johnson CC, Dalal S, Baggaley R, Taegtmeyer M. A public health approach to addressing and preventing misdiagnosis in the scale-up of HIV rapid testing programmes. J Int AIDS Soc. 2017;20:22190. doi: 10.7448/IAS.20.7.22190

93. Kinuthia J, Drake AL, Matemo D, Richardson BA, Zeh C, Osborn L et al. HIV acquisition during pregnancy and postpartum is associated with genital infections and partnership characteristics: A cohort study. AIDS. 2015;29:2025.

94. MacIntyre DA, Chandiramani M, Lee YS, Kindinger L, Smith A, Angelopoulos N et al. The vaginal microbiome during pregnancy and the postpartum period in a European population. Sci Rep. 2015;5:1-9.

95. Masson L, Passmore J-AS, Liebenberg LJ, Werner L, Baxter C, Arnold KB et al. Genital inflammation and the risk of HIV acquisition in women. Clin Infect Dis. 2015;61:260-9.

96. Morrison C, Fichorova RN, Mauck C, Chen P-L, Kwok C, Chipato T et al. Cervical inflammation and immunity associated with hormonal contraception, pregnancy, and HIV-1 seroconversion. J Acquir Immune Defic Syndr. 2014;66:109-17.

97. Sheffield JS, Wendel GD, McIntire DD, Norgard MV. The effect of progesterone levels and pregnancy on HIV-1 coreceptor expression. Reprod Sci. 2009;16:20-31.

98. Marston M, Risher K, Mahy MI. HIV acquisition in pregnancy: implications for mother-to-child transmission at the population level in sub-Saharan Africa. J Int AIDS Soc. 2021;24:e25783.

99. Gregson S, Donnelly CA, Parker CG, Anderson RM. Demographic approaches to the estimation of incidence of HIV-1 infection among adults from age-specific prevalence data in stable endemic conditions. AIDS. 1996;10:1689-97. doi: 10.1097/00002030-199612000-00014

100. Williams B, Gouws E, Wilkinson D, Karim SA. Estimating HIV incidence rates from age prevalence data in epidemic situations. Stat Med. 2001;20:2003-16. doi: 10.1002/sim.840

101. Rice B, Machingura F, Maringwa G, Magutshwa S, Kujeke T, Jamali G et al. Brief report: Adolescent girls who sell sex in Zimbabwe: HIV risk, behaviours, and service engagement. J Acquir Immune Defic Syndr. 2022;90:263-9. doi: 10.1097/QAI.0000000000002948

102. Karim SSA, Baxter C. HIV incidence rates in adolescent girls and young women in sub-Saharan Africa. Lancet Glob Health. 2019;7:e1470-e1. doi: 10.1016/S2214-109X(19)30404-8

103. Oster AM, France AM, McClung RP, Buchacz K, Lyss SB, Peters PJ et al. The CDC HIV Outbreak Coordination Unit: developing a standardized, collaborative approach to HIV outbreak assessment and response. Public Health Rep. 2021:333549211018678. doi: 10.1177/00333549211018678

104. Oster AM, France AM, Panneer N, Banez Ocfemia MC, Campbell E, Dasgupta S et al. Identifying clusters of recent and rapid HIV transmission through analysis of molecular surveillance data. J Acquir Immune Defic Syndr. 2018;79:543-50. doi: 10.1097/QAI.0000000000001856

105. Ragonnet-Cronin M, Hodcroft E, Hue S, Fearnhill E, Delpech V, Brown AJ et al. Automated analysis of phylogenetic clusters. BMC Bioinformatics. 2013;14:317. doi: 10.1186/1471-2105-14-317

106. Kosakovsky Pond SL, Weaver S, Leigh Brown AJ, Wertheim JO. HIV-TRACE (TRAnsmission Cluster Engine): a tool for large scale molecular epidemiology of HIV-1 and other rapidly evolving pathogens. Mol Biol Evol. 2018;35:1812-9. doi: 10.1093/molbev/msy016

107. Wertheim JO, Leigh Brown AJ, Hepler NL, Mehta SR, Richman DD, Smith DM et al. The global transmission network of HIV-1. J Infect Dis. 2014;209:304-13. doi: 10.1093/infdis/jit524

108. Campbell EM, Boyles A, Shankar A, Kim J, Knyazev S, Cintron R et al. MicrobeTrace: retooling molecular epidemiology for rapid public health response. PLoS Comput Biol. 2021;17:e1009300. doi: 10.1371/journal.pcbi.1009300

109. Pantazis N, Thomadakis C, Del Amo J, Alvarez-Del Arco D, Burns FM, Fakoya I et al. Determining the likely place of HIV acquisition for migrants in Europe combining subject-specific information and biomarkers data. Stat Methods Med Res. 2019;28:1979-97. doi: 10.1177/0962280217746437

110. Jamshidian M, Mata M. Complete case analysis. In: Chapter 2 - Advances in analysis of mean and covariance structure when data are incomplete. In: Lee S-Y, editor. Handbook of latent variable and related models. Amsterdam: North-Holland; 2007. p. 21-44.

111. Huque MH, Carlin JB, Simpson JA, Lee KJ. A comparison of multiple imputation methods for missing data in longitudinal studies. BMC Med Res Methodol. 2018;18:168. doi: 10.1186/s12874-018-0615-6

112. Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach. Geneva: World Health Organization; 2021 (https://www.who.int/publications/i/item/9789240031593, accessed 23 June 2022).

113. Data quality standards of practice for national HIV estimation models. Geneva: Joint United Nations Programme on HIV/AIDS (UNAIDS); 2021 (https://www.unaids.org/sites/default/files/media_asset/data-quality-standards-of-practice-for-national-hiv-estimation-models_en.pdf, accessed 27 June 2022).

114. Eaton JW, Dwyer-Lindgren L, Gutreuter S, O'Driscoll M, Stevens O, Bajaj S et al. Naomi: a new modelling tool for estimating HIV epidemic indicators at the district level in sub-Saharan Africa. J Int AIDS Soc. 2021;24:e25788.

CHAPTER 6 – DIGITAL HEALTH DATA

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Key recommendations

Interoperability

UPDATE 1. Explicitly build in interoperability standards, data use rules and obligations and transparent data governance in digital health systems to allow the secure exchange and use of health data:

UPDATE a) Use technical, organizational and legal interoperability standards to facilitate data governance and to smooth data exchange and use between health care sector partners.

NEW b) Publish agreed-upon standards, rules, frameworks and conditions for data use by health ministries, partners and civil society to improve transparency, data sharing and use.

Unique identifiers

UPDATE 2. Use unique identifiers that replace names and personal information with anonymous alphanumeric codes to allow person-centred data to support a person accessing services over time and across facilities, districts, health and disease programmes:

UPDATE a) Unique identifiers, supported by data protection policies, should preserve individual anonymity, thereby separating personal and confidential data from health data that are being routinely shared.

UPDATE b) Unique identifiers should be progressively introduced across facilities, districts, disease programmes and other health care to promote person-centred services.

NEW c) Adopt national technical and legal protections for an individual's unique identifier and for individuals to access the data associated with their unique identifiers.

Privacy, security, data access and control

UPDATE 3. Invest in secure and confidential data systems, protected by policies and rights, with different data security levels for different data elements and different health care users:

UPDATE a) Establish different data security levels for data elements and appropriate data access based on health care needs and data users (care givers, implementers, health ministries, partners and civil society).

NEW b) Personal data should be kept confidential and not be disclosed to unauthorized parties; personal data should be accessible only to the data subject and to other explicitly authorized parties.

NEW c) Security includes suitable policies and regulation, not simply technical security.

NEW d) Patients should have access to their own health data through a portable, persistent, protected personal health record. Over time, person-centred data should support people to increasingly use and shape how their data are used.

NEW e) Both the benefits and risks of data are elevated for key populations. Confidentiality and security issues are, therefore, paramount, and personally identifying data should never be used beyond the care giver and point of access to services if not protected by clear policies and rights.

6.1 Introduction

6.1.1 Overview

The exponential growth in, and use of, health data necessitates systematic investment in digital health care systems. Capitalizing on this growth in digital data in health care is a major opportunity for a country's health care services to work in concert to improve health outcomes of all individuals. Health care systems are complex, involving many different individuals, facilities, conditions and treatments, and the data used in health care are often personal and sensitive. Thus, the transition from paper-based systems to digitization of health data, the so-called "maturation pathway", also poses major risks, particularly in the context of HIV and communicable diseases.

Some of the challenges going forward for this digital transition are technical, but the success of digital systems also heavily depends on appropriate strategies for governance and a policy environment that protects health care data and individual rights.

The success of digital systems heavily depends on appropriate strategies for governance and policy that protects data and individual rights.

The current investments forging the transition from paper-based to digital data systems mark a generational change, and country capacity needs to be in place to build, own, maintain and support these digital systems and initiatives (see Box 6.1, "Digital disruption"?). Person-centred data lead to questions of governance and of who is consulted, has access to, controls and benefits from the data. Person-centred data not only mean that the data are about a person, but also that the data subject is consulted in the design, development and implementation of digital systems. Understanding the value and benefits in digital initiatives will enable buy-in and foster trust. In the long-term, benefits and access need to be justified in terms of person-centred services.

Digitization of health data can lead to improved patient outcomes in a number of ways. Digital systems can improve the responsiveness of health care systems, enable cross-cutting disease reporting, ease the burden of aggregate reporting of health data, improve capability for programme data use, enable real-time use of data and enable seamless sharing of data with other facilities and agencies. But risks also come with digitization

of health data: tracking individuals for nefarious reasons, risk of loss of privacy or loss of control over one's personal data and risk that data are used without understanding their context. Safeguarding against such risks is paramount for digital health data to be useful and adopted. Some aspects of health care are not possible, or not easy, to address with digital solutions. This includes, for example, reasons for HIV treatment dropout or avoidance of care and, generally, anywhere that the context is critical to interpretation of the data.

This chapter discusses digital health data and the transition from paper-based to digital systems. Several aspects of this transition are acutely important for functioning health care systems and highlight key areas where countries need to invest: interoperability, unique identifiers, data security, privacy and confidentiality, and data access. These aspects are the focus of this chapter.

Applicability beyond digital systems

The level of adoption of digital data systems in health care varies across countries and may be at different stages of maturation in different districts or different disease programmes within countries. Some recommendations in this chapter that are specific to digital systems may, therefore, be implemented only in districts, facilities or disease programmes where digital systems are in place. However, several aspects of this chapter cover topics related simply to data and so are agnostic to how the data are stored (that is, on paper or digitally). Not having a comprehensive digital infrastructure in place should not be viewed as a barrier to implementing many of the recommendations in this chapter. Many aspects of the sections on interoperability (exchange and use of data), unique identifiers, privacy, security and confidentiality, and legislation covered in section 6.4 are relevant to the handling of personally identifiable data regardless of whether the data are stored in digital or paper form.

Box 6.1 "Digital disruption"?

There are multiple pathways to transition from paper-based to digital recording and use of data in a health care system. This transition presents an opportunity for change. However, given the scope of data collection, use and storage, such a change has the potential to be widely disruptive. There may be disruptions to how systems are managed, differences in the way data are disaggregated and reported, changes to data security protocols, fluidity in the scale and ease at which data are shared, and modifications to data access and use, such as how patients interact with data about themselves.

While the transition to digital systems could be viewed as simply moving to an "improved" paper-based system, the scope of this transition highlights the potential to transform the culture of data use. Few opportunities for change present themselves within the health care system that are so wide-ranging in their implications. If the disruption caused by transitioning to digital systems is seen as an opportunity for change rather than a cause of consternation, the transition can allow for innovative approaches that improve patient outcomes – strongly underpinned by human rights and values such as the principles for digital development *(1)*. Then, this transition to digital has a huge potential to improve global health.

The digital divide

Digital health services are useful only if they are used. The term "digital divide" refers to the gap between those who can access digital services and those who cannot. Lack of digital access, in general, may limit access to health services via, for instance, digital booking systems, to one's own personal health data, and to health educational resources that are digitized. A 2017 UNICEF report suggested that three of every five African adolescents ages 15 to 24 are not using the internet *(2)*. There is also a substantial digital divide reported by gender, with approximately 250 million fewer women than men having online access globally *(3)*. Three broad reasons are suggested for the digital divide: cost, digital literacy, and a view that internet access lacks relevance to one's life *(3)*.

In developing digital health systems, there must be consideration of equity – for those with the least digital connectivity, those who may be slower to adopt digital technologies and those with less digital literacy. Consideration is needed to assure that inequalities in access to health care are not exacerbated by increased digitization. Some digital services, such as those that benefit staff and facilities by reducing time for data entry, will improve health outcomes for all. In contrast, digital services that require a device for access, such as digital booking systems, may inadvertently create barriers for some individuals; providing access to such services may need consideration for those impacted by the digital divide.

WHO resources for digital health data

This chapter is guided by the nine principles for digital development *(1)* that have been designed to incorporate best practices into digital systems. Box 6.2 lists these principles, and Box 6.3 highlights the importance of the first principle – "design with the user" – using a case example from the Blantyre district, Malawi.

Box 6.2 Principles for digital development

Design with the user	Be data-driven
Understand the existing ecosystem	Use open standards, open data, open source and open innovation
Design for scale	Reuse and improve
Build for sustainability	Address privacy and security
	Be collaborative

Source: Principles for digital development (website), 2018 *(1)*

The following WHO resources on digital systems in health care have also informed the content of this chapter:

- *Digital implementation investment guide (DIIG): integrating digital interventions into health programmes (4)*
- *Global strategy on digital health 2020–2025 (5)*
- *Recommendations on digital interventions for health system strengthening (6)*
- *Digital adaptation kits (DAKs) (7-9)*
- *Digital documentation of COVID-19 certificates: vaccination status: technical specifications and implementation guidance (10).*

WHO SMART guidelines

To support the efforts to expand digitization, to ease transition along the maturation pathway and to simplify the adoption of WHO clinical and data recommendations, WHO is formulating SMART guidelines *(11)*. These guidelines will aid the development of health information systems with progressive levels of digitization so as to enable scalability and to minimize inadvertent errors. SMART guidelines are Standards-based, Machine-readable, Adaptive, Requirements-based and Testable. They are formulated in five layers (L1-L5) *(11)*:

L1 Narrative guidelines: the narrative format that is widely available as PDF documents of WHO guidelines, such as the WHO HIV strategic information guidelines.

L2 L2 Digital adaptation kits (DAKs): an operational layer that provides a package of documentation to help smooth operationalization of L1 guidelines in digital systems. The DAKs *(12)* each cover a specific domain of health care and provide a suite of tools, including clinical decision logic, data dictionaries, generic business process workflows, personas, functional requirements, core data needs and indicator definitions. Examples are the DAK for family planning *(8),* the DAK for antenatal care *(7)* and the DAK for HIV programmes *(9)*.

L3 Machine-readable recommendations: software-neutral, standards-based specifications based on documentation provided in L2, such as indicator definitions, data dictionaries and clinical decision-support logic. L3 focuses on ensuring the fidelity of guidelines with interoperability standards when deployed in digital systems and on enabling adoption and interoperability on a larger scale.

L4 Executable reference software: the L3 layer deployed in a fully functioning, interoperable software system.

L5 Dynamic precision health model: the application of advanced analytics to provide continuous improvement of clinical, public health and data guidelines.

Box 6.3 Case example: A user-defined, digital platform for holistically managing HIV programme performance in Blantyre, Malawi

Blantyre is one of 28 districts in Malawi and has a total population of 1 251 484, of which 800 264 reside in the city; slightly more than half of the population (52.3%) is 15–65 years old *(13)*. The district has a commercial centre with a highly mobile population and a high burden of HIV, with prevalence standing at 15.3% (140 000 people living with HIV), compared with 12.8% at the national level. In 2021 alone, 2700 people were newly infected with HIV in Blantyre district, accounting for 8.1% of all new infections in Malawi. This translates to 3.4 new infections per 1000 adults *(14)*. Reducing new infections calls for health systems strengthening, a coordinated approach and timely information of good quality for decision support.

Through the Blantyre District Health Office, the National AIDS Commission, the Department of HIV and AIDS, Community Health Services Section and other key partners, the Ministry of Health is implementing the Blantyre HIV Prevention Strategy. The aim is to locally lead a contextually specific and adaptive HIV response to optimize prevention programmes and reduce HIV incidence. Data plays a central role in the approach. The Prevention Adaptive Learning and Management System (PALMS) integrates and analyses data from all relevant sources to support decision-making along the HIV prevention cascade: prevention targeting, demand creation, service delivery and sustained use of ART. The system is available to stakeholders at all administrative levels of the health system.

Box 6.3 (continued) Case example: A user-defined, digital platform for holistically managing HIV programme performance in Blantyre, Malawi

PALMS was developed with a user-centred design (UCD) philosophy at every stage. UCD starts with the future users of the system and designs around their needs rather than imposing an external design on them – in other words, meeting potential users where they are. This involves conducting extensive user interviews before engineering starts and maintaining a continuous feedback loop with users to ensure that the system is making their work easier, not adding additional burden. It is crucial that users also see at the end of every development cycle that their feedback is implemented.

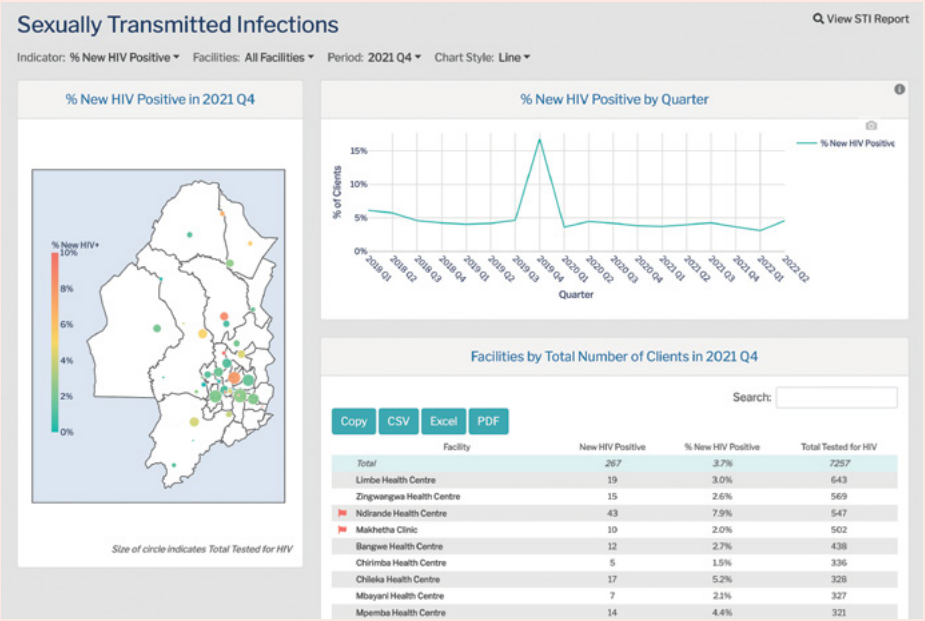
Using a UCD approach is critical for several reasons. First, asking users to change their work patterns to fit a digital system has low chances of success. Rather, a system that aligns with routine activities and supports users at key moments creates instant end-user value. Second, a UCD approach reduces the burden of training because users see a system that reflects their day-to-day workflow. They are more likely to intuitively understand the data they are seeing and find the system features they need. The best designed digital platforms are adopted without extensive training and support. Finally, the UCD approach increases user engagement, which is critical to the success and sustainability of any system. Users who can see their needs reflected will use the system regularly. This use will create the momentum and capability for the system to be taken over locally after the end of the design project's lifetime.

The UCD approach has been successful in the development of PALMS. Data visualizations have been continually adjusted or expanded to meet user requests. PALMS design workshops have been well-attended by users from across the health sector, and multiple features, such as the Integrated Disease Surveillance and Response for HIV (IDSR-HIV) dashboards, were completely defined by stakeholders. Usage has been frequent, with 241 active users since the launch of the platform in November 2021 and over 30 daily log-ins. In several facilities the platform is in regular use with minimal training. Putting the user first is a major contributor to the success of any software system and underscores the first principle for digital development: "design with the user".

Fig. 6.1. shows a PALMS dashboard presenting HIV rates among those diagnosed with an STI across all health facilities in Blantyre district (by quarter from 2018 to 2021). The line graph shows evidence of a gradual decrease in the incidence of new HIV infections, with a slight disruption in Q4 2019. Q4 2019 was a known data quality issue. Still, the ability to see such data quality issues has become an important feature in PALMS. The facility table provides red flags against health facilities with alarming trends. These flags identify facilities that need targeted supportive supervision or programmatic interventions to resolve such trends.

Box 6.3 (continued) Case example: A user-defined, digital platform for holistically managing HIV programme performance in Blantyre, Malawi

Fig. 6.1 PALMS dashboard – HIV rates of STI clients in Blantyre district



Developed by Cooper/Smith in collaboration with Georgetown University through the Blantyre Prevention Strategy.
Accessible at: https://palms.coopersmith.org/

Source:

- National Statistical Office, 2019 *(13)*
- UNAIDS, 2022 *(14)*.

6.2 Interoperability

6.2.1 Overview

In order for data to be used effectively, data needs to be exchanged between, and understood by, the many different stakeholders in the health care system. Interoperability enables this exchange and a common understanding of the data. This section outlines the different types of interoperability, the benefits of an interoperable health care system and considerations for progressive and sustainable adoption of interoperability within health care data systems.

Interoperability is the ability of different applications to access, exchange, integrate and use data in a coordinated manner, through the use of shared application interfaces and standards, within and across organizational, regional and national boundaries to provide timely and seamless portability of information that is used to optimize health outcomes *(4)*.

Interoperability is multifaceted, encompassing technical conventions, or standards, that stakeholders may adopt on how to write and structure data, how to code terminology and how to carry out the secure exchange of data. Interoperability also encompasses the environment in which businesses, agencies and other stakeholders operate so that organizational and legal boundaries do not hinder data use and data exchange, and so that aspirational goals set by governments and health ministries can foster collaboration between those operating in the health care sector. Many of the benefits of interoperability hinge on strong governance and legal frameworks in health and beyond. Interoperability allows data to be shared within a health system, so that health care can be organized around people rather than as separate services.

Interoperability in the health care sector is commonly split into three broad areas, each of which is addressed in this section:

- **organizational interoperability,** which concerns governance and the efficient orchestration of different stakeholders working in the health care system;
- **legal interoperability,** which outlines the legal frameworks to facilitate smooth data use and exchange between different partners;
- **technical interoperability,** which concerns data models, the format and grammar of data and the standards for data exchange and ensures security and privacy.

Benefits of interoperability

Ensuring interoperability within health care data systems has a number of purposes and provides a range of benefits depending upon how broadly they are adopted – at the POC, within a facility, or between facilities *(15)*. Some interoperability initiatives will improve patient outcomes directly, for example, by allowing health care providers to access longitudinal health data of patients recorded by different service providers or facilities. Some interoperability initiatives will drive efficiencies or reduce burden – resource or staff – on the health care system indirectly, for example, by lessening redundant data entry. Reducing manual re-entry of data reduces errors, thus avoiding potential adverse events for patients, minimizes additional bookkeeping burden on clinical and clerical staff and ensures comprehensiveness of patient records.

At the POC adoption of technical standards enables devices and software to communicate with each other, leading to faster transfer of information and, ultimately, allowing health care workers to respond to patient needs more quickly. Responsive health care systems that can use real-time data are particularly pertinent in emergency settings and in providing prevention activities to vulnerable populations *(16)*. Access to a wealth of data enables health care systems to be proactive in anticipating patient needs (as with focused prevention activities, for example) *(17)*.

Within a facility improved data sharing across departments enables a more rapid and comprehensive response. For example, a patient being treated for multiple comorbidities can have their medical record accessible across multiple systems, enabling all health workers involved in coordinating their care to access the most up-to-date information on the patient. Furthermore, data sharing can reduce burden on administrative systems by, for example, streamlining billing and deduplicating patient records.

Between facilities, adoption of interoperability standards offers many benefits. Publication of standards and business processes allows developers of software systems to continue development in isolation from deployed systems, lowering the expenses associated with integration, as the protocols being followed are publicly available. Providing a model of

decision-making processes within and between facilities, such as via mapping of business processes *(18)*, enables efficient orchestration and minimizes redundancy of different systems in the same clinical workflow. Sharing data between facilities may reduce loss to follow-up when patients migrate to a different location and improve supply chain decision-making by ensuring that real-time data are available. Ensuring that a minimum data set is shared with the health ministry health can improve public health planning. Memoranda of understanding (MOU) and other cooperative agreements between organizations working in the same health care system drive efficiencies by advancing mutually beneficial goals. Translating messages of exchanged data between siloed systems becomes increasingly costly as the number of systems increases *(19)*. Given the potential for such a large number of systems and the vast volume of messages being exchanged within health care systems, following a standardized approach will be cheaper and less complex in the long run *(19)*.

As HIV programmes shift towards differentiated service delivery, telemedicine and community-led services and monitoring, interoperability between the numerous community-driven digital health data solutions and facility data systems will become increasingly important. As the community of stakeholders widens, it will be important to map 1) where relevant data flows exist, 2) the policy environment and 3) adopted technical and security standards.

Interoperability at all levels (at POC, within a facility, between facilities) ultimately improves the provision of continuous, person-centred services. However, widespread and sustained commitments to interoperability are difficult to achieve due to the complexity of health and of the health care system, the volume of data exchanged, and the number of actors involved. Therefore, incentives for full interoperability need to be built into the system both at the technical level, with the participation of all organizations, and legally.

6.2.2 Organizational interoperability (governance)

To maximize the benefits from investments in digital systems, countries need to ensure that the systems follow and maintain interoperability standards. The health care system is complex, involving many stakeholders working in overlapping areas. National digitization strategies need to acknowledge this complexity and convene stakeholders to develop data systems that reflect and benefit the different participating public and private systems.

Organizational interoperability concerns data use and exchange between different organizations working in digital health. Organizational interoperability is about the alignment of various organizations' goals and expectations and the relationships among organizations working in the same areas. Organizational interoperability aims to remove obstacles to the use and exchange of data among stakeholders. A number of initiatives may facilitate organizational interoperability, as outlined below.

Strategy documents

Strategy documents published by governments, funders or organizations can help align the goals of those working in the same area. Such documents can provide guidance on agreed technical standards and rules to ensure compatible sharing and use of data and an enabling policy environment for collaboration. For example, USAID has published *A vision for action in digital health*, which promotes four main strategic priorities, including country-level capacity building in digital health and the promotion of national digital-health strategies *(20)*. The Digital investment principles *(21)*, launched at the World Health Summit in 2018, provides principles to help donors align their investments in health care systems around the world. This set of principles was co-signed by many government ministries, nongovernmental agencies, funders and other implementing partners.

Business process mapping

The mapping of business processes in the health care system, represented by graphical workflows (Box 6.4), show the context of responsibilities and relationships to all those working in the same area. They also clearly document how data are being exchanged.

Partnerships, data sharing agreements, MOUs and other collaborations

Collaborative agreements between organizations and administrations can facilitate the sustained adoption of interoperable digital systems. For instance, The Global Digital Health Partnership, which comprises 30 countries and WHO, exchanges best practices in digital health and aids the implementation of digital health initiatives *(22)*. In December 2010 the United States Department of Health and Human Services and the European Commission signed an MOU to encourage cooperation in the area of health-related information. This included recognition of shared goals towards the "development of internationally recognized and utilized interoperability standards and interoperability implementation specifications for electronic health record systems that meet high standards for security and privacy protection" *(23)*. Similar MOUs were signed between the United States and representatives of the United Kingdom's National Health Service England *(24)*. Data sharing agreements can be used to define the roles of different organizations involved in the agreement, the technical standards that should be adopted by organizations using the data, the specifics of the data that will be shared and how the data will be used and processed.

Box 6.4 Example of business process models in WHO DAKs

WHO's DAKs provide guidance on moving from paper-based to digital systems to ensure the fidelity of WHO guidelines during this transition *(12)*. DAKs are published for specific health care domains such as family planning *(8)*, antenatal care *(7)* and HIV *(9)*. To support the transition to digital systems, DAKs provide a package of tools, including a summary of key business processes, graphical representations (workflows) of those business processes, specification of core data elements, algorithms of clinical decision-logic and definitions of WHO indicators using the specified data elements.

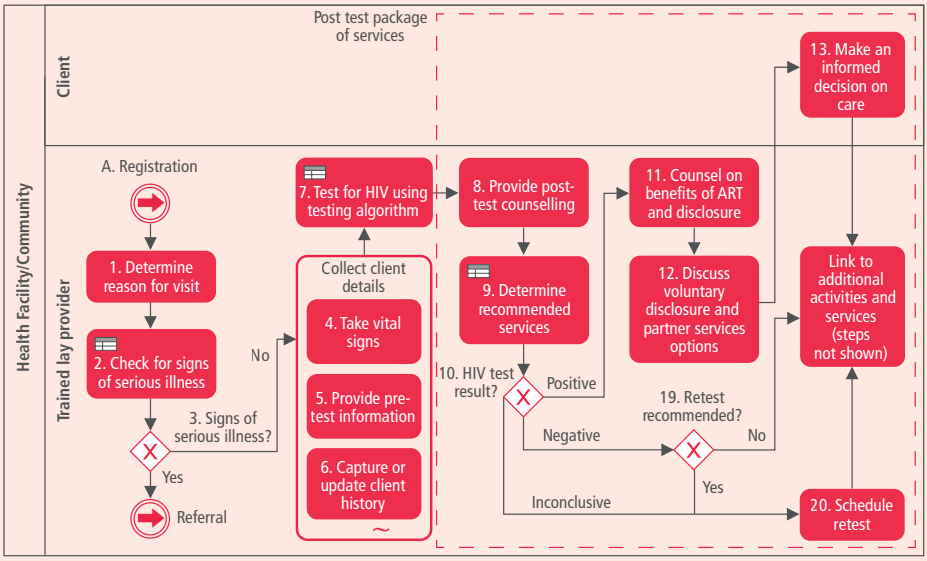
Business process workflows are graphical outlines of the key activities (from start to finish) in a health care system and are intended to be understandable to the wide variety of individuals involved in the activity, from developers to users. The approachable format of business process workflows aims to aid understanding and collaboration between stakeholders and show how digital advances may fit into existing workflows. The business processes in DAKs are generic and intended to be customized by countries. Business processes provide the context for each activity and the basis for core data needs. Business processes are written in a standard notation *(25)* that allows the complexity of clinical workflows to be expressed, such as the triggering of events, decision points, transfer of data, and the involvement of multiple individuals or organizations.

Fig. 6.2 shows the business process workflow for HIV testing as an example. The process is initiated after registration (a separate business process). After the provider checks for signs of serious illness (steps 2–3) and collects the client's details (steps 4–6), an HIV test is performed using an HIV testing algorithm

Box 6.4 (continued) Example of business process models in WHO DAKs

(step 7). Then, post-test counselling may be provided (step 8), depending on test results, such as the provision of HIV prevention services, and the health care worker then determines recommended post-test services (step 9). The next activity depends upon the result of the HIV test (step 10): a negative or inconclusive result may warrant a retest (step 19) (and potentially a scheduling of that retest (step 20)); a positive result would trigger counselling on the benefits of ART and disclosure and on partner services (steps 11–12). Several other activities may continue on from that point (steps 13 onwards).

Fig. 6.2 Business process diagram for HIV testing (abridged)



Source: WHO, 2022 *(9)*

6.2.3 Legal interoperability

Legal interoperability aims to enforce organizational interoperability and to ensure that there are no legal barriers that might prevent or restrict the sharing or understanding of data between organizations working across different regions, countries or jurisdictions. It also lays out the rules and obligations for data sharing and use within the health system, including sharing a minimum data set with the health ministry. Legal hurdles should not hinder data sharing or cooperation between organizations working in health care, where the benefits of such cooperation will improve patient outcomes and be mutually beneficial for the organizations involved.

Legal frameworks need to consider data ownership and protection, privacy protocols, the rights of individuals to access their health care data and how those data will be processed, storage of data and policies and frameworks that secure and encourage sharing and use.

Legal interoperability can be assured by 1) reviewing legal barriers that may prevent or restrict the sharing, use and storage of data for actors in different jurisdictions, 2) evaluating the concordance of legislation affecting stakeholders under different jurisdictions (so-called "coherence" checks) and 3) reviewing existing and new legislation in the context of digital systems ("digital applicability") *(26)*.

6.2.4 Technical interoperability

Technical interoperability encompasses a range of areas. **Semantic interoperability** covers the standards for the meaning of data elements and relationships between them. **Syntactic standards** specify data formats, or the "grammar" of the data to be shared. Technical interoperability also covers standards that define protocols for data exchange that ensure security and privacy.

Conventions for technical interoperability are usually defined via an international "standard", which is developed and maintained by international organizations such as the International Organization for Standardization (ISO), Health Level Seven International (HL7) and SNOMED International. Some standards are free to use, but some need to be purchased or require licensing. Standards are referred to with a code. Standards exist for many physical products. For instance, the commonly called "FFP2 mask" mandated in many countries during the COVID-19 pandemic *(27)* follows the standard EN149:2001+A1:2009, while the standard specifying the safety and efficacy requirements for natural rubber and latex male condoms is outlined in standard ISO 4074 *(28)*.

Standards exist for a huge range of digital data, terminologies and the meaning of data elements, and many technical standards are specific to health care. Some of these define standard terminology for data elements. Logical Observation Identifiers Names and Codes (LOINC) is a standard for clinical terminology and diagnostics, such as LOINC code 82810-3, which describes pregnancy status *(29)*; associated with it is a list of answers in code LL4129-4 (that is, pregnant, not pregnant or unknown) *(30)*. SNOMED Clinical Terms (SNOMED CT) is a collection of clinical terminology for use in electronic health records *(31)*. WHO has developed the International Classification for Diseases (currently in its 11th edition, ICD-11), a system of clinical terminology of diseases and health problems *(32)*, the International Classification of Health Interventions (ICHI) *(33)* and the Classification of digital health interventions v1.0: a shared language to describe the uses of digital technology for health *(34)*.

Technical standards for health care data may also specify data models. Data models specify metadata about multiple data elements as well as the organization of and relationships among the data elements, specifying concepts, such as "patient" and "diagnostic test", intended for use in electronic health records. These standards do not provide details regarding implementation, such as the databases or information technology (IT) infrastructure. For instance, international standard ISO/TS 22220 defines demographic and other identifying data elements suited to capturing information on the individual accessing services in health care settings *(35)*.

Standards also may define the format, or "grammar", of how data are written. Adopting a standard for the syntax of data enables common understanding of what is a data element and what is the value of that data element – for instance, when data are exchanged. Two standards specifying such syntax and commonly used to write data are JSON (JavaScript Object Notation) and XML (Extensible Markup Language).

6.2.5 Data use and exchange

It is important to be able to share data between facilities and between systems to provide continuous, person-centred services when, for example, an individual moves to a different location and clinical setting. Fast Health care Interoperability Resources (FHIR, pronounced "fire") is a popular specification for data exchange maintained by HL7 *(36)*. The FHIR specification is composed of 1) definitions of data models commonly used in a health care setting (termed "resources"), 2) data formats (for example, JSON and XML) and 3) protocols for exchanging data (for example, in the case of FHIR, a RESTful application programming interface). FHIR defines almost 150 resources, which highlights its wide-ranging intended use. These resources cover clinical, administrative and billing and research data that may arise in the context of health care.

FHIR is growing in popularity for a number of reasons *(19)*: FHIR is built upon commonly available and widely used web standards (OAuth, HTTPS). The specification is extensible and, therefore, applicable in a wide variety of health care contexts. Furthermore, FHIR has been designed to be straight-forward to implement and learn, and the full specification of FHIR is freely available[1] to view and use. FHIR is used in several countries that are part of the Global Digital Health Partnership *(22)*. As an example, Box 6.5 includes discussion of FHIR-compliant data exchange protocols for COVID-19 digital certificates for vaccination status and test results *(10, 37)*.

Box 6.5 Multi-layered interoperability in COVID-19 digital certificates

COVID-19 digital certificates are an example of the multi-faceted requirements for interoperability outlined in this section.

Technical interoperability

WHO's Digital documentation of COVID-19 certificates (DDCC) gives technical specifications and implementation guidance for describing vaccination status and test results *(10, 37)*. It includes FHIR-compliant implementation guidance and is published in a publicly facing code repository *(38)*. The technical specifications provided in the documents and associated annexes exemplify the semantic and syntactic interoperability standards and requirements.

Organizational interoperability

The WHO DDCC technical specifications and implementation guidance provide generic business process workflows and present case examples of workflows. These outline, for instance, the different personas involved in the implementation of the digital vaccination certificates and the flow of data within common activities. The DDCC also includes a chapter on national governance, which provides critical considerations for determining how entities and organizations will work together to implement DDCC solutions.

[1] The current specification is v4.0.1.

Box 6.5 (continued) Multi-layered interoperability in COVID-19 digital certificates

Legal interoperability

Legal interoperability is the linchpin interoperability component for the COVID-19 certificate work. Legal interoperability drives organizational interoperability and technical interoperability with public health policies, data protection policies and international agreements. For example, the European Union has passed legislation to provide a legal basis for different administrations to implement the COVID-19 digital certificates. In June 2021 the European Parliament issued a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates *(39)*.

6.3 Unique identifiers

6.3.1 Overview

UIDs are numeric or alphanumeric codes that support individuals to identify themselves when accessing a variety of health services and support health workers in linking relevant health information when providing services.[1] The UID should be anonymized and used in individual-level health data systems. A well-designed UID is free of any personally identifiable information (that is, "content-free" unique identifiers[2]). Information such as location, place of issue or date of birth should not be part of the UID, as these may be used to identify individuals and, thus, breach individual privacy.

Depending on the UIDs used, verification of information may be required to identify the person accessing health care services. For example, for the dispensing of restricted medications. Note that many systems do not require identify verification, especially in the context of HIV prevention services. Should verification of information be needed, a number of methods exist including photographs or identification cards.[3]

This section discusses benefits and risks of health UIDs, implementation considerations, technical standards and guidance documents for development of UIDs, and two case examples of UIDs (boxes 6.6 and 6.7).

Benefits and risks of health UIDs

Assignment of a UID ensures that each individual can be correctly and repeatedly identified when accessing health care services across the health care system. Implemented safely and securely, a UID enables information on individuals to be captured, stored and shared across a wide range of health services, whether within a facility (such as between testing and treatment services), between facilities or between subnational regions. They can also facilitate linkage of patients across different information systems used by different health service providers. Such data sharing allows the health care system to be more efficient and responsive, especially in emergencies. Also, it helps people to access people-centred health services in a continuous manner as they move between facilities, diseases and health programmes as well as to provide

[1] Some of the content of this section is adapted from UNAIDS/PEPFAR; 2014 *(40)*.

[2] "A content-free identifier contains no personally identifying information, and nor does the identifier convey any information other than uniqueness" *(40)*.

[3] See such standards as ISO/IEC 7810 for identification cards, ISO/IEC 7811 for recording printed and magnetic data on identification cards and ISO/IEC 7816 for smart cards.

access to social services. As they are implemented in a wider area and across a wider range of services, the complexity of the implementing system increases, and so do the benefits and risks of using UIDs. In contrast to siloed digital systems, where each system may have its own UID, a widely-used UID promotes efficiencies such as deduplication of records and benefits programmes – for example, by automating aggregation of strategic information and tracking stocks of drugs and diagnostics. They allow confidential data to be kept separate from routinely shared information under specific rules of access. However, ultimately there are still risks to data security and confidentiality, which need to be secured with robust data security policies.

There are risks of security breaches in both electronic and paper-based systems. However, such risks can be mitigated with different access rules and are substantially reduced if individual records are labelled using content-free UIDs. Linking information on an individual's interaction with the health care system over time benefits the individual, particularly as HIV treatment is life-long. For example, an individual's medical history may inform a clinician of current diagnoses and prescriptions. UIDs are a fundamental building block of a digital health system. The use of UIDs may greatly increase the effectiveness and efficiency of both case surveillance and patient monitoring based on a situation analysis, for instance, by reducing repeat diagnostic tests, not repeatedly asking patients about their medical history, and enabling a seamless referral process.

UIDs also pose risks. They may risk identifying individuals if the content of the identifier is not free of personal information or if it is linked to personal information. If there are no protecting policies and laws, the scope of use of the UID may need to be only within the community or the implementing organization, for example, those that work with sex workers, men who have sex with men or people who inject drugs. Extension of the use of UIDs from the community or implementing organization to the wider health care system or social security systems in any context should be assessed carefully. Although linking of personally identifiable data across the breadth of health system services can yield improvements in health care provision, health care data should not be linked to immigration and police systems that might discourage individuals in stigmatized groups from seeking health care services. For UIDs to be applied in a manner that ensures improved health outcomes, national laws and organizational regulations need to be in place to protect individuals.

Considerations for key populations

In 2020, 65% of all new HIV infections globally occurred in key populations. Recent shifts towards community-led monitoring and delivery *(41)*, many of which are led by key population networks, underscore the importance for key population programmes of investing in secure digital data systems. Given that the risks of data collection are accentuated for key populations, it is of paramount importance that programmes serving key populations, including community-based and community-led services, invest in secure digital data systems. In many settings consensual same-sex sexual activity, sex work or drug use and possession are criminalized and associated with stigma, discrimination and violence. People from key and vulnerable populations may face stigma and discrimination even from health care workers. If individuals are aware that information on their behaviours, or that they may be a member of a key population, is to be recorded, this knowledge may act as a barrier to accessing services, they may withhold information about their individual risk factors, or they may stay away from services entirely.

Just as the risks of UIDs, if not sufficiently anonymized, are greater for members of key populations, so are the benefits – for instance, separating additional personal information from clinical records while facilitating data linkage across facilities, regions and disease programmes means that UIDs can preserve the anonymity of sensitive key population-related data and enhance privacy and access to services for people from key populations. Because of the particular importance of UIDs to key populations, this section frames several aspects of UIDs around key populations. Addressing the concerns of the most vulnerable populations means that they will also be addressed for those from other populations.

Where personally identifying information is routinely collected on recipients of treatment, information that might indicate an individual's engagement in stigmatized or criminalized behaviours or their key population status must not be collected unless those data are clinically relevant. Clinical information such as alcohol or other drug dependence, concomitant medications (including OAMT) and hormone therapy, and sexual risk behaviour has relevance to clinical care and can be included in secure clinic records.

6.3.2 Development path for UIDs

Implementation of UIDs should take place in a step-wise fashion, reflecting country context. The following steps are suggested:

1. **Situation analysis.** Countries should conduct a situation analysis that reviews current policies, data sources and systems and identifies incremental improvements, costs, risks and benefits. This analysis should be tailored to the country context and involve the participation of people who will be using the system for programmatic decisions (see Situation analysis, below).
2. **Data security.** The next step is to invest in improved security, which includes investments in the security of databases, safeguards and increased linkage and interoperability of data systems at facility, programme and national levels.
3. **Data use.** Countries should invest in data use to improve programmes, including investment in dashboards and visualization, and analytical capacity, which are critical at this stage so that data are used widely for programme improvement.
4. **Programme improvement and sustainability.** As data sources are increasingly linked and used, medium-term sustainability needs to be planned. This includes planned application for programme improvement, human resources, financing, interoperability and open access, policies and links between HIV programmes and other national health and social systems. At this step:
    a. The benefits to individuals and programmes should be carefully identified and, if possible, costed out at each level of the system.
    b. The maturation pathway for early, middle and advanced stages of the technical components should be developed (see Technical components, below).
    c. This step should integrate HIV monitoring into a national UID system to support people-centred HIV and health services over time.

Implementation should also be based on country examples of models of UID that have worked and have benefited individuals and programmes.

Situation analysis

A situation analysis considers the potential approaches for the transition from paper-based to electronic records and should be a first step in this transition. This analysis seeks to provide a snapshot of the HIS, the resources currently being invested in health information and an overview of laws, policies and practices concerning the collection, storage, analysis, security and use of health information. The analysis should also indicate the best place to begin, and the approaches needed, to further develop the information system.

This situation analysis should involve the following actions:

1. **Existing identifiers and options**
    a. Provide an inventory of the health UIDs currently used by programmes, facilities, insurance providers and other relevant stakeholders.
    b. Assess wider national and insurance identifiers, their acceptability and use.
2. **Programme data use, collection, capacities and processes**
    a. Review data use, assessing the major country databases, how they are linked and used and the degree to which they are interoperable.
    b. Assess databases and systems across health and disease programmes and how they can be strengthened, secured and used in an integrated manner.
    c. Identify capacities and processes for collection of health information in key health services, including those that present the best opportunities for change.
    d. Provide an inventory of the forms used and data collected and reported at health facilities.
3. **Data security, confidentiality[1] and policies**
    a. Assess existing privacy, confidentiality and security laws, policies and guidelines and their implementation and enforcement in the health sector in terms of privacy, security, data collection, data standards, access, data ownership, storage, transfer, use, disposal and stewardship. Consider protection for data integrity, including from inadvertent or malicious inappropriate disclosure, ensuring the availability of data even when there is system failure or user errors and protecting data from unauthorized alteration. See section 6.4.2 for a comprehensive situation analysis focused on privacy, security and confidentiality of a digital system.
    b. Review country policies specifically on the use of UIDs.
    c. Review country strategy documents on the use of UIDs.

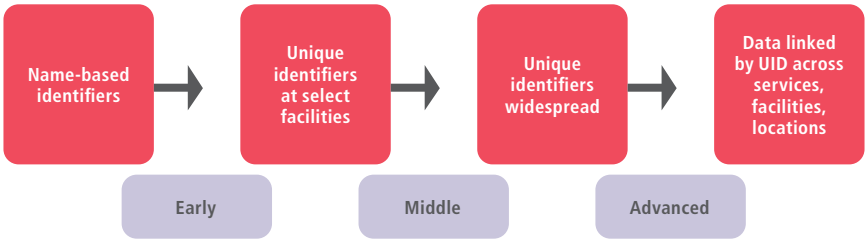
[1] *Confidentiality* refers to the right of individuals to protection of their data, during storage, transfer and use, to prevent unauthorized disclosure of that information to third parties. *Security* refers to the technical approaches that address issues covering the physical, electronic and procedural aspects of protecting information collected by HIV services. See section 6.4.

4. **Physical, human and financial resources**
    a. Assess the electricity, telephone and internet connectivity of health facilities at district, subnational and central levels.
    b. Assess the availability of computers, hardware, software, staff computer skills and facilities with electronic medical or health records. Assess in-country capacity and skills for setting up and maintaining a UID system.
    c. Assess telecommunications infrastructure and access, including costs and options for protecting data transmissions.
    d. Assess current financial resources dedicated to the above.
5. **Perceptions**
    a. Ensure meaningful involvement with patients and health care workers on the benefits and risks of UIDs and electronic records. Assess popular conceptions or misconceptions and issues of trust, buy-in and reducing barriers to health services.
    b. It is particularly important to have meaningful involvement in such consultations by individuals from groups that are likely to be most at risk from misuse or leaks of data (such as people from key or vulnerable populations and adolescents).
6. **Collate risks and benefits**
    a. Identify the risks and benefits of, and options for, transition to UIDs and electronic health information systems.
    b. Define a step-wise maturity path and time frame.

Transition to the use of UIDs and electronic health records

Fig. 6.3 presents the broad stages of the maturation pathway for implementing UIDs and electronic health records. Three broad transitions are included in this figure: 1) an early-stage

Fig. 6.3 Broad stages and transitions of the maturation pathway for UIDs



transition from name-based identifiers to UIDs in select facilities; 2) a middle-stage progressive transition to more widespread use of UIDs in a digital system; and 3) an advanced-stage, in which data are linked nationally via UIDs and, thus, made available across different services, facilities and geographical locations.

The maturation pathway to an advanced stage may not necessarily follow a strict order, although certain improvements will have prerequisites. The situation analysis outlined above will identify the starting point and assess the practicality and feasibility of implementation.

Table 6.2 Key components and stages of implementing UIDs

Area	Early	Middle	Advanced
Method of individual identification	• Mix of name-based and UID records	• UIDs at select facilities	• UIDs nationwide • Data linked across services using UIDs
IT hardware and software infrastructure	• Paper systems using forms and filing systems	• Basic computers • Appropriate hardware (for example, label printers) and supply chain solutions for consumables (for example, ribbons, labels)	• Central database for UIDs • Linkage between programme databases
Interoperability	• No digital systems	• Technical interoperability adopted within select facilities • Business processes mapped within select facilities • National strategy on interoperability	• Technical standards adopted consistently nationwide • Procurement strategy ensures interoperability • Legal measures to minimize barriers to data sharing and use • Collaborative agreements to ensure interoperability across jurisdictions
Privacy, security and confidentiality	• Paper files retained by clients or kept under lock and key at facility	• Using UIDs within digital systems stored without personally identifiable content	• Different security levels for data access • Provenance measures recording access and modifications to data • National laws protecting personal data and privacy
Reporting, M&E and data use	• Data officer transcribes paper records into electronic health register for reporting or data use	• Automated data aggregation at programme level • Formation of a central analysis team	• Automated data aggregation at all levels generated from individual-level data • Local analyses of care and capacity • Nationally standardized dashboards, visualizations and reports • Synthesis and validation of health data against CRVS and other departments • Automated data review • Evidence-based decision-making at individual, facility, programme and national levels
National electricity and telecoms infrastructure	• Paper-based record system • Records retained at facility or by clients	• Offline electronic upload of data • On- or offline data access	• Fully online systems • Services linked within facility and across facilities
Sustainability of programme maintenance and improvement	• Patient monitoring is only system in place to track individuals over time • Challenging to link individual's data within and between facilities	• Limited ability to track individuals within a facility • Appointment scheduling, follow-up within a facility • Within-facility linkage of individual information from clinic to lab and pharmacy	• Individual records updated in real time with clinical, lab, pharmacy and other data • Person-based records linked with death registry data • Publicly available standards so system development can occur independently

Abbreviations: CRVS = civil registration and vital statistics; IT = information technology; M&E = monitoring and evaluation; UID = unique identifier

Development stages of a UID system

Each stage in the maturation pathway has different costs, benefits and risks. The key technical components in each successive stage differ, are outlined in Table 6.2 and expanded upon below.

Method of individual identification

The initial stage of implementing UIDs is the replacement of name-based paper records with records labelled with a unique alphanumeric code for each individual without any personally identifying information. Digitization of records using UIDs will then require secure databases deployed in facilities. Transition to an advanced stage requires expanding this system to capture and link individuals' interactions with the health care system across services and facilities and over time.

Informational technology hardware and software infrastructure

The IT infrastructure – the hardware and the software – of the electronic health record system is a critical element in the evolution towards a person-centred health record. Decisions will need to be taken concerning what IT elements can be used or repurposed for use and what new investments will be required to develop the full UID and electronic health record. The starting point will be identified based on three elements summarized by the situation analysis described above:

- the scope of the data to be collected;
- the software and hardware currently in place, its age, adaptability, etc. (for example, legacy systems); and
- the extent to which the systems are linked and interoperate.

The process of transition begins with the creation of a secure, interoperable database structure (hardware and software) for health records, either in a facility, at programme level or nationally. The next step is to extend online or offline access to this database to the services in a single facility and across different facilities.

Historically, systems that keep data relevant for HIV case management were often developed in isolation. Thus, many countries find themselves with highly fragmented information systems with little or no interoperability. This situation is exacerbated by the closed nature of proprietary systems and the limited capacity to maintain interoperability among these separately evolving systems over time. In contrast, the advanced stage of development of an electronic record system achieves a fully interoperable data system that allows the linkage of information from a variety of sources, including vital statistics data, to help identify the status of individuals who are lost to follow-up.

WHO provides various resources focusing on investment in digital interventions and strengthening of the health system:

- Digital implementation investment guide (DIIG): integrating digital interventions into health programmes *(4)*
- Recommendations on digital interventions for health system strengthening *(6)*
- National eHealth strategy toolkit *(42)*.

Introducing the UID is one of the most important early steps in building a health system organized around the person rather than the service, allowing the person to access a range of services at different facilities, over time and across health programmes.

Interoperability

Interoperability is the ability of different systems to exchange data and understand the data exchanged (see section 6.2). Interoperable health information systems ensure that all the relevant information about a single individual can be linked together for the benefit of that person's health care over time and across facilities – the advanced stage outlined above. Adoption of a UID system enables interoperability by providing the anonymous identifier that can be shared across devices, facilities and disease programmes to link data on the same individual.

The UID provides the anonymous identifier that can be shared across devices, facilities and disease programmes to link data on the same individual.

Privacy, security and confidentiality

Privacy, security and confidentiality are paramount in health care information systems. Security must address both the protection of data from inadvertent or malicious inappropriate disclosure and the non-availability of data due to system failure and user errors. There is the risk of breaches in information security with both paper-based and electronic records. These risks are considerably reduced by labelling individual records with content-free UIDs that are not constructed with personal information and allow the separation of additional personal information from clinical records. However, risks still remain.

After the initial stage in which name-based records are replaced with content-free UIDs, the advanced stage involves differentiation of health data into categories of sensitivity. Differentiated access and data security protocols should be implemented also to protect identifying elements such as names, addresses and telephone numbers. A fully evolved national system requires legal, regulatory and policy frameworks to protect data, as well as strong enforcement capability and procedures to rapidly address data security breaches. Section 6.4 discusses these topics further.

Reporting, M&E and data use

Digitization of health care records facilitates analysis of the information contained in individual records for programme management and improvement and for research.

In the early stage, capacity can be built through engagement of a data officer to upload information from a paper record into an electronic health record. This electronic record makes possible regular assessment of the quality of data at the health facility level, the generation and use of individual and programme management dashboards, as well as use of other data analysis and reporting tools.

The middle stage of capacity building is forming a central analysis team to manage databases in a robust way, with regular data quality assessment and follow-up.

The advanced stage of development involves conducting local analyses of care and programmatic capacity with standardized dashboards, data visualization and reports to ensure regular use of the data for decision-making, as well as management of the individual and of the programme from facility to national levels.

National electricity and telecommunications infrastructure

The feasibility of different UID implementations will depend upon national electricity and telecommunications infrastructure. Some solutions may require a mixture of online and offline systems. The advanced stage would be a fully connected system, which can be used across

facilities and in community care. It would provide an important basis for organizing health care around individuals as they move between facilities, across health services and over their lifetimes.

Sustainability of programmes and improvements

Instituting UIDs in interoperable health systems lays the groundwork for their sustainability. Although investments are needed, particularly in early development and in the transition from paper to electronic records, in the long run digital person-centred data systems offer unparalleled opportunities to improve patient care, analyse trends and identify gaps in service provision. In the medium term, countries will need to undertake analysis and planning based on the experiences of data use and evidence of individual and programme benefits, risks and costs. Planning will need to include investment in policies, maintenance, hardware, software, human resources and analytical capacity to ensure the robustness and sustainability of the system.

6.3.3 System architecture and methods of UID

Technical resources

This section presents the basic components of system architecture and the UID. This guidance should enable programme managers to discuss the key considerations with the technical specialists who will develop UID systems. It should be used in conjunction with documents that provide more detailed technical information, including the following:

- *Standard guide for properties of a universal healthcare identifier* (ASTM E-1714-07R13) *(43)*;
- *Standard guide for implementation of a voluntary universal healthcare identification system* (ASTM E-2553-07 *(2013) (44)*;
- *Health informatics: identification of subjects of health care* (ISO/TS22220:2011) *(35)*;
- *Health informatics: patient healthcard data. Part 5: identification data* (ISO 21549-5:2015) *(45)*;
- *Health informatics: guidance on patient identification and cross-referencing of identities* (DS/CEN/TR 15872) *(46)*.

Considerations for system architecture

The system architecture will depend on the layers of paper, power and networks in facilities. There are three layers:

- **Layer 1 – Paper:** facilities with no reliable power or telecommunications; cold chain may be powered by generators. Such facilities can support only paper systems.
- **Layer 2 – Power:** facilities with a minimum of reliable daily power (solar, generator, power lines and uninterrupted power supply) sufficient to charge/operate an efficient computer. These can support offline electronic systems.
- **Layer 3 – Network:** facilities with reliable daily telecommunications and power can have clinic operations dependent on internet-based applications. These can support mixed online/offline or fully online systems.

The overall system design, including identifying necessary communications links, should consider the following equipment requirements, depending on the layer of the facility:

Data entry workstations

Each person entering data from paper forms into a computer needs a data entry terminal, unless scannable forms are used. If scannable forms are used, each site needs at least one workstation paired with a form scanner.

Central registry servers

At least one larger-capacity server located centrally is needed to host the national UID registry. In addition, at least one larger-capacity server located centrally is needed to receive and process transaction files and generate response files.

Distributed registry servers and cloud computing

Most countries will not want to depend on a single server that must be operational at all times to process all requests to the patient registry, since the failure of a single communications link or router would cause widespread outage. Ways to avoid the problem of a single point of failure would be to use cloud-based servers or regional servers (an outage then affects only one region and is likely to simplify troubleshooting and repair). Cloud hosting has the potential to offer accessible, flexible and stable hosting infrastructure, and it can be configured to have security and data protection on a par with on-premises hosting. However, cloud computing may mean servers are located, and data stored, in another country, which may raise questions of data protection policies (see section 6.4 on privacy, security, data access and control). If cloud computing is considered, data protection policies in the country where the data are stored should be consulted. If strong laws and data governance models protecting personal data are in place where servers are located, then cloud computing may be a suitable option for making data accessible, enabling scalability and maximum server uptime.

Interoperability

Effective national health information systems should enable data to be shared and understood across clinics, hospitals, laboratories, pharmacies and individuals, regardless of the application or vendor. Interoperability ensures that data can be shared and understood in such a manner. Interoperable health care record systems need supportive governance, an enabling policy environment and technical standards for data content and exchange (see section 6.2).

Technical components of a UID system

Attributes and security of a UID

To maximize the benefits of a UID, several system attributes or functions are required *(40)*:

- an identifier scheme consisting of alphanumeric characters that do not represent any aspect of the identity of the individual (a content-free UID);
- differentiation of the security of different types of information with different rules of access;
- cross-references to any local, site-specific, individual identifiers that may be in use;
- mechanisms to hide or encrypt identifiers;
- software to mass-register individuals and appropriate personnel to carry out this task;
- software to search, identify, match, encrypt and in other ways manipulate the underlying information; and
- administrative and telecommunications infrastructure, including central governing authority.

The use of UIDs improves the anonymity of existing name-based person-centred records but must be augmented by appropriate and ongoing measures to protect the information. Some of these protections are the following:

- Robust measures to control access, including software security, physical access security, encryption protection and an authentication mechanism, must be in place to prevent unauthorized access and ensure legitimate access.
- Training programmes are required to ensure that all staff with access to personally identifiable health information are aware of their responsibilities and have the necessary skills to perform their tasks consistently and correctly.
- Security measures should be specified, including audit trails for tracking inappropriate access and steps preventing possible misuse.

While not containing personally identifying information, UIDs may link to personally identifying information. For organizations that generate, access or use personally identifiable health information, the following measures should be implemented:

- access protection;
- user authentication;
- audit trails;
- training and education;
- physical security;
- organizational policies and procedures;
- promotion of an organizational culture conducive to protecting privacy;
- appropriate classification of data into identifiable, non-identifiable and non-person-associated, to aid in determining appropriate system security measures;
- built-in computer security in hardware, operating systems, application software and communication protocols and methods;
- appropriate segregation of computer networks by firewalls into private, semi-private and public networks;
- periodic testing of the security of the system to identify the strengths and weaknesses of security and protection;
- proper disposal of electronic and paper health records, by electronic scrubbing of old media using software designed for that purpose and by shredding paper records.

Section 6.4 presents more detailed guidance on protecting the privacy, confidentiality and security of personal health information.

Box 6.6 Case example of implementation of UID numbers in a health care setting in South Africa

South Africa has developed the Health Patient Registration System (HPRS), which follows individuals longitudinally through their life course, including assignment of a health UID, the health patient registration number (HPRN). The HPRS, provides a patient registry and a Master Patient Index (MPI), and provides core patient administration functionality including recording attendances and scheduling appointments. Patients can be followed through the HPRN as they access different facilities, with the potential to improve the delivery of services to patients, as well as provide better data to aid strategic decision-making and planning.

The HPRN (a 10-digit randomly-assigned numeric identifier with the last digit being a checksum) was chosen instead of the South African national ID number as the UID in order to protect patient privacy as well as to ensure that a single system could be

Box 6.6 (continued) Case example of implementation of UID numbers in a health care setting in South Africa

applicable to all patients, as a national ID is not a pre-requisite for accessing health care. The national ID is however considered a key additional unique identifier critical to de-duplication and the integrity of the MPI, and services are encouraged to request and record whenever possible. All health registration data are considered sensitive data and may not be shared for any purpose other than for provision of health care (see below).

Implementation of the HPRS was made possible by a collaborative effort between national government departments (the departments of Health, Home Affairs, Basic Education and the South Africa Social Security Agency) and provincial departments of health, starting in 2013.

By March 2019 there were 3059 primary health care facilities and 34 hospitals implementing the HPRS, with over 45 million individuals registered (in a total population of almost 59 million). Although there were delays in 2018/2019 due to the complexity of linking patient data from hospital systems, it is estimated that almost 70% of the population had been registered in the system by the time that the 2018/19 Annual Report was published *(47, 48)*.

Patient privacy is enshrined in the South African constitution of 1996 and the National Health Act of 2003 which requires patient consent for the disclosure of personal information, with limited exceptions. The Protection of Personal Information Act *(49, 50)*, reaffirmed these provisions related to health as part of a general approach to personal privacy protection, and recently came into full effect resulting in a renewed focus on patient privacy. Whereas public sector personal health services and associated information systems are largely managed at provincial level at present, national eHealth strategies, the Health Normative Standards Framework, and the information system provisions in the current National Health Insurance Bill, all envisage a shared national standards-based health information exchange with the HPRS as the client registry. Already a number of national and facility-based systems interoperate with the HPRS to retrieve patient details in a standards-compliant manner, including the National Health Laboratory Service.

Sources:

- Department of Health of South Africa, 2020 *(47)*
- Department of Health of South Africa, 2019 *(48)*
- Protection of Personal Information Act, 2013 *(49)*
- WHO Regional Office for Africa, Regional Workshop on Unique Identification and Application go HIV Patient Monitoring and Case Surveillance, 2019 *(50)*.

Box 6.7 UIDs and data use for programme improvement among people who inject drugs in Pakistan

Background

The Nai Zindagi Trust is a Pakistani non-profit organization established in 1989 to support people who inject drugs with needs-based and context-appropriate lifesaving services. People who inject drugs, their spouses or intimate partners and their children receive comprehensive HIV prevention services and are provided free treatment and care if they are living with HIV.

Pakistan has a concentrated HIV epidemic among key populations, primarily among people who inject drugs, followed by hijra (transgender) sex workers, trans and gender diverse people, men who have sex with men, male sex workers and female sex workers, in that order *(51)*. In Pakistan laws criminalize injecting or using drugs, with a possible maximum penalty of life imprisonment. The prevailing legal environment, stigma and discrimination create barriers to health care services.

Despite these challenges, Nai Zindagi Trust provides regular health services to approximately 34 000 people who inject drugs, and to their partners and children, through a mobile outreach approach at 44 sites across 58 districts. Services such as those listed in Table 6.3 are provided at more than 500 hotspots six days a week, reaching about 8000 people who use drugs daily and providing sterile needles and syringes and follow-up services.

Table 6.3 HIV prevention and treatment services provided by the Nai Zindagi Trust through mobile outreach

HIV prevention services	HIV treatment services
• Needle–syringe provision	• POC CD4 testing
• HIV testing and counselling	• POC VL testing
• HIV prevention services for spouses of clients	• Linkage to ART for clients, partners and family members who test HIV-positive
• Condom provision	• Differentiated ART services and adherence monitoring
• Basic primary health care	• Rehabilitative ART adherence support

Data collection

Since the start of the project, an electronic health management information system using UIDs has captured data at each service delivery point, including both facilities and community outreach. Direct upload of service delivery data was interrupted during the COVID-19 pandemic, however, due to the lack of safety in sharing portable devices, and it was replaced for a time with paper-based data collection. UIDs are generated for each client at registration and help avoid duplication in the absence of any other credential such as national identity cards. At the time of client enrolment, field staff collect baseline data, including demographic information and risk behaviours, as part of registration for a UID. All service delivery components are captured, including each client–staff interaction with the date, time, location, supplies provided. Commodity data are directly linked with an inventory management system to manage procurement.

Box 6.6 (continued) UIDs and data use for programme improvement among people who inject drugs in Pakistan

Data use for programme improvement

Using an electronic person-centred system that is updated in real time enables field staff to adapt their services as needed – for example, if clients change location. This enables continuity of care and services as and when clients need them, which is critical to improve access for this highly vulnerable population. Safeguards are built in to prevent accidental or deliberate data breaches. These include restrictions on data transfer by users, different user access levels for databases, encrypted transfer protocols and ensuring that dashboards do not show clients' identity (only de-identified data are used for analytic purposes).

Reports are automatically generated and analysed to monitor service delivery trends and outcomes. Reports can be customized for different levels of implementing entities and for different indicators at granular levels. Using this electronic system enhances the ability of managers at all levels to conduct regular data reviews through customized and interactive dashboards. It also aids in field-based monitoring for verification of service delivery and improves data quality. Being able to use longitudinal data from multiple sites in one system allows deeper understanding of HIV and service utilization of drug users over time and across service locations.

Apart from its operational use, the electronic health information system provides accurate information on programme and disease trends that, together, inform planning, scale-up of services, costing, commodities forecasting, monitoring of staff–client ratios, estimating travel distances, adjusting the timing of service delivery and estimating resource needs.

Source:

- Ahmed et al., 2019 *(51)*
- Iversen et al., 2021 *(52)*
- Iversen et al., 2021 *(53)*
- Malik et al., 2019 *(54)*

6.4 Privacy, security, data access and control

6.4.1 Overview

The increasing volume of digital data, along with the increasing use and transfer of these data and the concentration of data in centralized data warehouses, heightens both the risks and the consequences of data breaches. Digital health care systems need to be designed from the start and implemented with privacy, security and confidentiality in mind. These topics warrant serious scrutiny, not only to avoid breaches due to malicious or nefarious behaviour, but also to avoid inadvertent breaches due to the design or implementation of the system that houses and transfers the data.

By their very nature health care data can include highly personal information. For people from key populations and other marginalized or vulnerable groups, disclosure of this information could mean stigmatization or discrimination, sometimes from health care workers, and even criminal arrest. This risk may directly discourage an individual from interacting with the health care system. Privacy, security and confidentiality are, therefore, of paramount importance for these populations.

Who has access and control over personal health data has serious ramifications for patient safety and health outcomes, and building trust with patients is acutely important in marginalized populations. Empowering patients to be partners in improving their own health outcomes is a key benefit of having transparent legislation assuring rights-based access and control of one's own health data.

This chapter focuses on the implementation of digital health systems so as to ensure privacy, security and confidentiality and reduce the risk of harm to individuals. This chapter also discusses access to and control of personal health data.

Throughout this section the following terms are used *(55)*:

- **Privacy** is both a legal and an ethical concept. The legal concept refers to the legal protection that has been accorded to an individual to control both access to and use of personal information. It provides the overall framework within which both confidentiality and security are implemented.
- **Confidentiality** refers to the right of the individuals to protection of their data during storage, transfer and use to prevent unauthorized disclosure of that information to third parties.
- **Security** refers to the technical approaches that address physical, electronic and procedural aspects of the protection of information collected as part of health care services. Security must address protection of data from inadvertent or malicious inappropriate disclosure as well as non-availability of data due to system failure and user errors.

Privacy, security and confidentiality should be considered in the context of the type of data being discussed. Five types of data can be distinguished, as described in Table 6.4 *(56)*:

Table 6.4 Types of health data

Type	Example
Personally identifiable health information *(57)*	Medical records that include personal identifiers such as name and address (may still be using content-free UIDs)
Pseudo-anonymized health information	Medical records without any identifiers (for example, name, address) using a content-free UID that can be used to link records
Anonymized health information	Medical records with all identifiers removed (and no key retained)
Aggregated health information	HIV indicators disaggregated by age and sex, COVID-19 dashboards
Non-personal health information	Drug stocks in a facility

6.4.2 Situation analysis to assess privacy, confidentiality and security of a digital system

A situation analysis should be the first step in designing and implementing a digital system that ensures security and the maintenance of confidentiality and privacy. UNAIDS has developed a tool for this purpose, *The privacy, confidentiality and security assessment tool (56)*.

The tool assesses privacy, confidentiality and security through facilitation of a series of discussion workshops with key stakeholders, including detailed questionnaires for participants. The tool was developed to determine how policies for privacy, confidentiality and security have been developed and implemented in the health care system. The focus for development of these tools was HIV systems, but the tool is applicable to reviewing any system that houses personally identifiable health information.

The tool partitions the assessment at the levels of health facility, data warehouse and policy. It is suggested that health ministries host these workshops. Guidance is provided on the organization and logistics of these workshops. The focus here is on personally identifiable health information, but policies and protocols should be reviewed for all five types of data shown in Table 6.4. For each level (health facility, data warehouse, policy), there are sets of questions in the following areas, with an abridged set of questions shown:

Table 6.5 Questions used for situation analysis to assess privacy, confidentiality and security of personally identifiable data

Area	Questions
Governance and policy	• What legislation and policies are in place regarding access to personally identifiable information? • Are there clearly defined roles and access levels for those with access to personally identifiable data? • How often are reviews of legislation and policies conducted? • What governance structure is in place to provide oversight regarding use, collection and dissemination of data and oversight of security practices? • Are staff responsibilities and training regarding security provided? • How are security breaches monitored and responded to? • Do these policies extend to other associated networks?
Data collection	• How are data collected? • What data are collected? • How is the quality of that data assessed?
Data storage	• Are there guidelines on the archiving of data? • Which physical provisions secure stored (digital) data? • Which physical provisions secure stored (paper-based) data? • How are data transferred to newer technologies? • How is the inventory of computational infrastructure tracked?
Data backup	• How are data backed up on computers and laptops? • How are data backed up on servers? • How are audit logs of data transactions within the system recorded? • What is the business continuity plan? (in case of data breach, ransomware, shut down of systems due to infrastructure issues (for example, internet or power outages), etc.)

Table 6.5 (continued) Questions used for situation analysis to assess privacy, confidentiality and security of personally identifiable data

Area	Questions
Authorization and access control	• What policies exist for different security levels of access to data? • How is secured access to data determined (passwords, security levels, validation of access protocols)? • What are the protocols surrounding passwords? • How is access revoked (after employment termination, during session inactivity)? • What user verification, if any, is used (smart cards, etc)?
Data release	• What policies exist for data release? • What conditions need to be met for release of (and receiving) personally identifiable information? • How do data release protocols differ between use for clinical care, public health, research, and exceptional statutory purposes?
Transmission security	• What hardware, and what firewalls and antivirus software, are used for the transfer of data between different networks and through the internet? • What protocols exist regarding transfer of data using removable media? • What protocols exist regarding transfer of paper records? • What protocols exist for handling mail containing personally identifiable information?
Data disposal	• Review of protocols and regulations for disposal of digital/paper data.

Source: Abridged from UNAIDS, 2019 *(56)*

This situation analysis will provide context for developing the most feasible approach to strengthening the privacy, security and confidentiality of systems that handle health care data.

6.4.3 Data access and control

Patients are the primary stakeholders in their own health. Accessing one's personal health data and legal assurance of its protection can build patients' engagement with health systems and motivate individuals to see themselves as partners in their own health. Legislation is an important mechanism for ensuring that patients have access to, and control of, their own health data. These guidelines recommend that countries have rights-based, legal protections in place for access to, and control of, such personal health information.

Box 6.8 Personal health data

While examples cited consider personal information across many different contexts, this chapter discusses personal health data. The definition of personal health data varies by country and legislation. Aside from the mentioned examples, personal health data, or patient data, is considered here to mean all data, in any form, that are generated, created, collected or retained that relates to a patient, a patient's clinical encounter or a patient's clinical research encounter *(58)*.

Legislation is needed not just to guarantee individuals access to their personal health data but also to provide transparency for many other parties that may generate, access, process or store personal health data. These data may be used by health care workers to provide care, by health ministries for public health reasons, for research purposes or, where consent has been granted, for commercial purposes. Such legislation has been implemented in many countries around the world, as outlined in examples below. A country's legislation on access, control and processing of personal data must be comprehensive and detailed. A full account of such legislation is beyond the scope of these guidelines, as they typically cover personal data in general, with special considerations for health data. This section, therefore, focuses on key aspects of legislation that are important to personal health data and where data elements may have a highly personal and sensitive nature, such as HIV status. Such provisions are the following:

- access by data subjects
- portability of data
- rights of data subjects to revoke access
- assurances on governance, including appointment of data protection officers and national supervisory boards for data protection
- security assurances for personal health data against unlawful or accidental access
- responsibilities of those processing data, including security assurances, notification of data breaches and sharing of data with third parties
- assurances for marginalized populations
- penalties and enforcement for lack of compliance, negligence
- limiting personal data to only what is necessary or clinically relevant.

These aspects of legislation may improve health outcomes via 1) encouraging individuals to engage as partners in their own heath (such as assurances for data subjects of access of personal health data), 2) providing legal grounds for incentives for improvements in other areas of the health care system (such as assurances of portability for health care interoperability or performance management), or 3) by building trust between the health care system and its clients, which is especially important for individuals in marginalized or vulnerable groups.

Access by data subjects

Individuals must have rights to access their data and the ability to rectify any incomplete or inaccurate data. For instance, Article 15 of the General Data Protection Regulation (GDPR), adopted in the European Union and European Economic Area (EU/EEA), states that "the data subject shall have the right to obtain … access to the personal data" *(59)*. Article 16 ensures rights to rectification of incomplete or inaccurate data *(60)*. Legal protections may also be in place to allow individuals to find out whether a party holds, or processes, personal information on them. For instance, Section 23.1a of the POPI Act in South Africa states that "a data subject … has the right to request a responsible party to confirm … whether or not the responsible party holds personal information about the data subject" *(61)*.

Portability (interoperability) of data

Portability relates to ensuring interoperability and the structure and format of the data themselves. Portability of data empowers individuals to exchange data with others, should they so wish (see section 6.2 for further discussion of interoperability). For instance, section 38, subsection 1, of the Data Protection Act, 2019, of Kenya states that "a data subject has the right to receive personal data concerning them in a structured, commonly used and machine-readable format" *(62)*.

Revocation of access

Legislation should stipulate the rights of individuals to revoke others' access to personal health data, including erasing said data, sometimes termed the "right to be forgotten". For instance, Section 5 of the POPI Act of the Republic of South Africa includes the right of data subjects "to request, where necessary, the correction, destruction or deletion of his, her or its personal information" *(63)*.

Assurance of governance

Legislation should describe governance measures, such as the appointment of data protection officers for enterprises that process personal information or the formation of national supervisory boards for data protection. For instance, a legal requirement of Section 21(b) of the Data Protection Act of the Philippines *(64)* is that any entity processing personal data must designate one or more individuals to be accountable for compliance with the Act. Article 51 of the GDPR of the EU/EEA *(65)* requires countries to monitor the application of the GDPR via an independent public authority.

Security assurances

Legislation should provide details of the security measures that need to be followed by entities processing, accessing or storing personal health data. Table 6.6 provides examples of security measures in current legislation.

Table 6.6 Examples of security measures in data protection legislation

Security measure	Example
Security awareness and training for staff	Title 45, Code of Federal Regulations, Section 164.308(a)*(5)*(i), USA *(66)*
Follow international standards	Chapter 2, Section 7, Data Privacy Act of 2012, Philippines *(67)*
Regularly review that security safeguards are effectively implemented	Section 19.2c, POPI Act, South Africa *(68)*
Security access management (role-based access)	Title 45, Code of Federal Regulations, Section 164.308(a)*(4)*(i), USA *(66)*
Monitoring of security breaches	Chapter 5, Section 20.c.4, Data Privacy Act of 2012, Philippines *(69)*
Pseudonymization during processing of personal data	Article 32.1a, GDPR, EU/EEA *(70)*
Encryption of data	Article 32.1a, GDPR, EU/EEA *(70)*
Data disposal to preserve privacy	Health Information Privacy Code, Rule 5c, 2020, New Zealand *(71)*

Responsibilities of those processing data

Legislation should clearly state the responsibilities of those individuals or organizations that are processing or storing personal health data. This includes stipulation of security measures and any monitoring that must be implemented. For example, the Data Protection Act of Ghana, 2012, includes assurances of notification of data breaches by entities processing personal data: "where there are reasonable grounds to believe that the personal data of a data subject has been accessed or acquired by an unauthorised person, the data controller … shall notify the Commission, and the data subject" *(72)*.

Assurances for marginalized populations

Legislation should recognize that data breaches have the potential to cause greater harm to certain groups in the population, particularly groups that are marginalized or vulnerable. Legal provisions need to provide explicitly for such populations. For instance, Article 9 of the EU/EEA's GDPR explicitly prohibits the processing of data concerning health or data concerning a natural person's sex life or sexual orientation unless one of a range of conditions applies, such as medical diagnosis or the provision of health or social care or treatment *(73)*.

Penalties and enforcement

Penalties for failure to comply with the legislation on data access and its protections must be outlined in legislation. This includes how penalties will be enforced.

Data minimization

Legislation should stipulate that only data that are clinically relevant or that are necessary for clinical management can be collected. Such provisions protect against undue collection of personal data and so reduces the consequences of malicious or inadvertent breaches of privacy. For instance, Article 5.1c of the GDPR of the EU/EEA states that "personal data shall be adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed ('data minimization')" *(74)*.

6.4.4 Indirect benefits

Providing legal protections for the continuity of access and maintenance of rights of access to data has many secondary benefits that may drive other areas of digitization of the health care system. As individuals move locations, maintenance of access also requires the movement of personal health care data across regions and facilities. This encourages initiatives easing that process, such as the use of interoperability standards (section 6.2) and the adoption of widely used, content-free UIDs (see section 6.3). Enabling patients to access their data creates a demand for digital platforms and devices that can host these data and via which individuals can gain access. This, in turn, will promote interoperability standards as a means to ease the exchange and understanding of health care data.

References

1. Principles for digital development [website]. 2018 (https://digitalprinciples.org/principles/, accessed 23 June 2022).
2. The State of the World's Children 2017: children in a digital world New York: United Nations Children's Fund (UNICEF); 2017 (https://www.unicef.org/reports/state-worlds-children-2017, accessed 23 June 2022).
3. World Development Report 2021: data for better lives. Washington (DC): World Bank; 2021. p. 164, Chapter 5.
4. Digital implementation investment guide (DIIG): integrating digital interventions into health programmes. Geneva: World Health Organization; 2020 (https://www.who.int/publications/i/item/9789240010567, accessed 15 June 2022).
5. Global strategy on digital health 2020-2025. Geneva: World Health Organization; 2021 (https://apps.who.int/iris/handle/10665/344249, accessed 23 June 2022).
6. Recommendations on digital interventions for health system strengthening. Geneva: World Health Organization; 2019 (https://www.who.int/publications/i/item/9789241550505, accessed 15 June 2022).
7. Digital adaptation kit for antenatal care: operational requirements for implementing WHO recommendations in digital systems. Geneva: World Health Organization; 2021 (https://www.who.int/publications/i/item/9789240020306, accessed 15 June 2022).
8. Digital adaptation kit for family planning: operational requirements for implementing WHO recommendations in digital systems. Geneva: World Health Organization; 2021 (https://www.who.int/publications/i/item/9789240029743, accessed 2 April 2022).
9. Digital adaptation kit for HIV: operational requirements for implementing WHO recommendations within digital systems Geneva: World Health Organization; 2022 (https://www.who.int/publications/i/item/9789240054424, accessed 18 December 2022).
10. Digital documentation of COVID-19 certificates: vaccination status: technical specifications and implementation guidance, 27 August 2021. Geneva: World Health Organization; 2021 (https://www.who.int/publications/i/item/WHO-2019-nCoV-Digital_certificates-vaccination-2021.1, accessed 15 June 2021).
11. Mehl G, Tunçalp Ö, Ratanaprayul N, Tamrat T, Barreix M, Lowrance D et al. WHO SMART guidelines: optimising country-level use of guideline recommendations in the digital age. Lancet Digit Health. 2021;3:e213-e6.
12. Tamrat T, Ratanaprayul N, Barreix M, Tunçalp Ö, Lowrance D, Thompson J et al. Transitioning to digital systems: the role of World Health Organization's Digital Adaptation Kits in operationalizing recommendations and interoperability standards. Glob Health Sci Pract. 2022;10.
13. 2018 Malawi Population and Housing Census. Main report. Zomba, Malawi: National Statistical Office; 2019 (http://www.nsomalawi.mw/index.php?option=com_content&view=article&id=226&Itemid=6, accessed 19 May 2022).
14. Country factsheets. Malawi 2020. HIV and AIDS estimates [webpage]. Geneva: Joint United Nations Programme for HIV/AIDS (UNAIDS); 2022 (https://www.unaids.org/en/regionscountries/countries/malawi?, accessed 23 June 2022).

15. Pronovost P, Johns M, Palmer S, Bono R, Fridsma D, Gettinger A et al., editors. Procuring interoperability: achieving high-quality, connected, and person-centred care. Washington (DC): National Academy of Medicine; 2018.

16. Perlin JB. Health information technology interoperability and use for better care and evidence. Jama. 2016;316:1667-8. doi: 10.1001/jama.2016.12337

17. Institute of Medicine (US) Committee on Quality of Health Care in America. Crossing the quality chasm: a new health system for the 21st century Washington (DC: National Academies Press; 2001.

18. Decision model and notation [webpage]. OMG Standards Development Organization; 2022 (https://www.omg.org/dmn/, accessed 3 March 2022).

19. Benson T, Grieve G. Principles of health interoperability Cham, Switzerland: Springer Nature; 2021.

20. A vision for action in digital health [webpage]. Washington (DC): United States Agency for International Development; 2020 (https://www.usaid.gov/digital-health-vision, accessed 29 June 2022).

21. The principles of donor alignment for digital health [website]. Digital Investment Principles; 2018 (https://digitalinvestmentprinciples.org/, accessed 29 June 2022).

22. The Global Digital Health Partnership [webpage]. Washington (DC): Office of the National Coordinator for Health Information Technology (ONC); 2021 (https://www.healthit.gov/topic/global-digital-health-partnership, accessed 29 June 2022).

23. Collaboration with the European Union [webpage]. Item 6a of the Memorandum of Understanding. Washington (DC): Office of the National Coordinator for Health Information Technology (ONC); 2020 (https://www.healthit.gov/topic/collaboration-european-union, accessed 29 June 2022).

24. Collaboration with the United Kingdom [webpage]. Washington (DC): Office of the National Coordinator for Health Information Technology (ONC); 2020 (https://www.healthit.gov/topic/collaboration-united-kingdom, accessed 29 June 2022).

25. Business process model and notation: Object Management Group; 2020 (https://www.bpmn.org/, accessed 7 March 2022).

26. Interoperability frameworks. In: ID4D practitioner's guide. [webpage]. Washington (DC): World Bank; 2022 (https://id4d.worldbank.org/guide/interoperability-frameworks, accessed 29 June 2022).

27. Senate passes FFP2 mask mandate for public transport Berlin: The Official Website of Berlin; 2022 (https://www.berlin.de/en/news/coronavirus/7240429-6098215-senate-passes-ffp2-mask-mandate-public-t.en.html, accessed 29 June 2022).

28. Male latex condom: specification, prequalification and guidelines for procurement, 2010. Geneva, New York, Research Triangle Park (NC): World Health Organization, United Nations Population Fund, Family Health International; 2010, updated 2013 (https://apps.who.int/iris/handle/10665/44383, accessed 29 June 2022).

29. 82810-3 Pregnancy status [webpage]. Regenstrief Institute, Inc. and the Logical Observation Identifiers Names and Codes (LOINC) Committee; 2022 (https://loinc.org/82810-3/, accessed 29 June 2022).

30. LL4129-4 Pregnant|Not pregnant|Unknown [webpage]. Regenstrief Institute, Inc. and the Logical Observation Identifiers Names and Codes (LOINC) Committee; 2022 (https://loinc.org/LL4129-4/, accessed 29 June 2022).

31. Use SNOMED CT [webpage]. SNOMED International; 2022 (https://www.snomed.org/snomed-ct/Use-SNOMED-CT, accessed 29 June 2022).

32. International Classification of Diseases 11th Revision Geneva: World Health Organization; 2022 (https://icd.who.int/en, accessed 2 July 2022).

33. International Classification of Health Interventions (ICHI) Geneva: World Health Organization; 2022 (https://icd.who.int/dev11/l-ichi/en, accessed 2 July 2022).

34. Classification of digital health interventions v1.0: a shared language to describe the uses of digital technology for health. Geneva: World Health Organization; 2018 (https://apps.who.int/iris/handle/10665/260480, accessed 2 July 2022).

35. ISO/TS 22220:2011 Health informatics — Identification of subjects of health care [webpage]. Geneva: International Organization for Standardization; 2022 (https://www.iso.org/standard/59755.html, accessed 29 June 2020).

36. Welcome to FHIR [website]. HL7 FHIR; 2022 (http://hl7.org/fhir/, accessed 29 June 2022).

37. Digital documentation of COVID-19 certificates: test result: technical specifications and implementation guidance. Geneva: World Health Organization; 2022 (https://www.who.int/publications/i/item/WHO-2019-nCoV-Digital_certificates_diagnostic_test_results-2022.1, accessed 23 June 2022).

38. WHO digital documentation of COVID-19 certificates (DDCC) [webpage]. Geneva: World Health Organization; 2021 (https://worldhealthorganization.github.io/ddcc/, accessed 29 June 2022).

39. Regulation (EU) 2021/953 of the European Parliament and of the council [webpage]. Brussels: Official Journal of the European Union; (https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32021R0953, accessed 29 June 2022).

40. Joint United Nations Programme on HIV/AIDS, President's Emergency Plan for AIDS Relief. Considerations and guidance for countries adopting national health identifiers. Geneva: Joint United Nations Programme on HIV/AIDS (UNAIDS); 2014 (https://www.unaids.org/en/resources/documents/2014/national_health_identifiers, accessed 23 June 2022).

41. 2016 United Nations Political Declaration on Ending AIDS sets world on the Fast-Track to end the epidemic by 2030 [webpage]. Joint United Nations Programme on HIV/AIDS (UNAIDS); 2016 (https://www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2016/june/20160608_PS_HLM_PoliticalDeclaration, accessed 29 June 2022).

42. National eHealth strategy toolkit. Geneva: World Health Organization and International Telecommunication Union; 2012 (https://apps.who.int/iris/handle/10665/75211, accessed 23 June 2022).

43. Standard guide for properties of a universal healthcare identifier (UHID) [webpage]. West Conshohocken (PA): ASTM International; 2022 (https://www.astm.org/e1714-07r13.html, accessed 29 June 2022).

44. ASTM E2553-07*(2013)* Standard guide for implementation of a voluntary universal healthcare identification system [webpage]. Washington (DC): American National Standards Institute (ANSI); 2013 (https://webstore.ansi.org/Standards/ASTM/astme2553072013, accessed 29 June 2020).

45. ISO 21549-5:2015 Health informatics — Patient healthcard data — Part 5: Identification data Geneva: International Organization for Standardization; 2015, accessed 29 June 2022).

46. DS/CEN/TR 15872 Health informatics - guidance on patient identification and cross-referencing of identities Albany (NY): Engineering 360; (https://standards.globalspec.com/std/1670178/ds-cen-tr-15872, accessed 30 June 2022).

47. Annual report 2019/2020. Pretoria: Department of Health of South Africa; 2020.

48. Annual report 2018/2019. Pretoria: Department of Health of South Africa 2019 (https://www.health.gov.za/annual-reports/, accessed 8 March 2022).

49. Protection of Personal Information Act (POPIA) [webpage]; 2013 (https://popia.co.za/, date accessed 20 July 2022).

50. Report on the WHO AFRO regional workshop on unique identification and application to HIV patient monitoring and case surveillance: Pretoria, South Africa: 21-23 October 2019 Geneva: World Health Organization; 2019 (https://www.who.int/publications/m/item/report-on-the-who-afro-regional-workshop-on-unique-identification-and-application-to-hiv-patient-monitoring-and-case-surveillance, accessed 11 July 2022).

51. Ahmed A, Hashmi FK, Khan GM. HIV outbreaks in Pakistan. Lancet HIV. 2019;6:e418.

52. Iversen J, Zafar M, Busz M, Maher L. Adherence to antiretroviral therapy among HIV positive men who inject drugs in Pakistan. Int J Drug Policy. 2021;96:103281.

53. Iversen J, Zafar M, Busz M, Maher L. HIV incidence and associated risk factors in female spouses of men who inject drugs in Pakistan. Harm Reduct J. 2021;18:1-9.

54. Malik M, Jamil MS, Johnson CC, Pasha MS, Hermez J. Integrating assisted partner notification within HIV prevention service package for people who inject drugs in Pakistan. J Int AIDS Soc. 2019;22.

55. Guidelines on protecting the confidentiality and security of HIV information: proceedings from a workshop, 15-17 May 2006, Geneva, Switzerland. Interim guidelines. Geneva: Joint United Nations Programme on HIV/AIDS; 2007 (http://data.unaids.org/pub/manual/2007/confidentiality_security_interim_guidelines_15may2007_en.pdf, accessed 23 June 2022).

56. The privacy, confidentiality and security assessment tool — user manual. Geneva: Joint United Nations Programme on HIV/AIDS (UNAIDS); 2019 (https://www.unaids.org/en/resources/documents/2019/confidentiality_security_tool_user_manual, accessed 23 June 2022).

57. Data security and confidentiality guidelines for HIV, viral hepatitis, sexually transmitted disease, and tuberculosis programs: standards to facilitate sharing and use of surveillance data for public health action. Atlanta (GA): Centers for Disease Control and Prevention; 2011 (https://www.cdc.gov/nchhstp/programintegration/data-security.htm, accessed 23 June 2022).

58. Liddell K, Simon DA, Lucassen A. Patient data ownership: who owns your health? J Law Biosci. 2021;8:lsab023.

59. Art. 15 GDPR Right of access by the data subject. In: General Data Protection Regulation (GDPR) [website]. Hamburg: Intersoft Consulting; (https://gdpr-info.eu/art-15-gdpr/, accessed 29 June 2022).

60. Art. 16 GDPR Right to rectification. In: General Data Protection Regulation (GDPR) [website]. Hamburg: Intersoft Consulting; (https://gdpr-info.eu/art-16-gdpr/, accessed 30 June 2022).

61. Section 23 Access to personal information. In: Protection of Personal Information Act (POPIA) [website]. Accessible Law; 2019 (https://popia.co.za/section-23-access-to-personal-information, accessed 29 June 2022).

62. The Data Protection Act, 2019. Kenya Gazette Supplement No. 181 (Acts No. 24). Nairobi: The Goverment Printer; 2019 (http://kenyalaw.org/kl/fileadmin/pdfdownloads/Acts/2019/TheDataProtectionAct__No24of2019.pdf, accessed 29 June 2022).

63. Section 5 Rights of data subjects. In: Protection of Personal Information Act (POPIA) [website]. Accessible Law; 2019 (https://popia.co.za/section-5-rights-of-data-subjects, accessed 30 June 2022).

64. Sec. 21. Principle of Accountability. In: Chapter VI: Accountability for transfer of personal information. Republic Act 10173 – Data Privacy Act of 2012. Manila: National Privacy Commission; 2012, accessed 30 June 2022).

65. Art. 51 GDPR Supervisory authority. In: General Data Protection Regulation (GDPR) [website]. Hamburg: Intersoft Consulting; (https://gdpr-info.eu/art-51-gdpr/, accessed 30 June 2022).

66. § 164.308 Administrative safeguards. In: Code of Federal Regulations (CFR) [website]. Washington (DC): Federal Register, National Archives; 2003 (https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-C/part-164/subpart-C/section-164.308, accessed 30 June 2022).

67. Sec. 7. Functions of the National Privacy Commission. In: Chapter II: The national privacy commission. Republic Act 10173 – Data Privacy Act of 2012 [website]. Manila: National Privacy Commission; 2012 (https://www.privacy.gov.ph/data-privacy-act/#7, accessed 30 June 2022).

68. Section 19 Security measures on integrity and confidentiality of personal information. In: Protection of Personal Information Act (POPIA) [website]. Accessible Law; 2019: Accessible Law; 2019 (https://popia.co.za/section-19-security-measures-on-integrity-and-confidentiality-of-personal-information/, accessed 30 June 2022).

69. SEC. 20. Security of Personal Information. Chapter V Security of personal information. Republic Act 10173 – Data Privacy Act of 2012 [website]. Manila: National Privacy Commission; 2012 (https://www.privacy.gov.ph/data-privacy-act/#20, accessed 30 June 2022).

70. Art. 32 GDPR Security of processing. In: General Data Protection Regulation (GDPR) [website]. Hamburg: Intersoft Consulting; (https://gdpr-info.eu/art-32-gdpr/, accessed 30 June 2020).

71. Health Information Privacy Code 2020. In: Privacy Act 2020 [website]. Wellington (NZ): Privacy Commissioner; 2020 (https://www.privacy.org.nz/privacy-act-2020/codes-of-practice/hipc2020/, accessed 30 June 2022).

72. Data Protection Act 2012 [website]. Accra: Data Protection Commission (DPC); 2012 (https://www.dataprotection.org.gh/index.php/data-protection/data-protection-acts-2012, accessed 30 June 2022).

73. Art. 9 GDPR Processing of special categories of personal data. In: General Data Protection Regulation (GDPR) [website]. Hamburg: Intersoft Consulting; (https://gdpr-info.eu/art-9-gdpr/, accessed 10 July 2022).

74. Art. 5 GDPR Principles relating to processing of personal data. In: General Data Protection Regulation (GDPR) [webiste]. Hamburg: Intersoft Consulting; (https://gdpr-info.eu/art-5-gdpr/, accessed 30 June 2022).

CHAPTER 7 – STRENGTHENING DATA USE FROM ALL SOURCES

7

CHAPTER 7 – STRENGTHENING DATA USE FROM ALL SOURCES

7.1 Introduction

7.1.1 A comprehensive data use framework

Incorporating data from multiple sources is essential to the ability to make a comprehensive assessment of programme performance. Data systems differ, however, due to differences in local infrastructure capacity, digital health governance and planning, and the resources invested in building and maintaining systems. Therefore, as countries plan investments in their data systems, it is important to take into account the strengths and limitations of each data source for the interpretation and use of the information generated.

A national HIV monitoring and evaluation plan or framework should incorporate data from multiple sources for use at different management levels. Most core data elements in primary data collection tools have multiple uses (for example, for aspects of patient care and monitoring as well as for programme monitoring and management). A schematic that maps the critical data elements, sources, users and purposes of use can help managers ensure that the right data are available at the right frequency and at the right management levels to support data-driven decision-making. All data collected should have clear utility, and efforts should be made to simplify recording and reporting.

Data on HIV prevention, testing and treatment outcomes, as well as related infections such as STIs and viral hepatitis, can be collected in many ways, including routinely reported data from all patients across all facilities; summary aggregated data from district health information systems; population-based surveys; case surveillance; observations of cohorts of people living with HIV; and periodic evaluation, among others. Programme input and processes also can be monitored through facility surveys or updated lists of service availability; documenting the availability and training of staff; and monitoring the availability of HIV medicines and diagnostics at various levels of the health system through logistics management information systems.

Incorporating community-based and community-led service data

Although a majority of routine HIS are based at health facilities, effective programme monitoring and programme management also require data from health services that are delivered in the community, also called community-based service delivery. Data systems must be able to capture and integrate data on the delivery of community-based health services, delivered via mobile or satellite clinics and often by peer or outreach workers.

Some health services are led by and delivered by community members to their peers. These are particularly important for members of key populations who face stigma, discrimination and criminalization and, therefore, may not seek services at conventional health facilities. Community-led services have been shown to be critical for closing gaps in reaching underserved or marginalized populations. Special considerations for ensuring more complete monitoring and the incorporation of data from community-based and community-led services into the HIS include the following:

- Where community-led organisations are providers of services, (including the provision of community-based services) their data systems should be co-ordinated with those of other service providers (including public, government, and non-community-led NGOs). Ownership of this data should be clarified, and measures agreed to ensure data security and protection of confidentiality of service users.
- Ensuring community engagement regarding the linkage of data systems of community-led services those of other service providers is particularly important for populations that often experience stigma and discrimination in health care settings.
- Strategic linking of UIDs for services provided in community-based settings will help to avoid double counting of services reported through both community-based services and facility-based services through referrals.

7.1.2 Sources of data on HIV and their use

In considering how best to collect key data on the HIV programme and response, efforts should be made to review current monitoring systems, to better link the monitoring of related services such as those for STIs, TB, viral hepatitis and cervical cancer, and to include an integrated set of quality of care (QOC) indicators relevant for programme management. Evaluations or special surveys can be considered when analyses require more data than those collected through routine monitoring systems or when the routine monitoring system is not expected to yield reliable information.

The most common sources of data are:

- routine health information systems, which provide an ongoing flow of real-time data about people receiving services that are derived from individual-level data systems;
- HIV case surveillance systems;
- laboratory reporting systems;
- logistics management information systems;
- health facility assessments to gauge service availability;
- civil registration and vital statistics (CRVS) systems to provide basic data on births and deaths;
- probability-based surveys of key populations and households (such as bio-behavioural surveys (BBS) *(1)*, Population-based HIV Impact Assessment (PHIA) *(2)*, Demographic and Health Surveys (DHS) *(3)* and AIDS Indicator Surveys (AIS) *(4)*), conducted infrequently but offering a representative cross-section of the population. Such surveys can assess correlates of service use, behaviours, biomarkers, health outcomes and impact and can track trends over time;
- special surveys and studies such as drug resistance surveys and measures of quality of care;
- community-led monitoring, which is important to better understand successes and failures and especially to assess the determinants, perceptions, values and experiences of people living with HIV, key populations and the broader community concerning access to and use of services.

Another type of strategic information comes from mathematical models, which synthesize routine data from programmes, survey data and population data to estimate outcomes such as the numbers of new infections, AIDS-related deaths and people living with HIV.

This chapter covers use of data to improve quality-of-care assessments, to incorporate community-led monitoring, building linkages between person-centred data and logistics management and health facility assessments to improve efficiencies, and reviewing data from population-based surveys and modelled estimates.

7.2 Measuring and improving the quality of person-centred care

7.2.1 Background and rationale

Each year poor-quality care contributes to 5.7–8.4 million deaths from all causes in low- and middle-income countries (LMICs), comprising 15% of total deaths in these countries *(5)*. More lives are lost due to poor-quality care than to lack of access to health care *(6)*. In addition to the tremendous loss of life, annual economic losses associated with poor quality care are enormous, exceeding US$ 6 trillion *(6)*. People's trust in health systems can be severely eroded if they have repeated negative experiences with poor quality health services and/or unsafe care which leads to unnecessary, avoidable human suffering and harm *(7)*.

People living with HIV and those accessing HIV prevention, testing, treatment and related services deserve high-quality care to attain and sustain optimal health outcomes and live long, healthy lives *(5, 6)*. Access to services alone is not sufficient to ensure good health outcomes if there are gaps in QOC. Identifying, measuring and acting upon opportunities to strengthen quality across the cascade of care *(6)* will be critical to reach global targets for ending HIV/AIDS, to achieving the health-related Sustainable Development Goals and to improving people's health and well-being *(8)*.

Quality is a cross-cutting concept that must be well-integrated into all health system determinants and aspects of service delivery in order to facilitate "effective outcomes and impact" for the recipients of care *(9)*. Because health systems are complex, multi-level adaptive networks of interdependent elements *(10)*, QOC must be measured within and across health system levels from the point of service delivery, to coordination of care between stakeholders, through evaluating adherence to policies and comparison with standards. Health systems should strive to increase interoperability of tools and systems, such as EMR and existing patient tracking systems, to ensure a systems-level approach that will increase the accountability of programme management and facilitate better care for people seeking and using HIV services.

Measurement, the second of five foundational requirements for quality health services, requires stakeholders to "track the delivery of quality health services and promote accountability" *(7)*. Collecting strategic information at multiple client–provider interfaces and service delivery points can provide greater visibility into services that can be addressed by quality improvement initiatives.

Goal and use of this subsection

This section outlines how QOC can be measured in order to improve services and health outcomes; it can be used to inform quality improvement (QI) data systems and so promote quality across the cascade of care. Data on QOC are distinct from data quality; Chapter 3, section 3.11, provides more information about data quality and use. More information about planning QOC and the foundational requirements for quality health services beyond measurement and beyond an HIV focus can be found in WHO's *Quality health services: a planning guide (7)*.

The framework for measuring QOC presented in this section highlights key indicators that can be calculated using the minimum dataset defined in chapters 2–4. Users may want to review these chapters before reading this QOC section.

Defining QOC

QOC is briefly defined as "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge" *(5)* and WHO's *Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach*, 2021 *(6)*. For further explanation of the QOC key terms defined in this chapter and the glossary, see WHO's 2019 publication, *Maintaining and improving quality of care within HIV clinical services (5)*. Health policy-makers and users of data are encouraged to use these definitions and standards for quality in their local context in order to foster a shared understanding among stakeholders, including the community and recipients of care, of what QOC means.

7.2.2 Measuring QOC

Ideally, QOC is measured through existing strategic information systems. Thus, QOC data depend on the strength of national health management information systems. A health system's framework for measuring QOC should:

- support the national strategic direction for quality
- clearly define what data should be collected from which sources
- be cognizant of capacity for measurement
- strategize how data will be contextualized by triangulation with other data sources
- plan how data will be used to drive QI and impact *(7)*.

Since person-centred care emphasizes integrated care for HIV and related infections over the life course, QOC measurements should attempt to capture the quality of this care, across the multiple service delivery points where people living with HIV obtain care, through longitudinal client-level data, supplemented by data from other sources. Further, QOC measurement should take into consideration the diversity of people seeking HIV services and use data collection and analysis strategies that safely explore and analyse this diversity, especially when determining how to disaggregate data for certain subpopulations *(6)*. All data used to measure the quality of HIV services should be either anonymized or de-identified and securely stored at all times. See Chapter 6 for more information on privacy, security and confidentiality.

To minimize the burden of additional data collection, approaches and tools for measuring QOC should rely primarily on routinely collected data and existing data collection tools (Table 7.1). A first step in the QOC process is to determine what national, subnational or programme indicators and data are available and how well they meet specific needs for QOC measurement. Building in mechanisms to share QOC findings and to adapt and alter approaches to services, based on data and implementation experience, are key.

Although routinely collected data and existing tools should be the primary data sources, in some situations additional approaches may be warranted, especially to gather data on patient experiences and client satisfaction that may not be otherwise captured through routine programmatic data focused on service delivery. Additional qualitative methods to collect and analyse patients' and health care workers' experiences may be necessary. Person-centred measurement and monitoring systems should consider including use of questionnaires as one tool to measure patients' perceptions of and satisfaction with integrated care *(11, 12)*. Further information about tools can be found in the Institute for Healthcare Improvement's *Quality improvement essentials toolkit (13)* and the *WHO quality toolkit*, which includes additional resources and country examples *(14)*.

Table 7.1 Approaches for collecting data on QOC

QOC data sources	Description and primary use
Extracts from electronic medical records	EMR systems may be able to generate patient-level data reports on QOC data elements or indicators if QOC was integrated into their design. QI teams can work with health informatics teams to ensure that QI and health data systems are interoperable so that these reports can be routinely generated.
Quality audits	Extracting data from a representative sample of patient files or records enables collection of patient-level data on demographics, services offered and provided, and the result or health outcomes associated with those services in order to assess the quality of service delivery and care. These may include formal death audits.
Quality improvement documentation journals	Maintaining a QI documentation journal at each health facility with QI activities supports documentation of ongoing QI projects, including the activity's phase, Plan-Do-Study-Act (PDSA) cycle diagram,[a] progress notes and results. Additionally, QI documentation journals support sharing of best practices by documenting methods and processes with sufficient detail so that other health facilities can test the same practices.
Patient satisfaction survey	Collecting data on peoples' experience of care, including their perceptions of QOC and satisfaction with services, may require a supplementary data collection tool, such as a written or oral survey in qualitative or quantitative format. Validated measures and tools should be used, when available, to capture data on patient satisfaction *(10)*.
End-user focus group discussions	Focus group discussions gather in-depth information from patients about their experiences with services and in some cases from their parents, caregivers or family members who are also affected by the care that the health system provides *(15)*. End-user focus group discussions can also be used to validate tools to measure individuals' experience or satisfaction with care *(15)*. These discussions may be held in close coordination with stakeholders, such as peer groups or community-based organizations, who have earned the trust of the local community or sub-populations and may be particularly able to lead or support an open discussion with a respectful atmosphere for all engaged.

[a] The Plan-Do-Study-Act (PDSA) cycle is essentially "the scientific method adapted for action-oriented learning" and another tool that can be used during Rapid Cycles of Learning to map the steps for testing a change *(13)*. For further information about PDSA cycles and diagrams that can be integrated into QI documentation journals, see Fig. 5 of *Maintaining and improving QOC within HIV clinical services (5)* or the PDSA Worksheet in the *Quality improvement essentials toolkit* from the Institute for Healthcare Improvement *(13)*.

Analysis of QOC data can identify gaps in quality, areas for strengthening and areas that may require further data collection and in-depth analysis. Comparing results with baseline data or a pre-determined benchmark or target also can help to assess whether performance is improving and whether a desired standard of care is being met *(11)*.

Priority populations for measuring QOC include those who may have different experiences of care. These include:

- children, adolescents and young adults who may be transitioning from paediatric/adolescent HIV-related care to adult care, accessing sexual health services and/or seeking ART management support *(16)*;
- pregnant and breastfeeding women and their infants; QOC indicators should measure the care that mother–infant pairs affected by HIV receive from pregnancy to birth and through the post-natal period *(12)*;

- key populations such as men who have sex with men, sex workers, trans and gender diverse people, people who inject drugs and people in prisons and other enclosed settings will benefit from a focus on measuring the quality of services to assess key factors related to enabling environment; measure the quality of specific interventions and address stigma and discrimination;
- individuals with advanced HIV will benefit from a focus on the quality of services addressing their leading causes of mortality (for example, bacterial and fungal infections);
- older age and elderly people living with HIV as subpopulations more likely to have co-morbidities or multi-morbidities *(6, 17)*.

While indicators can be disaggregated for priority populations when confidentiality can be preserved, disaggregation alone is not sufficient to ensure that QOC for sub-populations is adequately measured; the community and other stakeholders can be engaged to ensure that QOC for subpopulations remains a priority and is appropriately measured.

QOC measurement should also aim to include key programmatic areas that persons living with HIV may access during their care journey. For example, mental health conditions (such as depression) and HIV-associated neurocognitive disorders (for example, dementia) often affect people living with HIV *(18)*. Palliative care is an essential component of the comprehensive package of care *(6)* and a stage of the HIV care continuum *(17)* at the end of life for people living with HIV. It should also be considered when measuring QOC. Psychosocial services are also integral to comprehensive support for people living with HIV, as are support for survivors of gender-based violence, nutritional assistance and needle–syringe programmes.

7.2.3 Community engagement in measuring QOC

The community plays an invaluable role in measuring QOC and holding all stakeholders accountable for offering high-quality care to all people seeking and using HIV services, including subpopulations such as key populations. Community stakeholders and community-led organizations, especially those involving specific subgroups, experience QOC first-hand and so may be best equipped to identify what is important to these groups and what gaps in services or service quality particularly affect them.

Contributions from community stakeholders during the processes of defining QOC, collecting data and contextualizing analyses of QOC measurement should be highly valued and respected, as the community offers invaluable insights into elements of QOC that quantitative data may not. Additional data collection methods and data sources, such as those used in community-led monitoring (CLM), can be valuable additions to QOC measurement through routine data, helping to ensure that the community perspective is well captured *(19)*. This is covered in more detail in section 7.3.

7.2.4 A QOC framework for selecting indicators

A QOC measurement framework should encompass:

- factors of greatest importance and concern to people accessing HIV prevention, testing, treatment and related services at different stages of life;
- multiple stakeholders engaged in the health care system, including physicians, provider organizations and patients or clients, and a review of the challenges and enablers they face in the provision of quality of care, along with measures of their performance *(20)*;
- validated measures and tools to capture data, even for person-centred measures where the reference standard is self-reporting;

- clinical indicators and patient-reported indicators, such as the following:
  - **Patient experience indicators** should be prioritized *(5)* and focus on measuring what matters most to people using HIV services so that services can be adapted to their specific needs.
  - **Patient perception indicators** can be used to measure patient satisfaction at all stages of the cascade of care, including perceptions of integrated services, since perceived quality of integrated services contributes to health outcomes *(16)*.
  - **Patient knowledge indicators**, which ask patients to report their level of knowledge about health services or HIV, can be included, as knowledge of health services relates to person-centred, inclusive and accessible care.
  - **Patient outcome indicators** should focus on the outcomes that people living with HIV and those receiving HIV prevention, testing, treatment or related services feel are most important; these may be informational, physical, psychological, social, relational, interpersonal, sexual, socioeconomic and emotional priorities *(21, 22)*.

Person-centred QOC indicators framework

A simple framework that considers the above factors can guide the selection of indicators to make up a QOC indicators list (Table 7.2). A complete list of QOC indicators would include: A) services received throughout the entire HIV cascade of care and beyond to care offered for related conditions (A.1 to A.5) and B) all seven domains of quality health services (B.1 to B.7). Indicators from all of these domains should be considered while selecting indicators that are most relevant and feasible to implement or update in a country-specific context.

Table 7.2 Patient-centred QOC indicators framework

Theme		Element
A) Stage of care	A.1	Person-centred prevention
	A.2	Person-centred testing
	A.3	Person-centred treatment
	A.4	Coordination of person-centred care[a]
	A.5	Overarching enablers of person-centred care[b]
B) Quality domain	B.1	Effective: "providing evidence-based health care services to those who need them" *(5)*
	B.2	Safe: "avoiding harm to people for whom the care is intended" *(5)*
	B.3	People-centred: "providing care that responds to individual preferences, needs and values" and also considers whether care is accessible and inclusive for all people needing services, including those living with HIV *(5)*
	B.4	Timely: "reducing wait times and sometimes harmful delays for both those who receive and give care" *(5)*
	B.5	Equitable: "providing care that does not vary in quality on account of age, sex, gender, race, ethnicity, geographical location, religion, socioeconomic status or linguistic or political affiliation" *(5)*
	B.6	Integrated: "providing care that is coordinated across levels and providers and makes available the full range of health services throughout the life course" *(5)*
	B.7	Efficient: "maximizing the benefit of available resources and avoiding waste" *(5)*

[a] Two or more services/providers are required to work together to provide quality care to individuals, including people living with HIV (for example, for related conditions such as TB or STIs, as well as pregnancy and PMTCT).

[b] Encompasses the communications, interactions and interdependencies of all stakeholders and actors (for example, policies, guidelines) that contribute to the quality of services.

7.2.5 Priority indicators

Table 7.3 presents indicators recommended for all programmes intending to comprehensively measure and monitor QOC for people receiving HIV services. Web Annex B provides additional indicators for programmes with the capacity to adopt and sustain more indicators for more robust QOC monitoring. The majority of indicators highlighted in this subsection have been recommended in Chapters 2, 3, and 4 of these guidelines and draw from the minimum dataset (Web Annex A).

Table 7.3 Priority indicators for quality of care

Ref. no.	Short name	Indicator definition	QOC domain
Care stage: prevention			
PRV.17	Condom use (key populations and general population)	% of people who used condoms with a non-regular partner in the last 12 months (see general population and key population indicator descriptions in Chapter 8)	People-centred
Care stage: testing			
HTS.4	Linkage to ART	% of people newly diagnosed with HIV initiated on ART	Efficient
Care stage: treatment			
ART.1	People living with HIV on ART	Number and % of people on ART among all people living with HIV at the end of the reporting period	Effective
ART.3	People living with HIV on ART who have suppressed VL	% of people living with HIV on ART (for at least six months) who have virological suppression	Efficient
ART.6	VL testing coverage	% of people living with HIV on ART (for at least six months) with VL test results	Effective
DSD.3 (NEW)	Coverage of DSD ART models among people living with HIV on ART	% of people living with HIV enrolled in DSD ART models among those eligible for DSD ART (for facilities with electronic HIS) or among people living with HIV currently on ART (facilities with paper-based systems) during the reporting period	People-centred
DSD.5 (NEW)	VL suppression among people living with HIV engaged in DSD ART models	% of people living with HIV and engaged in DSD ART models who have virological suppression	Efficient
Coordination of person-centred care			
VER.1	Viral suppression at labour and delivery	% of HIV-positive pregnant women who are virally suppressed at labour and delivery	Efficient
VER.2	Early infant diagnosis (EID) coverage	% of HIV-exposed infants who receive a virological test for HIV within two months (and 12 months) of birth	Integrated
DFT.1	TB screening coverage among new ART patients	% of people living with HIV newly initiated on ART who were screened for TB	Integrated
DFT.5	TB treatment initiation among diagnosed	% of people living with HIV newly initiated on ART and diagnosed with active TB who initiated TB treatment	Integrated

Table 7.3 (continued): Priority indicators for quality of care

Ref. no.	Short name	Short description	QOC domain
Overarching enablers of person-centred care			
SDC.1	Avoidance of health care due to stigma and discrimination (key populations)	% of key population members who avoid health care because of stigma and discrimination.	Equitable
SDC.2	Avoidance of health care due to stigma and discrimination (people living with HIV)	% of people living with HIV who avoid health care because of stigma and discrimination	Equitable
QOC.1[a] (NEW)	Patient satisfaction with care	% of people attending HIV treatment or prevention services who self-report they are satisfied or highly satisfied with the quality of HIV-related care they receive Possible data sources: client satisfaction surveys, exit interviews with clients, focus group discussions	People-centred
QOC.2[a] (NEW)	Self-reported referral & follow-through	% of people attending HIV treatment or prevention services who self-report receiving referral to a non-HIV-specific service and who self-report receiving that service National programmes should select the non-HIV-specific services that should be included in this indicator (for example, mental health, nutritional support). Possible data sources: referral registers, surveys	Integrated
QOC.3[a] (NEW)	Patient feedback mechanism	% of health facilities having at least one mechanism to monitor patient feedback (for example, customer/patient satisfaction surveys, exit interviews) Possible data sources: health facility surveys and audits	People-centred
QOC.4[a] (NEW)	Guidelines for HIV clinical care	% of health facilities that report adhering to clinical practice guidelines, clinical pathways and/or clinical protocols/algorithms to guide a) HIV testing and b) HIV treatment Possible data sources: health facility surveys and audits. Countries should determine which guidelines, pathways or protocols should be included for HIV prevention, testing or treatment, such as national or WHO resources.	Effective

[a] Indicator requires special studies or data elements not included in the minimum dataset.

While the list of indicators in Table 7.3 aims to capture key indicators and areas, it is not comprehensive. Health systems may need to include other measures to gain a more comprehensive understanding of QOC in their specific context. In addition to the Priority (see summary priority indicators section, p. xxiii) and additional indicators (Web Annex B),

a number of other measures pertaining to QOC of other service areas can be introduced, based on the health system's specific priorities. Measures for other service areas may require data elements beyond those in the minimum dataset, but they should still rely primarily on the health system's routinely collected data and existing data sources. Examples include supply chain stock-outs or on-time ART pick-up, which can identify which elements are effective and which require strengthening.

Disaggregations

Since QOC can vary based on a number of factors, data should be disaggregated in order to analyse whether there are variations in QOC among different subpopulations. Disaggregations by age, gender and subpopulation (for example, pregnant women, adolescents, men who have sex with men, people who inject drugs, sex workers, trans and gender diverse people, people in prisons and other enclosed settings and people living with HIV with TB) should be performed when possible *(5)* and when there is a sufficient volume of data to avoid revealing information about individuals, especially members of groups that may be marginalized or criminalized. Health facilities should have equitable access to their disaggregated data to support their own analysis, monitoring and decision-making.

Improving and sustaining QOC and quality management strategies requires planning and commitments from policy-makers to maintain sufficient resources *(5)*. Programmes should continue striving to improve QOC at all stages of the cascade of HIV prevention, testing and treatment and related services from birth through the end of life. Integration of QOC measures and principles into programmes – for example, by incorporating key QOC concepts and indicators into national strategic information frameworks and routine data systems *(5)* – will enable programmes to contribute their maximum to ensuring that the health system offers high-quality care to all people receiving HIV services.

7.3 Community-led monitoring

Community engagement of people living with and affected by HIV through CLM is fundamental to using data to improve the quality of HIV and related services. Community engagement creates an enabling environment for stakeholders to work together to address health-related issues and promote well-being and, ultimately, to achieve positive health impact and outcomes *(23)*.

CLM is an accountability and advocacy strategy with the primary objective of improving quality, accessibility and utilization of HIV services by holding duty-bearers and health care service providers accountable for the quality of HIV services. It is led and implemented by community-led organizations of people living with HIV, networks of key populations, other affected groups and other community entities at the local, national, regional and global levels *(6, 19).* CLM places the recipient at the centre of monitoring and advocacy. It may be undertaken independently or in collaboration with other key stakeholders *(6)*. It is important not to confuse CLM with community-based HIV service delivery or with the routine collection and reporting of internal programme data by community-led service providers *(5, 24)*.

The recipients of health care services have the greatest stake in improving the quality and accessibility of HIV prevention, testing and treatment programmes, and they are often the first to detect problems and diagnose root causes. Thus, community groups, such as those involving people living with HIV, members of key populations, young people, women and girls, and other groups affected by HIV, should determine the focus of CLM. Community consultation should decide this focus, reflecting the priorities and values of these communities and free from the influence of external entities and agendas. CLM may address issues ranging from the quality, effectiveness and accessibility of services *(6)* to the broader structural and social issues

that impede access to services *(19)*. CLM compiles evidence on what works well, what is not working and what needs to be improved. The data collected complement local and national monitoring and provide key information to fill critical gaps in the decision-making process that leads to evidence-informed improvements of services. Through the CLM process, community-led organizations and key population groups increase their technical capacity to gather, analyse, secure, use and own data.

Methods that involve the collection of data outside of settings where HIV services are provided can engage and gather important information from people not reached by programmes, including reasons that clients might not access HIV prevention, testing, treatment and care services *(19, 23)*. Table 7.4 lists examples of quantitative and qualitative methods for CLM data collection that may take place in community settings or in facilities where services are provided.

Table 7.4 Examples of data collection methods used in CLM across different settings

Community-based data collection	Facility-based data collection
• Community dialogue • User survey • Focus group discussion • Door-to-door survey • Surveys administered online (particularly for those accessing virtual interventions)	• Observational survey • Interview of service users at facilities • HIV treatment facility leader survey • Facility-supported adherence club survey • Facility-based focus group discussion • Community score cards and citizen report cards

Source: Baptiste et al., 2020 *(25)*

Structured input from CLM should become an essential component of a national HIV health information system, but many settings lack established processes for this. CLM is independent from routine health care service delivery and information systems based on clinical data. It shifts the power dynamic, making community-led organizations essential stakeholders empowered to understand more about programme and service delivery and influence decision-making to improve and shape services. Programme managers and service providers should review findings from CLM relevant to the clients they serve and consider implications for adapting and improving how they provide services to these groups.

As with collection and analysis of other health data, CLM should be ongoing. The processes of data collection, analysis and interpretation, including those of data sharing and triangulation in collaboration with relevant stakeholders, should be undertaken at least semi-annually *(6)*. The goal is to give recipients of care a forum to share evidence and experience through a collaborative and solutions-oriented process.

Typically, CLM does not involve the review and extraction of individual-level data from clinical records and registers. As with other forms of data sharing, in order for community-led organizations external to service provision to access and review clinical records, strong data security protocols and protections must be in place. Data should be shared only following a formal data-sharing request, review and approval process. To ensure client privacy and confidentiality, it is essential that all programme data accessed by external organizations are

anonymized through de-identification (that is, removal of all personally identifiable information) and aggregation of data. Aggregated data should be provided only if the numbers are large enough to prevent identification of individuals with specific recorded characteristics or events.

Data collected through CLM are owned by the community-led networks leading the work. These data may be stored separately by the organizations themselves, or, where appropriate and with agreement, they can be incorporated into national data systems to highlight results related to particular health service delivery.

Triangulating data from CLM alongside routine programme data and other data sources such as surveys is essential to gain a comprehensive understanding of whether HIV programmes are meeting their objectives and responding to the needs of those affected by HIV. Taken together, this information can inform policy and programming decision-making to address identified gaps.

Mechanisms should be developed to facilitate the sharing of findings from CLM with health facility managers and community-led organizations. A collaborative approach is best, engaging with other stakeholders such as ministries and funding partners in the processes of triangulation with data from other sources, interpretation and use for evidence-based actions. In some settings data observatories have been established, consisting of community-led organizations and other stakeholders, and have proved an effective mechanism for sharing and analysing data and formulating recommendations to improve programme planning, policy and service delivery *(19)*. In some settings community-led organizations that conduct CLM are included in Country Coordinating Mechanisms, National HIV/AIDS Councils and other decision-making bodies to strengthen linkages between CLM and other strategic information processes.

Resources for CLM

To ensure the systematic inclusion and sustainability of CLM, community groups need technical, financial and material resources to support systems that collect data in a format that is compatible with national systems. In many settings investment in community-led networks and organizations is underfunded, limiting their ability to develop the capacity to lead and deliver CLM.

Reference groups can be formed to support community groups to undertake CLM. These groups can include content and methodological experts from academic institutions, representatives from national HIV programmes and government and other stakeholders. Ultimately, policy-makers, health care providers, data analysts and users, and community members have a stake in improving the access, experiences and health outcomes of clients through improved service delivery. In addition, driving advocacy by these community-led organizations, bringing together routine person-centred data with findings from CLM as part of an inclusive multi-stakeholder process can offer insights into needs and gaps that may otherwise be missed.

7.4 Logistics management information systems

An uninterrupted supply of ARV drugs and diagnostics commodities for HIV prevention, testing and treatment of people living with HIV is a prerequisite for all HIV programmes. An effective and sustainable supply chain system for drugs and other commodities is complex and has many stakeholders. A well-run distribution system keeps drugs in good condition, rationalizes drug storage points, uses transport as efficiently as possible, reduces theft and fraud and provides information for forecasting needs.

The supply of ARVs must be continuous and uninterrupted at all service delivery points. Treatment interruptions could lead to the development and onward transmission of drug-resistant HIV, with potentially disastrous public health consequences. In addition, with the implementation of DSD, drug data can provide an important measure of multi-month dispensing, to assess at a granular level the frequency of clinic visits at district and facility levels. Data on months' supplies of drugs dispensed can identify patterns across a country and contribute to the measurement of efficiencies and outcomes of differentiated care.

One way that efficiencies can be improved is by linking drug supply and aggregated, deduplicated individual-level data. Inaccuracies in patient or client data, due to loss to follow-up and multiple entries of the same person at different facilities, can lead to significant drug wastage or stock-outs. In addition, it can lead to inappropriate budgeting and an inefficient use of financing. Linking logistics management information systems (LMIS) with deduplicated, aggregated and either anonymized or de-identified individual-level data through interoperable systems could more accurately estimate stock levels, improve forecasting and procurement, and reduce drug wastage. In countries that have taken this approach – for example Malawi (see Box 7.1) – it has reduced drug wastage and stock-outs.

Box 7.1 Case study: Malawi

In Malawi the unified in-house management information system for service and logistics data quality has helped avoid challenges with system interoperability and data. The Department of HIV/AIDS and Viral Hepatitis at the Ministry of Health developed a comprehensive HIV programme management information system (DHAMIS) that includes a supply chain module for tracking and allocation of ARVs and other HIV programme commodities. DHAMIS natively combines HIV programme and logistics data from all facilities since 2004 and stock data from the central warehouse in Malawi in one central management information system.

Data domains include:

A. monthly and quarterly HIV service reports from all facilities, for example, number of patients on each ART regimen, number of antenatal clinic attendees, number of clients tested for HIV;

B. geo-referenced inventory of facilities and services;

C. uniquely coded HIV commodity list;

D. quarterly physical stock counts from all facilities;

E. bi-monthly inventory reports from the central warehouse;

F. commodity transactions between the central warehouse and all facilities, including scheduled bi-monthly distributions from the warehouse, ad hoc/on-demand allocations to facilities, stock relocations between facilities and disposal of damaged or expired items;

G. selected staffing, training and performance data for HIV service providers at all facilities;

H. programme coordination, for example, schedules for quarterly supportive facility supervision, action items from supervision.

Box 7.1 (continued) Case study: Malawi

Short codes are used for all ART regimens and formulations across all strategic information tools and are linked to individual-level data sources such as patient treatment cards, EMRs and VL test requisition forms. All site-level service and logistics data are simultaneously updated and always linked. This implementation has resulted in remarkably accurate mid-term forecasts for all main regimens (+/-5% over two years) and minimal losses and stock-outs through proactive relocation of over/under-supplies and visibility of site-level expiries and wastages. The Malawi Ministry of Health has been able to do this successfully with paper records and quarterly site visits. The continued deployment of point-of-care electronic medical record systems for patient-level data at all larger facilities is a major investment that has reduced the burden of data aggregation and reporting and improved accuracy and timeliness.

In Chapter 3 this guideline makes a key recommendation on linking data to reduce drug wastage and stock-outs and includes a new indicator on multi-month ARV dispensing. Another indicator on stock-outs remains in place (percentage of months with any day(s) of stock-out of any routinely dispensed ARV drug during the reporting period). The use of standard dashboards and regular analysis as part of the health information system, and reviewing their performance at national district and facility levels to better match drug stocks to deduplicated and aggregated individual-level data, will be important for programme improvement. In conclusion, the better use of drug and diagnostic data, linked with deduplicated aggregate patient data and the reliable disaggregation of patient cohorts by regimen and formulation, with quarterly review, is a major opportunity to ensure that drugs are always available at the point of use and to improve efficiencies and reduce wastage in HIV programmes.

7.5 Health facility assessments

The ready availability and good quality of health services are integral to strong primary health care and universal health coverage and contribute to achieving the Sustainable Development Goals. Data collected from health facility assessments monitor the capability and performance of health facilities and can support evidence-based decision-making in health sector reviews, planning, management and policy-making. The domains assessed can range from services provided to whether practice follows policies and protocols and whether the environment supports providers in providing high-quality services. For HIV services the objective is to generate reliable and regular information on service delivery (such as the availability of key human and infrastructure resources); on the availability of basic equipment, basic amenities, essential medicines and diagnostic capacities; and on the readiness of health facilities to provide basic health care interventions.

One of the major challenges to interpreting findings from facility assessments is understanding how well the sample of facilities included reflects the range of facilities providing services. For example, private facilities are usually excluded from assessment, are under-sampled or have particularly low response rates. Depending on the local context and coverage of private services, this underrepresentation could result in considerable information gaps. Such factors should be taken into account when considering the generalizability of facility survey results. General health facility survey tools include the Service Availability and Readiness Assessment (SARA) *(26)*, which has a module on HIV services.

7.6 Civil registration and vital statistics

CRVS systems provide the data required on the number of births in the population as well as deaths and causes of death for the HIV-related mortality measure. The completeness and accuracy of vital registration data vary considerably among countries. The usability of CRVS data for monitoring the health sector response to HIV depends on strict compliance with reporting requirements; reporting both primary and underlying cause of death; confidentiality of the deceased and his or her family when reporting stigmatized causes of death such as HIV; and the consistency, completeness and accuracy of civil registration across populations (for example, key populations and other marginalized populations) and geographic areas (for example, urban/rural). Other types of special studies, using verbal autopsy, mortuary surveillance and minimally-invasive autopsy, can provide additional data that may be helpful for estimating HIV-related mortality and adjusting for the bias in weak CRVS systems. Cross-referencing or linking routine HIV data and other information systems that measure deaths and causes of death can increase completeness and strengthen the value of information obtained for both systems.

7.7 Population-based survey data

Population-based surveys are very important for capturing the situation of people who are not engaged in health services. For example, if a country has ART treatment coverage of 70%, understanding why the remaining 30% are not engaged in care is possible only through a population-based survey that reaches a representative group of people not engaged with health services. Thus, surveys complement routine programme data.

Many guidance documents describe the proper design, sampling, data collection and analysis of population-based surveys covering HIV both in the general population (for example, DHS *(3)*, AIS *(4)*, PHIA *(2)* and HIV Drug Resistance (HIVDR) surveys *(27)*), and in key populations at elevated risk of HIV acquisition (such as, bio-behavioural surveys (BBS) *(1)*, or people living with HIV (for example, the People Living with HIV Stigma Index *(28)*).

Many of these documents address population-based surveys as a surveillance tool to measure prevalence of disease, key risk behaviours and attitudes related to stigma and discrimination as well as health services use and coverage. Biomarkers collected by these surveys can be used to estimate HIV prevalence, HIV incidence, VL suppression or other health outcomes.

Key considerations when using indicators from population-based surveys to assess and improve service delivery include the following:

- Population-based surveys, designed to provide rigorous, probability-based samples, are resource-intensive, usually are implemented only periodically and are powered to provide reasonably precise estimates only at relatively large geographic levels (for example, a province). Managers and stakeholders may rely on the more frequent and granular data coming from routine HIS and use population-based survey data to periodically calibrate and assess the representativeness of findings from routine facility systems.
- Survey data have confidence intervals, which should be considered when using results to assess performance. When using survey data to compare performance against targets or to judge the relative performance of two areas, overlapping confidence intervals should push managers to weigh other sources of evidence on performance (for example, consistent performance over time, performance in related areas or related measures of service quality).

- Probability surveys of key populations use special sampling methods to obtain more representative samples of marginalized, highly mobile individuals with a wide range of risk levels. Different sampling approaches result in representation of very different segments of the key population community. Generalizing or aggregating key population survey results for national-level estimates should be done carefully and interpreted with these potential limitations in mind. Implementing recurring key population surveillance with consistent methodologies, sampling strategies and locations can improve comparability and help monitor trends.
- Due to the complexity of sampling and the dependence on community engagement in conducting probability surveys of key populations, managers should ensure that the process of reviewing and interpreting results involves community stakeholders.
- Drug resistance surveys require systematic samples of patients on ART who provide specimens for HIV drug resistance testing. The most challenging aspect of conducting these surveys is the feasibility of assuring that samples of ART patients across facility types and geographic areas are representative.
- Data are seldom collected on HIV prevalence or other outcomes among children and adolescents. This is because of the very large sample size that would be required to reach enough children to have meaningful statistics. In addition, some surveys do not interview people under age 18 since most have not reached the age of consent to participate in research, although most large household surveys such as DHS and PHIA receive permission to interview persons age 15 and older. As a result the number of children and adolescents living with HIV and newly infected with HIV are often estimated using models.

7.8 Mathematical modelling

Estimating the number of people newly infected with HIV or who have died of AIDS-related causes is important for understanding the potential impact and costs associated with implementing interventions and services for HIV prevention, testing and treatment. Using modelled estimates is helpful because it is impossible to directly count the numbers of people living with HIV, of people who are newly infected with HIV or of people who have died from HIV-related causes. Models incorporate data from geographical and population-specific surveys and other forms of surveillance data (for example, case reporting, mortality, programme and clinical data) and make assumptions about HIV transmission and survival in order to estimate these and other outcomes. Modelled estimates – and the lower and upper bounds around these estimates – provide a scientifically appropriate way to describe HIV epidemic levels and trends.

Modelling tools, such as those offered through the UNAIDS-supported Spectrum AIM model *(29)*, can indicate where the greatest transmission risk exists and can guide countries to focus on their largest programmatic gaps. They can generate age- and gender-specific estimates of the numbers of people living with HIV and new infections at subnational levels *(30)*. Using tools such as the Spectrum suite of software to estimate these numbers makes it possible to compare estimates over time and across countries and are used to report on progress toward the Sustainable Development Goals. These models are regularly updated and refined, ensuring that the latest understanding of the HIV epidemic is used to create the estimates.

Modelling also can provide information to answer other programmatic questions. For example, the number of adult HIV infections averted by ART or prevention interventions under different criteria and rates of scale-up can be explored in the Spectrum Goals module. Resource needs modules can be used to estimate the impact of key new recommendations on AIDS-related mortality, the number of infant infections and treatment needs and costs.

Optima HIV is another tool for epidemic projection and prioritization of HIV response as well as evaluation. Optima is a mathematical model of HIV transmission and disease progression integrated with an economic and financial analysis framework and a formal mathematical optimization routine. Analyses determine the optimized approach to get as close as possible to defined objectives (for example, national strategic plan targets) within political, ethical and logistical constraints, with a common target of minimizing new HIV infections and AIDS-related deaths. The Optima HIV tool also is available online free of charge *(31)*.

WHO and collaborating organizations have recently developed a variety of tools to assist with drug quantification and supply management. Several are available for download *(32-34)*, with a description of their main purposes and programmatic focus. A flexible tool also has been developed for costing investments in critical enablers, such as integrated treatment and rights literacy programmes, legal services, stigma and discrimination reduction programmes and training for health care workers and law enforcement *(35, 36)*.

Many other models and tools exist that use different inputs and can explore different questions of priority to health policy-makers. These can be applied jointly through model comparison exercises. Including data from models, surveys and special studies in regular data reviews is important to triangulate and validate assessments of programme performance and for contextualizing the data.

7.9 Data quality review, triangulation and use

A systems approach to improving data quality includes establishing a data quality review (DQR) process. Such a process will help countries be more confident that their data accurately reflect the status of the populations served and the performance of their programmes. Through a collaborative effort of WHO, the Global Fund and Gavi, a harmonized, health sector-wide framework for DQR was developed *(37)*. It is applicable from the level of health facilities up to the national level. The DQR framework complements systems in place for routine monitoring, supervision and evaluation of programmes. WHO recommends that DQR be integrated into HIS at the point of data entry and included in routine data reviews conducted at a national level at least annually. At the same time, these tools are flexible and can be adapted or used in different contexts and for different purposes.

The DQR framework focuses on the quality of selected core tracer indicators on maternal health, immunization, HIV and TB across different dimensions of quality. Countries may also select other indicators or expand the set of indicators based on their needs and resources. Its analysis looks at both programme-specific and systemic issues, and it quantifies problems related to data completeness, accuracy and external consistency.

The data quality dimensions included in the DQR are:

- **Completeness and timeliness:** whether data reported through the system are available and on time, enabling the complete calculation of indicators.
- **Internal consistency of reported data:** the plausibility of reported data compared with historical values of the same indicators or an expected relationship between those two indicators. This dimension also considers reporting accuracy compared with source documents in health facilities.
- **External consistency with other data sources:** the level of agreement between two sources of data measuring the same health indicator.
- **External comparisons of population data:** the adequacy of the population data used in the calculation of health indicator denominators, such as a rate or proportion.

In addition to periodic data quality assessment (DQA) and DQR processes (which are discussed in more detail in section 3.11), front-end measures to design data collection forms and other tools can improve data quality and reduce the time that health care professionals and administrative staff spend on reporting tasks. Periodic review of these tools should ensure that they are consistent with current guidelines, indicator definitions and patient flow. Analysing data from these tools and generating outputs that help managers and stakeholders identify problems and areas for focus is a key aspect of routine review and use of data for decision-making. Having a simplified and standard methodology that provides a common approach to these reviews is important.

This guideline promotes and supports managers' practice of regularly reviewing available data from across the HIV services cascade, supplemented periodically with data from models, surveys and special studies to triangulate and validate assessments of programme performance, including impact. Fundamentally, data reviews consist of a prioritized, simple set of selected indicators based on the recommended minimum datasets that can be analysed at national, subnational and facility levels. National programme managers should conduct this type of routine data review at least on an annual basis, and ideally more frequently, with emphasis on fundamental geographic divisions (subnational, facility) and disaggregated by age, gender and key population to highlight differences in service access (coverage) and quality. Subnational area managers (for example, provincial/regional or district/county level) may conduct more frequent data reviews – for example, quarterly – while facility managers may look at their data even more often to monitor progress and to support staff in delivering services more efficiently and effectively.

7.10 Evaluation and operational research

In addition to routine programme data, programmes need regular evaluations and a system for conducting operational research to learn from implementation and answer complex questions or to test new approaches in service delivery. Evaluation, operational research and implementation science employ research methods to address such questions, which complement routine data review as a data-driven approach to continuous quality improvement and service coverage.

Since resources are limited, it is crucial to focus investment on programmes and services that are appropriate to needs, can be well-implemented and are effective and efficient. By establishing and updating a regular evaluation agenda, countries can stay focused on primary programme priorities and addressing the worst bottle-necks in implementation. Research and evaluation studies should be planned and managed as discrete projects with formal processes and oversight. The evaluation and research agenda should also consider feasibility, that is, what data are already available, so that evaluation design can focus on checking information and filling gaps rather than gathering redundant data. Sound design and management of evaluation and operational research require technical expertise to ensure that the approach is tailored to the needs of the specific country and programme context. In practice, individual-level data are much better suited to addressing salient research questions than aggregate data.

References

1. World Health Organization, Centers for Disease Control and Prevention, Joint United Nations Programme on HIV/AIDS, FHI 360. Biobehavioral survey guidelines for populations at risk for HIV. Geneva: World Health Organization; 2017 (https://www.who.int/publications/i/item/978-92-4-151301-2, accessed 24 June 2022).
2. Justman JE, Mugurungi O, El-Sadr WM. HIV population surveys—bringing precision to the global response. N Engl J Med. 2018;378:1859-61.
3. Demographic and health surveys (DHS) program [website]. Rockville (MD): ICF; 2022 (https://dhsprogram.com/, accessed 14 July 2022).
4. AIDS Indicators Survey (AIS) [webpage]. Rockville (MD): ICF; 2022 (https://dhsprogram.com/methodology/survey-types/ais.cfm, accessed 14 July 2022).
5. Maintaining and improving quality of care within HIV clinical services. Geneva: World Health Organization; 2019 (https://apps.who.int/iris/handle/10665/325857, accessed 24 June 2022).
6. Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach. Geneva: World Health Organization; 2021 (https://www.who.int/publications/i/item/9789240031593, accessed 23 June 2022).
7. Quality health services: a planning guide. Geneva: World Health Organization; 2020 (https://apps.who.int/iris/handle/10665/336661, accessed 14 July 2022).
8. Sustainable Development Goals. SDG indicators. Metadata repository [webpage]. New York: United Nations; 2022 (https://unstats.un.org/sdgs/metadata/, accessed 27 May 2022).
9. Primary health care measurement framework and indicators: monitoring health systems through a primary health care lens. Geneva: World Health Organization and the United Nations Children's Fund (UNICEF); 2022 (https://www.who.int/publications/i/item/9789240044210, accessed 14 July 2022).
10. Pelletier L, Beaudin C, editors. HQ solutions: resource for the healthcare quality professional. Philadelphia: Wolters Kluwer Health; 2018.
11. NCD services integration guidance. Guidance on the inclusion of NCD prevention and control within national responses for HIV/AIDS, TB, reproductive health, and national programmes to strengthen health systems. Geneva: World Health Organization.
12. WHO recommendations on maternal and newborn care for a positive postnatal experience. Geneva: World Health Organization; 2022 (https://www.who.int/publications/i/item/9789240045989, accessed 14 July 2022).
13. Quality improvement essentials toolkit [webpage]. Boston: Institute for Healthcare Improvement; 2022 (http://www.ihi.org/resources/Pages/Tools/Quality-Improvement-Essentials-Toolkit.aspx, accessed
14. WHO quality toolkit Geneva: World Health Organization; 2022 (https://qualityhealthservices.who.int/quality-toolkit/qt-home, accessed 14 July 2022).
15. Larson E, Sharma J, Bohren MA, Tunçalp Ö. When the patient is the expert: measuring patient experience and satisfaction with care. Bull World Health Org. 2019;97:563.

16. Standard of care for people living with HIV. London: British HIV Association; 2018 (https://www.bhiva.org/file/KrfaFqLZRlBhg/BHIVA-Standards-of-Care-2018.pdf, accessed 27 July 2022).

17. Harding R. Palliative care as an essential component of the HIV care continuum. Lancet HIV. 2018;5:e524-e30.

18. Chibanda D, Benjamin L, Weiss HA, Abas M. Mental, neurological, and substance use disorders in people living with HIV/AIDS in low-and middle-income countries. J Acquir Immune Defic Syndr. 2014;67:S54-S67.

19. Establishing community-led monitoring of HIV services. Geneva: Joint United Nations Programme on HIV/AIDS (UNAIDS); 2021 (https://www.unaids.org/en/resources/documents/2021/establishing-community-led-monitoring-hiv-services, accessed 24 June 2022).

20. Smith P, Mossialos E, Papanicolas I, Leatherman S, editors. Principles of performance measurement. In: Performance measurement for health system improvement: experiences, challenges and prospects (Health economics, policy and management). Cambridge: Cambridge University Press; 2010 (https://www.euro.who.int/__data/assets/pdf_file/0007/135970/E94887_Part_I.pdf, accessed 14 July 2022).

21. Bristowe K, Murtagh F, Clift P, James R, Josh J, Platt M et al. The development and cognitive testing of the positive outcomes HIV PROM: a brief novel patient-reported outcome measure for adults living with HIV. Health Qual Life Outcomes. 2020;18:1-10.

22. Harding R, Jones CI, Bremner S, Bristowe K, West B, Siegert RJ et al. Positive outcomes: validity, reliability and responsiveness of a novel person-centred outcome measure for people with HIV. HIV Med. 2022;23:673-83. doi: 10.1111/hiv.13224.

23. WHO community engagement framework for quality, people-centred and resilient health services. Geneva: World Health Organization; 2017 (https://apps.who.int/iris/handle/10665/259280, accessed 24 June 2022).

24. Frequently asked questions: community-led monitoring. Geneva: Joint United Nations Programme on HIV/AIDS (UNAIDS); 2021 (https://www.unaids.org/sites/default/files/media_asset/faq_establishing-community-led-monitoring-hiv-services_en.pdf, accessed 24 June 2022).

25. Baptiste S, Manouan A, Garcia P, Etya'ale H, Swan T, Jallow W. Community-led monitoring: when community data drives implementation strategies. Curr HIV/AIDS Rep. 2020;17:415-21.

26. Service availability and readiness assessment (SARA) [webpage]. Geneva: World Health Organization; 2022 (https://www.who.int/data/data-collection-tools/service-availability-and-readiness-assessment-(sara)?ua=1, accessed 14 July 2022).

27. Laboratory-based survey of acquired HIV drug resistance using remnant viral load specimens. Geneva: World Health Organization; 2021 (https://www.who.int/publications/i/item/9789240025417, accessed 29 July 2022).

28. The people living with HIV stigma index [website]. Amsterdam: Global Network of People Living with HIV (GNP+); 2022 (https://www.stigmaindex.org/, accessed 14 July 2022).

29. Spectrum suite of policy models [website]. Glastonbury (CT): Avenir Health; 2022 (https://avenirhealth.org/software-spectrum.php, accessed 18 May 2022).

30. Eaton JW, Dwyer-Lindgren L, Gutreuter S, O'Driscoll M, Stevens O, Bajaj S et al. Naomi: a new modelling tool for estimating HIV epidemic indicators at the district level in sub-Saharan Africa. J Int AIDS Soc. 2021;24:e25788.

31. Optima Consortium for Decision Science [website]. Melbourne: Optima HIV; 2022 (http://hiv.optimamodel.com/, accessed 18 May 2022).

32. Avenir Health [website]. Glastonbury (CT): Avenir Health; 2022 (http://www.avenirhealth.org/, accessed 18 May 2021).

33. Global price reporting mechanism [webpage]. Geneva: World Health Organization; 2011 (https://www.who.int/hiv/amds/gprm/en/, accessed 18 May 2021).

34. Procurement & supply management toolbox [website]. Geneva: World Health Organization; 2020 (https://www.psmtoolbox.org/en/, accessed 18 May 2021).

35. The human rights costing tool (HRCT): a tool to cost programs to reduce stigma and discrimination and increase access to justice. Geneva: Joint United Nations Programme on HIV and AIDS (UNAIDS); 2012 (https://www.unaids.org/en/media/unaids/contentassets/documents/data-and-analysis/tools/The_Human_Rights_Costing_Tool_v_1_5_May-2012.xlsm, accessed 14 July 2022).

36. The user guide for the HIV-related Human rights costing tool: costing programmes to reduce stigma and discrimination, and increase access to justice in the context of HIV. Geneva: Joint United Nations Programme on HIV/AIDS (UNAIDS); 2012 (https://unaids-test.unaids.org/sites/default/files/unaids/contentassets/documents/document/2012/The_HRCT_User_Guide_FINAL_2012-07-09.pdf, accessed 14 July 2022).

37. Data collection and analysis tools [webpage]. Geneva: World Health Organization; 2022 (https://www.who.int/data/data-collection-tools, accessed 14 July 2022).

CHAPTER 8 – PRIORITY INDICATORS

8

CHAPTER 8 – PRIORITY INDICATORS

8.1 Introduction

This chapter details the recommended priority indicators, including core indicators, organized by five programme areas:

- prevention, including indicators on condom programming, PrEP, PEP, needle-syringe programmes, OAMT, VMMC;
- testing and treatment, including indicators on HIV testing, HIV treatment and care, vertical transmission, TB/HIV, multi-month ARV dispensing;
- related infections, including indicators on STIs, viral hepatitis and cervical cancer;
- impact, including indicators on HIV incidence and AIDS-related mortality;
- stigma and discrimination.

For each indicator the rationale behind the indicator is provided, how the numerator and denominator (if applicable) should be obtained and potential disaggregation categories.

8.1.1 Disaggregation

Disaggregated data are needed to assess equity and performance in health service access and health outcomes among different geographic and sociodemographic subpopulations and important patient subgroups. Routine assessment of equity in service delivery and quality across groups is fundamental to honouring the commitment of the HIV response to equity. In terms of improving programme performance, the fastest way to achieve overall programme targets lies in identifying and closing the gaps of the most underserved groups. The subpopulations benefiting from disaggregated analysis include those defined by geography (for example, cities and other administrative regions of epidemiologic importance, that is, region/province, district/county, facility), age group, gender (male/female/trans and gender diverse), priority populations (for example, key populations and adolescent girls and young women) and important groups that require differentiated patient management or services (for example, pregnant women and TB/HIV patients). Maintaining consistency of disaggregation categories across different indicators is critical for effective analyses and helps to streamline the process and improve the accuracy of recording data onto forms.

Age. Disaggregation by age helps managers identify bottlenecks in service quality and uptake that affect children and adolescents differently from adult patients, as well as barriers to health seeking or adherence that vary by age. With respect to age, the age bands in these guidelines might differ between the indicators; narrower age bands are recommended in settings with robust electronic health information systems. In order to monitor and strengthen PMTCT services, a number of indicators specific to vertical transmission use narrower age bands in their definitions. For example, early infant diagnosis looks at 0–2 months and 2–12 month age groups, while ARV coverage during the breastfeeding period defines the risk period as up to 24 months after birth, reflecting the average duration of breastfeeding in different countries.

Gender. Gender is described differently in different countries and cultures. In this guideline gender is a standard disaggregation variable that includes male, female, and other. The category of other includes trans and gender diverse people who choose an identity other than male or female. It should be noted that trans and gender diverse people are included both as a category for gender disaggregation and as a key population subgroup. This repetition is purposeful and intended to increase the monitoring of programmes providing services to this community.

Key populations. Due to the importance of key populations facing disproportionate stigma and discrimination as well as other challenges in accessing services, it is important to review data disaggregated by key population, where it feasible and safe to collect. Disaggregation by key population (men who have sex with men, people living in prisons and other closed settings, people who inject drugs, sex workers, trans and gender diverse people) should be done only where feasible and when data security and confidentiality can be ensured. (See section 2.2.2 for guidance on collecting information on key populations for prevention interventions to allow for this disaggregation, section 3.8 for testing and treatment interventions, and section 6.4 for further guidance on privacy, security and confidentiality.) It is also important that, when key population data are reported as a priority population disaggregation, data are reported separately for each key population. Special consideration should also be given to the methods for collecting and analysing disaggregated data by key population status; there is the potential for stigma and discrimination against these groups in health care settings and members of key populations may not want their status identified. For these reasons, these guidelines discourage recording of key population status in patient monitoring tools that also include personally identifying information. Key population status may be recorded in the delivery of HIV prevention or testing services if it can be done in a non-identifying manner or anonymously. Mechanisms can be adopted to ensure that key population status is linked to clinical records only for de-identified data analysis. In the absence of this level of data security, disaggregating the priority indicators by key populations will be limited to facilities that offer services specifically for key populations. Key population data may also be collected from surveys for these same indicators, which also can provide more in-depth information on experience, service delivery and outcomes.

Geography. Disaggregation by geography enables managers to focus services more effectively and to focus services more effectively. Location information can reveal possible differences in access to and use of services affecting certain populations or environments (for example, cities and other administrative regions of epidemiologic importance, that is, region/province, district/county, facility), thereby drawing attention to underserved communities. Conversely, finding better programme performance in particular locations could spotlight innovative prevention, care and treatment activities that the entire programme could learn from. The dissemination of geographically disaggregated data through maps, in particular, requires special precautions for small population sizes. For example, identifying numbers or sociodemographic characteristics of people living with HIV or key population members in localized areas may result in breaches of confidentiality or have an adverse effect on individuals and groups in settings where stigma, discrimination and/or criminalization are prevalent.

8.1.2 Time periods

In general, the priority indicators use an unspecified reporting period. They can be calculated over different periods of time to answer programme management questions at different levels and as required for differing reporting purposes. Some indicators have specific reporting periods (for example, "in the last 12 months") that are important because they reflect recommended service delivery guidelines or the way that the indicator is collected.

The collection of person-centred data and tracking individuals means that programmes can look at uptake of services over time. For example, in addition to the reporting period, many indicators have other time elements to consider. These types of indicators track patient/client service utilization over a period of time – For example, whether a second VL test was conducted and results reviewed within six months of an initial VL result of >1000 copies/mL; and whether HIV-exposed infants received a virological test for HIV within two months of birth. For these indicators, aggregate data collection and reporting may be challenging and require special paper-based forms and registers or digital systems that can track information for the same patient over time.

8.1.3 Inclusion of community-based service data

Although a majority of routine health information systems are based at health facilities, effective programme monitoring and programme management also require data from health services delivered in community-based settings. Increasingly, data systems must be able to capture and integrate data on the delivery of community-based services, delivered via mobile or satellite clinics and often by peer or outreach workers.

Avoiding double counting of individuals reported through community-based services and facility-based services is essential – for example, when patients are referred from community-based services to facilities for follow-up and/or confirmation of test results. Ensuring the community's engagement regarding the linkage of community- and facility-based data systems is important.

8.2 Priority indicators by programme area

8.2.1 HIV prevention

PRV.1 Condoms distributed

Total number of condoms distributed during the reporting period

What it measures

This indicator measures the number of condoms distributed through different modalities.

Rationale

- Proactive distribution of condoms is a strategy for ensuring adequate availability.
- By analysing the proportion of condoms distributed through different modalities, national programmes can optimize their investment in socially marketed and public-sector (that is, free) condom distribution.

Numerator

Total number of condoms distributed and sold during the reporting period

Denominator

NA

Method of measurement

Data obtained from programme records (for example, local distribution offices, central warehouse stock records). This indicator is important for analysing monthly and annual trends. The best approach is to sum the number of condoms given out from different service delivery points. Where these data are not available, the number of condoms distributed out of central warehouses is acceptable. The recommended reporting period is 12 months.

Disaggregation

- Condom type (male, female)
- Distribution type (commercial sector, social marketing, public sector)
- Provider type (key population-led or community-led organization, public sector provider, other entities such as private for-profit and not-for-profit organizations, including faith-based, international, nongovernmental)

PRV.2 Total PrEP recipients

Number of people who received PrEP at least once during the reporting period

What it measures

This indicator measures the number of people receiving any PrEP product during the reporting period, including people starting PrEP for the first time, restarting PrEP, continuing PrEP or switching from one PrEP product to another.

Rationale

- The use of ARV medicines by people who are HIV-negative before they are exposed to HIV can prevent HIV infection.
- Through disaggregation, this indicator can help managers compare the uptake and use of PrEP among different types of users (for example, by first-time users, and members of priority populations).

Numerator

Number of people prescribed or dispensed any form of PrEP at least once during the reporting period. Individuals prescribed different PrEP products or regimens at different times during the reporting period should be counted only once.

Denominator

NA

Method of measurement

Individual-level data obtained from programme records.

If individual-level data are not available, the indicator can be reported using aggregate programme data. Because de-duplication is not possible, individuals prescribed multiple PrEP products or formulations at different times during the reporting period maybe counted multiple times, and the number reported may be greater than the number of unique individuals receiving PrEP during the reporting period.

Disaggregation

- Gender (female, male, other[1])
- Age (15–19, 20–24, 25–49, 50+ years)
- Key populations (men who have sex with men, people living in prisons and other closed settings, people who inject drugs, sex workers, trans and gender diverse people)[2]
- PrEP product and formulation (oral, long-acting device, long-acting injectable). Some people may start, continue, stop and restart, one or multiple times with different products or formulations in a given reporting period. Because of this, the percentages of recipients receiving different PrEP products may total more than 100%.

● Core indicator

[1] The category of other includes trans and gender diverse people who choose an identity other than male or female.

[2] See sections 2.2.2 for guidance on collecting information on key populations for prevention interventions to allow for this disaggregation and section 6.4 on maintaining data privacy, security and confidentiality.

- Experience with PrEP (first time, continuing, or restarting following a period of not taking PrEP)
- Provider type (key population-led or community-led organization, public sector provider, other entities such as private for-profit and not-for-profit organizations, including faith-based, international, nongovernmental)
- Setting: facility-based service (including hospitals, health clinics, general practice offices, etc.) or community-based service (including drop-in centres, community service delivery points, mobile clinics or vans, outreach teams, community support groups, etc.)
- Cities and other administrative regions of epidemiologic importance

PRV.3 PrEP coverage (NEW)

% of people prescribed PrEP among those identified as being at elevated risk for HIV acquisition

What it measures

Measures PrEP uptake among the group estimated to be vulnerable to HIV acquisition.

When calculated at the programme/service provider level, the denominator includes all individuals accessing the service identified as being at elevated risk for to HIV acquisition.

Rationale

- WHO recommends that PrEP be offered as an additional prevention choice for people at substantial risk of HIV infection as part of combination HIV prevention approaches.
- Uptake and use of PrEP reflects people's awareness and interest in lowering their risk for HIV through the use of ARVs.

Numerator

Number of unique individuals prescribed or dispensed any form of PrEP at least once during the reporting period. Individuals prescribed different products or regimens at different times during the reporting period should be counted only once.

Denominator

a) Programme/service provider level: number of individuals who received a negative HIV test during the reporting period and identified as being at elevated risk for HIV acquisition (includes people requesting/receiving any HIV prevention intervention, people from key populations, people with known risk factors or assessed as being at risk of HIV acquisition)

b) Population level: population-level estimate of the number of people who would benefit from PrEP, for example as derived from a PrEP need estimator tool

Method of measurement

Individual-level data obtained from programme records.

If individual-level data are not available, the indicator can be reported using aggregate programme data. Because de-duplication is not possible, individuals prescribed multiple PrEP products or formulations at different times during the reporting period may be counted multiple times, and the number reported may be greater than the number of unique individuals receiving PrEP during the reporting period.

Disaggregation

- Gender (female, male, other[1])
- Age (15–19, 20–24, 25–49, 50+ years)
- Key populations (men who have sex with men, people living in prisons and other closed settings, people who inject drugs, sex workers, trans and gender diverse people)[2]

[1] The category of other includes trans and gender diverse people who choose an identity other than male or female.

[2] See sections 2.2.2 for guidance on collecting information on key populations for prevention interventions to allow for this disaggregation and section 6.4 on maintaining data privacy, security and confidentiality.

- PrEP product and formulation (oral, long-acting device, long-acting injectable). Some people may start, continue, stop and restart, one or multiple times with different products or formulations in a given reporting period. Because of this, the percentages of recipients receiving different PrEP products may total more than 100%.
- Experience with PrEP (first time, continuing or restarting following a period of not taking PrEP)
- Provider type (key population-led or community-led organization, public sector provider, other entities such as private for-profit and not-for-profit organizations, including faith-based, international, nongovernmental)
- Setting: facility-based service (including hospitals, health clinics, general practice offices, etc.) or community-based service (including drop-in centres, community service delivery points, mobile clinics or vans, outreach teams, community support groups, etc.)
- Cities and other administrative regions of epidemiologic importance

PRV.4 Volume of PrEP prescribed (NEW)

Total volume of PrEP product prescribed

What it measures

The total volume of PrEP product prescribed can be used to forecast future commodity needs.

Rationale

The total volume of PrEP product prescribed or dispensed can be used to calculate the total number of days (or months/years) available for product use, which can be used derive indicators examining the level of PrEP provided relative to need.

Numerator

The total sum of the volume of PrEP product prescribed for each PrEP recipient during the reporting period

Denominator

NA

Method of measurement

Individual-level data obtained from programme records. Either the volume of PrEP prescribed or the volume of product dispensed can be used if this is available, for example from pharmacy data.

The total volume of PrEP product prescribed (or dispensed) can then be used to derive the total number of days (or months/years) of product use based on the duration of HIV prevention provided by each unit of product. Such an indicator could be described, for example, as the number of person-years of PrEP protection provided. This measure can then be used to examine the level of PrEP availability to monitor trends and for modelling the impact of PrEP at the population level. It can also be used to derive the following additional indicators useful for understanding the quantity of PrEP product available relative to need:

a) numerator: total number of days available for product use denominator: total number of PrEP recipients

b) numerator: total number of days available for product use denominator: estimates of the total number of people who would benefit from PrEP

Disaggregation

- Gender (female, male, other[1])
- Age (15–19, 20–24, 25–49, 50+ years)
- Key populations (men who have sex with men, people living in prisons and other closed settings, people who inject drugs, sex workers, trans and gender diverse people)[2]
- PrEP product and formulation (oral, long-acting device, long-acting injectable)

● Core indicator

[1] The category of other includes trans and gender diverse people who choose an identity other than male or female.

[2] See sections 2.2.2 for guidance on collecting information on key populations for prevention interventions to allow for this disaggregation and section 6.4 on maintaining data privacy, security and confidentiality.

- Provider type (key population-led or community-led organization, public sector provider, other entities such as private for-profit and not-for-profit organizations, including faith-based, international, nongovernmental)
- Setting: facility-based service (including hospitals, health clinics, general practice offices, etc.) or community-based service (including drop-in centres, community service delivery points, mobile clinics or vans, outreach teams, community support groups, etc.)
- Cities and other administrative regions of epidemiologic importance

PRV.5 Number of PEP recipients (NEW)

Number of people prescribed PEP during the reporting period

What it measures

Measure of total number of individuals receiving PEP in a defined period.

Rationale

PEP should be offered and initiated as early as possible for all individuals with an exposure that has the potential for HIV transmission, preferably within 72 hours.

Numerator

Number of people prescribed PEP during the reporting period

Denominator

NA

Method of measurement

Individual-level data obtained from programme records

Disaggregation

- Gender (female, male, other[1])
- Age (15–19, 20–24, 25–49, 50+ years)
- Key populations (men who have sex with men, people living in prisons and other closed settings, people who inject drugs, sex workers, trans and gender diverse people)[2]
- Exposure type (occupational, non-occupational violent, non-occupational consensual sex)
- Provider type (key population-led or community-led organization, public sector provider, other entities such as private for-profit and not-for-profit organizations, including faith-based, international, nongovernmental)
- Setting: facility-based service (including hospitals, health clinics, general practice offices, etc.) or community-based service (including drop-in centres, community service delivery points, mobile clinics or vans, outreach teams, community support groups, etc.)
- Cities and other administrative regions of epidemiologic importance

[1] The category of other includes trans and gender diverse people who choose an identity other than male or female.

[2] See sections 2.2.2 for guidance on collecting information on key populations for prevention interventions to allow for this disaggregation and section 6.4 on maintaining data privacy, security and confidentiality.

PRV.6 PEP completion (NEW)

% of PEP recipients completing PEP course

What it measures

This indicator measures the successful completion of PEP among all PEP recipients in a defined period.

Rationale

Individuals should be provided with adherence support to increase rates of completion of HIV PEP.

Numerator

Number of people completing a course of PEP among those starting in reporting period

Denominator

Number of people starting PEP during the reporting period, excluding those whose PEP course is due to be completed after the end of the reporting period

Method of measurement

Individual-level data obtained from programme records

Disaggregation

- Gender (female, male, other[1])
- Age (15–19, 20–24, 25–49, 50+ years)
- Key populations (men who have sex with men, people living in prisons and other closed settings, people who inject drugs, sex workers, trans and gender diverse people)[2]
- Exposure type (occupational, non-occupational violent, non-occupational consensual sex)
- Provider type (key population-led or community-led organization, public sector provider, other entities such as private for-profit and not-for-profit organizations, including faith-based, international, nongovernmental)
- Setting: facility-based service (including hospitals, health clinics, general practice offices, etc.) or community-based service (including drop-in centres, community service delivery points, mobile clinics or vans, outreach teams, community support groups, etc.)
- Cities and other administrative regions of epidemiologic importance

[1] The category of other includes trans and gender diverse people who choose an identity other than male or female.

[2] See sections 2.2.2 for guidance on collecting information on key populations for prevention interventions to allow for this disaggregation and section 6.4 on maintaining data privacy, security and confidentiality.

PRV.7 HIV in PEP recipients (NEW)

% of PEP recipients testing HIV-positive three months after PEP was prescribed

What it measures

This indicator measures HIV infection status among individuals after receiving PEP.

Rationale

WHO recommends all individuals potentially exposed to HIV should be encouraged to undergo HIV testing three months following the exposure.

Numerator

Number of people testing positive for HIV three months after receiving PEP during the reporting period

Denominator

Number of people receiving PEP during the observation period. To allow for observation of a 3-month test result, the observation period must be set at least three months prior.

Method of measurement

Individual-level data obtained from programme records

Disaggregation

- Gender (female, male, other[1])
- Age (15–19, 20–24, 25–49, 50+ years)
- Key populations (men who have sex with men, people living in prisons and other closed settings, people who inject drugs, sex workers, trans and gender -diverse people)[2]
- Exposure type (occupational, non-occupational violent, non-occupational consensual sex)
- Provider type (key population-led or community-led organization, public sector provider, other entities such as private for-profit and not-for-profit organizations, including faith-based, international, nongovernmental)
- Setting: facility-based service (including hospitals, health clinics, general practice offices, etc.) or community-based service (including drop-in centres, community service delivery points, mobile clinics or vans, outreach teams, community support groups, etc.)
- Cities and other administrative regions of epidemiologic importance

[1] The category of other includes trans and gender diverse people who choose an identity other than male or female.

[2] See sections 2.2.2 for guidance on collecting information on key populations for prevention interventions to allow for this disaggregation and section 6.4 on maintaining data privacy, security and confidentiality.

PRV.8 NSP coverage (NEW)

% of people who inject drugs provided with needles-syringes during the reporting period

What it measures

This indicator measures access to needle–syringe programmes by people who inject drugs, measured either at the programme or service provider level among individuals accessing HIV prevention services, or at the population level using relevant estimates of the population size of people who inject drugs.

Rationale

People who inject drugs require ongoing access to needles–syringes. Needle-syringe programmes should be accessible and achieve good coverage among people who inject drugs.

Numerator

Number of people receiving needles-syringes during the reporting period

Denominator

a) Programme/service provider level: number of people who inject drugs who access the service

b) Population level: population size estimate of people who inject drugs in relevant geographic area

Method of measurement

Individual-level data obtained from programme records

Disaggregation

- Gender (female, male, other[1])
- Age (<25, 25+ years)
- Provider type (key population-led or community-led organization, public sector provider, other entities such as private for-profit and not-for-profit organizations, including faith-based, international, nongovernmental)
- Setting: facility-based service (including hospitals, health clinics, general practice offices, etc.) or community-based service (including drop-in centres, community service delivery points, mobile clinics or vans, outreach teams, community support groups, etc.)
- Cities and other administrative regions of epidemiologic importance

[1] The category of other includes trans and gender diverse people who choose an identity other than male or female.

PRV.9 Regular NSP access (NEW)

% of people who inject drugs accessing a needle-syringe programme (NSP) at least once per month during the reporting period

What it measures

This indicator measures the frequency that people who inject drugs access a NSP.

Rationale

Frequent and regular access to an NSP by people who inject drugs is encouraged to ensure availability of sterile injecting equipment.

Numerator

Total number of people receiving needles-syringes at least once per month during the reporting period, either:

a) number of people accessing an NSP at least once in each 30-day period of the reporting period

b) number of people accessing an NSP at least once per month on average during the reporting period

Denominator

a) Programme/service provider level: number of people who inject drugs accessing service

b) Population level: population-size estimate of people who inject drugs in relevant geographic area

Method of measurement

Individual-level data obtained from programmatic records.

Disaggregation

- Gender (female, male, other[1])
- Age (<25, 25+ years)
- Provider type (key population-led or community-led organization, public sector provider, other entities such as private for-profit and not-for-profit organizations, including faith-based, international, nongovernmental)
- Setting: facility-based service (including hospitals, health clinics, general practice offices, etc.) or community-based service (including drop-in centres, community service delivery points, mobile clinics or vans, outreach teams, community support groups, etc.)
- Cities and other administrative regions of epidemiologic importance

[1] The category of other includes trans and gender diverse people who choose an identity other than male or female.

PRV.10 Needles–syringes distributed

Number of needles–syringes distributed per year per person who injects drugs

What it measures

Measure of the quantity of needles–syringes distributed through needle–syringe programmes.

When measured at the programme/service provider level among people who inject drugs accessing needle–syringe programmes, this indicator measures the average volume of needles–syringes provided per person who inject drugs.

Measured at the population level, this indicator measures the total number of clean units of injecting equipment in circulation that might be used by the overall population of people who inject drugs, noting that secondary distribution of equipment within networks is a significant source of sterile equipment among people who inject drugs.

Rationale

- When measured at the population level with a denominator that is the estimated number of people who inject drugs, this indicator allows understanding of the country's progress towards national coverage of needle–syringe programmes for all people who inject drugs.
- When measured at the programme/service provider level with the denominator that is the number of people who inject drugs reached by the programme, this indicator allows understanding of the quality of the programme and whether adequate needle–syringes are being distributed to programme recipients.

Numerator

a) number of needles-syringes distributed by NSPs in the reporting period

b) number of needles-syringes sold to people who inject drugs by pharmacies or other outlets in the reporting period

Denominator

a) Programme/service provider level: number of people who inject drugs accessing service

b) Population level: population-size estimate of people who inject drugs in relevant geographic area

Method of measurement

Individual-level data obtained from programme records.

New sterile needles and syringes may be available from pharmacies or other sources in addition to needle–syringe programmes. If data on pharmacy distribution is available, it can be included in this indicator.

Report the indicator including the total number of needle–syringes from both NSPs and pharmacies in the numerator if data are available; the proportion of needles–syringes from each source should be reported also.

Disaggregation

- Gender (female, male, other[1])
- Age (<25, 25+ years)

● Core indicator

[1] The category of other includes trans and gender diverse people who choose an identity other than male or female.

- Provider type (key population-led or community-led organization, public sector provider, other entities such as private for-profit and not-for-profit organizations, including faith-based, international, nongovernmental)
- Setting: facility-based service (including hospitals, health clinics, general practice offices, etc.) or community-based service (including drop-in centres, community service delivery points, mobile clinics or vans, outreach teams, community support groups, etc.)
- Cities and other administrative regions of epidemiologic importance

PRV.11 OAMT coverage

% of opioid dependent people receiving opioid agonist maintenance treatment (OAMT) at a specified date

What it measures

Measure of the coverage of OAMT among people who are opioid dependent. Measured at either the service provider or population level.

Rationale

By providing a direct method of reducing the number of injection risk acts per person who inject drugs, OAMT is a critical component of effective harm reduction services.

Numerator

Number of people on OAMT at specified census date

Denominator

a) Programme/service provider level: number of opioid dependent people accessing service

b) Population level: population size estimate of opioid dependent people in relevant geographic area

Method of measurement

Individual-level data obtained from programme records.

The total population of people who are opioid dependent includes both people who inject drugs as well as people who consume opioids by other routes of administration. Not all OAMT recipients will have a history of injecting and not all people who inject drugs will use or be dependent on opioids.

Disaggregation

- Gender (female, male, other[1])
- Age (<25, 25+ years)
- Provider type (key population-led or community-led organization, public sector provider, other entities such as private for-profit and not-for-profit organizations, including faith-based, international, nongovernmental)
- Setting: facility-based service (including hospitals, health clinics, general practice offices, etc.) or community-based service (including drop-in centres, community service delivery points, mobile clinics or vans, outreach teams, community support groups, etc.)
- Cities and other administrative regions of epidemiologic importance

Core indicator

[1] The category of other includes trans and gender diverse people who choose an identity other than male or female.

PRV.12 Total person-years on OAMT (NEW)

% of person-years of follow-up (PYFU) on OAMT among opioid dependent people

What it measures

Measure of the proportion of person time in which individuals who are opioid dependent are covered by OAMT.

Rationale

Evidence demonstrates that HIV risk is reduced among individuals who are opioid dependent during periods when receiving OAMT.

Numerator

Total PYFU on OAMT during defined reporting period.

Calculated from the sum of the time on OAMT of each OAMT recipient during the reporting period.

Denominator

a) Programme/service provider level: estimated PYFU for all opioid dependent people accessing service during defined reporting period

b) Population level: estimated PYFU for total population of opioid dependent people in relevant geographic area during defined reporting period

Method of measurement

Individual-level data obtained from programme records.

Disaggregation

- Gender (female, male, other[1])
- Age (15–19, 20–24, 25–49, 50+ years)
- Provider type (key population-led or community-led organization, public sector provider, other entities such as private for-profit and not-for-profit organizations, including faith-based, international, nongovernmental)
- Setting: facility-based service (including hospitals, health clinics, general practice offices, etc.) or community-based service (including drop-in centres, community service delivery points, mobile clinics or vans, outreach teams, community support groups, etc.)
- Cities and other administrative regions of epidemiologic importance

[1] The category of other includes trans and gender diverse people who choose an identity other than male or female.

PRV.13 OAMT minimum duration (NEW)

% of OAMT recipients who received treatment for at least six months

What it measures

This indicator uses a cohort analysis to measure the proportion of OAMT recipients retained on treatment for at least six months and is a measure of how OAMT is prescribed and of retention in the OAMT programme.

Rationale

Evidence demonstrates that maximum benefit from OAMT is gained when treatment lasts at least six months.

Numerator

Number of people in cohort retained in OAMT for at least six months

Denominator

Number of people starting OAMT during defined cohort recruitment period

Method of measurement

Individual-level data obtained from programme records

Disaggregation

- Gender (female, male, other[1])
- Age (15–19, 20–24, 25–49, 50+ years)
- Provider type (key population-led or community-led organization, public sector provider, other entities such as private for-profit and not-for-profit organizations, including faith-based, international, nongovernmental)
- Setting: facility-based service (including hospitals, health clinics, general practice offices, etc.) or community-based service (including drop-in centres, community service delivery points, mobile clinics or vans, outreach teams, community support groups, etc.)
- Cities and other administrative regions of epidemiologic importance

[1] The category of other includes trans and gender diverse people who choose an identity other than male or female.

PRV.14 OAMT minimum dose (NEW)

% of OAMT recipients receiving a maintenance dose greater than or equal to the recommended minimum dose

What it measures

Measures the proportion of OAMT recipients receiving the recommended minimum maintenance dose.

Rationale

Evidence demonstrates that maximum benefit from OAMT is gained when individuals receive at least the recommended minimum maintenance dose.

Numerator

Number of people, at a specified date, maintained on methadone or buprenorphine receiving recommended minimum maintenance dose (WHO guidance recommends doses of ≥60 mg of methadone or ≥8 mg of buprenorphine[1])

Denominator

Number of people receiving maintenance dose of methadone or buprenorphine at a specified date, excluding: a) individuals currently being inducted on OAMT and yet to reach the maintenance dose and b) individuals on reducing doses of OAMT.

Method of measurement

Individual-level data obtained from programme records

Disaggregation

- Gender (female, male, other[2])
- Age (15–19, 20–24, 25–49, 50+ years)
- Provider type (key population-led or community-led organization, public sector provider, other entities such as private for-profit and not-for-profit organizations, including faith-based, international, nongovernmental)
- Setting: facility-based service (including hospitals, health clinics, general practice offices, etc.) or community-based service (including drop-in centres, community service delivery points, mobile clinics or vans, outreach teams, community support groups, etc.)
- Cities and other administrative regions of epidemiologic importance

[1] *Guidelines for the psychosocially assisted pharmacological treatment of opioid dependence,* WHO, 2009 (https://www.who.int/publications/i/item/9789241547543).

[2] The category of other includes trans and gender diverse people who choose an identity other than male or female.

PRV.15 VMMC scale-up

Total number of voluntary medical male circumcisions (VMMCs) performed according to national standard during the reporting period

What it measures

This indicator measures progress in scaling up male circumcision services.

Rationale

- WHO and UNAIDS recommend VMMC as an efficacious intervention for HIV prevention in priority[1] countries and regions with high HIV prevalence and low male circumcision prevalence.
- Randomized controlled trials have shown that VMMC provided by trained health professionals with proper equipment can reduce the risk of men heterosexually acquiring HIV infection.

Numerator

Total number of people undergoing VMMC performed according to national standard during the reporting period

Denominator

NA

Method of measurement

Individual-level data obtained from programme records (for example, VMMC registers)

The recommended reporting period is 12 months

Disaggregation

- Age (0–4, 5–9, 10–14, 15–19, 20–24, 25–49, 50+ years)
- HIV status (HIV-positive, HIV-negative, unknown status)
- Provider type (key population-led or community-led organization, public sector provider, other entities such as private for-profit and not-for-profit organizations, including faith-based, international, nongovernmental)
- Setting: facility-based service (including hospitals, health clinics, general practice offices, etc.) or community-based service (including drop-in centres, community service delivery points, mobile clinics or vans, outreach teams, community support groups, etc.)
- Cities and other administrative regions of epidemiologic importance

Core indicator

[1] The 15 priority countries are Botswana, Eswatini, Ethiopia, Kenya, Lesotho, Malawi, Mozambique, Namibia, Rwanda, South Africa, South Sudan, Uganda, the United Republic of Tanzania, Zambia and Zimbabwe.

PRV.16 VMMC adverse events

a) Number or (b) % of adverse events during the reporting period

What it measures

This indicator measures whether VMMC services meet national standards of safety and effectiveness.

Rationale

- Staff conducting medical circumcisions must have appropriate training and access to proper equipment.
- Trends in adverse events may indicate where service providers need additional support.
- Intraoperative adverse events may include pain, excessive bleeding, anaesthesia-related effects, excessive skin removal, damage to the penis, sharps injury to personnel. Postoperative adverse events may include abnormal pain, excessive swelling, infection, haematoma, bleeding, difficulty urinating, wound disruption, scar or disfigurement, injury to glans, excessive skin removal.
- Moderate or severe adverse events include complications resulting in death or hospitalization within 30 days or permanent disability.

Numerator

Number of people experiencing at least one moderate or severe adverse event during or following circumcision surgery during the reporting period

Denominator

a) NA

b) Total number of individuals undergoing VMMC performed according to national standard during the reporting period

Method of measurement

Individual-level data obtained from programme records

This indicator can be reported as simply the absolute number of men experiencing adverse events occurring in the reporting period or can be reported as a proportion of the number of procedures conducted.

Disaggregation

- Age (0–4, 5–9, 10–14, 15–19, 20–24, 25–49, 50+ years)
- Type and seriousness of adverse event
- Timing of adverse event (intraoperative, postoperative)
- Service site
- Provider type (key population-led or community-led organization, public sector provider, other entities such as private for-profit and not-for-profit organizations, including faith-based, international, nongovernmental)
- Setting: facility-based service (including hospitals, health clinics, general practice offices, etc.) or community-based service (including drop-in centres, community service delivery points, mobile clinics or vans, outreach teams, community support groups, etc.)
- Cities and other administrative regions of epidemiologic importance

PRV.17 Condom use (key populations and general population)

- % of people who used condoms with a non-regular partner in the last 12 months (general population)
- % of sex workers who used a condom the last time they had sex with a client
- % of men who used a condom the last time they had anal sex with a non-regular male partner
- % of trans and gender diverse people who used a condom during last anal sex with a non-regular partner
- % of people who inject drugs who used a condom the last time they had sex with a partner in the last month

What it measures

This indicator measures the extent to which condoms are used by people who are likely to have higher risk sex.

Rationale

- Condom use at last high-risk sex act gives a good indication of overall levels and trends of protected and unprotected sex.
- Changes in condom use are the combined result of community norms around condom use, availability of condoms and motivation of individuals to protect themselves when engaging in sex.
- Quantifying the number of unprotected high-risk sexual acts is a critical input for modelling HIV transmission.

Numerator

Number of respondents reporting condom use at last specified encounter:

For the general population: number of respondents who say they used a condom the last time they had sex with a non-marital, non-cohabitating (non-regular) partner in the last 12 months

For sex workers: number of sex workers who report using a condom with their most recent paying client

For men who have sex with men: number of men who have sex with men who report that a condom was used the last time they had anal sex with a non-regular partner in the last 6 months*

For trans or gender diverse people: number of trans or gender diverse people who report that a condom was used the last time they had anal sex with a non-regular male partner in the last 6 months*

For people who inject drugs: number of people who inject drugs who report that a condom was used the last time they had sex with a partner in the last 1 month*

Denominator

Number of respondents:

For the general population: number of respondents who report having had sex with a non-marital, non-cohabitating partner in the last 12 months

For sex workers: number of sex workers who report having commercial sex in last 12 months*

For men who have sex with men: number of men who have sex with men who report having had anal sex with a non-regular male partner in the last 6 months

For trans and gender diverse people: number of trans and gender diverse people who report having had anal sex with a non-regular male partner in the last 6 months

For people who inject drugs: number of people who inject drugs who report having had sex with a partner in the last 1 month

* Countries may apply different time periods to define which active key population members are eligible for the survey or are asked questions about condom use (for example, sex workers with a client in the last month). When a different time period defines a key population group more relevant for the epidemic context or consistent with a key population programme focus, countries should use that time period instead of the one given in the definition of the recommended indicator.

Method of measurement

For the general population: General population surveys (such as Population-Based HIV Impact Assessment, Demographic and Health Survey, AIDS Indicator Survey). Health facility records could also collect this routinely in specialized clinics, for example, HIV adolescent clinics, STI clinics, male health clinics. Trends should be interpreted along with independent changes in the percentages of people who have had more than one sexual partner and the number of people with a non-regular partner within the last 12 months, by sex and age.

For key populations: Representative surveys of key populations (for example, bio-behavioural surveys, behavioural surveillance surveys, HIV sentinel sero-surveillance surveys). Where possible, results should be compared with rates of consistent condom use. In countries where many men who have sex with men in the subpopulation surveyed are likely to have partners of both sexes, condom use with female as well as male partners should be investigated.

Disaggregation

- Gender (female, male, other[1])
- Age (<25, 25+ years)

[1] The category of other includes trans and gender diverse people who choose an identity other than male or female.

8.2.2 HIV testing services

HTS.1 People living with HIV who know their HIV status (first 95)

Number and % of people living with HIV who know their HIV status

What it measures

This measures the number and percentage of people living with HIV who have been tested and know their HIV status.

Rationale

- Knowledge of HIV status is the entry point for people living with HIV to treatment and the continuum of care, and for those who test HIV-negative and remain at elevated risk of HIV acquisition, to prevention interventions.
- Disaggregated estimates can reveal gaps in access to testing among important groups of people living with HIV

Numerator

Number of people living with HIV who have received their diagnosis and are still alive

Denominator

Estimated number of people living with HIV

Method of measurement

For the numerator: Best estimate based on available data sources

1. **Direct estimates from HIV case surveillance** systems of the number of people living with HIV diagnosed with HIV, reported by a surveillance system and who are still alive. HIV case surveillance data can be used if reporting from all facilities providing confirmatory HIV testing and treatment services has been in place since at least 2014 and if people who have died, been lost to follow-up, etc., are removed from the numerator. Only confirmed HIV diagnoses should be counted. Mechanisms should be in place to de-duplicate individuals reported multiple times or from multiple facilities.
2. **Modelled estimates**, for which the modelling approach depends on the availability of country data. For countries with robust case surveillance and vital registration systems, the number of people who know their HIV status can be derived using the Case Surveillance and Vital Registration (CSAVR) fitting tool in the Spectrum AIDS Impact Module (AIM). For countries with household population survey data that either directly capture the number of HIV-positive respondents who report that they know their status or the number of HIV-positive people who report ever having been tested, UNAIDS recommends (as of 2018) that the first 90 be modelled using the Shiny First 90.[1]

● Core indicator

[1] European Centre for Disease Control (ECDC) tool available at: HIV Modelling Tool (europa.eu) and UNAIDS Shiny first 90 tool available at: https://shiny.dide.imperial.ac.uk/shiny90/

[2] The category of other includes trans and gender diverse people who choose an identity other than male or female.

[3] Recommended in settings with robust electronic health information systems.

For the denominator: Estimation models, for example, Spectrum AIM, are the preferred source for the number of people living with HIV. Regarding estimating the number of children who know their status in countries with modelled estimates based on household survey data: Since household surveys are often restricted to respondents of reproductive age, a separate estimate of knowledge of HIV status among children (0–14 years old) may need to be constructed using programme data in order to produce an overall (that is, all ages) estimate. In this case UNAIDS recommends that countries use the number of children on ART, as reported in GAM Indicator 2.2, as a proxy measure. This represents the most conservative measure of knowledge of status in the population.

Disaggregation

- Gender (female, male, other[2])
- Age (0–4, 5–9, 10–14, 15–19, 20–24, 25–49, 50+ years)[3]
- Key populations (men who have sex with men, people living in prisons and other closed settings, people who inject drugs, sex workers, trans and gender diverse people)[4]
- ANC attendees
- Cities and other administrative regions of epidemiologic importance

[4] Where feasible and data security and confidentiality can be ensured (see monitoring considerations in section 3.8 on key populations for further guidance, and section 6.4 on maintaining data privacy, security and confidentiality.)

HTS.2 HTS test volume and positivity

Number of HIV tests performed (volume) and the % of HIV-positive results returned to people (positivity)

What it measures

This indicator measures HIV test volume and positivity across service delivery approaches and populations.

Rationale

- Knowledge of HIV status is the entry point for people living with HIV to treatment and the continuum of care, and for those who test HIV-negative and remain at risk to prevention interventions.
- Testing volume disaggregated by age, sex, testing approach and HIV status helps to assess the gaps among various settings, contexts and populations and better target service delivery.

Numerator

Number of tests conducted in which a new HIV-positive result or diagnosis was returned to a person during the reporting period (positivity)

Denominator

Number of tests performed where results were returned to a person during the reporting period (testing volume)

Method of measurement

For the numerator and denominator: Patient monitoring tools, for example, HIV testing service records, HTS or lab registers, logbooks and reporting forms at facility and community levels or EMRs. Reported data should be a count of the number of tests conducted and their results were returned to a person and not the number of unique persons who tested during the reporting period. The method of measurement intends to prevent double counting when multiple assays are used to confirm an HIV-positive diagnosis according to the national testing algorithm. This indicator does not include self-testing.

Disaggregation

- Gender (female, male, other[1])
- Age (0–4, 5–9, 10–14, 15–19, 20–24, 25–29, 30–34, 35–39, 40–44, 45–49, 50+ years)[2]
- Key populations (men who have sex with men, people living in prisons and other closed settings, people who inject drugs, sex workers, trans and gender diverse people)[3]
- TB status (presumptive TB, diagnosed TB, none)
- Testing entry point:

  Facility-level testing: Provider-initiated testing and counselling in clinics or emergency facilities, ANC clinics (including labour and delivery), voluntary counselling and testing (within a health facility setting), family planning clinics (only in high HIV burden settings), TB clinics, other facility-level testing

[1] The category of other includes trans and gender diverse people who choose an identity other than male or female.

[2] Recommended in settings with robust electronic health information systems.

[3] Where feasible and data security and confidentiality can be ensured (see monitoring considerations in section 3.8 on key population for further guidance and section 6.4 on maintaining data privacy, security and confidentiality.)

Community-level testing: Mobile testing (for example, through vans or temporary testing facilities), voluntary counselling and testing centres (not within a health facility setting), other community-based testing.

- Cities and other administrative regions of epidemiologic importance

HTS.3 Individuals testing positive for HIV (NEW)

% testing positive among people who received an HIV test in the reporting period

What it measures

Measures the proportion of people testing positive for HIV. Individuals receiving more than one HIV test in the reporting period are counted only once in the denominator.

Rationale

- Knowing the HIV test positivity among individuals by testing approach is critical to understanding the reach of HIV testing services, and the number of people aware of their status and receiving person-centred services.

Numerator

Number of people who test HIV-positive in the reporting period and have results returned to them[1]

Denominator

Number of people receiving an HIV test in the reporting period

Method of measurement

For the numerator and denominator: Patient monitoring tools, for example, HIV testing service records, HTS or lab registers, logbooks and reporting forms at facility and community levels or EMRs

Disaggregation:

- Gender (female, male, other[2])
- Age (0–4, 5–9, 10–14, 15–19, 20–24, 25–29, 30–34, 35–39, 40–44, 45–49, 50+ years)[3]
- Key populations (men who have sex with men, people living in prisons and other closed settings, people who inject drugs, sex workers, trans and gender diverse people)[4]
- TB status (presumptive TB, diagnosed TB, none)
- Testing entry point:

  Facility-level testing: Provider-initiated testing and counselling in clinics or emergency facilities, ANC clinics (including labour and delivery), voluntary counselling and testing (within a health facility setting), family planning clinics (only in high HIV burden settings), TB clinics, other facility-level testing

  Community-level testing: Mobile testing (for example, through vans or temporary testing facilities), voluntary counselling and testing (VCT) centres (not within a health facility setting), other community-based testing.
- Cities and other administrative regions of epidemiologic importance

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● Core indicator

[1] HIV diagnosis is not based on a single test but rather application of a full testing algorithm according to national guidelines.

[2] The category of other includes trans and gender diverse people who choose an identity other than male or female.

[3] Recommended in settings with robust electronic health information systems.

[4] Where feasible and data security and confidentiality can be ensured (see monitoring considerations in section 3.8 on key populations for further guidance and section 6.4 on maintaining data privacy, security and confidential).

HTS.4 Linkage to ART

% of people newly diagnosed with HIV initiated on ART

What it measures

This measures the extent of linkage to care and initiation of treatment following an HIV-positive diagnoses.

Rationale

- In the era of "Treat All", all people diagnosed as living with HIV should be rapidly initiated on treatment to optimize treatment outcomes and prevent new infections.
- Disaggregated reporting by time since diagnosis (for example, 28 days) provides an indication of the quality of care with respect to national guidelines on when treatment should be started.

Numerator

Number of people newly diagnosed with HIV and started on ART during the reporting period

Denominator

Number of people newly diagnosed with HIV during the reporting period

Method of measurement

For the numerator and denominator: Patient monitoring records/tools (for example, HTS register, ART register) or EMR. Data systems that collect individual-level data and use a unique identifier can easily calculate the numerator for this indicator. In the absence of a cohort system of tracking, this indicator would be considered a proxy unless client records are linked. Countries with aggregate reporting need data collection forms that categorize those who initiate ART by the timing of their HIV diagnosis. This can result in some mismatch between numerator and denominator, as some who are diagnosed with HIV toward the end of the reporting period (and so counted in the denominator) may initiate ART after the reporting period (and so not counted in the numerator). This should be considered in the interpretation of the indicator.

- Gender (female, male, other[1])
- Age (0–4, 5–9, 10–14, 15–19, 20–24, 25–29, 30–34, 35–39, 40–44, 45–49, 50+ years)[2]
- Key populations (men who have sex with men, people living in prisons and other closed settings, people who inject drugs, sex workers, trans and gender diverse people)[3]
- TB status (presumptive TB, diagnosed TB, none)
- Time to start ART (within 7, 30 or 90 days of diagnosis, as per country guidelines)
- Disaggregation by time since diagnosis (for example, 28 or 90 days) provides an indication of the quality of care with respect to national guidelines on when treatment should be started
- Cities and other administrative regions of epidemiologic importance

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● Core indicator

[1] The category of other includes trans and gender diverse people who choose an identity other than male or female.

[2] Recommended in settings with robust electronic health information systems.

[3] Where feasible and data security and confidentiality can be ensured (see monitoring considerations in section 3.8 on key populations for further guidance and section 6.4 on maintaining data privacy, security and confidential).

HTS.5 HTS partner services

Number of people who were identified and tested using partner testing services and who received their results

What it measures

This measures the coverage and impact of the testing cascade of services for partners and other contacts[1] of people living with HIV, including key population members.

Rationale

- Contact testing, including among sexual partners, has been shown to increase the diagnosis of already-infected contacts and partners of newly identified HIV cases.
- Among serodiscordant couples, partner notification and testing can be a critical step in preventing infection of the uninfected partner.
- Contact and/or partner notification and testing should be voluntary and provided with supportive services.

Numerator

For the general population: Number of elicited partners and other contacts[1] of people diagnosed with HIV who received HTS

Additional cascade data collected:

- Number of people diagnosed with HIV (index cases) offered partner services
- Number of people diagnosed with HIV (index cases) accepting partner services
- Number of contacts/partners of people living with HIV whose information is elicited from people diagnosed with HIV (index cases)

For key populations: Number of elicited contacts[1] of members of key populations who received HTS.

Additional cascade data collected:

- Number of key population members offered social network-based/partner services
- Number of key population members accepting social network-based/partner services
- Number of contacts of key population members elicited

Denominator

NA

Method of measurement

Patient monitoring data (HIV index testing services register or logbook, HTS registers or reporting forms) or EMR

[1] Contacts defined as current or past sexual partner(s), biological children/parents (if index case is a child) or anyone with whom a needle was shared. Biological children should only include children of an HIV-positive mother. Children of male-index clients (fathers) should only be included when the biological mother is HIV-positive, she is deceased or her HIV status is not known or not documented. Conversely, if the index client is the child, his/her mother should be tested, and if the mother is HIV-positive or deceased, the father should be tested as well. In addition, all biologic siblings of the index child should be tested.

Disaggregation

- By index case gender (male, female, other[2])
- Age (0–4, 5–9, 10–14, 15–19, 20–24, 25–49, 50+ years)[3]
- HIV status of partner or contact (already known positive, newly diagnosed positive, negative)
- Key populations (men who have sex with men, people living in prisons and other closed settings, people who inject drugs, sex workers, trans and gender diverse people)[4]
- Cities and other administrative regions of epidemiologic importance

[2] The category of other includes trans and gender diverse people who choose an identity other than male or female.

[3] Recommended in settings with robust electronic health information systems.

[4] Where feasible and data security and confidentiality can be ensured (see monitoring considerations in section 3.8 on key populations for further guidance and section 6.4 on maintaining data privacy, security and confidential).

HTS.6 HIVST distribution

Total number of HIV self-test (HIVST) kits distributed during the reporting period

What it measures

This indicator measures trends in the distribution of HIVST kits within a country at the lowest distribution point.

Rationale

- Self-testing is an increasingly common mode of HIV testing that is not captured in other indicators of HTS coverage.
- Monitoring the implementation of this type of testing among target populations will help programme managers track progress and forecast the need for supportive services such as linking clients to confirmatory testing and/or ART, as needed, as well as commodity supply chain needs.

Numerator

Number of individual HIVST kits distributed

Denominator

NA

Method of measurement

HIV self-testing register or logbook

The number of individual HIVST kits distributed, rather than the number of individuals receiving HIVST kits, should be counted. To prevent double counting, data should be recorded at the lowest distribution point, that is, the site or individual giving self-test kits to those who are self-testing. The recommended reporting period is quarterly/every 3 months.

Disaggregation

- Gender (female, male, other[1])
- Age (10–14, 15–19, 20–24, 25–29, 30–34, 35–39, 40–44, 45–49, 50+ years).[2] Note: Age of consent to self-test varies by country context, which may require adaptation.
- In all settings: key populations (men who have sex with men, people living in prisons and other closed settings, people who inject drugs, sex workers, trans and gender diverse people) and other priority populations[3]
- HIVST approach, as specified by national programme, for example, community-based, facility-based, secondary distribution (such as, by index case, key population member, ANC client)
- HIVST distribution by type of sites, as specified by national programme (for example, community outreach, door-to-door, mobile, workplace, antenatal clinic, primary care, outpatient department, STI clinic, family planning clinic)
- HIVST distributed for use by: self, sex partner, drug-injecting partner, social contact, other
- Cities and other administrative regions of epidemiologic importance

[1] The category of other includes trans and gender diverse people who choose an identity other than male or female.

[2] Recommended in settings with robust electronic health information systems.

[3] Where feasible and data security and confidentiality can be ensured (see monitoring considerations in section 3.8 on key populations for further guidance and section 6.4 on maintaining data privacy, security and confidential).

HTS.7. HTS linkage to prevention (NEW)

Among those testing HIV-negative and identified as being at elevated risk for HIV acquisition, % of people who receive an HIV prevention intervention within defined period

What it measures

Measures the proportion of people receiving HIV prevention within set period (for example, same day, 7, 14 or 28 days) after receiving a negative HIV test result.

Rationale

- Access to HIV prevention interventions is important to reduce the risk of HIV acquisition among individuals testing HIV-negative. Ensuring individuals at ongoing risk are successfully linked to relevant HIV prevention is an important outcome following HIV testing.

Numerator

Number of people who receive an HIV prevention intervention within a defined period after receiving a negative HIV test result

Denominator

Number of people testing negative for HIV in the reporting period and identified as being at elevated risk for HIV acquisition (includes people requesting/receiving any HIV prevention intervention, people from key populations, people with known risk factors or those assessed as being at risk of HIV acquisition)

Method of measurement

Individual-level data obtained from programme records

The indicator should exclude current PrEP recipients, as they are tested on a regular basis. As ongoing PrEP recipients are engaged in prevention, the number of days to intervention uptake is 0.

Disaggregation

- Gender (female, male, other[1])
- Age (<15, 15–19, 20–24, 25–49, 50+ years)[2]
- Key populations (men who have sex with men, people living in prisons and other closed settings, people who inject drugs, sex workers, trans and gender diverse people)[3]
- HIV prevention intervention (including PrEP, OAMT, NSP, STI services, VMMC)
- Provider type (key population-led or community-led organization, public sector provider, other entities such as private for-profit and not-for-profit organizations, including faith-based, international, nongovernmental)
- Cities and other administrative regions of epidemiologic importance

[1] The category of other includes trans and gender diverse people who choose an identity other than male or female.

[2] Recommended in settings with robust electronic health information systems.

[3] Where feasible and data security and confidentiality can be ensured (see monitoring considerations in section 3.8 on key populations for further guidance and section 6.4 on maintaining data privacy, security and confidential).

HTS.8. HIV retesting coverage (NEW)

% of people testing HIV-negative who tested again within a defined period of time after their previous test

What it measures

This indicator measures the rate of retesting for HIV among those at ongoing risk of HIV acquisition.

Rationale

- For those individuals who test negative for HIV but are at ongoing risk of HIV acquisition, retesting is encouraged. The recommended frequency of re-testing will differ for different groups in different settings. The level of retesting examined by this indicator should aligned with national recommendations.

Numerator

Number of individuals who tested HIV-negative assessed to be at elevated risk for HIV acquisition who had another HIV test within a defined period after previous test.

Denominator

Number of people assessed as being at elevated risk for HIV acquisition (includes people requesting/receiving any HIV prevention intervention, people from key populations, people with known risk factors or those assessed as being at risk of HIV acquisition) who received an HIV-negative test result in the reporting period.

Method of measurement

Individual-level data obtained from programme records

Disaggregation

- Gender (female, male, other[1])
- Age (<15, 15–19, 20–24, 25–49, 50+ years)[2]
- Key populations (men who have sex with men, people living in prisons and other closed settings, people who inject drugs, sex workers, trans and gender diverse people)[3]
- Provider type (key population-led or community-led organization, public sector provider, other entities such as private for-profit and not-for-profit organizations, including faith-based, international, nongovernmental)
- Cities and other administrative regions of epidemiologic importance

[1] The category of other includes trans and gender diverse people who choose an identity other than male or female.

[2] Recommended in settings with robust electronic health information systems.

[3] Where feasible and data security and confidentiality can be ensured (see monitoring considerations in section 3.8 on key populations for further guidance and section 6.4 on maintaining data privacy, security and confidential).

HTS.9 People from key populations who know their status

% of key population respondents who tested positive for HIV in the past 12 months or who know their current status

What it measures

This indicator measures progress in providing HIV testing services to members of key populations.

Rationale

- To receive the care and treatment required to live healthy, productive lives and to reduce the chance of transmitting HIV, people living with HIV must know their HIV status.
- In many countries, focussing testing and counselling on locations and populations with the highest HIV burden is the most efficient way to reach people living with HIV and ensure that they know their HIV status.

Numerator

Number of respondents who know that they are living with HIV (Q3 = a) or number of respondents who report having tested for HIV in last 12 months (Q1 = b & Q2= a or b) AND the result was negative (Q3 = b)

Q1. Do you know your HIV status from an HIV test? a. No, I have never been tested; b. Yes, I have been tested

Q2. If yes, when were you last tested? a. In the past 6 months; b. 6–12 months ago; c. More than 12 months ago

Q3. Was the result of your last test: a. Positive; b. Negative; c. Inconclusive

Denominator

Number of key population survey respondents

Method of measurement

Representative surveys of key populations (for example, bio-behavioural surveys, behavioural surveillance surveys, HIV sentinel sero-surveillance surveys)

Disaggregation

- Gender (female, male, other[1])
- Age (10–14, 15–19, 20–24, 25–29, 30–34, 35–39,40–44, 45–49, 50+ years)[2]
- Cities and other administrative regions of epidemiologic importance

[1] The category of other includes trans and gender diverse people who choose an identity other than male or female.

[2] Recommended in settings with robust electronic health information systems.

8.2.3 HIV treatment

ART.1 People living with HIV on ART

Number and % of people on ART among all people living with HIV at the end of the reporting period

What it measures

Measures progress towards providing ART to all people living with HIV, that is, treatment coverage, taking into account total attrition during the reporting period.

Rationale

- WHO currently recommends treatment for all people living with HIV to achieve viral suppression.
- This indicator is central to accountability for national health sector strategic plans, effective programme management and donor programming.
- This indicator is essential to measurement of the second 95 target: that 95% of the people who know their HIV-positive status are accessing ART by 2025.

Numerator

Number of people on ART at the end of the reporting period (HIV patient monitoring data from, for example, ART registers, patient records or EMRs). For key populations survey data may be required.

Denominator (for calculation of ART coverage)

1. To determine treatment coverage: estimated number of people living with HIV (from models, such as Spectrum AIM)
2. To gauge progress toward the second 95 target: number of people living with HIV who know their HIV status (from surveys or models)

Method of measurement

For the numerator: Generated by determining the number of people living with HIV on ART at the end of the last reporting period plus the number of people living with HIV initiated on ART during the current reporting period, taking into account retention/attrition status by the end of the reporting period. Retention and attrition analysis should be conducted as part of reporting on this indicator. The numerator should NOT INCLUDE people who have stopped treatment, died or were otherwise lost to follow-up during this period. Consistent with methods for defining the total attrition from ART indicator (see ART.2), these status classification categories should be reported separately to the national level and used to calculate the number of people living with HIV who are on ART.

For the denominator: Epidemiological models such as Spectrum AIM are the preferred source for estimating the number of people living with HIV. Denominator 2 should be consistent with the numerator used for indicator HTS.1 People living with HIV who know their HIV status (first 95 target). The recommended maximum reporting frequency is 12 months. Shorter reporting intervals, for example, three months, are recommended where feasible.

Disaggregation

- Gender (female, male, other[1])
- Age (0–4, 5–9, 10–14, 15–19, 20–24, 25–29, 30–34, 35–39, 40–44, 45–49, 50+ years)[2]
- Key populations (men who have sex with men, people living in prisons and other closed settings, people who inject drugs, sex workers, trans and gender diverse people)[3]
- Cities and other administrative regions of epidemiologic importance

Additional or alternative disaggregation may be appropriate in some settings, depending on the health information system capacity.

[1] The category of other includes trans and gender diverse people who choose an identity other than male or female.

[2] Recommended in settings with robust electronic health information systems.

[3] Where feasible and data security and confidentiality can be ensured (see monitoring considerations in section 3.8 on key populations for further guidance and section 6.4 on maintaining data privacy, security and confidential).

ART.2 Total attrition from ART (Updated)

Number and % of people living with HIV on ART at the end of the last reporting period and those newly initiating ART during the current reporting period who were not on ART at the end of the current reporting period

What it measures

Measures progress towards promoting retention on ART and mitigating loss, that is, attrition from ART.

This indicator is central to understanding total attrition (loss) from ART during a reporting period and to understanding net progress towards reaching the second 95 target.

Rationale

- WHO currently recommends treatment for all people living with HIV to achieve viral suppression. ART attrition analyses by treatment outcome category are essential to achieving this goal.
- This indicator is central to understanding total attrition (loss) from ART during a reporting period and to understanding net progress towards reaching the second 95 target.
- This indicator is closely related to ART.1 People living with HIV on ART and is measured by using the same methods and programmatic outcome classification categories.

Numerator (attrition)[1]

Number of people living with HIV reported on ART at the end of the last reporting period

plus

Number of people living with HIV newly initiated on ART during the current reporting period

minus

Total number of people living with HIV on ART at the end of the current reporting period

Denominator (for calculation of total attrition rate)

Number of people reported on ART at the end of the last reporting period *plus* those newly initiated on ART during the current reporting period

Method of measurement

For the numerator: Determined from HIV patient monitoring tools (for example, ART registers, patient records, EMRs)

Calculation of numerator (attrition):

Attrition = [(total on ART at the end of the last reporting period) + (total newly initiated on ART during current reporting period)] – (total on ART at the end of the current reporting period)

Core indicator

[1] Numerator definition updated for clarity. Calculation of the indicator and what it measures as far as attrition remains unchanged.

This will calculate the total number of individuals who are classified as having died, stopped treatment and/or been lost to follow-up by the end of the current period. These treatment outcome classification categories should be reported separately to the national level and used for calculation of indicator ART.1 People living with HIV on ART. Definitions of treatment outcomes should remain consistent with established standards, with the following exception: The recommended threshold for designation of people living with HIV on ART as lost to follow-up is 28 days after the last missed appointment.

For the denominator: The number of people living with HIV who are on ART at the end of the previous reporting period plus the number of people living with HIV newly initiated on ART during the current reporting period

Disaggregation

- Gender (female, male, other[2])
- Age (0–4, 5–9, 10–14, 15–19, 20–24, 25–29, 30–34, 35–39, 40–44, 45–49, 50+ years)[3]
- Key populations (men who have sex with men, people living in prisons and other closed settings, people who inject drugs, sex workers, trans and gender diverse people)[4]
- Treatment outcome category (died, stopped treatment, lost to follow-up)
- Cities and other administrative regions of epidemiologic importance

Additional or alternative disaggregation may be appropriate in some settings, depending on the health information system capacity.

[2] The category of other includes trans and gender diverse people who choose an identity other than male or female.

[3] Recommended in settings with robust electronic health information systems.

[4] Where feasible and data security and confidentiality can be ensured (see monitoring considerations in section 3.8 on key populations for further guidance and section 6.4 on maintaining data privacy, security and confidential).

ART.3 People living with HIV on ART who have suppressed viral load

% of people living with HIV on ART (for at least six months) who have virological suppression

What it measures

Measures clinical outcomes, specifically viral suppression of patients on ART regardless of ART initiation date.

Rationale

- Viral load suppression (VLS) represents the expected outcome of ART programme services that is, the third 95 target.
- VLS is also the best available measure of adherence to ART

Numerator

Number of people living with HIV on ART for at least six months and with at least one routine VL test result who have virological suppression (<1000 copies/mL[1]) during the reporting period.

Denominator

Number of people living with HIV on ART at least six months with at least one routine VL result in a medical or laboratory record during the reporting period, to monitor progress towards the third 95 target

In addition, this can also be presented as the number with suppressed VL among all people living with HIV to calculate population-level viral suppression.

Method of measurement

For the numerator and denominator: Patient monitoring tools (for example, ART register, patient records, EMRs, laboratory records) or acquired HIVDR surveillance, population-based surveys (such as, the Population-Based HIV Impact Assessment) that collects data on ART coverage and viral suppression

This indicator must be interpreted along with VL testing coverage to assess the potential for bias, that is, whether VL testing occurs in only a particular subset of people receiving ART.

Note: First routine VL testing is recommended at six months after ART initiation. As per ART.7, the time window for early VL monitoring can include a margin of +/– one month, that is, for reporting purposes a routine VL test can take place any time from five to seven months after initiation of ART.

Disaggregation

- Gender (female, male, other[2])
- Age (0–4, 5–9, 10–14, 15–19, 20–24, 25–29, 30–34, 35–39, 40–44, 45–49, 50+ years)[3]
- Key populations (men who have sex with men, people living in prisons and other closed settings, people who inject drugs, sex workers, trans and gender diverse people)[4]
- Cities and other administrative regions of epidemiologic importance

Additional or alternative disaggregation may be appropriate in some settings, depending on the health information system capacity.

● Core indicator

[1] The following thresholds are recommended by WHO to distinguish between treatment failure (>1000 copies/mL) and undetectable (≤50 copies/mL) thresholds (2021 *WHO Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach* (https://apps.who.int/iris/handle/10665/342899).

[2] The category of other includes trans and gender diverse people who choose an identity other than male or female.

[3] Recommended in settings with robust electronic health information systems.

[4] Where feasible and data security and confidentiality can be ensured (see monitoring considerations in section 3.8 on key populations for further guidance, and section 6.4 on maintaining data privacy, security and confidential).

ART.4 New ART patients

Number of people living with HIV who initiated ART

What it measures

This indicator measures the expansion of ART programmes.

Rationale

- Monitoring trends in new ART patients provides managers with important information for forecasting the need for ARV and allocation of staff to ensure quality of care for ART.
- Initiation of ART is one of the sentinel events for HIV surveillance.

Numerator

Number of people living with HIV who initiated ART in accordance with national treatment guidelines during the reporting period

Denominator

NA

Method of measurement

HIV patient monitoring tools (for example, patient records/EMRs, ART registers)

The recommended reporting period is 12 months.

Disaggregation

- Gender (female, male, other[1])
- Age 0–4, 5–9, 10–14, 15–19, 20–24, 25–49, 50+ years)[2]
- Key populations (men who have sex with men, people living in prisons and other closed settings, people who inject drugs, sex workers, trans and gender diverse people)[3]
- Other priority populations
- Cities and other administrative regions of epidemiologic importance

[1] The category of other includes trans and gender diverse people who choose an identity other than male or female.

[2] Recommended in settings with robust electronic health information systems.

[3] Where feasible and data security and confidentiality can be ensured (see monitoring considerations in section 3.8 on key populations for further guidance and section 6.4 on maintaining data privacy, security and confidential).

ART.5 Late ART initiation

% of people living with HIV who initiate ART with a CD4 count of <200 cells/mm^3

What it measures

Measures the proportion of people living with HIV who have AIDS at the time that they initiate ART. Often CD4 count monitoring is performed at HIV diagnosis. WHO recommends CD4 count measurement at diagnosis and same day/rapid initiation of ART for all people diagnosed with HIV.

Rationale

- Late initiation of ART is a risk factor for treatment failure and, therefore, is important to monitor.

Numerator

Number of people living with HIV initiating ART during the reporting period with a baseline CD4 count of <200 cells/mm^3

Denominator

Number of people living with HIV initiating ART during the reporting period who have a baseline CD4 cell count

Method of measurement

For the numerator and denominator: HIV patient monitoring tools (for example, patient records/EMRs, ART registers, laboratory records)

The recommended reporting period is 12 months.

Disaggregation

- Gender (female, male, other[1])
- Age 0–4, 5–9, 10–14, 15–19, 20–24, 25–49, 50+ years)[2]
- Key populations (men who have sex with men, people living in prisons and other closed settings, people who inject drugs, sex workers, trans and gender diverse people)[3]
- Other priority populations
- Cities and other administrative regions of epidemiologic importance

Additional recommendation for settings with robust electronic HIS, for example, EMRs:

- Monitoring mean and median CD4 cell counts among those who initiate ART and have a baseline CD4 cell count.

● Core indicator

[1] The category of other includes trans and gender diverse people who choose an identity other than male or female.

[2] Recommended in settings with robust electronic health information systems.

[3] Where feasible and data security and confidentiality can be ensured (see monitoring considerations in section 3.8 on key populations for further guidance and section 6.4 on maintaining data privacy, security and confidential).

ART.6 Viral load testing coverage

% of people living with HIV on ART (for at least six months) with viral load test results

What it measures

Assesses the extent to which VL testing is available in the country and enables appropriate interpretation of VL suppression data. This indicator is essential for monitoring access to viral load testing as well as the interpretation of the indicator ART.3 PLHIV on ART who have suppressed viral load and its representativeness.

Rationale

- WHO recommends routine VL testing at six months and 12 months after ART initiation and every 12 months thereafter.
- Many countries are still in the process of scaling up VL testing capacity.
- This indicator is critical to decide whether VL suppression as measured through routine data is likely to be representative of all patients on ART.

Numerator

Number of people living with HIV on ART with at least one routine VL test result during the reporting period

Denominator

Number of people living with HIV on ART for at least six months

Method of measurement

For the numerator and denominator: Patient monitoring tools (for example, patient records/EMRs, ART register, cohort reporting forms, laboratory information system)

It is critical to de-duplicate records and avoid double-counting when identifying the appropriate numerator. The denominator excludes patients who have died, transferred to another facility or been classified as lost to follow-up.

Disaggregation

- Gender (female, male, other[1])
- Age (0–4, 5–9, 10–14, 15–19, 20–24, 25–49, 50+ years)[2]
- Key populations (men who have sex with men, people living in prisons and other closed settings, people who inject drugs, sex workers, trans and gender diverse people)[3]
- Other priority populations
- Cities and other administrative regions of epidemiologic importance

[1] The category of other includes trans and gender diverse people who choose an identity other than male or female.

[2] Recommended in settings with robust electronic health information systems.

[3] Where feasible and data security and confidentiality can be ensured (see monitoring considerations in section 3.8 on key populations for further guidance and section 6.4 on maintaining data privacy, security and confidential).

ART.7 Early viral load testing (at six months)

Number and % of people living with HIV on ART who had a viral load result reviewed by six months after initiation of ART

What it measures

Measures the extent to which people newly initiating ART receive appropriate and rapid follow-up VL testing to check virologic suppression and to provide an early warning to prompt adherence support and avoid HIV drug resistance.[1]

Rationale

- WHO currently recommends VL testing for all people living with HIV at six months after ART initiation to assess VLS and, in the event of non-suppression, to identify persons in need of intensive adherence counselling and follow-up.
- Virologic suppression is essential to the 95–95–95-related impact goals.
- This indicator complements the VL testing coverage (ART.6) and VL suppression (ART.3) indicators.

Numerator

Number of people living with HIV on ART who were eligible for VL monitoring at six months after initiation of ART during the reporting period and who had a VL test performed and result reviewed by six months after ART initiation

Denominator

Number of people living with HIV on ART eligible for VL monitoring at six months after initiation of ART during the reporting period

Method of measurement

For the numerator and denominator: Patient monitoring tools (for example, ART registers, cohort reporting forms, patient records/EMRs, laboratory information system)

The time window for early VL monitoring can include a margin of +/– one month, that is, a routine VL test can take place any time from five to seven months after initiation of ART.

Disaggregation

- Gender (female, male, other[2])
- Age (0–4, 5–9, 10–14, 15–19, 20–24, 25–49, 50+ years)[3]
- Key populations (men who have sex with men, people living in prisons and other closed settings, people who inject drugs, sex workers, trans and gender diverse people)[4]
- Other priority populations
- Cities and other administrative regions of epidemiologic importance

[1] It important that patient monitoring systems can identify viral load tests conducted at six months after ART initiation and that this is taken into account within HIV surveillance so as not to disrupt surveillance of population-level viral load.

[2] The category of other includes trans and gender diverse people who choose an identity other than male or female.

[3] Recommended in settings with robust electronic health information systems.

[4] Where feasible and data security and confidentiality can be ensured (see monitoring considerations in section 3.8 on key populations for further guidance and section 6.4 on maintaining data privacy, security and confidential).

ART.8 Appropriate second viral load test after adherence counselling

% of people living with HIV receiving ART with VL ≥1000 copies/mL who received a follow-up viral load test within three months

What it measures

Measures the extent to which people living with HIV with non-suppressed VL receive appropriate follow-up VL testing to check virologic suppression.

Rationale

- Virologic suppression is essential to the 95–95–95-related impact goals.
- This indicator complements the VL testing coverage (ART.6) and VL suppression (ART.3) indicators.

Numerator

Number of people living with HIV on ART who received a follow-up VL test three months after a VL test result of ≥1000 copies/mL during the reporting period[1]

Denominator

Number of people living with HIV on ART with VL ≥1000 copies/mL during the reporting period

Method of measurement

For the numerator and denominator: HIV patient monitoring tools (for example, ART registers, EMRs, laboratory information system)

The recommended maximum reporting period is 12 months. Shorter reporting intervals, for example, three months, are recommended where feasible.

Disaggregation

- Gender (female, male, other[2])
- Age (0–4, 5–9, 10–14, 15–19, 20–24, 25–49, 50+ years)[3]
- Key populations (men who have sex with men, people living in prisons and other closed settings, people who inject drugs, sex workers, trans and gender diverse people)[4]
- ART regimen
- Receipt of enhanced adherence counselling (yes/no/unknown)
- Cities and other administrative regions of epidemiologic importance

[1] Recommendation on timing of second viral load test updated from six months in the 2020 WHO Consolidated HIV strategic information guidelines: driving impact through programme monitoring and management (https://www.who.int/publications/i/item/9789240000735) to three months in the 2021 WHO Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach (https://apps.who.int/iris/handle/10665/342899) in line with updates to the algorithm for treatment monitoring.

[2] The category of other includes trans and gender diverse people who choose an identity other than male or female.

[3] Recommended in settings with robust electronic health information systems.

[4] Where feasible and data security and confidentiality can be ensured (see monitoring considerations in section 3.8 on key populations for further guidance and section 6.4 on maintaining data privacy, security and confidential).

ART.9 ARV toxicity prevalence

% of ART patients with treatment-limiting ARV toxicity

What it measures

Measures the incidence of serious ARV toxicities among ART patients.

Rationale

- As use of ARVs is scaled up, people living with HIV have the potential for prolonged exposure to ARVs and the potential to experience ARV-related toxicity.
- ARV-related toxicities are some of the most common reasons reported for ART non-adherence, treatment discontinuation or substitution of drugs and, thus, are important to monitor.

Numerator

Number of ART patients who have stopped treatment or switched regimen due to toxicity in the reporting period

Denominator

Number of ART patients in the reporting period

Method of measurement

For the numerator and denominator: HIV patient monitoring tools (ART registers, patient records/EMRs). To enable reporting codes for reasons for ART stop or switch are provided in patient monitoring tools (Web Annex H HIV patient card and Annex K ART register)

"Treatment-limiting" toxicity is defined as follows: A serious adverse drug reaction that results in drug discontinuation or substitution. In addition, any reaction that leads to treatment interruption or requires changing the drug or regimen because of an adverse drug reaction is also considered a serious adverse drug reaction.

Disaggregation

- Gender (female, male, other[1])
- Age (0–4, 5–9, 10–14, 15-19, >19 years)[2]
- Key populations (men who have sex with men, people living in prisons and other closed settings, people who inject drugs, sex workers, trans and gender diverse people)[3]
- ART regimen
- Pregnancy status
- Type of toxicity (gastrointestinal, skin, peripheral neuropathy, central nervous system, weight gain, hepatic dysfunction, haematological, fatigue, headache, bone dysfunction, metabolic, kidney dysfunction)
- Cities and other administrative regions of epidemiologic importance

[1] The category of other includes trans and gender diverse people who choose an identity other than male or female.

[2] Recommended in settings with robust electronic health information systems.

[3] Where feasible and data security and confidentiality can be ensured (see monitoring considerations in section 3.8 on key populations for further guidance and section 6.4 on maintaining data privacy, security and confidential).

ART.10 People from key populations living with HIV on ART (NEW)

% of key population survey respondents testing positive for HIV who are on ART

What it measures

This indicator measures progress towards providing ART services for members of key populations.

Rationale

- This indicator is central to measuring and improving access to treatment and care services and outcomes among key populations.
- It enables measurement of the second 95 target for treatment: that 95% of the people who know their HIV-positive status are accessing ART by 2030.

Numerator

Number of key population respondents on ART

Denominator

Number of key population survey respondents testing positive for ART

Method of measurement

Representative surveys of key populations (for example, bio-behavioural surveys, behavioural surveillance surveys, HIV sentinel sero-surveillance surveys)

Disaggregation

- Gender (female, male, other[1])
- Age (0–4, 5–9, 10–14, 15–19, 20–24, 25–29, 30–34, 35–39, 40–44, 45–49, 50+ years)[2]
- Key populations (men who have sex with men, people living in prisons and other closed settings, people who inject drugs, sex workers, trans and gender diverse people)[3]
- Provider type (key population-led or community-led organization, public sector provider, other entities such as private for-profit and not-for-profit organizations, including faith-based, international, nongovernmental)
- Cities and other administrative regions of epidemiologic importance

[1] The category of other includes trans and gender diverse people who choose an identity other than male or female.

[2] Recommended in settings with robust electronic health information systems.

[3] Where feasible and data security and confidentiality can be ensured (see monitoring considerations in section 3.8 on key populations for further guidance and section 6.4 on maintaining data privacy, security and confidential).

VER.1 Viral suppression at labour and delivery

% of HIV-positive pregnant women who are virally suppressed at labour and delivery

What it measures

This indicator measures viral suppression at the time of delivery among HIV-positive pregnant women.

Rationale

- Viral suppression at the time of delivery is a service quality measure at a critical point in the vertical transmission risk period.
- Two different denominators give indicators similar to general measures of viral suppression among people living with HIV: The programme-based/service delivery denominator, that is, those on ART, delivering in a facility and having a viral load test, measures the third "95" target. The population-based denominator, that is, viral load among all estimated pregnant women living with HIV, regardless of ART status or ANC/facility attendance, measures population viral load suppression (of pregnant women living with HIV).

Numerator

Number of HIV-positive pregnant women on ART during pregnancy and delivering at a facility during the reporting period who were virally suppressed (<1000 copies/mL) at delivery

Denominator (for calculation of % ART coverage)

Number of HIV-positive pregnant women on ART during pregnancy who deliver at a facility during the reporting period and had a viral load test during delivery, or the estimated total number of pregnant women living with HIV

Method of measurement

For the numerator: Patient monitoring tools/EMRs (for example, PMTCT registers, patient records)

For the denominator:

- Population-based denominator: modelling-based estimates (for example, Spectrum AIM)
- Programme-based/service delivery denominator: programme records, labour and delivery registers/EMRs

Note: This indicator should be interpreted with consideration of the VL testing coverage of pregnant women living with HIV at delivery.

The recommended reporting period is 12 months.

Disaggregation

- Age (<15, 15–19, 20–25, 25+ years)
- Timing of ART initiation (during pregnancy, on ART at first ANC visit)
- Cities and other administrative regions of epidemiologic importance

VER.2 Early infant diagnosis (EID) coverage

% of HIV-exposed infants who receive a virological test for HIV within two months (and 12 months) of birth

What it measures

This indicator measures early HIV diagnosis in infants.

Rationale

- High coverage of early virological testing of infants helps initiate ART early in children with confirmed HIV infection and supports counselling on efforts to prevent seroconversion of those with a negative early test result.
- Current PMTCT guidelines recommend virological testing for HIV-exposed infants within two months of birth.

Numerator

Number of HIV-exposed infants born during the reporting period who received a virological HIV test within two months (and 12 months) of birth

Denominator

Estimated number of HIV-positive women who delivered during the reporting period

Note: The denominator is a proxy measure for the number of infants born to HIV-infected women.

Method of measurement

For the numerator: Programme records (for example, PMTCT registers, laboratory records)

For the denominator: Modelling-based estimates (for example, Spectrum AIM)

The recommended reporting period is 12 months.

Disaggregation

- Test result (HIV-positive, HIV-negative, indeterminate, other) to enable calculation of the percentage positive and the percentage with an indeterminate result among HIV-exposed infants receiving a virological test
- Age of infant (<2 months, 2–12 months) to allow the separate calculation of the proportion of exposed infants receiving virological testing within two months of birth and within 12 months of birth
- Cities and other administrative regions of epidemiologic importance

VER.3 Infant ARV prophylaxis coverage

% of HIV-exposed infants who initiated ARV prophylaxis

What it measures

This indicator measures the delivery of prevention services to HIV-exposed infants immediately after birth.

Rationale

- ARV prophylaxis for HIV-exposed infants is critical for reducing the risk of mother-to-child transmission in the immediate postpartum period – part of Prong 3 of the PMTCT strategy.
- In particular, coverage of HIV-exposed infants who are born in facilities should be very high.
- When using the programme-based/service delivery denominator, the indicator measures coverage among only HIV-exposed infants who are born in facilities, which is a direct measure of a programme's ability to meet standards of care.

Numerator

Number of HIV-exposed infants born within the past 12 months who were started on ARV prophylaxis at birth

Denominator

a) Programme-based/service delivery denominator: Number of HIV-positive women who delivered in a facility within the past 12 months.

b) Population-based denominator: Number of HIV-positive women who delivered within the past 12 months

Method of measurement

For the numerator: Programme records (for example, PMTCT registers)

a) For the programme-based/service delivery denominator: Programme records, labour and delivery registers

b) For the population-based denominator: Modelling-based estimates (for example, Spectrum AIM)

Note: The population-based denominator is a proxy measure for the number of infants born to HIV-infected women.

The recommended reporting period is 12 months.

Disaggregation

- ARV drug regimen
- Cities and other administrative regions of epidemiologic importance

VER.4 ART coverage in pregnant women

% of HIV-positive pregnant women who received ART during pregnancy and/or at labour and delivery

What it measures

This indicator measures whether a recommended course of ART has been provided to HIV-positive pregnant women.

Rationale

- Providing ART for HIV-positive pregnant women is a critical strategy for preventing vertical transmission of HIV.
- In an era of "Treat All", all HIV-positive pregnant women should be given a recommended regimen of ART as soon as possible after diagnosis, including during labour and delivery.

Numerator

Number of HIV-positive pregnant women who delivered during the reporting period and received ART during pregnancy and/or at labour and delivery

Denominator

a) **Programme-based/service delivery denominator**

Number of HIV-positive pregnant women who delivered during the reporting period and attended ANC or had a facility-based delivery

b) **Population-based denominator**

Number of HIV-positive pregnant women who delivered during the reporting period

Method of measurement

a) For the numerator and programme-based/service delivery denominator: Programme records (for example, PMTCT registers, ARV registers, labour and delivery registers)

b) For the population-based denominator: Modelling-based estimates (for example, Spectrum AIM)

The recommended reporting period is 12 months.

Disaggregation

Numerator:

- Timing of ART initiation (1. already on ART at first ANC visit, 2. newly on ART during pregnancy, 3. newly on ART during labour and delivery, 4. on non-recommended ART regimen)

The primary indicator calculation should include ART status categories 1, 2 and 3. Removing the women in category 1 "already on ART at first ANC visit" from the numerator and denominator gives a measure of ART coverage among HIV-positive pregnant women newly diagnosed during ANC. Dividing category 2 by the sum of categories 2 and 3 gives the proportion of new ART initiations occurring during pregnancy rather than at delivery. Calculating the indicator with those in category 4 (non-recommended ARV regimen) included in the numerator gives a broader measure, that is, coverage of HIV-positive pregnant women receiving any ARV drug.

VER.5 ART coverage in breastfeeding mothers

% of HIV-exposed breastfeeding infants whose mothers are receiving ART at 12 (and 24 months) postpartum

What it measures

This indicator measures the programme's ability to reduce the risk of transmission via breastfeeding (Prong 3 of the PMTCT strategy).

Rationale

- In many countries the average breastfeeding period is 18–24 months. The long breastfeeding period represents an important risk period for HIV-exposed infants.
- Ensuring that HIV-positive mothers are retained on ART, especially during the breastfeeding period, is critical to sustaining the health of the mother and preventing infection of her infant.

Numerator

Number of HIV-exposed breastfeeding infants whose mothers are receiving ART at 12 months (and 24 months[1]) postpartum

Denominator

Number of HIV-exposed infants attending MNCH services for a 12-month visit (and 24-month visit or first visit after the end of breastfeeding)

Method of measurement

For the numerator: Programme records (for example, PMTCT registers, ART registers)

For the denominator: Programme records (for example, MCH service records)

Disaggregation

- Age (<15, 15–19, 20–24, 25+ years)
- Timing of ART initiation (already on ART at first ANC visit, newly on ART during pregnancy or labour and delivery
- Cities and other administrative regions of epidemiologic importance

[1] Or a timeframe matched to median duration of breastfeeding in the country.

VER.6 Final outcome of PMTCT

% of HIV-exposed infants whose final HIV outcome status is known

What it measures

This indicator measures quality of programme follow-up to track exposed infants and ascertain final HIV status.

Rationale

- Effective PMTCT programmes must follow HIV-exposed infants until the end of the breastfeeding period to ensure that the full cascade of services and support is provided to HIV-positive mothers and their infants.
- The ability to ascertain final outcome status through routine programme data across multiple points of care is a key challenge.

Numerator

HIV-exposed infants born within the past 12 months (or 24 months in breastfeeding settings) who have known final HIV outcome status

Denominator

a) **Programme-based/service delivery denominator**

Number of HIV-exposed infants who were born within the 12 months (or 24 months in breastfeeding settings) prior to the reporting period and registered in the birth cohort

For example, for the reporting period January to December 2021 the denominator would be the number of HIV-exposed infants born between January to December 2020 in non-breast feeding settings and January to December 2019 in breastfeeding settings.

b) **Population-based denominator**

Estimated number of HIV-positive women who delivered within the past 12 months (or 24 months in breastfeeding settings)

Method of measurement

For the numerator and programme-based/service delivery denominator: Cohort birth tracking

For the population-based denominator: Modelling-based estimates (for example, Spectrum AIM)

Disaggregation

- Outcome status (HIV-positive, HIV-negative, no longer breastfeeding)
- Cities and other administrative regions of epidemiologic importance

VER.7 HIV prevalence among women attending ANC (NEW)

% of pregnant women who are HIV-positive at the time of their first test during the current pregnancy

What it measures

HIV prevalence among pregnant women attending ANC, including those who were diagnosed with HIV before their first ANC visit and those testing positive during their current pregnancy.

Rationale

HIV prevalence among ANC attendees is used for surveillance to measure HIV prevalence and incidence and to monitor trends in HIV infection when the following conditions are met to ensure that HIV prevalence among ANC clients is consistently representative of HIV prevalence among all pregnant women:

- ANC attendance is high and all women are recorded (for example, not missing large private-sector ANC services).
- HIV testing is offered to all pregnant women and not restricted to only higher-risk women or interrupted due to stock-outs of test kits.
- Only the first HIV test result is used to calculate HIV prevalence during a single pregnancy.
- Women who are already known to be HIV-positive and/or are already on ART prior to their first ANC visit during a pregnancy and, therefore, are not tested for HIV, are recorded and included in routine reporting. All HIV-positive women must be included in both the numerator and denominator when calculating HIV prevalence among pregnant women.

See section 5.2 4 on routine antenatal HIV testing for more detail.

This indicator is also useful for estimating the number of women in need of PMTCT services for programme planning purposes.

Numerator

Number of ANC attendees who tested HIV-positive at their first test during the current pregnancy *plus* number of ANC attendees known to be HIV-positive before their first ANC visit

Denominator

Number of ANC attendees receiving their first HIV test during pregnancy *plus* number of ANC attendees known to be HIV-positive before first ANC visit

Method of measurement

ANC registers, patient monitoring tools, EMRs (for example, patient records)

The recommended reporting period is 12 months.

Disaggregation

- Age (<15, 15–19, 20–24, 25–29, 30–34, 35–39, 40–49, 50+ years)
- HIV status at first test during current pregnancy (known positive, tested HIV-negative, tested HIV-positive, not tested)
- Cities and other administrative regions of epidemiologic importance

8.2.4 TB/HIV

TBH.1 TPT initiation

Number and % of eligible people living with HIV on ART who initiated TB preventive treatment

What it measures

This indicator measures the extent to which people on ART initiated treatment for latent TB infection.

Rationale

- TB preventive treatment (TPT) is a critical component of preventing TB-related morbidity and mortality among people living with HIV.
- In the wake of recent high-level global commitments and targets, this is a critical period to track the progress that countries have made in scaling up TPT coverage.

Numerator

Number of ART patients who initiated TPT during the reporting period

Denominator

Number of ART patients who are eligible for TPT during the reporting period

Method of measurement

For the numerator: Programme records (for example, ART registers)

For the denominator: Formula for determining the number of ART patients who are eligible for TPT during the reporting period

Number of people living with HIV on ART at end of last reporting period

minus

Number of notified HIV-positive TB patients in last reporting period

also minus, where possible

Number of people living with HIV who previously received TPT – actual, if available, or based on country estimate

also minus, where possible number/estimate of people living with HIV not eligible for TPT due to co-morbidities, including active hepatitis, chronic alcoholism and/or neuropathy

Disaggregation

- Gender (female, male, other[1])
- Age (0–4, 5–9, 10–14, 15–19, 20–24, 25–29, 30–34, 35–39, 40–44, 45–49, 50+ years)[2]
- Type of TPT regimen
- Cities and other administrative regions of epidemiologic importance

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● Core indicator

[1] The category of other includes trans and gender diverse people who choose an identity other than male or female.

[2] Recommended in settings with robust electronic health information systems.

TBH.2 TPT completion

Number and % of people living with HIV on ART who completed a course of TB preventive treatment among those who initiated TPT

What it measures

This indicator measures the effectiveness of scaled-up TPT programmes by assessing the proportion of patients who completed the recommended course of TPT.

Rationale

- Many countries have made progress in initiating eligible people living with HIV on TPT. However, rates of TPT completion remain poor or unknown.
- Assessment of TPT completion is a critical element of the TB/HIV cascade of services.

Numerator

Number of ART patients who completed a course of TPT during the reporting period

Denominator

Number of ART patients who initiated any course of TPT during the previous reporting period

Method of measurement

For the numerator and denominator: Programme records (for example, ART registers)

Defining "previous reporting period": For example, for annual reporting of January to December 2021, the previous reporting period is January to December 2020 (except for programmes with 1HP-exclusive national guidelines and implementation, in which case they may use January to December 2021). For quarterly or semi-annual reporting to the national level, the previous reporting period will depend on the TPT regimen and duration defined by national guidelines.

Note: For programmes using continuous isoniazid preventive therapy (IPT), TPT completion is defined as six months of treatment.

Disaggregation

- Gender (female, male, other[1])
- Age (0–4, 5–9, 10–14, 15–19, 20–24, 25–29, 30–34, 35–39, 40–44, 45–49, 50+ years)[2]
- Type of TPT regimen
- ART initiation (<12 months on ART, 12+ months on ART)
- Cities and other administrative regions of epidemiologic importance

● Core indicator

[1] The category of other includes trans and gender diverse people who choose an identity other than male or female.

[2] Recommended in settings with robust electronic health information systems.

TBH.3 TB diagnostic testing type

% of people living with HIV with TB symptoms who receive a rapid molecular test, for example, Xpert MTB/RIF, as a first test for diagnosis of TB

What it measures

This indicator measures the proportion of people living with HIV who screen positive for TB symptoms who receive a recommended test for diagnosis of TB.

Rationale

- People living with HIV should be screened for TB symptoms and, if found positive, be tested for TB.
- WHO recommends rapid-diagnostic molecular tests, for example, Xpert MTB/RIF, as the first test for diagnosis of TB among people living with HIV.

Numerator

Number of people living with HIV and having TB symptoms who were tested using a rapid molecular test (for example, Xpert MTB/RIF) as a first test during the reporting period

Denominator

Number of people living with HIV who are screened for TB and found to have symptoms during the reporting period

Method of measurement

For the numerator and denominator: Programme records (for example, laboratory register for smear microscopy and Xpert MTB/RIF, ART registers)

Disaggregation

- Gender (female, male, other[1])
- Age (0–4, 5–9, 10–14, 15–19, 20–24, 25–29, 30–34, 35–39, 40–44, 45–49, 50+ years)[2]
- Key populations (men who have sex with men, people living in prisons and other closed settings, people who inject drugs, sex workers, trans and gender diverse people)[3]
- Pregnant or breastfeeding women
- Cities and other administrative regions of epidemiologic importance

[1] The category of other includes trans and gender diverse people who choose an identity other than male or female.

[2] Recommended in settings with robust electronic health information systems.

[3] Where feasible and data security and confidentiality can be ensured (see monitoring considerations in section 3.8 on key populations for further guidance and section 6.4 on maintaining data privacy, security and confidentiality).

TBH.4 People living with HIV with active TB disease

% of people living with HIV newly initiated on ART who have active TB disease

What it measures

This indicator measures the burden of active TB disease among people living with HIV who are newly initiated on ART.

Rationale

- Early detection of TB among people living with HIV enables prompt TB treatment and early ART.
- This indicator also measures indirectly the extent of efforts to detect HIV-associated TB.

Numerator

Number of people living with HIV newly initiated on ART during the reporting period who have active TB disease.

"Newly initiated on ART" is defined as the number of people living with HIV who start ART in accordance with national treatment guidelines during the reporting period.

Denominator

Number of people living with HIV new on ART during the reporting period

Method of measurement

For the numerator and denominator: Programme records (for example, pre-ART and ART registers, TB register at the TB management unit)

The recommended national reporting period is 12 months, with monthly or quarterly reporting at subnational levels.

Note: Data are drawn from TB- and HIV-sided services and data sources. This indicator is related to indicator DFT.4. TB diagnosis among those tested for TB. However, the latter covers only TB diagnosed as a result of symptom screening of people living with HIV newly initiated on ART (that is, it does not cover TB cases initiated on ART that were referred from TB clinics).

Disaggregation

- Gender (female, male, other[1])
- Age (0–4, 5–9, 10–14, 15–19, 20–24, 25–29, 30–34, 35–39, 40–44, 45–49, 50+ years)[2]
- Key populations (men who have sex with men, people living in prisons and other closed settings, people who inject drugs, sex workers, trans and gender diverse people)[3]
- Pregnant women or breastfeeding women
- Cities and other administrative regions of epidemiologic importance

[1] The category of other includes trans and gender diverse people who choose an identity other than male or female.

[2] Recommended in settings with robust electronic health information systems.

[3] Where feasible and data security and confidentiality can be ensured (see monitoring considerations in section 3.8 on key populations for further and section 6.4 on maintaining data privacy, security and confidentiality).

DFT.1 TB screening coverage among new ART patients

% of people living with HIV newly initiated on ART who were screened for TB

What it measures

This indicator measures the extent to which people living with HIV newly initiated on ART are screened for active TB disease.

Rationale

- Routine TB screening among people living with HIV newly initiated on ART and those who are already on ART is essential to identifying presumptive TB cases in need of confirmatory diagnostic testing and to determine eligibility for TPT if active TB disease is ruled out.
- Screening is most critical at the time of ART initiation, when immune compromise is greatest. It is most commonly done as a part of pre-treatment clinical assessment.
- It is important to understand the cascade from ART enrolment to treatment of active TB disease; this indicator will highlight any obstacles between ART enrolment and screening for TB symptoms.
- This is the first of five "screening cascade" indicators considered priority for high burden TB/HIV settings.

Numerator

Number of people living with HIV newly initiated on ART who were screened for TB during the reporting period

"Newly initiated" is defined as the number of people living with HIV who start ART in accordance with national treatment guidelines during the reporting period.

Denominator

Number of people living with HIV who newly initiated ART during the reporting period

Method of measurement

For the numerator and denominator: Programme records (for example, ART registers, EMR)

Disaggregation

- Gender (female, male, other[1])
- Age (0–4, 5–9, 10–14, 15–19, 20–24, 25–49, 50+ years)[2]
- Cities and other administrative regions of epidemiologic importance

[1] The category of other includes trans and gender diverse people who choose an identity other than male or female.

[2] Recommended in settings with robust electronic health information systems.

DFT.2 TB symptom-screened positive among new ART patients

% of people living with HIV newly initiated on ART who were screened for TB symptoms and who screened positive

What it measures

This indicator measures the percentage of people living with HIV newly initiated on ART and screened for symptoms of active TB disease who screen positive.

Rationale

- Routine TB screening among people living with HIV newly initiated on ART and those who are already on ART is essential to identifying presumptive TB cases in need of confirmatory diagnostic testing and to determine eligibility for TPT if active TB disease is ruled out.
- Screening positivity rates vary based on background TB prevalence and other epidemiological and environmental factors. However, low screening positivity rates can signal inadequate or poor-quality TB screening, particularly in high burden settings.
- It is important to understand the cascade from ART enrolment to treatment of active TB disease; this indicator will highlight obstacles between ART enrolment and screening for TB symptoms.
- This is the second of five "screening cascade" indicators considered priority for high burden TB/HIV settings.

Numerator

Number of people living with HIV newly initiated on ART who screened positive for TB symptoms

Denominator

Number of people living with HIV newly initiated on ART during the reporting period who were screened for TB symptoms

Method of measurement

"Newly initiated" is defined as the number of people living with HIV who start ART in accordance with national treatment guidelines during the reporting period.

For the numerator and denominator: Programme records (for example, ART registers, EMR)

Disaggregation

- Gender (female, male, other[1])
- Age 0–4, 5–9, 10–14, 15–19, 20–24, 25–49, 50+ years)[2]
- Cities and other administrative regions of epidemiologic importance

[1] The category of other includes trans and gender diverse people who choose an identity other than male or female.

[2] Recommended in settings with robust electronic health information systems.

DFT.3 TB testing among those symptom-screened positive

% of people living with HIV newly initiated on ART and screened positive for TB symptoms who then are tested for TB

What it measures

This indicator measures the percentage of people living with HIV newly initiated on ART and screened positive for TB symptoms who then had clinical evaluation and/or appropriate TB diagnostic testing.

Rationale

- Appropriate TB diagnostic testing is essential for people living with HIV who symptom-screen positive for TB.
- It is important to understand the cascade from ART enrolment to treatment of active TB disease; this indicator will shed light on any obstacles between positive screening for TB symptoms and proper diagnostic testing, based on national clinical guidelines.
- This is the third of five "screening cascade" indicators considered priority for high burden TB/HIV settings.

Numerator

Number of people living with HIV newly initiated on ART who are investigated for active TB disease with appropriate diagnostic testing[1]

Denominator

Number of people living with HIV newly initiated on ART and screened positive for TB symptoms during the reporting period

Method of measurement

"Newly initiated" is defined as the number of people living with HIV who start ART in accordance with national treatment guidelines during the reporting period.

For the numerator and denominator: Programme records (for example, ART registers, EMR)

Disaggregation

- Gender (male, female, other[2])
- Age 0–4, 5–9, 10–14, 15–19, 20–24, 25–49, 50+ years)[3]
- Cities and other administrative regions of epidemiologic importance

Consider disaggregating the type of diagnostic testing, for example, GeneXpert testing, LF-LAM, sputum acid-fast bacilli (AFB) examination (alone) or other diagnostic testing.

[1] "Appropriate diagnostic testing" refers to WHO-recommended testing modalities.

[2] The category of other includes trans and gender diverse people who choose an identity other than male or female.

[3] Recommended in settings with robust electronic health information systems.

DFT.4 TB diagnosis among those tested for TB

% of people living with HIV newly initiated on ART and tested for TB who are diagnosed with active TB disease

What it measures

This indicator measures the percentage of people living with HIV newly initiated on ART and, having screened positive for active TB disease, were evaluated and/or had appropriate TB diagnostic testing and were confirmed to have active TB disease.

Rationale

- Appropriate TB diagnostic testing based on national clinical/WHO guidelines is essential for people living with HIV who screen positive for TB.
- It is important to understand the cascade from ART enrolment to treatment of active TB disease; this indicator will highlight any obstacles between diagnostic testing and TB diagnosis.
- This is the fourth of five "screening cascade" indicators considered priority for high burden TB/HIV settings.

Numerator

Number of people living with HIV newly initiated on ART who were diagnosed as having active TB disease

Denominator

Number of people living with HIV who newly initiated ART and screened positive for TB symptoms who had appropriate diagnostic testing during the reporting period[1]

Method of measurement

"Newly initiated" is defined as the number of people living with HIV who start ART in accordance with national treatment guidelines during the reporting period.

For the numerator: Programme records (for example, ART registers, EMRs)

For the denominator: Programme records (for example, ART registers, EMRs)

Disaggregation

- Gender (female, male, other[2])
- Age (0–4, 5–9, 10–14, 15–19, 20–24, 25–49, 50+ years)[3]
- Cities and other administrative regions of epidemiologic importance

Note: This indicator is related to but distinct from indicator TB.4 Percentage of people living with HIV newly initiated on ART who have active TB disease.

[1] "Appropriate" diagnostic testing refers to WHO-recommended testing modalities.

[2] The category of other includes trans and gender diverse people who choose an identity other than male or female.

[3] Recommended in settings with robust electronic health information systems.

DFT.5 TB treatment initiation among diagnosed

% of people living with HIV newly initiated on ART and diagnosed with active TB who initiated TB treatment

What it measures

This indicator measures the percentage of people living with HIV newly initiated on ART and, having screened positive for TB symptoms and had appropriate TB diagnostic testing that confirmed a diagnosis of active TB disease, then initiated TB treatment.

Rationale

- Once active TB disease is diagnosed, it is essential that TB treatment is promptly initiated and that quality clinical monitoring is provided (according to national clinical guidelines) to ensure treatment completion.
- It is important to understand the cascade from screening to treatment of active TB disease; this indicator will highlight any barriers between diagnosis and treatment.
- This is the fifth of five "screening cascade" indicators considered priority for high burden TB/HIV settings.

Numerator

Number of people living with HIV newly initiated on ART who were diagnosed with TB and who started treatment for active TB disease

Denominator

Number of people living with HIV newly initiated on ART who were diagnosed with active TB disease

Method of measurement

"Newly initiated" is defined as the number of people living with HIV who start ART in accordance with national treatment guidelines during the reporting period.

For the numerator and denominator: Programme records (for example, ART registers, EMRs)

Disaggregation

- Gender (female, male, other)
- Age (0–4, 5–9, 10–14, 15–19, 20–24, 25–49, 50+ years)[2]
- Cities and other administrative regions of epidemiologic importance

[1] The category of other includes trans and gender diverse people who choose an identity other than male or female.

[2] Recommended in settings with robust electronic health information systems.

8.2.5 Differentiated service delivery

DSD.1 Multi-month ARV dispensing (NEW)

% of people living with HIV and currently on ART who are receiving multi-month dispensing of ARV medicine during the reporting period

What it measures

Percentage of all people living with HIV and currently on ART who received a multi-month supply of ARV medicine (as specified below) at their most recent ARV medicine pick-up.

Rationale

- The recommendation for people living with HIV who are established on ART (see "Definitions," below) to receive multiple months of ARV medicines is a key component of care that responds to the needs and preferences of people living with HIV. For people living with HIV who are established on ART, multi-month dispensing has the potential to improve health outcomes and support long-term treatment adherence, while also reducing unnecessary clinic attendance, thus contributing to system efficiency. Broadly, multi-month dispensing can contribute to efforts to achieve the 95–95–95 targets.
- Adoption and rollout of multi-month dispensing as part of national government strategies and plans is increasing. Since 2016 DSD—including the option of multi-month dispensing—is recommended in WHO HIV treatment and public health guidelines. The extent to which these models of care have been scaled up in many countries is uncertain. Reporting on this indicator will support efforts to expand the offer of multi-month dispensing.

Numerator

Number of people living with HIV and currently on ART who received 3 – 5 or >6 months of ARV medicine at their most recent ARV medicine pick-up.

(The number receiving <3 months of ARV supply is also collected, for validation purposes.)

If countries cannot report on the number of months of ARV medicine dispensed by the disaggregations described above, they could, as an alternative, report the total number of people currently on ARV therapy and receiving ≥3 months of ARV medicine at their last medicine pick-up.

Denominator

Number of people living with HIV and currently on ART

Method of measurement

The data for this indicator are collected at the end of the reporting period from facility ARV therapy registers (including ART dispensed outside the facility, for example, at the community level), programme monitoring tools or other databases such as EMR systems. (If data are available from the private sector, these should be included.) Pharmacy ARV dispensing data can also be used for this indicator if EMR systems cover only a fraction of the total number of people living with HIV on ART.

All people currently on ARV therapy should be identified. People who have not received ARV medicine within 28 days of their scheduled medicine pick-up are considered lost to follow-up and should not be counted in the denominator or the numerator. For example, if ARV medicine was provided for three months (12 weeks), the time since the last medicine pick-up should be no longer than 16 weeks (12 weeks plus 28 days).

For the numerator: Registers/EMRs should capture the duration of ARV medicine dispensed for each patient currently on ARV therapy at their most recent medicine pick-up visit. If possible, this should be categorized as <3 months, 3–5 or >6 months and summarized for each age/sex group.

The denominator should match the total number of people currently on ARV therapy at the end of the reporting period.

Note: Multi-month ARV dispensing should not be confused with multi-month prescriptions. Someone who receives a six-month ARV medicine prescription but needs to attend clinic every one or two months for refills would not be counted as receiving multi-month dispensing.

Measurement frequency: Annual for national reporting. Quarterly reporting can be considered to monitor progress of implementation, particularly in the early stages of DSD scale-up and implementation, if feasible in country context and existing data systems.

Disaggregation

- Gender (female, male, other[1])
- Age (0–4, 5–14, 15–24, 25+ years)
- Key populations (men who have sex with men, people living in prisons and other closed settings, people who inject drugs, sex workers, trans and gender diverse people)[2]
- Cities and other administrative regions of epidemiologic importance

[1] The category of other includes trans and gender diverse people who choose an identity other than male or female.

[2] Where feasible and data security and confidentiality can be ensured (see monitoring considerations in section 3.8 on key populations for further guidance and section 6.4 on maintaining data privacy, security and confidentiality).

DSD.2 Uptake of DSD ART models among people living with HIV (NEW)

% of people newly enrolled in DSD ART models among those eligible

What it measures

Uptake of DSD ART models among people living with HIV and currently on ART who are newly eligible for DSD ART

Rationale

- It can be useful to track the uptake of DSD ART models among eligible people living with HIV on ART in order to compare trends in new enrolment in DSD ART over time.
- For facilities with paper-based reporting, collecting a denominator (in this case, number of people on ART newly eligible for DSD ART) would be onerous. Therefore, this measure is a count (no denominator) where paper tools are used.

Numerator

Number of people on ART ***newly*** enrolled in DSD ART models during the reporting period

Denominator

Number of people on ART ***newly*** eligible[1] for DSD ART models during the reporting period. For facilities with electronic health information systems, it is possible to measure uptake as a proportion of all people living with HIV eligible for DSD.

No denominator for facilities with paper-based reporting systems

Method of measurement

Patient monitoring tools (electronic or paper), for example, ART register/EMR

Measurement frequency: quarterly

Disaggregation

- Gender (female, male, other[2])
- Age (0–4, 5–14, 15–24, 25+ years)
- Key populations (men who have sex with men, people living in prisons and other closed settings, people who inject drugs, sex workers, trans and gender diverse people)[3]
- Category of DSD model (group models managed by health care workers, group models managed by clients, individual models based at facilities, and individual models not based at facilities). This requires each DSD ART model of care to be assigned to one of these categories to enable disaggregation.
- Cities and other administrative regions of epidemiologic importance

[1] Eligibility for DSD ART as defined in national guidelines.

[2] The category of other includes trans and gender diverse people who choose an identity other than male or female.

[3] Where feasible and data security and confidentiality can be ensured (see monitoring considerations in section 3.8 on key populations for further guidance and section 6.4 on maintaining data privacy, security and confidentiality).

DSD.3 Coverage of DSD ART models among people living with HIV on ART (NEW)

% of people living with HIV enrolled in DSD ART models among those eligible for DSD ART (for facilities with electronic HIS) or among people living with HIV currently on ART (facilities with paper-based systems) during the reporting period

What it measures

This indicator measures the rollout and implementation of DSD models of ART during the reporting period.

Rationale

- WHO recommends DSD models of care for eligible individuals to ensure that care meets the diversity of needs among people living with HIV.
- This indicator measures whether individuals who are eligible for DSD ART are receiving such services.

Numerator

Number of people living with HIV enrolled in DSD ART models during the reporting period

Denominator

Facilities with electronic health information systems: Number of people living with HIV on ART eligible for DSD ART models during the reporting period

Facilities with paper-based systems: Number of people living with HIV receiving ART at the end of the reporting period

Method of measurement

Patient monitoring tools (electronic or paper), for example ART register/EMR

Coverage measures *all* people living with HIV currently enrolled in DSD ART models, including those newly enrolled and those enrolled in prior reporting periods. For facilities with paper-based reporting, a proxy for the denominator of number of people eligible for DSD ART can be used.

Measurement frequency: quarterly

Disaggregation

- Gender (female, male, other[1])
- Age (0–4, 5–14, 15–24, 25+ years)
- Key populations (men who have sex with men, people living in prisons and other closed settings, people who inject drugs, sex workers, trans and gender diverse people)[2]
- Category of DSD model (group models managed by health care workers, group models managed by clients, individual models based at facilities, and individual models not based at facilities). This requires each DSD ART model of care to be assigned to one of these categories to enable disaggregation.
- Cities and other administrative regions of epidemiologic importance

[1] The category of other includes trans and gender diverse people who choose an identity other than male or female.

[2] Where feasible and data security and confidentiality can be ensured (see monitoring considerations in section 3.8 on key populations for further guidance and section 6.4 on maintaining data privacy, security and confidentiality).

DSD.4 Retention in DSD ART models (NEW)

% of people retained in DSD ART models during the reporting period

What it measures

Retention in DSD ART models among people living with HIV every 12 months after enrolment

This indicator is limited to facilities with electronic health information systems, as reporting would be onerous for facilities with paper-based reporting systems.

Rationale

- As DSD ART is scaled up, it is important to monitor retention on treatment to ensure clinical outcomes at least equivalent with conventional care.

Numerator

Number of people on ART known to be on treatment 12 months after enrolling in a DSD ART model[1] (also at 24, 36, 48, 60 months, etc. after enrolment in the model)

Denominator (for calculation of % ART coverage)

Number of people on ART enrolled in a DSD ART model 12 months ago, excluding individuals who transferred out (also 24, 36, 48, 60 months ago, etc.)

Method of measurement

EMR/electronic information systems

Measurement frequency: quarterly where feasible, maximum annually

Disaggregation

- Gender (female, male, other[2])
- Age (0–4, 5–14, 15–24, 25+ years)
- Key populations (men who have sex with men, people living in prisons and other closed settings, people who inject drugs, sex workers, trans and gender diverse people)[3]
- Cities and other administrative regions of epidemiologic importance

[1] Includes all people living with HIV on ART receiving DSD ART regardless of whether they switch models or there is a reduction in ARV drugs dispensed.

[2] The category of other includes trans and gender diverse people who choose an identity other than male or female.

[3] Where feasible and data security and confidentiality can be ensured (see monitoring considerations in section 3.8 on key populations for further guidance and section 6.4 on maintaining data privacy, security and confidentiality).

DSD.5 Viral suppression among people living with HIV engaged in DSD ART models (NEW)

% of people living with HIV engaged in DSD ART models who have virological suppression

What it measures

Measures HIV viral suppression at six months and 12 months after ART initiation and yearly thereafter among people living with HIV enrolled in DSD ART models

This indicator is limited to facilities with electronic health information systems and would be monitored in addition to viral load suppression by ART cohort for all people living with HIV and on ART.

Rationale

- Enables monitoring of viral load suppression by cohort of people living with HIV enrolled in DSD models for ART and progress towards the third 95 target
- Viral load suppression is also the best available measure of patient adherence to ART.

Numerator

Number of people enrolled in a DSD ART model with at least one routine viral load test during the reporting period who have virological suppression (<1000 copies/mL) at six and 6 months after ART initiation and yearly thereafter (that is, at 24, 36, 48 and 60 months, etc. after ART initiation).

Denominator (for calculation of % ART coverage

Number of people enrolled in a DSD ART model with at least one routine viral load result in a medical or laboratory record during the reporting period

Method of measurement

EMR/electronic information systems

Measurement frequency: quarterly where feasible, at least annually

Disaggregation

- Gender (female, male, other[1])
- Age (0–4, 5–14, 15–24, 25+ years)
- Key populations (men who have sex with men, people living in prisons and other closed settings, people who inject drugs, sex workers, trans and gender diverse people)[2]
- Cities and other administrative regions of epidemiologic importance

[1] The category of other includes trans and gender diverse people who choose an identity other than male or female.

[2] Where feasible and data security and confidentiality can be ensured (see monitoring considerations in section 3.8 on key populations for further guidance and section 6.4 on maintaining data privacy, security and confidentiality)

8.2.6 Sexually transmitted infections

STI.1. Syphilis testing coverage (NEW)

% of people tested for syphilis during the reporting period

What it measures

A: % of **people attending HIV prevention services** who were tested for syphilis during the reporting period

B: % of **people living with HIV** who were tested for syphilis during the reporting period

C: % of **pregnant women** who were tested for syphilis during the reporting period

Rationale

- Measuring the burden of syphilis among people living with HIV and among populations at elevated risk of HIV acquisition can help national planners determine the resources needed to address both diseases.
- Testing pregnant women for syphilis is important for their own health, and it is also the first step in the prevention of vertical transmission of syphilis. Knowing the testing coverage contributes to quality assessment across the full scope of antenatal care services.
- Testing for syphilis identifies individuals who would benefit from treatment.
- Testing coverage measures progress towards scaling up screening/testing and can be used to assess whether national screening guidelines are being followed.

Numerator

Number of people tested for syphilis during the reporting period:

A: Number of **people attending HIV prevention services** tested for syphilis

B: Number of **people living with HIV** tested for syphilis while attending HIV care and treatment services

C: Number of **pregnant women** tested for syphilis while attending ANC services

Denominator

Number of people attending HIV treatment or prevention services during the reporting period:

A: Number of **people attending HIV prevention services**

B: Number of **people living with HIV** attending HIV care and treatment services

C: Number of **pregnant women** attending ANC services

Method of measurement

Individual-level data obtained from programme records

If individual-level data are not available, the indicator can be reported using aggregate programme data. If aggregate data are used and it is not possible to exclude individuals who are tested more than once during the reporting period, the testing coverage estimates will be inflated.

Testing (screening) may be done using either a nontreponemal test (for example, venereal disease research laboratory [VDRL] or rapid plasma reagin [RPR]) or a treponemal test (for example, Treponema pallidum haemagglutination assay [TPHA], Treponema pallidum particle agglutination assay [TPPA], enzyme immunoassay or rapid treponemal test). For this indicator, having either type of test (treponemal or nontreponemal) is sufficient, although being tested with both is preferred.

Disaggregation

- Gender (female, male, other[1])
- Age (15–19, 20–24, 25–29, 30–49, 50+ years)
- Key populations (men who have sex with men, people living in prisons and other closed settings, people who inject drugs, sex workers, trans and gender diverse people)[2]
- HIV status (HIV-positive, HIV-negative, unknown status)
- HIV prevention intervention (for example, PrEP)
- For pregnant women, tested at any visit, tested at first ANC visit
- Cities and other administrative regions of epidemiologic importance

[1] The category of other includes trans and gender diverse people who choose an identity other than male or female.

[2] Where feasible and data security and confidentiality can be ensured (see monitoring considerations in section 3.8 on key populations for further guidance and section 6.4 on maintaining data privacy, security and confidentiality).

STI.2. Syphilis test positivity (NEW)

% of people who tested positive for syphilis during the reporting period

What it measures

A: % of **people attending HIV prevention services** who were tested for syphilis and had a positive syphilis test result during the reporting period

B: % of **people living with HIV** who were tested for syphilis and had a positive syphilis test result during the reporting period

C: % of **pregnant women** who were tested for syphilis and had a positive test result during the reporting period

Rationale

- Syphilis test positivity can be used to identify areas within a country that require additional support and can provide early warning of potential changes in HIV and STI transmission in the general population.
- Syphilis test positivity data are an important source for generating national, regional and global incidence and prevalence estimates for syphilis and congenital syphilis.

Numerator

Number of people who tested positive for syphilis during the reporting period (tested positive on both nontreponemal and treponemal tests or tested positive on either nontreponemal or treponemal test):

A: Number of **people attending HIV prevention services** who tested positive for syphilis

B: Number of **people living with HIV** who tested positive for syphilis

C: Number of **pregnant women** who tested positive for syphilis

Denominator

Number of people tested for syphilis during the reporting period:

A: Number of **people attending HIV prevention services** tested for syphilis

B: Number of **people living with HIV** tested for syphilis while attending HIV care and treatment services

C: Number of **pregnant women** tested for syphilis while attending ANC services

Method of measurement

Individual-level data obtained from programme records

If individual-level data are not available, the indicator can be reported using aggregate programme data.

Syphilis positivity can be a positive treponemal test, a reactive nontreponemal test or a combination of both. It is important to report the testing (screening) algorithm generally used in the country. If both treponemal and nontreponemal test results on an individual person are available, then syphilis positivity should be defined as having positive results in both tests. Collecting information on the testing algorithm used to determine positivity is important so that prevalence estimates can be adjusted to look at trends.

Disaggregation

- Gender (female, male, other[1])
- Age (15–19, 20–24, 25–29, 30–49, 50+ years)
- Key populations (men who have sex with men, people living in prisons and other closed settings, people who inject drugs, sex workers, trans and gender diverse people)[2]
- HIV status (HIV-positive, HIV-negative, unknown status)
- HIV prevention intervention (for example, PrEP service)
- Cities and other administrative regions of epidemiologic importance

[1] The category of other includes trans and gender diverse people who choose an identity other than male or female.

[2] Where feasible and data security and confidentiality can be ensured (see monitoring considerations in section 3.8 on key populations for further guidance and section 6.4 on maintaining data privacy, security and confidentiality).

STI.3. Syphilis treatment coverage (NEW)

% of people tested positive for syphilis who were treated based on national guidelines during the reporting period

What it measures

A: % of **people attending HIV prevention services** who tested positive for syphilis and were treated based on national guidelines during the reporting period

B: % of **people living with HIV** who tested positive for syphilis and were treated based on national guidelines during the reporting period

C: % of **pregnant women** who tested positive for syphilis and were treated based on national guidelines during the reporting period

Rationale

Prompt treatment of individuals positive for syphilis is important for improving their health and reducing sexual and vertical transmission of syphilis.

Numerator

Number of people who tested positive for syphilis and were treated based on national guidelines during the reporting period:

A: Number of **people attending HIV prevention services** who tested positive for syphilis and were treated based on national guidelines

B: Number of **people living with HIV** who tested positive for syphilis and were treated based on national guidelines

C: Number of **pregnant women** who tested positive for syphilis and were treated based on national guidelines

Denominator

Number of people who tested positive for syphilis during the reporting period:

A: Number of **people attending HIV prevention services** who tested positive for syphilis

B: Number of **people living with HIV** who tested positive for syphilis

C: Number of **pregnant women** who tested positive for syphilis

Method of measurement

Individual-level data obtained from programme records

If individual-level data are not available, the indicator can be reported using aggregate programme data.

Disaggregation

- Gender (female, male, other[1])
- Age (15–19, 20–24, 25–29, 30–49, 50+ years)
- Key populations (men who have sex with men, people living in prisons and other closed settings, people who inject drugs, sex workers, trans and gender diverse people)[2]
- HIV status (HIV-positive, HIV-negative, unknown status)
- Cities and other administrative regions of epidemiologic importance

[1] The category of other includes trans and gender diverse people who choose an identity other than male or female.

[2] Where feasible and data security and confidentiality can be ensured (see monitoring considerations in section 3.8 on key populations for further guidance and section 6.4 on maintaining data privacy, security and confidentiality).

STI.4. Gonorrhoea testing coverage (NEW)

% of people tested for gonorrhoea during the reporting period

What it measures

A: % of **people attending HIV prevention services** who were tested for gonorrhoea (molecular test, culture or POC test) during the reporting period

B: % of **people living with HIV** who were tested for gonorrhoea (using a molecular test, culture or POC test) during the reporting period

Rationale

- Infection with an acute bacterial sexually transmitted infection such as gonorrhoea is a marker of unprotected sexual intercourse and facilitates HIV transmission and acquisition.
- Measuring the burden of gonorrhoea among people living with HIV and among populations at risk of HIV can help national planners determine the resources needed to address both diseases.
- Testing for gonorrhoea identifies individuals who would benefit from treatment.
- Testing coverage measures progress towards scaling up screening/testing and can be used to assess whether national screening guidelines are being followed.

Numerator

Number of people tested for gonorrhoea (using a molecular test, culture or POC test) during the reporting period:

A: Number of **people attending HIV prevention services** tested for gonorrhoea (using a molecular test, culture or POC test)

B: Number of **people living with HIV** tested for gonorrhoea (using a molecular test, culture or POC test) while attending HIV care and treatment services

Denominator

Number of people attending HIV treatment or prevention services during the reporting period:

A: Number of **people attending HIV prevention services**

B: Number of **people living with HIV** attending HIV care and treatment services

Method of measurement

Individual-level data obtained from programme records

If individual-level data are not available, the indicator can be reported using aggregate programme data. If aggregate data are used and it is not possible to exclude individuals who are tested more than once during the reporting period, the testing coverage estimates will be inflated.

Disaggregation

- Gender (female, male, other[1])
- Age (15–19, 20–24, 25–29, 30–49, 50+ years)
- Key populations (men who have sex with men, people living in prisons and other closed settings, people who inject drugs, sex workers, trans and gender diverse people)[2]
- HIV status (HIV-positive, HIV-negative, unknown status)
- HIV prevention intervention (for example, PrEP)
- Diagnostic test used and anatomic site sampled
- Cities and other administrative regions of epidemiologic importance

[1] The category of other includes trans and gender diverse people who choose an identity other than male or female.

[2] Where feasible and data security and confidentiality can be ensured (see monitoring considerations in section 3.8 on key populations for further guidance and section 6.4 on maintaining data privacy, security and confidentiality).

STI.5. Gonorrhoea test positivity (NEW)

% of people who tested positive for gonorrhoea during the reporting period

What it measures

A: % of **people attending HIV prevention services** who were tested for gonorrhoea and had a positive test result during the reporting period

B: % of **people living with HIV** who were tested for gonorrhoea and had a positive test result during the reporting period

Rationale

- Gonorrhoea test positivity can be used to highlight areas within a country that require additional support and provide early warning of potential changes in HIV and sexually transmitted infection transmission in the general population.
- Gonorrhoea test positivity is important information for generating national, regional and global incidence and prevalence estimates for gonorrhoea.
- Data on gonorrhoea test positivity are important for understanding the challenges imposed by increasing resistance to currently recommended treatment options.

Numerator

Number of people who tested positive for gonorrhoea during the reporting period:

A: Number of **people attending HIV prevention services** who tested positive for gonorrhoea

B: Number of **people living with HIV** who tested positive for gonorrhoea

Denominator

Number of people tested for gonorrhoea (using a molecular test, culture or POC test) during the reporting period:

A: Number of **people attending HIV prevention services** tested for gonorrhoea (using a molecular test, culture or POC test)

B: Number of **people living with HIV** tested for gonorrhoea (using a molecular test, culture or POC test) while attending HIV care and treatment services

Method of measurement

Individual-level data obtained from programme records

If individual-level data are not available, the indicator can be reported using aggregate programme data.

Disaggregation

- Gender (male, female, other[1])
- Age (15–19, 20–24, 25–29, 30–49, 50+ years)
- Key populations (men who have sex with men, people living in prisons and other closed settings, people who inject drugs, sex workers, trans and gender diverse people)[2]

[1] The category of other includes trans and gender diverse people who choose an identity other than male or female.

[2] Where feasible and data security and confidentiality can be ensured (see monitoring considerations in section 3.8 on key populations for further guidance and section 6.4 on maintaining data privacy, security and confidentiality).

- HIV status (HIV-positive, HIV-negative, unknown status)
- HIV prevention intervention (for example, PrEP)
- Diagnostic test used and anatomic site sampled
- Cities and other administrative regions of epidemiologic importance

STI.6. Gonorrhoea treatment coverage (NEW)

% of people tested positive for gonorrhoea who were treated based on national guidelines during the reporting period

What it measures

A: % of **people attending HIV prevention services** who tested positive for gonorrhoea during the reporting period who were treated based on national guidelines

B: % of **people living with HIV** who tested positive for gonorrhoea in the reporting period who were treated based on national guidelines

Rationale

Prompt treatment of individuals positive for gonorrhoea is important for improving their health and reducing sexual and vertical transmission. Untreated gonorrhoea can result in pelvic inflammatory disease, ectopic pregnancy, infertility, blindness and disseminated disease.

Numerator

Number of people who tested positive for gonorrhoea and were treated based on national guidelines during the reporting period:

A: Number of **people attending HIV prevention services** who tested positive for gonorrhoea and were treated based on national guidelines

B: Number of **people living with HIV** who tested positive for gonorrhoea and were treated based on national guidelines

Denominator

Number of people who tested positive for gonorrhoea (using a molecular test, culture or POC test) during the reporting period:

A: Number of **people attending HIV prevention services** who tested positive for gonorrhoea

B: Number of **people living with HIV** who tested positive for gonorrhoea

Method of measurement

Individual-level data obtained from programme records

If individual-level data are not available, the indicator can be reported using aggregate programme data.

Disaggregation

- Gender (male, female, other[1])
- Age (15–19, 20–24, 25–29, 30–49, 50+ years)
- HIV status (HIV-positive, HIV-negative, unknown status)
- Key populations (men who have sex with men, people living in prisons and other closed settings, people who inject drugs, sex workers, trans and gender diverse people)[2]
- Cities and other administrative regions of epidemiologic importance

[1] The category of other includes trans and gender diverse people who choose an identity other than male or female.

[2] Where feasible and data security and confidentiality can be ensured (see monitoring considerations in section 3.8 on key populations for further guidance and section 6.4 on maintaining data privacy, security and confidentiality).

STI.7. Presence of STI syndrome (NEW)

% of people diagnosed with a particular STI syndrome during the reporting period

What it measures

A: % of **people attending HIV prevention services** who were diagnosed with one of five STI syndromes during the reporting period

B: % of **people living with HIV** who were diagnosed with one of five STI syndromes during the reporting period

Rationale

- Diagnosis and treatment of syndromic STIs improves health, reduces transmission of STIs and contributes to a reduction in the transmission of HIV.
- In most resource-limited settings, the WHO syndromic treatment guidelines are still the standard of care when laboratory diagnosis is not available or where the results will take several days.
- The WHO 2021 guidelines for the management of symptomatic infections covers five syndromes: urethral discharge syndrome, vaginal discharge syndrome, lower abdominal pain, genital ulcer disease syndrome, and anorectal discharge.
- In countries that are looking to start collecting STI syndromic data, the STI syndromes to focus on initially are: urethral discharge syndrome, genital ulcer disease syndrome and vaginal discharge syndrome.

Numerator

Number of people diagnosed with a particular STI syndrome during the reporting period:

A: Number of **people attending HIV prevention services** diagnosed with one or more of the STI syndromes

B: Number of **people living with HIV** diagnosed with one or more of the STI syndromes

Denominator

Number of people attending HIV treatment or prevention services during the reporting period

A: Number of **people attending HIV prevention services**

B: Number of **people living with HIV** attending HIV care and treatment services

Method of measurement

Individual-level data obtained from programme records

If individual-level data are not available, the indicator can be reported using aggregate programme data. If aggregate data are used and it is not possible to exclude individuals who are tested more than once during the reporting period, the testing coverage estimates will be inflated.

Disaggregation

- Gender (female, male, other[1])
- Age (15–19, 20–24, 25–29, 30–49, 50+ years)
- Key populations (men who have sex with men, people living in prisons and other closed settings, people who inject drugs, sex workers, trans and gender diverse people)[2]
- HIV status (HIV-positive, HIV-negative, unknown status)
- HIV prevention intervention (for example, PrEP)
- STI syndrome (urethral discharge syndrome, vaginal discharge syndrome, lower abdominal pain, genital ulcer disease syndrome, and anorectal discharge)
- Cities and other administrative regions of epidemiologic importance

[1] The category of other includes trans and gender diverse people who choose an identity other than male or female.

[2] Where feasible and data security and confidentiality can be ensured (see monitoring considerations in section 3.8 on key populations for further guidance and section 6.4 on maintaining data privacy, security and confidentiality).

STI.8. Repeat diagnosis of STI syndrome (NEW)

% of people diagnosed with a particular STI syndrome who were diagnosed with the same STI syndrome two or more times during the reporting period

What it measures

A: % of **people attending HIV prevention services** who were diagnosed with the same STI syndrome two or more times during the reporting period

B: % of **people living with HIV** who were diagnosed with the same STI syndrome two or more times during the reporting period

Rationale

Presenting with the same STI syndrome two or more times in a short period suggests that an individual was not treated appropriately, has an untreated partner or is practicing unsafe sex.

Numerator

Number of people who were diagnosed with a particular STI syndrome two or more times during the reporting period:

A: Number of **people attending HIV prevention services** diagnosed with a particular STI syndrome two or more times

B: Number of **people living with HIV** diagnosed with a particular STI syndrome two or more times

Denominator

Number of people diagnosed with a particular STI syndrome during the reporting period:

A: Number of **people attending HIV prevention services** diagnosed with a particular STI syndrome

B: Number of **people living with HIV** diagnosed with a particular STI syndrome

Method of measurement

Individual-level data obtained from programme records

Disaggregation

- Gender (female, male, other[1])
- Age (15–19, 20–24, 25–29, 30–49, 50+ years)
- Key populations (men who have sex with men, people living in prisons and other closed settings, people who inject drugs, sex workers, trans and gender diverse people)[2]
- HIV status (HIV-positive, HIV-negative, unknown status)
- HIV prevention intervention (for example, PrEP)
- STI syndrome (urethral discharge syndrome, vaginal discharge syndrome, lower abdominal pain, genital ulcer disease syndrome, or anorectal discharge)
- Cities and other administrative regions of epidemiologic importance

[1] The category of other includes trans and gender diverse people who choose an identity other than male or female.

[2] Where feasible and data security and confidentiality can be ensured (see monitoring considerations in section 3.8 on key populations for further guidance and section 6.4 on maintaining data privacy, security and confidentiality).

8.2.7 Viral hepatitis

HEP.1. HBV test coverage (NEW)

% of people who were tested for hepatitis B surface antigen (HBsAg) during the reporting period (laboratory-based test or rapid test)

What it measures

A: % of **people attending HIV prevention services** who were tested for HBsAg during the reporting period (laboratory-based test or rapid test)

B: % of **people living with HIV** who were tested for HBsAg during the reporting period (laboratory-based test or rapid test)

C: % of **pregnant women** who were tested for HBsAg during the reporting period (laboratory-based test or rapid test)

Rationale

- Measuring the HBV burden among people living with HIV and among populations at risk of HIV can help national planners determine the resources needed to address both diseases.
- Testing pregnant women for HBV in pregnancy is important for their own health, and it is also the first step in the prevention of mother-to-child transmission of HBV. Knowing the testing coverage contributes to quality assessment across the full scope of antenatal care services. This indicator also monitors programmatic targets used for validation in countries with a targeted HBV vaccination birth dose policy.

Numerator

Number of people tested for HBsAg during the reporting period:

A: Number of **people attending HIV prevention services** tested for HBsAg

B: Number of **people living with HIV** tested for HBsAg

C: Number of **pregnant women** tested for HBsAg

Denominator

Number of people attending HIV treatment or prevention services during the reporting period:

A: Number of **people attending HIV prevention services**

B: Number of **people living with HIV** attending HIV care and treatment services

C: Number of **pregnant women** attending ANC services

Method of measurement

Patient monitoring tools (electronic or paper), for example, hepatitis and HIV testing service records, lab registers, logbooks and reporting forms at facility and community levels, EMR/electronic information systems

Disaggregation

- Gender (male, female, other[1])
- Age (15–19, 20–24, 25–29, 30–49, 50+ years)
- HIV status (HIV-positive, HIV-negative, unknown status)
- Key populations (men who have sex with men, people living in prisons and other closed settings, people who inject drugs, sex workers, trans and gender diverse people)[2]
- Provider type (key population-led or community-led organization, public-sector provider, other entities such as private for-profit and not-for-profit organizations, including faith-based, international, nongovernmental)
- Cities and other administrative regions of epidemiologic importance

[1] The category of other includes trans and gender diverse people who choose an identity other than male or female.

[2] Where feasible and data security and confidentiality can be ensured (see monitoring considerations in section 3.8 on key populations for further guidance and section 6.4 on maintaining data privacy, security and confidentiality).

HEP.2. HCV test coverage (NEW)

% of people who were tested for HCV (HCV antibody, HCV RNA or HCV core antigen) during the reporting period (laboratory-based test or rapid test)

What it measures

A: % of **people attending HIV prevention services** who were tested for HCV during the reporting period (laboratory-based test or rapid test)

B: % of **people living with HIV** who were tested for HCV during the reporting period (laboratory-based test or rapid test)

Rationale

- Measuring the hepatitis burden among people living with HIV and in populations at risk can help national planners determine the resources needed to address both diseases. Testing for HCV co-infection among people living with HIV can inform clinicians on the need for further clinical and laboratory evaluation and the need to adapt treatment.
- Disaggregated estimates can point to gaps in diagnosing people infected with HCV.

Numerator

Number of people tested for HCV during the reporting period:

A: Number of **people attending HIV prevention services** tested for HCV (HCV antibody, HCV RNA or HCV core antigen)

B: Number of **people living with HIV** tested for HCV (HCV antibody, HCV RNA or HCV core antigen)

Denominator

Number of people attending HIV treatment or prevention services during the reporting period:

A: Number of **people attending HIV prevention services**

B: Number of **people living with HIV** attending HIV care and treatment services

Method of measurement

Patient monitoring tools (electronic or paper), for example, hepatitis and HIV testing service records, lab registers, logbooks and reporting forms at facility and community levels, EMR/electronic information systems

Disaggregation

- Gender (female, male, other[1])
- Age (15–19, 20–24, 25–29, 30–49, 50+ years)
- HIV status (HIV-positive, HIV-negative, unknown status)
- Key populations (men who have sex with men, people living in prisons and other closed settings, people who inject drugs, sex workers, trans and gender diverse people)[2]
- Provider type (key population-led or community-led organization, public-sector provider, other entities such as private for-profit and not-for-profit organizations, including faith-based, international, nongovernmental)
- Cities and other administrative regions of epidemiologic importance

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● Core indicator

[1] The category of other includes trans and gender diverse people who choose an identity other than male or female.

[2] Where feasible and data security and confidentiality can be ensured (see monitoring considerations in section 3.8 on key populations for further guidance and section 6.4 on maintaining data privacy, security and confidentiality).

HEP.3. HBsAg positivity (NEW)

Percentage of people who were tested for HBsAg and had a positive HBsAg test during the reporting period

What it measures

A: % of **people attending HIV prevention services** who were tested for HBsAg and had a positive HBsAg test result during the reporting period (laboratory-based test or rapid test)

B: % of **people living with HIV** who were tested for HBsAg and had a positive HBsAg test result during the reporting period (laboratory-based test or rapid test)

C: % of **pregnant women** who were tested for HBsAg and had a positive HBsAg test result during the reporting period (laboratory-based test or rapid test)

Rationale

- Testing for HBV identifies HIV and HBV co-infection so that HIV treatment regimens can be adjusted to treat chronic hepatitis B infection as well.
- The HBsAg positivity rate in ANC attendees can be used to monitor the prevalence of HBV in the population and give an indication of the HBV burden.

Numerator

Number of people who tested positive for HBsAg during the reporting period:

A: Number of **people attending HIV prevention services** who tested positive for HBsAg

B: Number of **people living with HIV** who tested positive for HBsAg

C: Number of **pregnant women** who tested positive for HBsAg

Denominator

Number of people who were tested for HBsAg during the reporting period:

A: Number of **people attending HIV prevention services** who were tested for HBsAg

B: Number of **people living with HIV** tested for HBsAg

C: Number of **pregnant women** tested for HBsAg

Method of measurement

Patient monitoring tools (electronic or paper), for example, hepatitis and HIV testing service records, lab registers, logbooks and reporting forms at facility and community levels, EMR/electronic information systems

Disaggregation

- Gender (female, male, other[1])
- Age (15–19, 20–24, 25–29, 30–49, 50+ years)
- HIV status (HIV-positive, HIV-negative, unknown status)
- Key populations (men who have sex with men, people living in prisons and other closed settings, people who inject drugs, sex workers, trans and gender diverse people)[2]
- Provider type (key population-led or community-led organization, public-sector provider, other entities such as private for-profit and not-for-profit organizations, including faith-based, international, nongovernmental)
- Cities and other administrative regions of epidemiologic importance

[1] The category of other includes trans and gender diverse people who choose an identity other than male or female.

[2] Where feasible and data security and confidentiality can be ensured (see monitoring considerations in section 3.8 on key populations for further guidance and section 6.4 on maintaining data privacy, security and confidentiality).

HEP.4. HCV positivity (NEW)

% of people with a positive HCV test result (HCV antibody, HCV RNA (PCR) or HCV core antigen) during the reporting period

What it measures

A: % of **people attending HIV prevention services** who were tested for HCV during the reporting period (laboratory-based test or rapid test)

B: % of **people living with HIV** who were tested for HCV during the reporting period (laboratory-based test or rapid test)

Rationale

Many people living with HIV and receiving ART die from liver disease resulting from untreated HCV. Testing people living with HIV for HCV identifies HIV and HCV co-infection and allows for adaptation of treatment. Highly effective hepatitis C treatment is newly available; it has a high rate of virus clearance regardless of hepatitis C virus subtype.

Numerator

Number of people newly[1] identified with a positive HCV test result (HCV antibody, HCV RNA (PCR) or HCV core antigen) during the reporting period:

A: Number of **people attending HIV prevention services** newly identified with a positive HCV test

B: Number of **people living with HIV** newly identified with a positive HCV test

Denominator

Number of people who were tested for HCV during the reporting period:

A: Number of **people attending HIV prevention services** who were tested for HCV

B: Number of **people living with HIV** who were tested for HCV

Method of measurement

Patient monitoring tools (electronic or paper), for example, hepatitis testing and HIV service records, lab registers, logbooks and reporting forms at facility and community levels, EMR/electronic information systems

Disaggregation

- Gender (female, male, other[2])
- Age (15–19, 20–24, 25–29, 30–49, 50+ years)
- HIV status (HIV-positive, HIV-negative, unknown status)
- Key populations (men who have sex with men, people living in prisons and other closed settings, people who inject drugs, sex workers, trans and gender diverse people)[3]
- Provider type (key population-led or community-led organization, public-sector provider, other entities such as private for-profit and not-for-profit organizations, including faith-based, international, nongovernmental)
- Cities and other administrative regions of epidemiologic importance

[1] Among persons tested regularly at short time intervals, seroconversion to anti-HCV suggests a recent HCV infection. Seroconversion to anti-HCV should be followed by a reflex RNA test (when available).

[2] The category of other includes trans and gender diverse people who choose an identity other than male or female.

[3] Where feasible and data security and confidentiality can be ensured (see monitoring considerations in section 3.8 on key populations for further guidance and section 6.4 on maintaining data privacy, security and confidentiality).

HEP.5. HBV treatment among people living with HIV (NEW)

% of people living with HIV and diagnosed with HBV infection who are on TDF-based ART

What it measures

Percentage of people living with HIV and infected with HBV who are currently on treatment

Rationale

- The prevalence of HBV is high among people living with HIV.
- The use of tenofovir offers good potential for harmonizing treatment across different populations, as tenofovir + lamivudine (or emtricitabine) is the preferred nucleoside reverse transcriptase inhibitor (NRTI) backbone for persons coinfected with HIV and HBV and also can be used among persons with TB and pregnant women.

Numerator

Number of people newly started on HBV treatment (TDF) during the reporting period +
Number of people living with HIV who are already on TDF-based ART

Denominator

Number of people living with HIV who were diagnosed with HBV

Method of measurement

Patient monitoring tools (electronic or paper), EMR/electronic information systems

Disaggregation

- Gender (male, female, other[1])
- Age (15–19, 20–24, 25–29, 30–49, 50+ years)
- Key population (men who have sex with men, people living in prisons and other closed settings, people who inject drugs, sex workers, trans and gender diverse people)[2]
- Cities and other administrative regions of epidemiologic importance

[1] The category of other includes trans and gender diverse people who choose an identity other than male or female.

[2] Where feasible and data security and confidentiality can be ensured (see monitoring considerations in section 3.8 on key populations for further guidance and section 6.4 on maintaining data privacy, security and confidentiality).

HEP.6. HCV treatment among people living with HIV (NEW)

% of people living with HIV and diagnosed with HCV infection who initiated HCV treatment (direct acting antivirals) during the reporting period

What it measures

Measures the number of people living with HIV and diagnosed with HCV infection who were evaluated for hepatitis disease progression, were found to be eligible for treatment and were placed on treatment.

Rationale

The prevalence of HCV is high, especially among people living with HIV who inject drugs. Treating people living with HIV for HCV improves quality of life and life expectancy and reduces mortality. Trends over time reflect progress in treating patients.

Disaggregation can indicate degree of equity in enrolment of specific priority populations.

Numerator

Number of people living with HIV newly started on HCV treatment during the reporting period

Denominator

Number of people living with HIV diagnosed with HCV during the reporting period

Method of measurement

Patient monitoring tools (electronic or paper), EMR/electronic information systems

Disaggregation

- Gender (female, male, other[1])
- Age (15–19, 20–24, 25–29, 30–49, 50+ years)
- Key populations (men who have sex with men, people living in prisons and other closed settings, people who inject drugs, sex workers, trans and gender diverse people)[2]
- Cities and other administrative regions of epidemiologic importance
- Medicine type (interferon or direct acting antivirals)

[1] The category of other includes trans and gender diverse people who choose an identity other than male or female.

[2] Where feasible and data security and confidentiality can be ensured (see monitoring considerations in section 3.8 on key populations for further guidance and section 6.4 on maintaining data privacy, security and confidentiality).

HEP.7. HCV cured among people living with HIV (NEW)

% of people living with HIV and co-infected with HCV who were confirmed to be cured of HCV during the reporting period

What it measures

Measures how many are cured among all those who completed treatment.

Rationale

Short courses of HCV treatment with direct acting antivirals (DAAs) lead to cure in >90% of patients and reduce mortality. Information on sustained viral response (cure) for HCV will measure treatment effectiveness and provide an incentive system, for example, cure certificates.

Numerator

Number of people living with HIV diagnosed with HCV infection who have completed HCV treatment and had a sustained virological response (SVR). SVR is assessed by a viral load measurement 12–24 weeks after the end of treatment.

Denominator

Number of people living with HIV and co-infected with HCV who completed HCV treatment and were assessed for sustained virological response

Method of measurement

Programme records, cohort studies, patient monitoring tools (electronic or paper), EMR/electronic information systems, combined with best estimates for the population with no viral load data

Disaggregation

- Gender (female, male, other[1])
- Age (15–19, 20–24, 25–29, 30–49, 50+ years)
- Key populations (men who have sex with men, people living in prisons and other closed settings, people who inject drugs, sex workers, trans and gender diverse people)[2]
- Cities and other administrative regions of epidemiologic importance
- Medicine type (interferon or direct acting antivirals)

[1] The category of other includes trans and gender diverse people who choose an identity other than male or female.

[2] Where feasible and data security and confidentiality can be ensured (see monitoring considerations in section 3.8 on key populations for further guidance and section 6.4 on maintaining data privacy, security and confidentiality).

8.2.8 Cervical cancer

CCA.1 Cervical cancer screening (NEW)

Number of women living with HIV who were screened for cervical cancer using any screening test

What it measures

Progress towards scaling up population-based screening for the prevention of cervical cancer among women living with HIV.

Rationale

To measure progress towards scaling up screening for the prevention of cervical cancer among women living with HIV. Since the screening interval between tests depends on the test used, the number of women screened may vary from year to year.

Numerator

Number of women living with HIV who were screened for cervical cancer using any screening test (HPV DNA test, visual inspection with acetic acid, cytology, other)

Denominator

NA

Method of measurement

Health facility patient registers, patient records

The number is generated by counting the number of women living with HIV among all women who were screened for cervical cancer in the last 12 months, using health facility patient registers or patient records as the source.

Each individual should be counted only once in the reporting period. If a second triage test or a follow-up test was performed as part of the screening strategy, that individual should be counted only once.

Disaggregation

- Age (15–19, 20–24, 25–29, 30–49, 50+ years)
- Lifetime screening test number (First in lifetime, second in lifetime, etc.)
- Cities and other administrative areas of epidemiologic importance

CCA.2 Pre-invasive cervical disease treatment (NEW)

% of women living with HIV who screened positive for pre-invasive cervical disease and received treatment for it

What it measures

Progress towards the treatment coverage target of 90% of women with a positive screening test receiving treatment as defined in the Global Strategy for cervical cancer elimination.

Rationale

- To assess availability, access and coverage of pre-invasive cervical disease treatment among women living with HIV who were diagnosed with precancerous lesions upon screening and were deemed eligible for precancer treatment in line with the WHO recommendations for screening and treatment to prevent cervical cancer.
- The WHO Global Strategy targets to eliminate cervical cancer are to vaccinate 90% of eligible girls against human papillomavirus (HPV), to screen 70% of eligible women at least twice in their lifetimes and to effectively treat 90% of those with a positive screening test or a cervical lesion, including palliative care when needed, all by 2030.

Numerator

Number of women living with HIV who received treatment after screening positive for pre-invasive cervical disease and were deemed eligible for treatment in line with the WHO recommendations

Denominator

Number of women living with HIV who screened positive for pre-invasive cervical disease.

Method of measurement

Health facility patient registers, patient records

Treatment options include thermal ablation, cryotherapy and excision treatment including Large Loop Excision of the Transformation Zone therapy.

Disaggregation

- Age (15–19, 20–24, 25–29, 30–49, 50+ years)
- Provider type (public-sector provider, private-sector provider)
- Cities and other administrative areas of epidemiologic importance

CCA.3 Invasive cervical cancer treatment (NEW)

% of women living with HIV diagnosed with invasive cancer who were treated

What it measures

Progress towards increasing access to treatment for invasive cervical cancer for women living with HIV

Rationale

The purpose of this indicator is to assess trends in availability and access to treatment services for invasive cervical cancer for women living with HIV. In the longer run, it is expected that the number of women living with HIV who received treatment for invasive cervical cancer will plateau and slowly decrease, as screening programmes expand detection and treatment of precancerous lesions, and coverage of human papillomavirus (HPV) vaccination increases in line with the WHO Global Strategy 90–70–90 elimination targets.

Numerator

Number of women living with HIV who received treatment after being diagnosed with invasive cervical cancer

Denominator

Number of women living with HIV who were diagnosed with invasive cervical cancer

Method of measurement

The number is generated from programmatic data from HIV or cervical cancer programmes, or from a national cancer registry, if HIV status is recorded there.

Disaggregation

- Age (15–19, 20–24, 25–29, 30–49, 50+ years)
- Invasive cervical cancer treatment episode (1st in lifetime, 2nd, 3rd, 4th, etc.)
- Treatment type (medical, surgical)
- Cities and other administrative areas of epidemiologic importance

CCA.4 Cervical cancer survival (NEW)

Crude probability of surviving 1 year after a diagnosis of cervical cancer

What it measures

This indicator measures the effectiveness of cervical cancer treatment for women diagnosed with cervical cancer.

Rationale

- Surveillance of cervical cancer survival among women living with HIV is essential in monitoring the access and effectiveness of treatment and follow-up to support the needs of cancer survivors. Adequate and complete follow-up is a prerequisite to conducting a survival study.
- It is calculated by assessing the percentage of women living with HIV who were diagnosed with invasive cervical cancer who were still alive 12 months after their cervical cancer diagnosis. It excludes those who were not followed for the 12-month period. In places with good retention and follow-up, 5-year survival can also be calculated, including only those individuals under observation with complete follow-up five years after their diagnosis of cervical cancer.

Numerator

Number of women living with HIV still alive 12 months after receiving a diagnosis of invasive cervical cancer

Denominator

Number of women living with HIV who received a diagnosis of invasive cervical cancer within a 12-month cohort observation period

Method of measurement

This indicator uses a cohort analysis to measure the proportion of women living with HIV who are still alive 12 months after their diagnosis with cervical cancer.

The source of data is Individual-level data obtained from programme records.

Disaggregation

- Age (15–19, 20–24, 25–29, 30–49, 50+ years)
- Cervical cancer stage at diagnosis (0, I, II, III, IV)
- Cities and other administrative areas of epidemiologic importance

8.2.9 HIV incidence

INC.1 HIV incidence

Estimated number of people newly infected with HIV per 1000 uninfected population

What it measures

This indicator measures progress towards ending the HIV/AIDS epidemic and achieving the goal of "zero new infections".

Rationale

The overarching goal of the global HIV/AIDS response is to reduce the number of people newly infected to fewer than 200 000 by 2030.

Numerator

Number of people newly infected with HIV during the reporting period

Denominator

Total number of uninfected population (or person-years exposed)

Method of measurement

Can be measured from individual-level programme data using methods described in Chapter 5

Mathematical modelling tools, such as Spectrum AIM, can also provide estimates of HIV incidence. These models incorporate data from geographical and population-specific surveys and other forms of surveillance data (for example, case reporting; mortality, programme and clinical data) and assumptions about HIV transmission.

Disaggregation

- Gender (female, male, other[1])
- Age (0–4, 5–9, 10–14, 15–19, 20–24, 25-29, 30-34, 35-39, 40-44, 45-49, 50+ years)
- Probable route of transmission[2] (Heterosexual sex, sex between men, unprotected intercourse during sex work, injecting drug use with unsterile equipment, nosocomial, vertical, other[3])
- Key populations[2] (men who have sex with men, people living in prisons and other closed settings, people who inject drugs, sex workers, trans and gender-diverse people) and adolescent girls and young women

● Core indicator

[1] The category of other includes trans and gender diverse people who choose an identity other than male or female.

[2] Where feasible and data security and confidentiality can be ensured (see considerations in section 5.1.1 for further guidance and section 6.4 on maintaining data privacy, security and confidentiality).

[3] The category of other may include needle accidents, blood transfusion, blood products or organ/tissue donations, tattoos, piercings, circumcision, or acupuncture.

8.2.10 AIDS-related mortality

MOR.1 AIDS mortality

Total number of people who have died from AIDS-related causes per 100 000 population

What it measures

This indicator measures the impact of HIV prevention, care and treatment programmes.

Rationale

In the era of "Treat All", effective diagnosis and treatment of people living with HIV should greatly reduce deaths due to AIDS-related causes.

Numerator

Estimated number of people dying from AIDS-related causes during the calendar year

Denominator

Total population, regardless of HIV status

Method of measurement

Individual-level programme data, civil registration and vital statistics records or other registries.

Mathematical modelling, such as Spectrum AIM, can also be used. Modelling tools require demographic data, HIV prevalence, the number of people receiving ART, HIV incidence and assumptions concerning survival rates. Additional data from verbal autopsy and/or data from vital reporting systems (and related estimates of underreporting and misclassification) may be used as inputs.

Disaggregation

- Gender (female, male, other[1])
- Age (0–4, 5–9, 10–14, 15–19, 20–24, 25–49, 50+ years)
- Key populations (men who have sex with men, people living in prisons and other closed settings, people who inject drugs, sex workers, trans and gender diverse people)[2]

● Core indicator

[1] The category of other includes trans and gender diverse people who choose an identity other than male or female.

[2] Where feasible and data security and confidentiality can be ensured (see monitoring considerations in section 3.8 on key populations for further guidance and section 6.4 on maintaining data privacy, security and confidentiality).

8.2.11 Stigma and discrimination

SDC.1 Avoidance of health care due to stigma and discrimination (key populations)

% of key population members who avoid health care because of stigma and discrimination.

What it measures

This indicator measures the extent to which perceived stigma and discrimination in health care settings results in members of key populations avoiding health care.

Rationale

- Health care settings are one of the most common places that members of key populations experience discrimination.
- Tracking the proportion of key populations that avoid health care due to stigma and discrimination provides managers with information about where to focus efforts to reduce discrimination and perceived discrimination by service providers as well as identifying areas where service utilization by members of key populations can be improved.

Numerator

Number of survey respondents from key populations who answer "yes" to any of the following: "Have you ever avoided seeking…A. any health care, B. HIV testing, C. HIV medical care, or D. HIV treatment, in the last 12 months due to any of the following: 1. fear of or concern about stigma, 2. fear or concern that someone may learn you were a [insert key population type], 3. fear of or concern about or experience of violence, 4. fear of or concern about or experience of harassment or arrest by police?

Denominator

Number of survey respondents from key populations

Method of measurement

Representative surveys of key populations (for example, BBS, BSS, HSS+)

Recommended measurement periodicity is every 2–3 years.

Disaggregation

- Age (<25, 25+)
- Key populations (men who have sex with men, people who inject drugs, sex workers, trans and gender diverse people)[1]

[1] Where feasible and data security and confidentiality can be ensured (see monitoring considerations in section 3.8 on key populations for further guidance and section 6.4 on maintaining data privacy, security and confidentiality)

SDC.2 Avoidance of health care due to stigma and discrimination (people living with HIV)

% of people living with HIV who avoid health care because of stigma and discrimination

What it measures

This indicator measures the extent to which perceived stigma and discrimination in health care settings cause people living with HIV to avoid seeking health care.

Rationale

- Health care settings are one of the most common places that people living with HIV and those perceived to be living with HIV experience discrimination.
- Tracking the proportion of people living with HIV who avoid health care due to stigma and discrimination provides managers with information about where to focus efforts to reduce discrimination and perceived discrimination by service providers as well as identifying areas where service utilization by people living with HIV can be improved.

Numerator

Number of survey respondents living with HIV who answer "yes" to any of the following: Have you ever avoided seeking… A. health-care, B. HIV testing, C. HIV medical care, or D. HIV treatment, in the last 12 months …due to any of the following: 1. fear of or concern about stigma, 2. fear or concern that someone may learn that you are HIV-positive, 3. fear of or concern about or experience of violence?

Denominator

Number of survey respondents living with HIV

Method of measurement

For the numerator and denominator: Representative surveys of people living with HIV (for example, PLHIV Stigma Index)

Disaggregation

- Age (<25, 25+)

For more information, contact:

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