World Health Organization

GUIDELINES

CONSOLIDATED GUIDELINES ON

PERSON-CENTRED HIV PATIENT MONITORING AND CASE SURVEILLANCE

JUNE 2017

HIV STRATEGIC INFORMATION FOR IMPACT

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Consolidated guidelines on person-centred HIV patient monitoring and case surveillance

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Please send any comments on this guide or suggestions to hiv-aids@who.int.

ABBREVIATIONS AND ACRONYMS

ANC	antenatal care
APMR	annual patient monitoring review
ART	antiretroviral therapy
ARV	antiretroviral (drug)
BMU	basic medical unit
CBO	community-based organization
CHW	community health worker
CPT	co-trimoxazole prophylaxis therapy
CTX	co-trimoxazole
CVD	cardiovascular disease
d4T	stavudine
DHIS	district health information software
DMIS	disease management information system
EBF	exclusively breast fed
EDD	estimated due date (of delivery)
EEA	European Economic Area
EFV	efavirenz
EMR	electronic medical record
EMTCT	elimination of mother-to-child transmission
EU	European Union
EWI	early warning indicator (for HIV drug resistance)
FP	family planning
GAM	Global AIDS Monitoring
GARPR	Global AIDS Response Progress Reporting
HBV	hepatitis B virus
HCV	hepatitis C virus
HEI	HIV-exposed infant
HIVDR	HIV drug resistance
HMIS	health management information system
IATT	Interagency Task Team
ICD	International Statistical Classification of Diseases and Related Health Problems
INH	isonicotinic acid hydrazide
IT	information technology
KP	key population
L&D	labour and delivery
LF-LAM	lateral flow urine lipoarabinomannan assay
LTBI	latent TB infection
LTF	lost to follow up

LQAS	lot quality assurance sampling
M&E	monitoring and evaluation
MIP	mother–infant pair
MNCH	maternal, newborn and child health
MSM	men who have sex with men
NHID	national unique health identifier
MoH	Ministry of Health
MSF	Médecins Sans Frontières
NCD	noncommunicable disease
NGO	nongovernmental organization
OI	opportunistic infection
OST	opioid substitution therapy
PCR	polymerase chain reaction
PEP	post-exposure prophylaxis
PID	personal identification number
PMTCT	prevention of mother-to-child transmission (of HIV)
PrEP	pre-exposure prophylaxes
PWID	people who inject drugs
RH	reproductive health
RPR	rapid plasma reagin (test for syphilis)
SBI	severe bacterial infection
SDG	Sustainable Development Goal
SI	strategic information
STI	sexually transmitted infection
TB	tuberculosis
TI	transfer in
TIER	three interlinked electronic register (system)
TO	transfer out
TPHA	*Treponema pallidum* haemagglutination (test for syphilis)
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
VL	viral load

KEY DEFINITIONS

Case refers to a person with a confirmed diagnosis of HIV who has been reported to an HIV surveillance programme, together with adequate identifying information to enable the person to be uniquely identified over time.

Case report refers to a report of a new HIV case (diagnosis) to a national HIV surveillance programme, as well as to reports of subsequent sentinel events related to existing cases. Case report forms may be completed and submitted manually or electronically; the term "case report form" includes both these options.

HIV case surveillance refers to the systematic reporting and analysis of standardized information about cases diagnosed with HIV to a public health agency responsible for HIV prevention, control and action. Case surveillance is also known as case notification or case reporting.

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

Indicator. In the context of monitoring and evaluation, an indicator is a quantitative or qualitative variable that provides a valid and reliable way to measure achievement, assess performance or reflect changes connected to an activity, project or programme. The sources of data for indicators should be clearly identified.

Integrated care is the 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 for multiple conditions (e.g. HIV, TB, pregnancy, diabetes, etc.) over time.

Linkages in health care are the relationships and processes used to connect two or more services within the same health facility or across facilities for the provision of a patient's care or treatment. By extension, an **interlinked** patient monitoring system can link a single patient across his or her records (patient cards or registers) through identifying data elements such as name, date of birth, sex or unique ID to ensure de-duplication of record-keeping and continuity of care across service delivery points (both programme and facility) and time.

A **patient** is a person who is given medical care or treatment. In the context of this document, a patient is a person living with HIV who is enrolled to receive antiretroviral treatment and/or other HIV-related treatment and care.

Patient management refers to the provision of care and treatment on behalf of and in consultation with a patient over time. Patient management is assisted by patient records (paper-based or electronic) of care provided during previous visits. Patient management may also be referred to as "clinical management" or "clinical monitoring".

Patient monitoring, also called "patient tracking", refers to the routine collection, compilation and analysis of data on patients over time and across service delivery points, using information taken from patient records and registers (either paper-based or entered directly into a computer). The primary purpose of patient monitoring is to enable clinical staff to record and use individual patient data to guide the clinical management of a patient over time and ensure continuity of care between health facilities.

Person-centred monitoring refers to monitoring that places the person at the centre of accessing and measuring a sequence of health services (e.g. from testing to linkage to treatment), and involves people and benefits to them in the monitoring process. In the context of this document, it refers to a shift from measuring services (e.g. the number of HIV tests or people on treatment) to supporting patients, cases and people receiving HIV and health services by putting them at the centre of monitoring. This approach has both benefits for medium-term HIV and chronic health care, and some risks.

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, and provides the overall framework within which both confidentiality and security are implemented.

Programme monitoring refers to the routine tracking of priority information about a programme, including its outputs (e.g. number of people served), quality, gaps and outcomes.

Security refers to technical approaches that address issues related to the physical, electronic and procedural aspects of protecting information collected as part of the scale up of HIV services. Security must address both protection of data from inadvertent or malicious inappropriate disclosure, and ensure availability of data even when there is system failure and user errors.

Sentinel event refers to a predefined event in the context of case surveillance for which relevant data are transmitted to the public health agency responsible for HIV surveillance. Sentinel events may include HIV diagnosis, initiation of antiretroviral treatment, immunological testing such as CD4 count and viral load, and death. Other sentinel events specific to monitoring children or pregnant women may also be included.

Strategic information is information that is interpreted and used for planning and decision-making to improve the direction and focus of a programme. Relevant data may be derived from a variety of sources (e.g. monitoring or surveillance systems, evaluations, programme reviews, surveys and case studies), and should be analysed holistically and strategically to improve the direction of the programme.

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.

Unique identifier is a numeric or alphanumeric code that supports an individual in identifying himself or herself to access a variety of health services. The code should be anonymous, but is linked to a database that has personal information, maintained separately.

INTRODUCTION

01

1. INTRODUCTION

1.1 Context

In 2015, WHO published consolidated guidelines on strategic information for HIV in the health sector, including new indicators organized along the cascade of HIV prevention, testing, treatment and care *(1)*. Those guidelines promote a people-centred approach to strategic information for HIV, which involves a shift from collecting aggregated service-level data (e.g. the number of HIV tests provided) to a focus on people as they receive a cascade of linked services to improve patient care and outcomes.

These guidelines **consolidate guidance on monitoring systems for patients and all cases of HIV as part of public health surveillance.** They recommend the use of unique identifiers to link patients across health services, allowing the sustainable measurement of the cascade of services. The guidelines promote the **use of routine data for patient care and enable reporting on most programme, national and global indicators**, including key global targets for HIV (Box 1.1).

Box 1.1 Global targets for HIV treatment to help end the AIDS epidemic adopted by the WHO Global Health Sector Strategy on HIV, 2016–2021 and UNGASS Declaration targets

90–90–90 target by 2020[1]

- 90% of people living with HIV know their HIV status.
- 90% of people diagnosed with HIV receive antiretroviral therapy.
- 90% of people living with HIV, and who are on treatment, achieve viral load suppression.

Reduction in incidence by 75% by 2020[2]

[1] Fast-track: ending the AIDS epidemic by 2030. Geneva: UNAIDS; 2014 (http://www.unaids.org/sites/default/files/media_asset/JC2686_WAD2014report_en.pdf, accessed 25 March 2017).

[2] 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 General Assembly; 2016 [A/RES/70/266] (http://www.unaids.org/sites/default/files/media_asset/2016-political-declaration-HIV-AIDS_en.pdf, accessed 25 March 2017).

Progressive shift towards person-centred monitoring

The guidance supports **a progressive shift from measuring services (e.g. the number of tests performed or people on treatment) to placing people and their access to linked HIV and health services** (prevention, testing, treatment and chronic care) at the centre of monitoring the health sector response to HIV. This shift can be achieved by putting at the centre of monitoring patients (people receiving medical care), cases (all people aware of their HIV status) and people receiving health services more widely (using unique identifiers).

Strengthening patient- or individual-level monitoring systems will be required to deliver "treat all" and differentiated care *(2)*, and to develop health systems that provide health services to people living with HIV over their lifetime. Specifically for HIV, this approach strengthens the delivery of the cascade of services, with a focus on linkage, retention in care and health outcomes, i.e. monitoring that can support people as they are tested, linked to treatment, retained and supported in different clinics or in the community.

SDGs applied to data

This approach is in line with the focus of the Sustainable Development Goals (SDGs) on people-centred development and "leaving no one behind", applied to data. In particular, two specific SDG targets (17.18 and 17.19) call for the increased availability of disaggregated data and enhanced analysis, and capacity to use data to improve programmes. These guidelines put these SDG targets into practice. There are major benefits of these data for person-centred services to better link services and retain people, along with some risks in terms of data security and confidentiality.

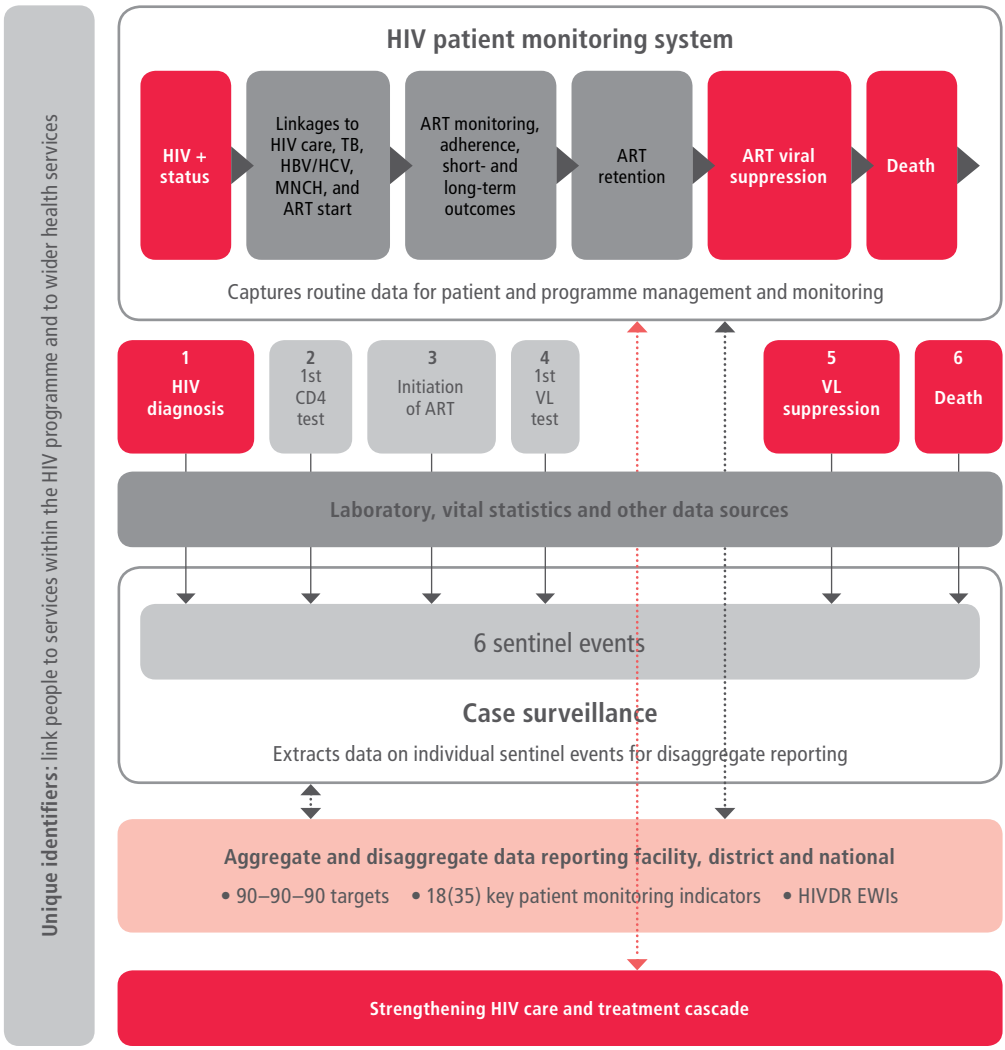
Improved health care

As HIV reporting is further linked to long-term health care over a person's lifetime, these guidelines also define a sustainable, routine monitoring system that:

- promotes the use of routine data for patient care and enables reporting on most programme, national and global indicators in a sustainable manner;
- supports the linkage of HIV patient care to wider health-care needs, and monitoring using unique identifiers and the principles of interoperability of data systems;

The links between HIV patient monitoring and case surveillance as promoted in this guidance are shown in Fig. 1.1.

Fig. 1.1 Links between HIV patient monitoring and case surveillance in a comprehensive strategic information system for HIV



ART: antiretroviral therapy; HBV/HCV: hepatitis B/C virus; MNCH: maternal, newborn and child health; TB: tuberculosis; VL: viral load; HIVDR EWIs: HIV drug resistance early warning indicators

1.2 Objectives of these guidelines

The overarching objective of these guidelines is to support countries in implementing the "treat all" approach and incorporating WHO strategic information indicators for HIV into routine national health information management systems (HMIS). In the short term, the guidance aims to support countries:

- to **update HIV patient monitoring and reporting tools** at the health facility level and expand the use of integrated monitoring tools in settings where treatment and care are integrated (e.g. where ART is provided in settings for maternal, newborn and child health [MNCH] and tuberculosis [TB]). It also aims to strengthen linkages, follow up and retention as patients move between different health facilities;

- to **expand existing HIV surveillance systems** to adopt or strengthen HIV case surveillance approaches that routinely capture and link individual data on all reported cases of HIV over time and from multiple sources. These include HIV testing sites, health facilities, laboratories and vital statistics registries, based on a defined set of sentinel events; and
- to **invest in the adoption or expansion of unique patient identifiers** to link individual patient records between different health services.

Depending on the country context, these guidelines also provide a trajectory for making longer-term progress on the use of routinely collected patient and programme data. These include the following:

- **increased and more sustainable use of routine patient data** – linked by unique identifiers – for patient care and for most ongoing reporting needs, supplemented by surveys and special studies only when necessary;
- **transition from paper to electronic health information systems**, which will support the routine disaggregation of data by time, person and place;
- **increased country capacity to analyse and use routine patient data** to improve programmes, including the delivery of chronic care services overall, particularly in the areas of patient linkage, retention and outcomes; and
- **increased attention to and investment in integrated health and related data systems** with robust technical specifications, policies and interoperability, including systematic measures to ensure data security and protect patient confidentiality.

1.3 Guiding principles

The following broad principles should guide implementation of the approaches described in this document:

- Countries should implement the guidance only after conducting a comprehensive situation analysis of existing strategic information systems. This review should be conducted with a view to developing a plan that progressively upgrades those systems based on national needs, priorities and available resources. The benefits and risks of different approaches need to be specifically assessed, based on country context, in consultation with affected communities, including people living with HIV.
- The use of individual patient data for public health purposes should always be based on strict protocols and procedures to ensure data security and protect patient confidentiality.
- Implementation of this guidance should contribute to the achievement of the 90–90–90 testing and treatment targets and scale up of country health information systems supported by major donors, including the Global Fund to Fight AIDS, Tuberculosis and Malaria and the US President's Emergency Plan for AIDS Relief.

1.4 Target audience

This document is primarily intended for national and subnational HIV programme managers, surveillance officers and other personnel involved in the design and use of monitoring and evaluation (M&E) systems, surveillance and tools for the collection, analysis and use of HIV health sector data. This will include health management information system (HMIS) officers, M&E officers, surveillance officers, data officers, programme managers and facility-based clinical staff. 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.

1.5 Methodology

The guidance in this document was developed by WHO staff and consultants based on document reviews, country situation analyses, consultative meetings and inputs provided by technical experts and partner organizations, including the Joint United Nations Programme for HIV/AIDS (UNAIDS), United States Centers for Disease Control and Prevention, the Global Fund to Fight AIDS, Tuberculosis and Malaria, and implementing countries.

In September 2016, an expert consultation to review and discuss a preliminary draft of this document was hosted by WHO and UNAIDS, with the participation of more than 50 people representing a wide range of countries and partner stakeholders. Participants provided comments on the overall approach to consolidation of the guidance, as well as detailed inputs on the chapters on patient monitoring, HIV case surveillance and unique identifiers. Participants also provided comments on subsequent drafts of the document.

The consultation and the final guidelines have been strongly informed by country examples and experiences. The consultation supported a step-wise approach to strengthening reporting, starting with a situation analysis of country contexts, and costing of improvements.

WHO first published guidance on patient monitoring for HIV care in 2006 *(3)*. An updated and standardized minimum dataset and tools for three interlinked patient monitoring systems for HIV care/ART, MNCH/prevention of mother-to-child transmission (PMTCT) and TB/HIV was published in 2012 *(4)*. Chapter 2 of this document and the related annexes provide an updated minimum dataset, and revised data collection and reporting tools for HIV patient monitoring, including the HIV patient card and ART register. These tools enable the monitoring of all patients in care and on treatment at the facility level.

In 2007, WHO updated the clinical staging of HIV infection in children and adults. This publication aligned the revised HIV staging with epidemiological definitions and included the first published surveillance case definitions for HIV. In 2013, WHO and UNAIDS published updated guidance recommending HIV case surveillance as part of second generation HIV surveillance *(5,6)*. The guidance in Chapter 3 of this document supports countries to progressively expand the scope of case surveillance to include the routine collection of individual patient data based on the six sentinel events.

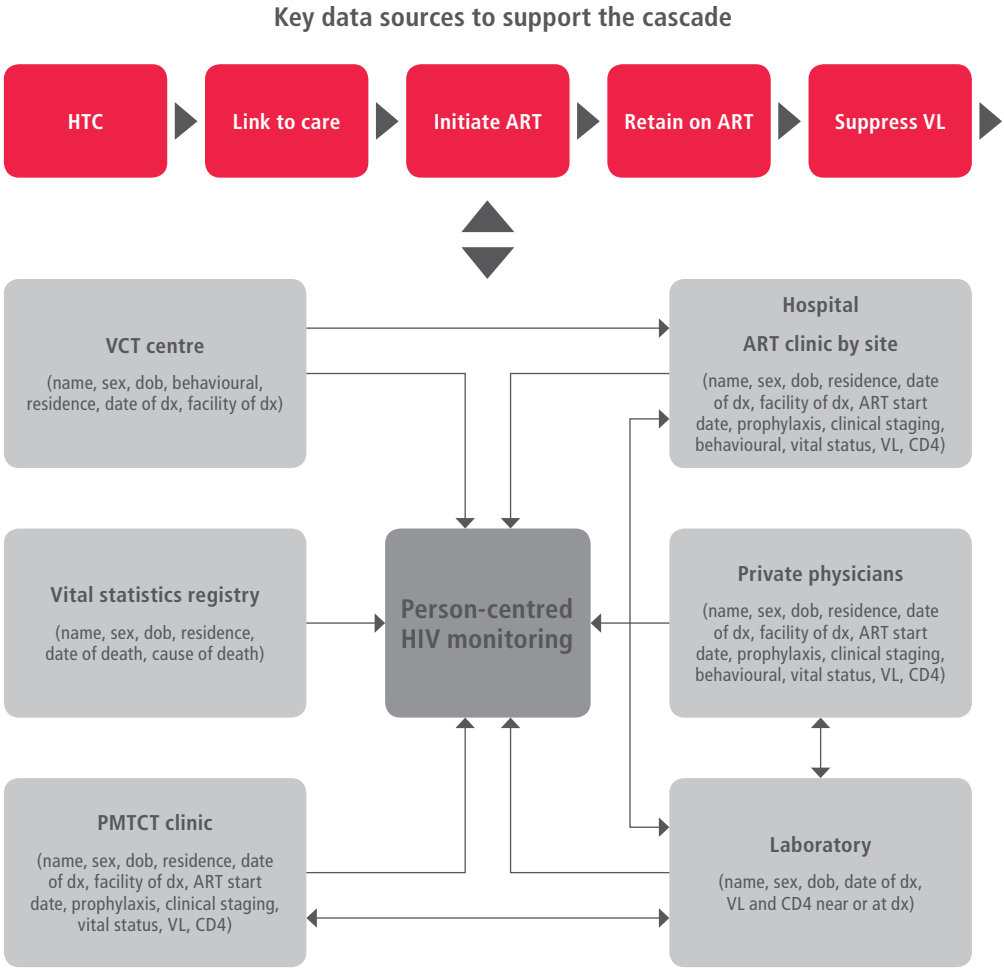
The guidance in the chapter 4 on unique patient identifiers was informed by (i) a three-day expert consultation on strategic information for key population programmes, with a focus on unique identifiers, extrapolation and coverage indicators, hosted by UNAIDS and WHO, and attended by 20 experts in March 2016, and (ii) a three-day "implementation and roadmap" workshop on national health identifiers hosted by WHO and UNAIDS in July 2016.

1.6 Major recommendations in the guidelines

These guidelines address HIV patient monitoring and case surveillance within a consolidated country monitoring system that supports patient care and enables reporting on most programme, national and global indicators. The guidelines describe how to develop a sustainable, routine patient monitoring and surveillance system, which can be supplemented with necessary surveys and special studies as needed. The guidelines are consolidated based on:

- standardized cascade of key sentinel events to support linkage and retention in care and systematic reporting;
- linking and using key data sources to improve care with investments in data systems, unique identifiers, interoperability and security;
- consolidating routine M&E systems for improved health care and for most reporting needs, supplemented by surveys where necessary.

Fig. 1.2 Major data sources required to report on the cascade of services



ART: antiretroviral treatment; dob: date of birth; dx: diagnosis; HTC: HIV testing and counselling; PMTCT: prevention of mother-to-child transmission; VCT: voluntary counselling and testing; VL: viral load

The major data sources are shown in Fig. 1.2, and main recommendations in the guidelines are shown in Table 1.1.

Four graphics at the end of the chapter illustrate the key guideline themes of (1) person-centred health data, (2) consolidated monitoring and evaluation (M&E) for the HIV cascade of services, (3) linking key data sources for long-term care, and (4) consolidated M&E system for care and reporting.

Table 1.1 Major recommendations in the guidelines

1. **Minimum dataset for patient care.** Countries should collect a minimum, standardized set of data necessary for the care and management of persons confirmed to be HIV-positive, a subset of which can be used to report on district, national and global indicators for programme monitoring and management. *WHO provides guidance on a minimum dataset for patient monitoring that reflects updates of the ARV guidelines.*
2. **Transitioning to "treat all".** Consistent with "treat all" and depending on national guidelines, once 90% ART coverage has been attained, countries should transition from using the pre-ART register and collecting HIV care indicators (e.g. indicators from the consolidated strategic information guidelines LINK.2 HIV care coverage, LINK.3 Enrolment in care) to using the ART register and dropping HIV care indicators from reporting requirements. *WHO provides guidance for this transition.*
3. **Simplification of tools.** For paper-based systems, patient monitoring tools (cards, registers and reports) should be simplified and standardized across facilities. *WHO provides generic tools for adaptation.*
4. **Integration and linkages.** Health workers should create a facility-based HIV patient card for every person who is confirmed HIV-positive and subsequently enters into care, regardless of the point of entry, and ART registers should be kept and used at all sites where ART is provided. The HIV card should form part of the facility-held patient folder or passport, and should be integrated with primary health care. *WHO provides a generic HIV patient card and ART register for country adaptation.*
5. **Data quality review and use for quality of care.** Countries should carry out periodic review of the patient monitoring system to collect key additional national and facility-based indicators (for paper-based systems); monitor and assess the quality of data; monitor and improve the quality of care; and collect facility-level early warning indicators (EWI) for HIV drug resistance (HIVDR). *WHO provides guidance on carrying out an annual patient monitoring review and improving the quality of care.*
6. **Standardization of sentinel events and indicators.** Countries should collect core information on a standardized set of sentinel events and indicators, including at a minimum, the six key cascade events described in these guidelines. *WHO provides guidance on key indicators for primarily paper-based monitoring systems and additional indicators for electronic systems or periodic review, especially of patient monitoring tools.*
7. **De-duplication of records to support facilities and improve data quality.** HIV case surveillance should provide de-duplicated counts of diagnosed persons and people on treatment for reporting, to be shared with facilities. *WHO provides guidance on these approaches.*
8. **Country situation analysis.** Improvements to HIV surveillance, patient monitoring and unique identifiers should be based on a country situation analysis that identifies and costs incremental improvements. *WHO provides a tool for country situation analysis.*
9. **HIV diagnosis and building on patient monitoring.** HIV case surveillance should start with the diagnosis of HIV and build on existing patient monitoring systems. *WHO provides guidance on HIV case definitions.*
10. **Key population (KP) data.** Routinely collected data can be used to describe access by key populations to services; however, confidentiality and security issues are paramount when collecting data related to KP, whether in patient monitoring or HIV case surveillance systems. In most settings, patient monitoring records should not include the KP category and any information collected should be used to support patient management and referral to care. The probable route of transmission can be assessed at the point of diagnosis and used to disaggregate data in HIV case surveillance systems. *WHO provides guidance on how to address issues around KP data collection and reporting.*
11. **Promote and use unique identifiers** that replaces names in HIV patient records shared within the national HIV programme. This anonymous code should be linked to their health records. *WHO provides definitions and examples of unique identifiers.*
12. **Transition progressively from paper-based to electronic patient information systems.** Countries should use a tiered approach to when and how patient and case-monitoring data from paper tools will be entered electronically based on resource availability by site or setting, starting with high-volume sites, e.g. with more than 2000 patients. *WHO provides an example of a tiered approach.*

13. **Strengthen and establish different data security levels.** Assess and establish different security levels for data elements, and invest in robust databases and policies to protect security and confidentiality based on risks and benefits in individual settings. *WHO provides the major headings to be included and provides reference to additional specialized guidance.*

14. **Invest in data systems and ensure interoperability.** Countries should invest in robust and secure data systems. As this is being done, strengthen the interoperability of electronic databases and opt for open-source standards for data systems. *WHO recommends that 5–10% of the programme budget be used to strengthen monitoring and evaluation.*

15. **Use individual data to improve programmes and long-term chronic health care.** *WHO recommends that data be linked to programme improvements and that evidence of these improvements be collected.*

- **Strengthen retention and transfer** by supporting the routine sharing of information between clinics.
- **Ensure linkage** by supporting the routine sharing of information between testing, treatment, laboratory, pharmacy and other health services.
- **Strengthen integration with long-term chronic health care** by using unique identifiers to share information and link HIV and wider health services.
- **Invest in data analyst capacity**, including central and district data analysts and routine dashboards to feed back data in real time for programme improvement.

1.7 How to implement the guidance in this document

Feedback from consultations with countries during the development of these guidelines emphasized the need to strengthen existing data systems and use the data collected by them. Improvements should not be introduced as a separate monitoring or surveillance system, but should aim to progressively strengthen and integrate patient monitoring, surveillance of all cases, and the use of unique identifiers to link data in HIV programmes and health systems. In addition, consultations with key populations stressed the importance of assessing the benefits and risks of the use of individual-level data in specific country and policy contexts. People-centred monitoring should be based on the benefits to patients, and they should be consulted on its development.

The guidelines should ideally be introduced in alignment with the timing of reviews of the M&E systems in countries, based on the following:

- **Country situation analysis.** Review current systems and identify incremental improvements and costs, with their risks and benefits. The country situation analysis needs to specifically assess data security and confidentiality, and identify potential patient and programme benefits. WHO provides a Situational assessment toolkit in Annex 3.5.2.
- **Strengthen, link and use data systems.** The first investments should be made in strengthening and securing information systems, and using the data to show programme benefits. This stage should strengthen data security and use, feed real-time data back to decision-making at all levels, and document benefits.
- **Programme improvement and sustainability.** The sustainability of the system and links to health and national data systems should be planned for the short-, medium- and long term, based on a review of benefits and costs. This maturation pathway should address the sustainability of human resources, financing, policies, interoperability and open access, and links of HIV services to the HMIS, and between HIV services as part of the broader health system. Key to this will be evidence of programme benefits, risks, as well as a maturation plan for short-, medium- and longer-term investments, in consultation with key stakeholders.

1.8 Learning from country experience

During consultations for these guidelines in 2016, several countries provided input on their current situation and identified programme improvements that could be achieved with the implementation of these guidelines. Several of these country perspectives are shown in Table 1.2. Country experience strongly informs these guidelines and highlights the importance of performing a situation analysis to guide implementation. Countries are at different stages of implementing approaches to the routine collection of patient data as the basis for strategic information on HIV, including patient monitoring and HIV surveillance systems. Brazil provides an example of an integrated system for routine collection of HIV patient data.

Table 1.2 Examples of country improvements to health information systems

Country	Situation analysis	Programme improvements and issues for further work
Patient monitoring		
Malawi	Health "passport" for all health services. Differentiated system in which all HIV sites with more than 2000 patients use electronic medical records, but most sites are still paper-based. Data are entered into electronic database centrally.	Validated quarterly reporting from routine system for programme management, and major benefits for drug forecasting. Next step is to integrate HIV with national ID and health passport.
Myanmar	Patient monitoring system adapted from generic WHO tools. Patient reporting system initially based on nongovernmental organization (NGO) programmes delivered by Médecins Sans Frontières (MSF).	Strong data on cascade routinely used to highlight gaps and improve late initiation of ART. Facilitates planning and global reporting. Challenge is transition to national system with investments in patient index, interoperability and links to the district health information software (DHIS) 2.
Western Cape, South Africa	Three-tiered patient monitoring system with paper at lowest level, entered into electronic register at district level, and electronic records in 15 sites. Tier.net in 3000 sites, which feeds back to patient management.	Regular, routine reports to facilities on loss to follow up, viral load data to improve patient care and de-duplicate data. Recently developed and implemented integrated (HIV, TB, antenatal care [ANC]) paper-based patient record towards integrated patient care and monitoring.
Zambia	Smartcard system used to link patient records, but does not cover all facilities. Not all facilities linked online; data collected on memory sticks from some sites.	Major benefit of being able to de-duplicate testing and treatment records for improved patient management and more accurate reporting.
Case surveillance		
Brazil (*see* **Box 1.2 and Fig. 1.3**)	Case reporting primarily built for payment purposes, not surveillance. Laboratories require CD4 count and viral load results to receive payment from Ministry of Health. Uses names and includes key population information to assess equal access.	Works well and improves follow up and payment. Major limitation is that system does not include private laboratories. Assesses access to key populations, ensures confidentiality and human rights protection.

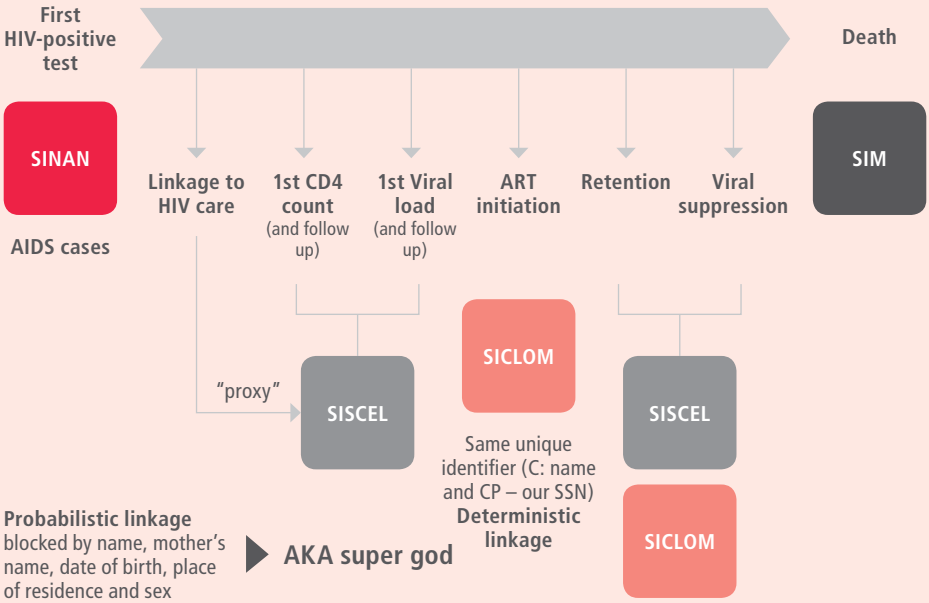
Haiti	Individual case surveillance introduced with single national dataset integrating multiple sources. Data de-duplicated and used to identify transfers. Minimal cost, as built on existing infrastructure and data.	Targeted HIV treatment services as populations migrate seasonally. Better directed prevention resources. Generates routine reporting.
Zimbabwe	Building case surveillance on patient monitoring system. Approximately 80% of records contain unique identifying national insurance number. Need to invest in national database to link facilities.	Major benefits for retention and contacting those lost to follow up, removing those who have gone to other facilities or who have died.
Unique identifiers		
Botswana	Routine use of national unique identification and insurance number for access to all HIV, health and social services.	Easier access, transfer and linkage to a range of HIV and health services.
Thailand	Unique identifiers used based on social insurance; links key databases for patient management.	Improved availability and speed of laboratory test results, improved reimbursement. Gap in data on migrants, who are not covered by national unique identification.

Box 1.2 Integrating systems for routine collection of HIV patient data in Brazil

A linked database that includes SISCEL, SIM, SICLOM and SINAN is used for patient monitoring and case surveillance. Through a statistical method, patients are linked in the different databases by patient name, mother's name, sex and date of birth to allow de-duplication of patients. This integration allows Brazil to monitor HIV infection, almost at the individual level, through all of its stages, starting with the diagnosis or – in the case of an infant – exposure.

- **Notifiable Disease Information System (SINAN).** The purpose of the SINAN system is to record and process data on notifiable diseases throughout Brazil. It collects mandatory notifications of AIDS and, since 2014, HIV cases in Brazil.
- **Mortality Information System (SIM).** This system is fed by data from standard death certificates at state and municipal levels, and gathered by state health departments.
- **Laboratory Test Control System (SISCEL).** This system manages CD4 and viral load tests performed on patients in all public laboratories. It does not collect information on tests performed in the private health-care system.
- **System for Logistic Control of Drugs (SICLOM).** This system manages the logistics of ARV drugs, including stock control and distribution. It stores information on ARVs by patient, including number and dates of dispensing, and type of ARV regimen. More than 97% of people in Brazil receive ART free of charge through the public unified health system (SUS).

Fig. 1.3 Patient clinical monitoring and case surveillance system, using probabilistic linkage in Brazil

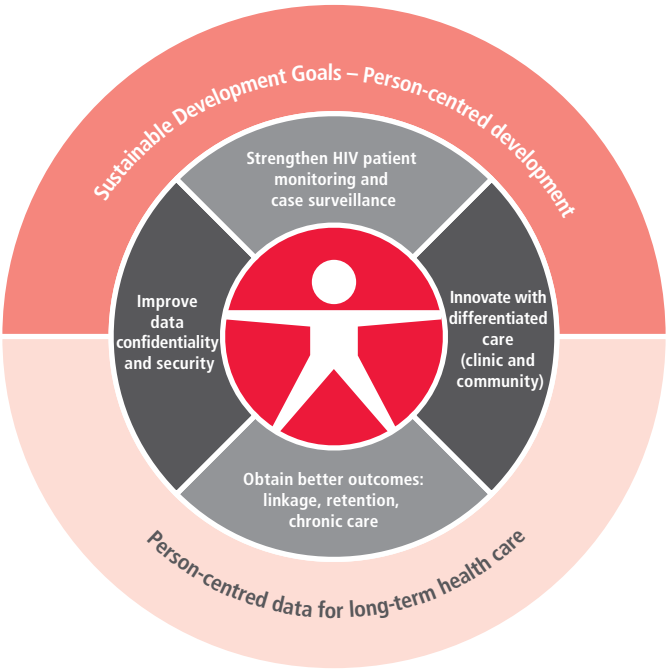


In 2016, the Ministry of Health launched the clinical monitoring report to analyse clinical indicators for patients monitored by the unified health system. Besides the national cascade of continuum of care for HIV, a cascade framework was developed as presented in Fig. 1.4. Linkage to care is disaggregated by age, race and by the five Brazilian regions. Using disaggregated data, an additional cascade has been developed to follow transgender people on ART. The November 2016 report also contains data on HIV diagnosis, treatment, viral suppression, late diagnosis, people who have been diagnosed but are not on ART, CD4 count at ART initiation, the number of patients newly enrolled on ART, ART regimens, number of ARVs and dates dispensed, undetectable viral load after six months on ART, and dispensing of post-exposure prophylaxis. The report may be found at http://www.aids.gov.br/publicacao/2016/relatorio-de-monitoramento-clinico-do-hiv.

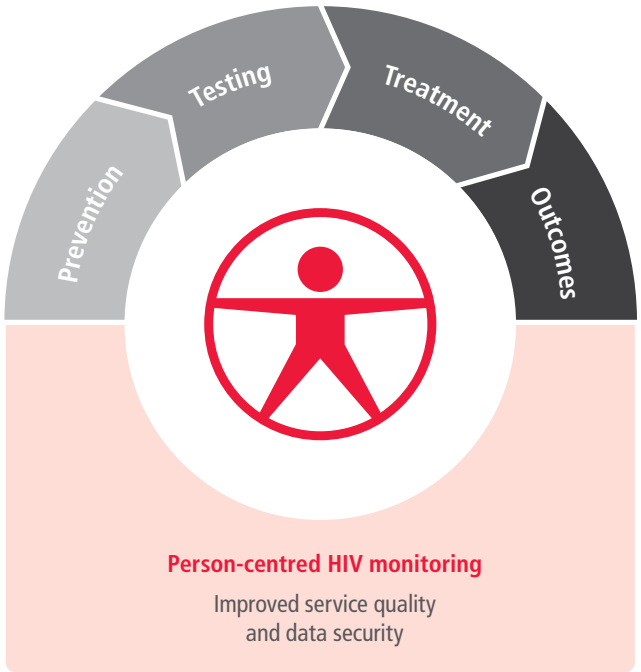
The main challenges facing the information systems are (i) underreporting in SINAN; (ii) use of private health insurance by 26% of the Brazilian population, while the information system covers only the public sector; (iii) incomplete information on exposure category in all systems; (iv) information on key populations; and (v) the lack of a unique identifier across all databases.

Source: Ministry of Health, Brazil

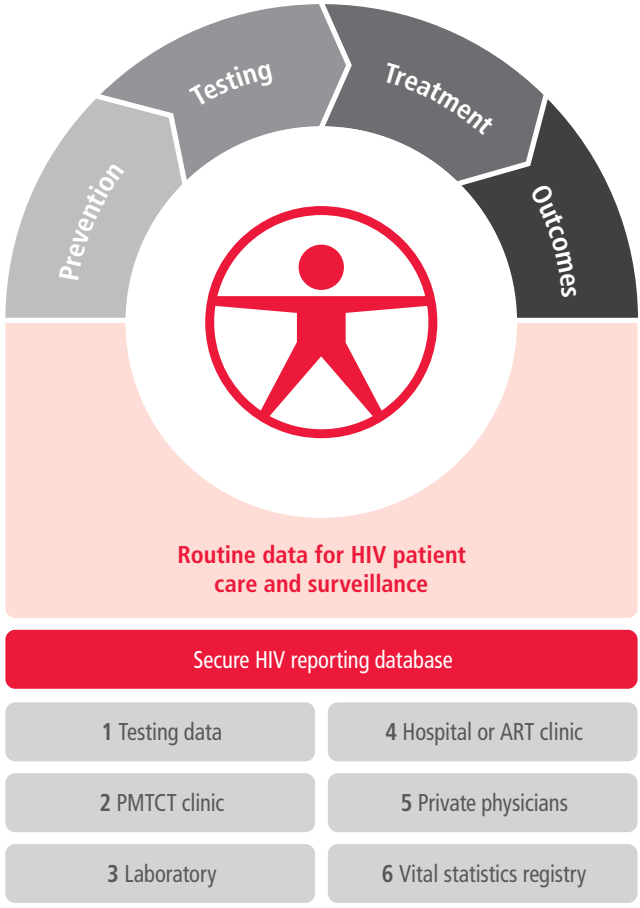
Person-centred health data



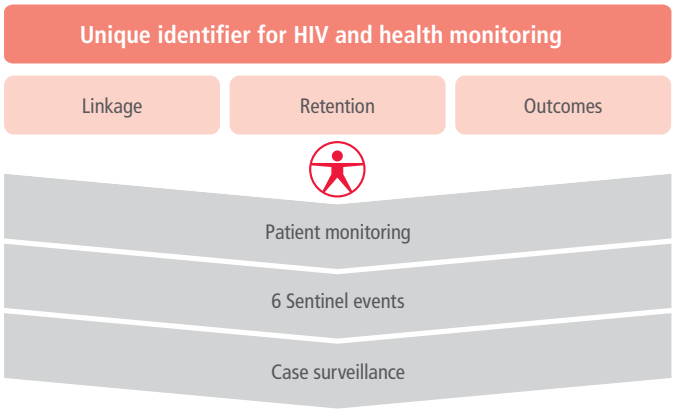
Consolidated M&E for the HIV cascade of services



Linking key data sources for long-term care



Consolidated M&E system for care and reporting



HIV PATIENT MONITORING

02

2. HIV PATIENT MONITORING

Summary of key recommendations in this chapter

1. **Patient care.** Countries should collect a minimum, standardized set of data necessary for the care and management of persons confirmed to be HIV-positive, a subset of which can be used to report on district, national and global indicators for programme monitoring and management. *WHO provides guidance on an updated minimum dataset for patient monitoring that reflects its latest ART guidelines.*

2. **Transition to "treat all".** Consistent with "treat all" and depending on national guidelines, once 90% ART coverage has been attained, countries should transition from using the pre-ART register and collecting HIV care indicators (e.g. indicators from the consolidated strategic information guidelines LINK.2 HIV care coverage, LINK.3 Enrolment in care) to using the ART register and dropping HIV care indicators from reporting requirements. *WHO provides guidance for this transition.*

3. **Simplification of tools.** For paper-based systems, patient monitoring tools (cards, registers and reports) should be simplified and standardized across facilities. *WHO provides generic tools for adaptation.*

4. **Integration and linkages.** Health workers should create a facility-held HIV patient card for every person who is confirmed to be HIV-positive and subsequently enters into care, regardless of the point of entry, and ART registers should be kept and used at all sites where ART is provided. *WHO provides guidance on integration and linkages for a patient monitoring system.*

5. **Data quality and use.** Countries should carry out periodic reviews of the patient monitoring system to collect key additional national and facility-based indicators (for paper-based systems); monitor and assess the quality of data; monitor and improve the quality of care; and collect facility-level early warning indicators (EWI) for HIV drug resistance (HIVDR). *WHO provides guidance on carrying out an annual patient monitoring review and using data to improve the quality of care.*

Additional recommendations relevant to this chapter

6. **Standardization of sentinel events and indicators.** Countries should collect core information on a standardized set of sentinel events and indicators, including at a minimum, the six key cascade events described in these guidelines. *WHO provides guidance on key indicators for primarily paper-based monitoring systems and additional indicators for electronic systems or periodic review, especially of patient monitoring tools.*

7. **Transition progressively from paper-based to electronic patient information systems.** Countries should use a tiered approach to when and how patient and case-monitoring data from paper tools will be entered electronically based on resource availability by site or setting, starting with high-volume sites, e.g. with more than 2000 patients. *WHO provides an example of a tiered approach.*

8. **Country situation analysis.** Improvements to HIV case surveillance, patient monitoring and unique identifiers should be based on a country situation analysis that identifies and costs incremental improvements. *WHO provides a tool for country situation analysis.*

2.1 Introduction

2.1.1 Purpose of HIV patient monitoring

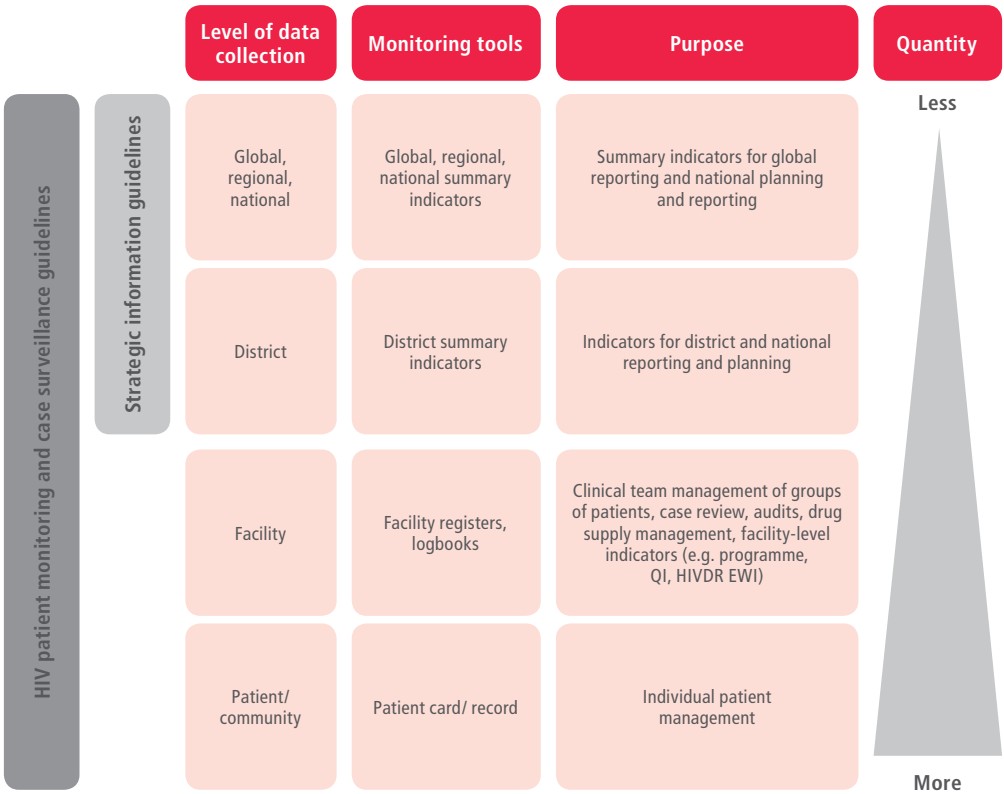
A patient monitoring system serves two main functions:

- It enables effective clinical management of patients.
- It generates data for programme monitoring.

Patient monitoring is essential for ensuring the quality and continuity of HIV care, and treatment for adults, pregnant and breastfeeding women, infants and children. It generates data that enable programmes to monitor the treatment and health status of patients over time, as well as to measure programme performance across health facilities and geographical settings. Because patient monitoring systems inform programme monitoring, they are an integral part of health information systems and the overall health system in many countries, contributing to the delivery of HIV, MNCH/HIV, TB/HIV and other services.

An effective HIV patient monitoring system also permits the measurement of standardized indicators at the subnational and national levels for in-country and global reporting. As discussed in Chapter 3, data routinely collected in health facilities through patient monitoring can also serve as an important source of data for case surveillance. Fig. 2.1 shows the levels of data collected in a patient monitoring system and related tools.

Fig. 2.1 Levels of data collected in the HIV patient monitoring system



EWI: early warning indicators; HIVDR: HIV drug resistance; QI: quality improvement

Source: Adapted from Patient monitoring guidelines for HIV care and antiretroviral therapy (ART). Geneva: WHO; 2006.

While the patient monitoring system produces both quality and quantity indicators (e.g. proportion eligible for co-trimoxazole [CTX] prophylaxis or receiving a viral load test, and number of people on treatment or lost to follow up), it is one among several sources of strategic information on HIV in the health sector. Other data sources for reporting on global, national or subnational indicators may include facility assessments, administrative data, special surveys, population-based surveys and vital registration. The approach to HIV case surveillance described in Chapter 3 both informs and complements patient monitoring by promoting the routine collection of patient data for defined sentinel events from all diagnosed cases of HIV, drawing upon a wider range of sources, including HIV testing sites and laboratories performing CD4 count and viral load testing.

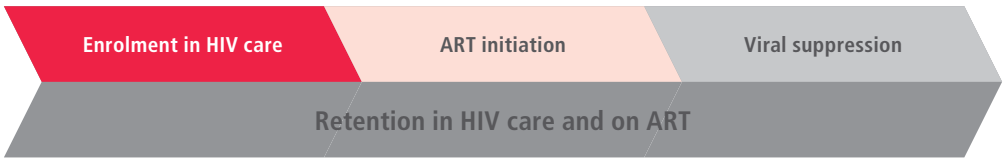
HIV patient monitoring should be integrated as closely as possible with patient monitoring for related conditions, especially for TB, and in all settings where patients are initiated or maintained on ART, including MNCH settings. Over the long term, countries should aim to integrate and/or link HIV patient monitoring with the monitoring of patients receiving care for other chronic conditions. Important issues related to integration and linkage of HIV patient monitoring with other parts of the health system are discussed in more detail in Section 2.4.

2.1.2 What's new in this guidance

The guidance in this chapter will enable national HIV programmes to update their HIV patient monitoring system to better manage, monitor and retain an increasing number of people living with HIV receiving ART over an extended period along the HIV care cascade (Fig. 2.2).

The updated guidance supports the capture of the main elements of clinical management and the cascade of HIV care, aided by monitoring of the most important clinical and programmatic indicators. The guidance provides a standardized, simplified and integrated approach to patient monitoring, with the aim of optimizing HIV treatment linkages, retention and outcomes over the medium term (5–15 years). The patient monitoring system also enables reporting on key subnational, national and global indicators, providing information for decision-making, and optimizing programme and patient outcomes.

Fig. 2.2 The HIV cascade of care within the HIV patient monitoring system



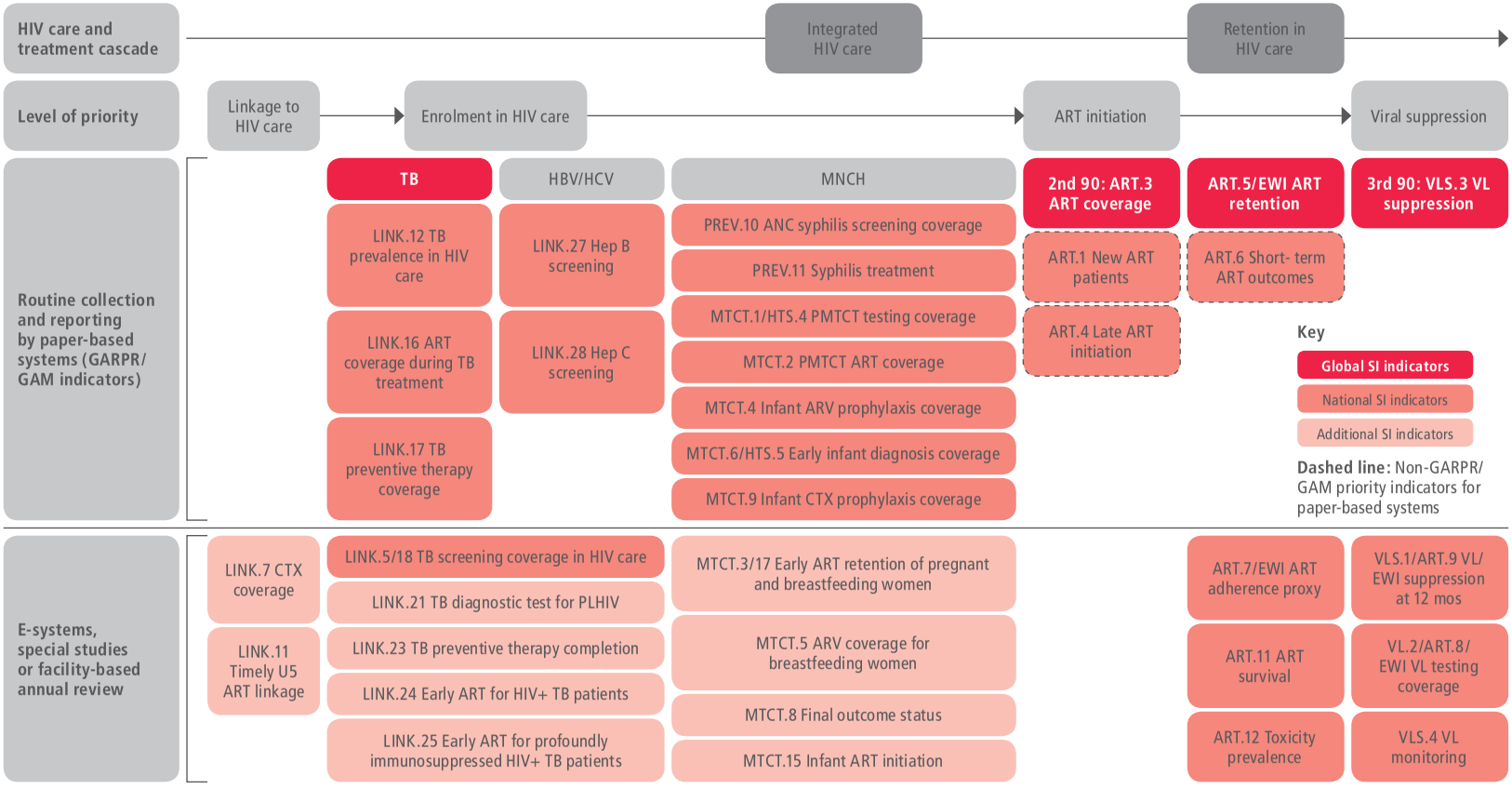
This chapter consists primarily of an update of the 2012 WHO interlinked patient monitoring systems guide and tools *(4)*. The update is based on an extensive review of newly available WHO guidelines and recommendations relevant to the routine patient monitoring system, including the following:

- Updated guidelines on ARVs for treatment and prevention, with new clinical and service delivery recommendations *(2)*:
  - *Treat all confirmed HIV-positive people regardless of CD4 count or clinical stage.* Elimination of assessment for ART eligibility; early initiation of ART in all populations; monitoring of lifelong ART for HIV-positive pregnant women;
  - *Revised ART regimens and codes.* One preferred first-line antiretroviral (ARV) regimen with efavirenz (EFV); discontinuation of stavudine (d4T), and new recommendations for second-line regimens for adults, adolescents and children failing first-line regimens;
  - *Updated infant prophylaxis approaches.* Definition of high-risk infants, and duration and number of ARV drugs for PMTCT in infants;
  - *Changes in routine monitoring and how to diagnose and confirm treatment failure.* Use of CD4 count at baseline only to identify patients with severe or advanced HIV infection (to be fast-tracked, screened for other opportunistic infections [OIs]) and not for follow up; and replacement by routine viral load monitoring at 6, 12, 24, months, etc. and for diagnosing and confirming treatment failure where available;
  - *Updates on how coinfections and comorbidities are assessed and recorded.* Use of CTX prophylaxis, diagnosis and management of TB, including the use of Xpert MTB/RIF and lateral flow urine lipoarabinomannan assay (LF-LAM), and presumptive TB treatment for seriously ill patients; assessing and managing noncommunicable diseases (NCDs), including cardiovascular diseases (CVDs) and depression; and diagnosis, prevention and management of other key co-conditions (viral hepatitis caused by hepatitis B virus [HBV] and hepatitis C virus C [HCV], other sexually transmitted infections [STIs] such as syphilis, and use of opioid substitution therapy [OST] for people who inject drugs [PWID]);
  - *The concept of differentiated care.* This includes recommendations for patient tracking and service delivery, such as decentralization of initiation and maintenance of ART at peripheral health facilities; distribution of ARVs by trained and supervised lay providers as part of community-based care; and reduction in the frequency of clinic visits and medication pick-up for stable patients;
  - *Using HIV patient monitoring tools across service delivery points.* Initiating and maintaining ART in (generalized epidemic) MNCH and (high-burden) TB settings, and settings where OST is provided, with referral and linkage to ongoing HIV care and ART where appropriate;
  - *Collecting information on integrated services within HIV care*. STI and family planning (FP) services can be integrated and TB treatment provided (if the burden is high) in HIV care settings.
- Updated guidelines on strategic information (SI) for HIV with simplified, priority indicators and targets organized in the cascade framework *(1)*:
  - The guidance includes indicators that reference the routine HIV patient monitoring system as a data source in the WHO 2015 Consolidated guidelines on strategic information for HIV in the health sector (Fig. 2.3).

  - These indicators are prioritized to optimize and strategize practical and simplified collection and reporting across the cascade by (i) routine paper-based systems (paper patient cards and registers); and further by (ii) electronic systems (electronic medical records or registers), special studies or annual patient monitoring review. Data elements from the HIV patient card, ART register and reporting tools have been cross-referenced with the numerator or denominator of the SI indicators, and relevant clinical and M&E guidelines to ensure consistency.

- Updates and clinical considerations relevant to HIV patient monitoring from other guidelines, including:
  - WHO 2013 *Definitions and reporting framework for TB (7)* and 2015 *A guide to monitoring and evaluation for collaborative TB/HIV activities (8).*
  - WHO 2014 *Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations (9)* and the WHO 2015 *Supplement tool to set and monitor targets for HIV prevention, diagnosis, treatment, and care for key populations (http://www.who.int/hiv/pub/toolkits/kpp-monitoring-tools/en/).*
  - WHO 2015 *Consolidated guidelines on HIV testing services (10).*
  - WHO 2016 *Guidelines for the screening, care and treatment of persons with hepatitis C infection (11)* and WHO 2015 *Guidelines for the prevention, care and treatment of persons with chronic hepatitis B infection (12).*
  - WHO 2014 *Supplement to the 2013 Guidelines on post-exposure prophylaxis for HIV and the use of co-trimoxazole prophylaxis for HIV-related infections among adults, adolescents and children (13).*
  - WHO 2016 *Recommendations on antenatal care for a positive pregnancy experience (14).*

Fig. 2.3 Overview of global, national and additional indicators from the Consolidated strategic information guidelines reported from the HIV patient monitoring system



Source: Consolidated strategic information guidelines for HIV in the health sector. Geneva: World Health Organization; 2015 *(1)*.

2.1.3 Implications of "treat all" for patient monitoring systems

Integration of patient monitoring across health services

The 2016 WHO recommendation that all patients diagnosed with HIV should initiate ART regardless of clinical or immunological status will lead to an increasing number of patients who:

- initiate ART in one setting (e.g. health clinic or hospital); but
- sometime thereafter, in part because of the differentiated care model, will pick up their drugs in another setting (e.g. community or local dispensary); and
- may become pregnant and/or acquire TB or another condition that requires acute or chronic care and treatment, either in the initial clinic or another service delivery point (e.g. ANC, TB or NCD clinic).

The updated guidance in this chapter aims particularly at supporting monitoring of patients as they move between health facilities over time. In particular, WHO now recommends the use of an HIV patient card and ART register at any site that provides ART, including antenatal care (ANC) and TB sites. This recommendation may facilitate the use of integrated facility-held patient cards, folders or booklets and interlinked patient registers, as well as the use of integrated electronic medical records (*see* Section 2.4.3).

Transitioning away from the pre-ART register

One of the biggest changes to the recommended patient monitoring system in this guidance is the removal of the pre-ART register. Previously, the pre-ART register monitored patients enrolled in HIV care but not yet eligible for or started on ART. Now that all people who are confirmed to be HIV-positive are eligible for treatment, this register is no longer required. In its place, a standardized list of patients who will or may not start ART soon after enrolling into HIV care is proposed (*see* Box 2.5). This list can be inserted at the front or back of the ART register and contains a minimum set of data elements that need to be captured, including whether the patient started ART, was lost to follow up, transferred out or died (*see* Annex 2.3.5).

While the pre-ART register is no longer recommended as part of generic patient monitoring systems, its use may need to be phased out as countries progressively implement the "treat all" approach.

WHO recommends the following:

- the continued use of existing pre-ART registers (or other locally feasible tools that contain the same, standardized data elements as the list shown in Box 2.5) as relevant by setting;
- transitioning to the list of patients who will or may not start on ART inserted in an existing ART register; and
- eventually using only the ART register once "treat all" is fully implemented.

Collecting and reporting of indicators from the patient monitoring system

The "treat all" approach may mean that indicators measuring enrolment in HIV care, HIV care coverage and their derivatives eventually become redundant and that – when "treat all" is fully implemented – these can be replaced with indicators calculating patients who are newly or currently on ART. Box 2.17 describes these issues in more detail.

2.1.4 Users of this guidance

The utility of this guidance will vary, depending on the roles and responsibilities of the user at different levels of the health system.

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

- to update and standardize minimum datasets (Section 2.2) and tools (Section 2.3) to implement HIV patient monitoring systems in line with national and global reporting requirements (Section 2.5);
- to harmonize systems across programme areas and within the broader HMIS, whether paper-based or electronic, to ensure effective linkage and integration of these systems. Over time, WHO recommends transitioning to electronic reporting at the appropriate level of the system (Section 2.7.4).

At **the facility level**, health-care providers and supervisors will use this guidance:

- to identify key data elements and relevant indicators for effective clinical care and programme management, in line with national and global treatment recommendations; and
- to improve patient monitoring and retention, supervision, mentoring and quality of care.

Additionally, at the **subnational and national levels**, programme managers will use this guide for:

- analysing and using data collected via the key indicators;
- providing feedback to health facility staff when evaluating programmes; and
- ensuring improved linkages, retention and outcomes along the HIV cascade of services.

2.1.5 Organization of the chapter

The guidance in this chapter is organized into five main sections:

- Section 2.2 describes the **essential minimum dataset** for patient monitoring (including recommended linking HIV variables for ANC, labour and delivery [L&D] and HIV-exposed infant [HEI] facility registers, and maternal and child health patient-held cards). A description of the updated minimum dataset is included, along with recommended linking HIV variables for MNCH and TB patient monitoring tools, and a dictionary of key terms.
- Section 2.3 describes **generic patient monitoring tools**, including the HIV patient card, community-based monitoring tool, transfer/referral form, ART register, cross-sectional and ART cohort reports. Annexes 2.3.2–2.3.6 provide examples of these generic tools.
- Section 2.4 discusses special considerations for **integration of and linkages within the patient monitoring system**, including with TB, MNCH and key population services, as well as monitoring EWI for HIVDR.
- Section 2.5 sets the backdrop for **measuring key global and national indicators** using the minimum dataset and patient monitoring tools (prioritized by whether they are primarily paper-based or electronic) to report on part of the HIV cascade of services to improve linkages, retention and outcomes. The Appendix includes instructions for and a description of key global and national indicators that use the HIV patient monitoring system as a primary data source and methods for collection.

- Section 2.6 provides guidance on the **periodic (annual) review of data to ensure data quality**, and **collecting key indicators not routinely collected by paper-based systems**. It also provides guidance on the **review and use of data to monitor aspects of quality of care**.
- Section 2.7 provides guidance **on adapting and implementing** the revised patient monitoring system (including a country example of a tool in Annex 2.7.6), transitioning from paper-based to electronic systems, and improving overall monitoring and reporting.

The guidance in this chapter does not address the collection or reporting of data related to prevention services for HIV-negative people or HIV testing. Collection of data on HIV testing from testing sites and laboratories for case surveillance is discussed in Chapter 3.

The guidance does not address all aspects of pharmacy services, with the exception of adherence monitoring. The guidance also does not include complete 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 *(7)* and on the WHO website at: (http://www.who.int/reproductivehealth/publications/monitoring/en/).

2.2 Minimum dataset and key definitions for HIV patient monitoring

2.2.1 Minimum dataset

The minimum dataset contains a core set of demographic, clinical and laboratory data. Each data element has a common definition and prescribed coding categories.

The minimum dataset provides a comprehensive assessment of all people living with HIV enrolled in HIV care. The primary purpose of the minimum dataset is to standardize patient information with a simplified and harmonized set of essential data elements corresponding to core patient management and programme monitoring functions. Box 2.1 highlights the new elements in WHO 2017 minimum dataset that reflects the latest WHO ARV treatment recommendations. Standardization also enables programme staff to compare data across populations, time, geographical areas and settings, and provides data for clinical teams to monitor the quality of care longitudinally and along the cascade of HIV services.

Annex 2.2.1 (2017 HIV patient monitoring system minimum dataset) lists the minimum data elements, including a definition and purpose for each element; and how the data can be used to improve individual patient care and programme monitoring. Many of the data elements are linked to national and global reporting indicators. Programmes may always choose to collect additional information depending on the local need and context.

2.2.2 Key terms used in the HIV patient monitoring system

Table 2.1 provides a list of key terminology and definitions for patient monitoring that are important for following up patients and for accurate measurement of key indicators for programme monitoring. The list of terms allows for harmonized definitions across data collection and reporting systems within a country and between countries.

Box 2.1 What is new in the WHO minimum dataset

HIV enrolment data

- Update to universal ART initiation, transitioning from previously recommended eligibility criteria
- Updates to status at enrolment to reflect differentiated care model
- Updates to prior ARVs received categories, including pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP)
- Addition of patient's district of residence
- Updates to family status
- Addition of date of first HIV-positive test as a prompt for action
- Updates to relevant chronic conditions (previously relevant medical conditions)
- Addition of concomitant medications

ART data

- Changes to status at start of ART
- Updates to newly recommended ARV regimens and codes (for adults, including pregnant and breastfeeding women, adolescents and children)
- Addition of switch to and substitution within third-line regimen (regimen, date and reason)
- Updates to ARV treatment-limiting toxicities/adverse drug reactions
- Updates to reasons for non-adherence, ARV drug substitutions and STOPping ART
- Updates to follow-up status codes and definitions
- Removal of clinical stage for routine monitoring. With the new ARV treatment guidelines, clinical stage is no longer necessary for identifying patients eligible for treatment. It may be useful at enrolment to be used for differentiated care in the absence of CD4 count to help define patients with advanced disease.
- Revision of follow-up education, support and preparation for ART categories

Data on co-conditions

- Changes to TB status codes
- Addition of hepatitis status
- Updates to reproductive/family planning choice and antenatal care
- Updates to comorbidities and coinfections (previously new OIs and other problems)
- Addition of vaccinations (received) per visit in alignment with well-child visits and existing immunization schedule

Laboratory data

- Updates to viral load and CD4 monitoring recommendations
- Revisions to recommended investigations (e.g. TB, hepatitis and others)

Table 2.1 Key terms and definitions used in this guidance

HIV care	Routine clinical assessment, monitoring and management, including ART, appropriate to a patient's needs
Newly enrolled in HIV care	Begins when a person with a confirmed HIV diagnosis presents to a facility where HIV care is provided and a patient card, file or chart is opened for the first time.[a] This could be at an HIV care/ART, MNCH or TB clinic. **WHO recommends** that all patients be enrolled in HIV care at their first facility visit following an HIV-positive diagnosis (which may take place in the same facility or on the same day as the HIV diagnosis). While ART may not be started on the same day as enrolment (e.g. due to treatment of existing OIs or the need for adherence or psychosocial counselling), this definition assumes that enrolment is followed by prompt starting of ART for all people living with HIV, regardless of CD4 cell count, 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 (e.g. patient seen by private practitioner, patient buys drugs themselves or is sent drugs), or PrEP or short-course ARV prophylaxis for PMTCT, and have not been counted as "newly enrolled" in a system that is being monitored nationally. 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 reported as "newly enrolled" once before), an attempt should be made to retrieve the records and confirm that the patient was previously on treatment. As programmes scale up the "treat all" recommendations, newly enrolled in HIV care should be very similar to STARTed on ART. Therefore, SI indicator LINK.3 Enrolment in care (newly enrolled in HIV care) has been replaced with ART.1 New ART patients for practical purposes in this guidance (*see* Box 2.18). [a] "Newly enrolled" patients do not include those who have been referred or transferred in with documentation (i.e. referral/transfer slip or patient records).
Retention in HIV care	A patient who is enrolled in HIV care and routinely attends these services, appropriate to the need. This excludes people who have died or were lost to follow up, but includes those who started ART and subsequently stopped ART (*see* definition below) for any number of reasons. 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 enrolling in HIV care or starting ART specifically. For example, global indicator ART.5 (ART retention) is defined as the number and percentage of people who are still alive and on ART at 12 months (or 36, 60 months) after initiating ART. When aggregated at the facility level, the numerator does not include those who transferred out by 12 (or 36, 60) months, those who have died, those who are known to have stopped ART or those lost to follow up. The cohort-based definition of retention, as included in the global indicator (ART.5 ART retention), is the most accurate and meaningful measure of treatment success. **WHO DOES NOT recommend the measurement or use of cross-sectional retention due to difficulty in interpretation.**
Viral load suppression	<1000 copies/mL

Terms	Definitions
TRANSFER IN (TI)	There are **four** types of transfer patients, but only one (the first) that is categorized as "Transfer In" on ART. 1. Refers to a patient who has been **receiving ART** at one facility in the country or system and transfers (changes primary location of where to receive HIV care/ART) to another facility in the same system **with records** (or at a minimum, knowledge of ARV regimen and ART start date). The patient 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 (TI)". 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 … ARVs…Last VL…" recorded, as well as any subsequent regimen changes (substitutions/switches/interruptions) thereafter. Most importantly, TI 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 (note TI in margin). Additionally, patients are **not** included in the number of cumulative ever started on ART at the facility (*see* definition below) as they were already recorded as "ever started ART" at another facility in the system. 2. Refers to a patient who has **received ART** from sources outside of the system or one who has received ARVs within the system without records or knowledge of ARV regimen or ART start date. This patient will be classified as having received "Earlier ARVs not transfer in" and will be "newly enrolled in HIV care" *(see below)*. 3. Refers to a patient **not yet started on ART** who transfers between facilities **with records**. This patient 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 "Transfer in: naive". 4. Refers to a patient **not yet started on ART** who transfers between facilities **without records**. This patient 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 and from MNCH or TB services into HIV services or vice versa.
START	Refers to the date on which a patient begins the first, original ART regimen in the system (or documents the date a patient started in any programme or under care of another practitioner if this date is known). For example, if a patient starts initial ART at clinic A, then transfers to clinic B, clinic A will record the patient as having started ART; clinic B will copy the date to the current clinic patient records, which precedes their first encounter date. This is the same as cohort month/year.
STOP	Refers to the date on which a patient intentionally stops an ART regimen (usually but not always in discussion with the clinical team) through a planned interruption of ART. STOP can be patient- or clinician motivated, and 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.

Table 2.1 Key terms and definitions used in this guidance (continued)

LOST TO FOLLOW UP (LTF)	A patient who has not been seen at the clinic for at least 90 days (three months) after the last missed appointment. When reporting, a three-month grace period should be observed before concluding that a patient is actually LTF (*see* indicator ART.5 ART retention). However, with the introduction of differentiated care, these periods may need to be reconsidered. While this is a practical definition of LTF for reporting purposes, most clients who do not present by three months of last missed appointment are unlikely to return thereafter. Therefore, for patient management, the facility should make every effort to contact patients (by phone, via community health worker) as soon as they miss an appointment, rather than waiting for the prescribed 90 days. This is particularly important when patients are routinely seen every three to six months (a patient may not have been seen for up to nine months if the facility adheres to the waiting period before attempting contact). LTF is an ambiguous outcome that may often include patients who have self-transferred (without proper documentation or referral from their original primary care facility) or who have died. Transfer out (TO) and death are two concrete outcomes that are also collected and it is important to understand what actually happened to the LTF patient to improve both clinical and reporting outcomes (*see* Box A1: Country experiences: cross-sectional analyses of outcomes among patients lost to follow up in the Appendix).
TRANSFER OUT (TO)	Refers to the date on which a patient who has been receiving ART at one facility transfers out of that facility.
DEAD	A patient who dies at any time after being enrolled in HIV care.
SUBSTITUTE	Substitution of ARV drugs within first-, second- or third-line regimens – record the date and reason why.
SWITCH	Switch from first-line to second-line regimens or from second-line to third-line regimens – record the date and reason why.
Cumulative ever started on ART	Number of patients who have ever started on ART as NEW at that specific facility. It does not include patients who transfer in, but includes patients who subsequently transfer out, or are categorized as DEAD, LTF or STOP.
HIV care coverage (current in HIV care)	A cross-sectional indication of people living with HIV receiving the appropriate services as needed (those who had a clinical encounter, test or received ART during a specified time period) (global indicator LINK.2 HIV care coverage). As countries scale up implementation of the "treat all" guidelines (*see* Box 2.18), this will practically comprise those currently on ART (*see* definition below) plus those who have stopped ART (but are still technically in care); however, operationally, the number of people current on ART may serve as a proxy.
ART coverage (current on ART)	A cross-sectional indication of people living with HIV who are currently on ART at a given facility, including patients who transfer in, and excluding patients who transfer out or are categorized as DEAD, LTF or STOP (global indicator ART.3 ART coverage 2).
Cohort	Group of patients who start ART in the same month (or quarter) and year, whose status is followed over time, using the ART register.
Net current cohort (cohort analysis report)	Patients in a given cohort for whom the facility is currently responsible, consisting of those who started on ART at the facility, minus those who have since transferred out, and plus those who have since transferred in.

Terms	Definitions
Final status (for HEI)	The final HIV status of the child at 18 months (or three months after cessation of breastfeeding, whichever is later) based on either HIV virological testing (i.e. polymerase chain reaction [PCR]) or rapid antibody testing, including: • HIV-positive • HIV-negative, no longer breastfeeding • HIV status unknown (died; LTF; transferred out; active in care but not tested at 18 months) (national indicator MTCT.8 Final outcome status).
Key population	A group of people who, due to specific higher-risk behaviours, are at increased risk of HIV regardless of the epidemic type or local context. Key populations also face legal or social barriers that increase their vulnerability to HIV and limit access to services, such as violence, stigma and discrimination, harassment and criminalization. Key populations include (1) men who have sex with men (MSM); (2) people who inject drugs (PWID); (3) people in prisons and other closed settings; (4) sex workers, and (5) transgender people. These categories are not mutually exclusive. Some countries may consider other vulnerable groups to be key populations.
Vulnerable group/ population	A group of people who are particularly vulnerable to HIV infection in certain situations or contexts, including adolescents (particularly girls in sub-Saharan Africa), orphans, street children, people with disabilities, and migrant or mobile workers.
Active TB disease	A person who exhibits signs or symptoms of active disease and tests positive for *Mycobacterium tuberculosis* on smear examination, culture or a 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.
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, and hence the renaming of LTBI therapy to TB preventive therapy *(15)*.
New TB case	A person who has never had treatment for TB or who has taken anti-TB drugs for less than one month.
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 (defaulter).

ANC: antenatal; ART: antiretroviral treatment; ARV: antiretroviral; HEI: HIV-exposed infant; LTF: lost to follow up; PMTCT: prevention of mother-to-child transmission; PrEP: pre-exposure prophylaxis: TB: tuberculosis: VL: viral load

2.3 Standardized data collection and reporting tools

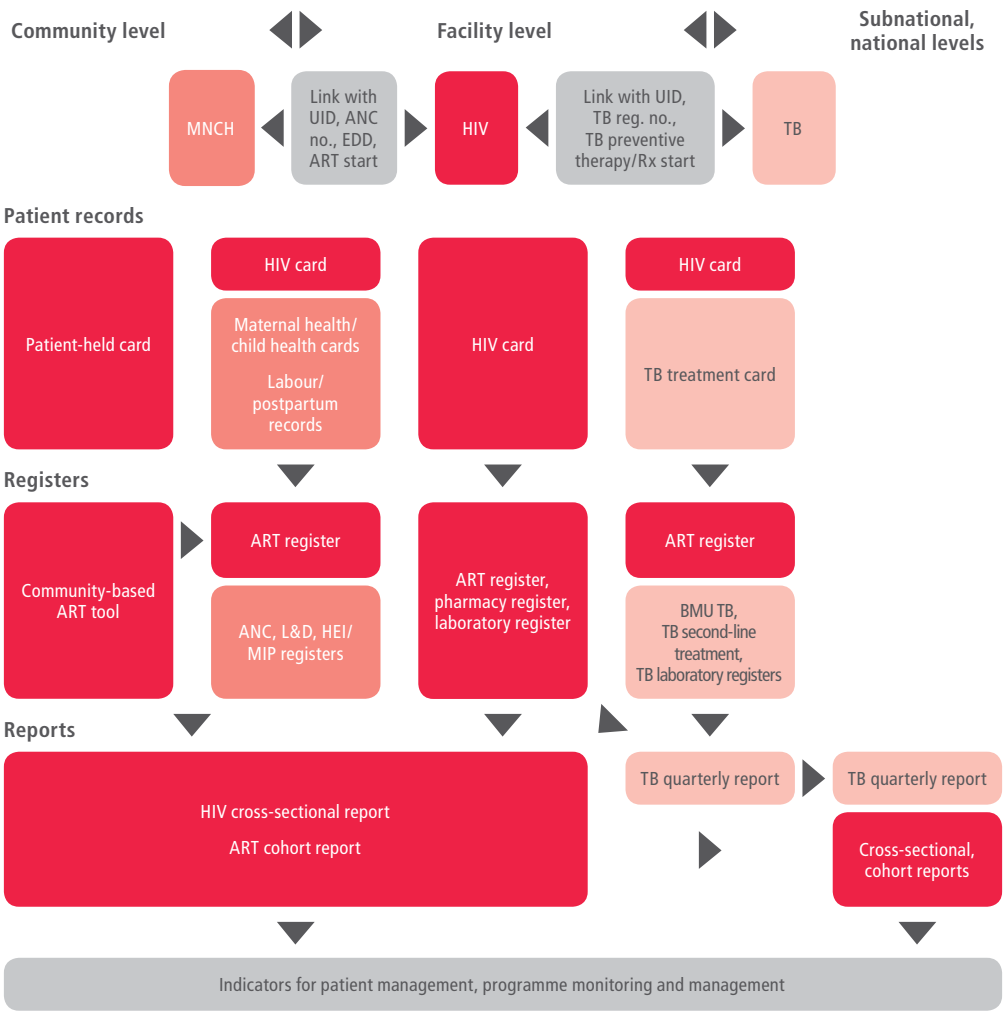
2.3.1 Overview

WHO recommends the following:

- Health workers should create an HIV patient card for every person who is confirmed HIV-positive and subsequently enters care, regardless of the entry point (i.e. HIV, MNCH, TB).
- ART registers should be kept and used at all sites where ART is provided.
- Community health workers (CHWs) engaged in ART delivery should routinely monitor and report on a key, minimum set of activities in a simple, standardized way.

Fig. 2.4 provides an overview of HIV patient monitoring systems, and data collection tools required for ART delivery in HIV care, MNCH and TB settings. The transfer/referral form (not shown) would be used to facilitate continuity of patient care between sites that provide HIV care and treatment. The generic HIV tools provided in this guidance are shown in red. MNCH-specific tools are shown in light red, and TB-specific tools are shown in dark pink. Additionally, there could be monitoring tools for other diseases or conditions that interlink with or can be integrated into the system (e.g. patient cards and registers for NCDs).

Fig. 2.4 Standardized HIV patient monitoring system and linkages by service delivery area and level



ANC: antenatal care; ART: antiretroviral treatment; BMU: basic management unit; EDD: estimated due date; HEI: HIV-exposed infant; L&D: labour and delivery; MIP: mother–infant pair; MNCH: maternal, neonatal and child health; Rx: treatment; TB: tuberculosis; UID: unique identifier

The annexes to this document provide the following updated generic tools:

- HIV care and treatment patient card (Annex 2.3.2);
- Community-based ART tool (Annex 2.3.3);
- Generic HIV care/ART transfer/referral form (Annex 2.3.4);
- ART register and list of patients who may not or will not start ART immediately (Annex 2.3.5);
- HIV cross-sectional report (Annex 2.3.6a); and
- ART cohort report (Annex 2.3.6b).

2.3.2 HIV care and treatment patient card

The HIV patient monitoring system is designed to capture and retain all people with a confirmed HIV diagnosis and follow them through the cascade of HIV care services, from enrolment in care and ART initiation to sustained viral suppression.

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, regardless of entry point (i.e. HIV care, MNCH, TB care). In an integrated care setting, the patient will receive HIV care and treatment at the same facility for life (e.g. at ANC if the patient started there). In a non-integrated care setting, this card would ideally move with patients as they transfer between service delivery points; e.g. a woman starts ART at the ANC clinic and transfers to the HIV 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 unique ID number. This is different from a patient clinic ID, and may or may not be unique to HIV care. An existing health, national or other ID may be used when available, as long as it is unique to the patient (*see* Chapter 4).
3. The health-care worker records information on the card to monitor the patient's 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 within the HIV patient monitoring system, and contains the entire HIV-specific minimum dataset. The facility-based HIV patient card may be referred to as a patient record or file in some settings. The card includes links to other services that the patient may be receiving at the same time, as well as specific patient records and registers, e.g. for maternal and child health (*see* Section 2.4.4) and for TB (*see* Section 2.4.5), including:

- reproductive and family planning choices, including current pregnancy status
- ANC number
- child vaccinations
- tests for STIs and their results
- nutritional support and infant-feeding practice, including current breastfeeding status, and
- HIV-exposed infant status, including name, date of birth, CTX prophylaxis, HIV test type, and result and final status (and unique ID once confirmed HIV-positive).

The HIV patient card comprises three different sections.

The **front page** contains a summary of the patient's demographic, family, and HIV care and ART information. This information is generally completed once, and updated as needed.

The **second section** is the encounter page. Each row comprises one 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 completed 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 columns; another blank photocopied sheet may be inserted or attached once these are filled.

Annex 2.3.2 provides a model of a generic HIV patient card.

Box 2.2 What is new on the HIV patient card

Revisions to the *Front* of the card

- Recommendations for starting card at point of entry
- Assignment of unique ID to all patients enrolling in HIV care, regardless of ART start date
- *No longer used for HIV-exposed infants prior to confirmation of HIV infection*
- *No longer records eligibility*
- Changes to status at enrolment to reflect differentiated care model and prior ARVs
- Changes to "Family status" (simplified, date of death added)
- Addition of date when first HIV-positive test done
- Changes to "Relevant medical conditions" (now "Relevant chronic conditions")
- Addition of "Concomitant medications"
- Addition of "TB status" box
- Changes to status at "Start ART"
- Addition of third-line regimens on front of card
- Addition of date columns to follow-up status box on front of card

Revisions to the *Encounter page* of the card

- Addition of "Vaccination" to the Pregnancy/reproductive health (RH)-FP choices column
- Addition of "Hepatitis status/information" column
- Changed title of "Potential side-effects" to "Treatment limiting toxicities/adverse reactions"
- Changed title of "New OIs" and other problems to "Comorbidities and coinfections"
- Changed isoniazid ("INH") to "TB preventive therapy", replaced "Pills dispensed" with "Record start or complete"

- Revised "ART adherence" to "Number of missed doses"
- Revised list in "Investigations" column

Revisions to the *Codes* page of the card

- Changes to "Codes for pregnancy/RH-FP choices" and "Codes for FP methods"
- Changes to "Codes for comorbidities and coinfections"
- Changes to "Codes for TB status" and "Codes for TB specimen test and results"
- Changes to "Codes for treatment-limiting toxicity", reasons for non-adherence, ARV drug substitution or stopping ART
- Updates to codes for "HIV-exposed infant final status"
- Addition of vaccination codes
- Addition of "Codes for hepatitis information"

Revisions to the *Back* of the card (follow-up education)

- Addition of information on prevention interventions
- Addition of infection control (for TB)
- Addition of HBV/HCV interventions
- Addition of "Date" columns
- Revision of line items to simplify and prioritize interventions.

2.3.3 Community-based patient monitoring tool

Under the differentiated care model recommended by WHO in 2016, patients with HIV who are stable on ART may require less frequent clinical visits and medication pick-up, and can access more decentralized service delivery points, including community-based services *(2)*. To accommodate larger numbers of patients enrolled in HIV care programmes, WHO also recommends task-shifting to allow clinical settings to focus on patients who are initiating treatment or who are unwell, and delegate the monitoring of stable patients to supervised lay providers. CHWs can play a pivotal role in this regard by:

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

Given the breadth of activities in which CHWs may engage, it is important that they should be 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 differentiated care, and linking between community and facility health workers.

While CHWs may monitor patients using their own tool, the information that is collected should always be reconciled with the facility-based ART register, which is the main aggregation tool for any cross-sectional or cohort report. This can be done on a monthly or quarterly basis (e.g. whenever CHWs have meetings at the facility) to ensure that the follow-up status of each patient is up to date (i.e. treatment regimen, STOP, DEAD, LTF, TO). If CHWs are picking up and distributing ARVs to patients in the community, their tool should be reconciled with the pharmacy dispensing records.

Box 2.3 What is new in the CHW data collection tool

These guidelines include a generic community-based patient monitoring tool for use by community health workers who provide or support HIV care and treatment in the community or outside the health facility (Annex 2.3.3). Recommended data elements for such a tool are shown in Box 2.4.

Box 2.4 Recommended HIV data elements for a CHW data collection tool

- Facility name and district
- Unique ID
- Name (age, sex)
- Phone number
- Address, including village and district
- Moved out of CHW catchment area (date, new address)
- Family members' HIV status
- Date of enrolment in HIV care
- Date of starting ART
- ARV regimen (including any changes)
  - dates dispensed
  - # pills dispensed
- TB symptoms (current cough, fever, weight loss, night sweats) Yes/No
- Other problems (ankle swelling, puffiness of the face, breathlessness, diarrhoea >2 weeks, severe headache (*source:* www.samumsf.org)
- Transfer out (date, to where)
- Dead (date)
- Treatment interruption (dates and reasons)
- Pregnancy status
- Visit date (reason for visit)

2.3.4 HIV transfer or referral form

To the extent possible, if a patient is referred to or transfers from another facility for care and treatment, a minimum amount of information should be recorded and sent with the patient to maximize continuity of care, retention on ART and viral suppression, as well as to avoid duplication in record-keeping and reporting. The generic form includes information that is 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.

Annex 2.3.4 provides a model referral form.

2.3.5 ART register

WHO recommends the following:

Consistent with the "treat all" approach, when a diagnosis of HIV infection is confirmed, the patient should be enrolled in HIV care immediately and entered into a longitudinal ART register when they start ART, preferably soon after enrolment.

The ART register:

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

WHO recommends that ART registers be kept wherever patients receive treatment and also use HIV patient cards, including at ANC or TB clinics. This facilitates data reconciliation for certain TB/HIV and HIV/MNCH indicators by grouping all patients on ART in one place, and allows for the longitudinal follow up of cohorts of pregnant and postpartum patients (in general, MNCH service registers are cross-sectional).

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 to better understand what has happened (e.g. patient recorded as DEAD three months after ART start).

Annex 2.3.5 provides a generic ART register, and a list of patients who can or will not start ART soon after enrolment into HIV care.

The updated generic ART register contains 20 rows, with one row per patient. Each row is divided into two (white and grey). The first page of the register is used to record information once (patient demographics, status at start of ART, key co-treatments, pregnancies, regimen substitutions and switches) and updated as necessary. The subsequent pages (2–6) are for the monthly follow up of patients on ART, starting at month 0 (the month in which the patient started ART) and continuing through 10 years (120 months). At each month, the follow-up status of the patient (on ART [regimen code]; STOPped [and reason]; LTF; TO [and to where]; DEAD) is recorded in the top (white) row and the current pregnancy or breastfeeding status (for women of reproductive age) in the bottom (grey) row. In addition, CD4 and VL test dates and results are recorded at key points (6, 12, 24, etc. months).

Box 2.5 What is new in the ART register

Removal of the pre-ART register

Consistent with the "treat all" approach, the pre-ART register is no longer necessary. However, for countries still transitioning to "treat all", programmes may still capture those who can or will not start on ART soon after enrolment in HIV care through locally feasible tools such as an appointment book, existing pre-ART registers, other facility patient enrolment registers or a simple updated list of patients appended to the front or back of the ART register (*see* Annex 2.3.5). It is recommended that these tools contain the following data elements:

- enrolment date;
- name, sex, age at enrolment;
- unique ID; and
- outcome (dead, LTF, transfer out, or start ART) and corresponding date.

Additional variables may include:

- baseline CD4 count;
- TB preventive therapy start month/year; and
- active TB disease month/year.

Consequently, **LINK.2 HIV care coverage** and **LINK.3 Enrolment in care** are no longer priority indicators (*see* Box 2.17).

Revisions to the *left-hand side* (Page 1) of the ART register

- *Revision of status at start ART* to include CD4 count, pregnant or breastfeeding and confirmed TB (TB+).
- *Addition of complete month/year* to TB preventive therapy column.
- *Addition of hepatitis screening columns.* Two columns have been added to facilitate aggregation of LINK.27 Hep B screening and LINK.28 Hep C screening indicators.
- *Addition of 3rd-line regimen switches and substitutions.*

Revisions to the *right-hand side* (Page 2) of the ART register

- *Changes in when to record CD4 count and viral load.* WHO recommends using CD4 count to assess the baseline risk of disease progression and decisions for starting and stopping prophylaxis for OIs. In settings where routine viral load monitoring is available and patients are stable on ART, routine CD4 monitoring can be stopped. CD4 counts can be taken at 6 and 12 months after starting ART and discontinued if the viral load is stable at 12 months; or continued every 6 months if not, or if viral load testing is unavailable. Where available, routine viral load testing should be conducted at 6 months after ART start, repeated at 12 months and every 12 months thereafter.
- *Revised ARV regimen codes.* Codes for recommended first-, second- and third-line drug regimens have been revised to reflect the 2016 WHO guidelines.
- *Revised follow-up status codes and definitions.* Previously, DROP and LOST (missing a single appointment or drug pick-up) were included as follow-up status codes in the ART register. Lost to follow up has replaced DROP; and LOST has been removed altogether.

- *Revised codes* for treatment-limiting toxicities/adverse drug reactions, reasons for substitution, switch and STOPping ART.
- *Addition of pregnancy, breastfeeding status.* Added code for currently pregnant (P) or breastfeeding (BF) in bottom row of ART follow-up status.
- *Removal of TB status screened at last visit* (Y/N) due to questionable accuracy.

2.3.6 Cross-sectional and cohort reports

Two reports comprise aggregated data from the ART register:

- The cross-sectional report tallies the numbers of cumulative and current patients in care and on ART, disaggregated by age and sex quarterly to annually.
- The cohort report records outcomes of groups of patients who started ART over 6, 12, 24, etc. months.

Cross-sectional report

The cross-sectional report provides a snapshot of data on patients at one point in time. Patients may vary in how long they have received treatment, if at all. The number of patients newly enrolled in care or who have started treatment (key indicator **ART.1 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 at any level. Likewise, patients who initiate ART late (key additional indicator **ART.4 Late ART initiation**) may provide information on how to better target resources or outreach.

The current number of patients in care or on ART (key indicator **ART.3 ART coverage**) (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 contribute to drug supply management at the health facility. Of those patients, the number of patients virally suppressed (key indicator **VLS.3 VL suppression**), regardless of length of treatment, can provide insight into the population-based viral load, whereas the proportion of patients receiving viral load test results (key additional indicator **VLS.4 VL monitoring**) demonstrates the uptake of routine viral load 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 LINK.12 TB prevalence in HIV care, LINK.16 ART coverage during TB treatment and LINK.17 TB preventive therapy coverage;
- **Hepatitis** – key indicators LINK.27 Hepatitis B screening and LINK.28 Hepatitis C screening; and
- **MNCH** – key indicators PREV.10 ANC syphilis screening coverage, PREV.11 Syphilis treatment, MTCT.1 PMTCT testing coverage, MTCT.2 PMTCT ART coverage, MTCT.4 Infant ARV prophylaxis, MTCT.6 Early infant diagnosis and MTCT.9 Infant CTX coverage.

Cohort analysis report

The cohort analysis report aggregates patient data based on when patients started ART (month/year). This allows for important and useful indicators along the HIV cascade of care and treatment, particularly with regard to the success of the programme, i.e. whether or not patients are still alive and on ART after six months and one, two, three or more years (key indicator **ART.5 ART** retention and key additional indicator **MTCT.3/17 Early ART retention of pregnant and breastfeeding women**); how many have died or been lost to follow up; how many have transferred out or stopped ART (but are still in care) (key indicator **ART.6 Short-term ART outcomes**); how many have substituted or switched regimens; and how many have a suppressed viral load (key additional indicator **VLS.1/ART.9 VL suppression at 12 months**).

These data are critical for patient and programme monitoring, and facilitate health worker follow up on negative outcomes such as large numbers of patients lost to follow up, patients who have died, those who have switched regimens or are not virally suppressed over the long term. Additionally, 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, and the point in time at which switches to second- and third-line regimens are happening.

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 (e.g. whether men are more likely to be lost to follow up 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 (e.g. for a December 2015 report, December 2015 might be baseline (Month 0) for some cohorts, Month 5 for those starting in August 2015, or Month 9 for those starting in April 2015).

Annex 2.3.6a provides a generic HIV cross-sectional report. Annex 2.3.6b provides an example of an ART cohort report.

Box 2.6 What is new in the cross-sectional and cohort reports

Cross-sectional report

- **Removal** of *eligible for ART tally*
- **Removal** of *newly enrolled and current in care* tables
- **Update** of *different ARV regimens* for adults, children, pregnant and breastfeeding women, and HIV-exposed infants based on the 2016 ARV treatment guidelines updates
- **Addition** of *Number of people living with HIV and on ART who have a suppressed viral load* disaggregated by sex and age
- **Addition/revision** of *priority global and national HIV indicators*
  - Revision of *TB/HIV indicators*

  - Addition of *hepatitis indicators*
  - Revision of *HIV/MNCH indicators*
- **Different** *periodicity of reporting* (monthly subnationally, quarterly nationally)
- **Recommended** *age disaggregation for all indicators*: <15, 15+ years for paper-based systems; <1, 1–4, 5–9, 10–14, 15–19, 20+ years for electronic systems unless otherwise noted

Cohort report

- **Recommendation** to use *quarterly versus monthly* cohorts
- **Removal** of *LOST* (temporary missed appointment) as an outcome
- **Replacement** of *DROP* with *Lost to follow up (LTF)*, defined as not having been seen for at least 3 months (90 days) from last missed appointment
- **Removal** of *CD4 fraction <200* and replacement with *viral load categories*:
  - Viral load: tested; result received; suppressed
- **Addition** of *3rd-line regimen* as outcome
- **Adaptation** of *long-term cohort analysis* (five plus years) and *pregnant or breastfeeding women ART cohorts*.

2.3.7 Other recommended tools to facilitate patient monitoring

WHO recommends three additional new tools to facilitate patient monitoring, shown in Box 2.7. New recommended data elements for inclusion in a pharmacy record to monitor patient adherence to ART are shown in Box 2.8.

Box 2.7 Other new WHO-recommended tools

- Appointment book in health facilities for tracking patients who miss scheduled visits or drug pick-ups;
- List of recommended data elements for monitoring adherence in patients from a pharmacy record (Box 2.8); and
- List of minimum recommended data elements for inclusion in an HIV patient-held card or passport (Box 2.11).

Box 2.8 Recommended data elements for inclusion in a pharmacy record to monitor patient adherence to ART *(ART.7 ART adherence proxy)*

- Date of pick-up;
- Number of days for which pills dispensed; and
- ARV regimen dispensed.

2.4 Integration and linkages

2.4.1 Monitoring and addressing gaps in the cascade of care

As one of the 90–90–90 targets, retention (alive and on ART) is a key indicator for patient and programme monitoring, and for the global HIV response. A systematic review of patient attrition across sub-Saharan Africa found that, on average, 13% of patients were lost to follow up, 9% were dead and 1% had self-transferred *(16)*. The use of indicators to monitor retention shown in Fig. 2.3 (Section 2.1.2.) enables health facilities and HIV programmes to measure and address gaps in the cascade that give rise to late presentation for care, loss to follow up and other challenges arising from patients moving in and out of health facilities (Box 2.9).

Box 2.9 Monitoring gaps in the cascade: key challenges

Late presenters – people who enrol in HIV care (and subsequently start ART) and present with advanced disease, defined as CD4 count <200 cells/mm^3 OR WHO stage III and IV AIDS-defining illness.[a] Programmes should aim to reduce the number of these patients by ensuring timely diagnosis and links between the testing facility and initiation of treatment.

Patients **lost to follow up** (LTF) require special attention. Community-based health workers can be important for tracking lost patients and understanding why they are no longer coming into a facility to receive care or treatment. These workers can link them back into care, ideally soon after they miss an appointment. These patients can generally be recategorized as dead, stopped (ART) or (self-) transferred out when the true outcome is understood (*see* Box A1 in the Appendix).

Patients who **transfer in** (TI) and **out** (TO) of facilities present an additional challenge in settings where unique identifiers do not exist or if patients present to a facility without their health records. Facilities should use a transfer or referral form containing a minimum of care and treatment information for transferring patients and confirm receipt of such patients with the referring facility (*see* Annex 2.3.4). Double-counting will be inevitable in settings where a patient receives care at multiple facilities in a given period if unique identifiers are not routinely used. Otherwise, if there is a primary facility in which the patient receives care, it is ideal that this facility monitor that patient's care and treatment outcomes. Patient-held cards may facilitate tracking of movement between facilities (*see* Section 2.4.3).

[a] Waldrop G, Doherty M, Vitoria M, Ford N. Stable patients and patients with advanced disease: consensus definitions to support sustained scale up of antiretroviral therapy. Trop Med Int Health. 2016;21 (9):1124–30. doi: 10.1111/tmi.12746 (http://www.ncbi.nlm.nih.gov/pubmed/27371814, accessed 2 May 2017).

Keeping patient records and linking patient information and records across health service delivery points are essential to ensure patient retention and prevent attrition. However, they also present major challenges in the case of chronic care, including for HIV.

At the individual patient level, keeping patient records that summarize clinical status and services provided over time are essential for patient management and continuity of care. Patient records allow health-care providers to understand what has happened to the patient previously, e.g. status of the patient at enrolment in care; weight; what prophylaxis, other medications, education and support were provided on earlier visits; the patient's family, pregnancy, contraception and TB status (checked at each visit); what laboratory tests were requested at the last visit, and previous experience with ARVs. If this information is not

recorded, the quality of care may be compromised, different or incorrect drug regimens may be prescribed, and patients may be counted as new when they have previously been enrolled in care and started on ART.

In addition to keeping patient records for patient management, clinical teams need to summarize data from groups of patients for planning, coordinating and improving care; ordering medicines and other supplies; and reporting for programme monitoring and management. Besides HIV care, patients need other services (e.g. TB treatment, family planning services, maternal health services, etc.) that require patient records to be linked across different delivery points. Linking patient records and interoperability across systems is also important for the smooth functioning of electronic patient monitoring systems and the accuracy of reporting.

Box 2.10 summarizes key approaches to monitoring and linking patients over time and across health service delivery points using patient monitoring tools. Several of these approaches are discussed in more detail in Sections 2.4.2 and 2.4.3.

Box 2.10 Summary of approaches to monitoring and linking patients over time and across health service delivery points with patient monitoring tools

- Ensure that an HIV patient card is created for all patients who enrol in HIV care, regardless of the service delivery point (e.g. HIV care, MNCH, TB) and recorded in an ART register as appropriate.
- Assign unique patient identifiers, if used (*see* Chapter 4).
- Use family charts/folders to keep patient records of members of one household or family together. This is particularly useful for mother–infant pairs and integrating family care.
- Use patient appointment systems or link pharmacy and clinical records to identify patients who miss scheduled appointments, and engage in follow up in a timely manner (may not wait for the full 90 days defined as LTF to find patient), whether for drug pick-up or clinical visit.
- Use patient-held cards or passports to facilitate tracking of patients who move between service delivery points (*see* Box 2.11).
- Reconcile data in registers (ART, ANC, L&D, HEI, TB) across services (MNCH, TB, HIV care).

2.4.2 Integrated patient monitoring tools for integrated services

The 2016 WHO ARV guidelines emphasize that chronic care requires integrating and linking related services to ensure comprehensive patient management over time. For example, the guidelines specifically recommend that, in high-burden settings, ART should be initiated and maintained in pregnant and postpartum women, and in infants at maternal and child health-care settings, and that ART and TB treatment may be provided in TB and HIV treatment settings, respectively. Integrated care of this kind requires that, to the extent possible, patient monitoring tools (records and registers) are also integrated.

Facility-held patient records

Integration within a patient monitoring system involves the use of a single patient card (or multiple cards kept in the same patient folder) to monitor and manage a patient's care for multiple conditions (e.g. HIV, TB, pregnancy, diabetes) over time. The folder contains the entirety of the patient's demographic information (e.g. name, sex, date of birth, etc.) that should not need to be completed on each disease-specific care and treatment card (though a unique ID or some similar minimum identifying information should be recorded in the event the patient's demographic information is lost or misplaced).

Innovative approaches to integrating patient records in both paper and electronic formats are being adopted in several settings.

Western Cape Province in South Africa has introduced a single patient record. It integrates information relevant for the assessment, care and treatment of HIV, TB and pregnancy (*see* Annex 2.7.6).

Malawi has integrated noncommunicable disease and antenatal care modules within its HIV electronic medical records system (WHO/UNAIDS HIV case based surveillance and patient monitoring system consultation, Geneva, September 2016).

Longitudinal registers

Integration of the ART register with patient registers for non-HIV-related treatment and care may be more complicated than integrating patient cards into a health folder, because registers are generally based on the start date of the treatment regimen, and patients may start treatment for different diseases on different dates. However, countries may consider a single register organized by expected birth cohort for a pregnant woman and her newborn child as she progresses through ANC, labour and delivery, and postnatal care (*see* Section 2.4.4). Otherwise, facility registers should – at a minimum – be able to link to related services that patients may be receiving concurrently (*see* Section 2.4.3 below).

2.4.3 Patient monitoring tools to link patients between services

A patient monitoring system is "interlinked" if it can link a single patient across records (patient cards or registers) through identifying data elements such as name, date of birth, sex or unique identifier to avoid duplication of record-keeping, and ensure continuity of care across different (i.e. non-integrated) service delivery points and time. For example, in the case of a patient receiving care at both an HIV and a TB clinic, the HIV patient card should contain the patient's TB registration number and the patient's TB treatment card should contain the HIV patient's unique number (*see* text in bi-directional dark grey arrows in Fig. 2.4). This allows the HIV and TB programmes to link this patient to both the ART register entry as well as the TB register entry. An electronic register can also facilitate linking patient information between service delivery points within HIV as well as across different programmes (*see* Section 2.7.4).

In some settings, patients have simple patient-held cards, booklets or "passports" in which appointment dates and other key identifying and clinical information are recorded. These may also be used to link records across service delivery points if unique patient or clinic IDs are included. WHO recommends that patient-held cards or booklets for HIV should contain the minimum set of data elements shown in Box 2.11.

Box 2.11 Minimum recommended data elements for inclusion in an HIV patient-held card or passport

- Name
- Date of birth
- Unique ID, if available
- ART point of care
- ART start date
- ARV regimen and date dispensed, and
- CD4 count and viral load results and dates.

In settings where HIV-related care and maternal and child health care are not integrated, i.e. they are provided in separate settings, patients may bring their maternal health cards to the HIV clinical appointment to help health workers complete the HIV patient card (e.g. estimated due date [EDD]) and provide appropriate clinical care (e.g. STI screening).

Referral and transfer forms are also an important tool for following patients as they move permanently to another clinic for HIV care (*see* Section 2.3.4).

2.4.4 HIV/MNCH patient monitoring

Box 2.12 What is in HIV/MNCH patient monitoring

- Recommended use of an HIV patient card and ART register in MNCH care settings;
- Recommendations on following mother–infant pairs;
- Updates to the HIV/MNCH indicators;
- Revision of codes for pregnancy/reproductive health–family planning choices and family planning methods;
- Updates to recommended HIV variables for MNCH monitoring systems.

The use of an HIV patient card is recommended for all confirmed HIV-positive patients who enrol in care and start ART in both MNCH and TB settings, as illustrated in Fig. 2.4 (*see* Section 2.3.1). The use of an ART register in MNCH or TB settings is also recommended.

The 2012 version of the HIV patient monitoring system *(4)* provided generic examples of the full scope of MNCH tools with integrated HIV data elements. While this guidance does not provide updated versions of these specific tools, the sections below contain recommendations for an updated minimum set of HIV data elements to be included in programme-specific maternal and child health patient cards, labour and postpartum records, ANC, L&D and HEI registers or MIP register.

Universal treatment of HIV-positive pregnant women

Since 2011, a concerted global effort has been under way to eliminate mother-to-child transmission (EMTCT) of HIV and syphilis, with the goals of eliminating new paediatric HIV infections; reducing the number of HIV-associated deaths of women during pregnancy, delivery or the puerperium; and improving maternal, newborn and child survival and health in the context of HIV *(17,18)*.

Following the release of the 2013 WHO ARV guidelines *(19)*, many countries adopted lifelong ART for all HIV-infected pregnant women as the preferred approach for PMTCT programmes in both high- and low-prevalence settings. In the 2016 revision of those guidelines, a new conditional recommendation to consider expanded prophylaxis for breastfed infants with high-risk exposure (i.e. mothers with a high viral load or not on ART) has been adopted in some countries. In addition, the conditional recommendation to offer HIV testing (nucleic acid test) to HIV-exposed infants at birth has been adopted by some countries. Breastfeeding recommendations were also revised in 2016 to support a longer period of breastfeeding, aligning with national recommendations, while emphasizing maternal ART adherence and viral load suppression. The 2016 guidelines also place greater emphasis on integration of family planning and STI management, among other services.

Monitoring and evaluation of PMTCT services need to capture the continuum of care of pregnant women living with HIV, from initiating and remaining on ART to maintaining viral suppression. It is therefore 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, e.g. by promoting the early provision of PMTCT interventions through the inclusion of pregnancy or family planning status of women of childbearing age at each visit, and capturing cross-referrals to and from MNCH services as necessary.

In addition, WHO has made three recent recommendations that will impact on the frequency of clinical contacts that an HIV-positive pregnant woman will have (*see* Box 2.13).

The patient monitoring system should support linkages with or the direct provision of PMTCT interventions. Efforts to eliminate mother-to-child HIV transmission need to include a comprehensive set of interventions as integral components of essential MNCH services, including primary prevention of HIV infection among women of reproductive age; prevention of unintended pregnancies among HIV-infected women; prevention of HIV transmission during pregnancy, delivery and breastfeeding; and provision of care, treatment and support to HIV-infected women and their children and families.

A woman has either already been identified as HIV-positive (and is or is not enrolled in HIV care) and then becomes pregnant; or she is identified as HIV-positive during 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, and to record this on her HIV patient card. If the woman is given a special PMTCT or ANC number, it should also be recorded to facilitate reconciliation of data. Box 2.13 describes new recommendations for clinical follow up of pregnant and postpartum women.

Women who are confirmed as HIV-positive in an MNCH setting should be enrolled in HIV care directly with an HIV patient card, and immediately entered into the ART register once started on ART. Ensuring that pregnant women have access and linkage to HIV care and treatment is critical to achieving the second "90" target. How this is done may vary according to the service delivery model and where ART is provided (e.g. at MNCH/ANC, separate ART clinic at same site, or separate ART clinic at different site).

Follow up of the mother–infant pair

Special attention needs to be given to following the mother–infant pair along the cascade of care, from ANC, labour and delivery (maternity), and postpartum maternal visits to child health clinics and ART services. HIV-exposed infants receive the full spectrum of care, i.e. ARV and CTX prophylaxis, timely testing, appropriate infant-feeding practices, testing for final outcome status, and ART if diagnosed HIV-positive. All care is monitored through the mother's HIV patient card, as it is critical to support her adherence, retention and viral load suppression to prevent HIV transmission to the child. However, once the infant is confirmed HIV-positive, a separate card should be created and the child should receive a unique ID number.

HIV data elements integrated into the following generic MNCH tools facilitate monitoring the cascade of care of the HIV-positive mother and her exposed infant in MNCH settings (*see* Box 2.14). Additional data elements relevant to MNCH care specifically are listed in the MNCH care section of Annex 2.2.1 (minimum dataset):

- Maternal health card;
- ANC, labour and delivery, postnatal care (PNC) registers;
- Labour and postpartum records; and
- Child health card.

WHO recommends the following:

An HEI register should be used to follow the entire cascade of care through to the final outcome of the exposed infant. However, in some settings, it may be possible to use a longitudinal MIP register to capture the range of PMTCT interventions specifically for HIV-positive mothers 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 (e.g. <10%);
- concentrated epidemics;
- service delivery occurring in the same facility or site; or
- services not being provided in the same place but having provisions for updating the register.

This recommended approach allows programmes to follow and interpret the cascade of care using actual facility-based versus estimated population-level denominators for many MNCH/HIV indicators (e.g. for MTCT.1 PMTCT testing coverage: actual number of pregnant women who attended ANC or had a facility-based delivery in the past 12 months versus estimated number of pregnant women who delivered within the past 12 months). Nevertheless, WHO recommends that the MIP register be organized by expected date of delivery, rather than ANC registration date, so that infant outcomes are roughly obtainable by birth cohort. With either option, mothers on ART would still be captured in an ART register wherever it is provided. Recording patient or unique ID numbers for ART, ANC and HEI in the relevant HIV and MNCH patient monitoring tools can help to link the mother–infant pair to care (*see* Section 2.4.2).

Box 2.13 Recommendations for the frequency of clinical contact during pregnancy and postpartum

The first recommendation is the 2016 recommendation to increase the minimum number of contacts from four to eight during the duration of a woman's pregnancy (one during the first trimester; two during the second trimester; and five during the third trimester) to reduce perinatal mortality and improve women's experience of care *(14)*.

The second recommendation relates to the differentiated care model for HIV-positive women already on ART who become pregnant *(2)*. If a woman is stable on ART, she may be accessing care every three to six months.

The third recommendation is anticipated in forthcoming WHO guidance on a differentiated care model for an HIV-positive woman who is started on ART while pregnant. This may include more frequent contacts (monthly) during ANC (similar to any new ART patient), with fewer contacts postpartum.

These recommendations may lead to different scenarios, and adaptations by service providers. For example, a pregnant woman who is started on ART during ANC may have more frequent contacts during the first and second trimesters than recommended for an HIV-negative pregnant woman, whereas a pregnant woman already on ART may have to increase her ANC contacts during the second and third trimesters to meet the new ANC care contact schedule recommendations.

Regardless of how a pregnant woman presents, service providers should aim to meet the recommended minimum number of contacts for both ANC and HIV care/ART to ensure the best outcomes for the woman and her infant.

Box 2.14 Data elements relevant for HIV care and treatment of pregnant and postpartum women and their newborns for inclusion in the maternal health card, labour and postpartum records, ANC and L&D registers, and child health card and HEI (or MIP) register

ANC

- Name, Date of birth, Age, Marital status
- Address
- Patient clinic ID number
- ANC number
- District
- Health facility
- Estimated due date (EDD)
- HIV status at enrolment
- Date positive HIV test confirmed OR HIV test date, HIV test result
- Partner test result

Box 2.14 Data elements relevant for HIV care and treatment of pregnant and postpartum women and their newborns for inclusion in the maternal health card, labour and postpartum records, ANC and L&D registers, and child health card and HEI (or MIP) register (continued)

- Date enrolled in HIV care
- Unique ID
- Date started ART
- ARV regimen (date and dose dispensed)
- Visit date
- Weight
- CD4 count (date sent, results)
- CTX (dates started and completed, dose in mg, number of days dispensed)
- Reproductive/family planning choice
- TB status
- TB preventive therapy (dates started and completed)
- Infant-feeding counselling
- ART adherence counselling
- ART adherence
- Malaria prevention counselling
- Syphilis test results
- Syphilis treatment
- Malaria intermittent preventive therapy (IPTp) dispensed
- Insecticide treated bednet (ITN) provided or referred

L&D, postpartum

- HIV status at admission
- Date positive HIV test confirmed OR HIV test date, HIV test result
- Date started ART
- ARV regimen
- Infant-feeding counselling
- Infant-feeding 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)

Child health card data elements

- Maternal HIV status
- Maternal syphilis test results
- Maternal syphilis treatment
- Infant date of birth
- Infant-feeding counselling (and date)
- Infant-feeding practice (and date recorded)
- Maternal ART (start date, ARV regimen)
- 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 age in weeks/months when started on CTX
- Infant final outcome status
- Date infant enrolled in HIV care
- Infant unique ID
- Infant ART start date
- TB status
- TB preventive therapy (dates started and completed)

HEI register data elements

- Date of birth (delivery)
- HIV-exposed infant registration number
- Mother's unique ID
- Exposed infant's name
- Mother's ART start date
- Maternal ART at 3 and 12 months (Y/N) postpartum
- 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 CTX
- TB status
- TB preventive therapy (dates started and completed)
- Infant HIV test sent
- Age in weeks/months when tested and date
- HIV test type

Box 2.14 Data elements relevant for HIV care and treatment of pregnant and postpartum women and their newborns for inclusion in the maternal health card, labour and postpartum records, ANC and L&D registers, and child health card and HEI (or MIP) register (continued)

- Infant HIV test result
- Date HIV test result given
- Final outcome status of HIV-exposed infant
- Date enrolled in HIV care
- Infant unique ID
- ART start date

2.4.5 TB/HIV patient monitoring

Box 2.15 What is new in TB/HIV patient monitoring

- Recommended use of an HIV patient card and ART register in TB care settings;
- Updates to the TB/HIV indicators;
- Revision of TB status codes;
- Updates to TB testing; and
- Revisions to the TB recording and reporting tools with new/updated recommended HIV variables for TB monitoring systems.

High comorbidity and mortality due to HIV-associated TB require an integrated approach to service delivery, as well as patient monitoring. WHO recommends 12 collaborative TB/HIV activities *(20)* that are monitored by global, national and optional indicators described in the WHO *Guide to monitoring and evaluation of collaborative TB/HIV activities (8)* and consolidated SI guidelines *(1)*. Several of these indicators are captured by the HIV patient monitoring system.

TB in people with HIV

Services provided to reduce the burden of TB among people with HIV, which are measured and reported from the HIV programme, include initiation of ART and the so-called "Three I's" (Intensified case-finding, TB preventive therapy with Isoniazid and Infection control) *(21)*. Important interventions that can be measured using the HIV patient monitoring system include the following:

- checking a patient's TB status at every visit **(LINK.5/18 TB screening coverage in HIV care)**;
- starting or completing TB preventive therapy for patients in whom active TB disease is ruled out **(LINK.17 TB preventive therapy coverage; LINK.23 TB preventive therapy completion)**;
- receiving an initial rapid diagnostic test such as Xpert MTB/RIF **(LINK.21 TB diagnostic test for people living with HIV)**;

- confirming TB **(LINK.12 TB prevalence in HIV care)**; and
- early initiation of ART **(LINK.24 and LINK.25)**.

HIV in presumptive and diagnosed TB patients

The TB definitions and reporting framework with integrated HIV recording and reporting forms have been previously developed and updated by WHO *(7)*. In addition, these guidelines provide 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 *(22)*. Although forms and registers may vary slightly between countries, the core data collected and definitions are remarkably 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, e.g. district health information software (DHIS)-2.

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

- co-trimoxazole preventive therapy (CPT) among TB patients **(LINK.22 CTX coverage)**
- initiation of ART **(LINK.16 ART coverage during TB treatment)**.

LINK.16 requires reconciliation with ART registers. Indicators LINK.13 HIV prevalence among TB patients, LINK.14 Mortality among HIV-positive TB patients and LINK.15 HIV testing among TB patients are national TB/HIV indicators collected specifically from TB programme records and therefore not included in this guidance.

Coordination of care, treatment and patient monitoring

Robust mechanisms for effective coordination, referral and communication between the 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/AIDS and TB programmes in tandem. In practice, HIV and TB clinics are often 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 them to their clinical worker in the HIV clinic, who in turn records the results in the HIV patient card.

WHO recommends the following:

An HIV patient card should be started for all patients who test HIV-positive at TB clinics, and that, once started on ART, they are entered in an ART register in that setting.

In settings with high 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 2.2 summarizes data sources and data elements required for monitoring and jointly managing HIV-associated TB. Box 2.16 lists additional HIV data elements recommended for inclusion in the TB patient monitoring tools.

Box 2.16 Additional HIV data elements recommended for inclusion in the TB treatment card and registers

- Unique ID
- Patient clinic ID number
- ANC number
- CD4 count (date sent, results)
- Viral load (date sent, results)
- ARV regimen (date and dose dispensed)

Table 2.2 Summary of data source and data elements required for monitoring the joint management of HIV-associated TB

HIV patient card and ART register (Annexes 2.3.2 and 2.3.5)		
HIV patient card	Status at start of ART	• Confirmed TB • On TB treatment • TB-exposed infant
	TB status	• Not done • No signs or symptoms of TB • 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 therapy	• Start/complete
	Other medicines dispensed	• Record TB / MDR-TB treatment regimen
	Investigations	• Xpert MTB/RIF, LF-LAM, TB sputum microscopy, CXR test and results
ART register (page 1)	TB confirmation	• Active TB at start of ART
	TB prevention	• TB preventive therapy start and complete (month/year)
	TB treatment	• TB treatment start month/year and TB registration number
Tuberculosis records and registers (WHO 2006;[a] 2013[b])		

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 Xpert MTB/RIF	HIV infection	Yes, No, Unknown
Laboratory register for culture, Xpert MTB/RIF and drug susceptibility testing (DST)	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 outcomes 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)	HIV-positive TB patients, HIV-positive TB patients on ART, HIV-positive TB patients on CPT
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, Lost to follow up, 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 second-line TB treatment, Number cured, Treatment completed, Treatment failed, Died, Lost to follow up, Not evaluated

[a] Revised TB recording and reporting forms and registers – version 2006. Geneva: WHO; 2006 (http://apps.who.int/iris/bitstream/10665/69608/1/WHO_HTM_TB_2006.373_eng.pdf?ua=1, accessed 3 May 2017).

[b] Definitions and reporting framework for tuberculosis – 2013 revision, updated December 2014. Geneva: WHO; 2013 (http://www.who.int/tb/publications/definitions/en/, accessed 3 May 2017).

ART: antiretroviral therapy; CPT: co-trimoxazole preventive therapy; CXR: chest X-ray; DST: drug susceptibility testing; LF-LAM: lateral flow urine lipoarabinomannan assay; MDR: multidrug resistant; RR: rifampicin resistant

2.4.6 Early warning indicators of HIV drug resistance

The emergence and transmission of some level of HIVDR is inevitable, even when appropriate regimens are prescribed and adherence to treatment is optimal. To address this challenge, WHO developed a global HIVDR surveillance and monitoring strategy in 2004 and updated it in 2015 *(23)*. The strategy consists of four key activities:

- annual monitoring of EWIs of HIVDR at all ART clinics or at a representative sample of ART clinics in a country;
- surveillance for pretreatment HIVDR in adult populations initiating first-line ART;
- surveillance for acquired HIVDR in adults and children on treatment; and
- surveillance for HIVDR in infants less than 18 months of age.

The WHO HIVDR strategy is designed to provide countries with actionable information to improve clinic and programme performance, and to support selection of an appropriate ART regimen. Monitoring of EWIs forms the foundation of the WHO-recommended HIVDR strategy. Monitoring of the EWIs of HIVDR provides a record of clinic and programme performance, which helps contextualize results from national surveillance of HIVDR. Additionally, clinic- and programme-level responses taken to improve suboptimal performance will support not only the minimization of preventable HIVDR, but also the optimization of population ART outcomes.

Many factors are associated with the emergence of HIVDR. They include viral factors (e.g. subtype, replication capacity and pre-existing polymorphisms); drug-related factors (e.g. drug potency, pharmacokinetics, drug–drug interactions, drug tolerability, and genetic barrier to selection of resistance), and programme factors (e.g. patient adherence, drug stock-outs and supply continuity, and retention of patients on treatment). Although viral and drug-related factors are often beyond the control of public health or programme action, the monitoring of programme factors associated with HIVDR can alert ART programmes to situations that may favour the emergence of HIVDR or virological failure at the population level.

EWIs monitor factors related to patient care (appropriate prescribing and viral load suppression at 12 months); patient behaviour (adherence); and clinic-level and programme management (follow up, retention on ART, and procurement and supply management of ARV drugs). EWIs use standardized definitions, which have evolved over time as programmes mature, lessons are learned and public health actions are refined.

Each EWI has an internationally agreed standardized definition and accompanying target(s). This allows clinics 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 (for pharmacy stock-out and viral load completion) (Table 2.3). Stratified EWI targets provide clinic-specific and programme-level benchmarks against which to assess performance, thus facilitating identification of areas with the greatest need and allocation of resources to close gaps in service delivery. ART clinic 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, thereby minimizing the emergence of preventable HIVDR and maximizing population-level ART outcomes.

Annual monitoring of EWIs allows for measurement of degrees of improvement or decline over time, both within and between clinics. To encourage their routine monitoring and use, EWIs have been fully integrated into the consolidated SI guidelines *(1)*.

WHO recommends the following:

- 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 as the annual patient monitoring review (APMR) (*see* Section 2.6) or 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 system and processes rather than creating parallel ones for EWI data collection and reporting.
- Except for "on-time pill pick-up" (ART.7), which cannot be generated through the APMR, use of the WHO EWI data abstraction tool (http://www.who.int/hiv/topics/drugresistance/en/), while encouraged as 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.5, VLS.1 and VLS.2, is validated during the APMR 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, and any data reported from the patient monitoring system should be qualified to the extent possible (e.g. % missing data) to facilitate interpretation of indicators.
- Gaps in clinic and programme-level performance should prompt appropriate and directed investigation(s).

Table 2.3 WHO-recommended early warning indicators (EWIs) of HIV drug resistance (HIVDR) and their respective targets

WHO-recommended EWIs of HIVDR	Target (green: good performance; amber: fair performance; red: poor performance)
Retention on ART at 12 months (ART.5 ART retention) % of patients retained on ART 12 months after ART initiation	Green: >85% Amber: 75–85% Red: <75%
On-time pill pick-up (ART.7 ART adherence proxy) % of patients that pick-up ART no more than two days late at the first drug pick-up after a defined baseline pick-up	Green: >90% Amber: 80–90% Red: <80%
Pharmacy stock-out[a] (not collectable through HIV patient monitoring system) % of months with any day(s) of stock-out of any routinely dispensed ARV drug	Green: 0% Red: >0%
Viral load suppression[b] (VLS.1 VL suppression at 12 months) % of patients with viral load <1000 copies/mL 12 months after ART initiation	Green: ≥90% Amber: 80–<90% Red: <80%
Viral load completion[c] (VLS.2 VL testing coverage) % of patients with a 12-month viral load test result available	Green: ≥70% Red: <70%

[a] Stock-out refers to lack of availability of first-line ARVs.

[b] The denominator for the viral load suppression indicator is the number of patients alive and on ART 12 months after treatment initiation who have a viral load test result available.

[c] The denominator for the viral load completion indicator is the number of patients alive and on ART 12 months after treatment initiation, who are therefore, consistent with the policy, expected to have a viral load test result available in the primary medical record. For all EWIs, a grey classification is applied in situations where a sampled ART clinic is unable to report on a specific indicator due to more than 30% missing data.

For a complete picture, EWIs should be reported from all ART clinics in a country (a census of clinics). However, EWI monitoring may initially be carried out through random primary sampling of ART clinics within a country to facilitate scale up of reporting to all clinics in a country over time in a representative fashion. Use of representative primary clinic sampling allows countries to calculate an aggregated national prevalence estimate for each EWI. In addition, this method can incorporate information from clinics with conveniently available data (e.g. sites with data readily available from electronic 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 sampling method for sampling patient records at the clinic level does apply. Section 2.6 includes a table to facilitate secondary clinic-level sampling that can also be used for sampling other key additional patient monitoring indicators during an APMR or for quality improvement activities. Annex 2.4.6 provides more detail on the overall recommended primary (clinic) and secondary (patient record) sampling methods for EWIs.

Section 2.3.7 (Other recommended tools) includes recommended data elements for a generic pharmacy record that may be used to collect the data required to calculate the on-time pill pick-up EWI **(ART.7)**. More detailed instructions on how to collect this and the other EWIs using the routine patient monitoring system can be found in the Appendix. Indicator **ART.7** is described using both a census and a sampling approach. All other EWIs are described as other non-EWI indicators – that is, as a census of all patients (versus a sample) in the relevant eligible population. An EWI data abstraction tool in Microsoft Excel format provided by WHO facilitates data abstraction and automatically assigns the appropriate classification (green, amber, red) at the clinic for a given indicator. The tool keeps track of complete entries and reports a grey score if ≥30% of information is missing. The Excel tool is available at the WHO HIVDR website: http://www.who.int/hiv/topics/drugresistance/en/. Although this tool is not required to collect and report data on EWI, with the exception of on-time pill pick-up, it does support data verification and validation, and provides the clinic and national programme with an at-a-glance colour-coded performance report, which facilitates interpretation. Countries should make every effort to harmonize the collection and reporting of these indicators by validating (through the APMR), strengthening and using the routine patient monitoring system rather than creating parallel systems.

2.4.7 Key populations

WHO recommends the following:

Information about risk behaviour, comorbidities or other medications dispensed, which is clinically useful, and referrals for prevention services may be noted in clinical records such as the HIV patient card. Importantly, all patients should be assured that this information will be kept confidential. In addition, individual information related to key populations and criminalized behaviours should not be included in ART registers or reported up to subnational or national data management units.

Background

Data relating to key populations are important for both patient management and programme monitoring. However, in many settings, consensual same-sex sexual activity, sex work or drug use are criminalized and/or stigmatized. Furthermore, in most settings, collecting identifiable information linked to these behaviours from patients receiving ART raises the potential for negative consequences both to individual patients and to providers delivering HIV services. These consequences may include the following:

- Data related to criminalized behaviours could be used by law enforcement officers and others to identify patients for questioning, detention or arrest.
- Awareness among patients that information on criminalized behaviours is being recorded may result in underreporting of risk behaviours and/or avoidance of that health service.
- Patients may be discriminated against by health-care workers and other service providers based on their behaviour or identity.

It is also worth noting that human risk factors are fluid over a person's lifetime. For example, persons may have been infected with HIV because they injected drugs or had unprotected sex in the past, but do not do so currently. Accordingly, identifying a person as belonging to a key population at one point in time may not always be useful for future patient management or programme monitoring.

Considerations for patient management

Clinical information such as alcohol or other drug dependence, concomitant medications (including OST and hormone therapy) and sexual risk behaviour can be included in secure clinic records. Important clinical information related to key populations that could be recorded on the HIV patient card provided in Annex 2.3.2 includes whether the patient is also receiving OST or hormone therapy at the ART clinic (under *Other meds dispensed*) 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 key populations (e.g. testing partners, couples counselling, pre- or post-exposure prophylaxis for partners of those receiving ART, targeted risk reduction or needle and syringe programmes) may be addressed and recorded on the back of the HIV patient card by counsellors, clinicians or other health workers.

Considerations for programme monitoring

ART registers can be accessed by a variety of clinic and other staff, and are difficult to keep confidential. For this reason, ART registers are not appropriate for the collection of data related to key populations. 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. Instead, HIV programme monitoring specific to key populations can be achieved through community-based (such as integrated biological and behavioural) surveys and other special surveys, or through periodic reviews of clinic records by authorized personnel for the purpose of programme monitoring. It is also possible to use 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.

Considerations when collecting data about gender

Transgender 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. It includes people who are transsexual, transgender or otherwise non-binary gender.

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

1. Current gender (check all that apply)

☐ Male

☐ Female

☐ Transgender male

☐ Transgender female

☐ Additional category (please specify):

2. Sex assigned at birth

☐ Male

☐ Female

2.5 Global and national strategic information (SI) indicators covered by the patient monitoring system

2.5.1 Introduction

This section includes a list of key indicators that measure and monitor programme performance, from facility to national level. The accompanying Appendix also provides instructions and special considerations for calculating the indicators (one table per indicator, except in cases where subsets are also included) using the generic paper-based HIV patient monitoring system presented in this guidance, and is organized by method of data collection, i.e. systems that are predominantly paper-based (patient cards, registers and maybe reports) versus those that are electronic, followed by disease or service delivery category (HIV, MNCH, TB, hepatitis). Special considerations for measuring indicators while transitioning to "treat all" are outlined in Box 2.17.

2.5.2 Minimum package of key indicators

This package includes global and national indicators (*see* Fig. 2.3) as prioritized by WHO's strategic information framework for monitoring the cascade of HIV care and treatment, including integration of patient care across MNCH, TB, STI and hepatitis (as relevant) care and treatment service delivery points.

The indicators are prioritized into two categories based on data collection and reporting capacity, in order to optimize accuracy of reporting while easing the burden of manual data aggregation, particularly in low-resource or high patient-volume settings (Table 2.5):

1. **18 key indicators** collected and reported by routine patient monitoring systems using paper patient cards and registers (and reports); and
2. **17 key additional indicators** that may be collected via electronic systems using electronic medical records (EMRs, or potentially electronic registers) (*see* Section 2.7.4 on transitioning to electronic systems), or less frequently using special studies (e.g. ART.11) or an annual patient monitoring review (*see* Section 2.6.2). All but three (ART.1, 4, 6) of the indicators in the first category are also UNAIDS Global AIDS Response Progress Reporting (GARPR, 2016) or Global AIDS Monitoring (GAM, 2017) indicators *(24,25)*. In the instructions tables, references to the GARPR or GAM indicators direct users to read in more detail what the global guidelines and considerations are for reporting on these. Similarly, references to the M&E guide to collaborative TB/HIV activities *(8)* and the Interagency Task Team (IATT) M&E framework for ART for HIV-positive pregnant and breastfeeding women and their infants *(26)* provide additional information for users on how these indicators may be collected and reported.

Box 2.17 Transitioning to "treat all"

In line with the 2016 WHO ARV guidelines, these guidelines do not address global indicator **LINK.2 HIV care coverage** (current in HIV care) and national indicator **LINK.3 Enrolment in care** (newly enrolled in care) either in its list of key indicators or as part of the generic toolkit (no pre-ART register). However, several key indicators currently use LINK.2 (LINK.7, LINK.5/18, 23) or LINK.3 (LINK.12, 17) as their denominators or a subset of their denominators or numerators. The following recommendations reflect the status of implementation of the "treat all" approach by setting.

WHO recommends the following:

- An HIV card should be started for all patients who are confirmed HIV-positive and enter into care, regardless of entry point and when they start ART.
- Countries should continue to collect and report LINK.2 and LINK.3 at the national and global level until they have reached **90% ART coverage** (of those enrolled in HIV care), and may then consider dropping them from reporting requirements. Once ART coverage is 100%, then LINK.2=ART.3 ART coverage and LINK.3=ART.1 New ART patients, and LINK.2 and LINK.3 become redundant. The subset of indicators (LINK.5/18, 7, 12, 17, 23) will reflect a population on ART rather than those simply enrolled in HIV care.
- Countries should continue to prioritize LINK.2 and LINK.3 at the facility level as they are relevant for quality of care.
- **LINK.5/18 TB screening coverage in HIV care, LINK.7 CTX coverage, LINK.21 TB diagnostic test for people living with HIV** and **LINK.23 TB preventive therapy completion** are collected via the HIV patient cards and ART register during an annual review.
- **LINK.12 TB prevalence in HIV care** and **LINK.17 TB preventive therapy coverage** have been revised to be a subset of those newly started on ART versus newly enrolled in HIV care. *See* indicator instructions in the Appendix for LINK.12 and LINK.17. For countries still transitioning, WHO recommends that subsets newly started on ART of global TB/HIV indicators LINK.12 TB prevalence in HIV care and LINK.17 TB preventive therapy coverage be collected via the ART register, and the remaining collected using an appended list of patients who enrol in HIV care and may not or will not start ART soon thereafter (*see* Annex 2.3.5).

Table 2.5 Minimum package of key indicators based on data collection and reporting capacity

Data collection and reporting capacity	Minimum set for paper card and registers	Minimum additional set for electronic systems, special studies or annual review
Indicators	5 ART (1,3,4,5,6)	3 ART (7,11,12)
	1 VLS (3)	3 VLS (1,2,4)
	5 MTCT (1,2,4,6,9)	4 MTCT (3,5,8,15)
	3 TB/HIV (LINK12,16,17)	5 TB/HIV (LINK.5,21,23,24,25)
	2 STIs (PREV 10,11)	
	2 HEP/HIV (LINK.27, 28)	
		2 LINKAGE (7, 11)
Subtotals	**18**	**17**
Total from HIV patient monitoring system	**35**	

Links between the indicators (subsets)

Understanding the links between the indicators will help programmes collect and aggregate data, and generate reports. Among the 18 key indicators for paper-based systems:

- six are "core" indicators (one of which is a common numerator that three indicators share);
- the remaining 12 indicators are subsets of these core six; and
- eight share the same numerator or denominator as the core six.

This is summarized in Table 2.6 and detailed in Fig. 2.5.

Many of the key additional 17 indicators are also subsets of these core six or of others. This is summarized in Table 2.6 and detailed in Fig. 2.6.

WHO recommends the following:

When aggregating any of the core indicators in a paper-based system, their subsets should be tallied at the same time to reduce redundant work, and maximize time and efficiency in the reporting process.

Table 2.6 Key HIV indicators and their subsets covered by the HIV patient monitoring system

ART.3 ART coverage 2 numerator: *# currently receiving ART* (GAM 1.2)	**VLS.3 Viral suppression** (GAM 1.4)	VLS.4 VL monitoring
	LINK.16 ART coverage during TB treatment numerator (GAM 10.1)	ART.12 Toxicity prevalence
ART.5 ART retention denominator: *# initiating ART up to 12, etc. months before beginning of reporting year* (GARPR 4.2)	ART.6 Short-term ART outcomes	VLS.1/ART.9 VL suppression at 12 months after initiation
		VLS.2/ART.8 VL testing coverage
		ART.11 ART survival
		MTCT.3/17 Early ART retention of pregnant and breastfeeding women
ART.1 New ART patients numerator: *# initiated ART within the past 12 months*	LINK.12 TB prevalence in HIV care (GAM 10.2)	LINK.11 Timely linkage from diagnosis to treatment among children under 5 years of age
	LINK.17 TB preventive therapy coverage (GAM 10.3)	MTCT.15 Infant ART initiation numerator
	LINK.27 Hepatitis B screening (GAM 10.6)	
	LINK.28 Hepatitis C screening (GAM 10.8)	
	ART.4 Late ART initiation	
MTCT.1/HTS.4 PMTCT testing coverage facility-based denominator: *# women who attended ANC or had facility-based delivery in past 12 months* (GARPR 3.4)	PREV.10 ANC syphilis screening coverage (GAM 2.4)	
	PREV.11 ANC syphilis treatment (GAM 2.4)	
MTCT.2 PMTCT ART coverage facility-based denominator: *# HIV+ women delivered in past 12 months and attended ANC or had a facility-based delivery* (GAM 2.3)	MTCT.4 Coverage of infant ARV prophylaxis (GARPR 3.7) facility-based denominator	
Numerator: *HIV-exposed infants born within the past 12 months*	MTCT.4 Coverage of infant ARV prophylaxis (GARPR 3.7)	MTCT.5 ARV coverage for mothers of breastfeeding infants
	MTCT.6/HTS.5 Coverage of early infant diagnosis (GAM 2.1)	
	MTCT.9 CTX coverage (GARPR 3.9)	
LINK.2 HIV care coverage[a] numerator: *# receiving HIV care* (GARPR 4.3)		LINK.5/LINK.18 TB screening coverage in HIV care
		LINK.23 TB preventive therapy completion

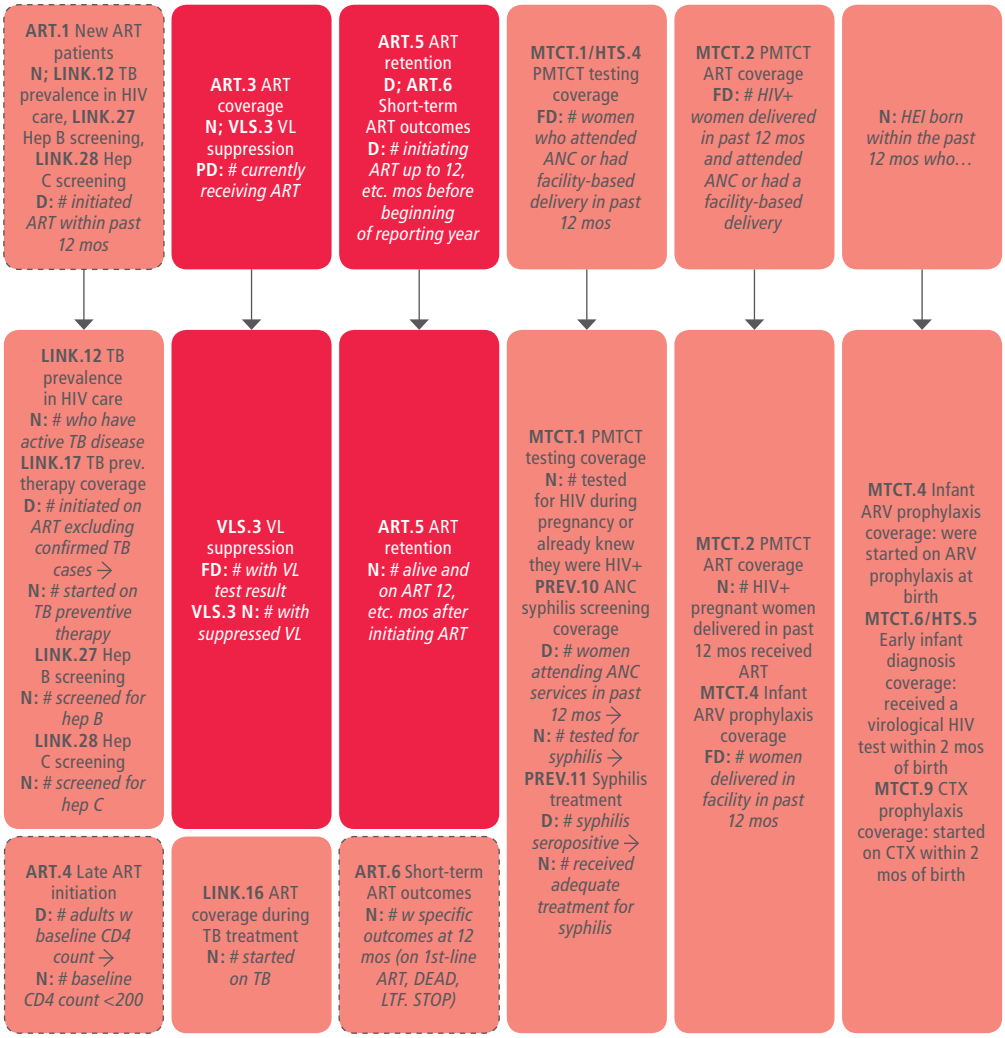
Key additional indicators	Paper-based indicator subsets	Additional indicator subsets
LINK.3 Enrolment in care[a] numerator: *# newly enrolled in HIV care*		LINK.7 CTX coverage
Denominator: *HIV+ new and relapsed TB patients identified during the reporting period*		LINK.24 Early ART for HIV-positive TB patients
		LINK.25 Early ART for profoundly immunosuppressed HIV-positive TB patients
LINK.21 TB diagnostic test for people living with HIV		
ART.7 ART adherence proxy		
MTCT.8 Final outcome status		
MTCT.15 Infant ART initiation		

[a] Not currently included as key indicator. *See* Box 2.17 for more details.

Note: The indicators in the grey boxes are the three global indicators.

ANC: antenatal care; ART: antiretroviral therapy; ARV: antiretroviral; CTX: co-trimoxazole therapy; GAM: Global AIDS Monitoring: GARPR: Global AIDS Response Progress Reporting; MTCT: mother-to-child transmission; PMTCT: prevention of mother-to-child transmission; TB: tuberculosis; VL: viral load

Fig. 2.5 Links between key indicators



Key

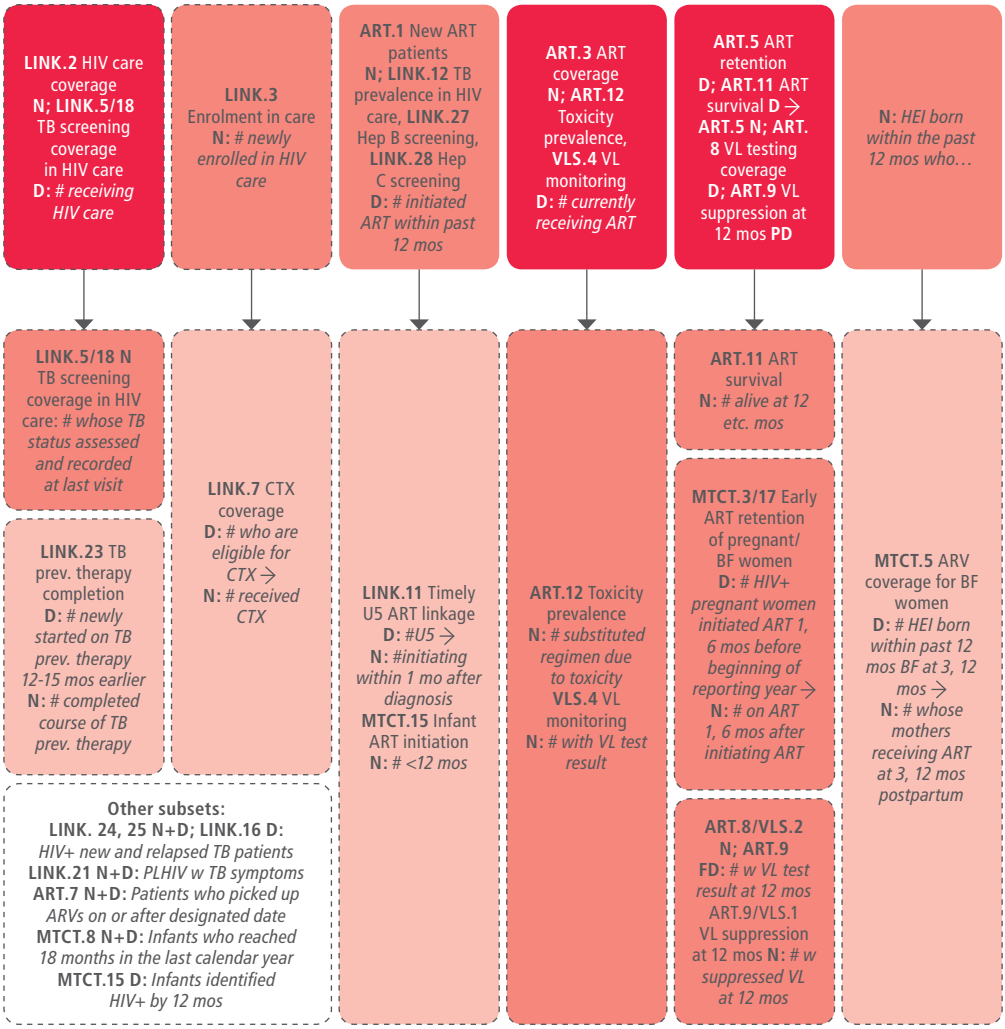
Global SI indicator

National SI indicator

PD: Population-level denominator
FD: Facility-/programme-based denominator
Solid line: GARPR/GAM indicators
Dashed line: Non-GARPR/GAM priority indicators

ANC: antenatal care; ART: antiretroviral therapy; ARV: antiretroviral; CTX: co-trimoxazole therapy; D: denominator; FD: facility-/programme-based denominator; GAM: Global AIDS Monitoring: GARPR: Global AIDS Response Progress Reporting; HEI: HIV-exposed infant; LTF: lost to follow up; HTS: HIV testing services; MTCT: mother-to-child transmission; N: numerator; PD: population-level denominator; PMTCT: prevention of mother-to-child transmission; SI: strategic information; TB: tuberculosis; VL: viral load

Fig. 2.6 Links between indicators



Key

- Global SI indicator
- National SI indicator
- Additional SI indicator

PD: Population-level denominator
FD: Facility-/programme-based denominator
Solid line: priority indicators for collection by routine paper-based system
Dashed line: non-priority indicators for collection by e-system, special studies or facility-based annual review

ANC: antenatal care; ART: antiretroviral therapy; ARV: antiretroviral; BF: breastfeeding; CTX: co-trimoxazole therapy; D: denominator; FD: facility-/programme-based denominator; GAM: Global AIDS Monitoring: GARPR: Global AIDS Response Progress Reporting; HEI: HIV-exposed infant; LTF: lost to follow up; HTS: HIV testing services; MTCT: mother-to-child transmission; N: numerator; PD: population-level denominator; PMTCT: prevention of mother-to-child transmission; SI: strategic information; TB: tuberculosis; VL: viral load

Disaggregation

WHO recommends the following:

- Indicator disaggregation should be prioritized by the capacity of the patient monitoring system.
- At a minimum, all indicators should be collected without disaggregation.
- Age may be simplified to <15 and 15+ years for paper-based systems, and <1, 1–4, 5–9, 10–14, 15–19, 20+ years for electronic systems, special studies or annual patient monitoring review.
- Non-MTCT indicators that recommend disaggregation by pregnancy or breastfeeding status should be collected via electronic systems, special studies or annual patient monitoring review.

Each category of disaggregation adds both a level of effort and complexity (and therefore error) in compilation; however, it also provides detail that allows for more comprehensive analysis and use of the data.

Annex 2.5 describes in more detail the priority consolidated SI indicators, including definitions for the numerator and denominator, recommended disaggregation and data elements necessary for measurement.

Table 2.7 Other important indicators not currently collectable from the HIV patient monitoring system

Consolidated SI guidelines indicator code	Level	Key information/remarks
KPOP.3 Key population ART coverage	**National**	Important, but potentially sensitive information may not be collectable in all settings, as it depends on the context and information systems. Special surveys may be required.
IMP.6 Equitable access to ART	**National**	Patient monitoring data may contribute to the ART coverage part of the indicator (*see* ART.3); however, other parts may require special surveys to collect potentially sensitive information on certain subpopulations, and model estimates for the number of people living with HIV.

2.5.3 Indicator instructions for HIV patient monitoring systems

The Appendix (page 162) contains detailed instructions on how to aggregate patient data on the 18 key HIV indicators using paper-based patient monitoring systems, as well as instructions on aggregating data for the 17 additional key indicators that may be collected through electronic patient monitoring systems or periodic review (*see* Section 2.6).

2.6 Periodic review and use of data from the HIV patient monitoring system[a]

2.6.1 Overview

WHO recommends the following:

- periodic review of the HIV patient monitoring system, including for quality of data and care;
- using the periodic review to collect key additional national, facility-based indicators, including the collection of clinic-level HIVDR EWI; and
- integrating these reviews as a key component embedded in routine supervision activities within the patient monitoring system.

Good-quality data are important to ensure that health workers and programme managers make well-informed decisions on clinical care, and facility and programme management. As countries scale up HIV services to implement "treat all" and report on the associated target indicators, it will be critical for sites to routinely assess and ensure data quality. As adequate data quality is being achieved, the information will be increasingly reliable for use in assessing and improving the quality of care.

To the extent possible, the annual review process outlined in this section should integrate any other periodic review of the HIV patient monitoring system. This includes components of the HIVDR surveillance and monitoring strategy described in Section 2.4.6. More specifically, the annual monitoring of clinic (facility)-level HIVDR EWI can be integrated into the APMR described below, and the secondary sampling methodology outlined in Annex 2.4.6 (method and sampling for collection of HIVDR EWI) is the same one that is recommended for sampling HIV patient cards as relevant for collection of key additional (Section 2.6.2, Step 2) or quality-of-care indicators (Section 2.6.3). Annex 2.4.6 provides a more detailed description of the methodology (including sampling) for collecting HIVDR EWI.

2.6.2 Periodic or annual patient monitoring review of data quality

As part of strengthening routine patient monitoring, a periodic review or APMR is a way to support active, episodic review of patient monitoring data, based on the generic HIV patient monitoring system (Fig. 2.7). It is a review of the patient monitoring records to help facilities accommodate quality reporting at different levels: HIV patient cards, ART register, ANC and L&D registers, and HEI register by the district management and clinical team to assess and improve the quality of patient-related data and care. This also includes collection of the 17 key additional indicators (*see* Fig. 2.3) recommended to be measured by electronic systems, special studies or **facility-based annual review**, as described in this section.

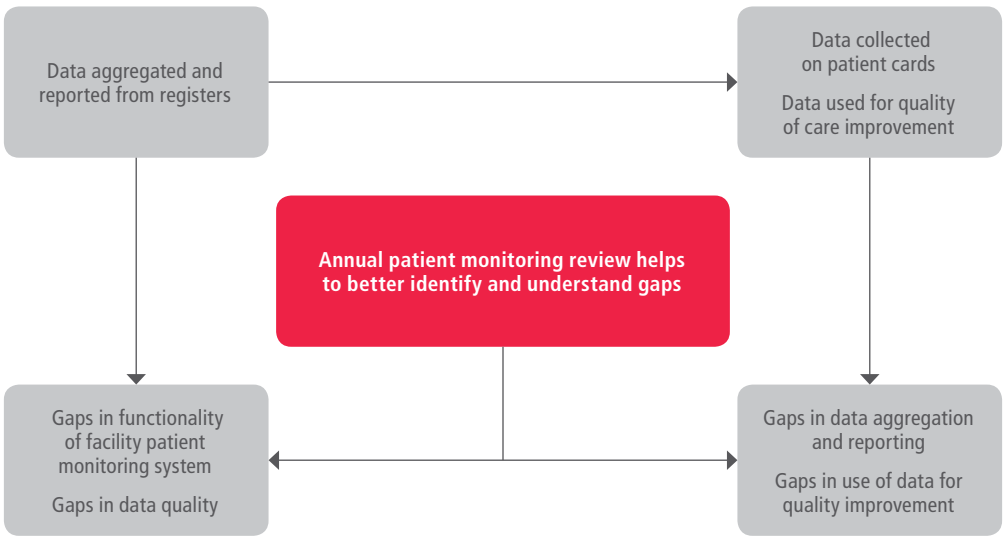
[a] Adapted in part from: Operations manual for delivery of HIV prevention, care and treatment at primary health centres in high-prevalence, resource-constrained settings, first edition for field testing and country adaptation. Geneva: WHO; 2008 (http://www.who.int/hiv/pub/imai/operations_manual/en/, accessed 17 January 2017).

The APMR includes five components (Box 2.18). It is not necessary to complete all five parts during every APMR visit. Depending on the need, one or more activities may be carried out during a single visit. For example, if a facility does not have adequate patient monitoring tools and if staff members are not well trained, it is not necessary to do components two to five. In such a facility, initial effort should concentrate on providing cards and registers, training staff in their use, and the importance of patient monitoring tools to track patients and promote continuity of care.

Box 2.18 Five components of an annual patient monitoring review

1. Rapid assessment of the patient monitoring system to identify gaps and areas for improvement;
2. Verifying data quality and tallying data for key additional indicators from a sample or census of the HIV patient cards;
3. Verifying data quality and tallying data for key additional indicators from the ART register;
4. Completion or verification of the ART cohort report; and
5. Validation of the cross-sectional report.

Fig. 2.7 Overview of annual patient monitoring review



An APMR:

- complements routine data collection, aggregation, reporting and use of data for improving the quality of care;
- complements the monthly or quarterly reporting of cross-sectional data by validating routine reports;
- uses routine patient monitoring systems to provide key indicators of what is happening in the provision of HIV, HIV/MNCH and TB/HIV services at facility level;
- can help collect or verify national and global HIV, HIV/MNCH and TB/HIV indicators, and may be combined with collecting HIVDR EWI (*see* Annex 2.4.6);
- provides information to the clinical team on quality of care and helps to analyse key indicators, including ART cohort analysis (i.e. for ART outcome monitoring); and
- helps identify and respond to problems if any; and enables the development of an action plan for quality improvement.

Responsible staff

An APMR should be a routine and integral part of the health-care system. Ensuring the quality of data, and assessing and improving the quality of patient care should be routinely done by the clinical team and the district programme management team as part of health-care delivery. Ideally, an APMR should be done as a collaborative effort between the following:

- facility clinical team: people who are familiar with the clinical guidelines and case management process;
- district team: HIV, TB/HIV, MNCH, health information staff on the district team;
- technical staff from partners active in the district; and/or
- regional team input: patient monitoring, HIV, TB/HIV or MNCH programme staff.

Time and effort required

The APMR methodology described in this section was field-tested in three countries.[a] Results indicated that:

- rapid assessment of the patient monitoring system is very important, as it can help to identify gaps and improve the overall system;
- register tallies can be done at a rate of approximately 100 patients/hour;
- card tallies can be done at a rate of about 100–150 cards/day or more, depending on how cards are filed;
- establishing the active population from registers takes about half an hour per register;
- supervisors and data clerks agree on integration into routine activities.

Components of an APMR

The first component is a rapid assessment and the four steps thereafter provide support for verifying data quality (*see* Box 2.19) and then using the data to improve quality of care (*see* Section 2.6.3).

[a] Guyana, Ethiopia, Namibia.

Step 1. Rapid assessment of the patient monitoring system at facility level

- Prior to the assessment, the team should make sure it has received all the necessary patient monitoring system reports from the facility.
- Assessment teams should come to facilities after having looked at the data from the facility, and having already identified potential issues and even solutions. This allows time to be used constructively by focusing on specific challenges. If regular assessments are carried out, this allows a focus on one or two issues at each visit, and identification of improvements made since the last visit.

A checklist should be used:

- to determine the extent of integration of the HIV, MNCH and TB patient monitoring systems. This will help determine which tools to use for the review.
- to assess whether the patient monitoring system is functional enough to undertake the other four activities of the review;
- to determine the quality and completeness of information generated by the patient monitoring system;
- to determine the human resource capacity and any (re)training needs at facility level;
- to formulate an action plan for solving problems that are identified during the rapid assessment.

Annex 2.6.2 provides a generic checklist. A more comprehensive, country situation analysis tool, which includes the possibility of asessing HIV case surveillance and unique identifiers at the same time, is available in Annex 3.5.2.

Box 2.19 Data quality: definitions, common issues and key principles

Incomplete, illegible or misplaced records cannot help clinicians understand how to manage patients or improve programmes, and will compromise patient care. More than a decade into the scale up of ART globally, poor quality of routinely collected data (incomplete, missing or implausible) may still hamper effective data use *(27)*.

In general, good data quality requires information to be:

- **accurate** (valid) – data measure what they are supposed to measure;
- **complete** – all forms and fields are filled in every time, and are legible;
- **reliable** (consistent) – data are measured consistently over time;
- **timely** – data are collected, analysed, used and reported on time (if there is a deadline), or within a time frame allowing feedback and improvement of clinical care;
- **precise** – data have sufficient detail to measure the entity of interest;
- **confidential** – data are kept secure and private during collection, storage, transfer, analysis and dissemination (*see* Section 3.4.11 for related information).

Data quality can be enhanced by carefully recording and transcribing information. However, because everyone makes mistakes, data quality assessments should be integrated into the periodic review or APMR and done routinely. Some examples of common data quality issues include:

- blank fields;
- illegible entries;
- unusual entries (e.g. larger or smaller than expected numbers, such as infant's weight = 3000 kg instead of 3000 g);
- rounding tendencies (e.g. heaping around numbers ending in 0 and 5);
- misplaced entries (e.g. number of current on ART mistakenly entered in cumulative number on ART box);
- repeated entries (e.g. 5687 new on ART and 5687 current on ART);
- misinterpreted entries (e.g. recording a percentage instead of a number).

Key principles to ensure good data quality include the following:

- **Simplify, minimize and standardize** data collection and reporting tools to only include information that is used for either patient monitoring or programme or facility management.
- **Employ and train lay and health workers** to perform data collection and reporting (*see* Section 2.7.3 for minimum recommendations).
- **Train** staff in the basics of good data quality (e.g. "the 3 Cs": completeness, consistency and correctness) and integrate this into daily practice, and encourage or train staff involved in data entry or reporting to **use the data**.
- Reinforce data quality training through routine review and **feedback** during **supervision and clinical mentoring** visits using the most recent data from the site (*see* Section 2.7.3).
- Include **data quality assessments** in supervision visits by external evaluators with actions linked to the results of the review.
- Ensure that all people who handle, process, stack and store records and registers containing information on HIV status and services maintain **strict confidentiality** of patient data (*see* Section 3.4.11 for related information).

Step 2. Verifying data quality and tallying additional key data from the HIV patient cards

Verifying information in patient records (primary data source)

It is most important to evaluate the accuracy (*see* Box 2.19) of the primary data source (i.e. HIV patient card). If this information is not of good quality, it will compromise everything being transcribed or aggregated further up the chain in the register and reports.

Clinical staff should be trained and evaluated in record-keeping. Clinical staff at the district level should also receive regular training on how to fill out and use the patient monitoring tools (*see* Section 2.7.3). This can be done using case observation by a clinical mentor, supervisor or external reviewer, or more efficiently in the form of district-based training in clinical record-keeping organized on a quarterly or six-monthly basis.

Routine review of patient records

Clinical staff should quickly scan the patient record at the end of each patient visit to ensure that all information has been filled out, is legible and accurate. The data clerk or other staff member who transcribes information from patient records needs to make a note of incomplete, missing or implausible information so that problems can be resolved. By placing problem folders aside and having time allocated for clerks to provide feedback to clinicians (in regular meetings) and clarify queries, clinical record-keeping can improve.

Verifying information during patient registration

Patient registration and subsequent clinical visits provide a good opportunity to verify or update patient demographic data and make sure information is complete. Addresses and telephone numbers should be checked and updated regularly, particularly if calling patients by phone is part of the standard operating procedure for tracing those who have missed appointments.

Periodic review of patient records

A periodic review of a sample of patient records is a good way to check for data quality. This approach could be incorporated into supervision visits by the district health management team or done during an annual or biannual patient monitoring review. For example, quarterly supervision could include randomly pulling 10 patient cards (folders or charts) and checking the data against the ART register.

Comparing changes in data (and possibly data quality) over time

Another way to check data quality is to compare information collected at one time point with information collected at another, and to assess whether both appear to be equally complete, consistent and valid at every interval. Ideally, data quality should improve over time, but increases in the number of people on ART may place a strain on the data collection system. When data quality declines, it becomes difficult to analyse trends in the data.

Cohort reports are useful for identifying changes in trends over time (increase in LTF or decrease in the proportion having viral load measured). If a negative trend is identified, e.g. a lower proportion of people having viral load measured at 12 months, then the first point of inquiry would be to see whether this is a data issue (e.g. results not being re-filed into folders) or a quality-of-care issue (e.g. viral load not being performed) (*see* Section 2.6.3 on using data to improve the quality of care).

Tallying key additional data from HIV patient cards

Most patient-related information is collected to help the clinical team perform routine individual patient care. Select indicators, collected through the routine patient monitoring system, or through periodic review, can be analysed by the clinical or district team for assessment of quality of care. These data are collected routinely on the HIV patient card or any other facility-held record. Table 2.9, Section A shows the key additional indicators below the line in Fig. 2.3 that may be calculated via a sample of HIV patient cards. The following is a more specific list of steps that may also be taken to collect clinic-level HIVDR EWI, as well as more broadly applied when measuring quality-of-care indicators, and should be carried out at the same time to the extent possible to optimize time spent and resources used (e.g. using the same sampled patient cards for abstraction of different data elements for the same relevant eligible patient population).

To tally key additional data using a sample of HIV patient cards, do the following:

A. **Identify the eligible patient population.** This should be limited to patients seen during the last calendar year. This is the denominator of the indicator being measured. For the key additional indicators, such as LINK.5/18 TB screening coverage in HIV care, the denominator is the number currently enrolled in HIV care. These numbers may be taken directly from the cross-sectional report (i.e. currently on ART) plus a tally from the list of patients who may not or will not start ART soon after enrolment into HIV care (previously the pre-ART register).

B. **Determine the sample size.** Once the total number in the eligible population has been tabulated, use Table 2.8 to determine the necessary number of eligible patients to sample. This is the same sampling methodology for collecting HIVDR EWI at facility level, and can be used to assess quality of care as well as quality of data.

Table 2.8 Guide for number of charts or cards to review by patient numbers in the facility[a]

Annual number of "eligible patients" at the clinic	Number to be sampled at the clinic
1–75	All
76–110	75
111–199	100
200–250	110
251–299	120
300–350	130
351–400	135
401–450	140
451–550	145
551–700	155
701–850	160
851–1600	175
1601–2150	180
2151–4340	200
4341–5670	210
5671–10 000	215
>10 000	220

[a] This is the sampling method required to estimate HIVDR EWI at facility level with 95% confidence interval of ±7% and true proportion of 50%. *See* Annex 2.4.6 for more details.

C. **Establish the sampling interval.** To establish the sampling interval, divide the total number of patients in the eligible population by the necessary sample size. This will yield the sampling interval (X). For example, using Table 2.8, if there are 3000 patients currently in HIV care, then the sample size will be 200, and X is 3000/200=15.

D. **Systematically sample from the eligible patient population.** Go through the ART register and list of patients who may not or will not start ART soon after enrolment into HIV care and mark every Xth patient within the eligible population until the sample size has been reached. Pull out the corresponding HIV patient cards using the unique or patient clinic ID. If the patient chart or card is physically missing or the patient is no longer eligible (e.g. dead, but not updated in the ART register) and the number of sample cards is inadequate, cycle through the ordered list again, i.e. counting 15 from the last patient in the list sampled. For EWI, if it is not feasible to sample every Xth record, consecutive sampling of records may be used (*see* Annex 2.4.6).

E. **Follow indicator instructions from the Appendix** for collecting each indicator. A tally sheet may be helpful. If HIV patient cards have missing information (e.g. no TB status recorded) for a particular indicator, include it in the overall tally, but note the percentage of patients with missing data to facilitate interpretation of the indicator and follow up on the reason(s) why. For HIVDR EWI, if missing data are ≥30%, the indicator is flagged for having insufficient data and the clinic is classified as "grey" (*see* Section 2.4.6).

Table 2.9 Data elements from recommended key additional indicators to tally by patient type

A. Using ART register and list of patients who may or will not start ART soon after enrolment into HIV care to identify eligible population and sample HIV patient cards to tally key additional indicators			
TB status completed at last visit[a] **(LINK.5/18)**	X	X	
TB symptoms (TB status = presumptive) **(LINK.21 D)**	X	X	
Investigated using Xpert as first test **(LINK.21 N)**	X	X	
Active TB disease (TB status = TB+) **(LINK.7 D1, LINK.24 D)**	X	X	
CD4 count <50 cells / mm^3 **(LINK.25 D)**	X	X	
CD4 count ≤350 cells / mm^3 **(LINK.7 D2)**	X		
Eligible for CTX = active TB (D1) + CD4 count ≤350 cells / mm^3 (D2) **(LINK.7 D)**	X	X	
Received CTX at last visit[a] **(LINK.7 N)**	X		X[b]
B. Using ART register to tally key additional indicators			
U5 initiating ART **(LINK.11 D)**		X	
Initiating ART within 1 mo of diagnosis **(LINK.11 N)**		X	
Initiating ART by 12 mos **(MTCT.15 N)**		X	
Started TB preventive therapy 12–15 mos ago **(LINK.23 D)**	X	X	
Completed TB preventive therapy **(LINK.23 N)**	X	X	
Started on ART within 8 weeks of TB+ diagnosis **(LINK.24 N)**	X	X	
Started on ART within 2 weeks of TB+ diagnosis **(LINK.25 N)**	X	X	

Patient category/data element	Adults, children 5+ years	Children <5 years[a]	HEI[a]
Substituted regimen due to toxicity (by ARV regimen, toxicity) **(ART.12 N)**	X	X	
C. Using HEI register to tally key additional indicators			
HEI born within the past 12 mos who are breastfeeding at 3 mos **(MTCT.5 D1)**			X
Mother on ART at 3 mos postpartum **(MTCT.5 N1)**			X
HEI born within the past 12 mos who are breastfeeding at 12 mos **(MTCT.5 D2)**			X
Mother on ART at 12 mos postpartum **(MTCT.5 N2)**			X
HEI who reached 18 months[a] **(MTCT.8 D)**			X
Final outcome status **(MTCT.8 N)**			X
Final outcome: HIV+			X
Final outcome: HIV-, not breastfeeding			X
Final outcome: in care, not tested			X
Final outcome: lost to follow up			X
Final outcome: transferred out			X
Final outcome: dead			X
HEI identified as HIV-positive by 12 mos **(MTCT.15 D)**			X

[a] Within prior calendar year
[b] If >4 weeks old
ART: antiretroviral therapy; ARV: antiretroviral; CTX: co-trimoxazole therapy, HEI: HIV-exposed infant; TB: tuberculosis

Step 3. Verifying data quality and tallying additional key data from the ART register

Verifying data in the ART registers

Comparison of patient records with registers HIV

One way to check data quality is to compare the information in the patient record (data source) with data in the register. This can be done with a random sample of patient cards, a purposive sample (e.g. all patients seen on a specific day, week or month, or all those enrolled in care or started on ART during a certain time period). The comparison can be comprehensive (verifying every data element in the ART register with the corresponding data element(s) in the patient card) or selective (e.g. verifying TB status assessed), depending on the time and resources available.

Updating the ART registers

Depending on patient volume, completing paper-based ART registers can be time-consuming. One important principle critical to ensuring good-quality data is to only collect data that are useful to health facility workers and programme managers once these are aggregated into cross-sectional and cohort analysis reports. This can minimize the amount and complexity of information collected. Ideally, registers should be updated on a daily or weekly basis if the patient load permits. For sites using electronic registers, real-time entry allows for the creation of appointments and missed appointment or LTF patient lists.

Taking care of backlogged ART register entries

If there is a backlog of patient cards that need to be entered into the ART register, there is no one best way to address this, aside from being systematic. Depending on the amount of the backlog, it may be helpful to set aside a day or several days during which data entry clerks go through all patient cards by ART start date (entered chronologically). The backlog can also be taken care of concurrently while entering new patients into the ART registers (leaving enough room in the registers to fill in the backlog of patients, or using a separate ART register). It may be easier to form quarterly or yearly (versus monthly) cohorts for very early patients in the national ART programme when there were very few patients starting ART, where dedicating an entire page to a small number of patients by monthly cohort would be wasteful. However, backlogs should be avoided to the extent possible, as they may cause inaccurate data entry, and require the expenditure of considerable time and effort on a laborious task.

Tallying additional key data from the ART register

Data that are not routinely reported can be aggregated during the APMR to assist the clinical team in improving the quality of care and measuring key additional indicators from the ART register (*see* Table 2.9, Section B), including the following:

- **LINK.11** Children under 5 years of age initiating ART within one month of diagnosis;
- **LINK.23** Patients in HIV care who completed TB preventive therapy, having started on therapy 12–15 months earlier;
- **LINK.24** HIV-positive new and relapse TB patients started on ART within 8 weeks of TB diagnosis (reconciled with TB register);
- **LINK.25** HIV-positive new and relapse TB patients with CD4 count <50 cells/mm^3 started on ART within 2 weeks of TB diagnosis (reconciled with TB register);
- **ART.12** numerator: substituted regimen due to toxicity within the past 12 months;
- **MTCT.15** numerator: infants started on ART by 12 months;

- Started on CTX; and
- Received viral load test results 2, 6 months after ART start (among pregnant women).

The following additional key indicators (*see* Table 2.9, Section C) can be aggregated from the HEI register:

- **MTCT.5** numerator and programme-based denominator: HIV-exposed breastfeeding infants born within the past 12 months whose mothers are receiving ART at 3 (and 12 months) postpartum;
- **MTCT.8:** final outcome status of HEI who have reached 18 months; and
- **MTCT.15** denominator: HIV-exposed infants identified as HIV-positive by 12 months.

Instructions for collecting these indicators can be found in the Appendix. A similar tally sheet to the one created to tally patient card indicators may be used here, but instead of having individual patients in the columns, have monthly cohorts (HIV care enrolment or ART start cohorts), with the indicators *(e.g. started on TB preventive therapy or TB treatment)* remaining in the rows.

Step 4. Completing or verifying the ART cohort report

The cohort analysis report (Annex 2.3.6b) contains important clinical and programme information pertaining to the cascade of HIV care. Ideally, the health facility should routinely complete the cohort report, but the district team may facilitate this process and the district health team or supervisor should, to the extent possible, ensure its accuracy by redoing the cohort analysis report using the ART register(s) during routine visits. However, there are different models for routine collection of data from cohorts receiving HIV services, depending on the size and type of the epidemic, the size of the country and its administrative units, as well as several other factors. For example, Malawi has opted for a centralized system with teams visiting sites for quarterly supervision where data are reviewed and tallied directly from the patient card. South Africa has a more decentralized system where each facility sends monthly and quarterly cohort information to the district level where it is checked and aggregated before being sent on to the provincial and national levels.

If ART registers are being used, cohort reports can be directly transcribed from the register. If not, an intermediary step should be used of transcribing from the patient card/folder to a "register" to aggregate the data.

Step 5. Validation of the cross-sectional report

Aggregating the cross-sectional report by hand can be tedious and prone to error. This is particularly the case for numbers disaggregated by age and sex, and the indicator, *current on ART*. The district health team or supervisor should pay special attention to this information in the report by going back to the ART register (or, on a less routine basis, to the patient cards) and re-aggregating the numbers, checking for consistency over time, and comparing information against other health facility reports where possible.

The updated quarterly report includes indicators for HIV, TB/HIV and HIV/MNCH, which involve tallies from multiple registers. These indicators should be reported on a quarterly basis as required by the national programme. During the APMR visit, the team can validate the most recent report, and help facilities aggregate quarterly indicators to calculate annual indicators as necessary for annual reporting (e.g. of the TB/HIV indicators).

Box 2.20 Other methods of verifying data

Validating facility-level reports

Once district health staff receive facility-level reports, it is important that they validate the data. This can be done using the checks described in this section, and contacting the health facility to verify information that may be missing, inconsistent or incorrect (e.g. by comparing the current report to past reports, checking for completeness, legibility and unusual numbers).

District feedback meetings

Regular district meetings held with each facility are a good venue for discussing data quality concerns or highlighting good data quality in the reports received and validated.

Electronic data verification

Data entered electronically comes from a paper form in most cases. Before assessing data quality in the electronic system, it is essential to validate this paper-based data source. Electronic systems are still vulnerable to poor data quality, usually at the point of data entry. Depending on the system, it is possible to build in automatic checks to call out errors such as fields left blank; numbers entered out of range; or numbers entered in the wrong format. Even with these automatic checks, it is important to always check data once they are entered and before they are aggregated to ensure good-quality registers or reports.

Triangulating data

Triangulation is a powerful technique that facilitates validation of data through cross-verification from two or more sources. There are many examples where this could be useful for monitoring of chronic care. For example, the proportion of patients who have received a viral load test or who have suppressed viral load reported through the patient monitoring system can be validated by triangulating with laboratory data reported for the same period. The number of people who have picked up drugs as ascertained through a pharmacy register can be compared with the number of people on ART measured through the patient monitoring system. As chronic care services (HIV, TB, etc.) are integrated, data triangulation from different sources will likely bring benefit without adding the burden of collecting more information. Similarly, triangulation can also be used by case surveillance to verify data sources, including the patient monitoring system (*see* Chapter 3).

2.6.3 Using data from the patient monitoring system to improve quality of care

The patient monitoring system is an important primary data source relevant for quality assurance and quality improvement efforts. The health facility is already collecting a considerable amount of information for routine patient monitoring, summarizing it in registers and logs, and reporting to district and national levels. Using this information to assess the quality of care provided to patients is a powerful opportunity to determine where there are gaps that need to be addressed in the cascade of care. This can complement other quality-of-care assessment methodologies such as patient interviews, direct observation of patient–provider interactions for assessment of health worker competence and practice, and other approaches.

The first step in improving the quality of HIV care is to identify the process that needs improvement. Given that most health facilities have limited time and resources, priorities for quality improvement and assurance should be important and relate to national guidelines and protocols; represent key community and clinic staff concerns; be measurable, and include identification of the level of the health system that is responsible for addressing specific issues, e.g. determining that laboratory equipment is broken occurs at the facility level, but replacing it is the responsibility of the district team. If patients are not receiving the necessary laboratory tests, the process can be improved by redesigning systems such as clinic flow patterns, and then testing these changes to see if they work.

Countries have already adopted a set of national HIV indicators, many of which can also be used to measure the quality of care. Additionally, patient chart or card abstraction can be a proxy for assessing the competence and practice of health workers in routine care settings. However, incomplete registers and patient charts or cards could pose a challenge in some settings.

The performance of health-care providers is an important predictor of quality of care, although other confounding factors may also influence patient care. Patient charts or cards could provide more obvious information such as adherence of health workers to national or global treatment guidelines or protocols, such as ARV regimens prescribed or interpretation and use of laboratory results.

Box 2.21 Key principles of quality improvement

- Use available data to help identify current gaps that need to be addressed.
- Ask staff and patients for ideas about what needs to be improved.
- Prioritize key opportunities for quality improvement.

The following provides broad guidance on steps for using a patient card in assessing the quality of care, and (steps 3, 4 and 5) may overlap with the second step of the APMR (tallying key additional indicators from the HIV patient cards) described in Section 2.6.2. To the extent possible, these two activities should be conducted together (tally indicators from the APMR at the same time as those for quality improvement, which may be the same in some cases).

Step 1. Determine which indicators to use

Performance measurement indicates what is really happening, as opposed to what is believed to be happening. It indicates whether tasks that are supposed to be done are being done, and done well. Even in small facilities where the staff knows the patients well, measuring performance will often result in surprising findings when the data are compiled. Some indicators are required for district or national reporting. However, the facility may choose to measure additional indicators based on its specific priorities. Table 2.9 may provide a starting point. It includes additional key indicators by eligible population, as measured annually. To start measurement, make sure that the indicator is clear, and develop a uniform process for data collection.

It is important that the indicator(s) used to assess the quality of care is well defined (*see* Box 2.22). To define a sound indicator:

- **Set the numerator.** Which patients received the service? For example, the number of patients from the denominator group who were prescribed CTX;
- **Set the denominator.** Which patients *should* receive the targeted service? In this case, it will be the sample of patients identified from the active case list, register(s) or sample of patient cards.

If the data are not already collected as part of the standard patient monitoring system (or are not contained in an electronic database that can produce the information), the following steps should be carried out:

- Define **how** the data will be recorded.
- Decide **who** will record the data.
- Determine **when** the data will be collected.

Steps 3–5 may be carried out at the same time as the APMR for a sample of HIV patient cards or collecting the HIVDR EWI, if the time frame and eligible population are the same.

Box 2.22 Examples of indicators used for quality improvement elsewhere

Many indicators are often collected routinely using national patient monitoring systems (*see* the list of indicators in Section 2.5). The following are taken from the list of key additional indicators from Table 2.9:

- **LINK.5/18:** Were patients assessed for active TB at the last clinical encounter?
- **LINK.7:** Did patients who were eligible for CTX prophylaxis receive it?
- **MTCT.6:** Did HIV-exposed infants receive a virological test for HIV within two months of birth?

Step 2. Define the time period to include in the review assessment

Performance is measured over a specific time frame. The patients who were actively seen during this time period are the only subjects included in the measured group, and are chosen from the case list or register. If the review is carried out annually, the time period may be the last calendar year; however, if the indicator is one that requires more immediate review, it may be the last quarter.

Step 3. Define the eligible population for the review

Depending on what will be assessed, only certain groups of patients may be eligible to be included in the review. For example, the indicator may apply to both men and women, and to children, or to the latter only in certain clinical conditions. Other criteria for inclusion could be whether the patient is new or has already been on treatment. The list of eligible patients may also need to be sorted by age or gender, depending on whether the indicator applies only to children, men or women. A review of charts needs to include all patients seen during the review period, including those who died or were transferred in from other health facilities.

Step 4. Decide how many patients to include in the review, e.g. a sample or all patients

Ideally, all patients would be included when measuring the indicator (100% sample or census), but this may be labour intensive without an electronic patient monitoring system. In settings with paper-based systems, the options are to review all patient charts (e.g. if the number of patients is small) or to use a sampling methodology. Table 2.8 is an example of a "look-up" sample size table showing the number of charts to include in the sample, depending on how many patients there are in the eligible population defined in Step 3. It is based on a desired level of statistical precision and mirrors the secondary sampling methodology for collecting HIVDR EWI at facility level (*see* Annex 2.4.6). In many settings, it may be simpler to review all charts if the patient population is less than 200 patients, for example. This sampling scheme is also used for the APMR when pulling out a sample of patient cards.

Step 5. Generate a random list of patient charts to review

If it is not possible to easily generate a random list of charts to review by patient, patient unique identifier or other facility enrolment number, there is a simple way to identify the patients to be included in the sample. This is done by dividing the total number of eligible patients identified in the register(s) or the active case list by the number of patients who need to be reviewed, based on Table 2.8. Use this number to create the sequence of the sample. For example, if there are 750 eligible patients for the CTX indicator, the look-up table indicates that the sample should be 146. If 750 is divided by 146, the result is 5. Take the ordered list (or patient cards arranged in order of enrolment) and select every fifth patient. Remember that the list must be one that records each patient no more than once. If the patient chart or card is physically missing or the patient is no longer eligible (e.g. dead, but not updated in the ART register) and the number of sample cards is inadequate, cycle through the ordered list again, i.e. counting five from the last patient in the list sampled.

Step 6. Understand the underlying process or system and make changes to improve HIV care

Once the basis for the gap or issue has been acknowledged, improvements can be made to whichever part of the overall system needs change (e.g. patient waiting time, drug supply management, etc.). These changes should be tested and the indicator(s) re-measured to analyse the impact on care. A simple run chart plotting the measurement data over time can provide a representation of progress in quality improvement. Fig. 2.8 provides an example of such a chart, displaying the proportion of patients on CTX by month. Such charts can be displayed in the clinic to inform staff about how the system is working, whether improvements are occurring, or whether they are needed.

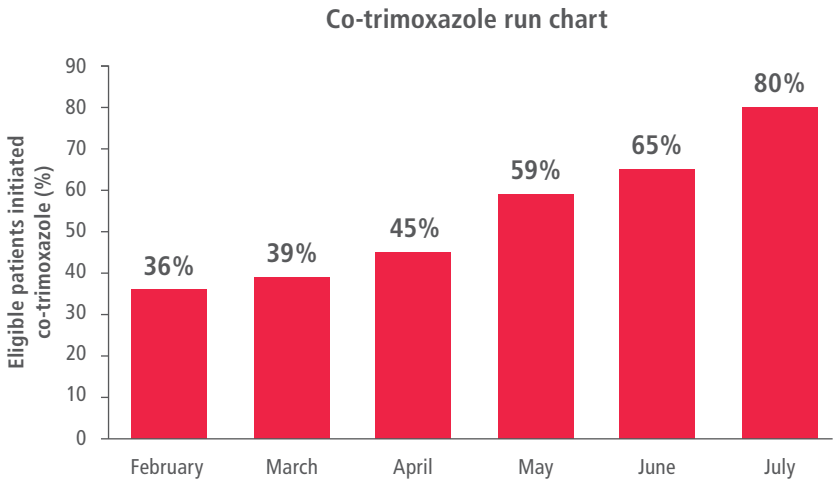
Both the APMR and quality-of-care monitoring can identify problems. For example, the data may show that the number of patients stopping ART may be increasing, or that adherence is suboptimal, or that the proportion of patients with almost perfect adherence has remained steady, rather than increasing. These problems may have multiple causes. When a problem is identified, it is important to do the following:

- Describe the problem in as much detail as possible. Specify when, where and with whom the problem occurred. Remember that some indicators may reveal problems that occurred months ago. Determine if the problem is still occurring.
- Investigate the causes of the problem. Different causes require different solutions. Keep asking "why" until the root causes of the problem are identified. In some cases, it may be helpful to conduct or participate in a special study to investigate the causes of a problem or to request help from the regional or national programme team.

- Identify solutions appropriate to the causes of the problem. For example, if health workers do not know how to perform a task, training may be a solution. On the other hand, if the cause is a lack of equipment or supplies, a different solution is needed. Solutions should:
  - remove the cause of the problem (or reduce its effects);
  - be feasible (affordable, practical, realistic);
  - not create another problem.

If a problem has several root causes, it may be necessary to implement several solutions to address all of them. For example, if there is a lack of both equipment and training, a solution needs to be found to both problems.

Fig. 2.8 Example of a co-trimoxazole coverage run chart



Data routinely collected through patient monitoring systems can also be used to inform supportive supervision visits by programme managers and for mentoring health-care providers, and can provide useful feedback for in-service training of health workers. Supportive supervision, clinical mentoring and in-service training for health workers in turn contribute to ensuring the quality of care.

Regular (e.g. monthly or quarterly) district meetings should be held with each facility. A small number of indicators should be presented at each meeting and these indicators compared across facilities and time. Indicators can be programmatic or for management purposes, depending on the need. Annual target-setting for enrolment at the district level should be discussed and enrolment targets set for each facility. A couple of the key programmatic indicators to follow are new and current patients on ART per facility per month, as measured against the target for the district. This allows the district to build up a view of coverage and overall retention in care across facilities, and permits sites that are performing well to share insights into managing large numbers of patients.

Box 2.23 Examples of how to collect and interpret quality-of-care indicators

ART.4 Late ART initiation: proportion of patients initiating ART with CD4 <200 cells/mm^3. Ideally, this proportion will decrease as patients are enrolled into HIV care and initiated on ART as soon as they are identified HIV-positive according to the 2016 WHO ARV guidelines. If the stages of the cascade are adequately followed, this proportion should approach zero. If it is high (e.g. >50%), it is important to understand why (HIV testing and counselling not being linked to HIV care, drug stock-out, etc.) and address the issue. Once the improvement in the system is made, the proportion should decrease over time. The indicator can come from the ART cohort report form, verified by reviewing the ART register and a sample of HIV patient cards if necessary (all patients initiating ART in the last X months would be the eligible population).

MTCT.8 Final outcome status: proportion of HEI with a final status outcome at 18 months. Following the HIV-infected mother and her HIV-exposed infant can be challenging in settings in which ANC, postpartum and child health care is separate from HIV care and treatment. If the proportion is low (e.g. <50%), it is important to understand where in the system the breakdown in follow up may be occurring, e.g. HEI status is not checked during postpartum or routine child health visit (immunizations); the HEI register is not updated or accessible; etc. It is important to know whether the infant has been diagnosed with HIV in order to start ART as soon as possible to suppress viral load and improve general health outcomes. Creative patient tracking methods may also help (*see* Section 2.4.3). This indicator would come from the HEI register and HIV patient cards of HIV-infected mothers over X time period. As the number of these may not be high, it may be necessary to take all cards rather than sample them.

LINK.5/18 TB screening coverage in HIV care: proportion of people enrolled in HIV care whose TB status was assessed and recorded at their last visit. The high comorbidity of TB in patients with HIV underlies the importance of making sure patients are assessed for active TB at every visit. Simplified algorithms comprising TB symptoms allow lay health workers to assess and refer patients from the community as relevant. If the proportion is low, as with the other example indicators, it is important to figure out why. The first step is to figure out if it is due to poor data quality – are the health workers assessing TB status but leaving the column blank? Or is it an issue of poor quality of care – are they recording ND (Not done)? Or is it an issue of poor quality of data and care – are they not assessing TB status at all and leaving the column blank? Observation of clinical encounters either by a clinical mentor or supervisor, or using a trained mystery patient may help clarify the underlying issue at hand. The second step is to address the issue – whether due to poor quality of data (why are the health workers leaving the column blank? Is it due to poor training or understanding of how to fill in the card? Are the codes too complicated? Do they not have enough time?) or care (why are the health workers not assessing TB? Are they not familiar with the protocol? Do they lack the necessary training? Do they not have enough time? Or do they not think it is important enough?) – or both. At the facility, this indicator would come from a sample of all HIV patient cards (the eligible population is all patients) over X time period. Alternatively, this indicator will also be collected on an annual basis during the APMR (*see* Section 2.6.2) as an additional key indicator.

Box 2.24 Data quality references and resources

Section 3.4 of the 2015 WHO *Consolidated strategic information guidelines for HIV in the health sector* describes a harmonized approach to assessing data quality for routine, annual and in-depth reviews of facility-level information (data quality review), available at: http://www.who.int/hiv/pub/guidelines/strategic-information-guidelines/en/. There is a working document, including a toolkit for two pieces of this approach – the annual and in-depth or periodic assessment of facility data quality, available at: http://www.who.int/healthinfo/facility_information_systems/data_quality_analysis_assessment/en/. The methodology involves a desk review, data verification and system assessment.

MEASURE Evaluation has compiled guides and tools for assessing data quality on its website, available at: http://www.cpc.unc.edu/measure/resources/tools/monitoring-evaluation-systems/data-quality-assurance-tools.

The Global Fund to Fight AIDS, TB and Malaria (The Global Fund) has developed a guide and tools for data and service quality assessment by its recipients, available at: http://www.theglobalfund.org/documents/lfa/LFA_TargetedDataQualityReview_Tools_en/.

Another method of data quality assessment is the use of lot quality assurance sampling (LQAS). LQAS is a method taken from industry that classifies "lots" – health centres, for example – as having "good" or "poor" data quality based on predetermined thresholds, and associated samples and decision rules. Malawi used this in their national AIDS programme to evaluate the accuracy of routine reports by health facility (*see* Hedt-Gauthier BL, Tenthani L, Mitchell S, Chimbwandira FM, Makombe S, Chirwa Z et al. Improving data quality and supervision of antiretroviral therapy sites in Malawi: an application of lot quality assurance sampling. BMC Health Serv Res. 2012;12:196).

Forester M, Bailey C, Brinkhof M, Graber C, Boulle A, Spohr M et al.; and for the ART-LINC collaboration of the Epidemiological Databases to Evaluate AIDS. Electronic medical record systems, data quality and loss to follow-up: survey of antiretroviral programmes in resource-limited settings. Bull World Health Organ. 2008;86:939–47.

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Quality-of-care references and resources

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Institute of Medicine (IOM). Crossing the quality chasm: a new health system for the 21st century. Washington, DC: 2001 (https://iom.nationalacademies.org/~/media/Files/Report%20Files/2001/Crossing-the-Quality-Chasm/Quality%20Chasm%202001%20%20report%20brief.pdf, accessed 5 April 2017).

Quality of care: a process for making strategic choices in health systems. Geneva: WHO; 2006 (http://www.who.int/management/quality/assurance/QualityCare_B.Def.pdf, accessed 5 April 2017).

Standards for quality HIV care: a tool for quality assessment, improvement and accreditation. Geneva: WHO; 2004 (http://www.who.int/hiv/pub/prev_care/en/standardsquality.pdf, accessed 5 April 2017).

2.7 Adaption and implementation of the HIV patient monitoring system

2.7.1 Introduction

This section provides guidance on the steps for adapting and implementing all or part of the HIV patient monitoring system outlined in this document, including recommendations for coordinating across programmes and services, and transitioning from a previous version of the patient monitoring system to the updated one. It lays out requirements for a patient monitoring system that is mainly paper-based, though much of the content may be universally applied to any system along the paper-to-electronic continuum. Section 2.7.4 addresses specific considerations and suggestions for when and how to transition from paper to electronic patient monitoring systems.

The generic tools and accompanying recommendations in this guidance should be adapted and customized to fit the specific setting of each country and programme. It is most important to meet the minimum requirements in order to provide essential, quality patient care.

2.7.2 Steps for country adaptation of the guidance

The generic HIV patient monitoring system is developed to support both integrated service delivery at the facility level and facilities 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) with ANC, labour and delivery, postpartum and newborn care, and with TB and other acute and chronic care services.

While not providing a detailed methodology, Table 2.10 shows the recommended actions to be taken (not necessarily in the order given) to adapt and operationalize the generic HIV patient monitoring system. Annex 3.5.2 provides a country situation analysis tool that may be used to carry out some of these steps. For settings in which a previous version of the system has already been implemented, these steps may be less involved.

Before and during implementation of 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 and indicators presented in this guidance are mainly reflective of settings in which the HIV epidemic is generalized (with some exceptions). However, in many regions, HIV may be concentrated among key populations. *See* section 2.4.7 for considerations specific to monitoring these populations.
- **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 patients is critical so that they receive an uninterrupted continuum of care, and the primary care facility remains the first point of contact for the patient. Additionally, careful monitoring of transferred patients (using a standardized referral form [Annex 2.3.4] and confirming receipt of the patient) reduces the potential for double reporting. The community ART monitoring tool (Annex 2.3.3) may also have to be adapted, depending on if and what kind of activities are being carried out by lay health workers in the community.
- **Stage of transition to "treat all".** This will influence the use of tools (e.g. Annex 2.3.5) and selection of indicators to monitor (or not) patients who may not or will not start ART soon after enrolment into HIV care (*see* Box 2.17 for more detail).

- **Stage of transition from paper to electronic system.** This will influence how tools are adapted. Revised paper tools will be printed and distributed, whereas electronic systems will be reconfigured, with appropriate linkages to the HMIS and other systems.

Table 2.10 Sixteen recommended steps to adapt the revised HIV patient monitoring system

Action	Updating an HIV patient monitoring system
1. Ministry of Health (MoH) – lead technical work group	MoH forms a technical work group to lead the review of the existing HIV patient monitoring system, strengthening of a harmonized national system and potential revision.
2. Stakeholder meeting	Gather key stakeholders to discuss the revision of the current HIV patient monitoring system. Bring in new actors (from chronic and communicable disease programmes, implementing partners) as necessary, depending on the scope of integration and linkages of the intended revised HIV patient monitoring system.
3. Inventory of 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 to recommended key indicators and the minimum dataset, and determine which to add to the current HMIS.
5. Identify the system and tools for data collection	Discuss whether the existing system is adequate (with the addition of data elements) for the recommended revised HIV patient monitoring system; add or remove tools as necessary.
6. Determine paper-based and electronic systems	Discuss whether the existing paper-to-electronic system is adequate and make changes as relevant (*see* Section 2.7.4).
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. Stakeholder consensus for system	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 facility, district, regional 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 on 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. Human resource considerations	Make an inventory of current staff members who carry out patient monitoring activities at each level and part of the overall system. Identify and plan to fill any gaps as necessary and retrain each cadre on the revised system accordingly (*see* Section 2.7.3).
13. Infrastructure considerations	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 2.7.4).
14. Data quality and use	Review data quality and use guidelines if existing; if not, develop and implement them based on these guidelines (*see* Sections 2.6.2 and 2.6.3).
15. Coordination across programmes and partners	Expand coordination across disease programmes and implementing partners as necessary, depending on the revised HIV patient monitoring system (*see* Box 2.25).
16. Sustainability	Include patient monitoring in programme budgets, funding proposals, strategic planning and policy documents to ensure sustainability and improvement of the revised patient monitoring system.

Box 2.25 Integration, collaboration and partnership

A successful HIV patient monitoring system is founded on the collaborative work and cooperation of various partners within the health sector. These include the following:

HIV programmes

A standardized minimum dataset should be the foundation of any national HIV patient monitoring system. This should define any data collected from any system, whether paper-based or on the paper-to-electronic system continuum. Sites with greater resources may always collect more data. The use of standardized tools facilitates supervision, aggregation and transfer of patients between facilities. The HIV patient monitoring system is a key component of any national HMIS. 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. Electronic systems should also be harmonized. At a minimum, the HMIS should contain the priority national and global HIV indicators. The patient monitoring system will contribute to many of these. Given that HIV has strong links to MNCH and TB programmes (and likely others), it is important to ensure that the relevant data elements are also harmonized across programmes (e.g. numbers of pregnant women receiving ART may come from both ANC clinics and HIV clinics).

National programmes

As access to ART is further scaled up, HIV will be one among a number of treatable chronic diseases that requires longitudinal patient follow up. Collaboration between related national programmes, including TB, MNCH, reproductive and sexual health, other communicable and chronic diseases, and strategic information or HMIS is important for the success of the HIV programme. Recommended activities include:

- using HIV patient cards and ART registers at TB and MNCH sites;
- including an HIV patient card as part of an integrated health facility patient folder or integrating HIV patient monitoring information in an integrated patient card (*see* Annex 2.7.6);
- reconciling programme registers to avoid double-counting;
- integrating service delivery at the facility (e.g. 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 HMIS; and
- standardizing HIV indicators across programme areas.

Other institutions

Collaboration between the HIV programme and institutions both in the country (e.g. UN organizations, community-based organizations [CBOs], faith-based organizations, private businesses, teaching institutions) and outside (foundations, donors, universities) may improve patient care and monitoring by providing resources and filling in gaps in care and services (e.g. psychosocial support by CBOs). Internal institutions may collaborate through involvement in relevant (technical or otherwise) working groups to broaden the range of support that may be needed around improving the overall programme.

2.7.3 Human resources and capacity-building

Patient monitoring requires the participation of a wide range of staff with overlapping responsibilities and is facilitated by task-shifting to lower-level cadres and even lay providers. Table 2.11 provides a suggested 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 2.26 outlines special considerations for strengthening human resources for patient monitoring, including training, clinical mentoring and supervision.

Table 2.11 Suggested staff roles and responsibilities for HIV patient monitoring

District health management teams and HMIS/M&E focal point	• Provide supervision of the monitoring system to ensure quality of care and data. • 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. • Provide feedback from previous reports, data quality audits 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. • Provide a link between the health centre and central level to ensure that all patient monitoring needs are met (e.g. adequate staff, tools and other resources), and convey any changes to national standards or norms.
Health facility in-charge	• Be familiar with the existing patient monitoring tools (both paper and electronic), and how they fit into the overall patient flow of the health facility (and community links); be alert to any stock-out and restock as necessary. • Be responsible for ensuring that all staff members who are designated to carry out any element of patient monitoring are adequately trained. • Be responsible for validating and analysing the final monthly/quarterly/annual report before it is transmitted to the next administrative level. • Ensure that the clinical mentor(s) and supervisor(s) include the patient monitoring system during their routine visits. • Have 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 observations made. • Be familiar with the minimum dataset and core indicators, and how to report and analyse them. • Be up to date with any changes to the patient monitoring system and ensure that the health centre adheres to national standards.

Staff	Roles and responsibilities for patient monitoring
Triage worker or receptionist or data clerk	• Maintain an appointment book and signal missed appointments. • Start or retrieve patient records. • Record patient data in the patient record (or register, depending on the HIV service provided).
ART aid or lay counsellor or professional counsellor	• Record patient data in the patient record (or register, depending on the HIV service provided).
Nurse or clinical officer or other clinician	• Record patient data in the patient record (or register, depending on the HIV service provided). • Record data on the patient-held card, or book or passport (if used). • Tally data and fill in routine reports. • Conduct patient reviews with the clinical team (using longitudinal records) and discuss patient 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, secretary or other staff member is not available: • Transcribe data from patient records to registers. • Tally data and fill in routine reports.
Data clerk or secretary or other staff member	• Organize and manage patient records and registers. • Transcribe data from patient records to registers. • Enter patient data into the database (if used). • Tally data and fill in routine reports. • Review registers 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.
Community health worker	• Initiate HIV testing and counselling in the community. • Monitor adherence and drug pick-up. • Follow up and trace lost patients.
External clinical mentors and supportive supervisors (e.g. from district team)	• Review the 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.
Pharmacist, pharmacy technician/ assistant	• Dispense drugs. • Manage drug-related toxicity. • Provide adherence counselling and monitoring.
Facility-based lay provider	• Enrol patients, fill demographic information in the cards; transfer information to registers. • Provide adherence counselling, treatment literacy and education. • Assess adherence (by pill counts). • Track patients (lost to follow up).

Box 2.26 Recommendations for strengthening human resource development

Training

- Integrate training into pre-service education.
- Integrate in-service and ongoing training.
- Provide support to trainees.
- Ensure that staff trained during medical, nursing, pharmacy or other degree programmes focus on 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 higher-quality 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;
- clinical case review;
- clinical team meeting;
- documentation of each visit (including recommendations). 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 patient back to the clinic when the clinical mentor is scheduled to 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 they need to perform their jobs effectively;
- can take place 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, and is following health centre rules and policies;
- should be regular, compassionate, helpful, adaptable and 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.

2.7.4 Transitioning from paper to electronic patient monitoring systems

WHO recommends the following:

A tiered approach to when and how patient monitoring data from paper tools are entered electronically, based on resource availability by site or setting.

Many high-burden countries start with paper systems at facility level and move towards electronic data management at the district or other subnational level. As the number of patients on ART increases, there may be an evolution towards earlier electronic entry over time. There also may be variation between what can be done routinely at all sites, and supported as a national system, and what can be supported at facilities with special funding for research projects or sentinel sites. This transition is driven by (a) the increasing difficulty of accurately and reliably retrieving data from a paper-based patient record system, and (b) by the time and effort required to maintain the system as the volume of data increases. The following list describes the various points of electronic entry across the paper-to-electronic continuum:

- **Electronic medical record (EMR).** All data are entered either from paper records or directly into a computer during the patient encounter.
- **Electronic register.** A subset of data from a paper patient card is entered electronically, generating reports.
- **Electronic report from paper register.** Data are entered from a paper register to generate reports.
- **Electronic report from paper reports.** Data from paper-based reports are entered into an electronic system at facility, district, other subnational or national level. In this case, facilities must still transfer information from paper card to paper register to paper report. For example, in Malawi, paper-based cards and registers are used at sites with <2000 patients on ART, whereas higher-volume sites use or are implementing the use of an EMR. South Africa uses a cut-off of 1000 patients for sites using paper versus electronic registers (Box 2.27).

It is important to keep in mind that the use of electronic systems for capturing and managing patient information imposes significant infrastructure requirements in addition to the resources to capture and enter the data. These infrastructure requirements include the following:

- reliable power to support computer operation at patient care sites;
- reliable power and telecommunication sources (networks) to support regional and national data aggregation;
- staff members who are trained to enter data into the computer, and to use it for functions such as creating reports; and
- IT technical support for both software and hardware.

Issues relating to the transition to electronic systems and use of unique identifiers are discussed further in Chapter 4.

Box 2.27 A tiered approach to electronic patient records in South Africa *(28)*

Due to the scale up of ART in high HIV burden countries, many treatment sites are no longer able to cope with monitoring large cohorts of patients using paper-based patient monitoring systems only. However, these same sites do not all have the necessary infrastructure and resources to implement full EMR systems. This realization has led Western Cape province in South Africa to develop the TIER (three interlinked electronic register) system – a three-tier approach to monitoring that comprises:

Tier 1: a paper-based system for sites with <1000 patients on ART;

Tier 2: an electronic version of the paper register for sites with >1000 patients on ART; and

Tier 3: full EMR software.

Each tier produces the same minimum set of reports, based on standardized data elements and indicators (and interoperability between all the tiers), with the second and third tiers capable of producing more detailed reports. This means that well-maintained paper registers may be rapidly digitized for later export into EMR systems.

A tiered approach enables ministries of health to strategically implement one of the three tiers in each facility offering ART services. The choice of tier is based on the context and resources at the time of implementation (Table 2.12). It is likely that, as resources become available and infrastructure improves, more and more facilities will transition to the next tier. The three tiers need to complement each other in order to easily facilitate movement between tiers. This approach provides a flexible solution, as any given health region could be running one or a combination of the three tiers at any given time. Most importantly, a tiered approach allows for an efficient system for harmonized monitoring of the long-term provision of routine HIV services along the cascade of care and treatment.

Table 2.12 Elements required within a three-tiered patient monitoring system

	Paper-based register	Electronic register	Networked online system
Proper folder flow and successful filing system	X	X	X
Standardized clinical stationery and reporting form	X	X	X
Protected time for transcribing data	X	X	X
Ample working space for capturing data	X	X	X
Electricity		X	X
Computer, printer, uninterrupted power supply (UPS), memory stick or CDs		X	X
Computer skills of person capturing data		X	X
Basic information technology (IT) strategy to limit viruses, send dispatches and update versions		X	X
Stable network and cabled facilities			X
Network points within facility			X
Central network team			X
IT technicians to support sites with responsive turnaround time			X

2.7.5 Improving national and global reporting

A few, good-quality, well-reported indicators are preferable to many, poor-quality, poorly reported indicators.

Good-quality data

Establishing good-quality primary data is the first step to improving reporting at any level. This means accurate patient-level data entered in the HIV patient card or directly into an EMR, and data quality checks at each step of transcription or aggregation.

A minimum set of indicators

As a second step, it is important to minimize and harmonize the number of reportable indicators. Although a certain number of global indicators are needed to meet global reporting requirements, it is up to individual countries to decide what needs to be reported at the national level. A good place to start is the adoption of the global indicators as national indicators, as these guidelines do in identifying the 18 key indicators (*see* Section 2.5). Any additional indicator beyond that should ideally be drawn from these guidelines as well as the 2015 WHO strategic information guidelines, and include strong justification for their adoption, standardized definitions, and clear instructions for collecting and reporting (e.g. standardized reporting forms across facilities). There may be additional indicators that are more useful for quality of care/improvement (Section 2.6.3), programme monitoring and management at the subnational or facility level. Box 2.28 provides an example of how indicators have been selected in South Africa.

Box 2.28 Country case study: data standardization and simplification in South Africa

In South Africa, ART was available in more than 3450 public health facilities across the country by end 2015. From the onset, facilities have been asked to send (on paper or electronically) monthly and quarterly cohort reports to districts or provinces where the data are aggregated. This has been possible only by keeping the number of indicators reported to an absolute minimum (two HIV indicators for cross-sectional reporting; 13 baseline HIV indicators, and eight HIV and TB/HIV longitudinal indicators for cohort reporting). An HIV M&E standard operating procedure has been written with clear indications of timelines and processes for data collection and transmission to upper health administrative levels. Responsibilities and accountabilities of the different actors are also addressed in detail. This document has also been useful in setting limits to data requirements by implementing partners.

Data aggregation

Once a standardized, harmonized (across facilities) and minimum set of indicators has been developed, it is important to facilitate their collection and reporting at each administrative level. For example, Section 2.5 and the accompanying Appendix include recommendations and instructions for tallying subsets of core indicators at the same time to reduce overall workload. This generally starts at the facility level using a paper-based form, with electronic entry at some level thereafter. It is important that each level be accountable for the data that are reported. For more details on the reporting of individual-level data, *see* Chapter 3 on case-based surveillance methods.

Indicator disaggregation

With paper-based systems, it is best to minimize the disaggregation (e.g. by sex, age) of indicators as each disaggregation category adds time and introduces opportunities for missing data and other errors in the tallying process; for example, for current on ART, requires two age groups (<15 years and 15+ years) instead of 10 (5-year age groups) (*see* recommendations for disaggregation in Section 2.5). Where possible, it may be preferable not to make disaggregation a requirement.

Reporting frequency

It is also important to consider the frequency of reporting, which may differ depending on the indicator. It may be more efficient to collect some indicators more frequently, such as monthly or quarterly (e.g. new patients on ART). Others may be best left until the end of the reporting period (year) to be tallied (e.g. current on ART).

Reporting tools, supervision and feedback

Countries may adopt the following additional procedures to optimize reporting:

- clear, standardized reporting forms with simple, precise definitions for numerators and denominators;
- simple tally tools to facilitate aggregation of paper-based reports;
- routine supervision visits to validate reports, check data quality and provide feedback (*see* Section 2.6);
- regular feedback loops to ensure that all levels of the health system understand how the reports are used, and how quality of care and services may be improved based on the indicators (i.e. data analysis and use).

Box 2.29 References and resources for adaptation and implementation

WHO recommendations for clinical mentoring to support scale up of HIV care, ART and prevention in resource-constrained settings, 2006 – based on Planning Consultation on Clinical Mentoring: approaches, and Tools to Support Scaling-up of Antiretroviral Therapy and HIV Care in Low-resource Settings, Geneva, Switzerland, 7–8 March 2005; and on Working Meeting on Clinical Mentoring: approaches and Tools to Support the Scaling up of Antiretroviral Therapy and HIV Care in Low-resource Settings, Kampala, Uganda, 16–18 June 2005.

Country experiences in implementing patient monitoring systems for HIV care and antiretroviral therapy in Ethiopia, Guyana and India: an overview of best practices and lessons learned. Geneva: WHO; 2010 (http://www.who.int/hiv/pub/me/patient/en/index.html, accessed 5 April 2017).

WHO, USAID, University of Oslo. *Health facility and community data toolkit.* Geneva: WHO; 2014 (http://www.who.int/healthinfo/facility_information_systems/Facility_Community_Data_Toolkit_final.pdf, accessed 5 April 2017). This provides further examples and recommendation on strengthening the overall health information system at the facility level.

2.7.6 Country examples of patient monitoring tools

Examples of patient monitoring tools developed in countries demonstrate how data can be collected and reported in different settings. Annex 2.7.6 shows a patient record from South Africa that integrates HIV, MNCH and TB patient data.

HIV CASE SURVEILLANCE

03

3. HIV CASE SURVEILLANCE

Summary of key recommendations in this chapter

1. **Standardization of sentinel events and indicators.** Countries should collect core information on a standardized set of sentinel events and indicators, including at a minimum, the six key cascade events described in these guidelines. *WHO provides guidance on key indicators for primarily paper-based patient monitoring systems and additional indicators for electronic systems or periodic review, especially of patient monitoring tools.*
2. **De-duplication of records to support facilities and improve data quality.** HIV case surveillance should provide de-duplicated counts of diagnosed persons and people on treatment for reporting, to be shared with facilities. *WHO provides guidance on such approaches.*
3. **Country situation analysis.** Improvements to HIV case surveillance, patient monitoring and unique identifiers should be based on a country situation analysis that identifies and costs incremental improvements. *WHO provides a tool for country situation analysis.*
4. **HIV diagnosis and building on patient monitoring.** HIV case surveillance should start with a diagnosis of HIV infection and build on existing patient monitoring systems. *WHO provides guidance on HIV case definitions.*
5. **Key population (KP) data.** Routinely collected data can be used to describe access by key populations to services; however, confidentiality and security issues are paramount when collecting data related to KP, whether in patient monitoring or case surveillance systems. In most settings, patient records should not include the KP category and any information collected should be used to support patient management and referral to care. The probable route of transmission can be assessed at the point of diagnosis and used to disaggregate data in HIV case surveillance systems. *WHO provides guidance on how to address issues around KP data collection and reporting.*

Additional recommendations relevant to this chapter

6. **Transition progressively from paper-based to electronic patient information systems.** Countries should use a tiered approach to when and how patient and case monitoring data from paper tools are entered electronically based on resource availability by site or setting, starting with high-volume sites, e.g. with more than 2000 patients. *WHO provides an example of a tiered approach.*
7. **Strengthen and establish different data security levels.** Countries should assess and establish different security levels for data elements, and invest in robust databases and policies to protect security and confidentiality based on risks and benefits in individual settings. *WHO provides the major headings to be included and provides reference to additional specialized guidance.*

8. **Invest in data systems and ensure interoperability.** Countries should invest in robust and secure data systems. As this is done, strengthen the interoperability of electronic databases and elect open-source standards for data systems. *WHO recommends that 5–10% of programme budgets be used to strengthen monitoring and evaluation.*

3.1 Overview

HIV case surveillance refers to the reporting of an initial diagnosis of HIV infection and defined sentinel events from every person diagnosed with HIV to a public health agency responsible for monitoring and controlling the epidemic. Key sentinel events include HIV diagnosis, entry into care, first CD4 count, initiation of ART, viral suppression and death. Information from each case is linked over time and stored as individual-level data in a database at subnational and/or national levels. HIV case surveillance is referred to in some countries as case notification or case reporting. The ability to link notifications or reports of sentinel events to a case over time and maintain data in disaggregated form at the individual level are the distinguishing features of HIV case surveillance systems.

Many low- and middle-income countries have historically relied on data collected through patient monitoring systems in health facilities. As described in Chapter 2, data collected through patient monitoring are aggregated at the facility level before being sent on to higher levels of the health system. While this system provides reasonably robust estimates of progress against key indicators, aggregate reporting does not permit collection of individual-level longitudinal data to monitor programme effectiveness. In addition, because aggregate data cannot subsequently be disaggregated into individual-level data, it is not possible to detect duplicate records, resulting in a possible overestimation of the number of people diagnosed with HIV and accessing services.

Case surveillance methods overcome this limitation by collecting individual-level data from each person diagnosed with HIV. Using this approach, one person's report can be distinguished from another's (i.e. case records can be "de-duplicated"), and information collected from different sources and across services and facilities can be linked by name, unique identifier code only or other person-specific variables. Fig. 1.2 shows the various data sources that can contribute to monitoring the HIV epidemic in a HIV case surveillance system.

The guidance in this chapter aims to help countries roll out or strengthen HIV case surveillance. Strengthening existing HIV surveillance systems may involve adding the reporting of HIV diagnosis to an existing AIDS case reporting system, adding the reporting of additional sentinel events to a system that only reports new HIV diagnoses and deaths, extending a system to include sentinel paediatric or pregnancy-related events, or collecting more detailed information about a specific sentinel event, such as the suspected mode of HIV transmission at diagnosis.

As with other infectious diseases, surveillance of HIV requires an ethical, legal and policy framework, 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. The following sections of this chapter discuss each of these concepts in turn.

The guidance in this chapter is supplemented by an online implementation tool (Annex 3.1.) that describes the building blocks of an effective HIV case surveillance system, provides step-by-step operational guidance to assessing current surveillance systems, and planning and implementing new or upgraded systems.

3.2 Ethical principles and considerations

HIV case surveillance should be implemented according to a commonly accepted set of ethical principles and considerations *(29)*. WHO identifies four ethical considerations that are fundamentally important for public health surveillance:

- **Common good.** Surveillance activities should be framed as a public good *(30)*. Benefits derived from surveillance activities must therefore be greater than individual private benefits *(31)*. Surveillance is justified, fundamentally, as a necessary requirement for the good of all.
- **Equity.** Public health surveillance should be used to further the pursuit of equity by identifying and addressing situations that lead to unfair health differences.
- **Respect for persons.** Public health ethics are concerned with the rights, liberties and other interests of individuals, as well as the well-being of the population at large. Wherever possible, individuals should be involved in decisions that impact upon them. In some cases, individuals should be free to make their own choices. In other cases, where population-level interventions may be necessary, individuals should be consulted and involved in decision-making. However, many individuals (such as young children) cannot make their own choices and the State has an obligation to protect them and promote their long-term health interests. Undertaking surveillance is one way of showing respect to them as persons. Another way is ensuring that data about individuals and groups are protected, and risks of harm are minimized to the greatest extent possible.
- **Good governance.** To ensure that the ethical challenges posed by public health action are addressed systematically and fairly, governance mechanisms must be accountable and open to public scrutiny. Accountability, transparency and community engagement are means for justifying public policy structures that promote respect for persons, equity and the common good. Transparency requires that surveillance policies and procedures be communicated clearly and that affected individuals or communities have knowledge of any decision-making processes concerning them. Among other things, transparency requires that the results of surveillance activities be publicly reported (in anonymous or aggregate form). Without such knowledge, communities cannot be empowered to either demand government action or act to protect themselves in the absence of alternatives.

The purpose of public health surveillance is to promote disease prevention and control. Case-based HIV surveillance is justified because it provides accurate, routine and cost-effective data with which to measure the magnitude and direction of the epidemic, the populations and regions with the greatest burden, and the impact of treatment and prevention efforts. The data can be used to prioritize resource allocation where the need for services and potential impact are greatest.

Public health professionals have an ethical obligation to maximize the potential benefits of data collected through surveillance systems, and to minimize the potential risks and harm to individuals. It is critical that surveillance programmes adhere to the highest standards to protect the confidentiality of the HIV surveillance data reported. These standards must include data security at all levels of the surveillance system, from collection to storage and dissemination. Although data analysis is done using individual-level data, only aggregate data and summary statistics should be disseminated to prevent the possibility of an individual being identified. Aggregate results from HIV surveillance programmes should be shared with all people involved with surveillance and the public.

Detailed considerations about data security and confidentiality are discussed in Section 3.4.11.

3.3 Reporting laws, regulations and policies

Many countries already have laws, regulations or policies that govern disease reporting to public health authorities. These should be reviewed and, if necessary, updated to include reporting on HIV-related sentinel events. While the nature of a country's reporting laws and regulations may vary, they should ideally address the following:

- HIV case definition;
- mandate to report persons diagnosed with HIV infection;
- agency authorized to perform HIV case surveillance;
- people who are required to report (e.g. physicians, HIV test counsellors, laboratories);
- reporting pathway;
- reportable events;
- mandatory variables to be reported;
- standardized case report form;
- minimum data elements required to count a case for surveillance purposes;
- time frame for reporting (i.e. within a set number of days following diagnosis or sentinel events);
- criteria for maintaining the security and confidentiality of surveillance data, including a clear prohibition against releasing information that may identify individuals outside of the surveillance programme or to health-care providers; and
- format for submitting data (e.g. paper or electronic).

An example of a reporting mandate is presented in Annex 3.3.

Laws, regulations and policies for HIV case surveillance must include measures to protect an individual's right to privacy, ensure the security and confidentiality of surveillance data, and specify how and when surveillance data may be shared or released. This issue is discussed in more detail in Section 3.4.11.

All laws, regulations, policies, standards and surveillance methods governing the surveillance programme should be outlined in a technical guidance document provided to all surveillance personnel and made available to the public.

3.4 Reporting process and procedures

3.4.1 Sentinel events

An HIV case surveillance system combines demographic, clinical, immunological and virological information, and possible information on the suspected mode of HIV acquisition for all reported cases of HIV. After a new case of HIV is reported through an HIV testing site, a comprehensive case surveillance system must be capable of capturing reports on all subsequent key events related to that case, referred to as "sentinel events" in this guidance, and also known as "reportable" or "notifiable" events. At a minimum, "reports" (or "notifications") should be made at each of the following sentinel events for adult, child and adolescent cases:

- HIV diagnosis (including confirmatory HIV test result from laboratories)
- entry into care
- first CD4 test
- initiation of ART
- viral load test, and
- death.

To use case surveillance to monitor the HIV epidemic among infants and children, additional reports will be needed for the following sentinel events for women and children:

- pregnancy, and
- live-births to HIV-infected pregnant women
- initial PCR test result of child between 4 and 6 weeks
- follow-up PCR or RTK test result at 9 and 18 months.

It is important to note that, because a new report should be submitted to the surveillance system at each sentinel event, case surveillance data will contain multiple reports concerning the same person. This creates a longitudinal database that follows people living with HIV along the continuum of care and permits the generation of care cascades. For some programmes, this may be considered as a simplified patient monitoring system for people in care, but differs from patient monitoring in that individuals are reported to the public health agency responsible for conducting surveillance.

Surveillance programmes should collect **all CD4 and viral load test results**. This allows programmes to determine changes in immune function and viral suppression, and to monitor continuity of care. Laboratory tests can also serve as proxies for entering and remaining in care. In situations where not all CD4 and viral load tests are reported, at a minimum, the CD4 count at time of entry into care and at the time of ART initiation, and the date on which the patient achieves viral suppression (<1000 copies/mL), should be reported to the surveillance programme.

Paediatric HIV surveillance can be used to determine the burden of HIV infection in children, monitor HIV infection in children (including but not limited to maternal transmission, which is particularly important for infection in older children). It is also used to measure the impact of PMTCT programmes, monitor progress towards elimination of mother-to-child HIV transmission, and provide data to inform programmes and policies *(32)*.

Surveillance for vertically transmitted HIV begins with reporting pregnancy in a woman living with HIV (recommended as part of reporting for adults and adolescents) and documenting the date on which ART was initiated to determine if this was done prior to pregnancy; during the first, second or third trimester; at delivery or post-delivery, and if the woman continued to receive ART post-pregnancy. For infant outcomes, it is important to document the use of ART until the infant is weaned, while for maternal health it is important to document continued use of ART past infant weaning.

Tracking perinatal transmission requires reporting of HIV-exposed infants and whether the infant was infected, had seroreverted or had not been infected. Sentinel events for infected infants should be reported in the same way as for adults and adolescents (i.e. with initial and follow up CD4 and viral load results, use of ART, disease progression, viral suppression, death). Given the need for both maternal and infant data, it is essential that case reports of HIV-exposed and -infected infants are linked to the case record of the mother.

Definitions of events captured in HIV case surveillance are shown in Box 3.1.

Box 3.1 Definitions of sentinel events used in HIV case surveillance systems *(33)*

Adults and children	
Sentinel event	**Definition**
First positive test indicative of HIV diagnosis	Earliest date of HIV diagnosis determined according to the national HIV testing algorithm
Entry to care	Date that any case of HIV is registered in clinical care; could be inferred by record of a CD4 test, viral load test or ART initiation
First CD4 test	The first CD4 test is the earliest CD4 percentage or count available. To be considered a CD4 test result at the time of diagnosis or entry into care, the test must have been conducted no later than 6 months from diagnosis or entry into care. Subsequent CD4 test results are classified as follow-up tests.
Initiation of ART	Date on which ART is prescribed for any case of HIV. This may be the same date as the date of entry into care in settings where all persons diagnosed with HIV are placed on ART at the time of starting care.
Viral suppression	Any viral load test result lower than 1000 copies/mL
Death	Date of death reported in any case of HIV, regardless of the cause of death. May be obtained from clinical record or vital registration data. Note that when available, causes of death, particularly the underlying cause, should be reported.
Children only	
Pregnancy in HIV-infected women	Any HIV diagnosis in a pregnant woman as determined by the national HIV testing algorithm, or a pregnancy in a woman previously diagnosed with HIV
HIV-exposed infants	Identifying variables of infants born to HIV-infected mothers
Infant antiretroviral (ARV) prophylaxis	Prescription of ARVs specifically to prevent infection among HIV-exposed infants
Infant polymerase chain reaction (PCR) tests	Dates and results of all PCR tests, including the one that confirmed infection

3.4.2 Sentinel events and corresponding strategic information indicators

HIV case surveillance can be used to measure progress against several of the WHO strategic information indicators for the monitoring and evaluation of the health sector response to HIV, including the 90–90–90 targets *(1)*. While the methodology for measuring these indicators differs (e.g. case surveillance variables are proxy versus actual data for currently or retained on ART), this information can nevertheless complement data collected through the patient monitoring system, and data collected through both approaches can be triangulated to improve accuracy and reliability.

Sentinel events for HIV case surveillance correspond to several of the priority strategic information indicators for HIV in the health sector published by WHO in 2015 *(1)*. Table 3.1 shows the core strategic information indicators and corresponding case surveillance variables (sentinel events) for adults and adolescents, while Table 3.2 shows indicators relating to PMTCT and the corresponding case surveillance variable.

Table 3.1 Core strategic information indicators and corresponding HIV case surveillance variable

Core strategic information indicators	HTS.1 Knowing status	LINK.1 Linkage to care LINK.8 Late diagnosis[2]	ART.3 Currently on ART[3]	ART.5 ART Viral suppression[4]	Deaths among people diagnosed with HIV[5]
HIV case surveillance variable	Date of first confirmed HIV positive test[1]	Date first entered care Date and value of first CD4 test	Date first prescribed ART Date first viral load test[4]	Date and value of follow-up viral load test	Date of death Primary cause of death

[1] Based upon national testing protocol

[2] Based on CD4 cell count <200 cells/mm^3 (not a core strategic information indicator)

[3] In settings where viral load tests are conducted as part of routine monitoring and are collected six months after ART initiation and annually thereafter. Note that in this situation, the date of ART initiation is six months prior to the date of first viral load test. "Currently on ART" includes those who initiated ART and who were retained on ART during the reporting period.

[4] Follow-up viral load measurement. Viral suppression is defined as viral load <1000 copies/mL.

[5] Although many persons who die from HIV infection meet the clinical criteria for AIDS, deaths in any person reported with HIV infection should be included.

Table 3.2 Prevention of mother-to-child transmission strategic information indicators and corresponding HIV case surveillance variable

Maternal indicators			
PMTCT strategic information indicators	**MTCT.1 Known status in pregnant women**	**MTCT.2 Currently on ART[3]**	**MTCT.3 ART Viral suppression[5]**
HIV case surveillance variable	Date of first confirmed HIV-positive test[1,2]	Date first prescribed ART Date first viral load test[4]	Date and value of follow-up viral load test[6]

[1] Based on national testing protocol

[2] Diagnosed prior to current pregnancy, during current pregnancy or postpartum

[3] Initiated prior to current pregnancy, during pregnancy or postpartum

[4] In settings where viral load tests are conducted as part of routine monitoring and are collected six months after ART initiation and annually thereafter. Note that in this situation, the date of ART initiation is six months prior to the date of first viral load test. "Currently on ART" includes those who initiated ART and who were retained on ART during the reporting period.

[5] ART retention can be estimated by the number of persons receiving follow-up viral load measurement. Viral suppression is defined as viral load <1000 copies/mL.

[6] Ongoing collection of viral load tests can be used as a proxy for retention on ART beyond lactation. Can use infant indicators for breastfeeding status; not a core PMTCT indicator.

Infant indicators				
PMTCT strategic information indicators	**HIV-exposed live births**	**MTCT.4 Infant prophylaxis**	**MTCT.6 Testing of exposed infants**	**MTCT.7 Infant seroconversion**
HIV case surveillance variable	Date of birth of HIV-exposed infant	Date received antiretroviral prophylaxis	Date, type and result of first HIV test[1,2]	Results of all HIV tests[3]

[1] Results of RNA testing at 4–6 weeks

[2] Results of HIV antibody test at 18 months according to national testing protocol

[3] Presence of HIV RNA at 4–6 weeks or later or confirmed HIV-positive by antibody test at 18 months or later and according to national testing protocol

3.4.3 Case definitions for HIV surveillance

Specific, standardized criteria are used to determine if an individual HIV case notification should first be reported. This is done using the national HIV surveillance case definition, typically using the WHO standard (Box 3.2). Standardization allows for comparability of information reported. In 2007, WHO updated the clinical staging of HIV and developed surveillance case definitions for HIV infection in adults (age 15 years and above) and children (under 15 years of age) *(34)*. Prior to the development of these case definitions, notification was done only for cases of AIDS. However, because AIDS represents end-stage HIV disease, AIDS case reporting by itself does not provide a full picture of the epidemic.

Box 3.2 WHO case definitions for HIV infection

Adults and children 18 months or older

HIV infection is diagnosed based on:

- a positive HIV antibody test (rapid or laboratory-based enzyme immunoassay). This is confirmed by a second HIV antibody test (rapid or laboratory-based enzyme immunoassay) relying on different antigens or different operating characteristics;

  and/or;

- a positive virological test for HIV or its components (HIV RNA or HIV DNA or ultrasensitive HIV p24 antigen) confirmed by a second virological test obtained from a separate determination.

Children younger than 18 months

HIV infection is diagnosed based on:

- a positive virological test for HIV or its components (HIV RNA or HIV DNA or ultrasensitive HIV p24 antigen) confirmed by a second virological test obtained from a separate determination done more than four weeks after birth;
- positive HIV antibody testing is not recommended for definitive or confirmatory diagnosis of HIV infection in children until 18 months of age.

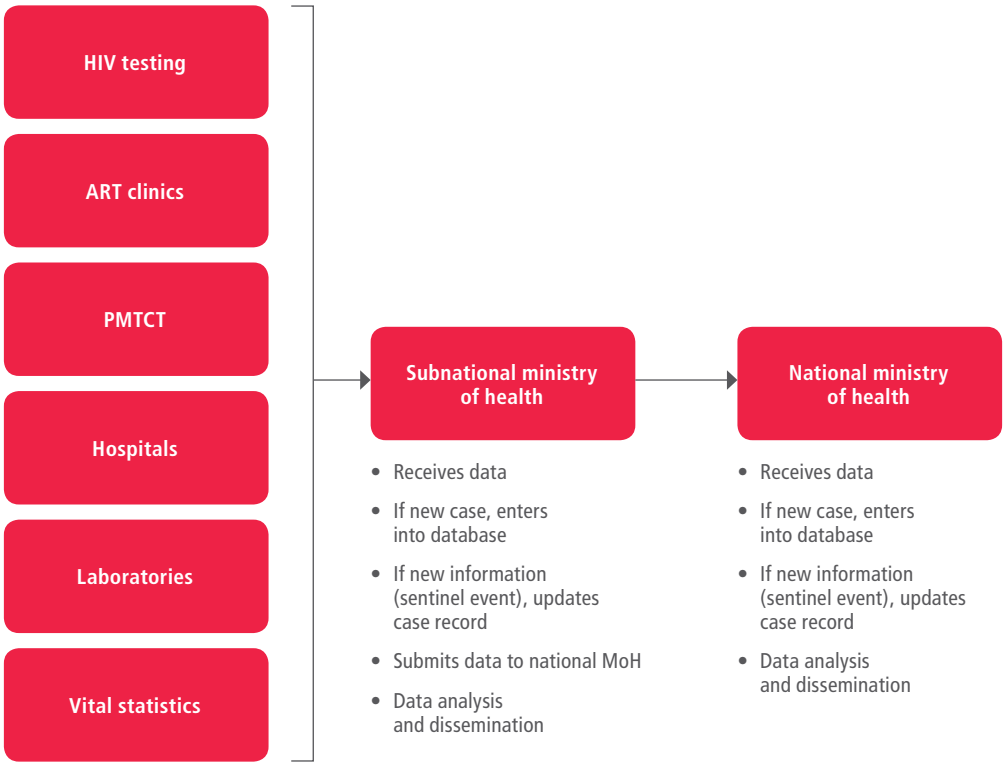
HIV national testing algorithms should be validated following the WHO consolidated HIV testing guidelines (http://www.who.int/hiv/pub/guidelines/hiv-testing-services/en/guidelines).

3.4.4 Reporting sites

An HIV case surveillance system should capture information on the defined sentinel events from all relevant facilities and services (e.g. where patients are diagnosed or receive care, from laboratories that conduct HIV diagnostic, viral load and CD4 tests, and from vital statistics registries). It is essential that reporting is conducted from all these sites – including private facilities and testing sites run by nongovernmental and community-based organizations – and is not limited to those within the public health-care system. Surveillance systems should identify and maintain a comprehensive and up-to-date list of all reporting sites.

Fig. 3.1 illustrates how data flow in many surveillance systems. Data from reporting sites are typically sent to the Ministry of Health at the local level and from there to the Ministry of Health at the national level. In some systems, reports may be sent directly to the national level. Regardless of the reporting pathway, subnational units should have access to their own data for analysis, local dissemination, and programme evaluation and planning.

Fig. 3.1 Example of reporting pathway and data flow within an HIV case surveillance system



ART: antiretroviral therapy, MoH: Ministry of Health; PMTCT: prevention of mother-to-child transmission

3.4.5 Approaches to identifying and reporting new HIV cases and subsequent sentinel events

Four different and complementary approaches can be used for identifying and reporting new HIV cases and subsequent sentinel events:

1. *Reporting by staff at the site:* in this approach to case surveillance, the personnel who diagnose and/or care for patients with HIV, or the records clerks (or comparable persons) are responsible for completing and submitting the case report (passive reporting).
2. *Ministry of Health personnel (usually surveillance staff) visit reporting sites* to review data sources to complete the case report (active reporting).
3. *Systems are programmed to report new cases and sentinel events:* in settings where EMRs are used and found to be accurate and complete, it is possible to have these systems programmed to report cases and sentinel events by preparing or extracting the data that are to be sent to or collected electronically by the surveillance programme.
4. *Laboratory reporting:* laboratories report directly to the surveillance programme all test results that may be indicative of HIV infection. Test results included are HIV diagnostic tests, CD4 and HIV RNA tests (viral load and early infant diagnostic tests).

Surveillance programmes should engage with key personnel at every reporting site to educate providers, assess data sources and data quality, provide information and supplies for reporting (case definitions, report forms, contact information of the surveillance officer) and determine how patients will be reported (active or passive reporting, and paper or electronic systems) to the surveillance programme. Ideally, all reporting sites should designate a person who is responsible for communicating with the surveillance programme, and for ensuring compliance with reporting processes and regulations, regardless of how the data are collected.

3.4.6 Data sources for reporting cases and subsequent sentinel events

Many sources can be used to identify cases of HIV and update records of previously reported cases based on subsequent sentinel events *(35)*. 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 for identifying people with HIV. In countries that use patient registers, these will likely serve as the main source of information for identifying cases and initiating case reports.

In many situations, one or more sources may identify a person diagnosed with HIV or receiving care, but there will not be sufficient information to fully document and report a case. In these circumstances, laboratory and medical records will also need to be reviewed to complete the new case report.

Patient registers

All health facilities should maintain a register of interactions with and information about the patient or client. HIV testing and care may be sought or provided in facilities offering a variety of services, such as voluntary counselling and testing, provider-initiated testing and counselling, voluntary medical male circumcision, ANC and PMTCT, facilities serving HIV-exposed infants, TB care and treatment, home-based counselling and testing, mobile and outreach testing and follow-up testing for people using self-test kits. ART registers in all such facilities should be reviewed to identify people who have newly entered care and those who have initiated ART. These patient registers typically record a unique identifier and/or a medical record number (also called "ART clinic number").

International Classification of Disease (ICD) codes

In settings where ICD codes are routinely used for billing or hospital discharge and deaths, the list of codes that comprehensively capture HIV disease can identify people who need to be reported to an HIV case surveillance system. WHO has developed a list of relevant ICD codes that may be found at http://www.who.int/healthinfo/global_burden_disease/GlobalCOD_method_2000_2015.pdf?ua=1.

Laboratories

Laboratory data are a vital component of HIV case surveillance. In settings that use registers or logbooks, surveillance or facility staff can review laboratory registers and logbooks to identify patients who have had HIV-related CD4 and viral load tests. In some settings, laboratories also conduct HIV antibody tests, usually for confirmatory testing, and these results should also be reported.

Some countries may have national or regional laboratories that test and then record all CD4 and/or viral load (and early infant diagnosis) test results. In these situations, direct reporting from laboratories to surveillance systems can be helpful in identifying new cases and in providing laboratory data to update records of previously reported cases. Direct laboratory reporting improves the quality and completeness of case surveillance data.

Other sources

Where vital registration systems are robust, they can be reviewed to identify people who died from HIV-related causes and were not previously reported as an HIV case. Where possible, vital registration systems should also be used to identify all deaths (HIV and non-HIV related) that occur among reported cases. This typically requires linking of electronic vital registration data with surveillance data. Recording of deaths is important because if deaths among persons diagnosed with HIV are underreported, the result is an overestimate of the number of persons living with HIV and the number lost to follow up from care.

It is possible that other types of service providers, such as social and community health workers or adherence counsellors who communicate with personnel responsible for reporting, may also serve as sources of information relevant to the surveillance system. Given that most antiretroviral drugs are used to only treat HIV infection, pharmacy records may also provide a useful routine source for identifying previously unreported patients. Pharmacy records can be particularly useful for identifying the date that ART is initiated, changes in treatment regimen and discontinuations in therapy that may reflect poor adherence.

3.4.7 Case report forms

The term "case report" refers to both reports of new HIV cases and to reports of subsequent sentinel events related to existing cases. Case report forms contain all the information needed for submission and reporting to the surveillance programme of a new case or a subsequent sentinel event. Case report forms may be completed and submitted manually or electronically; the term "case report form" includes both these options.

Case report forms must include sufficient information for surveillance programmes to describe the HIV epidemic according to person, place and time. Information collected should include basic demographic data, facility information and information related to the sentinel event(s) being reported. Because reports regarding the same individual are likely to be submitted from multiple sources, the surveillance programme must be able to identify reports that concern the same individual across sources and link these reports – preferably using a unique identifier – into a single, longitudinal case record (*see* Section 3.4.10).

It is recommended that all HIV testing programmes that do not currently collect information on the probable mode of transmission should be adapted to do so. Collecting this information requires sensitivity from health-care providers and others who conduct HIV testing and counselling, and additional training may be required. The security and confidentiality of these databases must be guaranteed (*see* Section 3.4.11).

WHO model case report forms are available in Annex 3.4.7. At a minimum, case report forms should include the following:

- Patient identifiers
  - unique patient identifier, where available (e.g. clinic number, health card number)
  - first and last names (other names if available and determined to be useful by the surveillance programme);
  - date of birth and age at time of diagnosis;
  - sex;
  - probable mode of transmission;
  - locating information, such as address and telephone number;
  - medical record/clinic number; and
  - CD4 count or viral load test result, if available.
- Facility information
  - facility name and address (and code if relevant)
    - name and contact details of person completing the form.
- Date case report form was completed (or date data were submitted electronically)
- Sentinel event(s)
  - date of diagnosis (day, month, year);
  - type of sentinel event for adults and adolescents (diagnosis, entry into care, initiation of ART, pregnancy, disease progression, viral suppression, death), and children (maternal and infant ART or prophylaxis, results from early infant diagnostic tests, infant infection) and date that the event occurred;
  - laboratory results and dates of specimen collection. The date that the sample was taken from the patient should be recorded, not the date that the test was conducted or the date that results were recorded.

In systems that include direct reporting from laboratories, the following minimum data elements should be reported:

- patient identifiers as described above;
- laboratory name and location;
- date of specimen collection;
- type of test conducted;
- test result;
- date that the case report form was completed;

- name and contact information of person submitting the report;
- name and contact information of person completing the form (or submitting the data electronically).

The minimum data required for a case to be counted within the HIV case surveillance system are:

- name or unique identifier;
- date of diagnosis;
- date of birth;
- sex; and
- age.

Case reports that are submitted with some but not all the minimum data elements will need to be further investigated, for example, by reference to the patient's clinical record, and the case record should then be updated with the required information.

3.4.8 Data management systems

The system for managing HIV case surveillance data should consist of an electronic database and related applications for managing all reported cases of HIV and subsequent sentinel events. The data management system can build on existing surveillance systems, be integrated with other case-based disease surveillance systems, or be a stand-alone system specifically designed for HIV case surveillance.

The HIV case surveillance database management system must be able to receive, process, clean, store, transfer and make data available for use. At a minimum, the data management system should have applications that allow for manual entry of data received from paper case report forms, computer-based matching to de-duplicate records and update previously reported case records with new information, quality checks, and data downloads for epidemiological and statistical analysis.

It is recommended that data systems be capable of receiving or extracting electronic data from digital medical records or registers, laboratories and pharmacies. To receive electronic data, an interoperability layer is required to ensure that the variables submitted are in the same format as expected by the surveillance database. The data systems should be designed for easy transfer of data between the subnational surveillance units, where they exist, and national surveillance programmes, either electronically between the programmes or by downloading relevant data from the subnational programme for manual transfer to the national level. These factors should be taken into consideration when selecting or developing the hardware and software needed for the data management system.

The surveillance data management system and related database should be able to document the date on which case report forms are received at the surveillance unit in paper or electronic form, the date of data entry (or upload), and any updates or edits to an existing record, including related sentinel events. Cases that are missing information required for a case to be counted in the surveillance system should be highlighted so that surveillance staff can follow up to obtain the missing information.

Additional information regarding data management systems can be found in Annex 3.1, HIV case surveillance toolkit, Section 1.4.

3.4.9 Data quality

Data processing should include routine data quality checks to determine the completeness of the variables reported, and to ensure that the values reported are valid and logical. Double data entry and comparison of manually entered data are recommended to reduce errors. Discrepancies that cannot be resolved between the case records from multiple sources, or any invalid or illogical values, should be identified and corrected by contacting the person who reported the case or sentinel event to validate the information against the original source documents. Providing feedback to the persons who complete case report forms, as well as to persons who complete patient records, is one way of improving data quality.

3.4.10 Case record-matching and person-specific identifiers

It is essential that HIV case surveillance systems are able to distinguish reports of new cases from reports containing new information on previously reported cases. This process is referred to as record-matching, record linkage or case de-duplication. If the information received is from a previously unreported case, a new case record should be created. If the information relates to a sentinel event for a previously reported case, the existing record should be updated with the additional information. Predetermined algorithms that determine possible matched cases often include patient names, person-specific identifiers, dates of birth and sex.

The Soundex code is a phonetic matching system that can be helpful in identifying misspelled names. The code can be created manually or using computer programmes.

The Soundex code alone is insufficient to match records and must be combined with other personal identifiers. Additional variables such as date of diagnosis can also be added to the algorithm. The matching process must be done at the national level. Depending on the setting, it may be useful to perform the matching process at the subnational level as well, e.g. if it is easier to do so because officials involved in surveillance and health-care providers may be more familiar with the cases. Record-matching must be done using standardized methods at both subnational and national levels. In addition to de-duplicating records within the case surveillance data management system, linkage of records between the case surveillance data and other external data files – such as vital statistics – must be performed to update case records. The UNAIDS and WHO Working Group on Global HIV/AIDS and STI Surveillance have provided additional information and examples of case-matching in the context of paediatric HIV surveillance (*see* reference *(32)*, pp. 60–1).

For effective matching, several personal identifiers must be collected. The most common personal identifiers are name and date of birth. However, because many people share the same name and/or date of birth, and in some cases, people may not know their exact date of birth, it is necessary to include multiple personal identifiers. When available, a national identification number or national identifier for health *(36,37)* should be collected for people diagnosed with HIV or receiving care (*see* Chapter 4).

HIV care and treatment programmes will often assign a facility-specific identification number that can uniquely identify patients within a given facility. While this is useful at the facility level and should be collected for de-duplication of facility-based reports, this number cannot replace a national identifier, name, date of birth or other personal identifiers within the surveillance programme.

In addition to personal identifiers, surveillance programmes may find it useful to assign unique HIV case record numbers that are used only within the surveillance system. These can be sequential numbers alone or may include numbers or letters representing the subnational units that report the case. For this to be effective, the unique HIV case report numbers must be assigned at the national level. The first step at the national level is determining that a case is new through case-matching, as described above. Cases that are determined to be new cases can then be assigned a unique – typically sequential – case record number. These surveillance case record numbers should be stored in the surveillance case database at the national and subnational levels.

Multiple reports for the same individual may contain discrepant information. For example, there may be different dates of birth or different dates of diagnosis. In this situation, the surveillance system should refer to the original source documents, reporting site, or the person who submitted the report. If this does not rectify the discrepancy, a predetermined hierarchy that uses the source considered most reliable should be applied.

Additional information about case record-matching can be found in Annex 3.1: HIV case surveillance toolkit, Section 1.4 D.

3.4.11 Security and confidentiality

HIV surveillance systems collect, store and use personal health information that is obtained for the public good. There is nevertheless a risk that the deductive or direct disclosure of this same information without consent could adversely affect people who are diagnosed and reported as HIV-positive. In addition, data related to the mode of transmission for people whose behaviour is criminalized, such as men who have sex with men, sex workers and drug users, could be used to identify people for questioning, arrest and detention.

Any inadvertent release of information may also damage relationships between the authorities responsible for HIV surveillance and the community. For this reason, surveillance systems must ensure that confidentiality is not breached and that the data are held securely.

Section 3.3 (Reporting laws, regulations and policies) emphasized the need for a comprehensive legal and policy framework to support HIV case surveillance, including measures to protect patient privacy and confidentiality *(38,39)*. Such a framework must also ensure that routine aggregate outputs from surveillance programmes are designed so that there is no risk of deductive disclosure of a person's HIV status, sexual orientation or involvement in sex work or drug use.

It is recommended that all organizations in a country's health-care system have a designated confidentiality and security officer who is responsible for ensuring the protection of patient privacy and data security within the organization. For HIV case surveillance, the national Ministry of Health should set the policies and standards for the collection, storage, transfer and use of surveillance data, and review these regularly to ensure that they are responsive to changes in technology, and in the social and political environment. The confidentiality and security officer within each organization should be responsible for implementing and ensuring compliance with policies and standards for data security. Recommended confidentiality and security policies, which should apply to all people involved with the collection, storage and use of HIV surveillance data, are described below.

Policies

Written policies and procedures must be developed and disseminated to all staff members who handle patient-level surveillance data at reporting sites, and at subnational and national levels. These policies and procedures should reflect all laws and regulations that govern the surveillance system. The security and confidentiality policies and procedures for HIV case surveillance should include the following:

- a description of the data collected, with specific attention to information that may identify any HIV case;
- the roles and responsibilities of all staff members who may obtain, transfer, manage or use surveillance data;
- confidentiality agreements in which all staff members involved in HIV case surveillance acknowledge that they are aware of the security and confidentiality policies and procedures, and agree to comply with them;
- controls to ensure the security of physical and electronic data, including case report forms, data entry devices, and systems and methods used to transport, transfer, store and use surveillance data;
- a description of who has jurisdiction over the data (e.g. national programme, local surveillance programme, HIV monitoring and evaluation programme), whether the data can be shared between programmes and, if so, the mechanism for data-sharing, including when, how, by whom, what specific data can be shared, and the formats in which data can be shared (e.g. in aggregate, at individual-level without identifiers or with identifiers, etc.);
- a mandate that any breach of security policies or procedures must be reported without delay to the confidentiality and security officer, and promptly investigated to minimize adverse outcomes, and that appropriate remedial and/or disciplinary steps must be taken to prevent a recurrence;
- requirements for at least annual training on security and confidentiality for all staff with access to surveillance data.

Recommendations for data collection, storage and use

- Collect minimal data required to achieve programme goals.
- Use the highest security standards for collecting, storing and using personally identifying data.
- Limit release or sharing of personally identifying data to those with a justifiable public health need (e.g. sharing with the TB surveillance programme for programmatic needs).
- Ensure that any programme receiving HIV case surveillance data adheres to the same or higher standards as those of the surveillance programme.
- Analyse de-identified data and disseminate in aggregate, ensuring sufficiently large numbers in any category to prevent the inadvertent identification of any individual.
- When paper documents are no longer required, they should be shredded using cross-cutting shredders and disposed of.
- Limit physical access to areas where confidential data are stored, and limit access to electronic files to personnel with justifiable reasons to use the data.
- When transporting personally identifying data by courier, require that the documents (paper or electronic) remain with the courier at all times until they are delivered to the surveillance programme.

- Contextualize and consider the sensitivity of information related to mode of transmission or risk behaviour, such as same-sex sexual activity, illicit drug use and sex work.

Electronic data security

- Use technological methods to restrict data access to authorized staff only (e.g. by requiring log-in names and passwords, and/or maintaining personal identifiers on computers with restricted access).
- Store surveillance data on a secure computer or network, and encrypt these when not in use.
- Encrypt personally identifiable data when transmission is necessary.
- Ensure that all electronic mobile devices used for reporting cases (e.g. smartphones, tablets, laptops) have restricted access, the ability to encrypt data, automatic monitoring to detect and report policy violations, wiping/erasing capacity before reuse, authentication prior to use, ability to reset passwords remotely, automatic locking of devices when idle, restricting application access to authorized users only, and restricting use for activities other than entering data for case reporting. Mobile devices should be pilot-tested using non-confidential test data prior to field use. Data should not be stored permanently on these devices. Data should be collected and transferred to the surveillance database and then removed from the mobile device as soon as possible.
- Use secure methods for data transmission, such as secure data networks, virtual private networks and secure file transport protocols. Alternatively, encrypt data for transmission. Mobile phones and personal digital assistant devices cannot transmit data securely.
- Use de-identified data for analysis.
- Encrypt back-up files and store in a secure location outside the surveillance programme to prevent loss of data due to property damage (e.g. fire, flood).
- Transmission of personally identifying data by email is discouraged. If this is the only option in some settings, the data must be encrypted.

Physical security

HIV case surveillance data must be kept in a physically secure location to which only authorized staff members have access. Building security can be ensured through alarm systems, security guards, video cameras and locks. Access to the surveillance programme office should be restricted to authorized personnel.

3.4.12 Performance methods and outcome standards for monitoring and evaluating case surveillance

Case surveillance systems must be routinely monitored to ensure that the surveillance processes are effective and that the data are of high quality. Surveillance programmes should undergo periodic comprehensive evaluations *(40,41)*, and routine monitoring and evaluation of programme performance. Surveillance programmes should conduct at least annual evaluations of the surveillance system process and data quality. Comprehensive evaluations may be performed in collaboration with external advisors.

Surveillance process monitoring

An effective case surveillance system needs to capture all persons diagnosed with HIV, ensure that cases are reported in a timely manner and that the information submitted for each case accurately reflects the data recorded in source documents (e.g. patient records). Monitoring the surveillance process should focus on the methods used to achieve complete, timely and accurate case reporting. Factors that produce complete reporting include comprehensive identification of reporting sources for case-finding, education of and communication with people who are responsible for identifying and reporting cases, a case report form that includes instructions on how to complete and submit the form, and contact information for clarification. It also includes ensuring adequate supplies of reporting forms, and routinely providing feedback to people who collect and use the surveillance data.

The timeliness of reporting is influenced by the reporting burden and adequacy of provider or surveillance staff time to report cases, the ease of identifying cases and completing case reports, and methods of submitting data.

The accuracy of the data submitted depends on the methods used to obtain the data and the performance of the person reporting the case. Although the accuracy of surveillance data is measured by the extent to which it correctly matches information from the source documents, the information in these source documents may be incorrect. For example, a medical record or register may list an incorrect date of birth or laboratory test result. The validity of the data recorded in source documents can be measured and evaluated as part of clinical and laboratory quality improvement and programme monitoring activities.

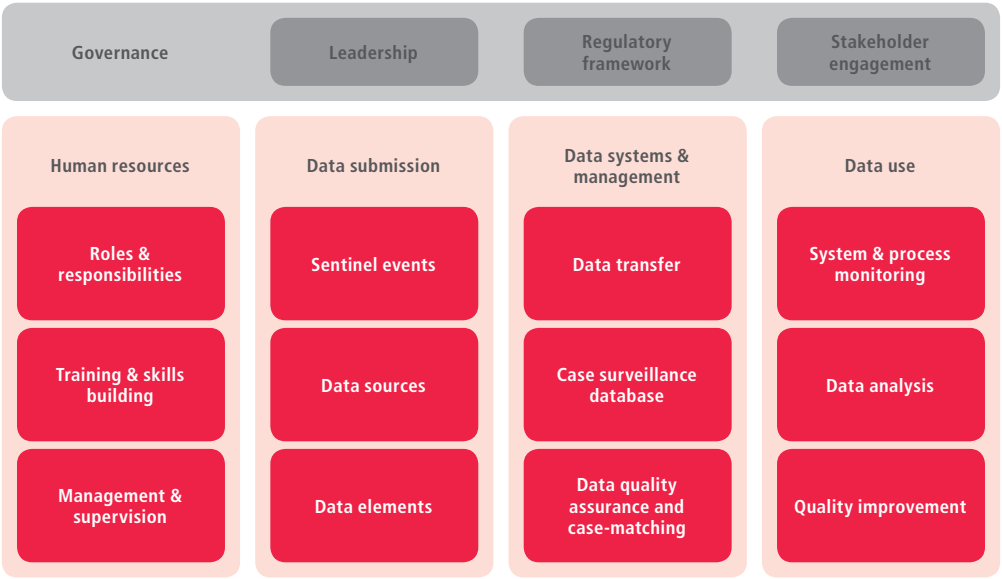
Countries should have standardized approaches for measuring surveillance system performance, including key variables such as timeliness, accuracy and completeness. Annex 3.1: HIV case surveillance toolkit provides detailed guidance on outcome measures and standards for performance of HIV case surveillance systems.

3.5 Surveillance system design and implementation

3.5.1 Determining the best approach

Fig. 3.2 shows the components of a HIV case surveillance system. These building blocks are further described in the toolkit in Annex 3.1: HIV case surveillance toolkit, Section 1.4 D.

Fig. 3.2 Building blocks of an HIV case surveillance system



Source: Annex 3.1: HIV case surveillance toolkit

The approach taken to designing and implementing HIV case surveillance will depend on the country context. In countries that have a well-established disease-reporting framework but do not report HIV, a mechanism for establishing HIV case surveillance may already exist and the methods for adding HIV case surveillance to the list of reportable diseases, the agencies responsible for overseeing and conducting surveillance, the reporting pathway and the persons responsible for reporting are likely to be in place. In this situation, implementation of case surveillance will focus on factors that are specific to HIV reporting, such as the case definition, reporting time frame, case report form, sentinel events, data sources, methods for identifying and reporting cases, data management systems, analysis and dissemination, security and confidentiality, performance standards, resources required and training.

In countries where case reporting of diseases may be limited or non-existent, the implementation process may involve many steps. The approach to implementing HIV case surveillance outlined below is designed to guide countries that lack a strong system of disease surveillance, particularly one that is case based. These strategies can also be applied to countries that wish to strengthen a current HIV surveillance system.

The process for developing and implementing HIV case surveillance should be directed by the Ministry of Health, with input from relevant stakeholders. Ideally, the Ministry of Health should establish a steering committee comprising organizations and agencies that will participate in and use outputs from the surveillance programme. These may include representatives from the national Ministry of Health programme or agency that oversees disease surveillance, HIV testing, care and treatment programmes, laboratories that conduct HIV-related tests, the national statistical and vital registration agencies, national monitoring and evaluation programme staff, health management information systems, national-level planning bodies, community organizations and implementing partners that provide services to people living with and affected by HIV, other relevant policy-makers and donors. The steering committee's role is to provide input into and support the design and implementation of case surveillance.

A technical working group comprising people with practical and technical expertise in disease surveillance, HIV patient monitoring systems, data collection and management systems, and HIV testing, care and treatment services should be responsible for designing the system, procedures and legal framework for case surveillance and its implementation. The technical working group should be overseen by the Ministry of Health.

3.5.2 Process for system development and expansion

Situational assessment

The surveillance system design must take into consideration the environment in which cases can be identified and reported. This is best accomplished through a situational assessment to determine the factors that will impact the success of the system and inform its design or adaptation. The situational assessment should include a desk review of existing documents and field visits to facilities and laboratories to observe registers, medical records and laboratory documentation systems, and to consult with health facilities and community-based organizations that perform HIV testing and provide services to people living with HIV. An example of a situational assessment tool is included as Annex 3.5.2 (Situational assessment) and Annex 3.1: HIV case surveillance toolkit, Section 2.3.

The assessment should examine existing:

- HIV reporting laws and regulations;
- policies for the protection of patient privacy, and data security and release to identify areas that need strengthening;
- organizational structures for disease surveillance, reporting pathways, processes, forms, data management and dissemination to assess the potential for using or building on these systems, and to estimate costs associated with developing or strengthening HIV case surveillance;
- data collection tools used in HIV testing, care and treatment programmes, laboratories that conduct HIV-related tests and vital registration systems to determine the availability and accessibility of data required for surveillance;
- data gaps or weaknesses in the HIV case surveillance system that need to be addressed;
- HIV patient and programme monitoring and reporting systems, and how these could be leveraged;
- potential for EMRs and laboratory information systems to transmit data directly to the surveillance programme;
- vital registration systems to understand the completeness of death ascertainment, recording of causes of death and data accessibility;
- technological capacity, infrastructure and systems that may facilitate or impede case surveillance;
- availability and need for human and financial resources.

Setting objectives for implementing or upgrading the case surveillance system

HIV case surveillance may be conducted by a newly established HIV surveillance programme, incorporated into existing disease surveillance programmes, or added as an enhanced component of an existing AIDS case surveillance system. Where feasible, integrating HIV case surveillance into existing disease reporting systems is recommended over other strategies because it leverages existing systems and personnel with relevant experience.

Based on the situational assessment, countries should identify their objectives for HIV case surveillance with a view to either implementing a new system or upgrading an existing one. Such objectives may include the following:

- measuring the number of and trends in HIV cases, relevant demographic information, mode of transmission, entry into care, time from diagnosis to entry into care, clinical characteristics at diagnosis (clinical stage and immunological status), initiation of and retention on ART, changes in clinical staging and immunological status, time from entry into care or from ART initiation to viral suppression, and death;
- measuring disease burden by mode of transmission and geographical region over time;
- identifying outbreaks or hotspots to enable rapid intervention;
- measuring the impact of prevention, care and control efforts; and
- using data for programme improvement and resource allocation.

Key considerations for implementing or updating the case surveillance system

The surveillance system design should include all the reporting processes and procedures outlined in this chapter, taking into consideration information obtained from the situational analysis. The design and implementation plan must determine which programmes within the Ministry of Health will have authority over the surveillance system, and will be responsible for receiving reports, managing, analysing and disseminating data, and for monitoring the performance of the system. Additional information regarding system design can be found in Annex 3.1: surveillance case toolkit, Sections 2.4 A and B.

The **reporting pathway** will need to be determined, e.g. whether reports should first be submitted to the subnational level and from there to the national level, or reported to the national level and then disseminated to subnational units. This will likely depend on the disease burden, resources and capacity at the subnational levels. At a minimum, the system should be able to describe the magnitude and direction of the epidemic, and measure the country's strategic information indicators for HIV that can be captured with HIV case surveillance (WHO HIV global indicators 4–9 *(1)*) by sex, age, geography, mode of transmission and time.

The situational assessment should have determined if the required surveillance variables are available in the registers, paper and electronic medical records, and/or laboratory information systems. Revisions to the data collection tools in Section 2.3 may be required prior to implementing case surveillance.

The WHO standard **case report** form for adults and children shown in Annex 3.4.7 can be adopted or adapted by countries, or countries may develop their own forms. Case report forms should be user friendly, include instructions on how they should be completed and submitted, and contain information on where and to whom questions can be addressed.

In many situations, a **unique patient identifier** may not exist, or may exist only for residents or adults, or may not be routinely used within the health-care system. Guidance for countries considering the introduction of a national health or other unique identifier appears in Chapter 4.

At the national and subnational levels, consideration should be given to finding **optimal ways to identify and report cases and sentinel events**. In some settings, it may be most efficient to have surveillance personnel assume this responsibility (i.e. active reporting), while in other settings, reporting may be handled by staff at reporting sites (passive reporting).

Methods for the **electronic transfer of data** from electronic medical records and registers and laboratory information systems to the surveillance programme should be developed by information technologists and data managers within the surveillance programme, or by outside

vendors if the surveillance programme lacks the necessary expertise. When selecting outside vendors, it is critical that these vendors are accessible after the system is deployed. Electronic reporting should be considered only in settings where there is a well-established stable power source and appropriate IT infrastructure. Countries should avoid embracing new technology if the required support is not available. Additional guidance regarding data management systems for HIV case surveillance can be found in Annex 3.1.

The following key principles should be followed when implementing or upgrading a data management system. The system should:

- be fully accessible to authorized surveillance personnel;
- be built with accessible and modifiable software;
- have local IT support for troubleshooting, and updating the databases and software used;
- be as simple as possible to meet surveillance requirements;
- collect multiple reports concerning individual cases;
- permit de-duplication;
- have adequate security protection;
- incorporate automated and manual data quality checks;
- be able to accept, clean and store data, and to export data for analysis;
- support transfer between the subnational and national levels;
- be compliant with national laws governing handling of public health data;
- ensure that data collected at these sites are compatible with the case report form in countries where most HIV testing and care occur in public health facilities that use standardized data collection tools;
- include interoperability for electronic uploads;
- have data standards and a data dictionary; and
- be developed and managed by skilled individuals or commercial suppliers.

The surveillance policies, processes and data systems must adhere to national or international standards for protecting patients' privacy and data security. Maintaining confidentiality and security must be considered at each step in the system design. For example, if facilities are submitting case reports, secure methods must be developed to transport these case reports to the surveillance programme.

The surveillance system should be designed in a way that maximizes the likelihood that the recommended **performance standards** will be achieved. For example, active surveillance conducted by designated surveillance personnel has been shown to improve the completeness, timeliness and accuracy of case surveillance. Reporting from laboratories improves the completeness of case ascertainment and laboratory variables.

Human and financial resources must also be considered in designing or upgrading the system. Depending on the size of the programme, staff may be shared across surveillance programmes (e.g. there may be a single epidemiologist for all disease notification systems at a subnational level). A surveillance system should include personnel who can perform the following functions:

- direct national surveillance;
- coordinate national surveillance;

- conduct national epidemiological analysis;
- manage national surveillance data;
- coordinate subnational surveillance;
- manage subnational surveillance data;
- conduct subnational epidemiological analysis;
- supervise facility-level reporting;
- conduct facility-level reporting;
- manage facility-level paper-based and electronic data; and
- review facility-level reports from the subnational level for data and clinical quality improvement.

Technical guidance document

The national regulations, laws, policies and procedures for HIV case surveillance should be recorded in an official technical guidance document that will serve as a reference tool for all people who participate in surveillance activities. The technical guidance document (also referred to as an operations manual) should be available at the national and subnational levels. The following components should be included in this document:

- glossary of terms;
- purpose of the document;
- purpose of HIV case surveillance;
- national HIV reporting mandate and policies;
- surveillance case definition;
- persons responsible for identifying and reporting cases;
- reporting pathways;
- reportable events and case definitions;
- timeline for reporting cases;
- reporting sources;
- required variables and model case report forms;
- methods for submitting case reports from laboratories and facilities;
- data transmission procedures between the national and subnational levels;
- description of hardware and software for data management;
- data dissemination plans (content, formats and frequency);
- monitoring processes and performance standards;
- security and confidentiality requirements and procedures;
- roles and responsibilities of programmes and personnel responsible for case surveillance activities;
- requirements for staff training in data collection, management and analysis; and
- list of key contacts at the national and subnational levels.

3.5.3 Process for system implementation

Pilot-testing

In countries with well-established case-based disease surveillance systems, implementation of the HIV surveillance system can build on existing programmes and infrastructure, and the operational framework for the system can be developed by experienced surveillance officers. In some countries, implementation methods may not be well defined. In these settings, it may be useful to pilot-test and evaluate the system. This will permit modifications to the system design prior to a national roll-out.

Pilot-testing may be conducted in a selected region or in selected sites throughout the country. The pilot should be planned for a specified time period and include an evaluation protocol that measures performance standards and other surveillance system attributes. The pilot may be followed by national roll-out or by additional pilot-testing until the system design is deemed appropriate for conducting surveillance nationally. The pilot should be designed to inform the human and financial resources required for implementing and sustaining HIV case surveillance.

Roll-out

Once the system design is considered complete, plans for national roll-out should be developed. This can be done in phases or with a single start date. Regardless of the approach to establishing surveillance nationally, all staff involved in conducting surveillance activities will need to be trained. Copies of the technical guidance document and supplies needed for case reporting (such as case report forms) will need to be distributed. Simple job aids may be useful in some settings. Enhanced and frequent monitoring is recommended until the system is well established and performance standards are met. Ongoing training of new facility and surveillance staff will be required. Feedback to surveillance and facility staff is also essential.

Data analysis and dissemination

Data should be analysed and disseminated as early as possible, giving due consideration to reporting delays and allowing adequate time for complete reporting.

Obtaining historical data may be a challenge for surveillance programmes in some countries. For people newly diagnosed with HIV or who reach a new sentinel event, case reports will be submitted. However, for people with HIV who are stable on ART and where viral load monitoring is not routine, decisions will be needed regarding the methods to obtain reports for these cases. Short-term surveillance staff may need to be hired to collect historical case reports.

3.6 Analysis, interpretation and presentation of case surveillance data

3.6.1 Overview

Data from HIV case surveillance can be used to describe the HIV epidemic in terms of people, place and time, and to detect outbreaks or clusters of infection. The data can also be used to describe the characteristics of people newly diagnosed with HIV, people newly diagnosed with advanced HIV disease or AIDS, people ever diagnosed with HIV or advanced HIV disease, and – in settings with reliable mortality data – people with HIV who have died.

It is important to understand that HIV case surveillance captures people who have been diagnosed with HIV and does not measure HIV prevalence or incidence directly. Data from HIV case surveillance have been used as inputs to mathematically model the rates of new

HIV infections *(42)*. There are also special HIV antibody testing methods that have been used to estimate HIV incidence.

HIV case surveillance data must be able to describe the sociodemographic characteristics and risk factors that can identify the mode of transmission, the geographical distribution of disease, and how these change over time.

Case report forms and systems should include probable routes of transmission (e.g. heterosexual sex, homosexual sex, injecting drug use), and these can be used to disaggregate surveillance data to monitor HIV diagnosis among key population groups. It is worth noting that peoples' risk behaviours may change between diagnosis and other sentinel events. For example, someone may become infected by sharing a contaminated needle/syringe but subsequently stop injecting, thereby leaving a key population category, and lead to an overestimate of people who inject drugs in the cascade analysis.

The data can be used to strengthen prevention and treatment activities in areas where most cases are being diagnosed, and to identify where the HIV epidemic is concentrated. Data from surveillance systems may also be combined with other information on the HIV epidemic, including data from programme monitoring, qualitative studies, vital statistics, censuses, surveillance for STIs, and surveys to account for changes in the epidemic. A range of analytical techniques can be employed to correlate data from surveillance with other data through triangulation, data synthesis and second generation surveillance.

Because HIV case surveillance systems compile HIV care cascade indicators that can then be analysed at the individual level (always ensuring confidentiality), they provide important opportunities to investigate and address potential gaps in the cascade to be investigated and addressed.

Moreover, case surveillance data can be used to answer the following questions:

- How many cases of new infections and advanced HIV disease/AIDS cases have been reported annually and how have these numbers changed over time?
- Among which population and age or gender groups are new diagnoses occurring and has this distribution changed over time?
- Which regions have the highest number and highest rate per 100 000 population of diagnosed HIV infections?

To ensure correct interpretation, data analysis must be directed and conducted by staff familiar with the data and its limitations. The analysis of surveillance data should consider how and by whom the data will be used. Assessing the data needs of stakeholders can help identify which types of analyses and presentation formats will facilitate the use of data for public health action. To encourage the use of surveillance data, the results should be available on the national Ministry of Health website. Ideally, data analysis should be developed so that they can be automated for future needs.

Surveillance programmes are responsible for ensuring that the data reported satisfy the minimum standards of quality, including completeness, timeliness and accuracy. Incomplete case ascertainment limits the representativeness of data, hampers comparative analysis, and diminishes the overall utility of HIV case reporting as a surveillance tool. Data analysis should allow sufficient time to account for reporting delays. Caution should be exercised when interpreting variables that do not have a high degree of completeness. Releasing data from an immature case surveillance system may lead to misinterpretation. To reduce the risk of inadvertent identification of individuals, it is essential that data be presented in a way that preserves the confidentiality of individuals.

3.6.2 Formats for data presentation

Several formats are commonly used to disseminate case surveillance data to the local, subnational and national levels. The type of format adopted must be suitable for the target audience. Surveillance data are typically presented in the following formats.

Annual HIV surveillance report

The focus of this type of report is the analysis and interpretation of data from the surveillance system. While usually limited to descriptive statistics, the report may also include more comprehensive analysis. The annual report usually covers characteristics of the HIV epidemic, including risk patterns observed, transmission categories, age groups, sex, geographical distribution and trends in these variables over time.

Annual epidemic report

This report is designed to make use of the broad range of strategic information available to the country. It will typically include HIV case surveillance data, as well as surveillance data from diseases frequently associated with HIV, such as TB, viral hepatitis and sexually transmitted infections.

Data fact sheets

Data sheets provide basic information on a specific topic, usually in simple language for a general audience. They may also be targeted to a specific audience, such as a member of a key population (e.g. men who have sex with men) or age group (e.g. children, adolescents, younger or older adults).

Presentations and slide sets

Oral presentations accompanied by visual display of the data can be a useful way to disseminate data within the government and to other stakeholders, such as community organizations, the public, donors and United Nations (UN) agencies.

3.6.3 Data analysis

Routine or ad-hoc analyses of surveillance data can be conducted to produce aggregate outputs that measure levels and trends in the following outcomes:

- new and cumulative diagnoses of HIV infection;
- new and cumulative diagnoses of advanced HIV disease or AIDS deaths;
- people living with HIV; and
- indicators of engagement in care (i.e. care cascade indicators).

Analyses of surveillance data need to describe the epidemic by person, place and time. The outcomes listed above should therefore be disaggregated by demographic and geographical characteristics, and examined over time.

Person

Analysing surveillance data by the characteristics of people who have HIV provides further specific information. The demographic variables most frequently used for analysing HIV data are age, sex and race/ethnicity. Consideration should be given to how gender is recorded and used in HIV case surveillance systems (*see* Section 2.4.7 for specific recommendations). Other variables, such as the probable route of transmission category, can be used as a proxy for key population groups and to disaggregate data by key population category. If possible, the characteristics of cases included in any surveillance system should be related to population

denominators so that rates can be calculated. Even though assessing the number of cases alone can be sufficient, variable-specific rates are more helpful for comparisons of the risk involved. For example, even if the number of cases of a particular condition is higher in one segment of a population than another, the rate in that population group could actually be lower if that group represents a large proportion of the population.

Place of residence and care

Analysis of surveillance data by place can identify regions with the highest prevalence and largest number of HIV cases, and those newly affected by HIV. It is important to recognize that the location from which the condition was reported might not be the place where the exposure occurred. This is particularly relevant for AIDS cases due to the potential for considerable passage of time between HIV infection and AIDS-defining illness. Analyses of place of residence compared with place of care can highlight important issues relating to the adequacy of service coverage.

Time

Analysis of surveillance data by time can reveal trends in disease progression among those reported to the system. The easiest analysis is usually a comparison of the number of cases diagnosed during a particular period (e.g. months or years). Such data can be organized into a table or graph to assess whether there has been an abrupt or gradual increase or decrease, or whether the trend is stable.

Another simple method of analysis compares the number of diagnoses for a current period (e.g. a given quarter or year) with the number diagnosed during the same period for the past several years. It is critical to use the date of diagnosis and not the date of the report when analysing trends. In addition, reporting delays should be considered in the analysis of trends. For example, if the median reporting delay is three months, then data for a given year should be analysed no less than three months after the end of that year.

Descriptive analysis

In general, HIV case surveillance systems can effectively use and present data through simple descriptive analysis. This involves measures of frequency. The most basic measure of disease frequency is a simple count of affected individuals or their characteristics. Case counts can be displayed for the population and for any of the variables collected. This allows for comparisons between groups, such as the distribution of the number of female and male cases over time. To account for differences in the case count, measuring the proportion (i.e. percentage) is useful. A percentage is calculated as the part of the total represented by various data elements. Added together, the percentages of the elements equal 100%.

Rates are also commonly calculated. This is done by dividing the number of cases (numerator) by the size of the population (denominator) for a specified period of time. Rates calculated from numerators of less than 20 should be denoted in a footnote as unreliable. When comparing rates between populations, it is typical to standardize the denominator to make direct comparisons. Standardization is usually expressed as a factor of 100, i.e. the number of events per population of 1000 or 10 000 or 100 000. This standardization will depend on the magnitude of the local surveillance data. For national data, the population size is most often standardized to 100 000. Calculation of rates requires reliable census data.

3.6.4 Factors influencing use and interpretation of data

Increases and decreases in the number of HIV case reports may be due to factors other than a true decrease or increase in the number of infections and deaths. The following factors may influence the interpretation of case-reporting data:

- Increases or decreases in the size of the population will affect both the number of infections, and the incidence and prevalence levels.
- Increases in HIV testing coverage or more effective modalities of testing may lead to more diagnoses but do not necessarily reflect changes in the epidemic.
- The adoption of a new case definition – particularly one that is broader – will result in an increase in the number of cases.
- When ART is provided to people with HIV clinical stage 1 or 2 disease, they may not progress to advanced HIV disease or they may progress more slowly. Changes in treatment guidelines regarding when to initiate ART can affect the interpretation of trends in advanced HIV disease/AIDS.
- Changes in case-reporting practices, such as efforts to increase reporting from private health-care providers, may increase the number of reports.
- Increases or decreases in the number of health-care facilities or other factors that affect the use of health-care services can affect diagnoses and reports of HIV. For example, implementing or increasing a user fee may result in fewer people seeking testing, which may reduce HIV diagnoses and case reports.
- Duplicate case reports (more than one report provided for an individual) may lead to counting a case or sentinel event more than once.

3.6.5 Displaying and interpreting data

Surveillance data are generally presented using figures, tables and maps. Figures and maps are useful for displaying high-level data, while tables are the best method to provide detailed information. All figures, maps and tables should have clear and comprehensive titles and, where relevant, include footnotes and definitions of abbreviations. Figures should include legends and the axes of graphs should be labelled. Tables should include column and row headings. Fig. 3.3–3.11 and Table 3.3 provide illustrative examples of published graphs and a table that presents case surveillance data.

Fig. 3.3 Map of geographical distribution of the HIV epidemic in Brazil showing HIV concentration in big cities in some regions

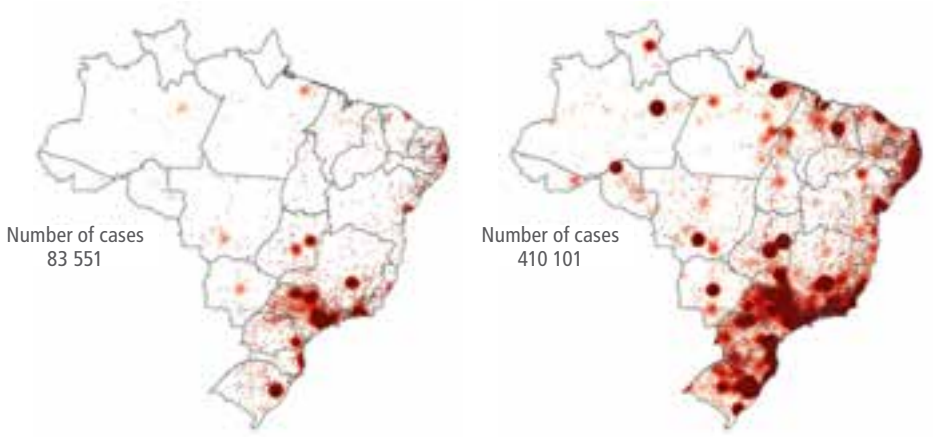
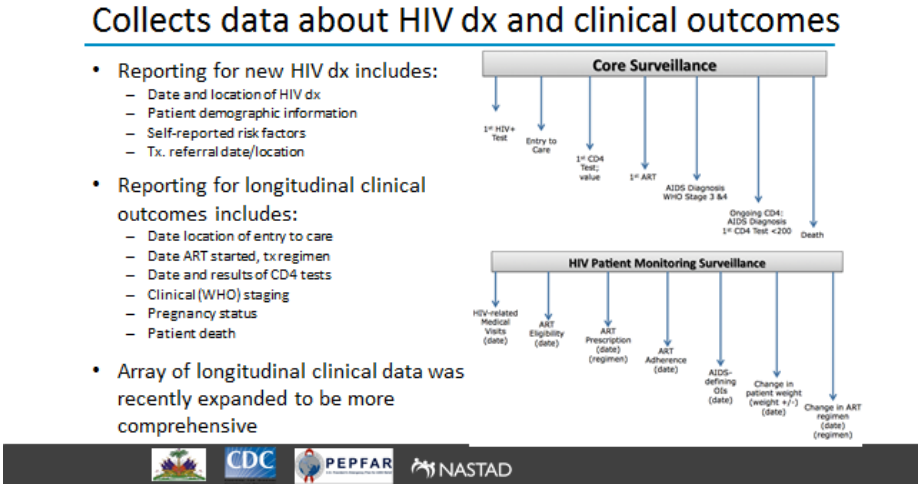
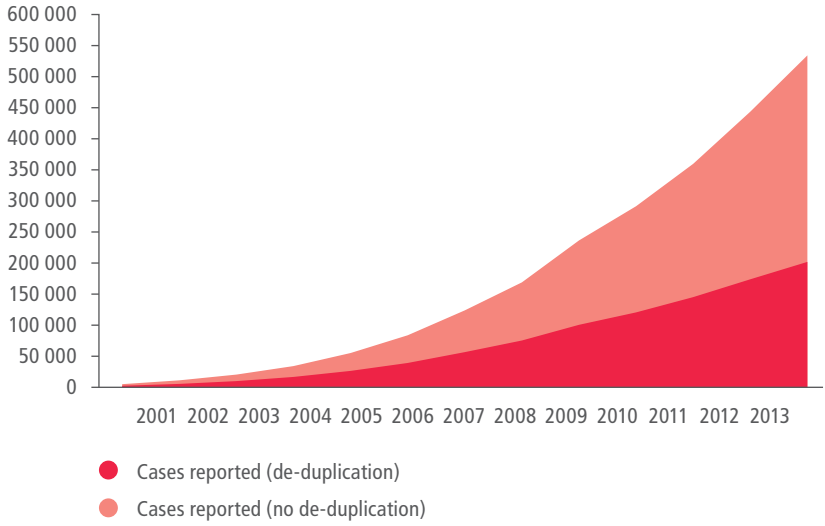


Fig. 3.4 HIV case reporting and patient monitoring system events collected by information systems in Haiti



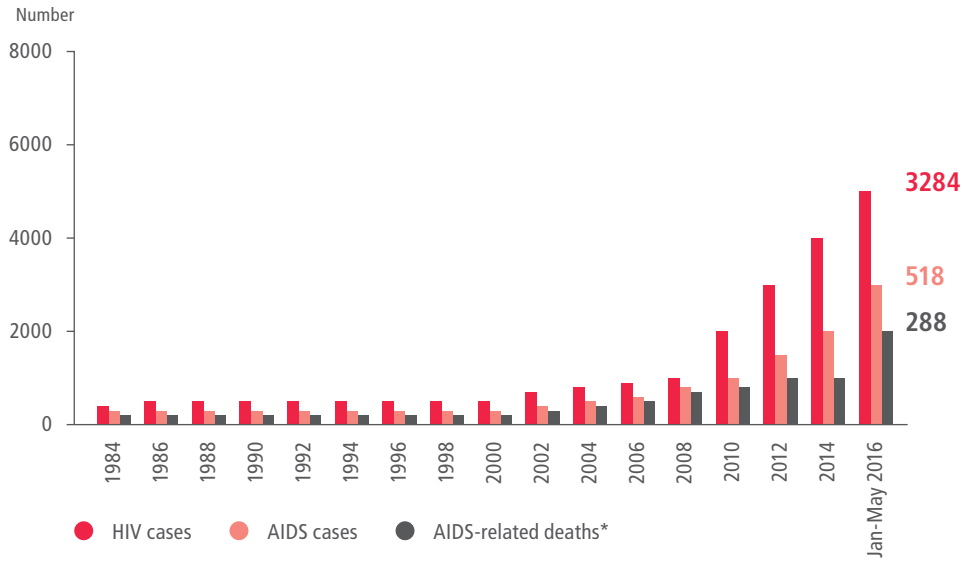
Source: Annex 3.1: HIV case surveillance toolkit

Fig. 3.5 Cumulative reports of new HIV diagnoses by year of report, Haiti, 2001–2013



Source: Ministry of Health, Haiti

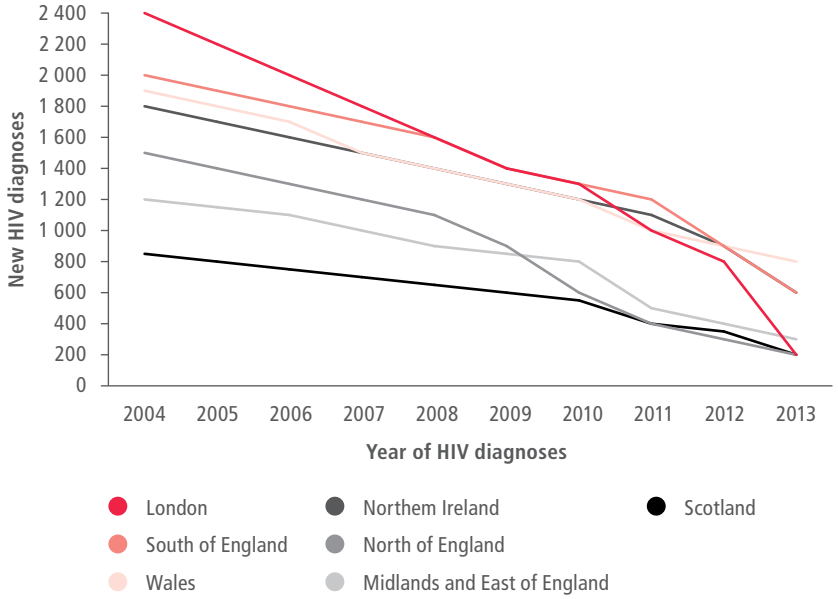
Fig. 3.6 HIV/AIDS cases reported and AIDS deaths, the Philippines, 1984–2016



* The Department of Health established a separate reporting mechanism for deaths in 2012. Prior to this, deaths were infrequently reported to the HIV/AIDS registry. It is likely that the number reflected here is an underestimate of the total number of deaths among people living with HIV in the Philippines.

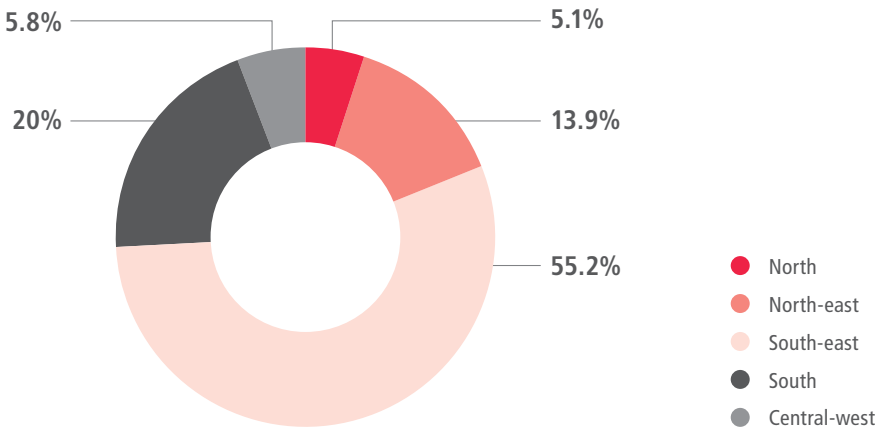
Source: Ministry of Health, Philippines

Fig. 3.7 New HIV diagnoses among heterosexual men and women by geographical area, United Kingdom, 2004–2013



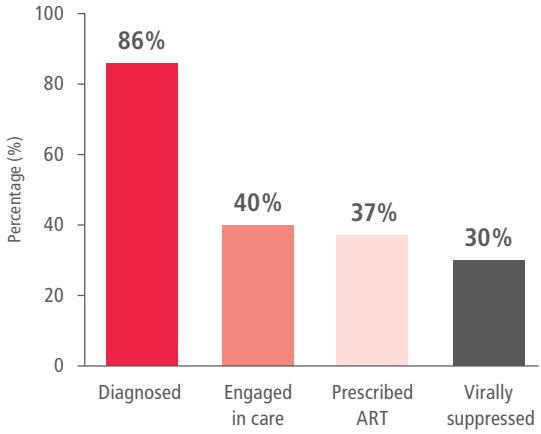
Source: Yin Z, Brown AE, Hughes G, Nardone A, Gill ON, Delpech VC et al. HIV in the United Kingdom 2014 report. November 2014. London: Public Health England; 2014 (data to end 2013) (https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/401662/2014_PHE_HIV_annual_report_draft_Final_07-01-2015.pdf, accessed 9 April 2017).

Fig. 3.8 Percentage distribution of AIDS cases by region of residence, Brazil, 1980–2013



Source: Brazilian Ministry of Health/Health Surveillance Department/Department of STDs, AIDS, and Viral Hepatitis

Fig. 3.9 Selected stages of HIV care, United States of America, 2014



Sources: CDC Fact Sheet. HIV in the United States: the stages of care, November 2014 (http://www.cdc.gov/nchhstp/newsroom/docs/factsheets/hiv-stages-of-care-factsheet-508.pdf, accessed 9 April 2017).

Monitoring the dynamics of the HIV epidemic using assays for recent infection and serotyping among new HIV diagnoses: experience after 2 years in France. J Infect Dis. 2007;196:377–83.doi:10.1086/519387

Table 3.3 New diagnoses by sex and transmission category, France, January 2003–March 2005

Transmission category	Women	Men	Total
MSM	–	1786 (38.3)	1786 (22.6)
Heterosexual	2584 (79.6)	1855 (39.8)	4439 (56.2)
IDU	39 (1.2)	153 (3.3)	192 (2.4)
Other[a]	5 (0.2)	8 (0.2)	13 (0.2)
Unknown	617 (19.0)	855 (18.4)	1472 (18.6)
Total	3245 (100.0)	4657 (100.0)	7902 (100.0)

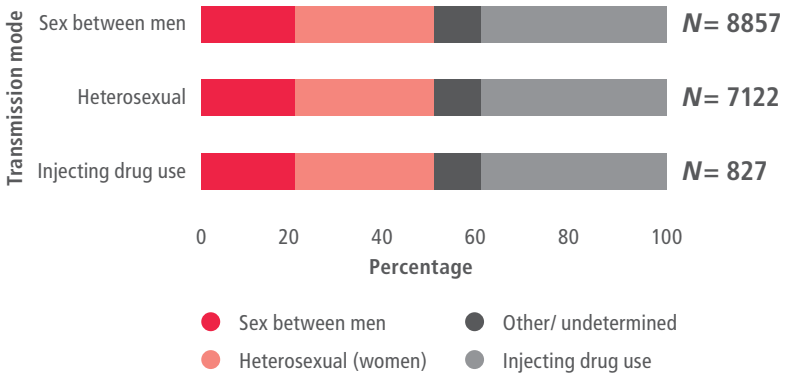
Monitoring the dynamics of the HIV epidemic using assays for recent infection and serotyping among new HIV diagnoses:

experience after 2 years in France. J Infect Dis. 2007;196(3):377–83.

Data are no. (%) of patients. IDU: injection drug user; MSM: men who have sex with men.

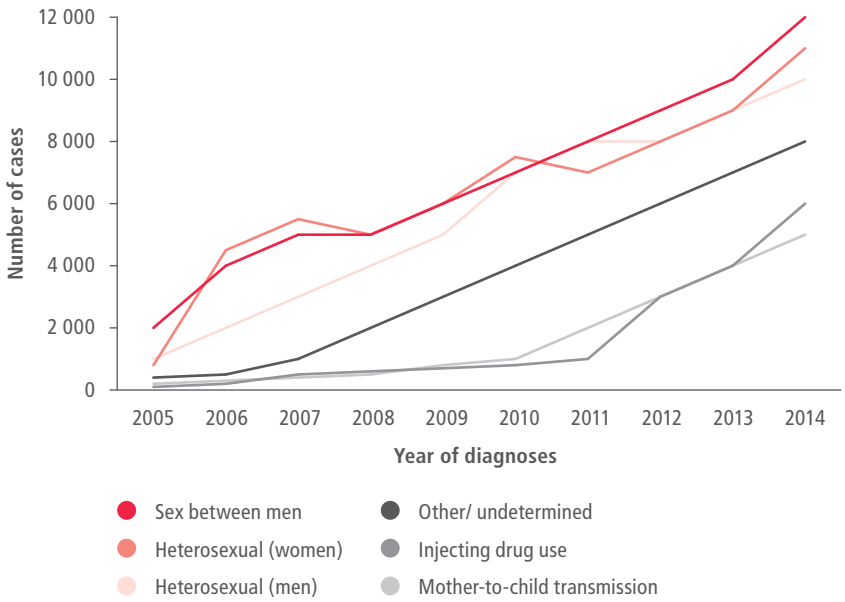
[a] Haemophilia or transfusion recipient.

Fig. 3.10 New HIV diagnoses by CD4 cell count per mm³ at diagnosis and by transmission mode, European Union/European Economic Area (EU/EEA), 2014



Source: HIV/AIDS surveillance in Europe. European Centre for Disease Prevention and Control, 2015.

Fig. 3.11 HIV diagnoses by mode of transmission, 2005–2014, EU/EEA



Data are adjusted for responding delay. Cases from Estonia and Poland excluded due to incomplete response on transmission mode during the period; cases from Italy and Spain excluded due to increasing national coverage over the period.

Source: HIV/AIDS surveillance in Europe. European Centre for Disease Prevention and Control, 2015.

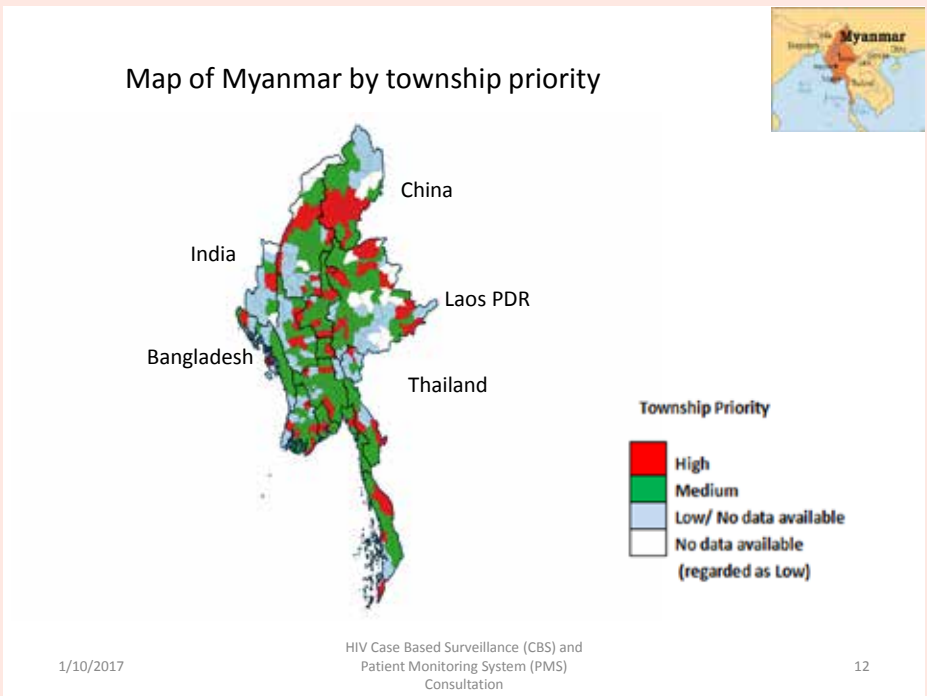
Box 3.3 Using case surveillance data to target HIV prevention in Myanmar

Myanmar has used data from HIV case reporting and other sources of information to estimate the geographical distribution of resource needs and risk of new HIV infections. Townships were categorized into three groups based upon HIV burden and whether the risk of new infections was high, medium or low, based upon the following variables:

- population size estimates of people who inject drugs, men who have sex with men and female sex workers;
- known HIV prevalence among key populations;
- HIV-positive case reports among TB patients;
- HIV-positive case reports among pregnant women; and
- HIV-positive case reports from ART services; and
- the existence of ART services.

Qualitative criteria included knowledge of local areas with HIV risk behaviour or higher risk of transmission (sometimes referred to as "hotspots"), townships located in border areas with considerable migrant or mobile populations, mining camps, economic zones or large prison populations. Identifying priority townships allows Myanmar to target interventions for HIV transmission in hotspots.

Based on this information, the Ministry of Health was able to identify the townships with high, medium and low priority for prevention interventions and services for HIV-infected persons, as presented in the map below.

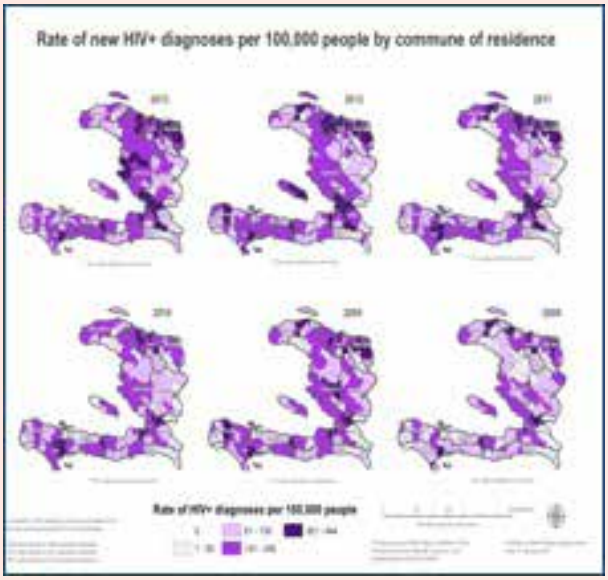


Source: Ministry of Health and Sports, Myanmar

Box 3.4 Using case surveillance data in Haiti

Haiti has had an HIV case-reporting system in place since 2010. Reporting of new HIV diagnosis includes date and location of HIV diagnosis, patient demographic information, self-reported risk factors, referral date and location. At the same time, reporting for longitudinal clinical outcomes includes date and location of entry to care, date ART started, regimen, date and results of CD4 tests, WHO clinical staging, pregnancy status and death. The data collected through the system allow Haiti to describe who is infected, where they are located, patient mobility and key service gaps.

Data are available down to the community (commune) and institutional levels. Longitudinal data are used to track clinical outcomes and can be used to analyse linkage to care, and to create care cascades at the national, regional, and down to the facility levels. A national report based on the data is used to present clinical cascades, ART outcomes and retention at the subnational level. A dashboard has also been developed to make key analyses readily available.



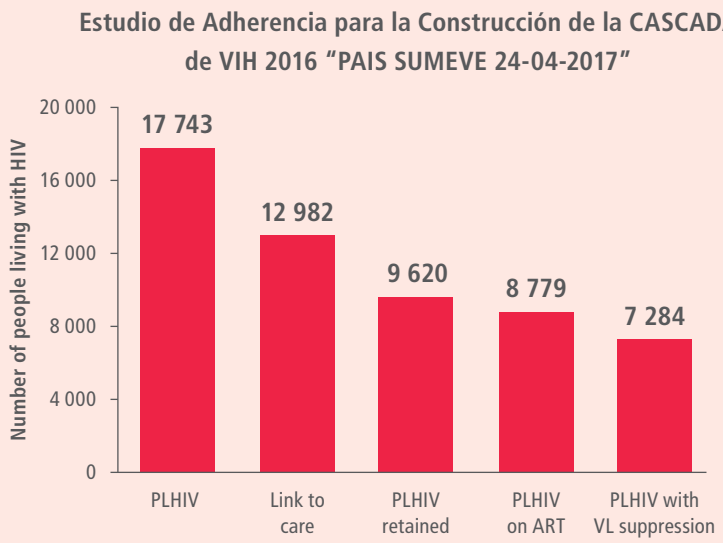
Box 3.5 HIV case reporting system to monitor the response to the HIV epidemic in El Salvador

The unified HIV case reporting surveillance system in El Salvador (called SUMEVE in Spanish) has been progressing over the past few years and now is completely digitized. It is a web application that collects nominal information since 2009, starting with all the persons who have a positive HIV test result in whichever type of heath service, HIV confirmation results, clinical follow up and prescription of ARV drugs for treatment.

Between 2015 and 2016, the HIV surveillance system was modified and improved to allow identification of gaps disaggregated by health centre and provinces for improving the quality of care of people on care and treatment.

Through the SUMEVE cascade analysis, the gaps in each pillar are identified as presented in Fig. 1. For example, among the over 17 000 HIV cases registered and alive, 73% were linked to care, 54% were retained in care, 50% of them were on treatment and 41% had viral load suppression (73% of those on treatment had viral load suppression). The system also allows cascade analysis by gender, and unique identifiers are being introduced to allow analysis by key populations.

Fig. 3.12 National cascade of care and treatment using the HIV case reporting system



Source: Ministry of Health, El Salvador

USING UNIQUE IDENTIFIERS FOR PERSON-CENTRED MONITORING OF HIV SERVICES

04

4. USING UNIQUE IDENTIFIERS FOR PERSON-CENTRED MONITORING OF HIV SERVICES

Summary of key recommendations in this chapter

1. **Promote and use unique identifiers** that replace names in HIV patient records shared within the national HIV programme. This anonymous code should be linked to their health records. *WHO provides definitions and examples of unique identifers.*
2. **Transition progressively from paper-based to electronic patient information systems.** Countries should use a tiered approach to when and how patient and case-monitoring data from paper tools will be entered electronically based on resource availability by site or setting, starting with high-volume sites, e.g. with more than 2000 patients. *WHO provides an example of a tiered approach.*
3. **Strengthen and establish different data security levels.** Assess and establish different security levels for data elements, and invest in robust databases and policies to protect security and confidentiality based on risks and benefits in individual settings. *WHO provides the major headings to be included and provides reference to additional specialized guidance.*
4. **Invest in data systems and ensure interoperability.** Countries should invest in robust and secure data systems. As this is being done, strengthen the interoperability of electronic databases and opt for open-source standards for data systems. *WHO recommends that 5–10% of the programme budget be used to strengthen monitoring and evaluation.*
5. **Use individual data to improve programmes and long-term chronic health care.** *WHO recommends that data be linked to programme improvements and that evidence of these improvements is collected.*
    - **Strengthen retention and transfer** by supporting the routine sharing of information between clinics.
    - **Ensure linkage** by supporting the routine sharing of information between testing, treatment, laboratory, pharmacy and other health services.
    - **Strengthen integration with long-term chronic health care** by using unique identifiers to share information and link HIV and wider health services.
    - **Invest in data analyst capacity,** including central and district data analysts and routine dashboards, to feed back data in real time for programme improvement.

Additional recommendations relevant to this chapter

6. **Data quality review and use for quality of care.** Countries should carry out periodic review of the patient monitoring system to collect key additional national and facility-based indicators (for paper-based systems); monitor and assess the quality of data; monitor and improve the quality of care; and collect facility-level early warning indicators (EWI) for HIV drug resistance (HIVDR). *WHO provides guidance on carrying out an annual patient monitoring review and improving the quality of care.*
7. **Key population (KP) data.** Routinely collected data can be used to describe access by key populations to services; however, confidentiality and security issues are paramount when collecting data related to KP, whether in patient monitoring or case surveillance systems. In most settings, patient records should not include the KP category and any information collected should be used to support patient management and referral to care. The probable route of transmission can be assessed at the point of diagnosis and used to disaggregate data in case surveillance systems. *WHO provides guidance on how to address issues around KP data collection and reporting.*

4.1 Overview

This chapter introduces key concepts related to unique health identifiers and the transition to electronic health information systems. It provides an overview of the key issues for countries to consider as they develop and implement person-centred health information systems that effectively identify and support the progress of people over time and across services.[a]

Unique identifiers are numeric or alphanumeric codes that support individuals to identify themselves when accessing a variety of health services. The code should be anonymous, but is linked to a database that does have personal information and is kept separately and securely. A well-designed unique identifier is free of any personally identifiable information. Information such as location, place of issue or date of birth should not be part of the identification number.

The overall purpose of assigning a unique identifier is to ensure that each person can be correctly and repeatedly identified when accessing health-care services. The code assigned to an individual person facilitates the capture and storage of all data relating to that person's interactions with the health system, including tracking the person's use of different health services for both prevention and treatment over time (e.g. at a testing facility, health facility, laboratory or pharmacy). The use of unique identifiers is an important element in the evolution from service-centred data to person-centred data to improve the quality of care for individuals, and is critical for supporting data linkages and retention in services as people move between health services in the same health facility, and between different health facilities and geographical locations.

Patient monitoring and case surveillance collect information from a variety of sources, including testing centres, health facilities, laboratories, vital statistics, private health sector, including private physicians, ANC and PMTCT clinics, and HIV prevention programmes. The use of unique identifiers will greatly increase the effectiveness and efficiency of both case surveillance and patient monitoring by ensuring that data derived from such diverse health and non-health sources are linked to a specific person.

[a] Some of the content in this chapter is adapted from Considerations and guidance for countries adopting national health identifiers. Geneva: UNAIDS; 2014 (http://www.unaids.org/en/resources/documents/2014/national_health_identifiers, accessed 9 April 2017).

As noted in previous chapters, the "treat all" approach means that an increasing number of people living with HIV will be taking ART, living longer and accessing a wider range of health and social services throughout their lives. To ensure continuity of care and differentiated care, unique identifiers can be used to link health facility and community monitoring at different levels of the health system. As part of implementing the "treat all" approach, unique identifiers can also contribute to the following:

- retaining individuals in prevention programmes rather than delivering just discrete services;
- de-duplicating testing data and facilitating linkage to treatment and care;
- supporting improved retention of people in treatment and care;
- improving the links between programmes and services, and assessing outcomes and impact; and
- ensuring confidentiality and security of individual health information.

In the absence of unique identifiers, programmes depend on aggregate data, which provide a limited understanding of how many people:

- are reached by prevention services, and not merely the number of people reached by any particular prevention intervention;
- test positive for HIV and not just the number of positive HIV tests performed;
- receive appropriate HIV treatment and care, and not just the number of visits recorded;
- are currently receiving ART, rather than just the number of ARVs dispensed; and
- are retained on treatment and care during the past 12 months.

4.2 Types of identifiers

The purpose of a unique identifier assigned to an individual is to ensure that the individual can be repeatedly and correctly identified when using health-care services. Different types of unique identifiers are already being used at different levels in many countries, depending on person and programme benefits. The systems required to support the use of unique identifiers increase in complexity, depending on the level of implementation, while the benefits also increase as the use of unique identifiers is expanded to the national level (Fig. 4.1 and Table 4.1).

Fig. 4.1 Levels of implementation of unique identifiers

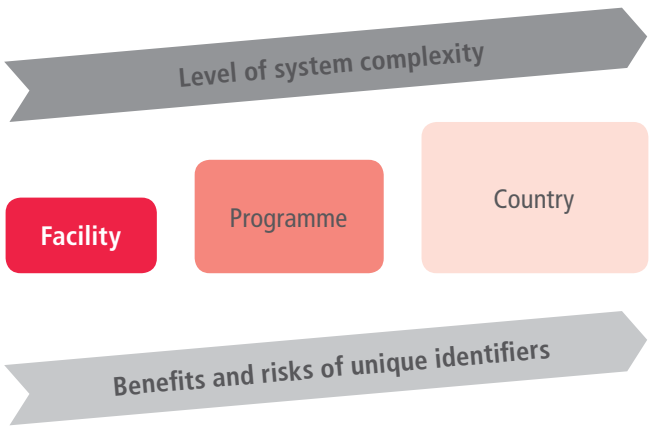


Table 4.1 Benefits and risks of health identifiers

Benefits and risks	Facility	Programme	Country
For person	1. Improved continuity of care 2. Anonymity of health records	1. Easier transfer of treatment when a person moves from one facility, community-based service or from self-standing dispensary to another	1. Improved linkage of HIV and health services 2. Easier reimbursement through health insurance
For programme	1. Better linkage of testing and treatment, and to community care 2. Need to invest in secure data system	1.Easier management of loss to follow up 2. De-duplication of records 3. Security of data records	1. Better management of stocks of drugs and diagnostics 2. Improved planning 3. Sustainability and open access of system

Facility-level identifiers are unique identifiers that are generated and used at a specific facility or clinic. This may be a stand-alone clinic or part of a larger facility. Identifiers that are unique only within a specific section or clinic in a larger health facility may also be referred to as "clinic identifiers". Facility-level identifiers are often paper-based notes recorded in a logbook or register. They are typically used as a person-centred service or health record identifier that may be used across the facility.

At the facility level, the benefits of the use of unique identifiers include improved continuity of care for individuals at the facility through appointments and follow up, improved linkage between clinical care in the facility and other services, such as laboratory services, pharmacy records and improved confidentiality of health data.

Programme- or service-level identifiers are those used across several facilities that are typically managed by the same provider or organization. This can include public sector and private services that operate across more than one facility. Programme-level identifiers may be disease-specific – for instance, HIV or TB programmes – or location-based, including hospital or community facilities.

The programme-level benefits of using unique identifiers across facilities include improved linkages between testing and treatment, continuity and transferability of care when people move between different health facilities and from health facility-based care to community-based settings, reduced loss to follow up and reduced duplication of health records for the same individual.

Facility- and programme-level identifiers have some limitations, including providing unique identification only within facilities or within those managed by a specific programme, and may therefore run the risk of duplicating records.

National-level identifiers are those that have been expanded for use among all public health facilities in a country. Such identifiers may be part of a broader national system that includes civil registration, vital event registries, syndromic or case surveillance activities or non-health related uses, such as social services or voter registration. In regions where people may receive care across national boundaries or in research studies with international cohorts, an identifier may involve neighbouring countries. As noted in the previous chapters, confidentiality and security risks increase in proportion to the volume of health information collected.

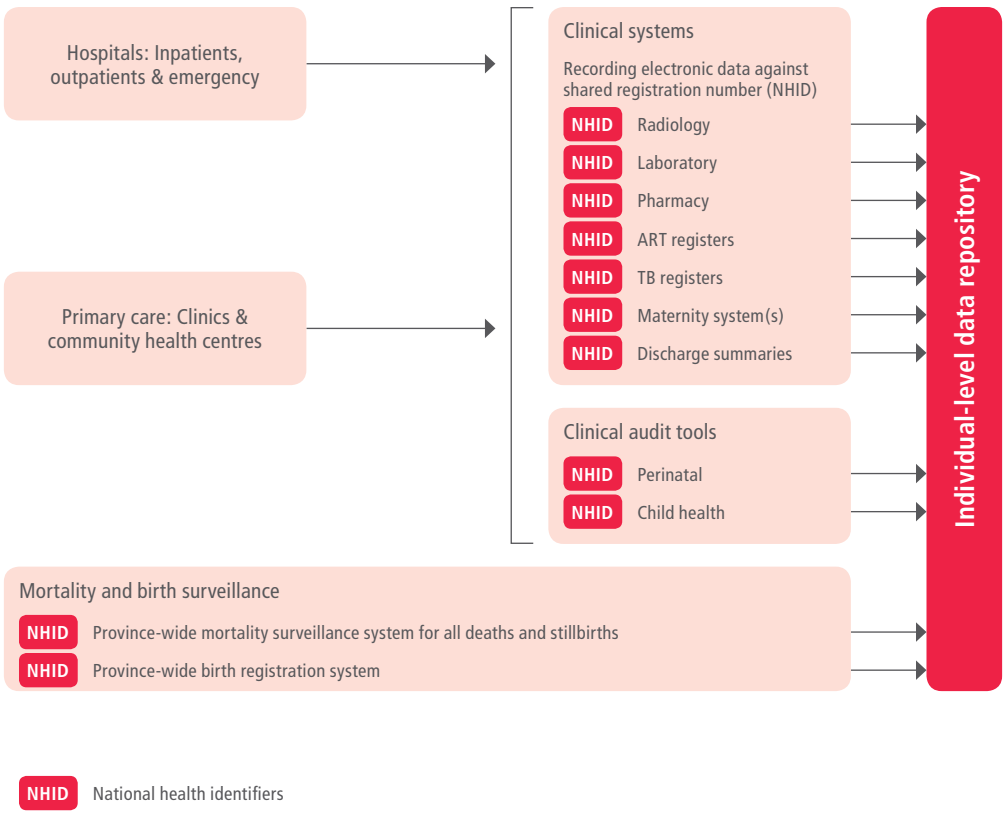
National-level identifiers enhance the capacity and reach of the more limited facility-

and programme-level identifiers described above. The benefits of a national unique health identifier include:

- the ability to develop a comprehensive, longitudinal health record of a person's service use, and costs and outcome of prevention or therapeutic services;
- strengthened systems for person-centred monitoring, improved linkage between HIV and other services, and easier referral and reimbursement;
- improved linking of sentinel events for the same person for case surveillance;
- improved data linkages for programme management and population-based research;
- the ability to accurately de-duplicate repeated elements of aggregate information;
- the ability to access and integrate information from different service providers and different provider electronic information systems;
- the ability to assess and improve data quality throughout the system; and
- improved management of programmes, services and consumable items such as drugs and diagnostics.

Unique identifiers provide the "glue" to link together different data sources for patient monitoring and surveillance. Their role in translating different data sources into a person-centred data repository is shown in Fig. 4.2.

Fig. 4.2 How unique identifiers link different health data sources for person-centred monitoring and programme management



The introduction and scale up of unique identifiers needs to be accompanied by appropriate legal frameworks, policies, protocols, training and infrastructure to ensure privacy, confidentiality and security of personal health information in all facilities that manage person-centred data at all levels of the health system.

4.3 Development path for unique identifiers

4.3.1 Situation analysis

The first step in developing a pathway for implementing unique identifiers is to carry out an analysis of the status of health information systems in the country. This provides core information that can be used to describe and define the main options and best approaches to beginning the transition from paper-based to electronic individual records, and the introduction of unique identifiers. The results of the situation analysis should provide a snapshot of the health information system, the resources being invested in health information (including software, hardware and human resources), and an overview of the laws, policies and practices concerning the collection, storage, analysis, security and use of health information. The analysis should also provide directions regarding the best place to begin and the approaches needed to further develop the information system.

The situation analysis should assess the elements discussed below:

1. Programme data use
    a. These form part of a wider review of patient, case and programme use of data, assessing the major country databases, how they are linked and used.
    b. Assess databases and systems across health and disease programmes, how they can be strengthened, secured and used in an integrated manner.
2. Data security and confidentiality
    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.
    b. Consult with patients and groups affected by data use on the benefits and risks (including health workers, patients and key population groups).
3. Data capacities and processes
    a. Identify capacities and processes for collection of health information in key health services, including those that present the best opportunities for change.
    b. Provide an inventory of the forms used, and data collected and reported at health facilities.
4. Physical and human resources
    a. Assess the electricity, telephone and Internet connectivity of health facilities at district, subnational and central levels.
    b. Assess the availability of computers, staff computer skills and facilities with electronic medical or health records.

5. Assess existing unique identifiers and options
   a. Provide an inventory of existing health identifiers used by programmes, facilities, insurance providers and other relevant stakeholders.
   b. Assess wider national and insurance identifiers, their acceptability and use.
6. Policies and perceptions
   a. Assess public perception of unique identifiers, electronic records, popular conceptions or misconceptions, as well as issues of trust and buy-in.
   b. Review country policies for the use of unique identifiers.
7. Identify the risks and benefits of and options for transitioning to unique identifiers and electronic health information systems.

Confidentiality relates 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 as part of the scale up of HIV services. Security must address both protection of data from inadvertent or malicious inappropriate disclosure, and non-availability of data due to system failure and user errors.

4.3.2 Transitioning to the use of unique identifiers and electronic health records

Implementing person-centred monitoring involves the progressive transition from name- and paper-based individual records and registers maintained at health facilities, and aggregate reporting of services to an electronic record coded with a unique identifier.

Table 4.2 summarizes the six essential elements of the transition or maturation process, as well as the benefits and risks of each element of the transition, which may be undertaken in the following three broad stages:

- early: switch from name-based records to unique identifiers associated with a single individual in a paper-based health record system;
- middle: the widespread use of unique identifiers and the deployment of an electronic data system with a mixture of online and offline elements; and
- advanced: data linked by unique identifiers in a fully online electronic health information system linked across services, facilities and with community care.

Table 4.2 Key components and stages of development of person-centred monitoring

Objective	Early	Middle	Advanced	Key benefits	Key risks
1. Person identification: assigning and using unique identifiers	• Name-based record • Aggregate data based on services, not people (tally sheets)	• Unique identifiers at facility level	• Programme or national unique identifiers • People-centred health record systems	• Enhanced people-centred data security and confidentiality • Continuity of people-centred care through a cascade of services • Enhanced retention and follow up • Enhanced quality of care • Improved programme efficiencies through data linkages to individuals	• Data security risks for both name-based and electronic records • Greater security with coded identifiers on records
2. Investing in databases and interoperability	• Low-cost paper-based record system • Traditional stationery costs	• Facility-based electronic data systems • Basic computer • Open-access software	• Fully interoperable data system • Linkage of information from multiple sources • Linkage with vital statistics, migration data • Useful for tracking individuals lost to follow up, etc.	• Access to all up-to-date health data • Minimal loss to follow up • Minimal data duplication	• High initial infrastructure costs • High training and technical support costs • Management of legacy systems in the context of system development and growth
3. Confidentiality and security	• Name-labelled paper files retained by the individual or kept under lock and key at facility	• Records coded with unique identifiers without personal content	• National system with health record data protected by law • Limited and enforced data access control	• Enhanced health data confidentiality and security • Electronic health records exist • Data access controls built into the electronic systems	• Security vulnerability for electronic records • Unauthorized access, hacking, loss of CDs, USB keys, computers, etc.

Table 4.2 Key components and stages of development of person-centred monitoring (continued)

Objective	Early	Middle	Advanced	Key benefits	Key risks
4. Data analysis, quality and use	• Data officer transfers data from paper record into electronic health record or register • Regular data quality reviews	• Programme- or central-level analysis of data and creation of management dashboards, and other data analysis and reporting tools	• Local analyses of care and programmatic capacity • Standardized dashboards, data visualization and reports • Individual care facilitated by ease of data access, aggregation and review • Regular use of data for decision-making at individual, facility, programme and national levels	• Data for enhanced individual follow up, tracking and management • Data for programme planning and management based on analysis, visualization, dashboards and regularly published reports • Evidence-based decision-making at all levels	• Systematic errors in data can lead to poor individual and programme management
5. Transition from paper to electronic systems	• Paper-based record system • Records retained at facility or by individual	• Offline electronic upload of data • On- or offline data access	• Fully online systems • Used across facilities, in community care • Links services within facility and across facilities	• Enhanced person-centred data security and confidentiality • Continuity of person-centred care through a cascade of services • Enhanced retention and follow up • Enhanced quality of care • Improved programme efficiencies through data linkages to individuals	• Data security risks for both name-based and electronic records • Greater security with coded identifiers on records
6. Sustainability of programme improvements	• Patient monitoring is only system in place to track individuals over time • Challenging to link individual 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	• Online data systems with unique identifiers allows tracking and follow up of individuals	• Requires sustained investment in maintenance, hardware, software support, human resources etc. to keep the system up and running

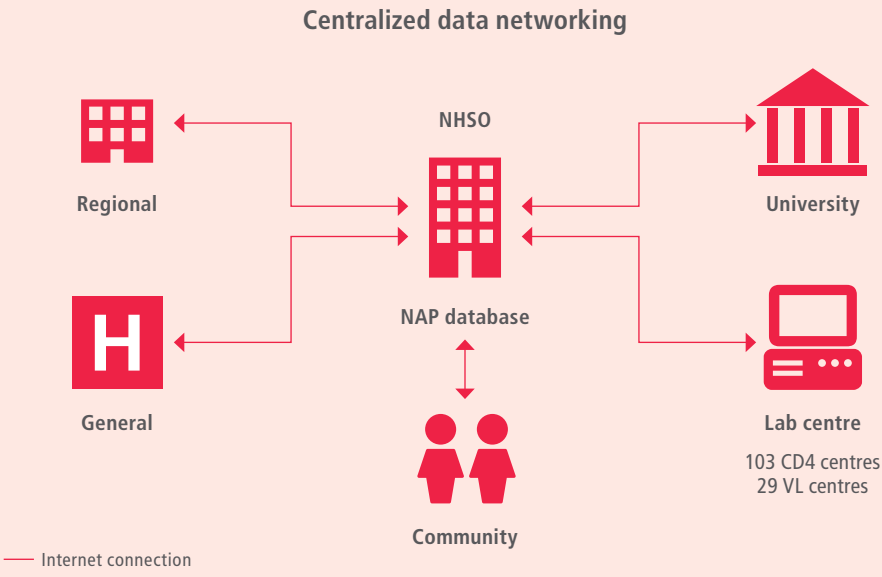
The incremental pathway to full implementation of unique identifiers and electronic health records need not follow a strict order, although some elements are required to be in place before other improvements are initiated. The point of departure and the priorities for implementation will depend on the findings from the situation analysis, as well as the practicality and feasibility of implementation. Technical aspects of each of the components are described in more detail in Section 4.3.3.

Box 4.1 Towards advanced use of unique identifiers in Thailand and Western Cape Province, South Africa

Thailand and Western Cape province in South Africa have followed a pathway to the advanced use of unique identifiers for person-centred care.

Thailand has an advanced health-care system with links among community hospitals, provincial-level general hospitals and regional-level health facilities. At birth, all Thai citizens are issued a 13-digit personal identification number (PID). The Ministry of the Interior collects data on all births and deaths at the district level. Health facilities record data on treatment and care for people with HIV and the data are stored in a central, web-based disease management information system (DMIS) at the National AIDS Programme. This system provides information for programme management as well as reimbursement through the National Health Security Office (NHSO). The PID links all individual-level information and is collected at the time of the first registration. The PID is encrypted and stored in the central database. The health data contained in the database are accessible only to authorized hospital users. The PID also serves as the National AIDS Programme (NAP) number and facilitates linkage of HIV-related data with other health information (Fig. 4.3).

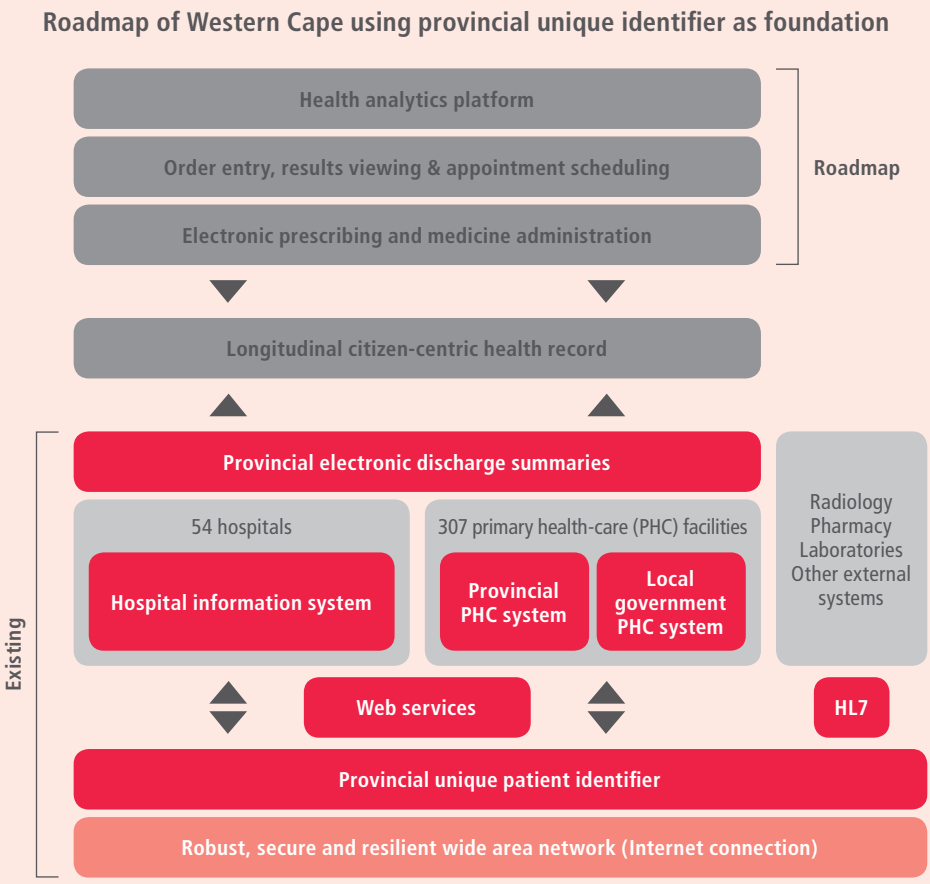
Fig. 4.3 Thai National AIDS Programme use of unique identifiers to link sources of information for improved individual and programme management



Source: Ministry of Public Health, Thailand

In Western Cape Province in South Africa, the development of the unique identifier system began with existing electronic identification and information systems (shown at the bottom of Fig. 4.4). At the core of this existing system is a provincial unique patient identifier that is linked electronically with (1) hospital information systems and provincial electronic discharge summaries; (2) primary health-care facilities, and (3) laboratory, pharmacy, radiology and other supporting systems. The long-term goal was to build the longitudinal citizen-centric health record comprising the existing information described above plus a new set of functionalities, including electronic prescribing and medicine administration; entry of orders; viewing test results and scheduling appointments, as well as a health analytics platform. This three-tiered system begins with paper records at the facility level, which are entered into an electronic register at district level and transmitted to the provincial level, where the data are aggregated into a centralized database. The data are used for individual and programme management through regular reports to facilities on loss to follow up, viral load data and de-duplication of health records.

Fig. 4.4 Development of the Western Cape unique identifier system



Source: Department of Health, Western Cape

HL7: Health Level-7 (set of international standards for transfer of clinical and administrative data between software applications)

4.3.3 Technical components and development stages of a unique identifier system

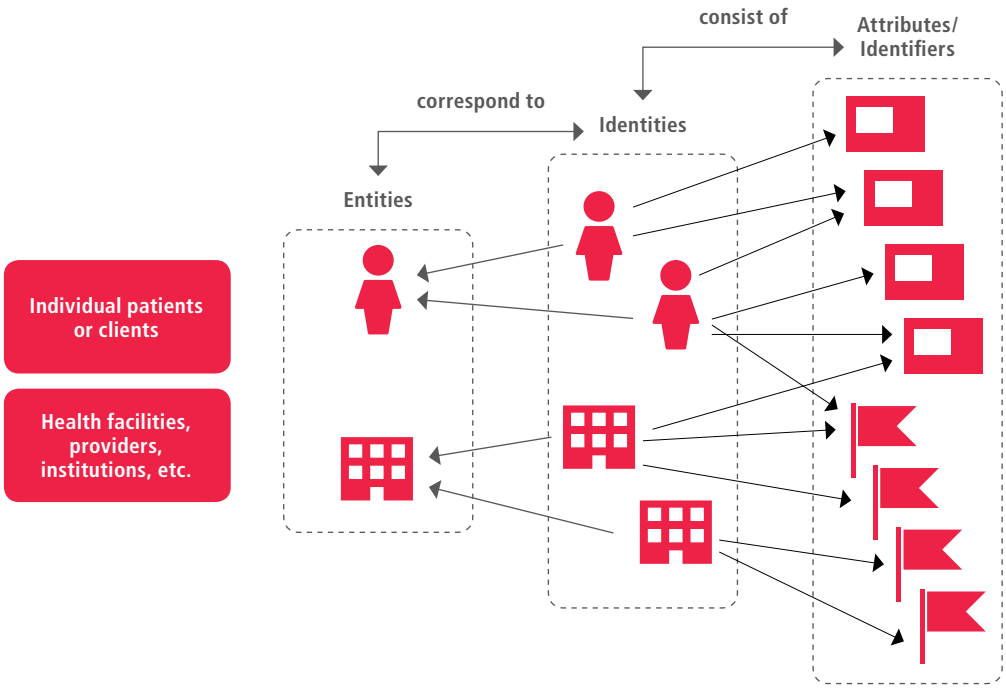
1. Individual identification: assigning and using unique identifiers

The first step in development begins with the replacement of names in paper records in facilities and programmes with records that are labelled with an anonymous code – the unique identifier – linked to a single person. This is a critical step in developing person-centred records. In paper-based systems, it may still be necessary to maintain a register of individual names, but this should be kept securely and separately from the actual health records.

The second stage of development is the addition of a comprehensive and secure database in the facility, with strong security and confidentiality, which contains individual records coded with unique identifiers to replace the name-based records.

The advanced stage is to expand the system so that it captures and stores all information relating to an individual's interactions across different health services and different facilities within the country, including information relating to HIV testing, laboratory results and pharmacy records. The use of a unique identifier across services and facilities ensures that an individual accessing health services in different facilities will not be assigned different identifiers. This ensures that all the important information about a person's health and care captured in various sites are attributed accurately to a specific individual, and is contained in one consolidated and complete health record (Fig. 4.5).

Fig. 4.5 A single individual using services in different facilities or programmes may have different health records relating to these facilities or programmes



2. Investing in databases and interoperability

In health care, interoperability is the ability of different systems and software to communicate, exchange data, and use the information that has been exchanged. The existence of interoperable health information systems ensures 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.

For two systems to be interoperable, they must be able to exchange data and then present that data in a way that a user can understand it. Data exchange schema and standards should permit data to be shared across clinics, laboratories, hospitals and pharmacies, regardless of the application.

Recently, a major direction in this area has been to support increasing interoperability and support of open-source systems for health information systems. One of the major challenges countries faced is fragmented data systems, which can tie users to legacy software, and cannot sufficiently communicate between sources of data necessary for decisions. This guidance recommends interoperability and open-source solutions for patient, case and health information systems.

The IT infrastructure – the hardware and the software – of the electronic health record system is a critical element of 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 unique identifier and electronic health record. The starting point will be identified by the situation analysis described in Section 4.3.1 and consist of at least three core elements:

- the scope of the data to be collected;
- the software and hardware currently in place, its age, adaptability, etc. (e.g. legacy systems); and
- the extent to which the systems are linked and interoperate with each other.

The process of transition begins with the creation of a secure database structure (hardware and software) for health records, either in a facility, at programme level or nationally. The next step is to extend the access to this database with online or offline access among the services in one single facility and across different facilities. The advanced stage of development is to achieve a fully interoperable data system that allows the linkage of information from a variety of sources, including vital statistics data and migration data to help identify the status of individuals who are lost to follow up.

Historically, systems that keep data relevant for HIV case management were often developed in isolation. 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.

Interoperability is also dependent on standardization. At the software level, exchange protocols need to be defined so that the different systems speak the same language or can understand one another. For business and market purposes, the developers of proprietary systems are not motivated to adhere to these standards and there is limited capacity to enforce the adoption of these standards.

Open-source software has the benefit of being more easily adapted to standardization; however, it often requires specific skills to be set up properly.

Interoperability also requires standardization at the semantic level for defining data elements and indicators. The careful management of definitions over time is required to prevent the information systems from diverging over time. This can be managed by keeping a single source of definitions, such as a registry or data dictionary, to which all systems must adhere.

There are several international standardization initiatives that offer useful guidance on making systems interoperable, including the Open Health Information Exchange and Interoperability Health Exchange.

Institutional and infrastructural contexts will, however, shape the trajectory of this interoperability work. An evolutionary approach towards standardization of hardware and software to achieve interoperability among data systems tends to have greater impact and longevity.

Countries have the responsibility of defining the national standards for interoperability and enforcing them. Individual health care and follow up are the primary benefits of interoperability of health data, with improved management of health programmes as a secondary advantage that, in turn, benefits individuals through efficiency gains and cost savings. As part of implementing these guidelines, interoperability and open-source approaches should be built into the planning and maturation path of patient and case-reporting systems.

3. Privacy, confidentiality and security

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, and provides the overall framework within which both confidentiality and security are implemented.

Confidentiality relates 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 physical, electronic and procedural aspects of protecting information collected as part of the scale up of HIV services. Security must address both protection of data from inadvertent or malicious inappropriate disclosure, and non-availability of data due to system failure and user errors.

Data confidentiality and security are critical in all health settings, including those that serve people living with HIV. The risk of breaches in information security is there with both paper-based and electronic records. These risks are considerably reduced by labelling individual records with unique identifiers that are not linked with personal information.

After the initial stage in which name-based records are replaced with unique identifiers without personal content, the second stage involves differentiation of health data into categories of sensitivity. Differentiated access and data security protocols should also be implemented 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, and strong enforcement capability and procedures to rapidly remediate data security breaches (*see* also Section 4.4).

4. Data analysis, quality and use

Electronic health records facilitate the ability to analyse information contained in individual records for programme management and improvement, and for research purposes. In this initial development phase, capacity can be built through the engagement of a data officer to upload information from a paper record into an electronic health record, thereby enabling the regular assessment of the quality of data at health-facility level, the generation and use of individual and programme management dashboards, and other data analysis and reporting tools. The intermediary stage of building capacity is the creation of a central analysis team

to manage databases in a robust way, with regular data quality assessments and follow up. The advanced stage of development involves the performance of local analyses of care and programmatic capacity with standardized dashboards, data visualization and reports to ensure regular use of the data for decision-making, and management of the individual and the programme from facility to national levels.

5. Transition from paper to electronic systems

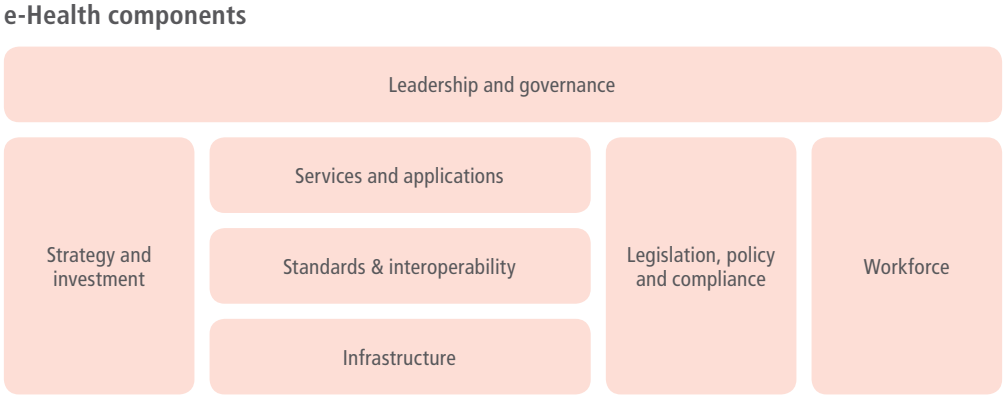
Paper-based systems remain the core of health record systems in many countries. The move to uploading information labelled with unique identifiers or to performing data entry directly into electronic systems is a critically important first step for managing the complexity of care of individuals, as well as for HIV programme management. The middle stage of evolution is to move to offline systems and a mixture of online and offline systems, and the advanced stage is full online systems, which can be used across facilities and in community care.

6. Sustainability of programme improvements

The ability to track and retain people in care and treatment, and link health data from different sources, different facilities and consistently over time represent sustainable programme improvements in the care of people with HIV and management of HIV programmes. These accrue from the transition to electronic health records and the use of unique identifiers.

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. The key components for medium-term planning are shown in Fig. 4.6.

Fig. 4.6 Components of medium-term planning for the use of unique identifiers



4.4 Attributes and security of a unique identifier system

To maximize the benefits of a unique identifier, wherein a single unique national identifier is assigned to each individual, and that identifier is managed in a sustainable and secure manner, seven system attributes or functions are required:

- an identifier scheme consisting of alphanumeric characters that do not represent any aspect of the identity of the individual;
- identification information;
- cross-references to local site-specific individual identifiers for existing individual identification numbers;
- 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 or in other ways manipulate the underlying information; and
- administrative infrastructure, including the central governing authority.

Scaling up of HIV and other health services in many countries will lead to the collection of increasing amounts of personal health information in a variety of sites, including in both preventive and therapeutic services. This requires specific attention to issues of confidentiality and security.

The use of unique identifiers 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 are given below.

- 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 preventing steps against possible misuse.

The following measures should be implemented by organizations that generate, access or use personally identifiable health information:

- 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 hardware and software 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; and
- 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.

More detailed guidance on protecting the privacy, confidentiality and security of personal health information can be obtained from *Guidelines on protecting the confidentiality and security of HIV information (39)* and *Protecting the confidentiality and security of personal health information in low- and middle-income countries in the era of the SDGs and big-data (43)*.

The degree to which national guidelines have been developed and implemented at facility, data repository/warehouse and national levels can be assessed by the using the recently published *The privacy, confidentiality and security assessment tool: protecting personal health information (44)* and *The privacy, confidentiality and security assessment tool: user manual (45)*.

4.5 System architecture and methods of unique identification

4.5.1 Technical resources

The basic components of system architecture and unique identification are presented in this section. This guidance should allow programme managers to discuss the key elements with the technical specialists who will develop unique identifier systems. The material 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 (UHID)* (ASTM E-1714-00) *(46)*;
- *Standard guide for implementation of a voluntary universal healthcare identification system* (ASTM E-2553-00) *(47)*;
- *Health informatics: identification of subjects of health care* (ISO/TS22220:2011) *(48)*;
- *Health informatics: patient health card data. Part 5: identification data* (ISO 21549) *(49)*; and
- *Health informatics: guidance on patient identification and cross-referencing of identities* (CEN/TR 15872) *(50)*.

4.5.2 Considerations for system architecture

The system architecture will depend on the tiers of paper, power and networks in facilities. Three tiers are recognized:

Tier 1 – Paper: facilities with no reliable power or telecommunications; cold chain may be powered by generators. Such facilities can support only paper systems.

Tier 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 electronic offline systems.

Tier 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 tier 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.

Biometric workstations (if considered as a unique identifier and required)

Each site receiving data needs at least one biometric workstation. This workstation is the place where photographs are taken and fingerprints are read to aid the subsequent identification of individuals. Since this can be a time-intensive process, consideration should be given to having a workstation for each person receiving applications to avoid long queues.

Central registry servers

At least one larger-capacity server located centrally is needed to host the national unique identifier 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

Most countries will not want to depend on a single server being operational at all times to process all requests to the patient registry, since the failure of a single communications link or router will cause widespread outage. One way to avoid the problem of a single point of failure is to use regional servers; an outage then affects only one region and is likely to simplify troubleshooting and repair.

Software development

Software should support increasing interoperability and open-source approaches, so that programmes are not locked into proprietary software solutions. The development of the software will require the following considerations.

Choosing the appropriate architecture for the application is essential. Architectural components include all the items needed to provide the service, such as servers, workstations, printers, software and communications facilities.

Design of the application should include menus, screens, behaviour and outputs. This step should include an expert review of the forms, reports and functionalities of the system. This will constitute a set of system specifications that will ease the job of the code developers.

Interoperability

Effective national health information systems should permit data to be shared across clinics, hospitals, laboratories, pharmacies and individuals, regardless of the application or vendor. The following five priority elements are necessary for achieving interoperability in health-care applications:

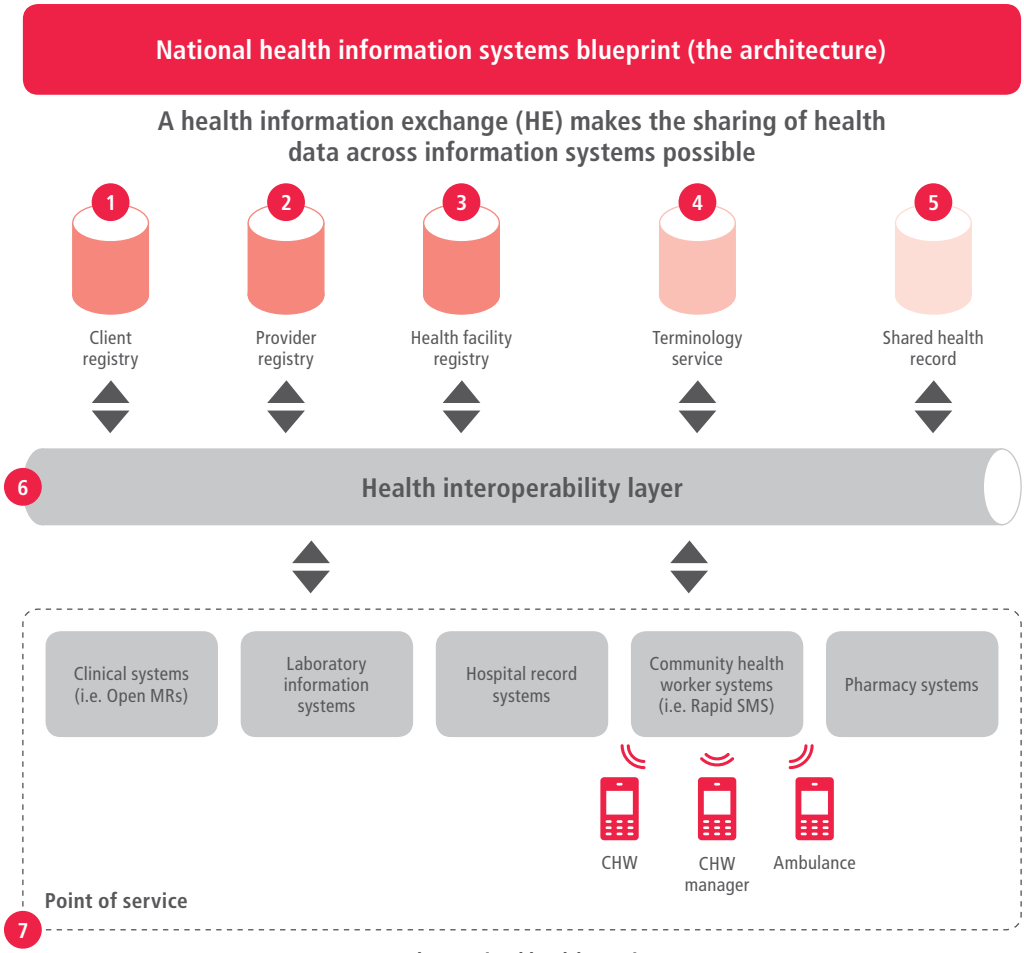
- individual identifiers;
- semantic interoperability among datasets;
- data interchange standards that allow communication and aggregation of datasets;
- core datasets; and
- high data quality *(51)*.

The system architecture should have internal attributes such as interoperability, and external attributes to support key health service questions, such as:

- Who receives health services?
- Who provides these services?
- Where did they receive the services?
- What specific care did they receive?

This will be increasingly important in supporting differentiated care in clinic and community settings, as illustrated in Fig. 4.7.

Fig. 4.7 Internal and external attributes of system architecture



Source: http://ohie.org/architecture/

4.5.3 Methods of unique identification

Depending on the personal identifiers used, suitable verification of information is required to identify the person accessing health-care services. These can include the following:

Photography

Photography is the most common and most easily understood way of identifying a person. Use of photographs requires some basic components: a computer, a digital camera, photograph management software, a suitable printer, and the identification card. When using a photograph to aid in the identification of a person, specific procedures and adequate training must be provided to the people taking the photographs, the people verifying the data and cards, and the people issuing cards.

Identification cards

ISO 7810 is an international standard for the physical characteristics of identification cards. ISO 7810-ID-1 specifies that the cards measure 85.60 mm × 53.98 mm. This is the most common size of bank, credit and debit cards, and driving licences.

ISO 7811 is an international standard for recording printed and magnetic data on identification cards. It contains standards for the embossed characters and several specific formats for recording magnetic data.

ISO 7816 is an international standard for identification cards with an embedded chip (smartcards) and electrical connections for the chip. Use of international standards is highly recommended where applicable and reasonable.

Biometrics

The most common physical traits used in recognizing individuals include height, sex, fingerprints, face (photographs) and iris. Whatever technology is chosen, biometric readers need to be available at all registration and presentation points, which could number from dozens in a heavily centralized model to thousands in a highly distributed model. To use this technology successfully, training is required. Training may be conducted at the facility level to minimize staff disruption or may be located more centrally to maximize the trainer's time.

Fingerprint scanners

Typical, inexpensive fingerprint scanners cost US$ 75–150. These scanners use a simple optical method to recognize the ridges in the fingerprints. Higher-quality, higher-resolution forensic optical scanning fingerprint readers cost US$ 400–700. All optical scanners are affected by skin dryness, how much water the person has consumed, low temperatures, and the condition of the skin. They typically have a 65–85% success rate. They do not work well for children under five years of age, people whose skin is worn down by performing manual labour, and elderly people.

Fingerprint scanners that rely on subdermal characteristics in addition to the skin ridges are more accurate, and some can be used in more harsh conditions. Less expensive units cost US$ 125–300, depending on the quality. Units designed for use in harsher conditions (moderate amounts of water and dust) cost US$ 600–1000. The latter are used in systems where more accuracy is needed, including automated teller machines and other banking functions to authenticate users.

Iris and iris/face scanners

Iris and iris/face scanners cost US$ 900–4000, depending on the accuracy of the equipment. They typically require a software development kit that costs US$ 500–1500. In addition, these scanners require a powerful desktop computer on which to run the programmes and store the images. As the volume of data is much higher with this type of scanner, they are less suitable for use in countries that do not have more current computers and robust high-speed networking to all facilities.

Pseudo identifiers

A combination of data elements derived from existing records, e.g. demographic, last name, DOB, sex. When combined they can provide unique identification, and can be used to establish baseline performance for record matching.

4.6 What to do next – "the how"

This guidance should be implemented based on country context and in a step-wise fashion. The following three stages are suggested:

1. **A situation analysis** that reviews current data sources, systems and policies, and identifies incremental improvements and costs, with their risks and benefits. This should be tailored to the country context, and involve people using the system for programme decisions (*see* Section 4.3.1). It should cover the seven components in section 4.3.1 and identify options, risks and costs as part of a wider review of patient, case and data use in the health programme.
2. **Data use for programme improvement.** The next step is to invest in improved security and use of the data for programme improvement. This includes
   a. investments in the security and robustness of databases, safeguards, and increased linkage and interoperability of data systems at facility, programme and national levels;
   b. investment in data use, dashboards and feedback, and analytical capacity, which are critical at this stage, so that data are used for programme improvement;
   c. documenting the benefits and risks of programme improvement to support the case for medium-term sustainability.
3. **Programme improvement and sustainability.** As data sources are increasingly linked and used, medium-term sustainability needs to be planned. This includes planned benefits for programme improvement, human resources, financing, interoperability and open access, policies, and links of HIV to national health and social systems. At this stage,
   a. the benefits to individuals and programmes should be carefully identified and, if possible, costed at each level of the system, as described in Section 4.2;
   b. the maturation pathway for early, middle and advanced stages of the six components shown in Section 4.3.3 should be developed;
   c. this should integrate HIV monitoring into a national unique identification system to support people-centred HIV and health services over time.

Implementation should also be based on country examples of models of unique identification that have worked, and that show individual and programme benefits as illustrated in Table 4.2 and Box 4.2.

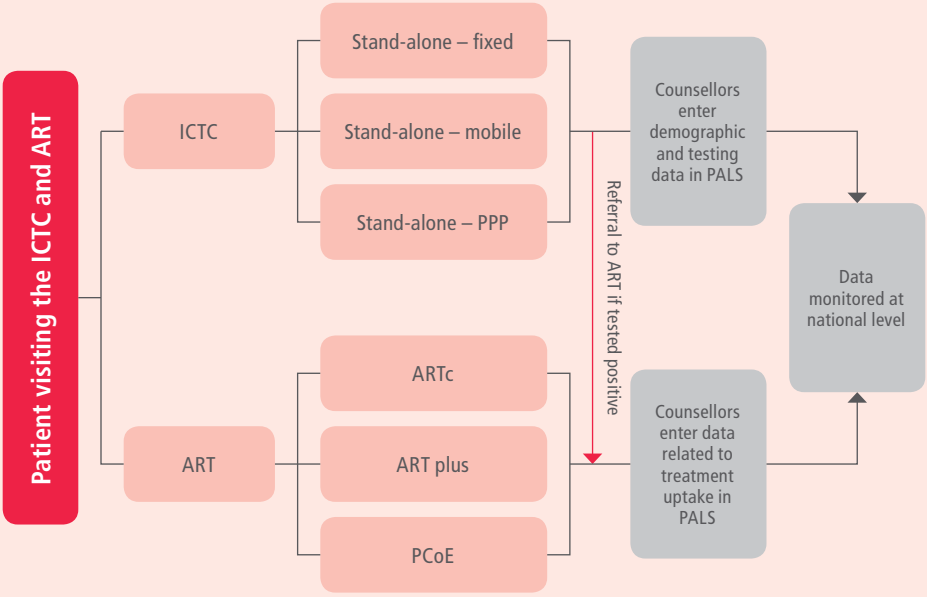
Box 4.2 Using unique identifiers to scale up electronic monitoring for pregnant women with HIV in India

The National AIDS Control Programme in India has rolled out a software package on HIV patient monitoring called PALS (PPTCT to ART Linkage System). The software helps to follow almost 15 000 HIV-positive pregnant women to facilitate delivery of all components of a "prevention of parent-to-child transmission" (PPTCT) programme. It is intended that the system will be extended to follow all people diagnosed with HIV at 20 000+ HIV counselling and testing centres.

The system uses 23-digit unique identifiers: type of client (2 digits), i.e. ANC or non-ANC + type of facility (6 digits), i.e. facility-based or stand-alone Integrated Counselling and Testing Centre (ICTC) + state code (2 digits) + district code (3 digits) + centre code (3 digits) + year of diagnosis (2 digits) + sample number (5 digits).

PALS is designed to be a tool for following people with HIV from their diagnosis to linkage with care and treatment initiation at ART centres. The system has the potential to be linked with the inventory management system (IMS) at ART centres, and will then be able to track retention as well as viral load. It is expected that the tool will become the backbone of India's National AIDS Control Programme to track progress towards the goal of ending AIDS as a public health threat by 2030.

Fig. 4.8 Flow of information in PALS



RU: reporting unit; ICTC: integrated counselling and testing centre; stand-alone PPP: stand-alone public–private partnership; ARTc: antiretroviral therapy centre; PCoE: paediatric centre of excellence

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APPENDIX: INDICATOR INSTRUCTIONS FOR HIV PATIENT MONITORING SYSTEMS

Contents

PART 1. KEY INDICATORS FOR GENERIC PAPER-BASED HIV PATIENT MONITORING SYSTEMS

01

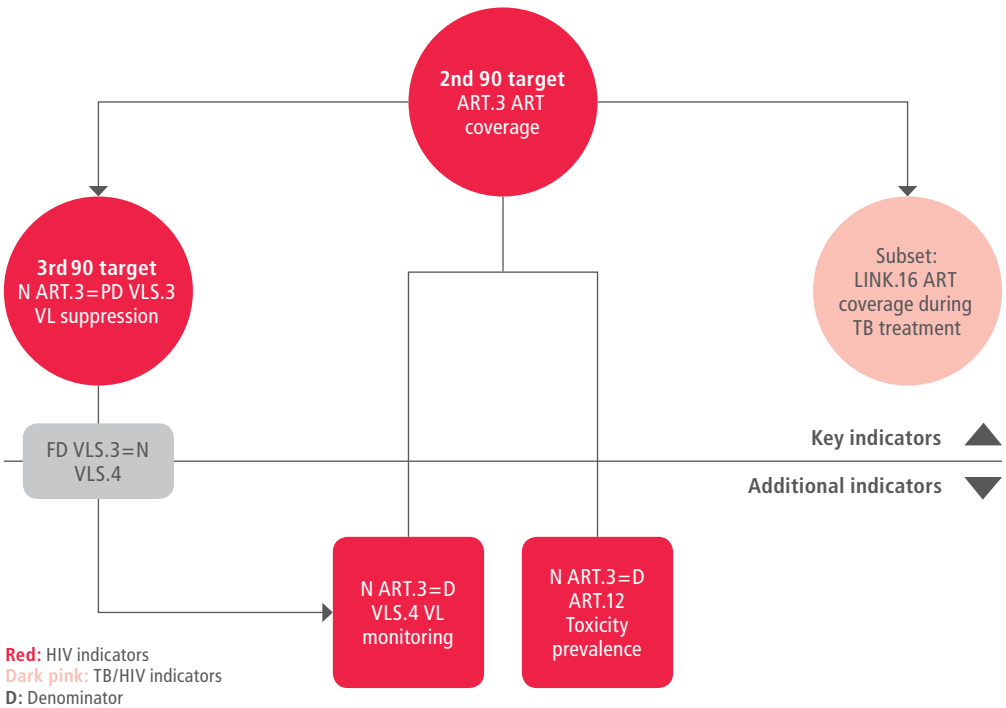
PART 1. KEY INDICATORS FOR GENERIC PAPER-BASED HIV PATIENT MONITORING SYSTEMS

Key HIV indicators

ART.3 ART coverage 2
ART.5 ART retention (EWI) (including key additional indicators **MTCT.3/17 Early ART retention**)
VLS.3 Viral load suppression
ART.1 New ART patients (including key additional indicator **ART.4 Late ART initiation**)
ART.6 Short-term ART outcomes (*see* **ART.5**)

ART.3 ART coverage

Fig. A1 ART.3 ART coverage indicator linkages



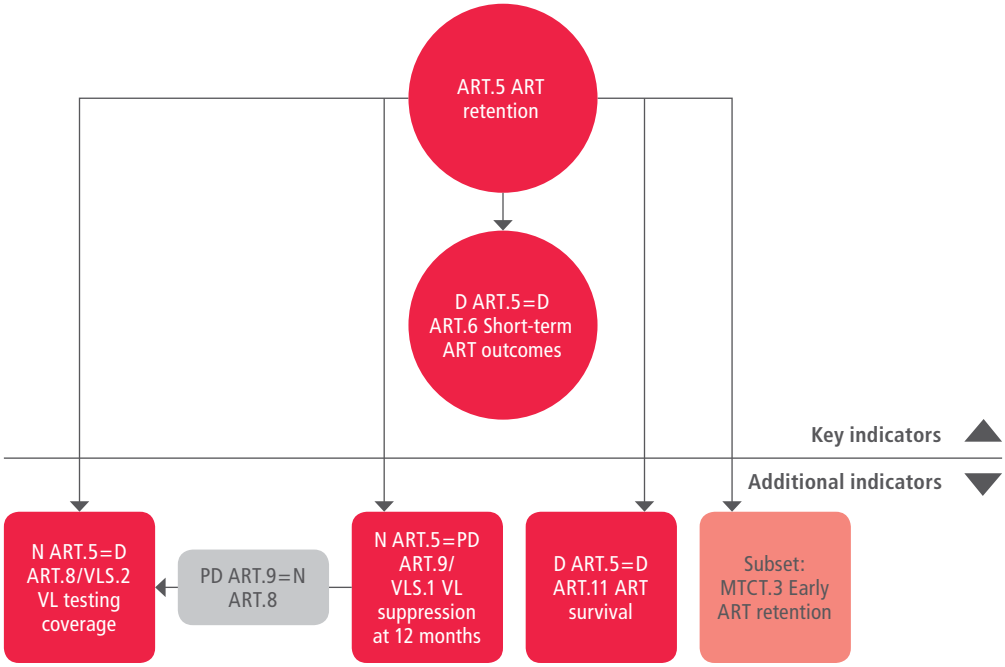
Red: HIV indicators
Dark pink: TB/HIV indicators
D: Denominator
FD: Facility-based denominator
PD: Population-based denominator
N: Numerator
Circle: Key paper-based indicators
Square: Key additional indicators

Indicator code and name	ART.3 ART coverage 2
Indicator definition	**Percentage of people living with HIV who are receiving ART**
Overview	This cross-sectional indicator provides information on the scope of an antiretroviral treatment (ART) programme. Programme managers can monitor the volume of patients currently receiving ART to allocate resources such as health workers and antiretroviral (ARV) drugs to sustain coverage. Policy-makers may use this information to advocate for the resources needed to continue providing lifelong ART to current and future patients. Programmes should expect to see an increase in ART coverage as the "treat all" recommendations are implemented. However, universal treatment may also lead to increased demands on the various services required to initiate a patient on ART (confirmation of HIV, baseline clinical and laboratory assessment, adequate supply of ARVs, adherence preparation, more frequent clinical consultations initially). These variables may therefore affect overall scale up and coverage.
Priority level	Global, national, subnational, facility ART coverage is the "second 90" and an important step in ending the AIDS epidemic. Its focus is on universal access to lifelong treatment. Increasing ART coverage has also been associated with decreasing TB case notifications and reduced mortality *(1)*.
Numerator	**Definition:** number of people living with HIV who are currently receiving ART [at the end of the reporting period] **Data source:** ART register, aggregated in the cross-sectional report **Data elements:** from ART register: *ARV regimen code* as follow-up status
Denominator	**Definition:** number of people living with HIV **Data source:** internationally consistent modelling estimates, e.g. Spectrum AIM **Data elements:** data do not come from the patient monitoring system.
Data collection methodology	***Numerator:*** this is a cross-sectional indicator. To obtain the numerator for the current number of people on ART, go through all ART register pages and look at the specific column of the last month of the reporting period (e.g. for the reporting period January–December 2015, look at the column for December 2015) for all cohorts (NB: months from ART start columns will be different for every cohort; e.g. it could be Month 0 for ART cohort starting December 2015 or Month 11 for ART cohort starting January 2015). Count the patient if, during that month, there is an ARV regimen code recorded. In cases where ARVs have been dispensed for more than a one-month period, there will be a line drawn through the month column indicating this (*see* Fig. A3). This also counts. This number will exclude any patients who have been classified as DEAD, STOP, TO or LTF by December 2015. If ART registers are also kept at maternal, newborn and child health (MNCH) and tuberculosis (TB) service delivery points, it will be necessary for programmes to aggregate numbers from all ART registers maintained across facilities. If transfer in/transfer out (TI/TO) patients are captured correctly, there should not be a need to reconcile these registers.
Subsets	This is also the *denominator* for **ART.12 Toxicity prevalence** and **VLS.4 VL monitoring**, and the *population-level denominator* for **VLS.3 Viral suppression**. Therefore, when tallying **ART.3 ART coverage** from the ART register, it is recommended to also tally these indicators as well as the numerator for **LINK.16 ART coverage during TB treatment**, a *subset* of **ART.3 ART coverage**.
Frequency	Facilities may aggregate data on a quarterly basis, but report on an annual basis to the national level. When reporting annually, use the last quarterly (or monthly) report – do not aggregate quarterly reports over the past year.

Indicator code and name	ART.3 ART coverage 2
Special considerations	In settings where ART is provided or monitored by community-based health workers, it is important that all these patients are also included in the facility-based ART register that is updated and tallied for this indicator (even if also captured in a community-based ART monitoring tool). Disaggregation by level of care may also be useful in these settings.
Disaggregation	• Sex • Age: – <15, 15+ (minimum for paper-based systems) – <1, 1–4, 5–9, 10–14, 15–19, 20+ for electronic systems • Sector (public, private) (Global AIDS Monitoring [GAM] only)
Transitioning to "treat all"	For countries that are implementing the "treat all" recommendations and have reached 90% ART coverage, the indicator **LINK.2 HIV care coverage** (or current in care) may no longer be a priority. In this case, the numerator for **ART.3 ART coverage 2** may be used as a proxy for HIV care coverage (in HIV care), given the removal of the pre-ART register from the generic HIV patient monitoring system. Alternatively, ART coverage plus those who have STOPped ART (but remain in care) may also be used. With the scale up of the "treat all" guidelines, **LINK.2** and **ART.3** should be practically identical over time (within a given period). However, for countries that have not yet implemented "treat all" or are using a phased implementation approach, **LINK.2 HIV care coverage** may still be relevant to collect, analyse and report (*see* Box 2.18).
References	*See* GAM indicator 1.2 (People living with HIV on antiretroviral therapy) for more information at: http://www.unaids.org/sites/default/files/media_asset/2017-Global-AIDS-Monitoring_en.pdf. The GAM indicator also recommends disaggregating by those newly initiated on ART during the reporting period. However, note that this is different from **ART.1 New ART patients**, in that it is only a subset of those newly started on ART.

ART.5 ART retention

Fig. A2 ART.5 ART retention indicator linkages



Red: HIV indicators
Light red: HIV/MNCH indicators
PD: Population-level denominator
D: Denominator
N: Numerator
Circle: Key paper-based indicators
Square: Key additional indicators

Indicator definition	**Percentage of people living with HIV and on ART who are retained on ART 12 months after initiation. Also recommended at 24, 60 months, 10 and 15 years**
Overview	This is a cohort-based indicator. An important part of the HIV care cascade, it measures the number of ART patients who are still on treatment 12, 24, etc. months after ART initiation. Several HIV programmes report ART retention at 12 and 24 months of treatment. However, within the past decade, substantial scale up of ART has improved the health and survival of people with HIV, and they are living longer. Hence, monitoring the retention rate beyond 12 or 24 months is critical, and WHO recommends that it also be measured at 60 months, 10 and 15 years.
Priority level	Global, national, subnational, facility-level HIV drug resistance (HIVDR) early warning indicator (EWI) Treatment interruption due to poor patient retention in care is a major barrier to achieving optimal patient and programme outcomes, including viral suppression. HIV programmes need to ensure timely ART initiation and prevent patient attrition, using locally feasible approaches that facilitate retention.

Indicator code and name	ART.5 ART retention
Numerator	**Definition:** number of ART patients alive and on ART 12 months (or 24, 60 months) after initiating ART **Data source:** ART register, aggregated in the ART cohort report form **Data elements:** from ART register: *ART start date, ART follow-up status* (*see* Table 2.1 for definitions)
Denominator	**Definition:** number of patients initiating ART up to 12 months (or 24, 60 months) before the beginning of the reporting year. This includes those who have died since starting ART, those who have stopped ART and those lost to follow up as of month 12 (or month 24, 60). **Data source:** ART register, aggregated in the ART cohort report **Data elements:** from ART register: *ART start date, ART follow-up status*
Data collection methodology	***Numerator:*** to obtain the numerator, facilities will go through the ART register pages of all patients who initiated ART in the 12-month period before the beginning of the reporting year; e.g. If the reporting period is 1 January to 31 December 2015, facilities will calculate this indicator by using all patients who started ART at any time during the 12-month period from 1 January to 31 December *2014*. Patients are determined to be alive and on ART if at 12 months, they have an ARV regimen code recorded in that column. When ARVs are dispensed for more than one month, a line drawn through the additional months dispensed will indicate that the patient is still receiving care in the facility or other point of care (*see* Fig. A3). At the facility level, the numerator excludes patients who are DEAD, STOP, TO or are LTF at 12 months among all those who started ART in the reporting period; however, it does include patients who STOPped but RESTARTed prior to month 12 and TI patients from another facility who started ART in the reporting period. At the national level, patients who are TI should be equal to those who are TO and do not need to be accounted for. This simple sum could also help in validating the facility reports. In the ART cohort report, the retention rate will be the total number of patients alive and on ART at 12 months for all cohorts initiating ART in the 12-month period before the beginning of the reporting year – irrespective of type of ARV regimen they are on (e.g. first-line, substitute first-line, second-line, substitute second-line, third-line, substitute third-line). ***Denominator:*** the denominator for this indicator is the total number of patients who initiated ART during the reporting period (*see* example in Fig. A3). This includes the number of patients on ART who started ART in the 12-month reporting period and those recorded as DEAD, STOP, TI or LTF. Count all patients in the ART cohorts with January to December 2014 start months. At the facility, exclude those who are TO, as they will be counted by the facility they transfer to. At the national level, as with the numerator, patients who are TI will equal those who are TO and do not need to be accounted for. In the **ART cohort report** (Annex 2.3.6b), this is the first row (started on ART at this clinic – original cohort) (± TI/TO) for each ART cohort starting ART in the 12 months prior to the beginning of the reporting period. **Measuring ART retention beyond 12 months:** for retention at 24 months and the reporting year 2015, take all patients who initiated ART in 2013 (24 months prior to the reporting year); for retention at 60 months, take all patients who initiated ART in 2010 (60 months prior to the reporting year); for retention at 10 years, take all patients who initiated ART in 2005, and 2000 for 15-year retention.

Indicator code and name	ART.5 ART retention
	Grace period A patient is lost to follow up if not seen for three months since the last missed appointment. In general, a grace period of 3 months can be observed when compiling this indicator (i.e. assess the cohort starting ART 27 months before the reporting period for 24-month retention and 15 months before for 12-month retention).
Frequency	It may be more practical for programmes to use quarterly (rather than monthly) cohorts to aggregate retention. For retention **past** 60 months, programmes may even opt to use yearly cohorts (all patients starting ART in a given year with 5-, 10-, 15-year retention). Facilities may also find it useful to measure 36- and 48-month (medium-term) retention, though it is not required at a global reporting level. Use the same methods described above to do so.
EWI of HIVDR	Patients not retained on ART have experienced treatment interruption and are therefore at risk for selection of drug-resistant virus, which could in turn compromise individual- and population-level treatment outcomes. The retention indicator monitors a facility's performance in maintaining patient engagement in care, effectively preventing deaths and minimizing unknown treatment outcomes, including treatment failure. WHO's suggested target for retention at 12 months is above 85%, while 75–85% is considered fair performance and <75% is considered poor performance.
Subsets	*Numerator:* this is also the *denominator* for **ART.8/VLS.2 VL testing coverage** and the *population-level denominator* for **ART.9/VLS.1 VL suppression at 12 months after ART initiation**. *Denominator:* this is also the *denominator* for **ART.6 Short-term ART outcomes** and **ART.11 ART survival**. Therefore, when tallying **ART.5 ART retention** from the ART register, it is also recommended to tally these indicators, as well as **MTCT.3/17 Early retention among pregnant and breastfeeding women**, a subset of **ART.5 ART retention**.
Monitoring retention among pregnant and breastfeeding women	**MTCT.3 Early ART retention rate of pregnant and breastfeeding women (revised to include MTCT.17)** ***Numerator:*** *number of pregnant or breastfeeding women on ART still alive and on treatment at 1 and 6 months after initiating ART* Due to the additional risk of HIV transmission to the HIV-exposed infant (HEI), pregnant and breastfeeding women require retention monitoring at more frequent and earlier intervals than the general population. Furthermore, if pregnant women initiate ART at antenatal care (ANC), they may not come in for follow up as frequently as necessary, rather choosing to follow the ANC visit schedule (*see* Box 2.14). The **MTCT.3 Early retention** indicator can capture those women LTF (which tends to be greatest by the second ANC visit). The methodology of calculating the indicator is the same (and in some ways simpler, as there are fewer intervening columns to scan), but looks at the follow-up status for month 1 and month 6 columns (instead of the 12, 24, etc. month columns). It is recommended that ART registers be kept in all settings where ART is provided. Therefore, there may be MNCH-specific ART registers where these numbers may be more easily derived. Otherwise, current pregnancy and breastfeeding status (P or BF) will be recorded in the bottom row of the ART follow-up status columns of the ART register. ***Denominator:*** *number of pregnant or breastfeeding women who initiated ART 1 and 6 months prior to the beginning of the reporting period.* The same methodology can be used to tally the number of patients who initiated ART 1 and 6 months (versus 12, 24, 60 months) before the start of the reporting period for this denominator, and whether the woman was alive and on ART at 1 and 6 months in the numerator (Month 1 and Month 6 columns should indicate the ARV regimen code, with no DEAD, LTF, TO or STOP codes). The *Status at start ART* column will give an indication of which patients were pregnant or breastfeeding at the start of ART.

Indicator code and name	ART.5 ART retention
	Monitoring retention across all pregnant women Women may become pregnant while already on ART or first learn of their positive HIV status during an ANC visit. Most pregnant women newly starting treatment might fall in the category of retention rate 12 months after ART initiation. However, increasingly large numbers of pregnant women might already be on ART for quite some time when they become pregnant. Regardless of when pregnant women started ART, it is important that all are retained in care. Therefore, countries may additionally consider monitoring retention for all groups of pregnant women on ART, regardless of the time of ART start, assuming enrolment in ANC care is point zero for all pregnant women.
Disaggregation	• Where relevant: sex, pregnancy, breastfeeding at initiation • Age: – <15, 15+ (minimum for paper-based systems) – <1, 1–4, 5–9, 10–14, 15–19, 20+ for electronic systems • Optional: coinfection with TB, coinfection with hepatitis B, people who inject drugs
Analysis of lost to follow-up (LTF) patients	This indicator measures retention based on facility data, and patients who miss an appointment more than 3 months (90 days) from last expected clinic visit are classified as LTF. Facility-level LTF does not automatically mean patients are not retained in ART programmes. LTF simply means that the outcome from the perspective of the clinic is unknown. Patients who are reported as LTF by a clinic often constitute unascertained death, self-transferred patients in care on ART/not on ART, true LTF patients, and those who are alive but not in care or on ART (*see* Box A1). Some patients who are LTF at facility level might be receiving care in another facility but did not inform their care providers (i.e. self-referral). It is strongly suggested that HIV programmes put effort into understanding the true outcomes among patients who are LTF, and re-engage those who are alive and not in care or on ART back into care. It may also be important to engage and educate patients on the importance of informing their care providers when they choose to receive care at another facility. Box A1 summarizes programme experience through cross-sectional analyses of outcomes among LTF patients by selected countries. Indicator **ART.11 [ART] survival** may be one method to unpack LTF patients (*see below*). **ART.11 [ART] survival – requires special study or quality-of-care monitoring** ***Numerator:*** *number of people living with HIV alive at 12, 24, 36 months, etc. after initiating ART* This number includes those on ART as well as those who have been classified as LTF but may still be alive. This second group of patients requires specific follow-up action in the community to reclassify their outcome and therefore, may not be routinely collected at all facilities (*see* Box A1). Note that these patients may or may not still be on ART. ***Denominator:*** same as **ART.5 ART retention** denominator In some programmes, LTF can be higher in the first 12 months after ART initiation. This is often due to a higher mortality within that first year, which in turn is attributed to delayed treatment initiation. HIV programmes and clinic managers can disaggregate retention data by population and location to better understand if mortality within the first 12 months differs by specific populations and geographical locations. Early mortality on treatment is high among patients presenting with advanced HIV infection. In such settings, strengthening early ART initiation for improving survival during this period is important.

Indicator code and name	ART.5 ART retention
References	*See* GAM indicators 1.3 (Retention on antiretroviral therapy at 12 months) for more information on ART.5 at: http://www.unaids.org/sites/default/files/media_asset/2017-Global-AIDS-Monitoring_en.pdf, and Appendices 2G and 2H of the IATT Option B/B+ M&E framework for more information on MTCT.3/17 at: http://www.emtct-iatt.org/wp-content/uploads/2015/05/IATT-Framework-May-2015.pdf

Fig. A3 Example of ART register showing ARVs dispensed for more than one month

Month 0	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6			Month 7	Month 8	Month 9	Month 10	Month 11	Month 12
Jan 2014	Feb	Mar	Apr	May	Jun	VL	CD4	Jul	Aug	Sep	Oct	Nov	Dec	Jan
1a	1a	→	→	→	→	→	→	1a	→	→	→	→	→	→

Box A1 Country experiences: cross-sectional analyses of outcomes among patients lost to follow up

Uganda: a sampling approach *(2)*

Background. Of 3628 patients initiating ART between 1 January 2004 and September 2007 at a rural clinic in Mbarara district, Uganda, 829 became LTF (6-month absence from the clinic).

Methods. A representative sample of 128 LTF patients was selected and followed up in the community. Patients were located by a health educator (tracker) at the clinic who was familiar with issues of confidentiality, the local geography and social norms. The tracker was provided with patient identifying information (name, sex, age and occupation) and residence (all administrative levels from district down to village). Once at the village, the tracker inquired about the exact location of the patient's residence. Upon locating the patient (or an informant close to the patient if not found), the tracker administered a short, structured questionnaire, including reasons for not returning to the clinic; whether the patient transferred to another clinic; whether the patient was still on ART; date and reason of death (childbirth, accident/trauma or illness).

Results. Of the 128 LTF patients, 13% could not be traced, 25% had died (mainly due to illness occurring shortly after the last clinic visit) and 62% were still alive. Of the 48 patients directly interviewed, 83% had seen a health provider at a different facility in the past 3 months (self-transferred), while 71% had taken ART in the past 30 days. The most common reasons cited for failure to return to the original clinic included lack of transport and distance to the clinic.

Malawi: unpacking LTF in urban Malawi *(3)*

Background. Between January 2006 and December 2010, 21 382 adult HIV-infected individuals accessed ART at two high-volume public clinics run by the Lighthouse Trust in Lilongwe, Malawi. A study was conducted to unpack what actually happened to patients who were suspected of being LTF (missed their next scheduled clinic appointment by at least 21 days).

Methods. The Back-to-Care (B2C) programme was developed to improve ART retention at these two facilities through tracing and follow up of LTF patients by phone or home visits to document true follow-up status.

Results. Of the 4560 patients suspected of being LTF, 30% could not be traced (actual LTF), mainly due to incorrect or incomplete addresses or change of residence; 21% were dead; 27% were still on ART (3% self-transferred, 13% officially transferred out, 4% remained in care with uninterrupted ART, and 6% remained in care but reported treatment gaps). The most common reasons for discontinuing ART were travel (46%), failure to remember (17%), lack of transport to the clinic (16%) and too weak/sick (12%).

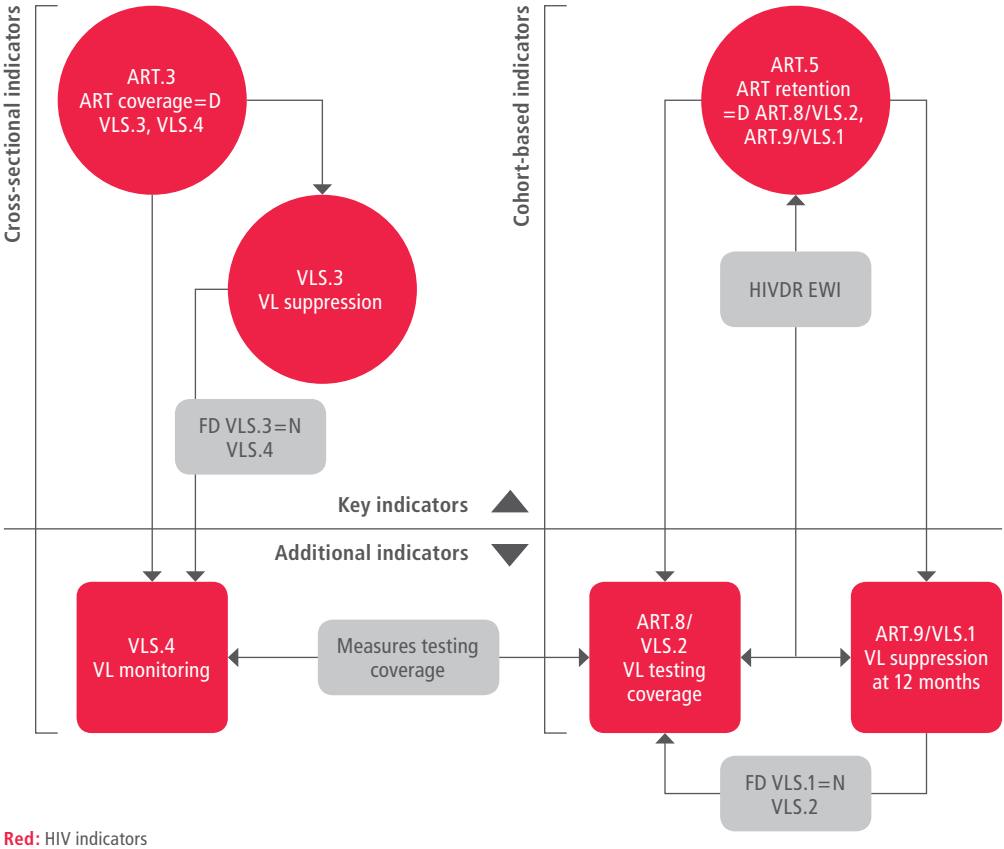
sub-Saharan Africa: a systematic review *(4)*

Background and methods. A systematic review and meta-analysis were undertaken of studies reporting on HIV patients on ART in lower- and middle-income countries with LTF as an outcome, and true outcomes for all or a subset of those patients LTF ascertained by tracing. A total of 28 studies (23 for self-transfer, 27 for death and 20 for stopping ART) were in the final analyses, including 10 806 LTF patients at approximately 258 ART facilities in 12 countries in sub-Saharan Africa and nine studies from South Africa alone.

Results. From the resulting meta-analysis, the pooled estimates of LTF patients who self-transferred was 18.6%, 38.8% had died (50.0% before 31 December 2007 and 30.0% after) and 28.6% had stopped ART.

VLS.3 Viral load suppression

Fig. A4 Linkages between viral load indicators



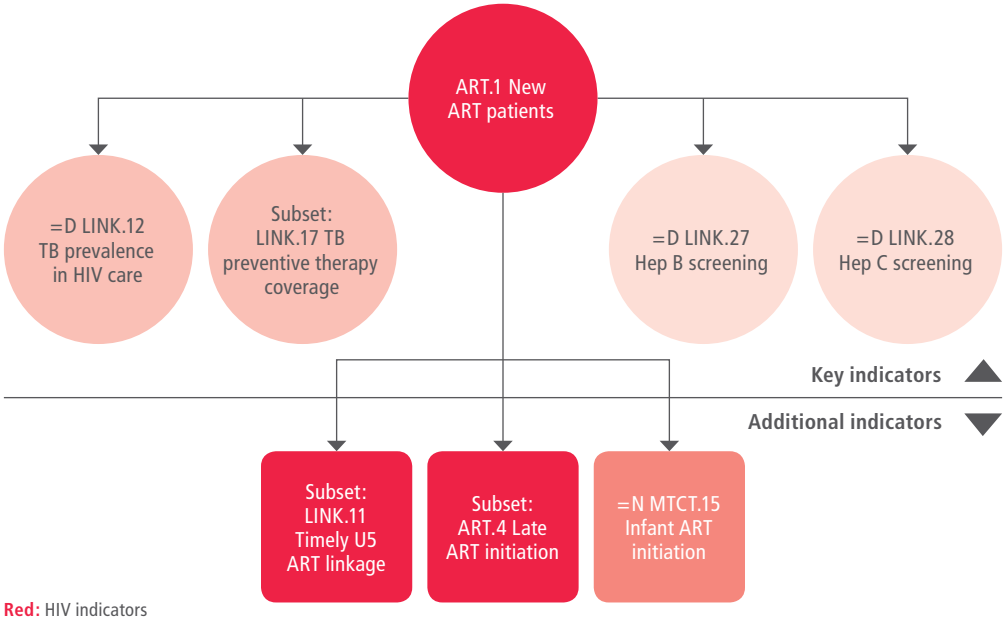
Red: HIV indicators
PD: Population-based denominator
FD: Programme denominator
D: Denominator
N: Numerator
Circle: Key paper-based indicators
Square: Key additional indicators

Indicator code and name	VLS.3 Viral load suppression
Indicator definition	**Percentage of people living with HIV and on ART who are virologically suppressed**
Overview	This is a cross-sectional indicator that reports the proportion of all patients on ART in the programme or a given facility who are virally suppressed. However, there are two prescribed denominators for this indicator that provide different numbers. In settings in which routine viral load monitoring (the goal) is available (testing coverage ≥75%), the population-based denominator may be relevant. The programme-based denominator limits the indicator to those who have received a viral load test, so may be more useful when testing coverage is <75% *(5)*; however, results should still be interpreted with caution. This includes accounting for missing data and, to the extent possible, qualification of whose viral load is being monitored (for example, if only those on ART who have failed treatment receive viral load tests, then the indicator may be biased towards high viral load counts and underestimate viral suppression). Population-based or drug-resistance surveys may also replace information from the HIV patient monitoring system in some settings where viral load monitoring is not routine.
Priority level	Global, national, subnational Viral suppression is the "third 90" and the goal of HIV treatment. Patients on ART who achieve and maintain viral suppression minimize their risk of disease progression and HIV transmission.
Numerator	**Definition:** number of people living with HIV and on ART [in the reporting period] who have a suppressed viral load (<1000 copies/mL) **Data source:** ART register, aggregated in the cross-sectional report **Data elements:** from ART register: *viral load, follow-up status*
Denominator	**Definition:** *Population-level:* number of people living with HIV receiving ART at the end of the reporting period (*see Numerator for* ***ART.3 ART coverage 2***) *Programme-based:* number of people on ART who had a viral load measurement during the reporting period **Data source:** ART register, aggregated in the cross-sectional report **Data elements:** from ART register: *viral load, follow-up status*
Data collection methodology	***Population-level denominator:*** *see numerator for* ***ART.3 ART coverage 2***. ***Programme-based denominator:*** this is the same as the numerator of **VLS.4 VL monitoring**. The denominator includes all patients who have at least one viral load recorded in the specific month columns for the reporting period (*see* numerator description). This excludes patients who are DEAD, STOP, TO or LTF (i.e. not known to be on ART at this facility). ***Numerator:*** of those identified in the denominator, count the patient if, during the reporting months, viral load has been recorded and is <1000 copies/mL. This excludes any patients who are DEAD, STOP, LTF or TO (i.e. not known to be on ART at this facility). For both the numerator and denominator, at the facility, exclude those who transferred out before the end of the reporting period. At the country level, patients who TI will equal those who TO and do not need to be accounted for.
Disaggregation	• Sex • Age: – <15, 15+ (minimum for paper-based systems) – <1, 1–4, 5–9, 10–14, 15–19, 20+ for electronic systems

Indicator code and name	VLS.3 Viral load suppression
Key VL indicators	There are a total of four key indicators that provide an overview of viral load suppression among the patient population (*see* Fig. A4): **VLS.3 VL suppression** is the cross-sectional indicator explained in this table. **VLS.4 VL monitoring** is a cross-sectional indicator that measures the proportion of patients who have received a viral load test result. This is critical for interpreting **VLS.3** (i.e. <75% renders the interpretation of **VLS.3** questionable). **VLS.1/ART.9/ART.15 VL suppression at 12 months** is the corresponding cohort-based version of **VLS.3**. This is also an EWI HIVDR and measures the proportion of patients with viral load suppression after a fixed duration on ART. The original 2015 strategic information (SI) indicator denominator was reconciled with the EWI HIVDR denominator (*see* table of instructions for **VLS.1**). **VLS.2/ART.8 VL testing coverage** is the cohort-based version of **VLS.4** and similarly functions as a measure of interpretability for **VLS.1**. If it is below a certain percentage (e.g. <70% or 80%), the use of a representative sampling methodology may be preferable (*see* table of instructions for **VLS.1** and **VLS.2**).
References	*See* GAM indicator 1.4 (People living with HIV who have suppressed viral loads) for more information at: http://www.unaids.org/sites/default/files/media_asset/2017-Global-AIDS-Monitoring_en.pdf

ART.1 New ART patients

Fig. A5 ART.1 New ART patients indicator linkages



Red: HIV indicators
Light red: HIV/MNCH indicators
Dark pink: TB/HIV indicators
Pink: Hep/HIV indicators
D: Denominator
N: Numerator
Circle: Key paper-based indicators
Square: Key additional indicators

Indicator definition	Number of people living with HIV who initiate ART
Overview	This number provides facilities and programmes with an indication of the scope of implementing the "treat all" approach. It will allow facilities to prepare and plan for their patients who will require adherence preparation, baseline monitoring and assessment, continued provision of ART and lifelong monitoring. Initially, the number of new ART patients may increase (substantially); however, over time, these numbers should stabilize and then even decrease as the number of new infections start to subside, subsequently reducing the number of people requiring treatment. Comparing cumulative numbers of new ART patients over time with the current number of ART patients (**ART.3 ART coverage 2**) may give facilities and programmes a broad indication of retention on treatment.
Priority level	National, subnational, facility
Numerator	**Definition:** number of people living with HIV who initiated ART within the past 12 months **Data source:** ART register (may be reconciled with MNCH, TB registers – *see* notes below), aggregated in the cross-sectional report **Data elements:** ART start date
Denominator	N/A
Data collection methodology	***Numerator:*** this is a cross-sectional indicator. To calculate the numerator for a 12-month period; e.g. January–December 2015, count all patients who started ART between from January 1 to December 31 2015 (January to December ART cohorts) looking at ART start date in the first column). This is also the *denominator* for **LINK.12 TB prevalence in HIV care, LINK.27 Hep B screening**, and **LINK.28 Hep C screening.** **Subsets** When tallying this indicator, it is possible to also tally its subsets: **LINK.11 Timely linkage from diagnosis to treatment among children under 5 years of age, LINK.12 TB prevalence in HIV care, LINK.17 TB preventive therapy coverage, LINK.27 Hep B screening** and **LINK.28 Hep C screening, ART.4 Late ART initiation** and the *numerator* for **MTCT.15 Infant ART initiation**.
Special considerations for monitoring	**ART.4 Late ART initiation** ***Numerator:*** *number of HIV-positive adults initiating ART within the past 12 months with baseline CD4 count of ≤200 cells/mm³* ***Denominator:*** *number of HIV-positive adults initiating ART within the past 12 months who have a baseline CD4 count)* Count all patients identified in the numerator for **ART.1** who have a baseline CD4 count recorded (*see status at start ART* column) (denominator), and of those, who have a baseline CD4 count of ≤200 cells/mm³ (numerator).
Disaggregation	• Sex • Pregnant or breastfeeding at start ART • Age: – <15, 15+ (minimum for paper-based systems) – <1, 1–4, 5–9, 10–14, 15–19, 20+ for electronic systems • Optional: other specific priority population, provider type (public/private)

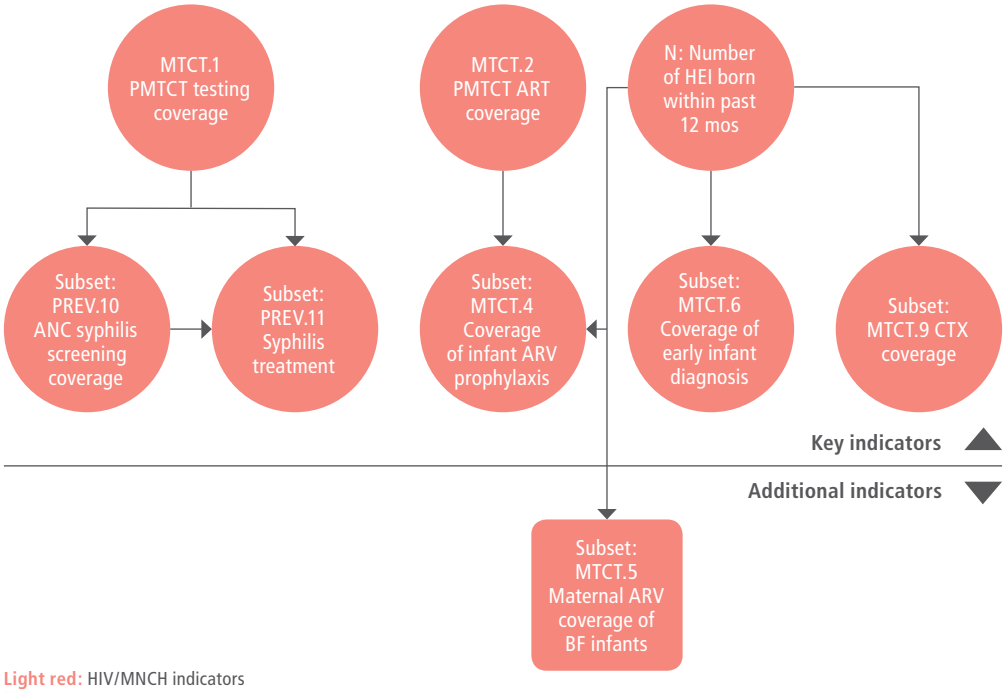
Indicator code and name	ART.1 New ART patients
Narrative	As it is recommended that ART registers are kept at all service delivery points providing ART (e.g. MNCH, TB), it will be necessary for programmes to aggregate numbers from all ART registers maintained across facilities. As long as transfer in/transfer out patients are captured correctly, there should not be a need to reconcile these registers. If, however, ART registers are not kept at all facilities where ART is initiated, the ANC/labour and delivery (L&D)/HEI or TB registers that may capture this information should be reconciled with the ART registers using unique ID numbers and ART start dates as reference points (TB Rx and pregnancy columns in ART register may also facilitate identification of potentially overlapping patients). For countries that are implementing the "treat all" approach and have reached 90% ART coverage, the indicator **LINK.3 Enrolment in care** (or newly enrolled in care) may no longer be a priority. New ART patients may act as a proxy for patients "newly enrolled in HIV care" given the removal of the pre-ART register from the generic HIV patient monitoring system. With the scale up of the "treat all" guidelines, these two numbers should be practically identical over time (within a given period). However, for countries who have not yet implemented "treat all" or are using a phased implementation approach, **LINK.3 Enrolment in car**e may still be relevant to collect, analyse and report (*see* Box 2.18). The definition of **ART.4 Late ART initiation** was revised to only include those with CD4 count <200 cells/mm^3 (removed CD4 count ≤350 cells/mm^3) as per the revised definition of advanced disease/late presenter *(6)*.

Indicator definition	**Percentage of patients with specific outcomes at 12 months**
Overview	This indicator provides information on outcomes of patients after the first year of treatment. While **ART.5 ART retention** shows those who are still alive and on ART after 12 months, these numbers unpack what has happened to those who are no longer on ART. It guides the facility to take any necessary action (e.g. if a large proportion of patients are LTF or STOP, it would be informative to figure out why; this would also be something to look into).
Priority level	National, subnational, facility
Numerator	**Definition:** number of ART patients with specific outcomes after initiating ART **Data source:** ART register, aggregated in the ART cohort report form **Data elements:** from ART register: *ART start date, ART follow-up status* = on first-line ART, DEAD, LTF, STOP (*see* Table 2.1 for definitions)
Denominator	**Definition:** number of patients initiating ART in the 12 months prior to the beginning of the reporting year. This includes those who have died since starting ART, those who have stopped ART and those lost to follow up as of month 12. Same as denominator for **ART.5 ART retention**. **Data source:** ART register, aggregated in the ART cohort report **Data elements:** from ART register: ART *start date, ART follow-up status*, aggregated in the ART cohort report
Data collection methodology	This indicator is a disaggregation of **ART.5 ART retention**, limited to 12-month outcomes. ***Denominator:*** the denominator for this indicator is the same as the denominator for **ART.5 ART retention** (at 12 months). In the **ART cohort report** (*see* Annex 2.3.6b), this is the first row (started on ART at this clinic – original cohort) (± TI/TO) for each ART cohort starting ART in the 12 months prior to the beginning of the reporting period. ***Numerator:*** to obtain the numerator, tally all patients identified in the denominator by specific 12-month outcome: on first-line regimen, DEAD, LTF, STOPped ART. This may also be tallied from the ART cohort report.
Disaggregation	• Sex • Pregnancy at initiation [and during ART] • Breastfeeding at initiation [and during ART] • Age: – <15, 15+ (minimum for paper-based systems) – <1, 1–4, 5–9, 10–14, 15–19, 20+ for electronic systems • Optional: coinfection with TB, coinfection with hepatitis B; site level; sites with retention rates <75%
Narrative	The name of this indicator was revised from "Medium-term ART outcomes" to "Short-term ART outcomes" and number of patients on second-line regimen was removed as an outcome. However, it is possible to carry out this disaggregation for every time point at which the indicator **ART.5 ART retention** is collected (e.g. yearly) as an exercise in monitoring and improving the quality of care, in which case it would be helpful to include patients on second-line (and eventually third-line) regimens as outcomes.

Key HIV/MNCH indicators

Indicator	Data source
PREV.10 ANC syphilis testing coverage (subset of **MTCT.1**) **PREV.11 ANC syphilis treatment** (subset of **MTCT.1**)	ANC register
MTCT.1 PMTCT testing coverage (includes **PREV.10** and **PREV.11**)	ANC, L&D register
MTCT.2 PMTCT ART coverage	ANC, L&D, ART registers
MTCT.4 Coverage of infant ARV prophylaxis **MTCT.6 Coverage of early infant diagnosis** **MTCT.9 CTX coverage**	HEI register (except MTCT.4 facility-based denominator=L&D register)

Fig. A6 Linkages between the key HIV/MNCH indicators



Light red: HIV/MNCH indicators
N: Numerator
Circle: Key paper-based indicators
Square: Key additional indicators

Indicator definition	**Percentage of pregnant women with known HIV status**
Priority level	National, subnational
Numerator	**Definition:** number of pregnant women attending ANC and/or who had a facility-based delivery who were tested for HIV during pregnancy or already knew they were HIV-positive **Data source:** ANC register, L&D register **Data elements:** HIV status at enrolment, HIV test result
Denominator	**Definition:** programme-based denominator: number of pregnant women who attended ANC or had a facility-based delivery in the past 12 months **Data source:** ANC and L&D registers **Data elements:** date enrolled [in ANC], HIV status at admission, HIV test result, date of delivery [at L&D]
Data collection methodology	***Programme-based denominator:*** count all women who were enrolled in ANC during the 12-month reporting period OR delivered at the facility (recorded in the L&D register), reconciling the latter with the former using the ANC number to avoid double counting. ***Numerator:*** count all women who were enrolled in ANC during the 12-month reporting period whose HIV status is known [P, N] or (had an HIV test and) received an HIV test result during ANC. Reconcile with all women in the L&D register whose date of delivery was in the 12 months reporting period and whose HIV status at admission was P or N, had (a previous HIV test date, or) any HIV test result recorded using the ANC number to avoid double counting of women already tallied from the ANC register. ***Disaggregation:*** for each woman enrolled in the ANC register during the reporting period, note whether their HIV status was positive at ANC enrolment OR their ANC HIV test result was positive once enrolled OR their ANC HIV test result was negative once enrolled.
STI linkages	**Subsets** **PREV.10 ANC syphilis screening coverage: % of ANC attendees who were tested for syphilis** ***Denominator:*** *number of women attending ANC services within the past 12 months* Take the number of those who were enrolled in ANC during the 12-month reporting period (the first part of the denominator described above). ***Numerator:*** *number of women attending ANC services within the past 12 months who were tested for syphilis* Of those women in the **PREV.10** denominator, count those who had a syphilis test result recorded (P, N or U). Disaggregate by first ANC visit and any ANC visit (tested for syphilis). **PREV.11 Syphilis treatment: treatment of syphilis in seropositive ANC attendees** ***Denominator:*** *number of syphilis-seropositive ANC attendees within the past 12 months* Of those women in the **PREV.10** numerator, count those whose syphilis test result was P (positive).

Indicator code and name	MTCT.1 PMTCT testing coverage
	Numerator: *number of syphilis-seropositive ANC attendees within the past 12 months who received at least one dose of benzathine penicillin 2.4 mU IM* Of those women in the **PREV.11** denominator, count those who have syphilis treatment recorded (IM PCN/1,2,3) in that column.
Disaggregation	• HIV status/test result – known HIV infection at ANC entry; – tested HIV+ at ANC during current pregnancy; – tested HIV– at ANC during current pregnancy
References	*See* GARPR 2016 indicator 3.4 (PMTCT testing coverage) for more information at: https://aidsreportingtool.unaids.org/static/docs/GARPR_Guidelines_2016_EN.pdf. *See* GAM 2017 indicator 2.4 (Syphilis among pregnant women) for more information at: http://www.unaids.org/sites/default/files/media_asset/2017-Global-AIDS-Monitoring_en.pdf **PREV.11** numerator definition was revised to match GAM 2.4 definition of "adequate" treatment.

Indicator definition	Number and percentage of HIV-positive pregnant women who received ART during pregnancy
Priority level	National, subnational
Numerator	**Definition:** number of HIV-positive pregnant women who delivered within the past 12 months and received ART **Data source:** ANC and L&D registers, ART register **Data elements:** ART start date, pregnancy status, expected due date (EDD), date of delivery, HIV status at admission, HIV test result
Denominator	**Definition:** facility-based denominator: number of HIV-positive pregnant women who delivered within the past 12 months and attended ANC or had a facility-based delivery **Data source:** ANC and L&D registers **Data elements:** date enrolled [in ANC], HIV status at admission, HIV test result, date of delivery [at L&D]
Data collection methodology	***Facility-based denominator:*** count all women who: • were enrolled in ANC (as recorded in the ANC register) and whose EDD was during the 12-month reporting period and whose HIV status at admission or HIV test result was positive: **OR** • delivered at the facility (recorded in the L&D register) during this same period with an HIV status at admission or HIV test result that was positive AND reconcile the latter with the former using the ANC number to avoid double counting.

Indicator code and name	MTCT.2 PMTCT ART coverage
	Numerator: • Of those identified in the denominator, count all women who were enrolled in ANC whose EDD was during the 12-month reporting period and whose HIV status or HIV test result was positive and whose ART start date was before the EDD. • Reconcile with all women in the L&D register whose date of delivery was in the 12 months reporting period and whose HIV status at admission or HIV test result was positive, and whose ART start date was prior to date of delivery. • Use the ANC number to avoid double counting of women already tallied from the ANC register. **If an ART register is also kept at ANC or L&D service delivery points:** • Count all women whose EDD in the pregnancy status column(s) was during the reporting period and ART start date prior to EDD and who had an ARV regimen code recorded in the (9)-month columns before the EDD (find the appropriate month column of the EDD, and count 9 months back from there on the follow-up status columns of the ART register). • May reconcile with ANC and L&D registers if necessary (ART register not complete, etc.). ***Note:*** this may appear to be a subset of **ART.3 ART coverage**, but it is not. The time periods are different: delivered in the last 12 months and received ART in the nine months before that, versus current on ART [as of the end of the reporting period].
Subsets	When tallying the facility-based denominator, it is possible to also tally its subset: the numerator and facility-based denominator for **MTCT.4 Coverage of infant ARV prophylaxis**.
Disaggregation	For each woman identified in the numerator count, note whether she was already on ART prior to pregnancy (ART start date is prior to date of conception or prior to EDD minus 9 months) or newly on ART during pregnancy (ART start date is within the 9-month period prior to estimated or actual date of delivery). • Already/newly on ART • Optional: pregnant women who inject drugs
References	*See* GAM indicator 2.3 (Preventing the mother-to-child transmission of HIV) for more information at: http://www.unaids.org/sites/default/files/media_asset/2017-Global-AIDS-Monitoring_en.pdf

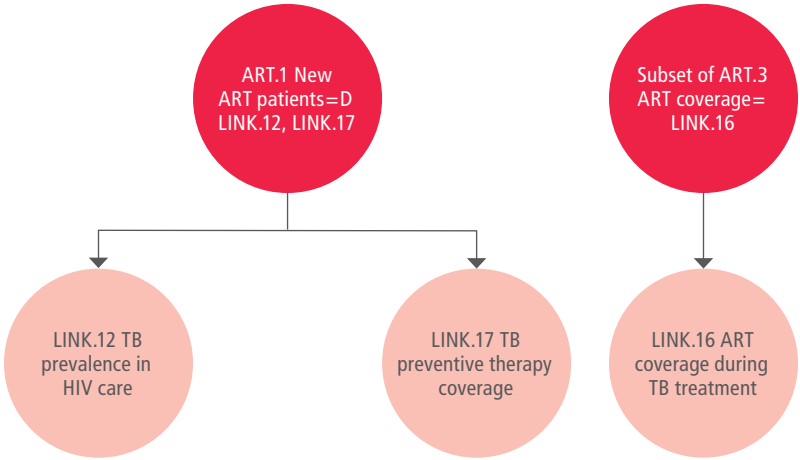
Indicator codes, names and definitions	**MTCT.4 Coverage of infant ARV prophylaxis:** *percentage of HIV-exposed infants who initiated ARV prophylaxis* **MTCT.5 ARV coverage for [mothers of] breastfeeding infants:** *percentage of HIV-exposed breastfeeding infants whose mothers are receiving ART at 3 (and 12) months postpartum* **MTCT.6 Coverage of early infant diagnosis:** *percentage of HIV-exposed infants receiving a virological test for HIV within 2 months of birth* **MTCT.9 CTX coverage:** *percentage of HIV-exposed infants started on CTX prophylaxis within 2 months of birth*
Overview	These indicators have been grouped together as they are all derived from the HEI register and are a subset of HEI born within the past 12 months. Each measures an essential part of HEI care, from ARV and CTX prophylaxis to testing. Maternal receipt of ART is also included as it is tied to the risk of transmission to the breastfeeding HEI. While final outcome status was also originally included, the denominator was revised to include a broader range of infants (*see* **MTCT.8** Final outcome status).
Priority level	National, subnational, facility
Numerator	**Definition:** number of HIV-exposed infants born within the past 12 months: **MTCT.4** who were started on ARV prophylaxis at birth **MTCT.5** who were breastfeeding and whose mothers were receiving ART at 3 (and 12) months postpartum **MTCT.6** who received a virological HIV test within 2 months of birth **MTCT.9** who started on CTX within 2 months of birth **Data source:** HEI register **Data elements:** date of birth/delivery and: **MTCT.4** Infant ARV prophylaxis: date and drug(s) dispensed **MTCT.5** Infant-feeding practice at 3 (and 12) months, maternal ART at 3 (and 12) months **MTCT.6** HIV test: date, age in weeks/months, polymerase chain reaction (PCR), result **MTCT.9** Age in weeks/months started CTX
Denominator	**Definition:** **MTCT.4** (population-based), **MTCT.6**, **MTCT.9** denominator: *number of HIV-positive women who delivered within the past 12 months (derived from internationally consistent modelling estimates)* **MTCT.4** Facility-based denominator: *number of HIV-positive pregnant women who delivered in a facility within the past 12 months (subset of MTCT.2 facility-based denominator)* **MTCT.5** Population-based denominator: *estimated number of HIV-exposed infants breastfeeding at 3 (and 12) months (including the estimated number of infants not attending clinic and who are still breastfeeding) (derived from survey data and other estimates)* **MTCT.5** Programme-based denominator: *number of identified HIV-exposed infants born within the past 12 months who are breastfeeding at 3 months (and 12 months) of age*

	Data source: **MTCT.4** Facility-based denominator: L&D register **MTCT.5** Programme-based denominator: HEI register **Data elements:** **MTCT.4** HIV status at admission, HIV test result, date of delivery [at L&D] **MTCT.5** Infant-feeding practice at 3 months (and 12 months)
Data collection methodology	***Numerators:*** count all HEI in the HEI register with a date of birth/delivery in the past 12 months (reporting period) and who: • **MTCT.4** Received ARV drugs at birth (date dispensed=date of birth) • **MTCT.5** Were breastfeeding at 3 months (infant-feeding practice at 3 months is exclusively breastfed [EBF] AND mother's ART start date is 3 months after HEI DoB/ maternal ART at 3 months=Y) • **MTCT.6** Received a virological HIV test within 2 months of birth (age in weeks/ months is ≤2 months AND test type is PCR – disaggregated by HIV test result [positive, negative, indeterminate, other]) • **MTCT.9** Started on CTX within 2 months of birth (age in weeks/months started CTX is ≤2 months) **MTCT.5** *Programme-based denominator:* Were breastfeeding at 3 months (infant-feeding practice at 3 months is EBF) (and 12 months) ***MTCT.4*** *Facility-based denominator:* count all women who delivered at the facility (recorded in the L&D register) during this same period with an HIV status at admission or HIV test result that was positive.
Subsets	**MTCT.4** *Facility-based denominator* is the same as the numerator for **MTCT.19 In-facility deliveries**, and a subset of the denominator for **MTCT.2 PMTCT ART coverage**.
References	*See* GARPR 2016 indicators 3.7 Coverage for infant ARV prophylaxis and 3.9 CTX prophylaxis coverage for more information at: https://aidsreportingtool.unaids.org/static/docs/GARPR_Guidelines_2016_EN.pdf. *See* GAM 2017 indicator 2.1 (Early infant diagnosis) for more information at: http://www.unaids.org/sites/default/files/media_asset/2017-Global-AIDS-Monitoring_en.pdf

Key TB/HIV indicators

LINK.12 TB prevalence in HIV care
LINK.16 ART coverage during TB treatment
LINK.17 TB preventive therapy coverage

Fig. A7 Linkages to the key TB/HIV indicators for paper-based systems



Red: HIV indicators
Dark pink: TB/HIV indicators
D: Denominator
Circle: Key paper-based indicators

Indicator code and name	LINK.12 TB prevalence in HIV care
Indicator definition	**Proportion of people living with HIV started on ART with active TB disease**
Priority level	Global, national, subnational
Numerator	**Definition:** number of persons living with HIV and started on ART during the reporting period who have active TB disease **Data source:** ART register, aggregated in the cross-sectional report **Data elements:** ART start date, status at ART start
Denominator	**Definition:** number of persons living with HIV started on ART during the reporting period **Data source:** ART register, aggregated in the cross-sectional report **Data elements:** ART start date
Data collection methodology	***Denominator:*** *see* **ART.1 New ART patients**. ***Numerator:*** of those identified in the denominator, tally those patients with **status at ART start = TB+**. Tally/reconcile TB status among people living with HIV (PLHIV) started on ART with TB register in respective reporting unit.

Indicator code and name	LINK.12 TB prevalence in HIV care
Frequency	Tally **LINK.12** at the same time as **ART.1** and its subsets, **LINK.17** (also a subset of **LINK.12**), **LINK.27** and **LINK.28**.
Disaggregation	• Sex • Age (<15, 15+)
Narrative	Revised original indicator definition from "newly enrolled in HIV care" to "started on ART" in line with "treat all" recommendations. Countries with <90% ART coverage (of those enrolled in HIV care) may also include patients not yet started on ART from the *delayed patients list* in the denominator, and add those who have active TB disease at enrolment into care (month/year matching month/year of enrolment) to the numerator. However, this should be extremely rare, as all PLHIV with TB should be started on ART promptly and not later than two to eight weeks after diagnosis.
References	*See* TB/HIV M&E guide indicator A.3 for more information *(10)*.

Indicator code and name	LINK.16 ART coverage during TB treatment
Indicator definition	**Proportion of HIV-positive new and relapse patients on ART during TB treatment**
Priority level	Global, national, subnational
Numerator	**Definition:** total number of HIV-positive new and relapse patients started on TB treatment during the reporting period who are already on ART or started on ART during TB treatment **Data source:** TB basic medical unit (BMU) register reconciled with the ART register **Data elements:** ART start date, follow-up status, TB Rx start date
Denominator	**Definition:** total number of HIV-positive new and relapse TB patients registered during the reporting period **Data source:** TB BMU register **Data elements:** visit date, TB status, investigations
Data collection methodology	***Numerator:*** this is a subset of **ART.3 ART coverage**. • Look through the ART register(s) and identify all patients currently on ART (follow-up status=ARV regimen) who were started on TB treatment, i.e. TB Rx column start date during the reporting period. • These patients must be reconciled with new and relapse cases notified in the TB registers for the same period (use TB registration number, ART start date and unique ID).
Frequency	Tally the numerator of **LINK.16** at the same time as the numerator of **ART.3** and its subsets.
Linkages	This indicator will be collected from the TB monitoring system and the numerator reconciled with the ART register.
Disaggregation	• Sex • Age (<15, 15+)

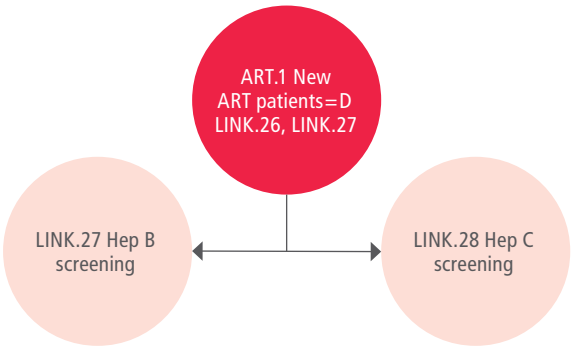
Indicator code and name	LINK.16 ART coverage during TB treatment
References	Measures the extent to which HIV-positive TB patients receive ART during TB treatment. Both treatments are necessary to reduce mortality. High coverage indicates a strong collaboration between HIV and TB programmes. *See* TB/HIV M&E guide indicator A.4 for more information *(10)*.

Indicator code and name	LINK.17 TB preventive therapy coverage
Indicator definition	**Proportion of people living with HIV started on ART, started on TB preventive therapy**
Priority level	Global, national, subnational
Numerator	**Definition:** number of people living with HIV started on ART who are started on treatment for latent TB infection during the reporting period **Data source**: ART register, aggregated in the cross-sectional report **Data elements:** ART start date, TB preventive therapy start date
Denominator	**Definition:** total number persons started on ART during the reporting period, excluding confirmed TB cases **Data source:** ART register, aggregated in the cross-sectional report **Data elements:** ART start date, status at ART start
Data collection methodology	***Denominator:*** *see* **ART.1 New ART patients**. Do not include/subtract those identified in the numerator for **LINK.12 TB prevalence in HIV care** (status at ART start=TB+). ***Numerator:*** of those patients identified in the denominator, tally those patients who have TB preventive therapy start date recorded (column on left-hand page of ART register) within the reporting period.
Frequency	Tally this indicator at the same time as **ART.1** and its subsets.
Disaggregation	• Sex • Age (<15, 15+)
Narrative	TB preventive therapy with isoniazid is the second "I" in the WHO TB/HIV "Three I's" strategy, and an important part of a comprehensive package of HIV care to help prevent TB in people with HIV. Excluding those with presumed or confirmed TB, WHO strongly recommends a TB preventive therapy course of at least six months for all people with HIV, and conditionally recommends a TB preventive therapy course of at least 36 months for those in high TB transmission settings *(7)*. *See* TB/HIV M&E guide indicator A.5 for more information *(10)*. Revised indicator to read "started on ART" instead of "newly enrolled in HIV care" in line with "treat all" recommendations. Countries with <90% ART coverage (of those enrolled in HIV care) may also include patients not yet started on ART (and do not have active TB disease) from the list of patients who may not or will not start ART soon after enrolment into HIV care in the denominator, and add those who started TB preventive therapy at enrolment into care (month/year matching month/year of enrolment) to the numerator.

Key hepatitis indicators

LINK.27 Hepatitis B screening
LINK.28 Hepatitis C screening

Fig. A8 Linkages to the key hepatitis indicators



Red: HIV indicator
Pink: Hep/HIV indicators
D: Denominator
Circle: Key paper-based indicators

Indicator codes and names	LINK.27 Hepatitis B screening LINK.28 Hepatitis C screening
Indicator definition	Percentage of people newly initiated on ART who were screened for hepatitis B or hepatitis C
Priority level	National, subnational
Numerator	**Definition:** number of adults and children newly initiated on ART who were screened for hepatitis B **(LINK.27)** or hepatitis C **(LINK.28)** during the reporting period using HBsAg tests or HCV antibody tests (followed by HCV RNA for those anti-HCV positive) **Data source:** ART register **Data elements:** HBsAg test month/year, HCV Ab test month/year
Denominator	**Definition:** number of people newly started on ART during the reporting period **Data source:** ART register, aggregated in the cross-sectional report (*see* **ART.1 New ART patients** numerator) **Data elements:** from ART register: *ART start date*
Data collection methodology	***Denominator:*** *see* ***ART.1 New on ART patients*** *numerator* ***Numerator:*** for each patient identified in the denominator described above, tally those who received an HBsAg / HCV Ab test during the reporting period (*see* HBsAg test/HCV Ab test Month/Year column)
Frequency	Tally these indicators at the same time as **ART.1** and its subsets.
Disaggregation	• Sex • Age (<15, 15+)
Narrative	*See* HBsAg test/HCV Ab test followed by HCV RNA for those anti-HCV positive Month/Year columns: newly added columns in ART register specifically for these indicators. Revised numerator and denominator definitions to read "newly initiated on ART" instead of "in HIV care" in line with "treat all" guidelines.

PART 2. KEY ADDITIONAL INDICATORS FOR ELECTRONIC SYSTEMS OR PERIODIC REVIEW

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PART 2. KEY ADDITIONAL INDICATORS FOR ELECTRONIC SYSTEMS OR PERIODIC REVIEW

Key additional HIV indicators

ART.7 ART adherence proxy (EWI)
ART.11 ART survival (*see* **ART.5**)
ART.12 Toxicity prevalence
VLS.1/ART.9/ART.15 VL suppression at 12 months after initiation (EWI)
VLS.2/ART.8 VL testing coverage (EWI) (*see* **ART.5**)
VLS.4 Viral load monitoring (*see* **ART.3**)
LINK.7 CTX coverage

Indicator code and name	ART.7 ART adherence proxy
Indicator definition	**Percentage of ART patients who pick up all prescribed ARV drugs on time**
Overview	The on-time pill pick-up indicator provides a high-level assessment of how well populations of patients at a clinic perform in picking up prescribed ART on or before the pill run-out date, if taken according to schedule. The target suggested by WHO for desirable clinic-level performance for on-time pill pick-up is above 90%, while 80–90% is considered fair performance and <80% is considered poor performance. Sustained long-term adherence to ART is critical to achieving the desired individual- and population-level benefits of HIV treatment. Studies document virological failure and selection of drug-resistant HIV among individuals receiving non-nucleos(t)ide reverse transcriptase inhibitor (NNRTI)-based regimens who experience treatment interruptions of more than 48 hours. Although the risk of HIVDR with non-NNRTI based regimens may be less, the indicator supports maximizing population viral load suppression and achieving the "third 90". Despite the clear link between suboptimal adherence to ART and the emergence of HIVDR, the estimation of patient and population adherence to ART may pose challenges. For example, patient self-reported adherence and provider perception of patient adherence have been shown to be unreliable.
Priority level	National (HIVDR EWI), subnational, facility-level HIVDR EWI
Numerator	**Definition:** number of patients who pick up all prescribed ARV drugs no more than 2 days late at the first pick-up after a defined baseline pick-up **Data source:** pharmacy records, HIV patient card **Data elements:** visit date (date of pick-up), ARV drugs dispensed, number of days of ARV drugs dispensed (number of days of remaining pills, if available and routinely ascertained and recorded)

Indicator code and name	ART.7 ART adherence proxy
Denominator	**Definition:** number of patients who picked up ARV drugs (on or after the designated sample start date) If the denominator is a census, it will be the same as the current number of patients on ART (*see numerator for **ART.3 ART coverage 2***). If the denominator is a sample, the numerator for **ART.3 ART coverage 2** will be the source of the eligible population for the clinic sample (as defined by Table 2.8). **Data source:** pharmacy records, HIV patient card, ART register (aggregated in the cross-sectional report) **Data elements:** pharmacy record or HIV patient card: visit date, ARV drugs dispensed; ART register: follow-up status (ARV regimen code)
Data collection methodology	*For a census denominator: see numerator* for **ART.3 ART coverage 2**. Using pharmacy registers, choose an arbitrary EWI start date some time after the date the denominator was reported. *For a sample denominator:* the "EWI start date" is the date designated as the start of patient sampling. Patients picking up their ART at the pharmacy, on or after this date make up the clinic sample (per Table 2.8). Data on consecutive patients (dispensing actions) should be abstracted until the required sample size is achieved. Ideally, the same sample start date is used for all participating clinics in a country. Facilities abstract "baseline pill pick-ups" until the sample size is achieved. The number of patients is the sample denominator. *Numerator:* for a given patient, record the pill pick-up date, regimen and number of days of ART dispensed. For these same individuals who provide baseline information, record the date of the first pill pick-up after the baseline pick-up. An EWI data abstraction tool provided by WHO facilitates abstraction of this indicator *(8)*.
Disaggregation	• Sex • Age (<10, 10–19, 20–49, 50+)
Narrative	This indicator is generally obtained from pharmacy records, which tend to be more accurate. On-time pill pick-up has been observed to predict clinic-level viral load suppression. As routine individual patient-level viral load testing is not available in all settings, this observation suggests that identifying clinics with less-than-desirable pill pick-up, then targeting their patient populations for adherence interventions, may lead to improvements in overall population-level viral load suppression, and therefore improved health outcomes. It is important for pharmacy visits to be linked to clinical records and visits so that the patient's record of all types of visits (clinical or drug pick-up only) are in one place and harmonized (ideally the HIV patient card). This may or may not happen in facilities, especially where ARV dispensing takes place outside of the clinician's office or in another facility entirely, but is important as LTF tracing and adherence counselling may be linked to late dispensing of ART. The WHO-recommended targets for clinic performance for this indicator are: green: >90% (excellent); amber: 80–90% (fair); red: <80% (poor).

Indicator code and name	ART.12 Toxicity prevalence
Indicator definition	**Percentage of ART patients with treatment-limiting toxicity**
Overview	This indicator measures the impact of toxicities on treatment outcomes. ARV-associated toxicities are among the most common reason reported for poor adherence to ART, treatment discontinuation or substitution of drugs. Routine monitoring will provide data on incidence and clinical significance of serious toxicities, and their impact on patient outcomes and attrition. It is a new indicator designated for national programme monitoring in the WHO 2015 consolidated SI guidelines *(9)*.
Priority level	National, subnational, facility
Numerator	**Definition:** number of people living with HIV and on ART within the past 12 months who substituted a regimen or interrupted treatment due to toxicity **Data source**: HIV patient card, ART register **Data elements**: ART start date, ART follow-up status, ARV regimen, date substituted (within first-, second-, third-line regimen), reason substituted, toxicity/serious drug reaction, ART no. missed doses, reason for poor adherence
Denominator	**Definition: ART 3.** Numerator: number of people living with HIV who are currently receiving ART [at the end of the reporting period] **Data source:** ART register **Data elements:** ART follow-up status
Data collection methodology	***Denominator:*** this is the numerator for **ART.3 ART coverage**. ***Numerator:*** for all patients identified in the denominator, in the ART register, look at the last columns on the first page labelled "substitutions" within first-, second- and third-line regimens. Count patients if they have substituted within any regimen during the reporting period (*see* date), and the reason is "toxicity/serious drug reactions" (code=1). Similarly, go through the relevant follow-up months of the ART register (note: months columns will be different for every cohort; e.g. it could be Months 0–11 for ART cohort starting January 2015 or Months 11–22 for ART cohort starting January 2014) and count all patients who have a treatment interruption (no ARV regimen code recorded). For these patients, pull out their HIV patient cards and find out the reason for their poor adherence (ART no. missed doses/why column). Count those with reason "toxicity/side-effects" (code=9) recorded.
Frequency	This indicator is best tallied at the end of the year when tallying **ART.3 ART coverage** (also the denominator for **ART.12**).
Disaggregation	For each patient, note the sex, age, current TB Rx on page 1 of the ART register. Also note the ARV regimen (code) the patient was on when experiencing the toxicity-related drug substitution and the associated toxicity category or categories recorded. • Sex • Age (<15, 15+) • TB/HIV coinfection • ARV regimen • Toxicity categories from minimum dataset

Indicator code and name	ART.12 Toxicity prevalence
Narrative	*What is new* • Revised denominator definition to include all those "current on ART" instead of "on ART in the past 12 months" to align with **ART.3 ART coverage** numerator. • A definition of treatment-limiting toxicity has been added to the minimum dataset and adapted into the generic HIV patient card. • In the HIV patient card, **toxicity** has code **1** as a reason (among others) for substituting and code **9** for poor adherence. The list of major toxicities was revised and accompanied with individual coding to capture major types of ARV toxicities as defined in the 2016 WHO ARV guidelines (for example, **K** for kidney dysfunction) *(1)*. • In the ART register, the same codes are used for regimen substitution.

Indicator code and name	VLS.1 Viral load suppression at 12 months after ART initiation
Indicator definition	**Percentage of people living with HIV and on ART who have virological suppression at 12 months after initiating treatment**
Overview	Unlike **VLS.3 Viral suppression**, this is a cohort-based indicator measuring viral suppression in those who have been on ART for 12 months. It may be viewed as a subset of the **ART.6 Short-term ART outcomes**. It is identical to **ART.9** and **ART.15**, another HIVDR EWI (*see* **ART.7** overview). It is an early indication of treatment success. However, as with **VLS.3**, in settings where viral load monitoring is not routine, this indicator may be best measured with a nationally representative HIVDR survey to provide an estimate (*see* **VLS.3**).
Priority level	National, subnational, facility-level HIVDR EWI
Numerator	**Definition:** number of people living with HIV who initiated ART 12 months (± 3 months) before the start of the reporting period and who have a suppressed viral load (<1000 copies/mL) at 12 months after initiating ART **Data source:** ART register, aggregated in the ART cohort report form **Data elements:** from ART register: *ART start date, viral load at 12 months* (*see* Table 2.1 for definitions).
Denominator	**Definition:** *Population-level:* number of patients alive and on ART after initiating ART in the 12 months (± 3 months) prior to the beginning of the reporting year. This is the same as the numerator for **ART.5 ART retention at 12 months**. *Programme-based and HIVDR EWI denominator:* number of patients alive and on ART after initiating ART 12 months (± 3 months) prior to the beginning of the reporting year and who received a viral load test result at 12 months. This is the same as the numerator for **VLS.2 VL testing coverage**. **Data source:** ART register, aggregated in the ART cohort report **Data elements:** from ART register: *ART start date, ART follow-up status=ARV regimen code*

Indicator code and name	VLS.1 Viral load suppression at 12 months after ART initiation
Data collection methodology	The methodology is similar to that for **ART.6 Short-term ART outcomes**, but the follow-up status is specific to viral load suppression at 12 months (versus ARV regimen type, LTF, STOP and DEAD). The period of time from when patients in the reporting year cohort start ART and the end of the reporting year can be up to 27 months (patients start ART January–December 2015 for reporting year ending December 2016 (+ 3 months' grace period). ***Population-level denominator:*** the denominator for this indicator is the numerator for **ART.5 ART retention** (at 12 months). ***Programme-based*** and ***HIVDR EWI denominator:*** this is the same as the numerator for **VLS.2 VL testing coverage** and is a subset of the population-level denominator. Of those identified in the population-level denominator, count those patients who also received a viral load test result at 12 months (± 3 months) – the result will be recorded in the 12-month VL column. ***Numerator:*** this is a subset of the population-level or programme-based denominator. Of those patients identified in the denominator, look at the 12-month VL column and count those who have a viral load <1000 copies/mL recorded.
Frequency	Tally this indicator at the same time as indicators **ART.5**, **ART.6** and **VLS.1**. **Pregnant and breastfeeding women** may require more frequent VL monitoring to ensure the prevention of HIV transmission. Pregnant women newly on ART may need particularly attentive follow up. As such, **3-month VL suppression** may be a useful facility-based marker in order to address any adherence issues just before and following delivery. This may be an adaptation in ART registers kept and used at MNCH service delivery points. Likewise, in the general population, **6-month VL suppression** may be a useful facility-based marker to address early adherence issues among patients who have just started ART. Rather than the collection of an additional indicator, health workers could use the ART register to scan cohorts of patients who have started in the past year looking at the 6-month VL column to spot and follow up any patients with viral load above 1000 copies/mL.
Disaggregation	• Age: – <15, 15+ (minimum for paper-based systems) – <1, 1–4, 5–9, 10–14, 15–19, 20+ for electronic systems • Pregnancy and breastfeeding at initiation where relevant
Narrative	This indicator was revised to include a programme-based denominator in order to match its cross-sectional counterpart, **VLS.3 VL suppression**, and be harmonized with the HIVDR EWI. A new row in the ART cohort report has been added (VL suppressed) to facilitate aggregation of this indicator.
EWI of HIVDR	There is a strong association between virological failure and HIVDR. Achieving high levels of viral load suppression in people on ART minimizes morbidity and mortality and decreases HIV incidence; furthermore, the emergence of HIVDR is prevented among those with virological suppression. The viral load suppression indicator measures how well clinics perform in reaching virological suppression targets. WHO's suggested target for desirable performance for this indicator is 90% or greater viral load suppression among those alive and on ART 12 months after treatment initiation, while 80% to less than 90% is considered fair performance and less than 80% is considered poor performance.

Indicator code and name	VLS.2/ART.8 Viral load testing coverage
Indicator definition	**Percentage of people on ART with VL results at 12 months after ART initiation**
Overview	This cohort indicator provides information on how widely used viral load monitoring is and therefore whether or not **VLS.1 VL suppression at 12 months** can be reliably collected using the routine patient monitoring system. This number should ideally be ≥70%.
Priority level	National, subnational, facility-level HIVDR EWI
Numerator	**Definition:** number of people living with HIV and on ART with viral load test result available at 12 months **Data source:** ART register, aggregated in the ART cohort report form **Data elements:** from ART register: *ART start date, VL at 12 months*
Denominator	**Definition:** number of people [alive and] on ART 12 months [after initiating ART] **Data source:** ART register, aggregated in the ART cohort report **Data elements:** from ART register: *ART start date, ART follow-up status* (*see* Table 2.1 for definitions)
Data collection methodology	***Denominator:*** the denominator for this indicator is the numerator for **ART.5 ART retention** (at 12 months). ***Numerator:*** this is the same as the programme-based and HIVDR EWI denominator for **VLS.1 VL suppression at 12 months**.
Frequency	Tally this indicator at the same time as indicators **ART.5**, **ART.6** and **VLS.1**.
Disaggregation	• Sex • Age: – <15, 15+ (minimum for paper-based systems) – <1, 1–4, 5–9, 10–14, 15–19, 20+ for electronic systems
Narrative	This indicator was revised slightly from what is written in the 2015 WHO consolidated SI guidelines *(9)*, so that the caveat to exclude those who did not have a viral load result from the denominator was removed. The denominator now includes all patients who are on ART at 12 months.
EWI of HIVDR	Attaining high levels of viral load suppression is inextricability linked with high levels of viral load test completion. The lack of routine viral load monitoring and appropriate action to detected virological failure is associated with the emergence of HIVDR, as patients remain on a failing regimen and accumulate resistance mutations. This viral load test completion indicator measures the proportion of patients with a 12-month viral load test result available in their medical records with a recommended EWI target of ≥70%.

Indicator code and name	VLS.4 Viral load monitoring
Indicator definition	**Percentage of people living with HIV and on ART who obtained at least one VL test result during the past 12 months**
Overview	Essential for interpreting **VLS.3 VL suppression**, as it provides the proportion of patients overall who have received a viral load test of those measured. If ≥75%, **VLS.3** may be measured using the routine HIV patient monitoring system. Otherwise, results should be interpreted with caution; or, estimates from a nationally representative HIVDR survey should be carried out (*see* **VLS.3**).
Priority level	National, subnational
Numerator	**Definition:** number of people living with HIV and on ART who have obtained at least one viral load test result during the past 12 months (subset of **ART.3 ART coverage 2**) **Data source:** ART register, aggregated in the cross-sectional report **Data elements:** from ART register: *ART start date, ART follow-up status*, VL test result
Denominator	**Definition:** number of people living with HIV and on ART [at the end of the reporting period] (numerator of **ART.3 ART coverage 2**) **Data source:** ART register, aggregated in the cross-sectional report **Data elements:** from ART register: *ART start date, ART follow-up status*
Data collection methodology	***Denominator:*** this is the same as the numerator of **ART.3 ART coverage**. ***Numerator:*** of the patients tallied in the denominator, count those who also received the viral load test result after the measurement was taken (in the past 12 months) (viral load result recorded in any of the VL columns that fall within the 12 months before the reporting period).
Frequency	Tally this indicator at the same time as indicator **ART.3** (and its subsets, including **VLS.3**).
Disaggregation	• Sex • Age: – <15, 15+ (minimum for paper-based systems) – <1, 1–4, 5–9, 10–14, 15–19, 20+ for electronic systems
Narrative	This indicator was revised to be a cross-sectional version of **VLS.2**. That is, "who had VL measured" was removed from the cross-sectional denominator definition, and the optional cohort denominator was removed completely. The indicator now measures coverage of viral load testing among those who are currently on ART, and can therefore aid in interpretation of global indicator **VLS.3 VL suppression** as intended.

Indicator code and name	LINK.7 Co-trimoxazole (CTX) coverage
Indicator definition	**Percentage of eligible HIV-positive individuals who received CTX**
Overview	CTX prophylaxis is an integral component of care to prevent common coinfections and an important intervention for specific populations, with the 2016 WHO recommendations *(1)*. This is a quality-of-care indicator that shows the extent to which patients who are eligible for CTX prophylaxis are receiving it. The tallying of this indicator will be through an annual review of all or a sample of HIV patient cards.
Priority level	Additional (national, subnational, facility)
Numerator	**Definition:** number of eligible HIV-positive individuals who received CTX **Data source:** HIV patient card, ART register **Data elements:** CTX start date, CD4 count, TB status, age/DoB
Denominator	**Definition:** number of HIV-positive individuals enrolled in HIV care who are eligible for CTX **Data source:** HIV patient card, ART register **Data elements:** CD4 count, TB status, age/DoB
Data collection methodology	According to WHO recommendations *(1)*, CTX prophylaxis is recommended for the following populations: 1. All HIV-positive adults and children in settings where malaria and/or severe bacterial infections (SBIs) are highly prevalent (setting specific) 2. All HIV-positive children <5 years of age 3. All HIV-positive adults, including pregnant women with advanced HIV clinical disease (WHO stage 3 or 4) or CD4 count <200 cells/mm^3 4. All HIV-infected adults and children with active TB disease (regardless of CD4 count) 5. All HIV-exposed infants from 4 to 6 weeks of age until exclusion of HIV infection (with age-appropriate HIV test to establish final diagnosis and complete cessation of breastfeeding). ***Denominator:*** go through all ART register pages and look at the specific column of the last month of the reporting period for all cohorts (if applicable, also go through the list of all those who may or will not start ART soon after enrolment into HIV care, looking specifically at the outcome and outcome date columns). Count the patient if, during that month, there is an ARV regimen code completed or if a patient has STOPped ART (still in care) (do not include any patients who have been classified as DEAD, TO or LTF by the end of the reporting period). If setting is defined as high-prevalence malaria/SBI, this will be the denominator. Otherwise, pull all the HIV patient cards for these patients, and count and tally all patients during the reporting period (by looking at visit dates within that time) with: • age <5 years at time of reporting period (or DoB not more than 5 years prior to reporting period) (front page of HIV patient card) • age = 5+ AND clinical stage = 3 or 4 at start of ART (front page) • age = 5+ AND CD4 count ≤200 cells/mm^3 (encounter page CD4 column) • TB status/Investigations =1–9, +, ++ or +++, T, RR, TI (encounter page TB status column)[1] AND going through the HEI register, count • HIV-exposed infants age 4 weeks+ (from date of delivery) at time of reporting period AND final status ≠HIV-negative (Date of delivery and Final status columns)

[1] Xpert MTB/RIF results: T=MTB detected, rifampicin resistance not detected; RR=MTB detected, rifampicin resistance detected; TI=MTB detected, rifampicin resistance indeterminate

	Numerator: as eligible patients are identified for the denominator, at the same time, look at the CTX column and visit date on the encounter page and count those who were dispensed CTX during/for the reporting period. For HIV-exposed infants in the HEI register, look at age in weeks/months started CTX column (making sure it is <2 months).
Disaggregation	Disaggregate by infants (<2 months) taking the HEI register tallies and age <15, 15+ when tallying numerator and denominator. Age (<2 months, <15, 15+)
Narrative	In recent years, new evidence has emerged showing that with expanded access to ART, there is broader benefit of CTX prophylaxis beyond the prevention of some AIDS-associated opportunistic diseases and the reduction of HIV-associated mortality in people with low CD4 cell counts. These benefits relate to prevention of malaria and SBIs in adults and children with HIV. *See* recommendations for CTX prophylaxis in Section 5.2.1 of the 2016 WHO ARV guidelines *(1)*.

Key additional HIV/MNCH indicators

Indicator	Data source
MTCT.3/17 Early ART retention of pregnant and breastfeeding women (subset of **ART. 5**)	ART register
MTCT.5 ARV coverage for [mothers of] breastfeeding infants (*see* **MTCT.4**)	ART, HEI registers
MTCT.8 Final outcome status	HEI register
MTCT.15 Infant ART initiation (numerator is subset of **ART.1**, denominator of **LINK.11**)	ART, HEI registers
LINK.11 Timely linkage from diagnosis to treatment among children under 5 years of age (subset of **ART.1**)	HIV patient card, ART register

Indicator codes, names and definitions	MTCT.8 Final outcome status: *percentage distribution of HIV-exposed infants by final outcome status*
Priority level	National, subnational, facility
Numerator	**Definition:** number of HIV-exposed infants who reached 18 months in the last calendar year with various final outcome status **Data source:** HEI register **Data elements:** date of birth/delivery, final status
Denominator	**Definition:** number of HIV-exposed infants who reached 18 months in the last calendar year **Data source:** HEI register **Data elements:** date of birth/delivery
Data collection methodology	***Denominator:*** count all HIV-exposed infants whose delivery/birth date was 18 to 30 months prior to the end of the reporting period (year). For example, for the reporting period ending in December 2015, count all infants who were born or delivered from July 2013 to June 2014. ***Numerator:*** of those infants identified in the denominator, tally those who had a final status recorded (disaggregated by status: HIV+, HIV– no longer BF, HIV status unknown [died, LTF, TO, active in care but not tested at 18 months]).
Disaggregation	Outcome status: • HIV-positive • HIV-negative no longer breastfeeding • HIV status unknown – Died – Lost to follow up – Transferred out – Active in care, but not tested at 18 months
Narrative	*See* Appendix 2B (routine indicator 11) in the 2015 IATT Option B/B+ M&E framework for more information. This indicator was revised from including HIV-exposed infants born within the past 12 (or 24 months in breastfeeding settings) to those who reached 18 months during the reporting period to more fully capture all exposed infants' final outcomes. According to current WHO guidelines for early infant diagnosis *(1)*, final outcome status should be assessed three months after cessation of breastfeeding. This will vary by setting.

Indicator code and name	MTCT.15 Infant ART initiation
Indicator definition	**Percentage of identified HIV-positive infants who initiated ART by 12 months of age during the reporting period**
Priority level	Additional (national, subnational, facility)
Numerator	**Definition:** number of infants started on ART by 12 months of age during the reporting period **Data source:** ART register, HEI register **Data elements:** date of birth, ART start date
Denominator	**Definition:** number of infants identified as HIV positive by 12 months of age **Data source:** HEI register **Data elements:** date of delivery, date of HIV test result, HIV test result, age in weeks/months when tested
Data collection methodology	***Numerator:*** this is a subset of **ART.1** and **LINK.11**. For all ART cohorts starting in the reporting period (e.g. past 12 months) in the ART register, look at age (column) (at start ART) and count all patients who were 12 months or younger. Tally the numerator for **MTCT.15** and denominator for **LINK.11** at the same as the numerator for **ART.1**. ***Denominator:*** in the HEI register, count all infants with date of delivery ≤12 months before start of the reporting period and a positive HIV test result (HIV test result=P) by 12 months of age (age in weeks/months when tested ≤12 months) [with appropriate test type for age]
Disaggregation	N/A
Narrative	While **MTCT.15** is an important quality-of-care and linkage indicator that can be measured periodically at the facility and nationally to make sure that the subset of HEI whose final status is confirmed HIV-positive receives immediate treatment to prevent disease progression and associated comorbidities, it is also the final intervention (and therefore potentially the least prioritized) measured along the PMTCT cascade: 1. PMTCT testing **(MTCT.1)**; and for those confirmed HIV+ 2. Maternal ART (coverage – **MTCT.2, 5**; retention – **MTCT.3, 17**); and 3. Infant ARV prophylaxis **(MTCT.4)**, CTX prophylaxis **(MTCT.9)** and infant testing **(MTCT.6)**; and for those confirmed HIV+ 4. Infant ART **(MTCT.15)**.

Indicator code and name	LINK.11 Timely linkage from diagnosis to treatment among children under 5 years of age
Indicator definition	**Percentage of children under age 5 who initiated ART within 1 month after diagnosis**
Priority level	Additional (national, subnational, facility)
Numerator	**Definition:** number of children under age 5 years living with HIV who initiated ART within 1 month after diagnosis within the reporting period **Data source:** HIV patient card, ART register **Data elements:** ART start date, age at start ART, unique ID, date HIV confirmed positive
Denominator	**Definition:** number of children under age 5 years living with HIV who initiated ART within the reporting period **Data source:** ART register **Data elements:** ART start date, age at ART start
Data collection methodology	***Denominator:*** count all children identified in the numerator for **ART.1 New ART patients** who are <5 years of age at start ART (age column). ***Numerator:*** pull all HIV patient cards for those children using their unique ID or patient clinic ID and look at date of confirmed HIV-positive test. Count all those with an ART start date one month or less from date of HIV-positive confirmation. These patients may be reconciled with HIV-exposed infants in the HEI register who have been confirmed HIV-positive during the reporting period using their date of birth/delivery or unique ID if recorded.
Subsets	When tallying this indicator, it is possible to also tally its subset: numerator for **MTCT.15**.
Frequency	Tally the denominator for **LINK.11** at the same time as the numerator for **ART.1**.
Disaggregation	N/A
Narrative	This may be included as a special subset of **ART.1 New ART patients**, and is recommended to be collected via electronic systems or at a sample of sentinel sites in settings with paper-based systems.

Key additional TB/HIV indicators

Tally the following indicators at the same time (during an annual patient monitoring review or other special survey).

LINK.5/18 TB screening coverage in HIV care

LINK.21 TB diagnostic test for people living with HIV

LINK.23 TB preventive therapy completion

LINK.24 Early ART for HIV-positive TB patients

LINK.25 Early ART for profoundly immunosuppressed HIV-positive TB patients

Indicator code and name	LINK.5/18 TB screening coverage in HIV care
Indicator definition	**Proportion of people living with HIV in care (including PMTCT) who were screened for TB in HIV care and treatment settings**
Priority level	National, subnational, facility
Numerator	**Definition:** number of persons enrolled in HIV care whose TB status was assessed and recorded at last visit during the reporting period **Data source:** HIV patient card **Data elements:** visit date, TB status (and Investigations, Refer [for cascade monitoring – *see Frequency*])
Denominator	**Definition:** number of persons enrolled in HIV care and seen for care during the reporting period **Data source:** HIV patient card **Data elements:** visit date
Data collection methodology	***Denominator:*** tally all patients who have had a visit date completed and any information filled in the corresponding encounter row during the reporting period. ***Numerator:*** tally those patients with any **TB status** recorded in the encounter row of the last visit during the reporting period.
Disaggregation	For electronic systems only: • sex • pregnant • age (<15, 15+)
Frequency	This indicator is one of several that measures the cascade of care – from screening, referral and investigations to diagnosis and treatment of TB – and may be collected using special surveys or facility-based annual review of HIV patient cards (*see* Section 2.6).
References	Intensified case-finding is the first "I" in WHO's "Three I's" TB/HIV strategy, which recommends the use of a simple algorithm relying on four clinical symptoms to screen all patients in HIV care for TB at *every* visit *(7)*. *See* TB/HIV M&E guide indicator B.1 for more information *(10)*.

Indicator code and name	LINK.21 TB diagnostic test for people living with HIV
Indicator definition	**Proportion of people living with HIV having TB symptoms who receive a rapid molecular test as a first test for diagnosis of TB**
Priority level	National, subnational, facility
Numerator	**Definition:** total number of people living with HIV having TB symptoms who were investigated using a rapid molecular test (e.g. Xpert MTB/RIF) as a first test **Data source:** HIV patient card **Data elements:** visit date, TB status, investigations
Denominator	**Definition:** total number of people living with HIV having TB symptoms identified through intensified case-finding at HIV care and treatment facilities during the reporting period **Data source:** HIV patient card **Data elements:** visit date, TB status
Data collection methodology	***Denominator:*** count all patients who have "Presumptive TB" recorded in the TB status column at any point during the reporting period. ***Numerator:*** of those patients identified in the denominator, count any who have "X" recorded in the Investigations column as a **first test** following the "Presumptive TB" code during the reporting period.
Disaggregation	N/A
Frequency	This indicator may be collected using special surveys or facility-based annual review of HIV patient cards (*see* Section 2.6).
Narrative	WHO strongly recommends the use of Xpert MTB/RIF as the initial TB diagnostic test for all adults and children with presumed MDR-TB or HIV-associated TB. It can quickly and accurately detect TB as well as rifampicin drug resistance. The technology is based on the GeneXpert platform, which may also be used for viral load monitoring in the future *(11)*.
References	*See* TB/HIV M&E guide indicator B.6 for more information *(10)*.

Indicator code and name	LINK.23 TB preventive therapy completion
Indicator definition	**Proportion of people living with HIV who complete the course of TB preventive therapy**
Priority level	National, subnational, facility
Numerator	**Definition:** total number of persons who completed the course of treatment for latent TB infection during the reporting period **Data source:** ART register, HIV patient card **Data elements:** TB preventive therapy complete date
Denominator	**Definition:** total number of persons in HIV care who were newly started on treatment for latent TB infection 12–15 months earlier **Data source:** ART register, HIV patient card **Data elements:** TB preventive therapy start date
Data collection methodology	**Denominator:** from the ART register, count all patients who have a recorded start date (TB preventive therapy column) that is 12 (annual reporting) or 12–15 (quarterly reporting) months prior to the reporting period. ***Numerator:*** of those patients identified in the denominator, count any patient whose TB preventive therapy complete month/year falls during the reporting period. Countries with <100% ART coverage (of those enrolled in HIV care) should also include patients who completed TB preventive therapy prior to starting ART by identifying them from the list of patients who may or will not start ART soon after enrolment into HIV care. For the denominator, add those patients who newly started TB preventive therapy 12 (or 12–15) months prior to the reporting period (*see* column under status at enrolment) not already included in the original ART register tally and pull their HIV patient cards. For the numerator, tally those patients from the HIV patient cards who completed TB preventive therapy (*see* TB status box on front of card) during the reporting period.
Disaggregation	N/A
Frequency	This indicator may be collected using special surveys or facility-based annual review of HIV patient cards or the ART register (*see* Section 2.6).
Narrative	In some settings, there is a dedicated TB preventive therapy register. This would greatly facilitate collection of this indicator. Where there is a register, count those patients who started TB preventive therapy 12 months prior and follow them to see whether they have completed therapy during the reporting period. Revised numerator to match TB/HIV M&E guide definition.
References	*See* TB/HIV M&E guide indicator B.13 for more information *(10)*.

Indicator code and name	LINK.24 Early ART for HIV-positive TB patients
Indicator definition	**Proportion of HIV-positive new and relapse TB patients who are started on ART within 8 weeks of TB diagnosis**
Priority level	National, subnational, facility
Numerator	**Definition:** total number of HIV-positive new and relapse TB patients registered started on ART within 8 weeks of TB diagnosis **Data source:** TB register, HIV patient card or ART register **Data elements:** TB status, investigations, ART start date, visit date
Denominator	**Definition:** total number of HIV-positive new and relapse TB patients identified during the reporting period **Data source:** TB register, HIV patient card or ART register **Data elements:** visit date, TB status, investigations
Data collection methodology	***Denominator:*** from the ART register or HIV patient cards, identify all patients who have confirmed (new and relapse) TB (TB status=TB+ in patient card or check in Status at ART start: TB+ column in ART register) during the reporting period. Reconcile this with those same patients identified through the TB register. ***Numerator:*** take all patients identified for the denominator and count those with an ART start date (on front of card or first column of ART register) within 8 weeks of TB diagnosis (TB status/Investigations column or TB lab register).
Subsets	**LINK.25 Early ART for profoundly immunosuppressed HIV-positive TB patients** ***Denominator:*** *number of HIV-positive new and relapse TB patients having CD4 cell count <50 cells/mm^3.* Using the same HIV patient cards pulled for the numerator of **LINK.24**, count patients who have CD4 count <50 cells/mm^3 (CD4 column) at time of TB diagnosis (TB status/Investigations columns). ***Numerator:*** *number of HIV-positive new and relapse TB patients during the reporting period with CD4 cell count <50 cells/mm^3 who are started on ART within 2 weeks of TB diagnosis.* Of those patients identified in the **LINK.25** denominator, count those with an ART start date within 2 weeks of TB diagnosis (*see* numerator for **LINK.24**).
Frequency	Both **LINK.24** and **LINK.25** may be collected during an annual review of patient cards.
Disaggregation	• Sex • Age (<15, 15+)
Narrative	Timely ART initiation is important to prevent high case fatality due to HIV-associated TB. Although it is important to monitor the timeliness of ART start, if countries have adopted the revised "treat all" guidelines, **LINK.24** and **LINK.25** may no longer be priority indicators. For countries that have yet to adopt them, or will undertake a phased approach to implementing the guidelines, these two indicators may remain a priority for national and subnational reporting.
References	*See* TB/HIV M&E guide indicators B.8 and B.9 for more information *(10)*.

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