SMART GUIDELINES

World Health Organization

DIGITAL ADAPTATION KIT FOR HIV

OPERATIONAL REQUIREMENTS FOR IMPLEMENTING WHO RECOMMENDATIONS IN DIGITAL SYSTEMS

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Digital adaptation kit for HIV: operational requirements for implementing WHO recommendations in digital systems

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LIST OF ABBREVIATIONS

ANC	antenatal care
ART	antiretroviral therapy
ARV	antiretroviral
BMI	body mass index
BPMN	Business Process Model and Notation
CDC	Centers for Disease Control and Prevention
CDS	clinical decision support
CHW	community health worker
CQL	Clinical Quality Language
CTX	co-trimoxazole
DAK	Digital adaptation kit
DE	data element
DIIG	Digital Investment Implementation Guide
DMN	Decision Model and Notation
DT	decision support table
DTDS	digital tracking and decision support
ED	event-driven
eHealth	electronic health
EID	early infant diagnosis
EMR	electronic medical record
FHIR	Fast Health care Interoperability Resources
HIV	human immunodeficiency virus
HL7	Health Level Seven International
HMIS	health management information system
HIVST	HIV self-test
HTS	HIV testing services
ICD	International Classification of Diseases
ICD-11	International Classification of Diseases (version 11)
ICF	International Classification of Functioning, Disability and Health
ICHI	International Classification of Health Interventions
ID	identification
IHE	Integrating the Health care Enterprise
ISCO	International Standard for Classification of Occupations
ITU	International Telecommunication Union
LOINC	Logical Observation Identifiers Names and Codes
M&E	monitoring and evaluation
MAPS	mHealth Assessment and Planning for Scale
mHealth	mobile health
MOH	ministry of health
NAT	nucleic acid test
NFXNREQ	Non-functional requirement
OpenHIE	Open Health Information Exchange
PEP	post-exposure prophylaxis
PMTCT	prevention of mother-to-child transmission of HIV
PrEP	Pre-exposure prophylaxis
RTD	rapid diagnostic test
SNOMED CT	Systematized Nomenclature of Medicine – Clinical Terms
STI	sexually transmitted infection
TB	tuberculosis
WHO	World Health Organization

1

OVERVIEW OF DIGITAL ADAPTATION KITS

Introduction

Background

Digital health – defined broadly as the systematic application of information and communications technologies, computer science and data to support informed decision-making by individuals, the health workforce and health systems, to strengthen resilience to disease and improve health and wellness *(1)* – is increasingly an essential enabler for health service delivery and accountability. Ministries of health have recognized the value of digital health as articulated in World Health Assembly resolution 71.7 *(2)* and the *Global strategy on digital health (3)*. Likewise, donors have advocated the rational use of digital tools as part of efforts to expand the coverage and quality of services, as well as to promote data use and monitoring *(4-6)*.

Despite the investments in and abundance of digital systems, however, there is often limited transparency in the health data and logic of these digital tools or in the relationship with evidence-based clinical or public health recommendations. This limited transparency not only undermines the credibility of such systems but also impedes opportunities for interoperability, which undermines the potential for improving continuity of care.

Evidence-based recommendations, such as those in WHO guidelines, establish standards of care and offer a reference point for informing the content of digital systems that countries adopt. However, guidelines are often available only in a narrative format that requires a resource-intensive process to be elaborated into the specifications needed for digital systems. This translation of guidelines for digital systems often involves subjective interpretation by implementers and software developers, which can lead to inconsistencies or inability to verify the content of these systems. In addition, where digital systems exist, the documentation of the underlying data and content may be unavailable or proprietary, requiring governments to start from scratch and expend additional resources each time they intend to deploy such a system. This lack of documentation of the health content can lead to dependence on one vendor and haphazard deployments that are unscalable or difficult to replicate across different settings.

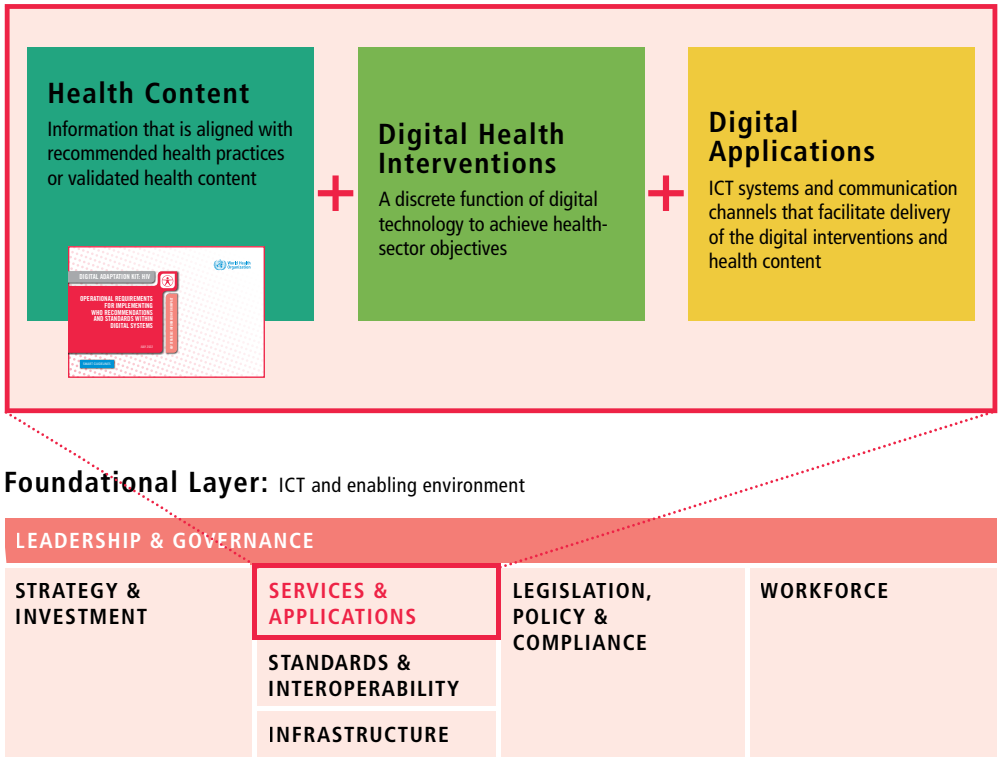
To ensure that countries can effectively benefit from digital health investments, "digital adaptation kits" (DAKs) are designed to facilitate the accurate reflection of WHO's clinical, public health and data use guidelines in the digital systems that countries are adopting. DAKs are operational, software-neutral, standardized documentations that distil clinical, public health and data use guidance into a format that can be transparently incorporated into digital systems. Although digital implementations comprise multiple factors – including (i) health domain data and content, (ii) digital intervention or functionality and (iii) digital application or communication channel for delivering the digital intervention – DAKs focus primarily on ensuring the validity of the health content (Fig. 1) *(1, 7)*. Accordingly, DAKs provide the generic content required in digital systems, independently of a specific software application and with the intention that countries can customize them to meet local needs.

For this particular DAK, the requirements are based on systems that provide the functionalities of digital tracking and decision support (Box 1) and include components such as personas, workflows, core data elements, decision-support algorithms, scheduling logic and reporting indicators. Operational outputs, such as spreadsheets of the data dictionary and the detailed decision-support algorithms, are included as practical resources that implementers can use as starting points when developing digital systems. Furthermore, data components within the DAK are mapped to standards-based terminology, such as the International Classification of Diseases (ICD), to facilitate interoperability.

The DAKs follow a modular approach in detailing the data and content requirements for a specific health programme area, such as antenatal care, family planning or sexually transmitted infections (STIs). This DAK focuses on providing the content requirements for a digital tracking and decision-support system for HIV care used by health workers in primary health care settings. It also includes cross-cutting elements focused on the client, such as self-care interventions, although these interventions are described from the perspective of the health worker, not from that of the clients.

This DAK focuses on providing the content requirements for a digital tracking and decision-support system used in primary health care settings by health workers for HIV.

Fig. 1. Digital adaptation kits and their role in digital health implementations



Box 1. What is digital tracking and decision support?

Digital tracking is the use of digitized records to capture and store clients' health information so as to enable follow-up of their health status and services received *(8)*. This may include digital forms of paper-based registers and case management logs as well as electronic patient records linked to uniquely identified individuals *(7, 8)*.

Digital tracking makes it possible to record and follow up patient services. This may be done through an electronic medical record (EMR) or other digital form of health records. Digital tracking aims to reduce lapses in continuity of care by stimulating timely follow-up contacts. It may also incorporate decision-support tools to guide health workers in: executing clinical protocols to deliver appropriate care, scheduling upcoming services, and following checklists for appropriate case management at the point of care. Some other descriptors include "digital versions of paper-based registers for specific health domains; digitized registers for longitudinal health programmes, including tracking of migrant populations' benefits and health status; case management logs for specific target populations, including migrant populations" *(8)*.

Health workers' decision support is defined as: "digitized job aids that combine an individual's health information with the health worker's knowledge and clinical protocols to assist health workers in making diagnosis and treatment decisions" *(8)*.Thus, a person-centred digital tracking and decision-support (DTDS) system is one used by health workers at the point of care; it includes a continuous record of health events and encounters that links to clinical decision-support systems to reinforce good practice. It also links to reporting and management tools to reinforce accountability. A DTDS record includes all the information required for detailing an individual's health status and the health interventions provided to them.

DTDS end-users are all health care providers, regardless of cadre or care level, including those operating outside formal health care facilities (for example, community health workers, health volunteers). DTDS systems emphasize the principle of "collect once, use for many purposes" *(9)*, in which data collected for service delivery can also be used for accountability (that is, they can be used to calculate aggregate indicators required for reporting, including monitoring provider, stock and system performance) *(10)*.

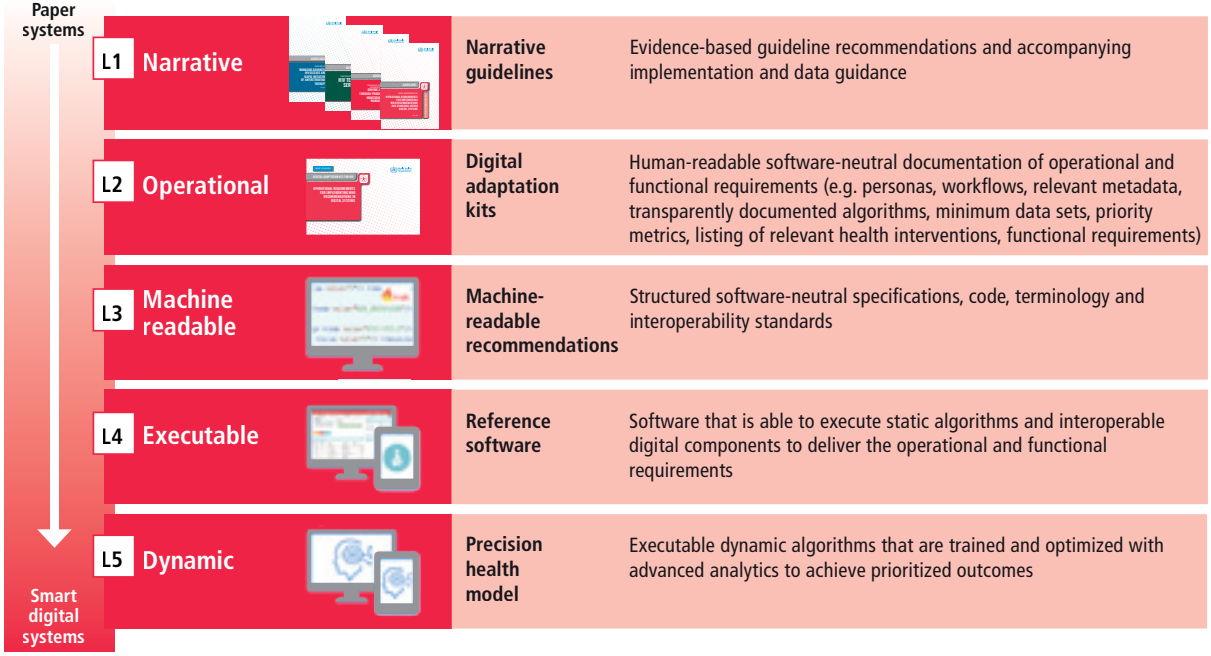
WHO has provided the following context-specific recommendation for the use of an integrated system that provides both digital tracking of clients' health status and decision support *(7)*:

Effective coverage **Accountability coverage**	Digital tracking of clients' health status and services (digital tracking) combined with decision support	**Recommendation 8:** WHO recommends digital tracking of clients' health status and services, combined with decision support under these conditions: • in settings where the health system can support the implementation of these intervention components in an integrated manner; and • for tasks that are already defined as within the scope of practice for the health worker. *(Recommended only in specific contexts or conditions)*

Digital adaptation kits within a strategic vision for SMART guidelines

The operational and standardized documentation reflected in the DAKs represents one step toward a broader vision of **S**tandards-based, **M**achine-readable, **A**daptive, **R**equirements-based and **T**estable (SMART) Guidelines. SMART Guidelines aim to maximize health impact through improved fidelity and uptake of recommendations through a systematic process for transforming guideline development, delivery and application into standards-based digital systems *(11, 12)*. Within this vision, DAKs serve as a prerequisite for developing computable, or machine-readable, guidelines, as well as executable reference software and advanced analytics for precision health. Fig. 2 provides an overview of the different layers of the SMART Guidelines continuum and where DAKs fit within this strategy *(12)*.

Fig. 2. Progressive layers across SMART Guideline components



Objectives

This DAK focuses on HIV. It aims to provide a common language across various audiences – managers of HIV programmes and other programmes, software developers and implementers of digital systems – to ensure a common understanding of the appropriate health information content within the defined health programme area of HIV. Its goal is to catalyse the effective use of these digital systems. The key objectives of the DAK are:

- to ensure adherence to WHO clinical, public health and data use guidelines;
- to facilitate consistency in the health content used to inform development of a person-centred digital tracking and decision-support (DTDS) system;
- to enable both health programme leads and digital health teams (including software developers) to have a joint understanding of the health content of the digital system, with a transparent mechanism to review the validity and accuracy of that content; and
- to provide a starting point for designing the core data elements and decision-support logic that should be included in DTDS systems for HIV.

Information detailed in this DAK reflects generic workflow processes, data and decision-support algorithms, as derived from WHO documents described below. This DAK also includes linkages to related services for sexually transmitted infections (STIs), tuberculosis (TB), hepatitis, and considerations for adolescents and key populations. Note that the outputs of the DAKs are intentionally generic and will need to be contextualized to local policies and requirements.

DAKs have also been developed for antenatal care (ANC), family planning (FP) and STIs, and this approach is being expanded to additional health domains, such as immunizations, postnatal care (PNC) and child health. To complement these, a forthcoming DAK for self-care interventions will take the perspective of a health care consumer. Together, these DAKs work towards a comprehensive approach for standardized software requirements for primary health care settings.

Components of a digital adaptation kit

The DAK comprises eight interlinked components:

1. health interventions and associated recommendations
2. generic personas
3. user scenarios
4. generic business processes and workflows
5. core data elements
6. decision-support logic
7. indicators and performance metrics
8. functional and non-functional requirements.

Table 1 provides an overview of each of these components, which this document elaborates. All information in the adaptation kit represents a generic starting point, which can then be adapted according to the specific context.

Table 1. Components of the digital adaptation kit

Component	Description	Purpose	Outputs	Adaptation needed
1. Health interventions and associated recommendations	Overview of the health interventions and WHO recommendations included in this DAK. DAKs are meant to be a repackaging and integration of WHO guidelines and guidance documents in a particular health domain. The list of health interventions is drawn from the universal health coverage (UHC) menu of interventions compiled by WHO *(13)*.	**Setting the stage** – To understand how this DAK would be applied to a digital tracking and decision-support system in the context of specific health programmes and interventions	• **List of relevant health interventions**, based on WHO's UHC essential interventions • **List of related WHO recommendations**, based on guidelines and guidance documents	• Contextualization to reflect current or planned national policies
2. Generic personas	Depiction of the end-users, supervisors and related stakeholders who would be interacting with the digital system or involved in the care pathway.	**Contextualization** – To understand the wants, needs and constraints of the end-users	• Description, competencies and essential interventions performed by these personas	• Greater specification and details on the end-users based on real people (that is, health workers) in a given context • High-level information to describe the provider of the health service (that is, general background, roles and responsibilities, motivations, challenges and environmental factors)
3. User scenarios	Narratives that describe how the different personas may interact with each other. The user scenarios are only illustrative and are intended to give an idea of a typical workflow.	**Contextualization** – To understand how the system would be used and how it would fit into existing workflows	• Example narrative of how the personas may interact with each other during a workflow	• Greater specification and details on the real needs of end-users in a given context
4. Generic business processes and workflows	A business process is a set of related activities or tasks performed together to achieve the objectives of the health programme area, such as registration, counselling, referrals *(1, 14)*. Workflows are a visual representation of the progression of activities (tasks, decision points, interactions) that are performed in the business process *(1, 14)*.	**Contextualization and system design** – To understand how the digital system would fit into existing workflows and how best to design the system for that purpose	• Overview matrix presenting the key processes in HIV services • Workflows for identified business processes, with annotations	• Customization of the workflows that can include additional forks, alternative pathways or entirely new workflows

Component	Description	Purpose	Outputs	Adaptation needed
5. Core data elements	Data elements required throughout the different points of the workflow. These data elements are mapped to International Classification of Diseases version 11 (ICD-11) codes and other established concept mapping standards to ensure that the data dictionary is compatible with other digital systems.	**System design and interoperability** – To know which data elements need to be logged and how they map to other standard terminologies (for example, ICD, Systematized Nomenclature of Medicine [SNOMED]) for interoperability with other standards-based systems	• List of data elements • Link to **data dictionary** with detailed data specifications in spreadsheet format (Web Annex A)	• Translation of "data labels" into the local language and additional data elements created depending on the context
6. Decision-support logic	Decision-support logic and algorithms to support appropriate service delivery in accordance with WHO clinical, public health and data use guidelines.	**System design and adherence to recommended clinical practice** – To know what underlying logic needs to be coded into the system	• List of decisions that need to be made throughout the encounter • **Link to decision-support tables** in a spreadsheet format specifying inputs, outputs and triggers for each decision-support logic (Web Annex B) • Scheduling logic for services (Web Annex B)	• Change of specific thresholds or triggers in a logic (IF/THEN) statement – for example, body mass index (BMI) cut-off, age trigger for "youth friendly" services • Additional decision-support logic formulas, depending on the context
7. Indicators and performance metrics	Core set of indicators that need to be aggregated for decision-making, performance metrics and subnational and national reporting. These indicators and metrics are based on data that can feasibly be captured from a routine digital system, rather than from survey-based tools.	System design and adherence to recommended health monitoring practices – To know what calculations and secondary data use are needed for the system, based on the principle of "collect once, use many" *(9)*.	• **Indicators table** with numerator and denominator of data elements for calculation, along with appropriate disaggregation (Web Annex C)	• Changing calculation formulas of indicators • Adding indicators • Changing the definition of the primary data elements used to calculate the indicator, based on data available
8. Functional and non-functional requirements	List of core functions and capabilities that the system must have in order to meet the end-users' needs and accomplish tasks in the business process.	**System design** – To know what the system should be able to do	• **Table of functional and non-functional requirements**, specifying the intended end-user of each requirement as well as why that user needs that functionality in the system (Web Annex D)	• Adding or reducing functions and system capabilities based on budget and end-user needs and preferences

Box 2. Guidance on Identification notation

Within the DAK identification (ID) numbers simplify tracking and referencing of each of the components. Note that the DAK represents an overview across the different components, while the comprehensive and complete outputs of each component (that is, data dictionary, decision-support tables) are included in appended spreadsheets. The notation guidance is as follows.

- Component 1: Health interventions and associated recommendations
  - No notations used
- Component 2: Generic personas
  - No notations used
- Component 3: User scenarios
  - No notations used
- Component 4: Business processes and workflows
  - Each workflow should have a "Process name" and a corresponding letter
    Each workflow should also have a "**Process ID**" that should be structured "**Abbreviated health domain**" (in this case, "HIV")."**Letter corresponding to the process**". – thus, for example, "HIV.A".
  - Each activity in the workflow should be numbered with an "**Activity ID**" that should follow the process name and process ID letter – thus, for example "HIV.B7".
- Component 5: Core data elements (data dictionary)
  - Each data element should have a running number and a "**Data Element (DE) ID**" that should be structured as follows:
    "**Abbreviated health domain**" (that is, HIV)."**DE**"."Sequential number of the data element" – thus, for example, "HIV.B7.DE.1", "HIV.B7.DE.2".
- Component 6: Decision-support logic
  - Each decision-support logic table should have a running number and a "**Decision-support table (DT) ID**" that should be structured as follows:
    "**Abbreviated health domain**" (that is, HIV)."**DT**"."Sequential number of the decision-support table" – thus, for example, "HIV.DT.01", "HIV.DT.02".
- Component 7: Indicators and performance metrics
  - Each indicator should have an "**Indicator ID**" that should be structured as follows:
    "**Abbreviated health domain**" (that is, HIV)."**IND**"."Sequential or reference number of the indicator" – thus, for example, "HIV.IND.PR.1", "HIV.IND.PR.2".
- Component 8: High-level system requirements
  - Each functional requirement should have a "**Functional requirement ID**" that should be structured as follows:
    "**Abbreviated health domain**" (that is, HIV)."**FXN.REQ**".
    "Sequential number of the functional requirement" – thus, for example, "HIV.FXN.REQ.1", "HIV.FXN.REQ.1".
  - Each non-functional requirement should have a "**Non-functional requirement ID**" that should be structured as follows:
    "**Abbreviated health domain**" (that is, HIV). "**NFXNREQ**".
    "Sequential number of non-functional requirement" – thus, for example, "HIV.NFXNREQ.001", "HIV.NFXNREQ.002)".

How to use this digital adaptation kit

Target audience

The primary audience for this DAK is health programme managers in ministries of health who will be working with their digital or health information systems counterparts to determine the health content requirements for a DTDS system. The health programme manager is responsible for overseeing clinical practices and policies for the health programme area, in this case HIV services.

The DAK also equips individuals responsible for incorporating health system processes and guidance into digital systems with the necessary components to kick-start the process of developing a DTDS system in a standards-compliant manner. These individuals are known as business analysts, and they are the interface between health content experts and software development teams. Specifically, the DAK contains key artifacts, such as data dictionaries and decision support algorithms, to ensure the validity and consistency of the health content in the DTDS system.

Using this adaptation kit requires collaboration between health programme managers responsible for HIV with counterparts in digital health and health information systems. Although each adaptation kit focuses on a particular health programme area (in this case HIV), the adaptation kits are meant to be used in a modular format and to link to other health programme areas in primary health care settings, in the effort to support integration across services.

Scenarios for using the digital adaptation kit

The adaptation kit may be used across a combination of different scenarios, some of which are listed below.

- **Scenario 1: Incorporating WHO guideline content into existing digital tracking and decision support systems**

Countries that already have digital systems in place, such as electronic medical records (EMRs) and decision support tools, may use the information in this adaptation kit to cross-check whether the underlying content and data for specific health programme areas, such as HIV, FP, or ANC, are aligned with WHO guidelines. Users of the adaptation kit can identify and extract specific decision algorithms that would need to be incorporated into their existing digital systems. By reviewing this systematic documentation, health programme managers and implementers can more readily identify differences across health domains in workflows, data inputs and decision logics in order to examine the rationale for deviations and to support future learning, for example from data analysis, including machine learning.

- **Scenario 2: Moving from paper to DTDS systems**

Some countries may currently have paper-based systems that they would like to digitize. The process of optimizing paper-based client-level systems into DTDS systems may seem overwhelming. In this scenario users may review the adaptation kit as a starting point for streamlining the necessary data elements and decision support that should be included in the optimized client-level digital system. Users may also refer to the paper-based tools to determine if there are fields or content missing that should also be included in the digital system.

Users should also review the WHO *Handbook for digitizing primary health care (15)*, which provides step-by-step guidance on how to map data on paper-based forms into a digital system, including ways of accounting for data elements that are redundant or may not add value to the health system.

- **Scenario 3: Linking aggregate HMIS (for example, the District Health Information Software 2 [DHIS2]) to DTDS systems used at the point of care**

In some instances countries may already have a digital system for aggregate reporting and HMIS but may not yet have implemented digital systems that function at the service delivery level. The adaptation kit can guide the development of a digital client record system, which operates at the point of care, and ensures that there are linkages between the aggregate and service delivery levels.

- **Scenario 4: Leveraging data standards to promote interoperability and integrated systems**

To support the design of interoperable systems, this DAK includes data elements mapped to ICD codes and other standards. The data dictionary in Web Annex A provides the necessary codes for different data elements, thus reducing the time needed for implementers to incorporate these global standards into the design of their digital systems.

Assumptions

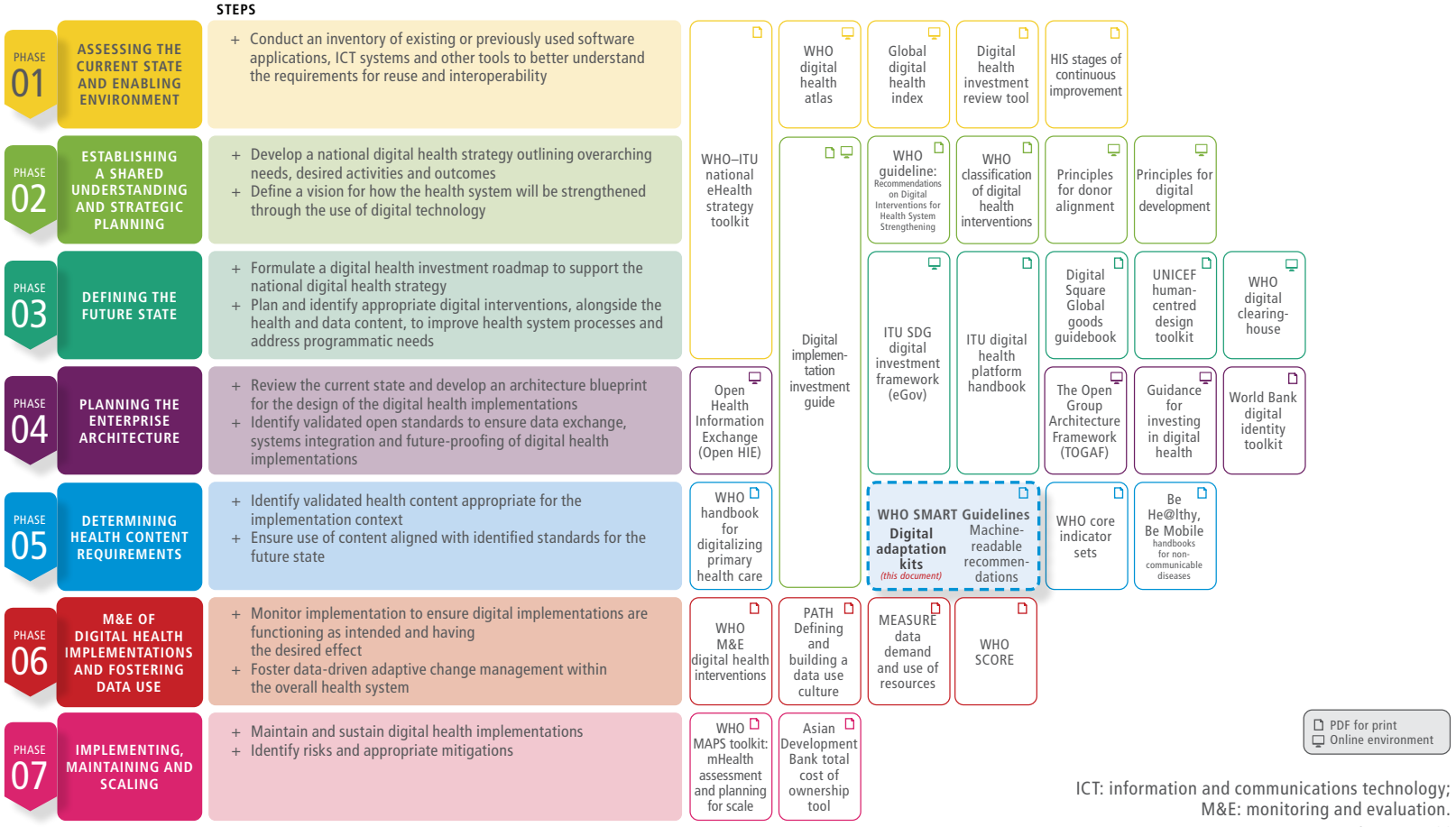
The use of this DAK for HIV is based on the following critical assumptions:

- Countries will need to adapt the content based on the country's policies.
- Health workers represented here are trained to provide HIV services, including services friendly to key populations and adolescents. Note that, because of this assumption, guidance provided regarding counselling is limited to key messages. However, additional back-and-forth counselling and training are assumed to take place.

Linkages to the digital ecosystem

The DAKs should be used once the ministry of health has developed a strategic vision for a DTDS system in primary health care settings. Where such a vision may not exist, users should first consult the WHO/International Telecommunication Union eHealth Strategy Toolkit, *WHO guideline: recommendations on digital interventions for health system strengthening* (2019) *(7)* and WHO's *Digital investment implementation guide (DIIG): integrating digital interventions into health programmes* (2020) *(1)* to better understand how to select and implement appropriate digital health interventions. Additionally, organizations planning to use DTDS systems should assess the maturity of the digital enabling environment and health information systems, using tools such as the *Health Information Systems Strengthening Resource Center: stages of HIS progression (16)*; *Health information systems interoperability maturity toolkit: model (17)*; WHO's Digital health atlas *(18)*; and the Global digital health index *(19)*. Fig. 3 presents, on the left, the stages and steps of planning and implementing a digital health enterprise and, on the right (in grey), useful resources for each stage.

Fig. 3. Digital adaptation kits within the broader digital health ecosystem



ICT: information and communications technology; M&E: monitoring and evaluation.

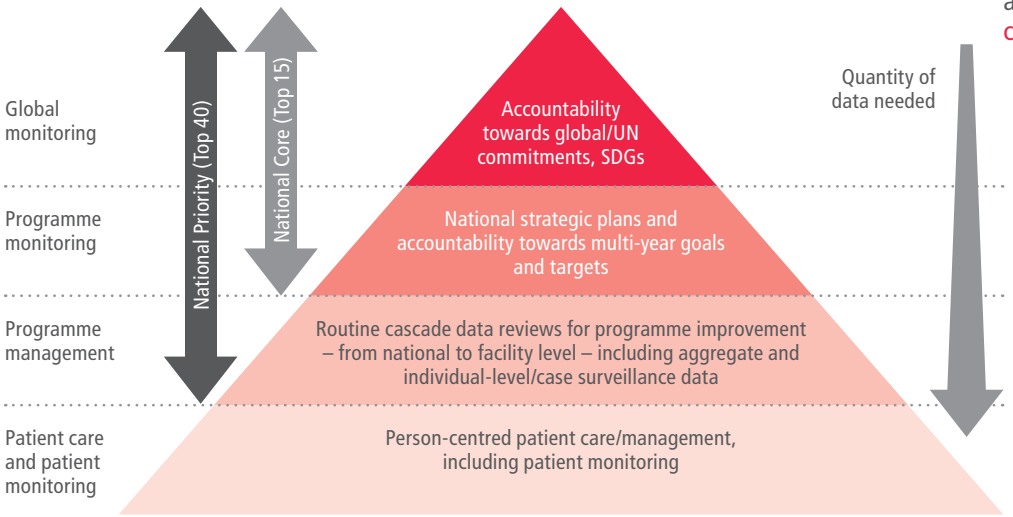
Source: Adapted from WHO *(1)*

The DAKs focus on services provided by health workers at primary health care facilities. They are intended to complement secondary data uses (Fig. 4) and related resources addressing other levels of the health system, namely:

- **Linkages to client-facing digital tools (for example, home-based records, self-care digital health interventions, community-based services)** Engaging with clients is a critical part of service delivery. Digital interventions addressed to clients – such as targeted client communication (for example, transmitting health information and reminders), collecting feedback on the quality of care, accessing their own medical records/home-based records and self-monitoring of their health and diagnostic data – are all emerging approaches for complementing the services provided by health workers. The content requirements for these client-facing digital tools will be included in an updated version of this adaptation kit.

- **Linkages to aggregate facility-based indicators and HMIS** Increasingly, countries that have established aggregate digital HMIS (through systems such as DHIS2) are moving towards client-level digital systems used by health workers at the point of care. Digital systems facilitate the ability to automatically compile data generated at the point of care and contribute to the aggregated facility-based indicators, thus reducing the burden of manual tabulations on health workers. This adaptation kit is intended to support the transition to client-level digital systems and inform the content requirements for digital systems used by health workers at the service provision level. A component of the adaptation kit provides aggregate indicators derived from individual-level data to facilitate linkage between these levels. However, complementary guidance dedicated specifically to aggregate-level data also should be consulted. Programme managers should use WHO's *Consolidated HIV strategic information guidelines* (2020) *(10)* and *WHO toolkit for analysis and use of routine health facility data: guidance for HIV programme managers (20)* to support the use of routine data at the facility management and district levels. (See also https://www.who.int/data/data-collection-tools/analysis-use-health-facility-data).

Fig. 4. Health data use cases



Source: Consolidated HIV strategic information guidelines. Geneva, WHO; 2020 *(10)*.

CONTENT OF DIGITAL ADAPTATION KIT FOR HIV SERVICES

II

COMPONENT 1 HEALTH INTERVENTIONS AND ASSOCIATED RECOMMENDATIONS

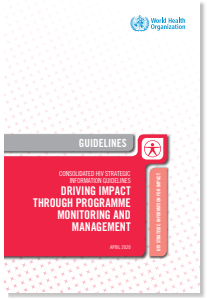
1.1. List of interventions referenced in this digital adaptation kit

Interventions referenced in this digital adaptation kit are based on WHO's universal health coverage list of essential interventions *(13)*.

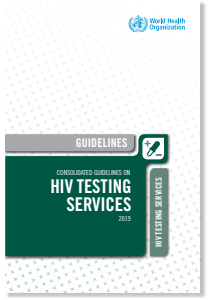
- health promotion and prevention of HIV
- diagnosis of HIV
- treatment of HIV
- treatment of complications of HIV.

1.2. WHO guidelines, recommendations and guidance

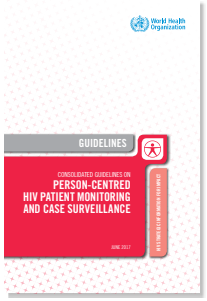
The interventions in this kit draw from the following WHO guidelines and guidance:



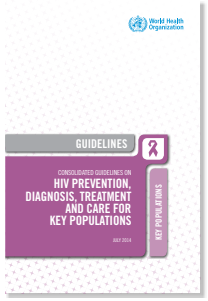
Consolidated HIV strategic information guidelines: driving impact through programme monitoring and management (2020)



Consolidated guidelines on HIV testing services (2019)[1]

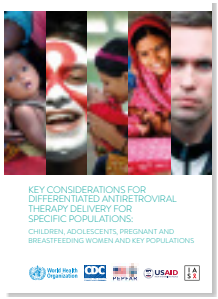


Consolidated guidelines on person-centred HIV patient monitoring and case surveillance (2017)

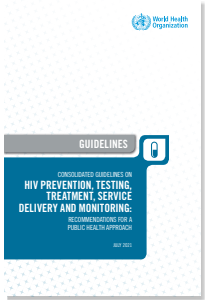


Consolidated guidelines on HIV prevention, diagnosis, treatment and care for key populations (2014)

[1] Full contents of the guideline are available as an application for Android and Apple devices. Accessible from: https://www.who.int/news/item/12-11-2020-who-hts-info-app.

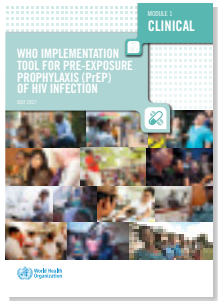


Key considerations for differentiated antiretroviral therapy delivery for specific populations: children, adolescents, pregnant and breastfeeding women and key populations (2017)

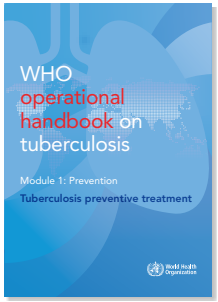


Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach (2021)

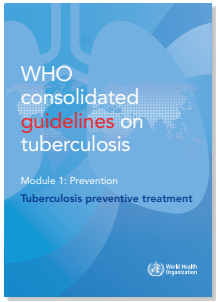
What's the 2+1+1? Event-driven oral pre-exposure prophylaxis to prevent HIV for men who have sex with men. Update to WHO's recommendation on oral PrEP (2019)



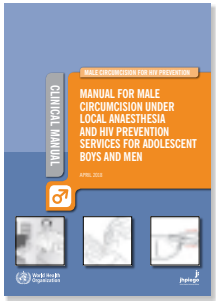
WHO implementation tool for pre-exposure prophylaxis of HIV infection (2017)[2]



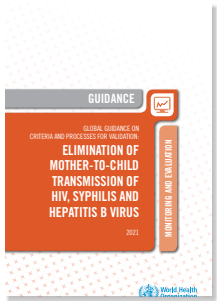
WHO operational handbook on tuberculosis: module 1: prevention: tuberculosis preventive treatment (2020)



WHO consolidated guidelines on tuberculosis: module 1: prevention: tuberculosis preventive treatment (2020)



Manual for male circumcision under local anaesthesia and HIV prevention services for adolescent boys and men (2018)[1]



Global guidance on criteria and processes for validation: elimination of mother-to-child transmission of HIV, syphilis and hepatitis B virus (2021)

[1] A new guideline was released in August 2020: https://www.who.int/publications-detail-redirect/978-92-4-000854-0.
[2] A new guideline was released in July 2022: https://www.who.int/publications/i/item/9789240053694.

COMPONENT 2 GENERIC PERSONAS

A persona is a depiction of a relevant stakeholder, or "end user" of the system. Although the specific roles and demographic profiles of the personas will vary depending on the setting, these generic personas are based on the WHO core competencies and credentials of different health worker personas. This is a starting point, generalized based on multiple contexts, and further contextualization will be required to truly understand the needs, motivations and challenges of the personas addressed.

2.1. Targeted generic personas

In the case of HIV, trained lay providers, nurses and non-physician clinicians who are providing HIV-related services are the primary personas for the digital client health record and decision support system. WHO describes the key competences of lay providers, nurses and non-physician clinicians as follows:

To encourage and guide task sharing, WHO has developed recommendations on which types of health workers can safely and effectively provide HIV prevention, testing and treatment services. These recommendations are included in WHO guidelines for HIV services. Many countries and programmes are changing policies and regulations to allow more types of providers to deliver services.

2.2. Related personas

In addition to the three central personas detailed above, other personas play a role in HIV services. These additional personas are listed in Table 3.

Table 2. Descriptions of key generic personas

Occupational title	Description *(21)*	Other names/examples	ISCO code
Trained lay provider	A person who has been trained and supervised to independently perform functions related to health care delivery and to deliver specific services but who has received no formal professional or paraprofessional certificate or tertiary educational degree. Peers can be trained to function as lay providers *(22)*.	Counsellor	3259 (Health associate professionals not elsewhere classified)
Nurse	A graduate who has been legally authorized (registered) to practice after examination by a state board of nurse examiners or similar regulatory authority. Education includes three, four or more years in nursing school, and it leads to a university or postgraduate university degree or the equivalent. A registered nurse has the full range of nursing skills *(23)*.	Registered nurse, clinical nurse specialist, advance practice nurse, practice nurse, licensed nurse, primary care nurse	2221 (Nursing professional)

Occupational title	Description *(21)*	Other names/examples	ISCO code
Trained non-physician clinician	A professional health worker who is capable of many of the diagnostic and clinical functions of a physician but who is not trained as a physician. These types of health workers are an important cadre for HIV care and treatment in some countries. Normally, completion of tertiary-level training in theoretical and practical medical services *(24)*. They work autonomously or with limited supervision of medical doctors and provide advisory, diagnostic, curative and preventive medical services more limited in scope and complexity than those carried out by medical doctors.	Clinical officer, health officer, physician assistant, nurse clinician	2240 (Paramedical practitioner)

ISCO = International Standard Classification of Occupations.

Table 3. Descriptions of related personas

Name	Description *(21)*	Other names/examples	ISCO code (if relevant) *(21)*
Client	In the context of this document, a client is a person who is given medical care, which may include HIV prevention, care or treatment services. Clients may be HIV-positive or HIV-negative, or they may not know their HIV status. A client living with HIV may be enrolled to receive antiretroviral treatment (ART) and/or other HIV-related treatment and care *(25)*.	Patient	N/A
Key populations	A member of a key population is someone who, due to specific higher-risk behaviours, is at an increased risk of HIV irrespective of the epidemic type or local context. Key population groups also often have legal and social issues related to their behaviours that increase their vulnerability to HIV. Five key populations are included in this kit: (1) men who have sex with men, (2) people who inject drugs, (3) people in prisons and other closed settings, (4) sex workers and (5) transgender people. Key populations are important to the dynamics of HIV transmission and are essential partners in an effective response to the epidemic *(26, 31)*.	Men who have sex with men, people who inject drugs, people in prisons and other closed settings, sex workers, transgender people	N/A
Special population client	A person from a specific group that requires or would benefit from differentiated client management or services. The groups may include key populations, paediatric or adolescent clients, adolescent girls and young women, pregnant or breastfeeding women, tuberculosis (TB) patients, serodiscordant partners and other specific priority populations *(10)*.	Key populations, pregnant women, adolescent girls and young women	N/A
Community health worker	A person who provides health education, referral and follow-up, case management and basic preventive health care and home visiting services to specific communities. Examples of HIV services that they provide include HIV testing, distributing HIV self-test (HIVST) kits, counselling in the community, monitoring adherence to ART and pre-exposure prophylaxis (PrEP) and drug pick-up, and following up and tracing lost patients. The occupation normally requires formal or informal training and supervision required by the health and social services authorities *(25)*.	Community health volunteer, village health worker, treatment supporter, health promotors, etc.	3253 (Community health workers) – varies by context

Name	Description *(21)*	Other names/examples	ISCO code (if relevant) *(21)*
Data entry clerk	An individual who helps to record, organize, store, compute and retrieve information, including patient records and registers. The knowledge and skills required are usually obtained through on-the-job training but may include post-secondary education. Clerks may also transcribe data, tally data, fill in routine reports and review the quality of data with others.	Data capturer	3252 (Medical records and health information technicians)
Physician	A legally qualified and licensed practitioner of medicine, concerned with maintaining or restoring human health through the study, diagnosis and treatment of disease and injury, through the science of medicine and the applied practice of that science. A medical doctor requires training in a medical school. Gaining a basic medical degree may take from five to nine years, depending on the jurisdiction and the university providing the training	Family doctor, general practitioner, medical officer, medical doctor	2211 (Generalist medical practitioners); 2212 (Specialist medical practitioner)
Specialist medical doctor	A doctor who diagnoses, treats and prevents illness, disease, injury and other impairments using specialized testing and diagnostic, medical, surgical, physical and psychiatric techniques. These providers may also plan, supervise and evaluate the implementation of care and treatment plans by other health care providers. They specialize in certain disease categories, types of clients or methods of treatment and may conduct medical education and research activities in their chosen areas of specialization.	Infectious disease specialist, specialist physician (internal medicine), surgeon, emergency medicine specialist, ophthalmologist, gynaecologist,	2212 (Specialist medical practitioner)
District health information officer	A manager supervising the monitoring system to track quality of care and data. This person provides a link between the health centre and central level to ensure that patient monitoring needs are met (for example, adequate staffing, tools and other resources) and implements changes to data standards or norms *(15)*.	District health manager, health management information systems focal point, monitoring and evaluation focal point, facility supervision manager	1342 (Health service manager)
Lab technician	A person who performs clinical tests on specimens of bodily fluids and tissues in order to get information about the health of a patient, as well as conducts tests and operates equipment for analysis of biological material, including blood and urine. This person normally has completed formal training in biomedical science, medical technology or a related field *(21)*.	Medical laboratory technician, medical laboratory assistant	3212 (Medical and pathology laboratory technicians)
Pharmacist	The pharmacist stores, preserves, compounds and dispenses medicinal products, as well as counsels on the proper use and adverse effects of drugs and medicines following prescriptions issued by other health professionals. This individual has completed university-level training in pharmacy or pharmaceutical chemistry *(21)*.	Dispenser	2262 (Pharmacists)

ISCO = International Standard Classification of Occupations; N/A = not applicable.

2.3. Additional considerations for contextualizing personas

This section provides an overview of the generic roles of the three targeted personas. It will be important to contextualize these personas to local settings. The descriptions of the generic personas given above can be supplemented by reflecting on these additional considerations:

- **background and demographics** (for example, gender, age, whether from the community, familiarity with digital devices, possession of a mobile phone/smartphone, etc.)
- **local environment** and any relevant contextual information about the surroundings (for example, work site characteristics; rural or urban; availability of electricity, water or Internet; distance from nearest referral facility, etc.)
- **expected roles and responsibilities:** What are the ***expected*** roles and responsibilities based on country context? How does this differ from the roles and responsibilities defined by WHO?
- **actual roles and responsibilities:** What are their ***actual*** roles and responsibilities, if there is any difference from what is expected?
- **context:** What is the availability of Internet connectivity? How are these personnel compensated? What is the distance to the nearest referral facility? What other personas/health workers do they interact with?
- **challenges:** What are the day-to-day challenges that the end user might face?
- **motivations:** What does success look like to them? Are there performance targets that they are expected to achieve?

For more details on developing personas, please refer to the WHO *Handbook for digitalizing primary health care (15)*.

2.4. Additional considerations for key populations

Data relating to an individual's risk behaviour and key population status are important both for providing appropriate services and for programme monitoring. However, in many settings consensual same-sex sexual activity, sex work or drug use and possession are criminalized and associated with stigma and discrimination. Collecting identifiable information linked to these behaviours from individuals accessing health services raises the potential for negative consequences both to clients and to service providers. Because of these sensitivities, it is recommended that data collected on criminalized and stigmatized populations remain anonymous.

HIV prevention services can be effectively and efficiently provided and individuals can be followed longitudinally using anonymous unique identification codes, without the collection of personally identifying information.

In the context of HIV treatment services where personally identifying information is routinely collected on treatment recipients, it is not recommended to collect information that might indicate an individual's engagement in stigmatized or criminalized behaviours or their key population status. Only information that is clinically relevant should be included in clinical records where individuals are personally identified. Clinical information such as alcohol or other drug dependence, concomitant medications (including opioid agonist treatment (OAT) and hormone therapy) and sexual risk behaviour has relevance to clinical care and can be included in secure clinic records.

COMPONENT 3 ILLUSTRATIVE USER SCENARIOS

User scenarios are narrative descriptions of how different personas would interact with each other. The user scenarios can help readers better understand how the system will be used and how it would fit into existing workflows. The following illustrative scenarios may be common in HIV services, but this is not an exhaustive set of possible interactions. They are intended only to give context to the workflows presented in Component 4.

3.1. User scenario for HIV testing services visit

Table 4. User scenario for HIV testing visit

Key personas	• trained lay provider: Richard • client: Winnie, 18-year-old girl • registration clerk: Felicia • clinical officer: Hadija
One of Winnie's sexual partners in the previous six months tested positive for HIV. This partner had accepted partner services, and so Winnie was contacted and counselled that she may have been exposed to HIV. Winnie has arranged to come to the HIV testing facility. Winnie is an 18-year-old adolescent who has come to the testing facility on the invitation of the health care provider who contacted her. At reception, the registration clerk, Felicia, checks Winnie in and learns that she is a new client who wants to be tested for HIV. Winnie attends a group pre-test information session and then is called in for testing. Her vital signs are taken; they are normal. Also, she is checked for signs of serious illness; she has none. Richard, a trained lay provider, gives Winnie a rapid antibody test, per the national testing algorithm. Winnie's HIV test result is negative. Richard then provides Winnie with post-test counselling and discusses other services with her. While talking about other services, Winnie expresses interest in PrEP. Richard asks Winnie to wait so that she can talk about PrEP with a clinical officer, Hadija, who also would be able to prescribe PrEP. Hadija talks to Winnie more about PrEP and checks to see if Winnie would be eligible for PrEP. Winnie has just tested negative for HIV, so that eligibility criterion is met. She also meets the other eligibility criterion, substantial ongoing risk of HIV infection, as she was treated for an STI in the past six months and is in a serodiscordant relationship. She has not had recent exposure to HIV, so she is not in need of or eligible for post-exposure prophylaxis (PEP). After being counselled on PrEP, Winnie decides that she would like to start taking it. Hadija also offers her other services, including family planning services and testing for STIs. After determining which tests to perform, Hadija writes lab orders for Winnie to take to the lab next, including one for a creatinine test (to check kidney function), as well as a prescription for PrEP. Hadija checks follow-up requirements and schedules a follow-up visit for one month later. Winnie then goes to the lab to have the necessary specimens collected, after which she goes to the pharmacy, where her drugs will be dispensed.	
Corresponding business processes (see Component 4)	This scenario refers to the following business processes: • HIV.A. Registration • HIV. B. HIV testing services visit • HIV. C. PrEP visit

3.2. User scenario for HIV care and treatment clinical visit

Table 5. User scenarios for HIV care and treatment clinical visit

Key personas	• Nurse: Irene • Client: Sam, a 41-year-old man on ART • Registration clerk: Anna
Sam is a 41-year-old man who has gone to the ART clinic for a routine clinical visit and to refill his ART medications. He has been receiving care at the facility since last year, after transferring from another facility where he had been receiving care. Between clinical visits, Sam receives his medications from a peer counsellor. When Sam checks in for his appointment, he shows the clerk, Anna, his appointment card, and the clerk finds him in the system by a unique identifier. He is also assessed for TB symptoms; he has none. Irene, a clinical officer, invites Sam into a private space and does a quick check to confirm he is not showing signs of a serious illness, which he is not. She also takes his vital signs. The ART clinic primarily provides services to men who have sex with men. Last month Irene completed a refresher training to educate and sensitize providers on working with key populations. She applies what she learned to offer friendly services tailored to Sam's individual needs. Irene looks up in Sam's record and sees that he began ART four years ago and that he was clinically stable at his last visit. The country's preferred first-line regimen for adults has been updated, but Sam is still taking the same regimen he started with, which is now an alternative first-line regimen for the country. Irene also sees that the results from Sam's last HIV viral load test showed that he was still virally suppressed, but he had not been told the results. Irene tells Sam the results of the viral load test results and records that these results have now been shared with Sam. Irene also sees in Sam's records that he hasn't reported any previous adherence issues and assess if he has any barriers and additional adherence support he would like to address with her. Sam informs that he has no issues to report today. Irene determines which other screenings and tests to perform, such as tests for coinfections. Irene counsels Sam on voluntary partner services. In passing, he tells her that his current partner's HIV status is negative and that his partner has started taking PrEP. Irene recommends routine voluntary HIV testing for Sam's partner nonetheless. As Sam is still clinically stable and meets all established on ART criteria and explains to Sam that he can have access to differentiated service delivery models or less frequent ART refills. Sam shows interest in less frequent ART refills for every 6 months so Irene provides a prescription for six months of medication. She schedules a follow-up clinical visit for Sam in six months. When Sam checks out, Anna gives him an appointment card with the date and time of his follow-up visit. Sam then goes to the pharmacy to pick up six months of medication.	
Corresponding business processes (see Component 4)	This scenario refers to the following business processes: • HIV.A. Registration • HIV.D. Care and treatment clinical visit

4.1. Overview of key business processes

A business process is a set of related activities or tasks performed together to achieve an objective of the health programme, such as registration, counselling or referrals *(1)*. Workflows are a visual representation of the progression of activities (tasks, events, interactions) that are performed within the business process *(1)*. The workflow provides a "story" for the business process being diagrammed and is used to aid communication and collaboration among users, stakeholders and engineers.

This DAK focuses on key business processes conducted by the nurse persona (described in Table 2) within HIV service delivery. The key HIV business processes are described in table 6. The workflows of the identified processes use standardized notation for business process mapping. Figure 5 first provides an overview of this notation. For each process type, the corresponding business processes, data elements and decision support needs are detailed in the subsequent sections of this document.

Table 6. Key HIV business processes

#	Process	Process ID	Personas	Objectives	Task set
	Name	ID used to reference this process throughout this adaptation kit	Individuals interacting to conduct the process	What the process seeks to achieve	The general set of activities performed within the process
A	Registration	HIV.A	• client • clerk or health care provider (for example, lay provider, nurse, clinician)	To ensure that the client is located in the records system and personal details are updated or, if not located, entered into the system to be put into a queue awaiting counselling.	*Starting point: Client arrives at facility and checks in with clerk.* • Search for client's record. • Review and update client's record. • Create a new client record.

#	Process	Process ID	Personas	Objectives	Task set
	Name	ID used to reference this process throughout this adaptation kit	Individuals interacting to conduct the process	What the process seeks to achieve	The general set of activities performed within the process
B	HIV testing services (HTS)	HIV.B	• client • health care provider	To diagnose individuals with HIV and facilitate their engagement in care and ART initiation as early as possible, as well as to counsel HIV-negative clients and link them to prevention and other services.	*Starting point: Client has been registered at the health facility (Process HIV.A) and called in for testing. HIV testing may be integrated with other care, such as ANC or family planning.* • Take client history. • Provide pre-test information. • Test, following national testing algorithm. • Provide test result, post-test counselling, and information on prevention services or counselling on ART initiation. • Schedule retests. • Offer voluntary partner services and family services. • Determine follow-up requirements. • Provide or offer integrated services. • Link or refer to prevention, care or treatment.
C	Pre-exposure prophylaxis (PrEP) visit	HIV.C	• client • health care provider (for example, nurse, clinician)	To provide the client with PrEP as a prevention choice for people at substantial risk of HIV infection, as part of a combination of HIV prevention approaches.	*Starting point: Client has been registered at the health facility and called in for testing. Client has expressed interest in PrEP or other prevention options.* • Take client history. • Test for HIV. • Check eligibility for PrEP. • Discuss PrEP or PEP. • Conduct screenings for STIs • Prescribe. • Provide adherence counselling. • Arrange for follow-up as needed.

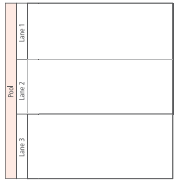
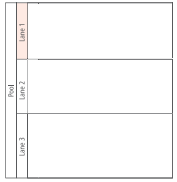
#	Process	Process ID	Personas	Objectives	Task set
	Name	ID used to reference this process throughout this adaptation kit	Individuals interacting to conduct the process	What the process seeks to achieve	The general set of activities performed within the process
D	Care and treatment clinical visit	HIV.D	• client • health care provider (for example, nurse, clinician)	To initiate ART and to provide HIV care, treatment and integrated health services.	*Starting point: Client has already been registered at the health facility and is being seen for a clinical visit. Service may be integrated with other care, such as antenatal or TB care.* • Take client history. • Perform retesting if client is new to ART. • Counsel. • Determine recommended screenings and tests. • Examine the client, including determining the HIV stage. • Determine recommended screenings and tests. • Review diagnostic results with client. • Provide adherence monitoring, counselling and support. • Determine client's eligibility for multi-month dispensing or differentiated service delivery for HIV treatment (DSD ART) models. • Manage common coinfections and comorbidities. • Determine and prescribe regimen. • Offer or provide other integrated services. • Arrange for follow-ups.
E	Prevention of mother-to-child transmission of HIV (PMTCT) – Delivery and postpartum care	HIV.E	• mother • infant or child • health care provider (for example, nurse, midwife, clinician)	To determine the newborn's or infant's HIV exposure and risk and the new mother's HIV status (if not known) and to link both to treatment, prevention or other services.	*Starting point: Client is at facility after labour and delivery or for a postnatal care visit.* • Check or update mother's history. • Determine if a maternal HIV test is needed and, if so, perform the test. • Provide post-test messages and link to services. • Plan for follow-up, as needed. • Assess risk to infant of acquiring HIV. • Conduct a nucleic acid test on newborn, if appropriate (Process HIV.F).

#	Process	Process ID	Personas	Objectives	Task set
	Name	ID used to reference this process throughout this adaptation kit	Individuals interacting to conduct the process	What the process seeks to achieve	The general set of activities performed within the process
F	PMTCT – Infant diagnosis and final HIV status	HIV.F	• infant or child • caregiver • health care provider (for example, nurse or clinician)	To determine if HIV-exposed infants or children without a final diagnosis are HIV-positive, assess for HIV exposure if not known and start them on ART or preventative care based on their status.	*Starting point: Infant/child has been registered at the health facility and called in for testing. HIV testing may be integrated with other health services (for example, during nutrition counselling or immunization).* • Take client history. • Check infant risk of acquiring HIV. • Determine appropriate HIV test. • Finalize infant HIV status. • Determine regimen. • Prescribe. • Determine follow-up requirements.
G	Diagnostics	HIV.G	• client • health care provider (for example, trained lay provider, nurse or clinician) or on-site lab technician • off-site lab technician	To investigate and obtain results through on-site or off-site diagnostics.	*Starting point: Provider has identified a need for some form of investigation or testing.* • Collect specimens. • Perform rapid or point-of-care diagnostics or send specimens to off-site lab. • Interpret and review results. • Follow-up with client

#	Process	Process ID	Personas	Objectives	Task set
	Name	ID used to reference this process throughout this adaptation kit	Individuals interacting to conduct the process	What the process seeks to achieve	The general set of activities performed within the process
H	Following up and contacting clients	HIV.H	• client • data clerk • facility staff and/or community health worker	To follow up by contacting clients to ensure that they are receiving the services they need and that records are updated; to increase retention and adherence and, ultimately, to improve patient outcomes.	*Starting point: Patient has a follow-up appointment scheduled or recommended.* • Identify patient record. • Check whether to contact/follow up. • Check for patient consent to contact. • Attempt to contact client. • Record outreach. • Record follow-up outcome and update record, if needed.
I	Referral	HIV.I	• client • health care provider • referral facility	To direct clients to services that are not available within the consultation facility.	*Starting point: Clinician has determined that client needs services not available in the clinician's facility.* • Determine if it is an emergency referral. • Discuss referral locations. • Contact destination facility. • Provide information to destination facility. • Discuss any questions with client.
J	Aggregate reporting and data use	HIV.J	• facility staff • facility-in-charge • district health officer/ staff	To aggregate client-level data into validated reports, use these data and submit reports from the facility level.	*Starting point: Scheduled time for periodic (usually monthly) reporting.* • Check data quality. • Correct fixable errors. • Generate and review aggregate reports. • Submit for approval. • Provide feedback and any changes required.

Note: Processes that are part of HIV service delivery but not included in this digital adaptation kit include configuration to local context, billing and dispensing. These processes may be required; such determination is highly country- and context-specific. If applicable, they could include checks of insurance coverage and take place at various points during a visit for HIV-related services.

Fig. 5. Business process symbols used in workflows

Symbol	Symbol name	Description
	**Pool**	A pool consists of multiple swim lanes that depict all the individuals or types of users involved in carrying out the business process or workflow. Diagrams should be clear, neat and easy for all viewers to understand the relationships across the different lanes. For example, a pool could depict the business process of conducting an outreach activity, which involves multiple participants, each represented by a different lane in that pool.
	**Swim lane**	Each individual or type of user is assigned to a **swim lane**, a designated area for noting the activities performed by or expected of that specific actor. For example, an HIV health worker may have one swim lane; the supervisor would be in another swim lane; the clients/patients would be depicted in yet another swim lane.
	**Start event or trigger event**	The work flow diagram should contain both a start and an end event, defining the beginning and the completion of the task.
	**End event**	There can be multiple end events depicted across multiple swim lanes in a business process diagram. However, for clarity, there should only be one end event per swim lane.
	**Activity, process, step or task**	Each activity should start with a verb, for example, "Register client", "Calculate risk". Between the start and end of a task, there should be a series of activities noted – the successive actions performed by the actor in that swim lane. There can also be sub-processes within each activity (see next row).
	**Activity with sub-process**	This symbol denotes an activity that has a much longer sub-process, to be detailed in another diagram. If the diagram starts to become too complex and unhelpful, the sub-process symbol should be used to reference this sub-process depicted in another diagram.

Symbol	Symbol name	Description
	**Call activity for a global process**	This symbol denotes an activity that may be used as a part of multiple processes. It is similar to a sub-process, but the activity may be called from any number of processes.
	**Activity with business rule**	This symbol denotes a decision-making activity that requires the business rule, or decision logic, to be detailed in a "decision table". The logic described in the decision table will come into play during this activity as outlined in the business process. It is usually reserved for complex decisions.
	Sequence flow	This denotes the flow direction from one process to the next. The End event should not have any output arrows. All symbols (except Start) may have an unlimited number of input arrows. All symbols (except End and the Gateway) should have one and only one output arrow. All other symbols should have one output arrow leading to a new symbol, looping back to a previously used symbol or pointing to the End symbol. Connecting arrows should not intersect each other.
	Message flow	This denotes the flow of data or information from one process to another. This is usually used for when data are shared across swim lanes or stakeholder groups.
	**Gateway**	This symbol is used to depict a fork, or decision point, in the workflow, which may be a simple binary (for example, yes/no) filter with two corresponding output arrows, or a different set of outputs. in this document there will typically be only two outputs that originate from the decision-point. If more than two "output" or flow direction arrows are needed, this is likely depicting "decision logic" or a "business rule" and should be depicted as an "Activity with Business Rule" instead.
	**Throw – Link**	The "Throw – Link" serves as an off-page connector at the end of a process or when there is no more room on the page for that workflow. It is the end of a process on the current page or the end of a sub-process that is part of a larger process. When used, there will need to be a corresponding "Catch – Link" on the other page that shows the continuation of the workflow.
	**Catch – Link**	The "Catch – Link" serves as the start of a new process that follows a previous process, a continuation of a process from a previous page, or the start of a sub-process that is part of a larger process. Every "Catch – Link" needs to align with at least one corresponding "Throw – Link" in a prior process diagram.
	**Ad hoc sub-process**	An ad hoc sub process can contain multiple tasks. One or more tasks in this shape should be performed, and they can be performed in any order. However, not all of these activities need to finish before moving to the next activity.

Fig. 6. Overview flowchart of general HIV business processes

The business processes included in this kit are shown in Fig. 6 and Fig. 7. The processes included are the ones with a letter assigned and are shown using the "Activity with sub-process" shape (which shows a plus sign). After registration, Fig. 6 branches to Fig. 7 for processes related to PMTCT.

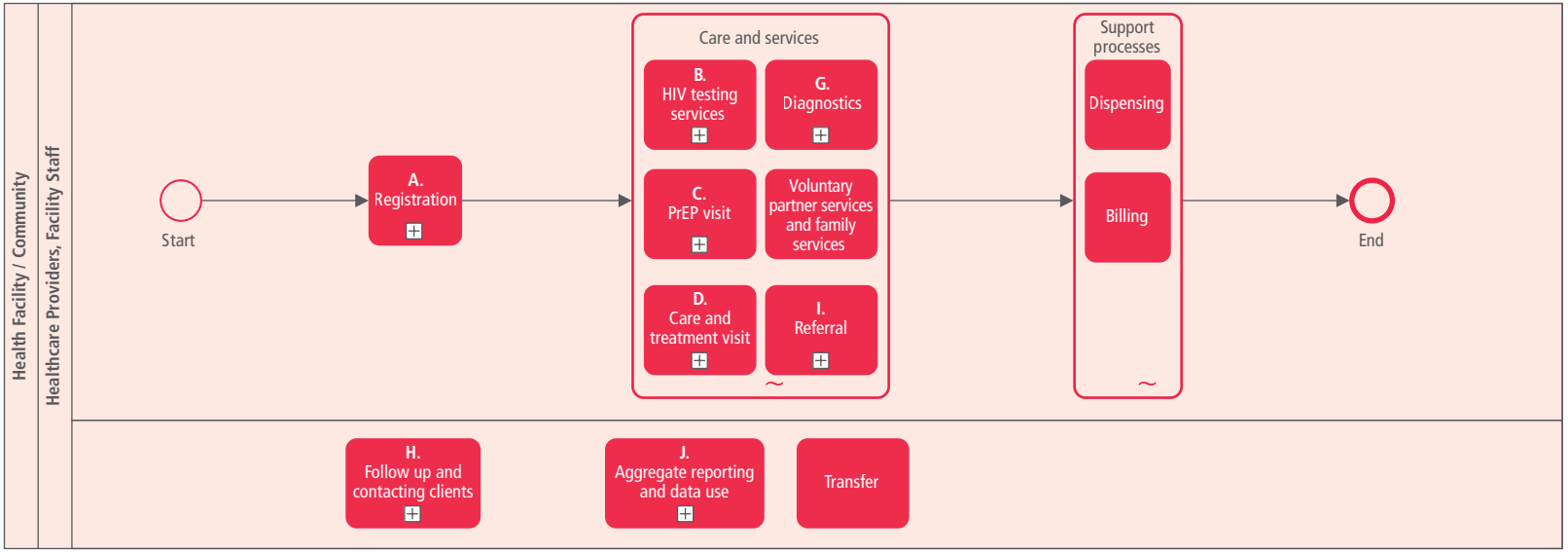
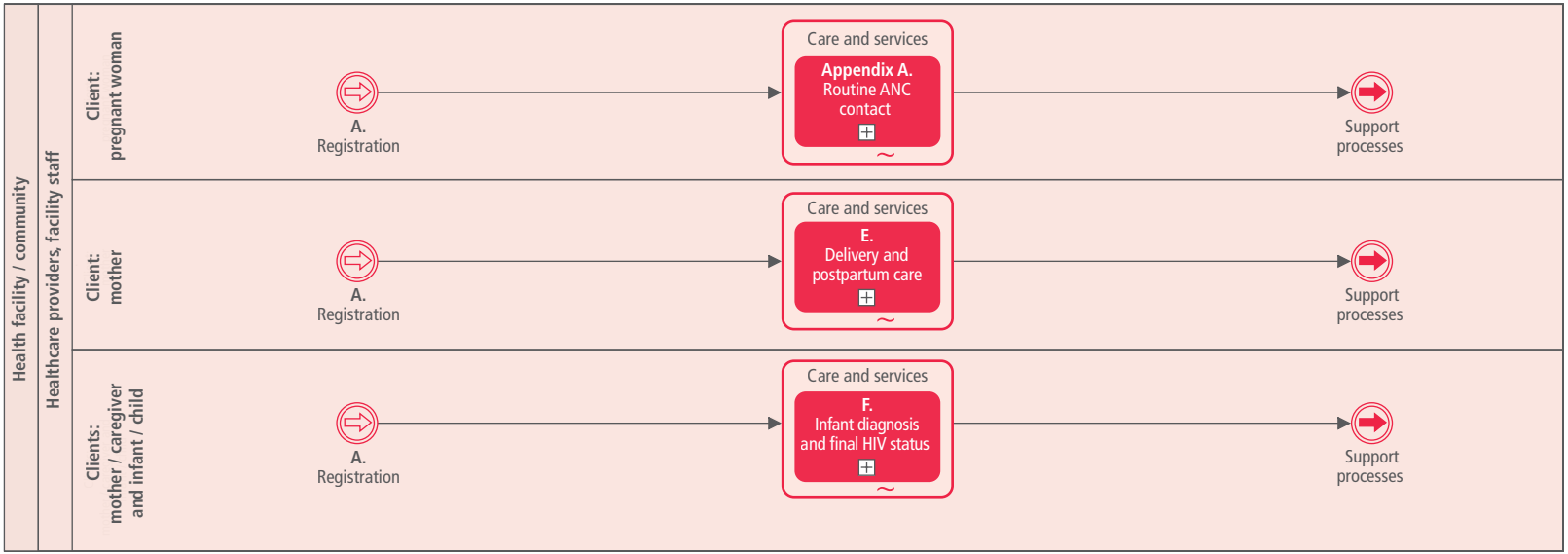


Fig. 7. Flowchart of key business processes – PMTCT



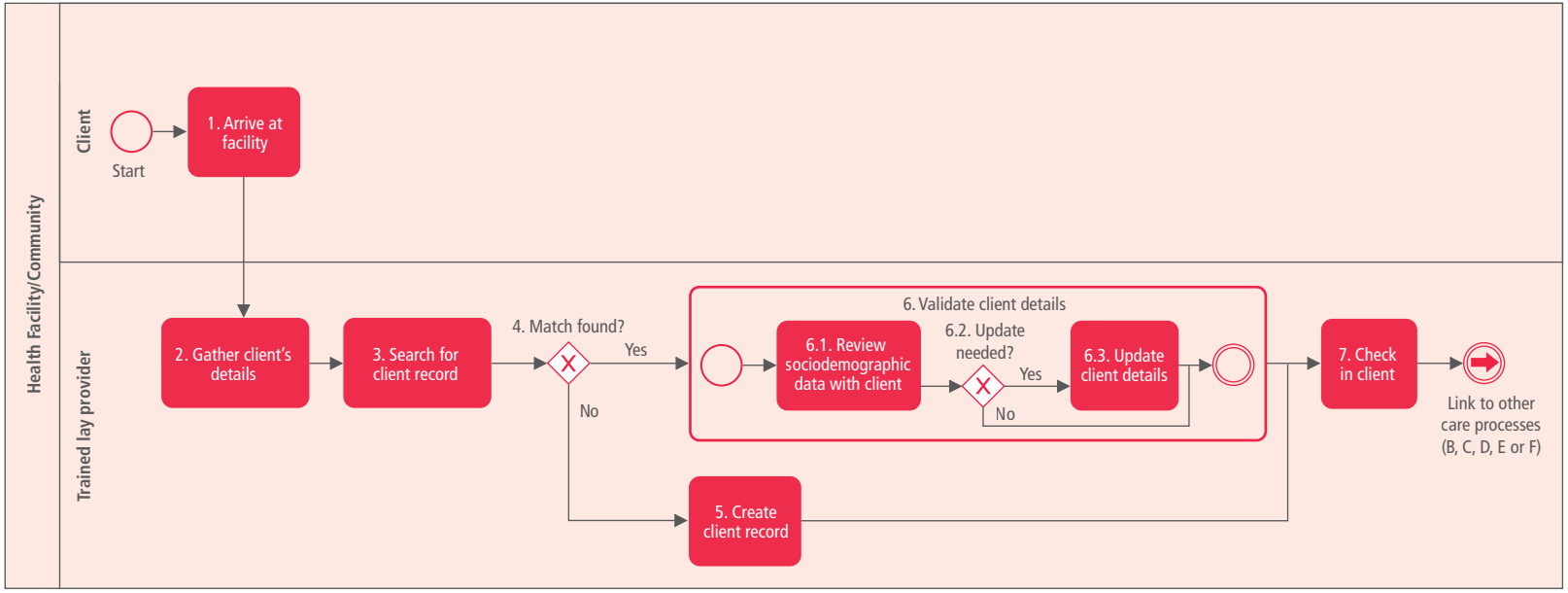
4.2. Workflows

The workflow visualization of progressive activities that occur in health systems help users and stakeholders understand their relation to each other, data elements and decision support needs. The workflows shown below depict processes that have not been generalized across different contexts and may not reflect variation and nuances across different settings. Also, the simplicity of the workflow may not adequately illustrate nonlinear steps that may occur.

A. Registration business process

Objective: To ensure client is found in the record system and personal details are updated or, if not located, entered into the system to be put into a queue awaiting counselling. Fig. 8 shows the flow of the registration process.

Fig. 8. Registration business process



A. Registration business process notes and annotations

1. Arrive at facility

- Client arrives at the health facility.
- (Client could already be registered at the health facility for another service.)

2. Gather client details

- Ask the client whether he or she has previously been issued a unique identifier.
- Does the client have a card/number/barcode?
- Does client say he or she is a returning, a new or a referred client?
- For returning clients, details will be retrieved from the registry of clients at this facility or, if possible, from a central client registry.
- Determine if the client is new to the health facility/health post.
- If a referral, check for referral slip or data from community-based services.

3. Search for client record

- This search process can be done through a variety of means depending on what mechanisms are available in the record system. For example, clients can be searched for by name, unique identifier, or QR code.

4. Match found?

- If multiple records are found and no unique ID, use option to merge records.

5. Create new client record

- If a previous unique identifier has been issued, use the same number to create the client record.
- If not, issue one to client, if possible, at that facility.

6. Validate client details

- Review and update client record or ask for information and complete new client record:
  - **6.1. Review sociodemographic data with client**
    Review client's non-clinical information, such as name, address, contact information, etc.
  - **6.2. Update needed?**
    Has the client moved? Has the client changed contact information? Has any other sociodemographic information changed?
  - **6.3. Update client details**
    Ask client to provide updated information if address or other details have changed since last contact.
- Merge/update client records.
- (May also happen during counselling.)

7. Check in client

- Add client to the relevant queue for counselling services.
- Send/share intake confirmation to referring facility as warranted.

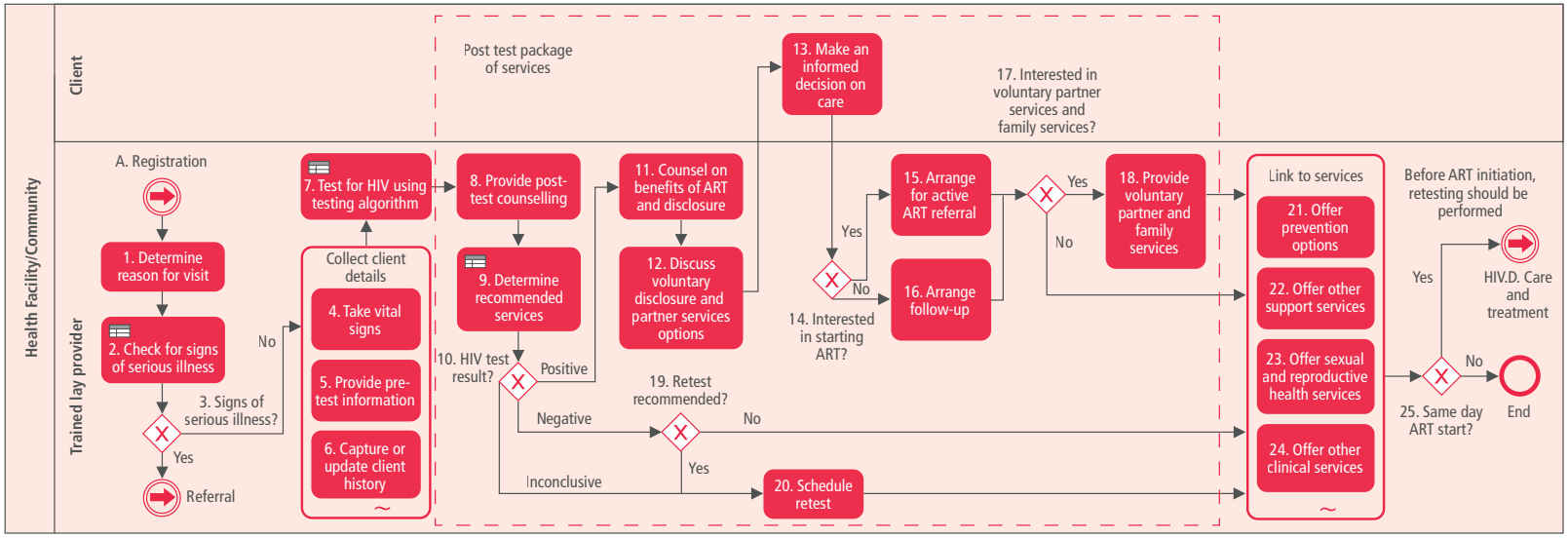
Link process based on visit type

- After a client is registered, move on to the process associated with the visit type, such as:
  - HIV testing services (HTS) (process HIV.B)
  - PrEP visit (process HIV.C)
  - Care and treatment clinical visit (process HIV.D)

B. HIV testing services

Objective: To diagnose individuals with HIV and facilitate their engagement in care and ART as early as possible, as well as to counsel HIV-negative clients and link them to prevention and other services. Fig. 9 shows the flow of the HTS process. (For the testing subprocess algorithm in step 7, see Web Annex B or *Consolidated guidelines on HIV testing services* (2019) *(22).*)

Fig. 9. HIV testing services (HTS) business process



B. HTS process notes and annotations

General notes

The term "HIV testing services" embraces the full range of services that should be provided together with HIV testing. This includes delivery of information and counselling (brief pre-test information and post-test counselling); linkage to appropriate HIV prevention, care and treatment services and other clinical and support services; and coordination with laboratory services to support quality assurance.

HTS for all clients, including key populations, must practice the "5 Cs": Consent, Confidentiality, Counselling, provision of Correct test results and Connection to comprehensive prevention, treatment and care services.

Examples of entry points for HTS are the following:

- Facility-based: HIV testing in a facility (for example, voluntary counselling and testing, inpatient and outpatient clinics, ANC, TB, STI, family planning/ contraceptive services).
- Community-based: HIV testing in a community setting outside of the facility (for example, outreach, community-based services, workplace, clubs, bars).
- HIV self-testing at facility or in the community.
- Provider-assisted referral (for example, index testing or assisted partner notification, including family, sexual and/or drug-injecting partners).
- Screening for TB symptoms should take place in reception at every visit, depending on the setting.

Local policies and requirements for informed consent should be applied. WHO suggests that verbal consent is sufficient for HIV testing and counselling. Clients should be informed of the testing process and of their right to decline testing.

- If a client opts out of testing, the client may be counselled on HIV prevention and community-based services, and condoms may be promoted and provided.
- Guidelines and guidance:
  - *Consolidated guidelines on HIV testing services*, (2019) *(22)*.

Steps for HTS process

1. Determine reason for visit

- Ask client if they have visited previously, search for client details in the system and determine reason for visit.

2. Check for signs of serious illness

- Any person who has signs of serious illness should be referred to the appropriate higher-level facility for management. Danger signs differ by age group.
- Decision logic:
  - HIV.DT.01. Check for signs of serious illness.
- Guidance and guidelines:
  - *Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach (2021) (27). Table 5.1 (reproduced in table 9 in this document).*

3. Has signs of serious illness

- If the client has danger signs of being seriously ill, this warrants a referral to a higher-level facility. Clear criteria for referral should be available.

Note: Steps 4, 5 and 6 may take place in parallel. Not all steps may need to be completed.

4. Take vital signs (not required)

- Vital signs, such as blood pressure and weight, may be taken and recorded.

5. Provide pre-test information

- Pre-test information messages
  - Evidence supports the use of concise pre-test information and messages that offer and encourage testing.
  - Pre-test counselling is not recommended as part of HTS.

6. Capture or update client history

- Discuss history with client and review available records. Examples of history may include other diagnoses, medications (including any use of ART), at risk for HIV or engages in HIV risk behaviours, partner's HIV status and whether the client has performed an HIV self-test and, if so, the results.
- Guidance and guidelines:
  - *Consolidated guidelines on HIV testing services* (2019) *(22)*:
    - 6.2.6 Couples and partners
    - Box 6.7. WHO recommendations and good practice statements on HTS for couples and partners.

7. Test for HIV using testing algorithm

- This subprocess may be called for during a number of different types of care.
- The type of test to use depends on national policies and may reflect a number of factors, such as the client's age, whether the client is pregnant, and the availability of tests at a facility.
- Based on results from each assay, next steps may involve performing the next assay or repeating an assay or recording test results.
- Decision logic:
  - HIV.DT.02. Test for HIV using testing algorithm
- Guidelines and guidance:
  - *Consolidated guidelines on HIV testing services* (2019) *(22)*:
    - Fig. 8.3. WHO standard testing strategy for HIV-1 diagnosis (among people ≥18 months of age)
    - 8.4.2 HIV and syphilis dual detection
    - Fig. 8.6. WHO recommended testing strategy for dual detection of HIV and syphilis in ANC settings
  - *Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach (2021) (27)*
    - Fig. 2.7 Simplified infant diagnosis algorithm
    - Fig. 2.8 Managing indeterminate test results: standard operating procedure

Note: In Fig. 9 post-test packages of services are represented in steps 8–20, inside dashed line.

- The core package of post-test services needs to include the following: concise counselling messages and effective supportive interventions, approaches and tools to facilitate rapid ART initiation and additional linkages to HIV prevention, care, support and other relevant services.

8. Provide post-test counselling

- Messages need to provide clients with the latest information and be clearly communicated to all people tested for HIV, regardless of the test result but tailored to their test result. These include:
  - that their HIV status and other personal information shared is

confidential

- the meaning of the test result
- that the result can be trusted

- the personal health benefits of early ART
- that people with HIV on ART who achieve and maintain viral suppression cannot transmit HIV to their partners
- the benefits of voluntary provider-assisted referral for people with HIV.
  - Because post-test messages amount to a lot of information at the time of diagnosis, some issues and information can be addressed and re-emphasized at subsequent visits.
- Guidelines and guidance:
  - *Consolidated guidelines on HIV testing services* (2019) *(22)*:
    - 4.3 Post-test key messages and information
    - 4.4.2 Linkage to care and rapid ART initiation for people with HIV.

9. Determine recommended services

- All people with HIV-positive diagnoses should be offered a package of support interventions that ensure timely linkage to care.
- It is also important to optimize the linkage of people who are HIV-negative, but at ongoing risk, to link them to effective prevention.
- Decision logic:
  - HIV.S.1 Determine recommended post-test services
  - HIV.DT.03 Determine retest recommendation.
- Guidelines and guidance:
  - *Consolidated guidelines on HIV testing services* (2019) *(22)*. Table 4.1. HIV prevention, treatment and care services.
  - *Preventing HIV during pregnancy and breastfeeding in the context of PrEP. Technical brief* (2017) *(29)*. Box 1. Eight elements of comprehensive HIV prevention in ANC and PNC settings where HIV incidence is high.
  - *Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach (2021) (27) Box 5.3: Screen, Treat, Optimize and Prevent AIDS among children (see table 10 in this document).*
  - *Consolidated guidelines on HIV testing services* (2019) *(22)*:
    - 4.3.1 Special considerations for people with an HIV-positive status
    - 6.2.4 Pregnant and postpartum women
    - 7.2.4 Retesting – when and who?

10. HIV test result?

11. Counsel on benefits of ART and disclosure

- People with no contraindication to rapid ART initiation should be fully informed of the benefits of ART and offered rapid ART initiation, including the option of same-day initiation. Rapid start of ART is especially important for people with very low CD4 cell counts, who face a high risk of death.
- Counselling should discuss the benefits and risks of disclosing HIV-positive status to partner(s) and support individuals and couples with disclosure. For couples, mutual disclosure has many benefits. People with HIV who can share their results with a trusted partner will often find it easier to cope with their diagnosis and to adhere to ART.

12. Discuss voluntary disclosure and partner services options

- It is important that providers discuss, as part of post-test counselling, options for partner services and encourage HIV-positive clients to use provider-assisted referral to inform their sexual and drug-injecting partner(s) about their potential exposure to HIV and offer them voluntary HTS.
- Planning for disclosure should include steps to maximize clients' physical safety.
- Women who disclose any form of violence by an intimate partner (or other family member) or sexual assault by any perpetrator should be offered immediate support. Health-care providers should, as a minimum, offer first-line support when women disclose violence. If health-care providers are unable to provide first-line support, they should ensure that someone else (within their health-care setting or another that is easily accessible) is immediately available to do so. Health-care providers should ask about exposure to intimate partner violence when assessing conditions that may be caused or complicated by intimate partner violence, in order to improve diagnosis/identification and subsequent care.
- Guidelines and guidance:
  - *Consolidated guidelines on HIV testing services* (2019) *(22)*:
    - Table 3.1. HIV Care and prevention services by test status
    - 4.3.6 Special considerations concerning disclosure
    - Box 5.10. Methods for delivering HIV partner services.

13. Make informed decision on care

- Some people need time to adjust to learning their HIV-positive status and may need further support for starting ART and choosing when and how to link to services. People should not be coerced to start immediately and should be supported in making an informed choice regarding when to start ART.
- Retesting should be done before ART initiation.
- Guidelines and guidance:
  - *Consolidated guidelines on HIV testing services* (2019) *(22)*:
    - 8.3.2 Retesting individuals with an HIV-positive status.

14. Interested in starting ART?

15. Arrange for active ART referral

- The tester makes an appointment for the client or accompanies the client to an appointment.

16. Arrange follow-up

- Arrange for follow-up of clients who are unable to enrol in HIV care on the day of diagnosis.

17. Interested in voluntary partner services and family services?

18. Provide voluntary partner services including family-based index case testing.

- Partner services include partner notification, contact tracing, index testing and family-based index case testing for reaching partners of people with HIV. In this kit we use the term "partner services" as an inclusive term encompassing a range of partner services packages and approaches including social network-based approaches. HIV partner services can be delivered in many ways, including patient referral and provider-assisted referral.
- Provider-assisted referral should be offered to all people with HIV as part of a voluntary, comprehensive package of testing, care and prevention.
- It is also important for HIV partner services to offer HIV testing for untested biological children of HIV-positive clients.
- Guidelines and guidance:
  - *Consolidated guidelines on HIV testing services* (2019) *(22)*:
    - 5.3.4 HIV partner services
    - 5.3.5 Social network-based HIV testing approaches.
    - Box 5.10. Methods for delivering HIV partner services
  - *WHO recommends social network-based HIV testing approaches for key populations as part of partner services package. Policy brief* (2019) *(32)*.

19. Retest recommended?

20. Schedule retest

- Not all groups or settings need post-test counselling messages encouraging periodic retesting. In certain situations, individuals who have been tested for HIV in the past can be retested. These include: individuals presenting with a diagnosis or receiving treatment for STIs or viral hepatitis; individuals with a confirmed or presumptive TB diagnosis; outpatients presenting with clinical conditions or symptoms indicative of HIV; individuals with recent HIV risk exposure; pregnant women with unknown or HIV-negative status in late pregnancy – at third trimester visit. More frequent retesting may be warranted based on individual risks factors and as part of broader HIV prevention interventions, such as for those taking PrEP or members of key populations presenting with an STI. Individuals with an HIV-inconclusive status should be retested in 14 days.

Link to services, steps 21–24

- Table 7 provides examples of services that may be offered to both HIV-positive and HIV-negative clients.
- Examples of links to other digital adaptation kits:
  - Family planning *(42)*
    - FP.B. Family planning counselling process
    - FP.C. Family planning service provision process.

21. Offer prevention options

- Messages should include information on HIV prevention interventions and how to access them, such as male and female condoms, PrEP for those at high ongoing risk, voluntary medical male circumcision for men and boys in eastern and southern Africa and harm reduction services for people who inject drugs.
- Provide information, followed by referral when appropriate, on available and effective HIV prevention options.
- Guidance and guidelines:
  - *Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach* (2021) *(27).*
  - *Manual for male circumcision under local anaesthesia and HIV prevention services for adolescent boys and men* (2018). *(33)*
    - VMMC basic facts, pp. 6–20.
  - *What's the 2+1+1? Event-driven oral pre-exposure prophylaxis to prevent HIV for men who have sex with men: update to WHO's recommendation on oral PrEP.* (2019) *(34)*
  - *Implementation tool for pre-exposure prophylaxis of HIV infection* (2017) *(35)*.
  - *Consolidated guidelines on HIV testing services* (2019) *(22)*:
    - 6.2.4 Pregnant and postpartum women.
    - 7.2.4 Retesting – when and who?
    - Table 6.1. Recommended time points for HIV retesting in pregnant and postpartum women.

22. Offer other support services

23. Offer sexual and reproductive health services

24. Offer other clinical services

25. Same-day ART start?

- If no, the process ends.
- If yes, move to HIV.D. Care and Treatment Clinical Visit process. Retesting should be done before initiating ART.

Table 7. Post-test services that may be offered to both HIV-positive and HIV-negative clients

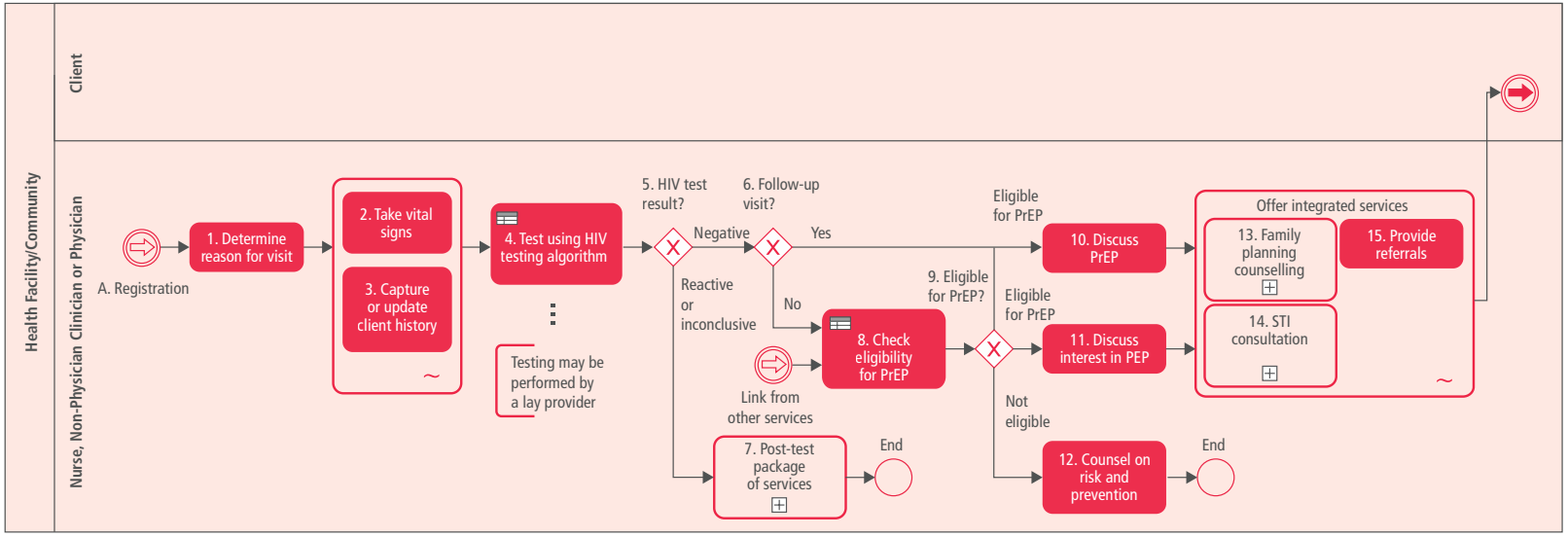
	People with HIV	People testing HIV-negative
Treatment	Antiretroviral therapy (ART)	NA
Prevention	Male and female condoms and condom-compatible lubricants	
		PrEP for people at substantial ongoing risk of HIV infection
		Post-exposure prophylaxis (PEP) following suspected exposure
		Voluntary medical male circumcision (VMMC) (in 14 priority countries)
	Harm reduction for people who inject drugs (needle and syringe programmes, opioid substitution therapy, other drug-dependence treatment and opioid overdose prevention and management)	
	Behavioural interventions to support risk reduction, particularly for people with HIV and members of key populations	
Sexual and reproductive health	Contraception and family planning	
	Prevention of mother-to-child transmission	NA
	Cervical cancer screening and treatment	
	Anal cancer screening (for men who have sex with men)	
	STI testing and treatment	STI testing and treatment for those with ongoing risk, including people from key populations
Other clinical services	Assessment and provision of vaccinations, such as for hepatitis B virus (HBV) for people from key populations, pregnant women and infants; and, where appropriate, tetanus vaccination for adolescent boys and men receiving VMMC	
	HBV testing and vaccination and hepatitis C virus (HCV) testing and treatment	HBV and HCV testing particularly for members of key populations, according to epidemiology, and treatment or vaccination
	Co-trimoxazole chemoprophylaxis to prevent Pneumocystis carinii pneumonia	
	Intensified TB case finding and linkage to TB treatment	
	Provision of isoniazid preventive therapy if person does not have TB	
	Malaria prevention (such as bed nets and prophylaxis), depending on epidemiology	
Other support services	Mental health services	
	Psychosocial counselling, support and treatment adherence counselling	
	Support for disclosure and partner services	
	Legal and social services	
	Services for responding to violence against women, including first-line support and psychosocial support, post-rape care and other support services including shelters, legal services and women and child protection services.	

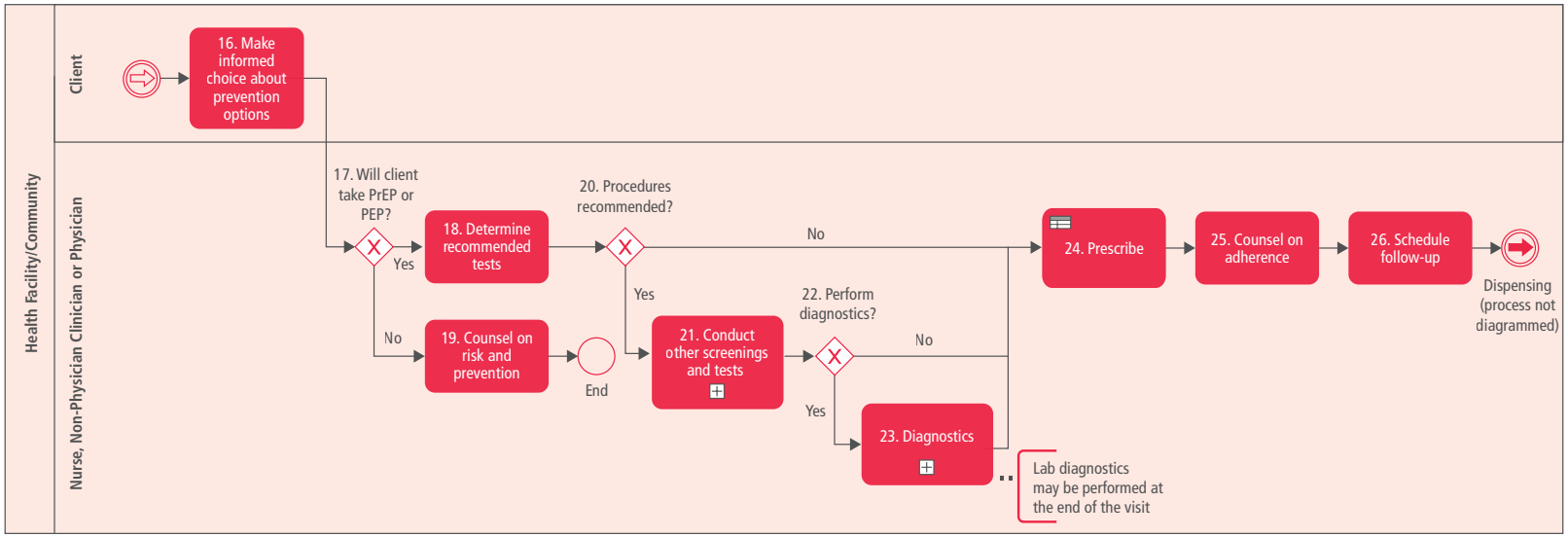
Source: Consolidated guidelines on HIV testing services. (2019) *(22)*.

C. PrEP visit

Objective: To provide the client with PrEP as a prevention choice for people at substantial risk of HIV infection, as part of a combination of HIV prevention approaches. Fig. 10 shows the flow of the PrEP visit process.

Fig. 10. PrEP visit business process




Health Facility/Community
Client
Nurse, Non-Physician Clinician or Physician
16. Make informed choice about prevention options
17. Will client take PrEP or PEP?
Yes
No
18. Determine recommended tests
19. Counsel on risk and prevention
End
20. Procedures recommended?
Yes
No
21. Conduct other screenings and tests
22. Perform diagnostics?
Yes
No
23. Diagnostics
Lab diagnostics may be performed at the end of the visit
24. Prescribe
25. Counsel on adherence
26. Schedule follow-up
Dispensing (process not diagrammed)

C. PrEP visit process notes and annotations

General notes

WHO recommends that oral PrEP should be offered as an additional prevention choice for people at substantial risk of HIV infection as part of combination prevention approaches. PrEP should not replace or compete with effective and well-established HIV prevention interventions.

- Guidelines and guidance:
  - *Implementation tool for pre-exposure prophylaxis of HIV infection* (2017) *(35)*:
    - Module 1: Clinical
    - Module 10: Testing providers
    - Module 12: Adolescents and young adults.
  - *Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach* (2021) *(27)*.
  - *Consolidated guidelines on HIV testing services* (2019) *(22)*.

Steps for PrEP process

1. Determine reason for visit

- Search for client details in the system and determine reason for visit.

2. Take vital signs

- Vital signs, such as blood pressure and weight, may be taken and recorded.

3. Capture or update client history

- Discuss history with client and review records. Examples of history to take include other diagnoses, medications (including any use of ART) and partner's HIV status.

4. Test using HIV testing algorithm

- Existing HIV infection should be ruled out by testing and should be performed the same day that PrEP is started, using a point-of-care rapid HIV test.
- Testing may be performed by a lay provider.
- A non-reactive self-test result is not sufficient to start PrEP. HIV testing that follows the national HIV testing algorithm should be performed before PrEP is started or restarted.
- Guidance and guidelines:
  - *Consolidated guidelines on HIV testing services* (2019) *(22)*.
- Decision logic:
  - HIV.DT.02 Test for HIV using testing algorithm

5. HIV test result?

6. Follow-up visit?

- If the client is returning for a refill of oral PrEP, some steps may be skipped.

7. Post-test package of services

- If the client tested positive for HIV, the client should be counselled and linked to care, based on an essential post-test service package.
- If the client's result was inconclusive, a follow-up appointment should be scheduled to retest, and the client should be given post-test messages.

- Guidelines and guidance:
  - *Consolidated guidelines on HIV testing services* (2019) *(22)*:
    - 4.3 Post-test key messages and information
    - 4.4.2 Linkage to care and rapid ART initiation for people with HIV.

8. Check eligibility for PrEP

- For new visits, check whether the client is eligible for PrEP or post-exposure prophylaxis (PEP).
- PrEP should be provided to individuals who want to use PrEP *if local criteria for PrEP use are met*. Easy and practical questions, framed in terms of people's behaviour, can be developed to screen individuals for PrEP and PEP.
- People who have been exposed to HIV in the preceding 72 hours should be offered PEP. For PEP to work well, it must be started as soon as possible after exposure and no later than 72 hours after exposure.
- PrEP providers should educate and counsel potential PrEP users about the risks and benefits of PrEP and may conduct an individualized risk–benefit assessment to determine eligibility.
- Eligibility criteria for PrEP include:
  - HIV-negative
  - No suspicion of acute HIV infection
  - Substantial risk of HIV infection
  - No contraindications to PrEP medicines (for example, use of tenofovir disoproxil fumarate/emtricitabine).
  - Willingness to use PrEP as prescribed, including periodic HIV testing.
- Decision logic:
  - HIV.DT.04 PrEP eligibility check.
- Guidelines and guidance:
  - *Implementation tool for pre-exposure prophylaxis of HIV infection* (2017) *(35)*. Module 1: Clinical.
  - *What's the 2+1+1? event-driven [ED] oral pre-exposure prophylaxis to prevent HIV for men who have sex with men* (2019) *(34)*. Fig. 2. Proposed algorithm for PrEP providers when considering how to offer ED-PrEP.

9. Eligible for PrEP?

- If the initial HIV serology test result is non-reactive (negative), and there are no history, signs or symptoms of an acute viral syndrome, the person could be offered and, if desired, initiated on PrEP. A single reactive (positive) test result is not sufficient to make an HIV-positive diagnosis. If the initial serology test result is reactive, additional testing is needed.

10. Discuss PrEP

- PrEP should be used daily during periods of substantial risk of HIV acquisition and can be stopped during periods of low or no risk.
- The provider can discuss the client's current risk and intention and, for current users, issues and concerns.
- PrEP providers should educate and counsel potential PrEP users about the risks and benefits of PrEP.
- For current users, investigate problems, such as side-effects the client is experiencing or has concerns about. Additional tests or a referral may be required, depending on the complexity and seriousness of the health condition.

- Guidelines and guidance:
  - *Implementation tool for pre-exposure prophylaxis of HIV infection* (2017) *(35)*.
    - Module 1: Clinical. "Key counselling regarding PrEP efficacy"; "Key counselling regarding PrEP safety".
    - Module 3: Counsellors. "Discussion prompts or questions for initial PrEP appointments", "Discussion prompts for follow-up PrEP appointments".
  - *What's the 2+1+1? event-driven oral pre-exposure prophylaxis to prevent HIV for men who have sex with men: update to WHO's recommendation on oral PrEP. Technical brief* (2019) *(34)*.
  - *Preventing HIV during pregnancy and breastfeeding in the context of PrEP. Technical brief* (2017) *(29)*. "Why offer PrEP to pregnant and breastfeeding women?"

11. Discuss interest in PEP

- If client is eligible, discuss PEP. People who have been exposed to HIV in the preceding 72 hours should be offered PEP. In people with ongoing potential exposure to HIV, there should be no gap between finishing PEP and starting PrEP.

12. Counsel on risk and prevention

- If client is not eligible for PrEP, the provider may counsel on risk and other prevention options, as well as promote and provide condoms.

Integrated services

13. Family planning counselling

- See processes in the Family Planning digital adaptation kit *(42)*:
  - FP.B. Family planning counselling process.
  - FP.C. Family planning service provision process.

14. STI consultation

15. Provide referrals

16. Make informed choice about prevention options

- If eligible, the client can make a choice whether to start, not start, continue or stop PrEP or PEP or to make a change.
- This choice may include starting ED-PrEP or switching to or from ED-PrEP if the client is eligible.

17. Will client take PrEP or PEP?

18. Determine recommended tests

- In addition to HIV testing, a package of screenings is recommended for new and continuing PrEP users. Screening for STIs prior to PrEP initiation, and periodically while taking PrEP, is important. People who are eligible for or using PrEP are often at risk for other STIs.
- Some PrEP services routinely start PrEP the day of the visit, provided specimens for suggested laboratory tests (other than HIV testing) are collected and sent to the laboratory and the client can be contacted if test results require additional action, confirmation or treatment.
- Guidelines and guidance:
  - *Implementation tool for pre-exposure prophylaxis of HIV Infection* (2017) *(35)*:
    - Module 1: Clinical. Tables 1 and 2.
    - Module 10: Testing providers. Table 1. Summary tool for starting or monitoring PrEP.

19. Counsel on risk and prevention

- If the client declines medication, the provider may counsel on risk and other prevention options as well as promote and provide condoms.

20. Procedures recommended?

21. Conduct other screenings and tests

- The provider may perform other screenings, including rapid diagnostics for STIs, and physical examinations. Diagnoses for these may reference other digital adaptation kits.

22. Perform diagnostics?

23. Diagnostics

- If diagnostics are to be performed, this may take place at this point. Or this may take place at another time during the process, or after, if the client needs to go to a lab.
- Lab diagnostics may be performed at the end of the visit.

24. Prescribe

- The optimal number of tablets to be dispensed for PrEP has not been determined and will likely vary by setting and population. If available, an extra month's supply of medicine provided at the first visit assures an adequate supply for daily dosing until the next clinic visit and may help users avoid rationing tablets.
- PEP should be continued for 28 days after the exposure.
- Decision logic:
  - HIV.DT.05 Determine PEP or PrEP regimen

- Guidelines and guidance:
  - *Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach* (2021) *(27).* Chapter 3: HIV prevention.
  - *What's the 2+1+1? event-driven oral pre-exposure prophylaxis to prevent HIV for men who have sex with men: update to WHO's recommendation on oral PrEP. Technical brief* (2019) *(34)*.

25. Counsel on adherence

- PrEP provides high levels of protection in people who take PrEP medicines regularly. Provide counselling on how to use PrEP effectively (adherence).
- Also, counsel on prevention of STIs, recognition of STI symptoms, and issues related to mental health, intimate partner violence and substance use.
- For new users, time is needed to build up protective levels of the drug. Additional HIV prevention measures should be taken for seven days.
- Provide condoms, contraception or safer conception services as needed.
- Guidelines and guidance:
  - *Implementation tool for pre-exposure prophylaxis of HIV infection* (2017) *(35)*. Module 3: Counsellors.

26. Schedule follow-up

- A person using PrEP should have an HIV test every three months, with additional tests recommended on a periodic basis.
- Guidelines and guidance:
  - *Implementation tool for pre-exposure prophylaxis of HIV Infection* (2019) *(35)*. Module 1: Clinical. Table 2.
- Explain importance of follow-up.
- If client consents to be contacted, confirm client's contact data and set up the process to enable follow-up.

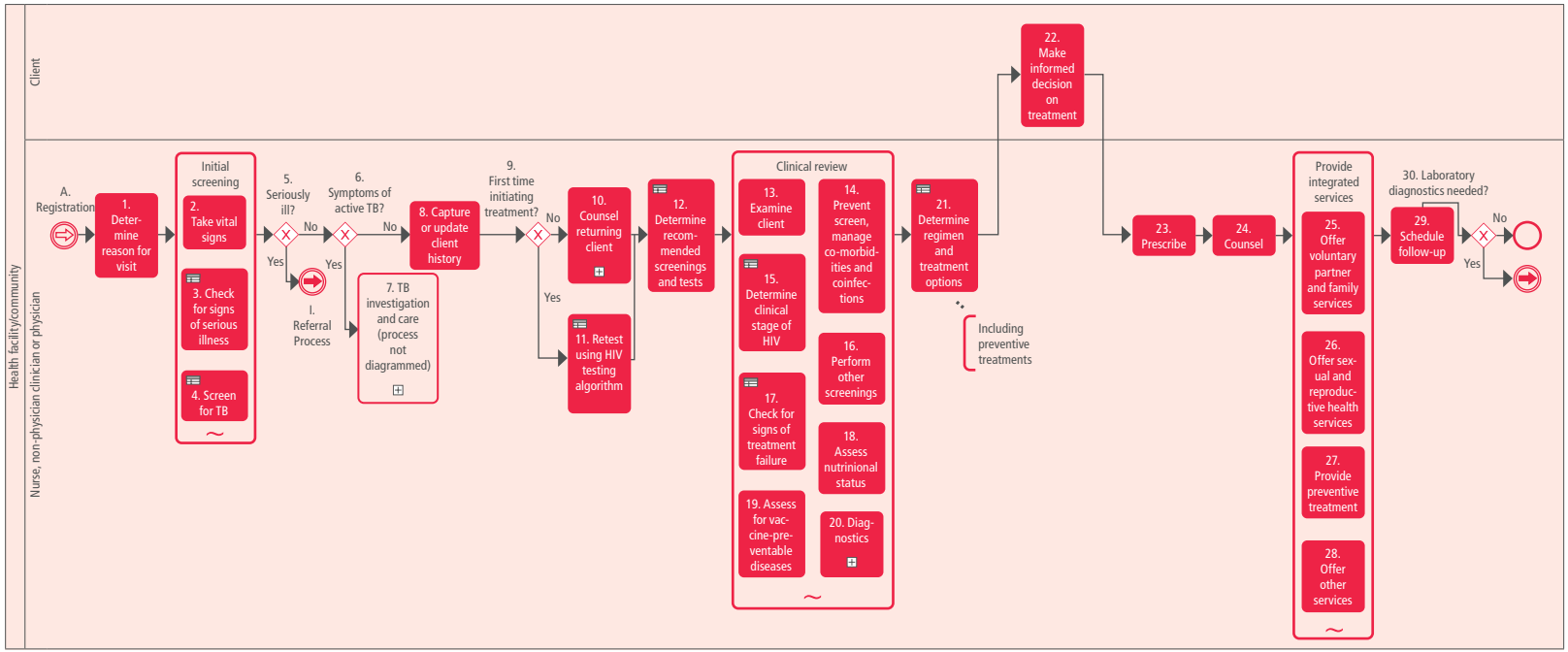
For adolescents and young adults

When taking PrEP, adolescents and young adults (24 years old or less) may benefit from more frequent clinic visits to address their changing routines and multiple needs. Providing adolescent-friendly services and flexible clinic schedules can improve access.

D. Care and treatment clinical visit

Objective: To initiate ART and to provide HIV care, treatment and integrated health services. Fig. 11 shows the flow of the care and treatment process.

Fig. 11. Care and treatment clinical visit business process



D. Care and treatment process notes and annotations

General notes

The choice to accept or decline ART ultimately lies with the person or his or her caregiver, and if they choose to defer initiation, ART can be offered again at subsequent visits. An overview of key elements of general care over the continuum of HIV care for people living with HIV is provided in Table 8.

Countries should establish a package of general HIV care interventions, in addition to ART, for people living with HIV to reduce HIV transmission, prevent illness and improve their quality of life. WHO has produced summary guidance on general care and prevention interventions and recommends a package of 13 prevention interventions for adults and adolescents living with HIV in resource-limited settings:

1. Psychosocial counselling and support
2. Disclosure and partner notification
3. Co-trimoxazole (CTX) prophylaxis
4. TB counselling, screening and preventive therapy
5. Prevention of common fungal infections
6. Treatment of STIs and support for reproductive health needs, including prevention of and screening for cervical cancer
7. Malaria prevention, using CTX, bed nets, etc. (particularly among pregnant women).
8. The use of vaccines for prevention of pneumococcal disease, influenza, hepatitis B and yellow fever.
9. Provision of adequate nutrition.
10. Family planning services.
11. Prevention of mother-to-child transmission (PMTCT) of HIV.
12. Needle and syringe programmes for people who inject drugs.
13. Clean water, sanitation and hygiene.

Guidance and guidelines:

- *Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach* (2021) *(27)*.
  - 6.2 General care for people living with HIV.

Steps for care and treatment process

1. Determine reason for visit

- Search for client details in the record system and determine reason for visit.

Initial screenings steps 2–4

Steps may be performed in parallel. One or more of these steps are often performed before meeting with the provider.

2. Take vital signs

- Also record weight, height, etc. For children, weight will be needed to determine dosage and to check for malnutrition.

3. Check for signs of serious illness

- Any person who has signs of seriously illness should be referred to the appropriate higher-lever facility for management. Danger signs differ by age group.

- Decision logic:
  - HIV.DT.01. Check for signs of serious illness.
- Guidance and guidelines:
  - *Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach* (2021) *(27)* Table 5.1 (reproduced in Table 9 in this document).

4. Screen for TB

- Adults and adolescents living with HIV should be screened for TB according to a clinical algorithm.
- Infants and children living with HIV who have poor weight gain, fever or current cough or who have a history of contact with a person with TB should be evaluated for TB and other diseases that cause such symptoms.
- Guidelines and guidance:
  - *WHO consolidated guidelines on tuberculosis: module 1: prevention: tuberculosis preventive treatment* (2020) *(36)*.
  - *WHO consolidated guidelines on tuberculosis Module 2: Screening – Systematic screening for tuberculosis disease* (2021) *(46).*
- Decision logic:
  - HIV.DT.06 Screen for TB

5. Seriously ill?

- Any person who has signs of serious illness should be referred to the appropriate higher-lever facility for management or receive emergency care, depending on availability and policies.

6. Symptoms of active TB?

7. TB investigation and care (flow not charted)

- Investigate for active TB.

8. Capture or update client history

- Discuss history with client and review available records. History-taking should include partner's HIV status and whether the partner is virally suppressed or on ART.
- Include checking medications, symptoms, whether taking all the prescribed drugs, immunization history, use of contraception, signs that she may be pregnant, drug use and nutrition.
- Check other comorbidity lists.
- Guidance and guidelines:
  - *WHO operational handbook on tuberculosis. Module 1. Prevention.* (2020) *(37)*. Chapter 5. TB preventive treatment, p. 46.

9. First time initiating treatment?

- This step checks whether the client is naïve to ART.

10. Counsel returning clients

- Discuss:
  - Adherence, such as whether client is picking up meds
  - Any lab results that which are new and have not been shared with the client. If viral load is not suppressed, evaluate for adherence concerns and set plan for enhanced adherence counselling if needed.
  - Issues and concerns
  - Adverse reactions and side effects.
  - Symptoms
  - Psychosocial well-being
  - Other challenges.
- For caregivers of young children, counselling should include a check on the caregivers' well-being and mental health.
- Guidance and guidelines:
  - *Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach* (2021) *(27)* 4.8 Monitoring ARV toxicity.
  - *Nurturing care ensures children affected by HIV survive and thrive* (2020) *(38)*.

11. Retest using HIV testing algorithm

- WHO recommends that all programmes retest people diagnosed with HIV prior to initiating lifelong ART. This retesting to verify an HIV-positive diagnosis is intended to catch human errors, such as mislabelling of test results.

12. Determine recommended screenings and tests

- Decision logic: HIV.DT.08 Determine recommended screenings and tests.
- Guidelines and guidance:
  - *Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach* (2021) *(27)*.
    - Table 4.1. Recommended tests for HIV screening and monitoring and approaches to screening for coinfections and noncommunicable diseases.
    - Table 5.1: Components of the package of care for people with advanced HIV disease.
    - Box 5.3: Screen, Treat, Optimize and Prevent AIDS among children (table 10 of this document). Table 1 (reproduced in Table 9).
  - *WHO recommendations for routine immunization – summary tables (39)*. Table 1. Summary of WHO position papers – recommendations for routine immunization (updated 2020).
  - *WHO operational handbook on tuberculosis. Module 1. Prevention (37)*. Table 6.1. Likely adverse events with drugs used for TPT.

13. Examine client

- Examine the client clinically, with a physical exam.

14. Prevent, screen and manage comorbidities and coinfections

- With ART, HIV is a chronic disease requiring lifetime care. WHO guidelines cover information on common and important concomitant conditions among people living with HIV, including: co-trimoxazole prophylaxis; the diagnosis, prevention and treatment of TB, viral hepatitis, malaria, sexually transmitted infections, cervical cancer prevention, nutrition, vaccinations, mental health and substance use.
- Guidelines and guidance:
  - *Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach* (2021) *(27).*
    - Chapter 6. General care and managing common coinfections and comorbidities.

15. Determine clinical stage of HIV

- Decision logic:
  - HIV.DT.09 Determine WHO clinical stage of HIV.
- Guidelines and guidance:
  - *Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection. 2nd ed.* (2016) *(24)*. Annex 10. WHO clinical staging of HIV disease in adults, adolescents and children.

16. Perform other screenings

- Conduct screenings based on recommendations and priorities and depending on the diagnostics that are available.

17. Check for signs of treatment failure

- Review new diagnostic results.
- Check nutrition and growth.
- Check for treatment failure, including clinical, immunological and virological failure. Viral load testing is recommended as the preferred monitoring approach to diagnose and confirm treatment failure.

- Decision logic:
  - HIV.DT.07 Check for treatment failure.
- Guidelines and guidance:
  - *Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach* (2021) *(27)*.
    - 4.7 Monitoring the response to ART.
    - Table 4.11. WHO definitions of clinical, immunological and virological failure for the decision to switch ART regimens.
  - *Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection.* 2nd ed. (2016) (24).
    - Annex 10. WHO clinical staging of HIV disease in adults, adolescents and children.

18. Assess nutritional status

19. Assess for vaccine-preventable diseases

- Based on immunization schedule for people living with HIV.

20. Diagnostics

- Viral load should be tested routinely for early warning of virological failure and monitored if clinical or virological failure are suspected.
- Decision logic:
  - HIV.DT.07 Check for treatment failure
- Guidelines and guidance:
  - *Updated recommendations on HIV prevention, infant diagnosis, antiretroviral initiation and monitoring* (2021) *(28)*.

21. Determine regimen and treatment options

- For continuing care, check the dosage and need for readjustment or whether treatment failure is suspected.
- For children, assess current weight and expected weight gain over the following six months and, if required, adjust ART dosages accordingly.
- Initiation of ART should always consider nutritional status, any comorbidities and other medications being taken to assess for possible interactions, contraindications and dose adjustment.
- Assessment and management of cardiovascular risk should be provided for all individuals living with HIV according to standard protocols recommended for the general populations.
- Decision logic:
  - HIV.DT.10 Determine ART regimen
  - HIV.DT.11 Check for known drug interactions.
- Guidelines and guidance:
  - *Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach* (2021) *(27)*
    - 4.10 Key ARV drug interactions.
    - Table 5.1: Components of the package of care for people with advanced HIV disease.
    - 4.6.3: Third-line ART.

– *Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach* (2021) *(27).*
  - Box 5.3: Screen, Treat, Optimize and Prevent AIDS among children
  - Annex 1: Dosages for ARV drugs
– WHO Paediatric ARV dosing dashboard *(41)*

22. Make informed decision on treatment option

- The client will choose the treatment option.
- Even if client is eligible to start ART, the choice to accept or decline ART ultimately lies with the person or his or her caregiver, and if the decision is to defer initiation, ART can be offered again at subsequent visits.

For children who test HIV-positive

Children under five years old who test HIV-positive are defined as having advance disease at presentation. However, those who have been on ART more than one year and who are clinically well should not be considered to have advanced disease and should be eligible for multi-month dispensing to ensure optimal adherence.

23. Prescribe

- Based on whether the client is clinically stable, meets the criteria for established on ART, and other factors, determine with client the frequency of visits and number of months of treatment to prescribe before a next clinical visit. Provide information on the different DSD models available for client's expression of interest and decision making. Enrol client in preferred DSD model.
- The scripting period should cover the period until the next clinical consultation (not until the following ART refill visit).
- Guidelines and guidance:
  – *Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach* (2021) *(27)* Chapter 7: Service delivery.

24. Counsel

- Counsel clients on adherence.
- For advanced disease, offer intensified adherence support for opportunistic infection, medication, ART and monitoring of condition.
- Guidelines and guidance:
  – *Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach* (2021) *(27).*

Link to care, steps 25–28

- Table 8 provides examples of services that may be offered to clients.
- Linkages to processes in other digital adaptation kits:
  - Family planning *(42)*
    - FP.B. Family planning counselling process
    - FP.C. Family planning service provision process.

29. Schedule follow-up

- Determine follow-up requirements and update client's care plan as needed.
- Explain importance of follow-up.
- If client consents to be contacted, confirm client's contact data and set up the process to allow follow-up.
- If possible, link children to family's schedule.
- Guidelines and guidance:
  - *Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach* (2021) *(27)* 7.5.3 Frequency of clinical visits and ART pick-up; Chapter 7: Service delivery.

30. Laboratory diagnostics needed?

- Additional testing or specimen collection may be needed and may happen after the visit.

Table 8. Overview of key elements of general care over the continuum of HIV care for people living with HIV

Service	At HIV diagnosis	At enrolment into care and initiation of ART	Established on ART	At treatment failure and switching ART regimen	At re-engagement following care interruption
General care					
Preparing people for ART	✓	✓			
WHO clinical staging Past and current HIV-related conditions	✓	✓		✓	✓
Preparing, assessing and supporting adherence	✓	✓	✓	✓	✓
Current medications		✓	✓	✓	✓
Pregnancy status Family planning and contraception	✓	✓	✓	✓	✓
Support for disclosure and partner notification	✓	✓			
Risk-reduction counselling and combination HIV prevention approaches	✓	✓	✓	✓	✓
Screening for, preventing and managing noncommunicable diseases		✓	✓	✓	✓
Screening for and managing mental health problems and substance use Psychosocial counselling and support		✓	✓	✓	✓
Managing pain and symptoms		✓	✓	✓	✓
Nutritional assessment and counselling		✓	✓	✓	✓
Infant and child feeding	✓	✓	✓	✓	✓
Nutritional, growth and development assessment for children and adolescents		✓	✓	✓	✓

Service	At HIV diagnosis	At enrolment into care and initiation of ART	Established on ART	At treatment failure and switching ART regimen	At re-engagement following care interruption
Preventing and treating coinfections					
Co-trimoxazole preventive therapy		✓	✓	✓	✓
Intensified TB case-finding		✓	✓	✓	✓
Isoniazid preventive therapy		✓		✓	✓
Screening for cryptococcal infection and fungal prophylaxis when appropriate		✓			✓
Screening for hepatitis B and C		✓		✓	✓
Malaria prevention (insecticide-treated bed nets and prophylaxis)		✓	✓	✓	✓
Screening for sexually transmitted infections		✓	✓	✓	✓
Preventing and screening for cervical cancer		✓	✓	✓	✓
Assessing for vaccine-preventable diseases other than HBV and HCV infection		✓	✓		✓

Source: Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach (2021).

Table 9. Components of the package of care for people with advanced HIV disease

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

	Intervention	CD4 cell count	Adults	Adolescents	Children <10 years
Prophylaxis and pre-emptive treatment	Co-trimoxazole prophylaxis	<350 cells/mm^3 or clinical stage 3 or 4 Any CD4 count in settings with high prevalence of malaria or severe bacterial infections	Yes	Yes	Yes For criteria, see Chapter 6
	TB preventive treatment[a]	Any	Yes	Yes	Yes
	Fluconazole pre-emptive therapy for cryptococcal antigen–positive people without evidence of meningitis	<100 cells/mm^3	Yes	Yes	Not applicable (screening not advised)
ART initiation	Rapid ART initiation[b]	Any	Yes	Yes	Yes
	Defer initiation if clinical symptoms suggest meningitis (TB or cryptococcal)	Any	Yes	Yes	Yes
Adapted adherence support	Tailored counselling to ensure optimal adherence to the advanced HIV disease package, including home visits if feasible	<200 cells/mm^3	Yes	Yes	Yes

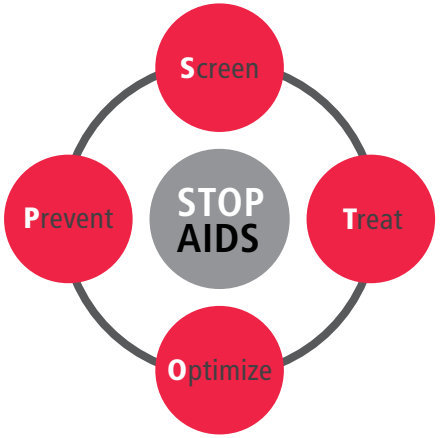
[a] TB preventive treatment should be provided in accordance with current WHO guidance *(27)*.

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

Source: Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach (2021) *(27).* Table 5.1. Separate table on prophylaxis considerations in Table 5.4 for adults.

Table 10. Screen, Treat, Optimize and Prevent AIDS among children

Screen[a]	
TB	• Screen for TB using available screening tools as indicated[b] • For those who screen positive, use the following diagnostic tests to confirm TB as applicable[c]: – Rapid molecular diagnostic on (induced) sputum, stool, gastric aspirate or nasopharyngeal aspirate or other extrapulmonary samples if relevant – LF-LAM assay[d]
Cryptococcal infection among adolescents	Serum or plasma or blood cryptococcal antigen screening followed by lumbar puncture if positive or symptomatic
Malnutrition	• Weight-for-height • Height-for-age • Mid-upper arm circumference among children 2–5 years old
Treat	
TB, severe pneumonia, severe bacterial infections, cryptococcal meningitis and severe acute malnutrition	In accordance with WHO guidelines
Optimize	
Rapid ART start	Preferably same-day but no later than seven days after diagnosis with optimal regimens[e]
ART counselling	In accordance with WHO guidelines
Prevent	
Bacterial infections and *P. jirovecii* pneumonia	Co-trimoxazole prophylaxis
TB	TB preventive treatment
Cryptococcal meningitis among adolescents	Fluconazole pre-emptive therapy if cryptococcal antigen positive or cryptococcal antigen unavailable
Vaccinations	• Pneumococcal vaccine • Human papillomavirus • Measles • BCG



[a] Screening refers to screening and diagnostics throughout this publication.

[b] For screening algorithms and screening tools, see *WHO consolidated guidelines on tuberculosis: module 1: prevention: tuberculosis preventive treatment (36)* and *WHO operational handbook on tuberculosis: module 1: prevention: tuberculosis preventive treatment (37)*. Screening and diagnosis of TB for adolescents is the same as for adults.

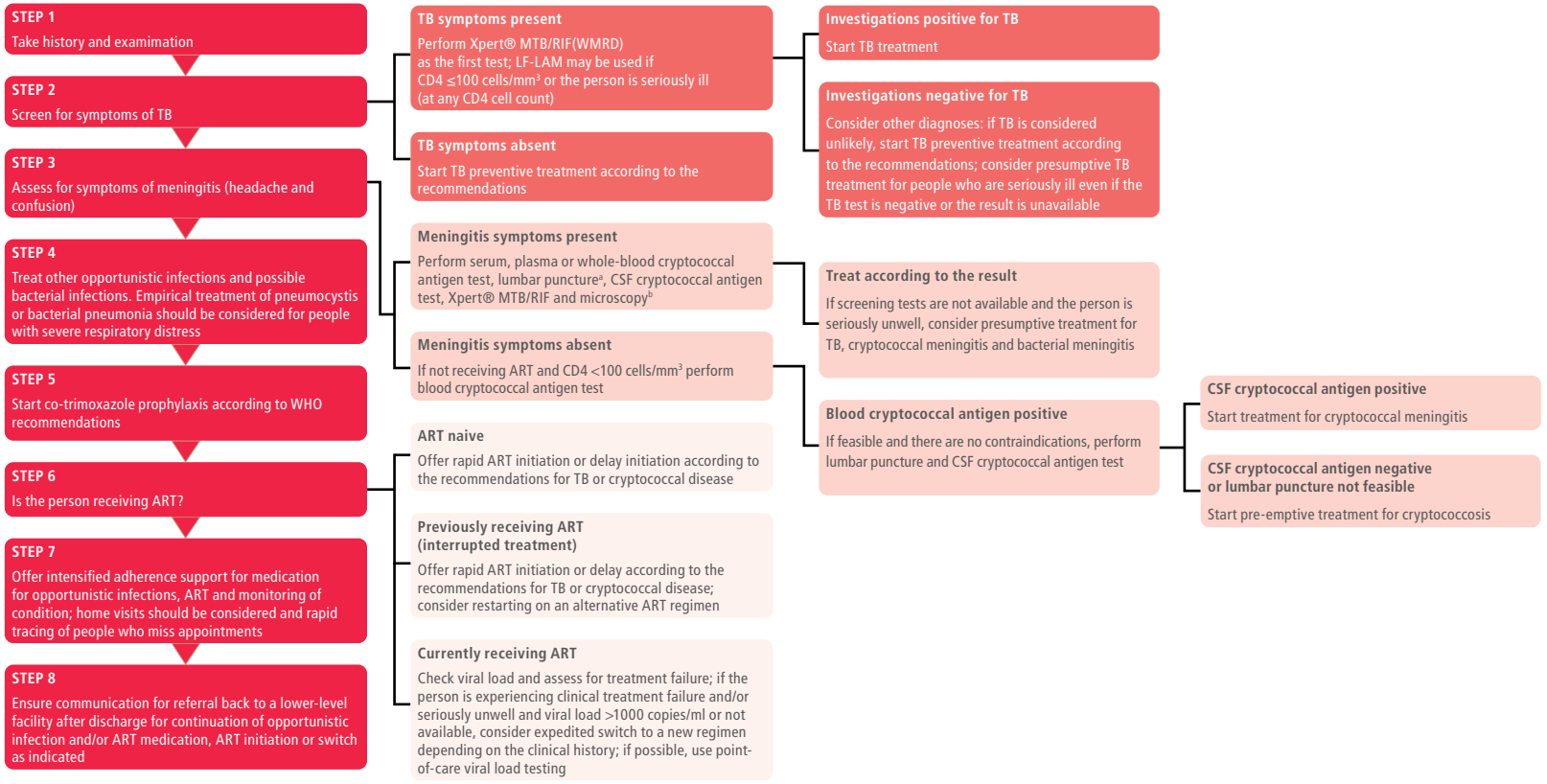
[c] A negative test result does not exclude TB for children living with HIV for whom there is a strong clinical suspicion of TB.

[d] *Package of care for children and adolescents with advanced HIV disease: stop AIDS: technical brief (47).*

[e] Unless TB or cryptococcal meningitis is diagnosed *(24)*.

Source: Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach (2021) *(27)* Box 5.3.

Fig. 12. Algorithm for providing a package of care for people with advanced HIV disease



ART: antiretroviral therapy; CSF: cerebrospinal fluid; TB, tuberculosis; LF-LAM: lateral flow urine lipoarabinomannan assay.

[a] Everyone who is cryptococcal antigen positive and has headache or confusion should have a lumbar puncture.

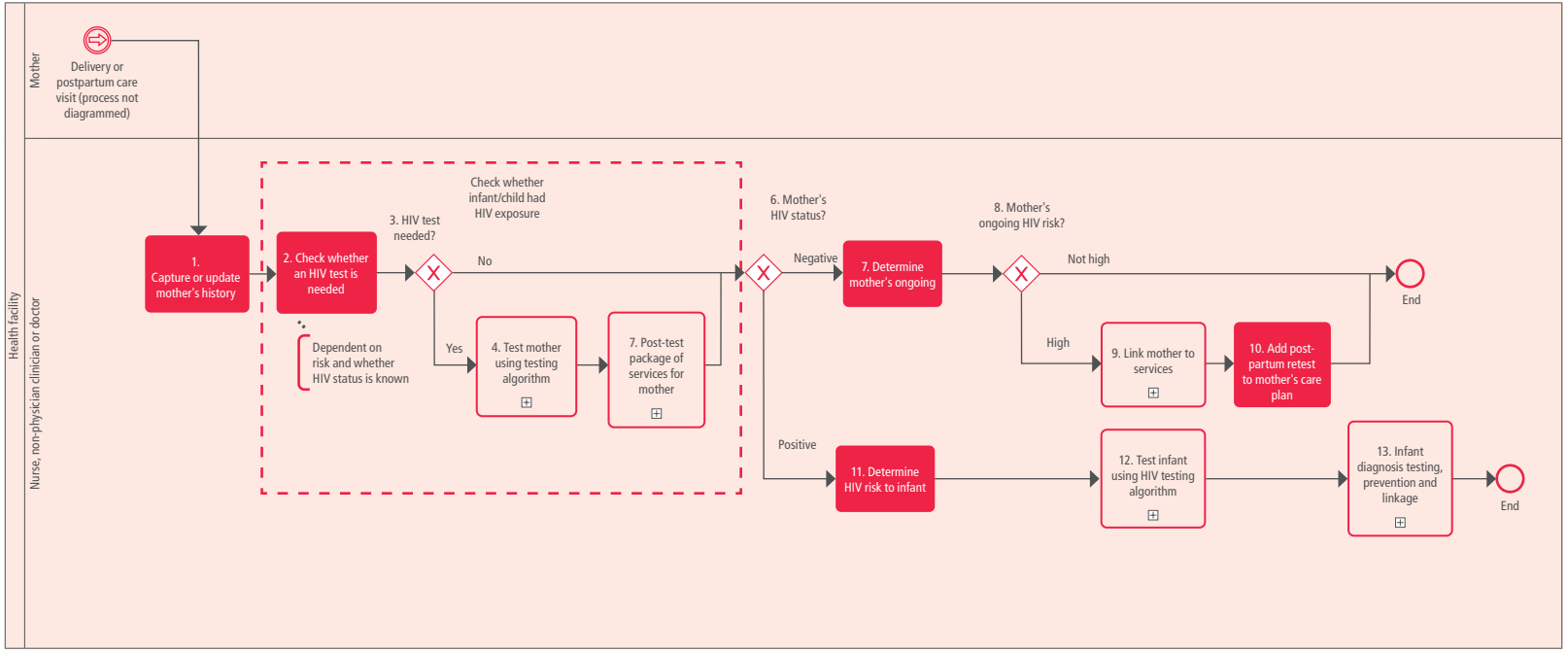
[b] In settings where test results are available quickly, testing for cryptococcal infection before TB infection would be more cost-effective.

Source: Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach. (2021) *(27)*.

E. PMTCT delivery and postpartum care

Objective: To determine the newborn's or infant's HIV exposure and risk and the new mother's HIV status (if not known) and to link both to treatment, prevention or other services. Fig. 13 shows the flow of the PMTCT delivery and postpartum care process.

Fig. 13. PMTCT delivery and postpartum care business process



E. PMTCT delivery and postpartum care process notes and annotations

General notes

The key principles for establishing whether HIV-exposed infants and children younger than 18 months are infected with HIV in low- and middle-income countries include:

- Assessing HIV exposure status by performing antibody testing of the mother. If HIV-positive, perform NAT on HIV-exposed infant.
- Ensuring regular follow-up for all HIV-exposed infants until final diagnosis, including final diagnosis, providing CTX prophylaxis and clinical and nutritional assessment.

For HIV-positive infants, do not delay ART. Immediate initiation of ART saves lives and should not be delayed while waiting for the results of the confirmatory test.

- Guidelines and guidance:
  - *Consolidated guidelines on HIV testing services* (2019) *(22)*.
  - *Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach* (2021) *(27).* Fig. 2.7 Simplified infant diagnosis algorithm; Fig. 2.8 Managing indeterminate test results: standard operating procedure; Chapter 3: HIV prevention; Chapter 4: Antiretroviral therapy.
  - *Global guidance on criteria and processes for validation: elimination of mother-to-child transmission of HIV, syphilis and hepatitis B virus* (2021) *(30).*

Steps for PMTCT delivery and postpartum process

1. Capture or update mother's history

- Check for the mother's HIV status and, if negative, how recent the test was. If warranted based on the HIV burden of the setting, risk factors or other criteria, perform a rapid diagnostic test (RDT) on the mother.

2. Check whether an HIV test is needed

3. HIV test needed?

4. Test mother using HIV testing algorithm

- If needed, test mother using national testing algorithm.
- Decision logic:
  - HIV.DT.02 Test for HIV using testing algorithm
- Guidelines and guidance:
  - *Consolidated guidelines on HIV testing services* (2019) *(22)*.
  - *Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach* (2021) *(27)*.

5. Post-test package of services for mother

- The core package of post-test services needs to include concise counselling messages and effective supportive interventions, approaches and tools to facilitate rapid ART initiation, and additional linkages to HIV prevention, care, support and other relevant services.
- Messages need to provide clients with the latest information and be clearly communicated to all people tested for HIV.

- Link mother to comprehensive HIV prevention services and offer and encourage partner testing services, including self-testing.
- Provide information, followed by referral when appropriate, on available and effective HIV prevention options.

6. Mother's HIV status?

7. Determine mother's ongoing risk

- Not everyone needs post-test counselling to encourage retesting at appropriate intervals. More frequent retesting may be warranted based on individual risk factors and as part of broader HIV prevention interventions, such as for those taking PrEP or for key population members presenting with an STI.
- Decision logic:
  - HIV.DT.03 Determine retest recommendation.
- Guidance and guidelines:
  - *Consolidated guidelines on HIV testing services* (2019) *(22)*
    - 7.2.4 Retesting – when and who?
    - 7.2.5 Testing pregnant and breastfeeding women
    - Table 6.1. Recommended time points for HIV retesting in pregnant and postpartum women
    - Table 4.1. HIV prevention, treatment and care services.

8. Mother's ongoing HIV risk?

9. Link mother to services

- Link mother to comprehensive HIV prevention services and offer and encourage partner testing services, including self-testing.
- Provide information, followed by referral when appropriate, on available and effective HIV prevention options.
- Decision logic:
  - HIV.DT.04 Determine PrEP eligibility.
- Guidelines and guidance:
  - *Preventing HIV during pregnancy and breastfeeding in the context of PrEP. Technical brief* (2017) *(29)*.
  - *Consolidated guidelines on HIV testing services* (2019) *(22)*. 4.3 Post-test key messages and information.

10. Add postpartum retest to mother's care plan

- If recommended based on risk, add a follow-up HIV test for a future clinical appointment.

11. Determine HIV risk to infant

- Check for risk factors to determine an exposed infant's HIV risk, which may affect the preventative measures and treatments recommended.
- Guidelines and guidance:
  - *HIV diagnosis and ARV use in HIV-exposed infants: a programmatic update* (2018) *(43)*. Annex 4. Risk assessment.

12. Test infant for HIV using testing algorithm

- For infants and children less than 18 months of age, NAT tests should be performed at a variety of time points, including birth testing (where of value), six weeks of age, and nine months of age.
- Confirmatory testing should be performed with a new specimen at ART initiation.
- Final diagnosis should be performed at 18 months of age or three months post-cessation of breastfeeding. If after 18 months of age, serology testing and the national HIV testing algorithm should be used.
- If both test results are indeterminate, do not report as positive or initiate ART but maintain prophylaxis in accordance with current guidance.
- Repeat samples should be given priority in the laboratory.
- A team of laboratories, clinicians or paediatricians, complex case experts (if possible) and caregivers should review repeated indeterminate results in two separate samples together with clinical information. Infants should be actively tracked to ensure follow-up and retention.
- Same-day point-of-care NAT should be considered and prioritized for infant diagnosis at all relevant time points to maximize cliniical benefits and linkage to treatment.
- Decision logic:
  - HIV.DT.02 Testing for HIV using testing algorithm (algorithm for testing of infants)
- Guidelines and guidance:
  - *Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach* (2021) *(27).*
    - Fig. 2.7 Simplified infant diagnosis algorithm
    - Fig. 2.8 Managing indeterminate test results: standard operating procedure

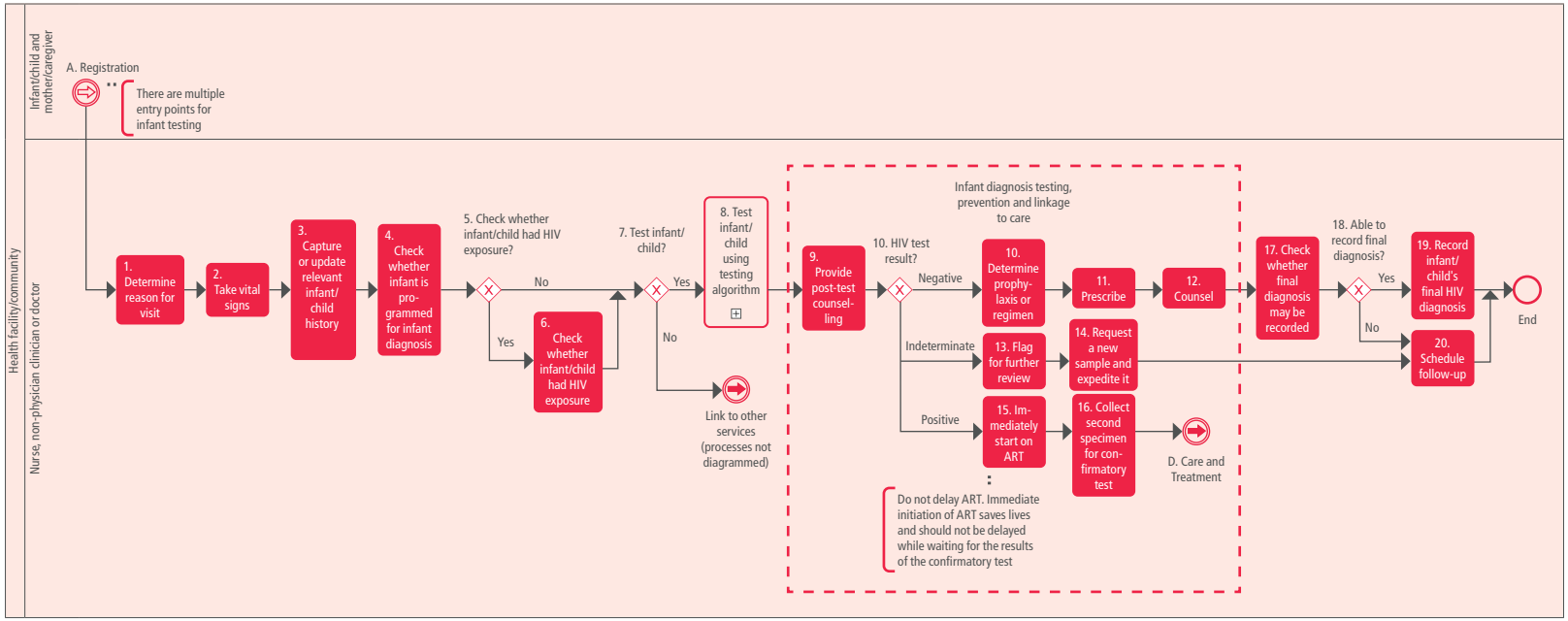
13. Infant diagnosis testing, prevention and linkage to care

- This testing subprocess applies the steps defined in the infant diagnosis procedure. (See Process HIV.F. Infant diagnosis and final HIV status.)

F. Infant diagnosis and final HIV status

Objective: To determine if HIV-exposed infants or children without a final diagnosis are HIV-positive, assess for HIV exposure if not known and start them on ART or preventative care based on their status. Fig. 14 shows the flow of the PMTCT infant diagnosis process.

Fig. 14. Infant diagnosis visit business process



F. Infant diagnosis and final HIV status

General notes

There are multiple entry points for routine infant testing, including at nutrition, inpatient, and TB clinics. In generalized epidemic settings, infants and children with unknown HIV status should be offered HIV testing in outpatient and immunization clinics.

The key principles for establishing whether HIV-exposed infants and children younger than 18 months old are infected with HIV in low- and middle-income countries are based on WHO recommendations:

- Conduct antibody testing of the mother to assess infant/child HIV exposure status. If HIV-positive, perform NAT on HIV-exposed infant.
- Perform NAT test for any HIV-exposed child outside of national infant testing algorithm who presents with clinical symptoms, irrespective of previous NAT results.
- Same-day point-of-care NAT should be considered and prioritized for infant diagnosis at all relevant time points to maximize clinical benefits and linkage to treatment.
- At nine months, perform NAT for HIV-exposed infants, symptomatic and asymptomatic, regardless of previous NAT results after delivery.
- Ensure that confirmatory testing is undertaken following any positive result.
- Ensure that indeterminate test results are repeat-tested immediately and given priority for rapid resolution.
- It is strongly recommended that test results from virological testing in infants be returned to the clinic and child/mother/caregiver as soon as possible.
- Positive test results should be fast-tracked to the mother–baby pair as soon as possible to enable prompt initiation of ART.
- Ensure regular follow-up for all HIV-exposed infants until final diagnosis, including providing CTX prophylaxis and clinical and nutritional assessment.
- For infants who test HIV positive, do not delay ART. Immediate initiation of ART saves lives and should not be delayed while waiting for the results of the confirmatory test.
- Guidelines and guidance:
  - *Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach* (2021) *(27)*.

Steps for infant diagnosis process

1. **Determine reason for visit**

- Search for client details in the system and determine reason for visit.

2. **Take vital signs**

3. **Capture or update infant's/child's history**

- Discuss history with client and review available records. History-taking should include mother's HIV status and whether virally suppressed or on ART.

4. **Check whether programmed for infant diagnosis**

- Check to determine whether a test is recommended and, if so, whether it is planned. Also confirm that a positive diagnosis is not already recorded.
- Even if HIV exposure is not recorded, perform NAT test for any HIV-exposed child that presents outside of national infant testing algorithm with clinical symptoms, irrespective of previous NAT results.

- Guidelines and guidance:
  - *Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach* (2021) *(27).*
    - Fig. 2.7. Simplified infant diagnosis algorithm.
    - Fig. 2.8 Managing indeterminate test results: standard operating procedure.

5. Need to check whether infant/child had exposure?

6. Check whether infant/child had known HIV exposure

- This activity looks at the mother's HIV status, time on ART and viral suppression. If the mother has not been tested, an RDT can be performed to check her HIV status.

7. Test infant/child?

- Provider makes a decision on whether the infant should be tested at that time.

8. Test infant/child using HIV testing algorithm

- The type of test to use will depend on national policies and may consider a number of factors, including availability of tests at a facility.
- Decision logic:
  - HIV.DT.02 Test for HIV using testing algorithm.
- Guidelines and guidance:
  - *Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach* (2021) *(27).*
    - Fig 2.7 Simplified infant diagnosis algorithm.
    - Fig. 2.8 Managing indeterminate test results: standard operating procedure.

9. Provide post-test counselling

- Messages for counselling clients after HIV testing are available from testing processes but should be tailored to the context and setting.
- Messages need to provide clients with the latest information and be clearly communicated to all people tested for HIV, regardless of the test result.
- Guidelines and guidance:
  - *Consolidated guidelines on HIV testing services* (2019) *(22)*.
    - 4.3. Post-test key messages and information.
    - 4.4.2 Linkage to care and rapid ART initiation for people with HIV.

10. Determine infant prophylaxis or regimen

- Guidelines and guidance:
  - *Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach* (2021) *(27)* Annex 1: Dosages for ARV drugs.
  - WHO Paediatric ARV dosing dashboard *(41)*.
  - *HIV diagnosis and ARV use in HIV-exposed infants: a programmatic update* (2018) *(43)*. Annex 5: Dosing and formulation options for infant prophylaxis.

  - *Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach* (2021) *(27)*.
    - Box 5.3: **S**creen, **T**reat, **O**ptimize and **P**revent AIDS among children.
    - Annex 1: Dosages for ARV drugs.
  - WHO Paediatric ARV dosing dashboard *(41)*.

11. Prescribe

- Provide script or order medications, including determining any refills that will be allowed.
- Guidelines and guidance:
  - *Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach* (2021) *(27)*. Tables and "General Principles".
  - *Updated recommendations on first- and second-line antiretroviral regimens. Policy brief* (2019) *(40)*.
  - *Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach* (2021) *(27).* Box 5.3. **S**creen, **T**reat, **O**ptimize and **P**revent AIDS among children.

12. Counsel

- Counsel on prophylaxis use and care.
- Infants should be actively tracked to ensure follow-up and retention.

13. Flag for further review

- If both test results are indeterminate, do not report as positive or initiate ART but maintain prophylaxis in accordance with current guidance.
- A team of laboratories, clinicians or paediatricians, complex case experts (if possible) and caregivers should review repeated indeterminate results in two separate samples together with clinical information.
- Decision logic:
  - HIV.DT.02 Test for HIV using testing algorithm
- Guidelines and guidance:
  - *Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach* (2021) *(27).*
    - Fig. 2.7 Simplified infant diagnosis algorithm.
    - Fig. 2.8 Managing indeterminate test results: standard operating procedure.

14. Request a new sample and expedite processing

- Ensure that indeterminate test results are repeat-tested immediately and given priority for rapid resolution.
- It is strongly recommended that test results from virological testing in infants be returned to the clinic and child/mother/caregiver as soon as possible, but at the very latest within four weeks of specimen collection.

15. Immediately start infant on ART

- Start ART without delay.

16. Collect specimen for confirmatory test

- At the same time, retest to confirm infection. Retesting after a first positive NAT, particularly in settings with low transmission rates, is important to avoid continuing unnecessary treatment. If the second test is negative, a third NAT should be performed before interrupting ART.

17. Check whether ready to record final diagnosis

- Determine whether the final diagnosis can be recorded, based on the infant's age, breastfeeding status and date breastfeeding stopped. The final diagnosis of HIV status can be assessed only at the end of breastfeeding. For infants/children less than 18 months old, NAT should be performed to confirm infection.
- Guidelines and guidance:
  - *Consolidated guidelines on HIV testing services* (2019) *(22)*. Table 4.1. HIV prevention, treatment and care services.

18. Criteria met to record final diagnosis?

19. Record infant's/child's final HIV diagnosis

- Guidelines and guidance:
  - *Consolidated HIV strategic information guidelines: driving impact through programme monitoring and management* (2020) *(10)*.

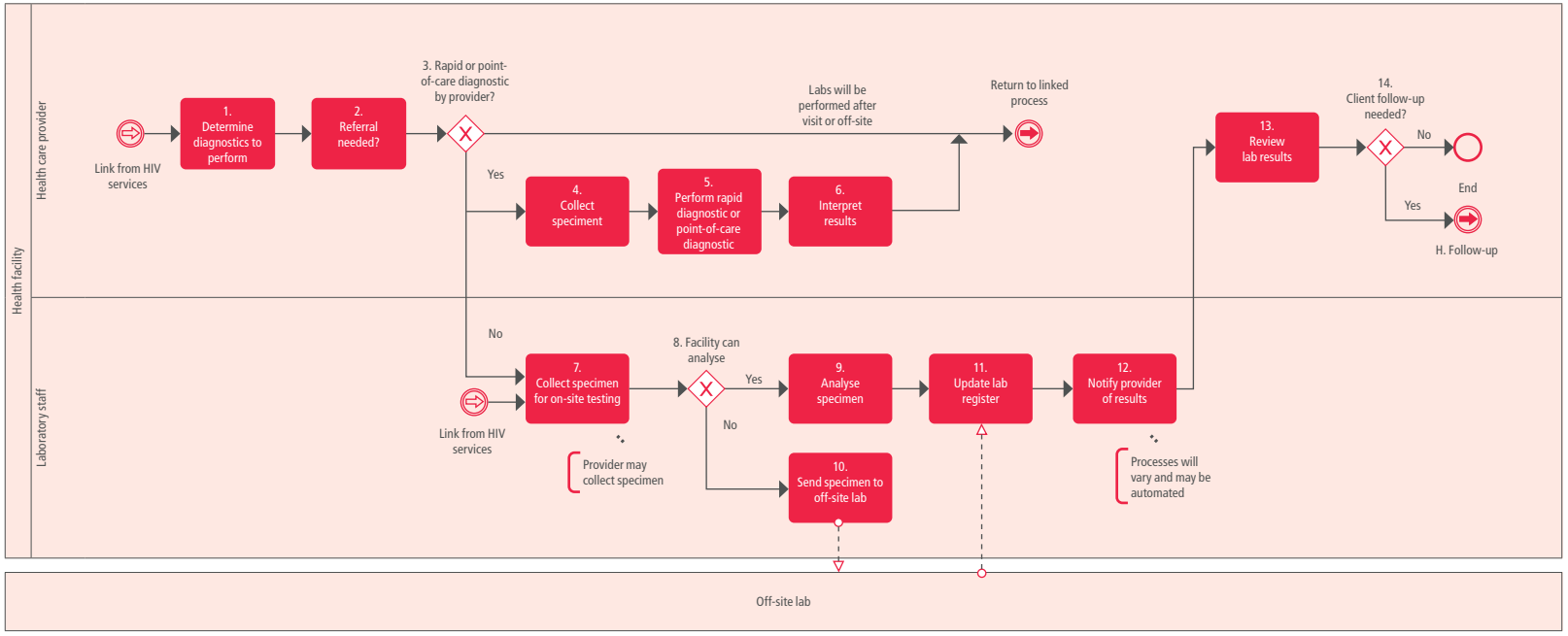
20. Scheduling follow-up

- Explain importance of follow-up.
- Add infant HIV virological testing to care plan.
- If guardian/caregiver consents to be contacted, confirm contact data and set up the process to allow follow-up.

G. Diagnostics business process

Objective: To investigate and obtain results through on-site or off-site diagnostics. Fig. 15 shows an example of the flow of a diagnostics process.

Fig. 15. Diagnostics business process



G. Diagnostics process notes and annotations

General notes

The clinician may order an investigation during an outpatient consultation or inpatient round. Investigations can include:

- An RDT performed by the health care provider.
- An order to perform the investigation at a laboratory or a diagnostic service at the current facility, if the service is available.
- An order to refer the client to another facility to perform the investigation there.
- An order to take a sample from the client and arrange to transport the sample to another facility.
- Other specialized diagnostic investigations.

Steps for diagnostics process

1. Determine diagnostics to perform

- Includes checking supply and prioritization based on urgency for the test.
- Check whether facility can accommodate the client and provide the needed services. If the facility is not able to perform the diagnostic or, alternatively, to collect and send the specimen, a referral may be required.

2. Referral needed?

- An order to refer the client to another facility to perform the investigation may be needed if the facility cannot perform it.

3. Rapid or point-of-care diagnostic by provider?

- Based on the types of diagnostics available at the facility, the providers' skill set, facility processes and task sharing arrangements, a specimen may be taken by the provider, on-site or at an off-site lab.
- If on-site, diagnostics may be performed at the end of the visit or else during the flow of steps and the client will return to a health care provider after diagnostics.

4. Collect specimen

- The health care provider briefs the client.
- The provider collects a specimen for rapid or point-of-care diagnostic.

5. Perform rapid diagnostic or point-of-care diagnostic

6. Interpret results

7. Collect specimen for on-site testing

- The investigation performer, such as a health care worker non-professional staff, or laboratory staff member, will brief the client and collect the specimen.

8. Facility can analyse?

- Establish whether the specimen can be analysed at this facility or should be sent to another facility.

9. Analyse specimen

- If the facility is able to analyse the specimen, this would include pre-analysis, analysis and post-analysis of the specimen.

10. Send specimen to off-site lab

- If the specimen needs to be transferred to another facility for analysis, health facility staff will collect the sample and send it to another facility for investigation.

11. Update laboratory register

12. Notify provider of results

- The results are communicated back to the ordering facility or health care worker. It is possible the client could also receive automated notification that the lab results have been returned.

13. Review lab results

- The provider reviews lab results and identifies whether results require reaching out to the client.

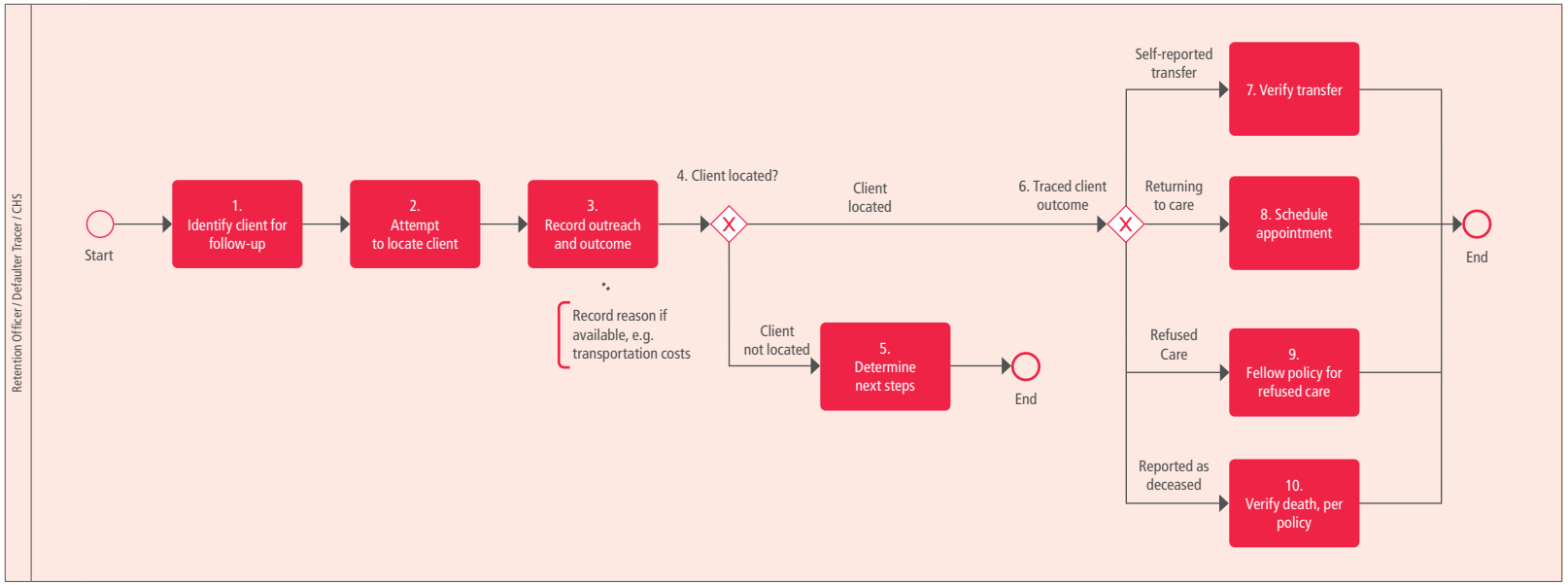
14. Client follow-up needed?

- If needed, client will be notified that results are available and be advised to visit the facility to receive results.

H. Following up and contacting clients

Objective: To follow up by contacting clients to ensure clients are receiving the services they need and that records are updated; to increase retention and adherence and, ultimately, to improve patient outcomes. Fig. 16 shows the flow of the follow-up process.

Fig. 16. Following up and contacting clients business process



H. Follow-up process notes and annotations

General notes

A provider may want or need to follow up with a client for various reasons, such as:

- To inform the client of test results coming back from a lab that should be acted on.
- A missed clinical appointment or drug pickup.

Facility and community workers may share information through multiple channels to assign work, use different paper-based or digital tools, to update data in the system. In this case, steps in the process may be repeated by different facility and community workers.

Guidelines and guidance:

- *Consolidated HIV strategic information guidelines: driving impact through programme monitoring and management* (2020) *(10)*.

Steps for follow-up process

1. Identify clients for follow-up

- Check whether client has stated communication preference or asked to not be followed up via certain methods.

2. Attempt to locate client

- Multiple communication methods may be used to try to reach clients, such as phone or in person.
- Lists of clients needing follow-up may be distributed to field or community workers based on criteria such as proximity of home addresses.

3. Record outreach and result

- The staff member records the outreach outcome.
- The staff member validates contact information and updates it as needed.
- The method of outreach and source of information are recorded. Information may come from a treatment supporter or family member as well as from the client.
- The outcome is recorded, such as the client is returning to care, the client reported transferring, a client has died, the client could not be located, etc. (Step 6).
- When follow-up is for missed care, a reason for missing care may be recorded, such as cost of transportation or missing work.

4. Client located?

5. Determine next steps

- This step may include changing the recorded status of the client after outreach, for example to "lost to follow-up", dropping the client from the follow up list, setting another time to try to reach the client, specifying a different outreach method, etc.
- Additional attempts to locate patients may be made until a patient is dropped from a list.
- The recommended threshold for designating people living with HIV on ART as lost to follow-up is 28 days after the last scheduled appointment (rather than the previous 90-day standard).

6. Traced client outcome?

- If the patient was located, depending on the outcome, different processes will be followed. More outcomes than are shown here are possible.

7. Verify transfer

- Verify transfer with the facility the client was referred to.

8. Schedule an appointment

- A community health worker or other provider may travel with the client to a facility to assure that the client keeps the appointment.

9. Follow policy for refused care

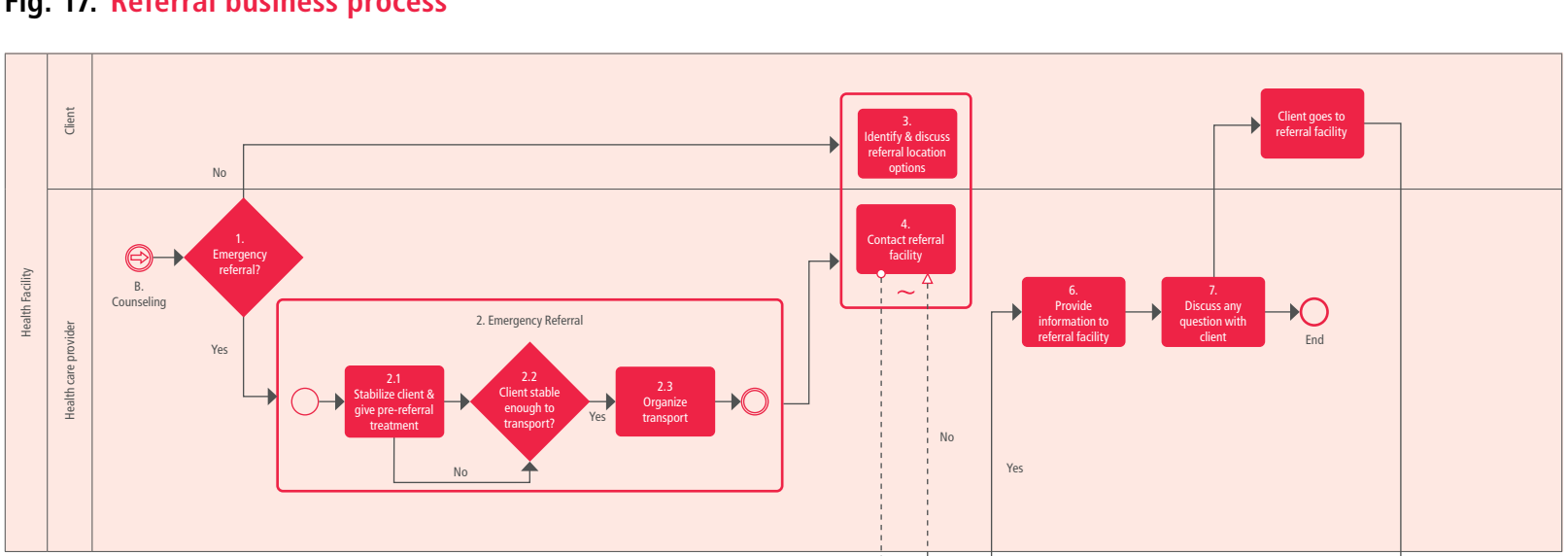
10. Verify death, per policy

- This usually requires a verbal autopsy and asking for cause of death. Generally, however, these data come from a survey.
- It is not always possible to find out the cause of death.

I. Referral business process

Objective: To direct clients to services that are not available in the consultation facility. Fig. 17 shows the flow of the referral process.

Fig. 17. Referral business process



I. Referral process notes and annotations

General notes

Examples of reasons for referral include:

- Health worker cannot provide the service due to a lack of training and skills.
- Facility does not have the supplies needed to provide the service.
- The facility cannot perform the service for other reasons.
- There is an emergency and the client needs immediate referral.

Steps for referral process

1. Emergency referral?

- If client needs immediate referral due to an emergency situation, bypass standard referral steps.
- In an emergency, a referral can be made at any time, including during registration, counselling and service provision.

2. Emergency referral

- 2.1 Stabilize client and give pre-referral treatment
  - The client is assumed to need emergency referral if her/his condition requires immediate medical attention. Stabilize the client's condition and provide any necessary treatment.
- 2.2 Client is stable enough to transport?
  - Once the client is stable enough to transport, immediately organize it.
  - If the client is still not stable, provide pre-referral treatment for stabilization.
- 2.3 Organize transport
  - For emergency referrals, the health facility usually arranges for an ambulance or other vehicle.

3. Identify and discuss referral location options

- In discussion with the client and his or her relatives, decide where the client will be referred. Discussions include:
  - How to get to the referral facility, including location and transportation options.
  - Whom to see and what is likely to happen.
  - Whether to follow up on return.
- Either the client or the client's relatives should decide on a referral location based on their preferences.

4. Contact referral facility

- Health workers should contact the referral facility to determine whether that facility can accommodate such a referral.

5. Can facility accommodate?

- Check whether facility can accommodate the client and provide the needed services.
- If the facility can accommodate the client, move on to step 6.
- Otherwise, find a different facility that is able to accommodate the client.
- A system can be set up to catalogue referral facilities, and what type of referral needs they can handle to accommodate a referral.

6. Provide information to referral facility

- Make appointment if needed.
- If not an emergency referral, client or family arranges transport.
- For emergency referrals, the health facility arranges transport, usually by phoning the district for an ambulance or other vehicle, and informing the receiving facility that emergency client is on the way.
- Fill out referral form, which can include notification of the referral destination.
- Provide the necessary clinical, sociodemographic and identity information to the referral facility. This can be done digitally if the appropriate systems are in place.

7. Discuss any questions with client

- Discuss any of the client's questions or concerns.

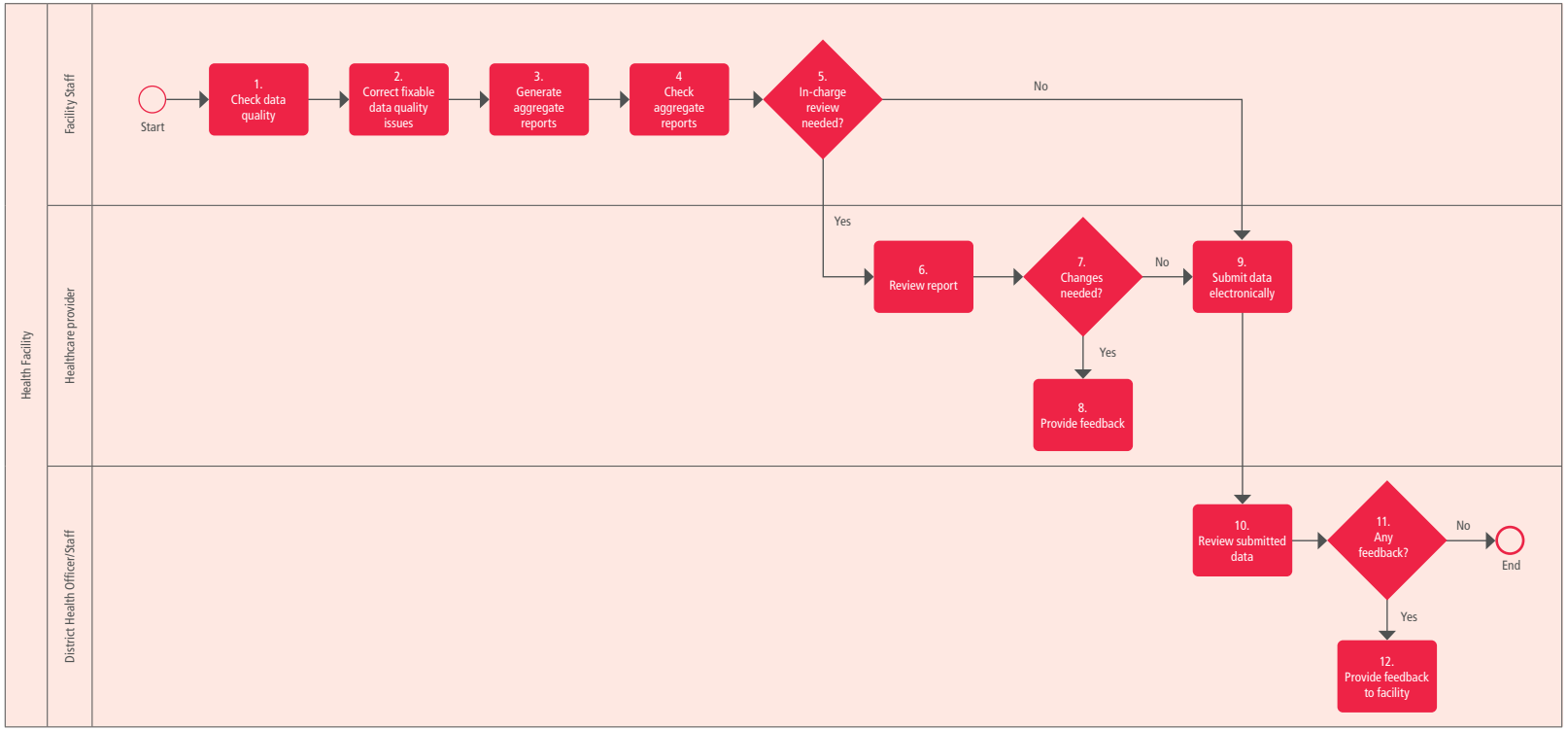
8. Receives client

- Referral facility receives the client, along with all the necessary clinical, sociodemographic and identification information, and provides services.

J. Aggregate reporting and data use business process

Objective: To aggregate client-level data into validated reports, use the data and submit reports from the facility level. Fig. 18 shows a sample flow of an aggregate reporting process.

Fig. 18. Aggregate reporting business process



J. Aggregate reporting and data use business process notes and annotations

Steps for aggregate reporting process

1. **Check data quality**

- Health facility reviews the accuracy, validity and completeness of data in the system. This can be automated and done digitally.

2. **Correct fixable data quality issues**

- Depending on local policy, this step might not be required.

3. **Generate aggregate reports**

- This can be automated and done digitally.

4. **Check aggregate reports**

- Depending on local policy, this step might not be required.

5. **Manager In-charge review needed?**

- Determine if the report needs to be reviewed by the manager in-charge of the facility.
- Some of the facility managers in-charge do not review reports.

6. **Review report**

- The in-charge reviews the reports. This can be done digitally.

7. **Changes needed?**

- Determine if the report is accurate or has any issues.

8. **Provide feedback**

- If there is any issue with the report, the in-charge provides feedback to the responsible person to make corrections to the client-level data. This can be done digitally.

9. **Submit data electronically**

- Reports and data may be used by the facility at multiple points during the business process or outside of the business process. This can be automated and done digitally.
- Depending on local policies, an active "submission" may not be needed, and the district-, provincial- and national-level ministries of health are able to access reporting data directly.

10. **Review submitted data**

- Use data in report to review progress and make decisions on improvements and other actions to take.

11. **Any feedback?**

- After review of the data, determine whether there is any feedback to give.

12. **Provide feedback to facility**

- If there is any feedback, the focal person provides it to the facility. If there are errors, the facility may be required to restart the process and resubmit.

4.3. Additional considerations for adapting workflows

The workflows shown in section 4.2 are meant to be generic and high-level. They will require customization and adaptation as they are being translated into a digital system for a specific context. We consider these workflows to be "80% complete", and the "other 20%" will need to be done through a series of human-centred design methods and mechanisms to complete the workflows for an implementation. For example, there might be additional workflows that need to be drawn out or there might be additional activities that a health worker in the facility is expected to conduct. Some workflows have not been included here because of the great extent of contextualization required; these include: billing, dispensing (if separate from service provision), and configuration (of facility-level specifics). Alternatively, there might be some activities and tasks shown in these workflows that a health worker would not be expected to do.

Although these workflows can be considered a starting point, it will be helpful to conduct further validation through interviews with the people involved or by observing their work to obtain a better sense of differences that would need to be reflected in the digital system.

This section outlines the minimum set of data corresponding to different points of the workflows within the identified business processes. This dataset can be used on any software system and lists the data elements relevant for service delivery and executing decision support logic, as well as for populating indicators and performance metrics. This section provides a high-level overview of the data elements. A more complete data dictionary in spreadsheet form, detailing the input options, validation checks and concept dictionary codes, is available in Web Annex A.

Countries will need to review and adapt this dataset. As with the workflows, we view this data dictionary as "80% complete", with the expectation that the "other 20%" will come directly from the users.

Inclusion of a data element in the table does not by itself indicate that collection of the data is required. Additionally, some data elements are dependent on other data elements (for example, test results are entered only when a test has been performed).

Collection of data should not prevent clients from receiving services or affect clinical care.

5.1. Simplified list of core data elements template

Table 11 presents a simplified list of core data elements. Skips in data element IDs are due to the fact that the full data dictionary (Web Annex A) is much larger, containing many more data elements. The complete list will need review to determine what data elements should be collected, calculated and reported in a country's digital tracking and decision support system.

Table 11. Workflow core data elements for identified business processes

Activity ID & name	Data element ID	Data element name	Description and definition
HIV.A2. Gather client details	HIV.A.DE1	First name	Client's first name
	HIV.A.DE2	Family name	Client's family name
	HIV.A.DE3	Visit date	The date and time of the client's visit
	HIV.A.DE4	Referral	If client was referred for care
	HIV.A.DE5	Referred by	How the client was referred
HIV.A6.1 Review sociodemographic data with client OR HIV.A5 Create client record	HIV.A.DE8	Unique identifier	Unique identifier generated for new clients or a universal ID, if used in the country
	HIV.A.DE14	Date of birth	The client's date of birth (DOB) if known
	HIV.A.DE17	Age	Age in years calculated from DOB
	HIV.A.DE18	Gender	Gender of the client
	HIV.A.DE30	[Administrative area]	This should be a context-specific list of administrative areas, such as villages, districts, etc. The purpose of this data element is to allow for grouping and linking client data to a particular facility's catchment area. This can be input into the system by the end user OR it can be automated in the database based on the end user's attributes.
HIV.B1. Determine reason for visit	HIV.B.DE1	Reason for HIV testing services visit	Reason for HIV testing services visit
	HIV.B.DE4	Referred through partner services	Whether client reported coming to the facility because of voluntary partner services and details, if so
	HIV.B.DE12	Contact with and (suspected) exposure to HIV	Whether the client reported having suspected exposure to HIV and the date of exposure
	HIV.B.DE14	Testing entry point	Where in the community or at a facility testing is taking place

Activity ID & name	Data element ID	Data element name	Description and definition
HIV.B6. Capture or update client history	HIV.B.DE28	Currently pregnant	Client is currently pregnant
	HIV.B.DE31	Breastfeeding	Client is giving infant breast milk
	HIV.D.DE494	Family planning method used	Method the client reports currently using at intake
	HIV.D.DE716	TB history of client	Whether TB screening or diagnostic testing was performed, the date of the test and result
	HIV.B.DE32	HIV status of partner	HIV status of the partner and treatment details, if HIV-positive
	HIV.B.DE42	HIV self-test	Reported use of an HIV self-test, date taken and result
	HIV.B.DE48	Key populations	Client is a member of a key population, which has an increased risk of HIV
HIV.B7. Test using HIV testing algorithm	HIV.B.DE105	HIV test	Whether an HIV test was done, the date of the HIV test and result
	HIV.B.DE110	HIV status	HIV status reported after applying the national testing algorithm
	HIV.B.DE114	Probable route of HIV transmission	Probable route(s) of transmission of HIV to client
HIV.B8. Provide post-test counselling	HIV.B.DE130	Counselling provided on diagnoses	Whether counselling was provided to a client given a diagnosis during the visit
HIV.D9 -> HIV.B9. Determine recommended services	HIV.B.DE136	Prevention services offered and referrals	Offer or refer to prevention services
	HIV.B.DE143	Sexual and reproductive health integrated services	Offer or refer to sexual and reproductive health services
	HIV.B.DE150	HIV testing for partners and biological children	Offer voluntary testing for all partners and biological children of HIV-positive clients (includes partner services and index case testing), as well as for partners and social contacts of clients from key populations, where appropriate
	HIV.B.DE152	Other clinical services	Other clinical services offered or referrals given to the client
	HIV.B.DE159	Other support services	Offer or refer for other support services
	HIV.B.DE171	Offered voluntary partner services	Whether the client was offered voluntary partner services or family services

Activity ID & name	Data element ID	Data element name	Description and definition
HIV.B21. Counsel on retest	HIV.B.DE177	Type of follow-up appointment	Type of follow-up appointment for testing services
HIV.C. PrEP visit			
HIV.C1. Determine reason for visit	HIV.C.DE1	Reason for PrEP visit	Client's reason for the PrEP visit
HIV.C3. Capture or update client history	HIV.C.DE8	Contact with and (suspected) exposure to HIV	The client had suspected or known exposure to HIV
	HIV.C.DE10	Currently on PrEP	The client is currently taking PrEP for HIV prevention.
	HIV.C.DE11	PrEP dosing type	Way in which PrEP is taken (daily or event-driven)
	HIV.C.DE16	HIV PrEP regimen	PrEP regimen
	HIV.C.DE21	PrEP history	The client's history of taking PrEP
	HIV.C.DE27	PEP history	The client's history in taking PEP
	HIV.C.DE30	Date(s) of past PEP use	When the client previously used PEP
	HIV.C.DE36	Pregnancy intention	Client's intention or desire in the next year to either become pregnant or prevent pregnancy
	HIV.C.DE41	Acute HIV infection symptoms	Symptoms that could suggest acute HIV infection
	HIV.C.DE50	Sex partner's HIV treatment status	Treatment adherence of client's sex partner, for partners who are HIV-positive
HIV.C9. Eligible for PrEP	HIV.C.DE56	Eligible for PrEP	The client is eligible for PrEP
HIV.C10. Discuss PrEP	HIV.C.DE57	Offered PrEP	After being evaluated as eligible for PrEP, the client was offered PrEP
HIV.C18. Determine recommended tests	HIV.C.DE58	Screenings and diagnostics recommended	Listing of recommended tests for PrEP
HIV.C24. Prescribe	HIV.C.DE101	Reason for PrEP regimen substitution	Reason that a substitution was made in the PrEP regimen

Activity ID & name	Data element ID	Data element name	Description and definition
HIV.D9. Determine recommended services	HIV.B.DE105	Link to confirmatory testing and ART	If the client tested positive for HIV, link the client to care for confirmatory testing and ART initiation
	HIV.B.DE136	Prevention services offered and referrals	Offer or refer to prevention services
	HIV.C.DE125	HIV self-test requested for	Whom the client plans to give the HIV self-test kit to (self, sexual partner, social contact, etc.)
	HIV.B.DE143	Sexual and reproductive health integrated services	Offer or refer to sexual and reproductive health services
HIV.D. Care and treatment visit			
HIV.D1. Determine reason for visit	HIV.D.DE1	Reason for HIV care and treatment visit	Whether visit was scheduled or unscheduled, clinical only or for ARV drug pick-up
HIV.D3. Check for signs of serious illness	HIV.D.DE15	Signs of serious illness	Signs that may indicate the client has a serious illness and needs triage or emergency referral
HIV.D4. Screen for TB	HIV.D.DE736	Symptoms of TB	Symptoms that may indicate active TB in clients living with HIV, based on a clinical algorithm
HIV.D8. Capture or update client history	HIV.D.DE36	ART start date	The date on which the client started or restarted ART
	HIV.D.DE43	Date of initiation on ART	The date on which the client was initiated on ART
	HIV.D.DE46	Transfer in for HIV care	Client is transferring in with records or known ART drugs and ART start date
	HIV.D.DE61	Health condition	Client's chronic and past health conditions, including diabetes, hypertension and infections
	HIV.D.DE464	Medications	Medications the client is taking (can be selected from drop-down list)
	HIV.D.DE69	Current antiretroviral regimen	The client's current ART regimen, including if it is a first-line, second-line or third-line treatment
HIV.D22 Determine regimen and treatment options	HIV.D.DE404	Type of treatment-limiting toxicity or serious drug reaction	Determine if any treatment-limiting toxicity occurred, defined as life-threatening illness, death, hospitalization, disability resulting in treatment discontinuation or substitution
HIV.D15. Determine clinical stage of HIV	HIV.D.DE156	Clinical stage	WHO clinical stage of client based on signs and symptoms currently and at start of ART, with any dates the stage changed
HIV.D22 Determine regimen/ treatment options	HIV.D.DE370	Regimen switch and substitutions	Any changes to regimen, dates and reason(s) for the switch or substitution
HIV.D10. Counsel	HIV.D.DE184	Reason ART stopped	Reason that client intentionally stopped ART

Activity ID & name	Data element ID	Data element name	Description and definition
HIV.D21. Diagnostics	HIV.G.DE1	CD4 count	Whether a CD4 cell count was done, type of test, the date of the test and result
	HIV.G.DE11	Viral load	Whether a viral load test was done, type of test, the date of the test and result
	HIV.D.DE340	Investigations ordered	Name of test ordered and results received for any relevant investigations carried out for client (including for TB)
	HIV.D.DE428	Enhanced adherence counselling provided	Whether the client was provided enhanced adherence counselling the visit
	HIV.G.DE16	Hepatitis B	Whether hepatitis B test was done, type of test, the test date and result
	HIV.G.DE36	Hepatitis C	Whether hepatitis C test was done, type of test, the test date and result
	HIV.G.DE58	Syphilis	Whether syphilis test was done, type of test, the date of the syphilis test and result
HIV.D25. Assess for vaccine-preventable diseases	HIV.D	Immunizations	Immunization history and any vaccinations provided, with the date given
HIV.D25. Prescribe	HIV.D.DE699	Malaria prophylaxis	Whether malaria prophylaxis was given
	HIV.D.DE396	Medications prescribed	Name or regimen code of all antiretroviral and other medications prescribed during the visit
	HIV.D.DE400	Other medications dispensed	Select if any other medications were dispensed to client, including preventive treatment
HIV.D33. Schedule follow-up visit	HIV.D.DE456	Date/time of follow-up appointment	Date and time the client is to return for monitoring, re-supply or any other reason
HIV.H. Following up and contacting clients			
HIV.H1. Identify client for follow-up	HIV.H.DE1	Reason for following up or contacting client	The reason that the client is being followed up
HIV.H. Attempt to locate client	HIV.H.DE12	Contact method	Method used to try to reach the client
	HIV.H.DE16	Source of information	Source of information about the client

Activity ID & name	Data element ID	Data element name	Description and definition
HIV.H. Record outreach and result	HIV.H.DE21	Outcome of outreach attempt	Detailed outcome of the attempt to locate the client
	HIV.H.DE36	Date of death	If deceased, the date that the client died
	HIV.H.DE37	Cause of death	Cause of death, if known
	HIV.H.DE39	HIV treatment outcome	The outcome for the client that is used for reporting retention. Included in total attrition from ART: death, stopped treatment and lost to follow-up. "Currently on ART" is included so that client outcome remains up to date.
	HIV.H.DE46	Transfer confirmed	Select if transfer to another facility is confirmed
	HIV.H.DE49	Adherence assessment	Whether client is adherent or not to ART regimen per national guidelines (immunological or virological monitoring)
	HIV.H.DE50	Reason(s) for adherence problem	Reason(s) that client is not adherent
	HIV.H.DE71	Reason antiretroviral therapy stopped	Reason that client intentionally stopped ART

5.2. List of calculated data elements

The preceding section listed the core data elements that should be included in digital systems in order to facilitate the decision support logic or indicators. Additional data elements derive from calculations based on the core data elements listed above. Table 12 lists those calculated data elements.

Table 12. Calculated data elements

Calculated data element label	Core data elements used for calculation	Description and definition
Age	• Visit date • Date of birth	("Visit date" – "Date of birth")/365.25
Body mass index (BMI)	• Body weight • Body height	"Body weight (kg)"/[("Height (cm)"/100)^2]
Estimated creatinine clearance (Cockcroft–Gault equation)	• Gender • Age • Serum creatinine • Weight • Sex factor for calculating creatinine clearance	"Sex factor" * ((140 – age) / ("Serum creatinine test result")) * ("Body weight (kg)" / 72) Sex factor: male = 1, female = 0.85 Age in years, serum creatinine in mg/DL, weight in kg
Virally suppressed	• Viral load test result	If Viral load test result (most recent test) <1000 copies/mL
Viral load suppression date	• Viral load test result • Date of HIV viral load sample collection • Virally suppressed	If virally suppressed, the first date of HIV viral load sample collection where the viral load test result is <1000 copies/ml after the most recent viral load test result >1000.
Late ART initiation	• Baseline CD4 count	Baseline CD4 count <200 cells/mm^3

5.3. Additional considerations for adapting the data dictionary

Some settings may require the inclusion of additional data elements into the full dataset or changes to response options based on contextual differences. Additionally, the transition from paper-based forms to digital systems may require some reflection on whether all data elements currently on the paper forms should be incorporated into the digital system.

Table 13 presents an initial list of possible customizations and configurations that programmes may want to make based on the national guidelines governing the digital tracking and decision support system is being implemented in.

Table 13. Potential customizations and configurations of the data element set

Points of customization and configuration	Description
Unique identifier	Unique identification of the client can be based on a national unique ID, a national health ID, biometrics, a system-generated unique identifier or something else.
Services provided	Services provided at the facility. These workflows focus primarily on HIV services. However, other services, and linkages to them, likely need to be included as well – for example, STI testing, ANC, postnatal care.
Counselling provided	Beyond the counselling provided for HIV-related services, there might be other counselling mechanisms that are built into business process workflows. These could include, but are not limited to, other reproductive health counselling, nutrition counselling and HIV counselling. In some contexts, counselling on HIV is also conducted in a group setting. Incorporation pf this counselling into the workflows should be considered in the digital tracking and decision support system.
Regimens provided	List of regimens available in the country, with further customization to specify the regimens available at the facility
Family planning methods provided	List of family planning methods available in the country, with further customization to specify the methods available at the facility
Facility identifier	Unique identifier of the facility. A reference to a facility registry or a reporting system (for example, DHIS2) should be included where possible.
Facility name	Name of the health facility based on a facility registry or a reporting system (for example, DHIS2) should be included where possible.

Points of customization and configuration	Description
Ownership	Denoting whether the facility is public or private, where relevant
Type of health facility	Type of facility, based on country terminology (for example, health centre, health post, dispensary, hospital)
GPS coordinates	Latitude and longitude coordinates can be included if relevant for mapping purposes. This can be helpful especially in the context of community health workers, who could be assigned "HIV service tasks" based on their catchment area and clients' visit histories.
Administrative areas	Administrative areas can be based on geographic location, catchment area, or another mechanism the country uses for managing health facilities
Catchment population	If known, it would be useful to include the catchment population in automated calculation of indicators.
Lab tests available	Whether or not certain lab tests are available at the health facility could affect staff members' workflow as well as clients' HIV service experience (for example, viral load testing, STI screening, blood pressure measurement, other rapid diagnostic tests).

The decision support logic component of the adaptation kit provides the decision logics and algorithms, as well as the scheduling of services, in accordance with WHO guidelines. In this adaptation kit, the decision logics and algorithms deconstruct the recommendations in the WHO HIV guidelines and guidance into a format that clearly labels the inputs and outputs that would be operationalized in a digital decision support system.

6.1. Decision support logic overview

Table 14 provides an overview of the decision support tables and algorithms for the different HIV module business processes. The structure of the decision tables is based on an adaptation of the Decision Model and Notation, an industry standard for modelling and executing decision logics *(45)*. These decision tables detail the business rules and the data inputs and outputs to support the HIV module business processes. The data inputs in each of the decision tables are aligned with the data element names listed in Component 5.

Table 14. Overview of decision support tables for HIV module

Activity ID & activity name	Decision table ID	Decision table description	Reference/source
HIV.B2. Check for signs of serious illness OR HIV.D3. Check for signs of serious illness	HIV.DT.01	Check for serious illness	*Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach* (2021) *(27)* Table 5.1. Components of the package of care for people with advanced HIV disease.
HIV.B7. Test for HIV using testing algorithm, HIV.C4. PrEP visit, HIV.D.11. Retest using HIV strategy, HIV.E4. Test [mother] for HIV using HIV testing algorithm, HIV.E12. Test [infant] for HIV using testing algorithm, HIV.F8. Test [infant] for HIV using HIV testing algorithm	HIV.DT.02	Test for HIV using testing algorithm	*Consolidated guidelines on HIV testing services* (2019) *(22)*. Fig. 2. WHO universal HIV testing strategy. 8.4.2 Multiplex testing for HIV-1 and other infections Figure 8.6. WHO recommended testing strategy for dual detection of HIV and syphilis in ANC settings. Fig. 8.4. WHO HIV testing strategy for early infant diagnosis. *Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach* (2021) *(27).* Fig. 2.7 Simplified infant diagnosis algorithm; Fig. 2.8 Managing indeterminate test results: standard operating procedure.
HIV.B9. Determine recommended services	HIV.DT.03	Determine retest recommendation	*Consolidated guidelines on HIV testing services* (2019) *(22)*. 7.2.4 Retesting – when and who? 7.2.5 Testing pregnant and breastfeeding women.
HIV.C8. Check eligibility for PrEP	HIV.DT.04	PrEP eligibility check	*Implementation tool for pre-exposure prophylaxis of HIV infection* (2017) *(35)*. Module 1: Clinical. Use criteria in pocket card, p. 4, Indications for PrEP (by history over the past 6 months) and Contraindications (with provider discretion). See also *Implementation tool for pre-exposure prophylaxis of HIV infection* (2017) *(35)*. Module 10. Testing providers. Table 1. Summary tool for starting or monitoring PrEP and *Preventing HIV during pregnancy and breastfeeding in the context of PrEP. Technical brief* (2017) *(29)*.
HIV.C.24 Prescribe	HIV.DT.05	Determine PEP or PrEP regimen	*Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach* (2021) *(27)* Chapter 3: HIV prevention.
HIV.D4. Screen for TB	HIV.DT.06	Screen for TB	*WHO consolidated guidelines on tuberculosis: tuberculosis preventive treatment.* (2020) *(36). Supplementary table.* *WHO consolidated guidelines on tuberculosis Module 2: Screening – Systematic screening for tuberculosis disease (47).*

Activity ID & activity name	Decision table ID	Decision table description	Reference/source
HIV.D17. Check for signs of treatment failure	HIV.DT.07	Check for treatment failure	*Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach* (2021) *(27).* Table 4.11. WHO definitions of clinical, immunological and virological failure for the decision to switch ART regimens. *Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection*. 2nd ed. (2016) *(24)*. Annex 10. WHO clinical staging of HIV disease in adults, adolescents and children.
HIV.D12. Determine screenings and diagnostics to perform	HIV.DT.08	Determine screenings to perform	*Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach* (2021) *(27).* Table 4.1. Recommended tests for HIV screening and monitoring and approaches to screening for coinfections and noncommunicable diseases. Table 5.1: Components of the package of care for people with advanced HIV disease Box 5.3. Screen, Treat, Optimize and Prevent AIDS among children Table 5.4. Recommendations for the package of prophylaxis interventions for people with advanced HIV disease Annex 1: Dosages for ARV drugs WHO Paediatric ARV dosing dashboard (41) *Considerations for developing a monitoring and evaluation framework for viral load testing* (2019) *(44)*. *Updated recommendations on HIV prevention, infant diagnosis, antiretroviral initiation and monitoring* (2021) *(28)*. *WHO recommendations for routine immunization – summary table*. (updated 2020) *(39)*. Table 1: Summary of WHO position papers - recommendations for routine immunization *WHO operational handbook on tuberculosis: module 1: prevention* (2020) *(37)*. Table 6.1. Likely adverse events with drugs used for TPT.
HIV.D15. Determine clinical stage of HIV	HIV.DT.09	Determine WHO clinical stage of HIV	*Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection*. 2nd ed. (2016) *(24)*. Annex 10. WHO clinical staging of HIV disease in adults, adolescents and children. Adapted by WHO from: WHO case definitions of HIV for surveillance and revised clinical staging and immunological classification of HIV- related disease in adults and children. 2007. (www.who.int/hiv/pub/guidelines/HIVstaging150307.pdf). *Children are classified as those <15 years old and adults are those ≥15 years.
HIV.D21. Determine regimen/treatment options	HIV.DT.10	Determine ART regimen	*Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach* (2021) *(27)* Chapter 4: Antiretroviral therapy.
	HIV.DT.11	Check for known drug interactions	*Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach* (2021) *(27).* 4.10 Key ARV drug interactions.

6.2. Scheduling logic overview

In addition to specific decision support logic, scheduling logic can facilitate the digital tracking of clients. For example, it is important for the health worker to know when the client's next visit is due, based on the recommendations for follow-up. In the HIV use case, there is only one "schedule", which is the follow-up schedule based on the client's care needs or the service that was provided. Table 15 provides an overview.

Table 15. Overview of scheduling logic

Scheduling logic ID	Scheduling logic description	Reference/source
HIV.S.1	HIV.B9. Determine recommended post-test services	*Consolidated guidelines on HIV testing services* (2019) *(22)*. Table 4.1. HIV prevention, treatment, and care services. *Consolidated guidelines on HIV prevention, testing, treatment, service delivery and monitoring: recommendations for a public health approach* (2021) 7.5.3 Frequency of clinical visits and ART pick-up; Chapter 7: Service delivery.

6.3. Decision tables

Each of the decision logics listed in the overview table (Table 14) is elaborated in Web Annex B. Table 16 describes the components of these decision tables, and Table 17 provides an example. For all the decision tables available for the HIV digital adaptation kit, please refer to the linked spreadsheet available in Web Annex B.

Table 16. Components of the decision tables

Decision ID	The name of the "decision" describing the algorithm or logic that is represented (for example, treatment of Chlamydia trachomatis). In Table 14 the decision table IDs appear in the second column.
Business rule	The description of the decision that needs to be made, based on If/Then statements with the appropriate Data Element Name for the variable. The rule should express the relationship between the input variables and the expected outputs and actions within the decision logic.
Trigger	The event that indicates where this decision support logic should appear within the workflow, such as the activity that would trigger this decision to be made.

<table>
<tr><th colspan="2">Inputs</th><th>Output</th><th>Action</th><th>Annotations</th></tr>
<tr><td>These inputs are the variables that determine the consequent actions or outputs.</td><td>If there are multiple input entries on the same row, these different inputs are considered "AND" conditions that all need to be in place at the same time.</td><td rowspan="2">The action or decision that results from the combination of input entries. This is the statement that immediately follows "THEN". Examples of outputs include a diagnosis, alerts/prompts for referrals, or counselling.</td><td rowspan="2">Concrete measures to be taken based on the output (for example, refer, provide counselling, conduct test). In some cases, output and action may be the same.
This field includes the content that would appear in the pop-up message that would notify the health worker of the appropriate next steps – for example, counselling, a case management approach or referral.</td><td rowspan="2">Additional explanations or descriptions, including possible pop-up alert messages and useful background information.
This field includes the content that would appear in pop-up messages that would notify the health worker of the appropriate next steps – for example, counselling, a case management approach or referral.</td></tr>
<tr><td colspan="2">Inputs placed on different rows are considered "OR" conditions and can be considered independently of the inputs on other rows.</td></tr>
</table>

Table 17. Example decision logic table for WHO clinical staging of HIV disease

Decision ID	HIV.DT.09. Determine WHO clinical stage of HIV
Business rule	"HIV diagnosis" = "HIV-positive"
Trigger	HIV.D15. Determine clinical stage of HIV

Inputs		Output	Action	Annotations
Clinical stage 1				
WHO clinical stage condition or finding = Asymptomatic		HIV clinical stage = WHO HIV clinical stage 1	Classify HIV as clinical stage 1	
WHO clinical stage condition or finding = Persistent generalized lymphadenopathy		HIV clinical stage = WHO HIV clinical stage 1	Classify HIV as clinical stage 1	
Clinical stage 2				
Estimated age ≥15 years	WHO clinical stage condition or finding = Moderate unexplained weight loss	HIV clinical stage = WHO HIV clinical stage 2	Classify HIV as clinical stage 2	
WHO clinical stage condition or finding = Recurrent respiratory tract infections		HIV clinical stage = WHO HIV clinical stage 2	Classify HIV as clinical stage 2	Recurrent respiratory tract infections, such as sinusitis, tonsillitis, otitis media, pharyngitis
WHO clinical stage condition or finding = Moderate unexplained weight loss		HIV clinical stage = WHO HIV clinical stage 2	Classify HIV as clinical stage 2	
WHO clinical stage condition or finding = Unexplained persistent hepatosplenomegaly		HIV clinical stage = WHO HIV clinical stage 2	Classify HIV as clinical stage 2	
WHO clinical stage condition or finding = Herpes zoster		HIV clinical stage = WHO HIV clinical stage 2	Classify HIV as clinical stage 2	
WHO clinical stage condition or finding = Angular cheilitis		HIV clinical stage = WHO HIV clinical stage 2	Classify HIV as clinical stage 2	
WHO clinical stage condition or finding = Linear gingival erythema		HIV clinical stage = WHO HIV clinical stage 2	Classify HIV as clinical stage 2	

Inputs		Output	Action	Annotations
WHO clinical stage condition or finding = Recurrent oral ulceration		HIV clinical stage = WHO HIV clinical stage 2	Classify HIV as clinical stage 2	
WHO clinical stage condition or finding = Papular pruritic eruption		HIV clinical stage = WHO HIV clinical stage 2	Classify HIV as clinical stage 2	
WHO clinical stage condition or finding = Fungal nail infections		HIV clinical stage = WHO HIV clinical stage 2	Classify HIV as clinical stage 2	
Estimated age ≥15 years	WHO clinical stage condition or finding = Seborrhoeic dermatitis	HIV clinical stage = WHO HIV clinical stage 2	Classify HIV as clinical stage 2	
Estimated age <15 years	WHO clinical stage condition or finding = Extensive wart virus infection	HIV clinical stage = WHO HIV clinical stage 2	Classify HIV as clinical stage 2	
Estimated age <15 years	WHO clinical stage condition or finding = Extensive molluscum contagiosum	HIV clinical stage = WHO HIV clinical stage 2	Classify HIV as clinical stage 2	
Estimated age <15 years	WHO clinical stage condition or finding = Unexplained persistent parotid enlargement	HIV clinical stage = WHO HIV clinical stage 2	Classify HIV as clinical stage 2	
Clinical stage 3				
Estimated age ≥15 years	WHO clinical stage condition or finding = Unexplained severe weight loss in adults	HIV clinical stage = WHO HIV clinical stage 3	Classify HIV as clinical stage 3	
Estimated age <15 years	WHO clinical stage condition or finding = Unexplained moderate malnutrition not adequately responding to standard therapy	HIV clinical stage = WHO HIV clinical stage 3	Classify HIV as clinical stage 3	For children younger than 5 years, moderate malnutrition is defined as weight-for-height < – z-score or mid-upper arm circumference 115 mm to 125 mm.

Inputs		Output	Action	Annotations
Estimated age ≥15 years	WHO clinical stage condition or finding = Unexplained chronic diarrhoea for longer than 1 month	HIV clinical stage = WHO HIV clinical stage 3	Classify HIV as clinical stage 3	
Estimated age <15 years	WHO clinical stage condition or finding = Unexplained persistent diarrhoea (14 days or more)	HIV clinical stage = WHO HIV clinical stage 3	Classify HIV as clinical stage 3	
WHO clinical stage condition or finding = Unexplained persistent fever (above 37.5°C, intermittent or constant, for longer than 1 month)		HIV clinical stage = WHO HIV clinical stage 3	Classify HIV as clinical stage 3	
Estimated age >6 weeks	WHO clinical stage condition or finding = Persistent oral candidiasis	HIV clinical stage = WHO HIV clinical stage 3	Classify HIV as clinical stage 3	
WHO clinical stage condition or finding = Oral hairy leucoplakia		HIV clinical stage = WHO HIV clinical stage 3	Classify HIV as clinical stage 3	
WHO clinical stage condition or finding = Pulmonary tuberculosis		HIV clinical stage = WHO HIV clinical stage 3	Classify HIV as clinical stage 3	
WHO clinical stage condition or finding = Lymph node tuberculosis		HIV clinical stage = WHO HIV clinical stage 3	Classify HIV as clinical stage 3	
WHO clinical stage condition or finding = Severe bacterial infections (such as pneumonia, empyema, pyomyositis, bone or joint infection, meningitis, bacteraemia)		HIV clinical stage = WHO HIV clinical stage 3	Classify HIV as clinical stage 3	
WHO clinical stage condition or finding = Severe recurrent bacterial pneumonia		HIV clinical stage = WHO HIV clinical stage 3	Classify HIV as clinical stage 3	
WHO clinical stage condition or finding = Acute necrotizing ulcerative stomatitis		HIV clinical stage = WHO HIV clinical stage 3	Classify HIV as clinical stage 3	
WHO clinical stage condition or finding = Acute necrotizing ulcerative gingivitis		HIV clinical stage = WHO HIV clinical stage 3	Classify HIV as clinical stage 3	

Inputs		Output	Action	Annotations
WHO clinical stage condition or finding = Acute necrotizing ulcerative periodontitis		HIV clinical stage = WHO HIV clinical stage 3	Classify HIV as clinical stage 3	
WHO clinical stage condition or finding = Unexplained anaemia (<8 g/dl)		HIV clinical stage = WHO HIV clinical stage 3	Classify HIV as clinical stage 3	Diagnosed based on laboratory testing and not explained by other non-HIV conditions; not responding to standard therapy with haematinics, antimalarial agents or anthelmintic agents as outlined in relevant national treatment guidelines, WHO Integrated Management of Childhood Illness (IMCI) guidelines or other relevant guidelines.
WHO clinical stage condition or finding = Neutropoenia (<0.5 × 109/L)		HIV clinical stage = WHO HIV clinical stage 3	Classify HIV as clinical stage 3	
WHO clinical stage condition or finding = Chronic thrombocytopaenia (<50 × 109/L)		HIV clinical stage = WHO HIV clinical stage 3	Classify HIV as clinical stage 3	
WHO clinical stage condition or finding = Symptomatic lymphoid interstitial pneumonitis		HIV clinical stage = WHO HIV clinical stage 3	Classify HIV as clinical stage 3	
Estimated age <15 years	WHO clinical stage condition or finding = Chronic HIV-associated lung disease, including bronchiectasis	HIV clinical stage = WHO HIV clinical stage 3	Classify HIV as clinical stage 3	
Clinical stage 4				
Estimated age ≥15 years old	WHO clinical stage condition or finding = HIV wasting syndrome	HIV clinical stage = WHO HIV clinical stage 4	Classify HIV as clinical stage 4	
Estimated age <15 years	WHO clinical stage condition or finding = Unexplained severe wasting not responding to standard therapy	HIV clinical stage = WHO HIV clinical stage 4	Classify HIV as clinical stage 4	

Inputs		Output	Action	Annotations
Estimated age <15 years	WHO clinical stage condition or finding = Unexplained stunting not responding to standard therapy	HIV clinical stage = WHO HIV clinical stage 4	Classify HIV as clinical stage 4	For children younger than five years of age: severe wasting is defined as weight-for-height < –3 z-score; stunting is defined as length-for- age/height-for-age < –2 z-score; severe acute malnutrition is either weight for height < –3 z-score or mid-upper arm circumference <115 mm or the presence of oedema.
Estimated age <15 years	WHO clinical stage condition or finding = Unexplained severe malnutrition not responding to standard therapy	HIV clinical stage = WHO HIV clinical stage 4	Classify HIV as clinical stage 4	Dyspnoea on exertion or non-productive cough of recent onset (within the past three months), tachypnoea and fever; AND Chest X-ray evidence of diffuse bilateral interstitial infiltrates; AND No evidence of bacterial pneumonia; bilateral crepitations on auscultation with or without reduced air entry.
WHO clinical stage condition or finding = Pneumocystis (jirovecii) pneumonia		HIV clinical stage = WHO HIV clinical stage 4	Classify HIV as clinical stage 4	Current episode plus one or more previous episodes in the past six months; acute onset (<2 weeks) of severe symptoms (such as fever, cough, dyspnoea, and chest pain) PLUS new consolidation on clinical examination or chest X-ray; response to antibiotics.
WHO clinical stage condition or finding = Recurrent severe bacterial pneumonia		HIV clinical stage = WHO HIV clinical stage 4	Classify HIV as clinical stage 4	
WHO clinical stage condition or finding = Recurrent severe bacterial infections (such as empyema, pyomyositis, bone or joint infection, meningitis, but excluding pneumonia)		HIV clinical stage = WHO HIV clinical stage 4	Classify HIV as clinical stage 4	Painful, progressive anogenital or orolabial ulceration; lesions caused by recurrence of herpes simplex virus infection and reported for more than one month. History of previous episodes. Visceral herpes simplex virus requires definitive diagnosis
WHO clinical stage condition or finding = Chronic herpes simplex infection (orolabial, genital or anorectal of more than one month in duration or visceral at any site)		HIV clinical stage = WHO HIV clinical stage 4	Classify HIV as clinical stage 4	
WHO clinical stage condition or finding = Oesophageal candidiasis (or candidiasis of trachea, bronchi or lungs)		HIV clinical stage = WHO HIV clinical stage 4	Classify HIV as clinical stage 4	

Inputs		Output	Action	Annotations
WHO clinical stage condition or finding = Extrapulmonary tuberculosis		HIV clinical stage = WHO HIV clinical stage 4	Classify HIV as clinical stage 4	
WHO clinical stage condition or finding = Kaposi sarcoma		HIV clinical stage = WHO HIV clinical stage 4	Classify HIV as clinical stage 4	Onset more than one month ago
Estimated age >1 month	WHO clinical stage condition or finding = Cytomegalovirus infection (retinitis or infection of other organs)	HIV clinical stage = WHO HIV clinical stage 4	Classify HIV as clinical stage 4	
Estimated age >1 month	WHO clinical stage condition or finding = Central nervous system toxoplasmosis	HIV clinical stage = WHO HIV clinical stage 4	Classify HIV as clinical stage 4	
WHO clinical stage condition or finding = HIV encephalopathy		HIV clinical stage = WHO HIV clinical stage 4	Classify HIV as clinical stage 4	
WHO clinical stage condition or finding = Extrapulmonary cryptococcosis, including meningitis		HIV clinical stage = WHO HIV clinical stage 4	Classify HIV as clinical stage 4	
WHO clinical stage condition or finding = Disseminated nontuberculous mycobacterial infection		HIV clinical stage = WHO HIV clinical stage 4	Classify HIV as clinical stage 4	
WHO clinical stage condition or finding = Progressive multifocal leukoencephalopathy		HIV clinical stage = WHO HIV clinical stage 4	Classify HIV as clinical stage 4	
Estimated age ≥15 years	WHO clinical stage condition or finding = Chronic cryptosporidiosis	HIV clinical stage = WHO HIV clinical stage 4	Classify HIV as clinical stage 4	
Estimated age <15 years	WHO clinical stage condition or finding = Chronic cryptosporidiosis (with diarrhoea)	HIV clinical stage = WHO HIV clinical stage 4	Classify HIV as clinical stage 4	
WHO clinical stage condition or finding = Chronic isosporiasis		HIV clinical stage = WHO HIV clinical stage 4	Classify HIV as clinical stage 4	

Inputs		Output	Action	Annotations
WHO clinical stage condition or finding = Disseminated mycosis (extrapulmonary histoplasmosis, coccidioidomycosis)		HIV clinical stage = WHO HIV clinical stage 4	Classify HIV as clinical stage 4	
WHO clinical stage condition or finding = Cerebral lymphoma		HIV clinical stage = WHO HIV clinical stage 4	Classify HIV as clinical stage 4	
WHO clinical stage condition or finding = B-cell non-Hodgkin lymphoma		HIV clinical stage = WHO HIV clinical stage 4	Classify HIV as clinical stage 4	
WHO clinical stage condition or finding = HIV- associated nephropathy or cardiomyopathy		HIV clinical stage = WHO HIV clinical stage 4	Classify HIV as clinical stage 4	
Estimated age ≥15 years	WHO clinical stage condition or finding = Recurrent septicaemia (including nontyphoidal Salmonella)	HIV clinical stage = WHO HIV clinical stage 4	Classify HIV as clinical stage 4	
Estimated age ≥15 years	WHO clinical stage condition or finding = Invasive cervical carcinoma	HIV clinical stage = WHO HIV clinical stage 4	Classify HIV as clinical stage 4	
Estimated age ≥15 years	WHO clinical stage condition or finding = Atypical disseminated leishmaniasis	HIV clinical stage = WHO HIV clinical stage 4	Classify HIV as clinical stage 4	

6.4. Additional considerations for adapting the decision support logic

Note that the decision support logic here is translated directly from the WHO Guidelines and Guidance documents as well as review by the panel of experts who have created those guideline documents. We do not anticipate the decision support logic to change much as the logic has been created and reviewed by the clinical experts. However, some level of adaptation may be needed depending on changes to the workflow and/or changes to the data dictionary.

Any changes to the decision support logic should be considered carefully, as an embedded decision support system can greatly affect the quality of care at the point of care. As helpful as decisions support logic can be to the health worker, incorrect decision support logic can also be detrimental. Thus, any new decision support logic should be carefully reviewed and agreed upon by in-country clinical experts.

Table 18 lists a minimum set of indicators that can be aggregated for decision-making, performance metrics and subnational and national reporting based on data collected from individual-level routine health systems. Additional indicators for consideration, not based on data collected from individual-level routine health systems, are compiled at the end of the table. Additional aggregate indicators are other indicators for consideration if relevant and feasible to collect. However, the numerator and/or denominator may not be collected at the individual level routine system in an HIV-specific module; those data elements are not reflected in the HIV digital adaptation kit data dictionary. Data elements denoted with "*" are not reflected in the HIV data dictionary. More detail on indicators, as defined in the 2020 WHO *Consolidated HIV strategic information guidelines: driving impact through programme monitoring and management (10)* are included in a workbook available in Web Annex C. In Table 18 the column of data elements uses the following notation: N = numerator, D = denominator.

Table 18. Indicators and performance metrics[1,2]

Reference number	Short name	Short description	Numerator calculation	Denominator calculation	Disaggregations	Data elements	Alignment
PR.3	**PrEP uptake**	Percentage of eligible people who initiated oral pre-exposure prophylaxis (PrEP) during the reporting period	COUNT of clients with oral PrEP start date in the reporting period	COUNT of clients eligible for oral PrEP in the reporting period AND offered oral PrEP in the reporting period during a visit date in the reporting period	Gender Age PrEP history Key populations PrEP dosing type	N: PrEP start date D: Eligible for PrEP, offered PrEP, visit date	GF KP-6, YP-4, similar to MER PrEP_NEW
PR.4	**PrEP continuation (at 3 months)**	% of pre-exposure prophylaxis (PrEP) users who continued oral PrEP for 3 consecutive months after having initiated PrEP during the reporting period	COUNT of clients with oral PrEP start date (or restart date) in the reporting period AND 3-month PrEP visit in the reporting period (after their oral PrEP start date) + COUNT of clients with event-driven oral PrEP use reported around at-risk exposures over a 3-month period in the reporting period	COUNT of clients with oral PrEP start date in the reporting period	Gender Age PrEP history Key populations PrEP dosing type	N: PrEP start date, 3-month PrEP visit, event-driven PrEP use reported for at risk exposures D: PrEP start date	
PR.5	**Currently on PrEP**	Number of people who received oral PrEP at least once during the reporting period	COUNT of clients with oral PrEP as medications prescribed AND date medications prescribed (for oral PrEP) in the reporting period	None	Gender Age PrEP history Key populations	Medications prescribed, date medications prescribed	GAM 3.15, MER PrEP_CURR

[1] Column headers are aligned with those in the *Consolidated HIV strategic information guidelines: driving impact through programme monitoring and management*. 2020. Other DAKs use the terms "Indicator code" instead of "Reference number" and "Indicator name" instead of "Short name" and "Short description", as used in the guidelines. The column "Data elements used" is added and aligned with the "IndDataElement" column in Annex 2.5 of *Consolidated guidelines on person-centred HIV patient monitoring and case surveillance* (2017).

[2] All of the indicators included are based on the *Consolidated HIV strategic information guidelines: driving impact through programme monitoring and management* (2020) *(10)*.

Reference number	Short name	Short description	Numerator calculation	Denominator calculation	Disaggregations	Data elements	Alignment
TL.1	**People living with HIV who know their HIV status (first 95)**	Number and percentage of people living with HIV who know their status	COUNT of clients with HIV status of HIV-positive AND date informed of HIV diagnosis is not null Excluding those with the following client HIV treatment outcomes at the end of the reporting period: • Lost to follow-up • Transferred out • Death (documented)	*Estimated number of people living with HIV	Gender Age Key populations Antenatal care clinic	HIV status, date informed of HIV positive diagnosis, HIV treatment outcome	GAM 1.1, GF HIV O-11
TL.2	**HTS testing volume and positivity**	Number of HIV tests conducted (testing volume) and the percentage of HIV-positive results returned to people (positivity)	COUNT of HIV tests with result of HIV-positive AND ((HIV test date in the reporting period AND date HIV test results returned to client in the reporting period) OR (HIV diagnosis date in the reporting period))	COUNT of HIV tests in the reporting period AND date HIV test results returned to client in the reporting period	Gender Age Key populations TB status Testing entry point	N: HIV test result, HIV test date, date HIV test results returned, date informed of HIV-positive diagnosis D: HIV test date, date HIV test result returned	Similar to GAM 1.8, similar to GF HTS-4, similar to MER HTS_TST
TL.3	**Linkage to ART**	Percentage of people newly diagnosed with HIV initiated on ART	COUNT of clients with HIV status of HIV-positive AND with date informed of HIV diagnosis in the reporting period AND ART start date in the reporting period	COUNT of clients with HIV status of HIV positive AND with date informed of HIV diagnosis in the reporting period	Gender Age Key populations TB status Time to start ART	N: HIV status, date informed of HIV positive diagnosis, ART start date D: HIV status, date informed of HIV positive diagnosis	GF HTS-5

* Data elements denoted with "*" are not reflected in the HIV data dictionary.

Reference number	Short name	Short description	Numerator calculation	Denominator calculation	Disaggregations	Data elements	Alignment
TL.4	**HTS index testing and partner notification**	Number of people who were identified and tested using index testing services and received their results	*Refer to indicator calculations in Web Annex C.*	None	Gender of index case Age *HIV status of partner Key populations		MER HTS_INDEX
TL.5	**HIVST distribution**	Number of HIV self-test kits distributed	COUNT of number of HIV self-testing kits provided in the reporting period	None	Gender Age *HIV status of partner Key populations Adolescent girl Young woman HIVST approach HIVST distribution site type HIVST distributed for use by	*Number of HIV self-testing kits provided	MER HTS_SELF, related to GAM 1.7
AV.1	**People living with HIV on ART**	Number and percentage of people on ART among all people living with HIV at the end of the reporting period	COUNT of clients with HIV status of HIV-positive AND HIV treatment outcome of currently on ART at the end of the reporting period. Exclude those with the following client HIV treatment outcomes at the end of the reporting period: • Lost to follow-up • Transferred out • Death (documented)	*Estimated number of people living with HIV	Gender Age Key populations * [Additional if system allows]	HIV status, currently on ART, HIV treatment outcome	GAM 1.2 & 3.5, GF TCS-1, MER TX_CURR

* Data elements denoted with "*" are not reflected in the HIV data dictionary.

Reference number	Short name	Short description	Numerator calculation	Denominator calculation	Disaggregations	Data elements	Alignment
AV.2	**Total attrition from ART**	Number and percentage of people living with HIV reported on ART at the end of the last reporting period and/or newly initiating ART during the current reporting period who were not on ART at the end of the reporting period	COUNT of clients with HIV status of HIV-positive AND currently on ART at the end of the prior reporting period AND not currently on ART at the end date of the current report period + COUNT of clients with HIV status of HIV-positive AND ART start date in the current reporting period AND not currently on ART at the end date of the current report period	COUNT of clients with HIV status of HIV-positive AND HIV treatment outcome of on ART at the end date of the prior reporting period + COUNT of clients with HIV status of HIV-positive AND with ART start date in the current reporting period	Gender Age Key populations HIV treatment outcome	N: HIV status, HIV treatment outcome, currently on ART, ART start date D: HIV status, HIV treatment outcome, currently on ART, ART start date	GF HIV O-21, similar to MER TX_ML
AV.3	**People living with HIV who have suppressed VL**	Percentage of people living with HIV on ART (for at least 6 months) who have virological suppression	COUNT of clients with HIV status of HIV-positive AND currently on ART AND ART start date on or before 6 months prior to reporting period end date AND with viral load test result date received within the reporting period AND with an HIV viral load test result <1000 copies/mL AND reason for HIV viral load test is routine viral load test	COUNT of clients with HIV status of HIV-positive AND currently on ART AND ART start date on or before 6 months prior to reporting period end date AND with viral load test result date received within the reporting period	Gender Age Key populations	N: HIV status, HIV treatment outcome, currently on ART, ART start date, date ART stopped, reason for HIV viral load test, viral load test result date received, viral load test result D: HIV status, HIV treatment outcome, currently on ART, ART start date, date ART stopped, viral load test result date received	Similar to GAM 1.4, similar to GF HIV O-12, similar to MER TX_PVLS

Reference number	Short name	Short description	Numerator calculation	Denominator calculation	Disaggregations	Data elements	Alignment
AV.4	**New ART patients**	Number of people living with HIV who initiated ART	COUNT of clients with HIV status of HIV-positive AND ART start date within the reporting period	None	Gender Age Key populations Pregnant Breastfeeding Serodiscordant partner	HIV status, ART start date	MER TX _NEW, related to GAM 1.2, related to GF HTS-5
AV.5	**Late ART initiation**	Percentage of people living with HIV who initiate ART with a CD4 count of <200 cell/mm^3	COUNT of clients with HIV status of HIV-positive AND ART start date within reporting period AND baseline CD4 count <200 cell/mm^3	COUNT of clients with HIV status of HIV-positive AND ART start date within reporting period AND baseline CD4 count is not null	Gender Age Key populations *[Other priority population] CD4 count Baseline CD4 count	HIV status, ART start date, baseline CD4 count	
AV.6	**Viral load testing coverage**	Percentage of people on ART (for at least 6 months) with viral load test results	COUNT of clients with HIV status of HIV-positive AND who are currently on ART AND with an ART start date ≥6 months before reporting period end date AND with any routine viral load test result received within the reporting period.	COUNT of clients with HIV status of HIV-positive AND who are currently on ART AND with an ART start date ≥6 months before reporting period end date Exclude those with the following client HIV treatment outcomes at the end of the reporting period: • Lost to follow-up • Transferred out • Death (documented)	Gender Age Key populations *[Other priority population]	N: HIV status, HIV treatment outcome, currently on ART, ART start date, viral load test result, date viral load test result received, reason for HIV viral load test D: HIV status, currently on ART, ART start date, HIV treatment outcome	

* Data elements denoted with "*" are not reflected in the HIV data dictionary.

Reference number	Short name	Short description	Numerator calculation	Denominator calculation	Disaggregations	Data elements	Alignment
AV.7	**Early viral load testing (by 6 months)**	Number and percentage of people living with HIV currently on ART who had viral load monitoring by 6 months after initiation of ART	COUNT of clients with HIV status of HIV-positive AND 5 to 7 months after ART start date is within the reporting period AND date of HIV viral load sample collection is 5 to 7 months after ART start date AND client received viral load test result at a visit date within the reporting period	COUNT of clients with HIV status of HIV-positive AND 5 to 7 months after ART start is within the reporting period Excluding those with the following client HIV treatment outcomes at the end of the reporting period: • Lost to follow-up • Transferred out • Death (documented)	Gender Age Key populations *[Other priority population]	N: HIV status, ART start date, date of HIV viral load sample collection, received, viral load test results, visit date D: HIV status, ART start date, HIV treatment outcome	
AV.8	**Appropriate second VL test**	Percentage of people receiving ART with VL ≥1000 copies/mL who received a follow-up VL test within 6 months after enhanced adherence counselling (or according to national guidelines)	COUNT of clients with HIV status of HIV-positive AND currently on ART AND date of HIV viral load sample collection within reporting period AND any viral load test result ≥1000 copies/mL within the reporting period where period between new date of HIV viral load sample collection and previous date of HIV viral load sample collection (viral load test with results ≥ 1000 copies/mL) ≤6 months	COUNT of clients with HIV status of HIV-positive AND currently on ART within the reporting period AND any viral load test result ≥1000 copies/mL within the reporting period	Gender Age Key populations ART regimen Received enhanced adherence counselling	N: HIV status, HIV treatment outcome, currently on ART, date of HIV viral load sample collection, viral load test result D: HIV status, HIV treatment outcome, currently on ART, viral load test result	

* Data elements denoted with "*" are not reflected in the HIV data dictionary.

Reference number	Short name	Short description	Numerator calculation	Denominator calculation	Disaggregations	Data elements	Alignment
AV.9	**ARV toxicity prevalence**	Percentage of ART patients with treatment-limiting toxicity	COUNT of clients with HIV status of HIV-positive AND with date ART stopped in the reporting period AND with reasons stopped ART was treatment-limiting toxicity + COUNT of clients with HIV status of HIV-positive AND currently on ART AND date of switch to [line of regimen] in the reporting period AND reason for regimen switch was treatment-limiting toxicity + COUNT of clients with HIV status of HIV-positive AND currently on ART AND date(s) of substitution within [line of regimen] in the reporting period AND reason for ARV drug regimen substitution was treatment-limiting toxicity	COUNT of clients with HIV status of HIV-positive AND currently on ART within reporting period	Gender Age Key populations Pregnant Breastfeeding	N: HIV status, HIV treatment outcome, currently on ART, date ART stopped, date of switch to [line of regimen], reason for regimen switch, date(s) of substitution within [line of regimen], reason for ARV drug regimen substitution D: HIV status, HIV treatment outcome, currently on ART	
TB.1	**TPT initiation**	Number and percentage of eligible people living with HIV currently on ART who initiated TB preventive treatment	COUNT of clients with HIV status of HIV-positive AND currently on ART AND TB preventive treatment (TPT) start date in the reporting period	COUNT of clients with HIV status of HIV-positive AND currently on ART AND date eligible for TB preventive treatment in the reporting period	Gender Age TPT regimen type ART start date *[Additional if system allows]	N: HIV status, HIV treatment outcome, currently on ART, TPT start date D: HIV status, HIV treatment outcome, currently on ART, eligible for TB preventive treatment	Similar to GAM 10.3, similar to GF TB/HIV-7

* Data elements denoted with "*" are not reflected in the HIV data dictionary.

Reference number	Short name	Short description	Numerator calculation	Denominator calculation	Disaggregations	Data elements	Alignment
TB.2	**TPT completion**	Percentage of people living with HIV currently on ART who completed a course of TB preventive treatment (TPT) among those who initiated TPT	COUNT of clients with HIV status of HIV-positive AND currently on ART AND TB preventive treatment (TPT) completion date within the reporting period	COUNT of clients with HIV status of HIV-positive AND currently on ART AND TPT start date in the prior reporting period	Gender Age TPT regimen type ART start date TB preventive treatment (TPT) recommended regimen TB preventive treatment (TPT) alternative regimen *[Additional if system allows]	N: HIV status, HIV treatment outcome, currently on ART, TPT completion date D: HIV status, HIV treatment outcome, currently on ART, TPT start date	Similar to MER TB_PREV
TB.3	**TB diagnostic testing type**	Percentage of people living with HIV with TB symptoms who receive a rapid molecular test (for example, Xpert MTB/RIF) as a first test for diagnosis of TB	COUNT of clients with HIV status of HIV-positive AND with symptoms of TB in the reporting period AND TB screening date in the reporting period AND first TB test performed is a rapid molecular test for TB	COUNT of clients with HIV status of HIV-positive AND with symptoms of TB in the reporting period	Gender Age Key populations Pregnant Breastfeeding	N: HIV status, symptoms of TB, TB screening date, TB screening type D: HIV status, symptoms of TB	
TB.4	**People living with HIV with active TB disease**	Percentage of people living with HIV newly initiated on ART who have active TB disease	COUNT of clients with HIV status of HIV-positive AND ART start date in the reporting period AND with active tuberculosis (TB) in reporting period	COUNT of clients with HIV status of HIV-positive AND ART start date in reporting period	Gender Age Key populations Pregnant Breastfeeding	N: HIV status, ART start date, active TB D: HIV status, ART start date	GAM 10.2

* Data elements denoted with "*" are not reflected in the HIV data dictionary.

Reference number	Short name	Short description	Numerator calculation	Denominator calculation	Disaggregations	Data elements	Alignment
VT.1	**Viral suppression at labour and delivery**	Percentage of HIV-positive pregnant women who are virally suppressed at labour and delivery	COUNT of currently pregnant clients with HIV status of HIV-positive AND (currently on ART at first antenatal care contact OR newly on ART during pregnancy) AND place of delivery is a health facility AND date of HIV viral load sample collection is on delivery date AND delivery date is in the reporting period AND viral load test result <1000 copies/mL	COUNT of currently pregnant clients with HIV status of HIV-positive AND currently on ART AND place of delivery is a health facility AND date of HIV viral load sample collection is on delivery date AND delivery date is in the reporting period	Age Timing of ART initiation (during pregnancy, already on ART at first ANC visit)	N: Currently pregnant, HIV status, HIV treatment outcome, currently on ART D: Currently pregnant, HIV status, HIV treatment outcome, currently on ART, date of HIV viral load sample collection, place of delivery, delivery date	
VT.2	**EID coverage**	Percentage of HIV-exposed infants who receive a virological test for HIV within 2 months (and 12 months) of birth	COUNT of infants who are an HIV-exposed infant AND who have an HIV test date within 2 months of infant date of birth AND HIV test type is a nucleic acid test for HIV	*Estimated number of HIV-positive women who delivered during the reporting period	HIV test result Age of infant	N: HIV-exposed infant, HIV test date, infant date of birth, HIV test type	GAM 2.1, GF PMTCT-3.1, MER PMTCT_EID

* Data elements denoted with "*" are not reflected in the HIV data dictionary.

Reference number	Short name	Short description	Numerator calculation	Denominator calculation	Disaggregations	Data elements	Alignment
VT.3	**Infant ARV prophylaxis coverage**	Percentage of HIV-exposed infants who initiated ARV prophylaxis	COUNT of infants who are an HIV-exposed infant AND infant date of birth within 12 months prior to reporting period end date AND infant ARV prophylaxis start date is infant date of birth	Population-based denominator: *Estimated number of HIV-positive women who delivered during the past 12 months Programme-based denominator: COUNT of women with HIV status of HIV-positive AND place of delivery is a health facility AND delivery date within 12 months prior to reporting period end date	None	N: HIV-exposed infant, infant date of birth, infant ARV prophylaxis start date D: HIV status, place of delivery, delivery date	
VT.4	**ART coverage in pregnant women**	Percentage of HIV-positive pregnant women who received ART during pregnancy and/or at labour and delivery	COUNT of women with HIV status of HIV-positive AND delivery date in reporting period AND ((currently on ART at labour and delivery) OR (currently on ART during pregnancy, for this pregnancy))	COUNT of women with HIV status of HIV-positive AND delivery date in the reporting period AND (visited an antenatal facility during reporting period OR place of delivery was a health facility)	Age Pregnant women who inject drugs Timing of ART initiation (already on ART at first ANC visit, newly on ART during pregnancy, newly on ART during labour and delivery, on non-recommended ART regimen)	N: HIV status, delivery date, HIV treatment outcome, currently on ART D: HIV status, delivery date, place of delivery	

* Data elements denoted with "*" are not reflected in the HIV data dictionary.

Reference number	Short name	Short description	Numerator calculation	Denominator calculation	Disaggregations	Data elements	Alignment
VT.5	**ART coverage breastfeeding mothers**	Percentage of HIV-exposed breastfeeding infants whose mothers are receiving ART at 12 (and 24 months) postpartum	COUNT of infants who are an HIV-exposed infant AND whose mothers are breastfeeding at a 12-month maternal and child health visit (AND at a 24-month maternal and child health visit) AND whose mothers are currently on ART at a 12-month maternal and child health visit (AND at a 24-month maternal and child health visit)	COUNT of infants who are an HIV-exposed infant AND whose mothers are breastfeeding at a 12-month maternal and child health visit AND (whose mothers are breastfeeding at a 24-month maternal and child health visit OR the first visit after end of breastfeeding)	Age Timing of ART initiation (already on ART at first ANC visit, newly on ART during pregnancy or labour and delivery)	N: HIV-exposed infant, breastfeeding, HIV treatment outcome, currently on ART D: HIV-exposed infant, breastfeeding	
VT.6	**Final outcome of PMTCT**	Percentage of HIV-exposed infants whose final outcome status is known	COUNT of infants who are an HIV exposed-infant AND with an infant date of birth ≤12 months (or ≤24 months if mothers are breastfeeding) from the reporting period end date AND with a final diagnosis of HIV exposed infant of non-null	COUNT of infants who are an HIV-exposed infant AND with an infant date of birth ≤12 months (or ≤24 months if mothers are breastfeeding) from the reporting period end date AND registered in the birth cohort	HIV exposed-infant HIV status of infant Breastfeeding	N: HIV-exposed infant, infant date of birth, final diagnosis of HIV-exposed infant D: HIV-exposed infant, infant date of birth, registered in birth cohort	MER PMTCT_FO
ST.1	**Syphilis screening coverage (in ANC)**	Percentage of antenatal care attendees tested for syphilis	COUNT of women with a contact date in the reporting period AND with a syphilis test date in the reporting period	COUNT of women with any contact date in the reporting period	Age *ANC visit number	N: contact date[1], syphilis test date D: contact date	GF PMTCT-4

* Data elements denoted with "*" are not reflected in the HIV data dictionary.

[1] Data element for ANC-related visit date is referred to as "contact date", aligned with ANC DAK.

Reference number	Short name	Short description	Numerator calculation	Denominator calculation	Disaggregations	Data elements	Alignment
ST.2	**Syphilis treatment coverage (in ANC)**	Percentage of antenatal care attendees testing seropositive for syphilis who are treated	COUNT of women with syphilis diagnosis of syphilis positive AND ((reporting period end date –contact date) ≤12 months) AND medications prescribed includes benzathine penicillin 2.4 MU AND route of administration is intramuscular	COUNT of women with syphilis diagnosis of syphilis positive AND (reporting period end date – contact date) ≤12 months	Age	N: syphilis diagnosis, contact date[1], medications prescribed, route of administration (of medication) D: syphilis diagnosis, contact date[1]	
DfC.1	**VMMC scale-up**	Number of VMMCs performed according to the national standard	COUNT of men with VMMC procedure date in the reporting period	None	Age HIV status	VMMC procedure date	GAM 3.17, GF MEN-1, MER VMMC_CIRC
DfC.2	**VMMC adverse events**	Number and percentage of circumcised males experiencing adverse events	COUNT of men with VMMC procedure date in the reporting period AND with adverse event reported from a VMMC AND adverse event severity is moderate or severe AND timing of adverse event ≤30 days from VMMC procedure date	COUNT of men with VMMC procedure date in the reporting period	Age Timing of adverse event *Service site	N: VMMC procedure date, adverse event reported from a VMMC, timing of adverse event, adverse event severity D: VMMC procedure date	
DfT.1	**TB screening coverage among new ART patients**	Percentage of people living with HIV newly initiated on ART who were screened for TB	COUNT of clients with HIV status of HIV positive AND who are first-time user of ART AND with ART start date in the reporting period AND with TB screening result positive for TB AND TB screening date in the reporting period	COUNT of clients with HIV status of HIV-positive AND who are first-time user of ART AND with an ART start date in the reporting period	Gender Age	N: HIV status, first-time user of ART, ART start date, TB screening result, TB screening date D: HIV status, first-time user of ART, ART start date	

* Data elements denoted with "*" are not reflected in the HIV data dictionary.

[1] Data element for ANC-related visit date is referred to as "contact date", aligned with ANC DAK.

Reference number	Short name	Short description	Numerator calculation	Denominator calculation	Disaggregations	Data elements	Alignment
DfT.2	**TB symptom-screened positive among new-on-ART patients**	Percentage of people living with HIV newly initiated on ART who were screened for TB symptoms and who screened positive	Count of clients with HIV status of HIV-positive AND who are a first-time user of ART AND with an ART start date in the reporting period AND with a TB screening result positive for TB AND with a TB screening date in the reporting period	COUNT of clients with HIV status of HIV-positive AND who are a first-time user of ART AND with ART start date in the reporting period AND with TB screening date in the reporting period	Gender Age	N: HIV status, first-time user of ART, ART start date, TB screening result, TB screening date D: HIV status, first-time user of ART, ART start date, TB screening date	Related to TB/ HIV-3.1a, related to MER TX_TB
DfT.3	**TB testing among those symptom-screened positive**	Percentage of people living with HIV newly initiated on ART and screened positive for TB symptoms who then are tested for TB	*Refer to indicator calculations in Web Annex C.*	*Refer to indicator calculations in Web Annex C.*			
DfT.4	**TB diagnosis among those tested for TB**	Percentage of people living with HIV newly initiated on ART and tested for TB who are diagnosed with active TB disease	*Refer to indicator calculations in Web Annex C.*	*Refer to indicator calculations in Web Annex C.*			
DfT.5	**TB treatment initiation among diagnosed**	Percentage of people living with HIV newly initiated on ART and diagnosed with active TB who initiated TB treatment	COUNT of clients with HIV status of HIV-positive AND who are first-time users of ART AND with an ART start date in the reporting period AND with TB diagnosis of active TB in the reporting period AND TB treatment start date in the reporting period	COUNT of clients with HIV status of HIV-positive AND are first-time user of ART AND with an ART start date in the reporting period AND TB diagnosis of active TB in the reporting period	Gender Age	N: HIV status, first-time user of ART, ART start date, TB diagnosis, TB treatment start date D: HIV status, first-time user of ART, ART start date, TB diagnosis	

Reference number	Short name	Short description	Numerator calculation	Denominator calculation	Disaggregations	Data elements	Alignment
DfH.1	**HCV screening coverage**	Percentage of people living with HIV on ART who were screened for hepatitis C during the reporting period	COUNT of clients with HIV status of HIV- positive AND currently on ART in the reporting period AND hepatitis C screening date in the reporting period AND IF (hepatitis C test result is positive), THEN (HCV RNA (viral load) test OR HCV core antigen test))	COUNT of clients with HIV status of HIV-positive AND currently on ART in reporting period	Gender Age	N: HIV status, currently on ART, hepatitis C screening date, hepatitis C test result, HCV RNA (viral load) test, HCV core antigen test D: HIV status, HIV treatment outcome, currently on ART	Consistent with GAM 10.6
DfH.2	**HCV treatment coverage**	Percentage of people living with HIV on ART and diagnosed with chronic HCV infection who initiated HCV treatment during the reporting period	*Refer to indicator calculations in Web Annex C.*				

Table 19. Other national priority indicators not defined in the indicator calculations[1]

Reference number	Short name	Short description	Alignment	Reason indicator is excluded[2]
PR.1	**Condom use (key populations & general population)**	Percentage of people who used condoms with a non-regular partner in the last 12 months (general population) Percentage of sex workers who used of a condom the last time they had sex with a client Percentage of men who used a condom the last time they had anal sex with a non-regular male partner Percentage of transgender people who used a condom during last anal sex with a non-regular partner Percentage of people who inject drugs who used a condom the last time they had sex with a partner in the last month	GF HIV O–4 & O–10, similar to GAM 3.6 & 3.18	This is a survey-based, population-level indicator
PR.2	**Condoms distributed**	Total number of condoms distributed during the reporting period	GAM 3.19	This indicator is based on supplies distributed by a service delivery point (or warehouse/ distribution office)
TL.6	**Know their status (key population)**	Percentage of key population members who tested for HIV in the past 12 months or who know their current HIV status	GAM 3.4	Survey-based indicator
ST.3	**Cervical cancer screening among women living with HIV**	Percentage of women living with HIV who have been screened for cervical cancer	Similar to GAM 10.8, similar to MER CXCA_SCRN	Survey-based
SD.1	**Avoidance of health care due to stigma and discrimination (key population)**	Percentage of key population members who avoid health care because of stigma and discrimination	GAM 4.2, GF HIV O-16	Survey-based
SD.2	**Avoidance of health care due to stigma and discrimination (people living with HIV)**	Percentage of people living with HIV who avoid health care because of stigma and discrimination		Survey-based
KP.1	**Coverage of HIV prevention (key population)**	Percentage of key population members reached with HIV prevention programmes with a defined package of services	Similar to GAM 3.7, similar to GF KP-1, similar to MER KP_PREV	A. Survey-based B. Programme-based

[1] Column headings are aligned with the 2020 WHO *Consolidated HIV strategic information guidelines: driving impact through programme monitoring and management (10)*. Other DAKs use "Indicator code" instead of "Reference number" and "Indicator name" instead of "Short name" and "Short description", as used in the guidelines.

[2] All of the indicators included are based on the 2020 WHO *Consolidated HIV strategic information guidelines: driving impact through programme monitoring and management (10)*.

Reference number	Short name	Short description	Alignment	Reason indicator is excluded[2]
KP.2	Needles and syringes distributed	Number of needles and syringes distributed per year per person who injects drugs	GAM 3.9, GF KP-4	A. Survey-based B. Programme-based
KP.3	Coverage of OST	Percentage of people who inject drugs receiving opioid substitution therapy	GAM 3.10, related to GF KP-5, related to MER KP_MAT	Suggested data elements are included in the data dictionary in the Web Annex A
KP.4	Safe injecting practices (people who inject drugs)	Percentage of people who inject drugs who report using sterile injecting equipment the last time they injected	GAM 3.8, GF HIV O-6	Survey-based
GW.1	Adolescent girls and young women HIV/SRH integration	Percentage of adolescent girls and young women seeking contraception/family planning who received an HIV test		See Family Planning DAK
DfI.1	Facility-level injection safety	Percentage of health care facilities where all therapeutic injections are given with new, disposable, single-use injection equipment		Site-level indicator
DfI.2	Rate of unsafe injections per person	Number of unsafe health care injections per person per year		Survey-based
DfB.1	Facility-level blood safety	Percentage of health facilities providing blood transfusions that meet requirements for safe and sufficient blood transfusion		Site-level indicator
DfB.2	Quality-assured blood testing	Percentage of blood units that are screened for bloodborne diseases in a quality-assured manner		Site-level indicator
BI.1	People living with HIV	Estimated number of people living with HIV	GF HIV I-13	Derived from mathematical modelling
BI.2	HIV prevalence among key populations	Percentage of specific key populations living with HIV	GAM 3.3, GF HIV I-9	Survey-based
BI.3	New HIV infections (per 1000 population)	Estimated number of people newly infected with HIV per 1000 uninfected population	GAM 3.1, GF HIV I-14	Derived from mathematical modelling
BI.4	Final MTCT rate	Estimated percentage of children newly infected with HIV from mother-to-child transmission among women living with HIV delivering in the past 12 months	GAM 2.2, GF HIV I-6	Derived from mathematical modelling
BI.5	AIDS mortality	Total number of people who have died from AIDS-related causes per 100 000 population	GAM 1.7, GF HIV I-4	Derived from mathematical modelling

COMPONENT 8 HIGH-LEVEL FUNCTIONAL AND NON-FUNCTIONAL REQUIREMENTS

Tables 20 and 21 list core functions and capabilities the system must have in order to meet the end users' need for a patient tracking and decision support system.

8.1. Functional requirements

Table 20. Functional requirements

Requirement ID	Activity ID and description	As a…	I want to…	So that…
HIV.FXN.REQ.001	HIV.A2. Gather client details	Clerk	…ensure that the privacy and confidentiality of clients are assured	…clients' rights and safety are protected and the facility is in compliance with any relevant international or local data protection policies.
HIV.FXN.REQ.002	HIV.A. Registration	Health care provider (for example, lay provider, nurse)	…be able to flag when a client wishes to be contacted with a reminder	…the client can be better supported to remain in care.
HIV.FXN.REQ.003	HIV.A. Registration	Health care provider (for example, lay provider, nurse)	…record if a client consents to follow-up	…the client's privacy regarding follow-up is protected.
HIV.FXN.REQ.004	HIV.A. Registration	Clerk or health care provider	…update the type of setting where care is being provided (in the community or facility)	…I can track where and in what settings cases are being identified (used for indicator TL.2 HTS testing volume and positivity).
HIV.FXN.REQ.005	HIV.B6. Capture or update client history	Health care provider (for example, lay provider, nurse)	…record the HIV status of partners or family members of clients, with proper consent	…I can provide specialized care (for example, in serodiscordant couples).

Requirement ID	Activity ID and description	As a…	I want to…	So that…
HIV.FXN.REQ.006	HIV.B. Post-test messages, HIV.C. Counsel, HIV.D. Counsel	Health care provider (for example, lay provider, nurse)	…have different question and language prompts when clients are from different populations	…I can better support populations such as adolescents, paediatric clients and caregivers and their unique needs.
HIV.FXN.REQ.007	HIV.B16. HTS, HIV.C26. PrEP, HIV.D29. Care and treatment clinical visit	Health care provider (for example, lay provider, nurse)	…see where I can refer clients for specialized counselling that I'm not qualified to provide	…I can direct clients to where they can get the confidential and sensitive support they need.
HIV.FXN.REQ.008	HIV.B. Schedule follow-up, HIV.C. Schedule follow-up, HIV.D Schedule follow-up	Health care provider (for example, lay provider, nurse)	…have the system automatically calculate the date when the client should return for care based on, for example, risk, prevalence or clinical stability	…I do not have to calculate this myself.
HIV.FXN.REQ.009	HIV.D5. Capture or update client history	Health care provider (for example, lay provider, nurse)	…be able to update the client history from client-held records	…the clients' history of HIV care can be available when they go to other facilities (for example, transfer, hospital, TB clinic) if history or transfer information is not available from past facilities directly.
HIV.FXN.REQ.011	HIV.D11. Counsel	Health care provider (for example, lay provider, nurse)	…have access to clients' ART history in one place	…I can support clients with adherence and ensure their regimens are working.
HIV.FXN.REQ.012	HIV.D7. Counsel	Health care provider (for example, nurse, clinician)	…have access to key test results in one place, such as viral load and CD4 counts	…I can better monitor how a client is responding to treatment.
HIV.FXN.REQ.013	HIV.D.15 Check for signs of treatment failure.	Health care provider (for example, nurse, clinician)	…see which criteria in the decision logic was met to indicate possible treatment failure	…I can review additional criteria not in the digital record and make a clinical judgment.
HIV.FXN.REQ.014	HIV.D15. Determine clinical stage of HIV	Health care provider (for example, nurse, clinician)	…see which clinical staging conditions or symptoms the client has already experienced	…the information may be used to help classify the client's HIV disease severity.
HIV.FXN.REQ.015	HIV.D20. Diagnostics	Health care provider (for example, nurse, clinician)	…be able to expedite diagnostic orders	…clients who may have urgent care needs can be identified, such as infants with HIV.
HIV.FXN.REQ.016	HIV.D18. Perform screenings	Health care provider (for example, nurse, clinician)	…have flexibility to perform screenings and clinical activities based on my clinical judgment	…I can screen clients for recommended, desirable or other tests in an efficient way.
HIV.FXN.REQ.017	HIV.D22. Determine regimen/treatment options	Health care provider (for example, nurse, clinician)	…have additional screenings and diagnostics recommended based on the medications the client is being prescribed	…the necessary screenings and diagnostics are identified during the visit.

Requirement ID	Activity ID and description	As a…	I want to…	So that…
HIV.FXN.REQ.018	HIV.H1. Identify client for follow-up	Facility or community staff member	…be able to identify clients who tested positive for HIV but have not linked to care	…I can follow up with clients who have not initiated care or may not have received confirmatory testing.
HIV.FXN.REQ.019	HIV.H7. Verify transfer	Facility or community staff member	…record when a client who self-reported as transferring is confirmed to have transferred	…I can better identify patients that are truly lost to follow-up.
HIV.FXN.REQ.020	HIV.I1. Emergency Referral?	Facility staff member	…bypass the standard flow at any point if there are signs of serious illness or emergency care is needed; urgent cases should be flagged and seen promptly	…the client can be referred, if needed.
HIV.FXN.REQ.021	HIV.I6. Provide information to referral facility	Health care provider (for example, nurse, clinician)	…be able to share the client's health records with the referral facility staff	…they can provide the care that the client needs.
HIV.FXN.REQ.022	HIV.I8. Receives client	Health care provider (for example, nurse, clinician)	…know what care and treatment the client received at the referral facility	…I can provide appropriate care if the client comes back to my facility.
HIV.FXN.REQ.023	HIV.J. Aggregate reporting and data use	Facility staff member	…produce a range of prepared and ad hoc reports and analyses	…I am able to use data collected at the facility, including for service delivery (beyond reporting purposes alone).
HIV.FXN.REQ.024	HIV.J. Aggregate reporting and data use	Health care provider (for example, lay provider, nurse, clinician)	…be able to view data on my own performance and service delivery	…I can understand trends and challenges and track my own performance over time.
HIV.FXN.REQ.025	HIV.J. Aggregate reporting and data use	Facility staff member	…be able to identify clients that left before a visit was completed	…I can better monitor facility performance (for example, through wait times and clients leaving before completing a visit).

8.2. Non-functional requirements

Table 21. Non-functional requirements

Requirement ID	Category	Non-functional requirement
HIV.NFXNREQ.001	Security-Confidentiality	Provide password protected access for authorized users
HIV.NFXNREQ.002	Security-Confidentiality	Provide ability for authorized users to view confidential data
HIV.NFXNREQ.003	Security-Confidentiality	Anonymise data that is exported from the system
HIV.NFXNREQ.004	Security-Confidentiality	Prevent system remembering username and password
HIV.NFXNREQ.005	Security-Confidentiality	Log out the user after specified time of inactivity
HIV.NFXNREQ.006	Security-Confidentiality	Provide encrypted communication between components
HIV.NFXNREQ.007	Security-Authentication	Notify the user to change their password the first time they log in
HIV.NFXNREQ.008	Security-Authentication	Adhere to complex password requirements
HIV.NFXNREQ.009	Security-Authentication	Provide a mechanism to securely change a user's password
HIV.NFXNREQ.010	Security-Authentication	Notify the user of password change to their account
HIV.NFXNREQ.011	Security-Authentication	Reset a user's password in a secure manner
HIV.NFXNREQ.012	Security-Authentication	Lock a user out after a specified number of wrong password attempts
HIV.NFXNREQ.013	Security-Authentication	Notify a user if their account is locked due to wrong password attempts
HIV.NFXNREQ.014	Security-Authentication	Provide role-based access to the system
HIV.NFXNREQ.015	Security-Audit trail and logs	Log system logins and logouts
HIV.NFXNREQ.016	Security-Audit trail and logs	Record all authentication violations
HIV.NFXNREQ.017	Security-Audit trail and logs	Log all activities performed by the user, including date and time stamp
HIV.NFXNREQ.018	Security-Audit trail and logs	Log access to views of individual client records
HIV.NFXNREQ.019	Security-Audit trail and logs	Log access to data summaries, reports, analysis and visualization features

Requirement ID	Category	Non-functional requirement
HIV.NFXNREQ.020	Security-Audit trail and logs	Log exchange of data with other systems
HIV.NFXNREQ.021	Security-Audit trail and logs	Generate analysis of the usage of different system features and reports
HIV.NFXNREQ.022	Security-Audit trail and logs	Log all data and system errors
HIV.NFXNREQ.023	Security-User management	Allow user with permission to create a new user and temporary password
HIV.NFXNREQ.024	Security-User management	Provide role-based access
HIV.NFXNREQ.025	Security-User management	Allow roles to be associated with specific geographical areas and/or health facilities
HIV.NFXNREQ.026	Security-User management	Allow cascading user management and assignment of roles
HIV.NFXNREQ.027	Security-User management	Allow user to change the user's own password
HIV.NFXNREQ.028	Security-User management	Allow users to enable and disable another user
HIV.NFXNREQ.029	Security-User management	Allow admin user to request password reset
HIV.NFXNREQ.030	Security-User management	Notify the user to regularly change the user's password
HIV.NFXNREQ.031	Security-User management	Allow each user to be assigned to one or more roles
HIV.NFXNREQ.032	Security-User management	Support definitions of unlimited roles and assigned levels of access, viewing, entry, editing and auditing
HIV.NFXNREQ.033	System requirements-General	Provide a unique version number for each revision
HIV.NFXNREQ.034	System requirements-General	Enable earlier versions of a record to be recoverable
HIV.NFXNREQ.035	System requirements-General	Enable deployment in an environment subject to power loss
HIV.NFXNREQ.036	System requirements-General	Work in an environment that is subject to loss of connectivity
HIV.NFXNREQ.037	System requirements-General	Generate IDs that are unique across different installations or sites
HIV.NFXNREQ.038	System requirements-General	Report version number when saving data to the database
HIV.NFXNREQ.039	System requirements-General	Be designed to be flexible enough to accommodate necessary changes in the future

Requirement ID	Category	Non-functional requirement
HIV.NFXNREQ.040	System requirements-General	Allow for offline and online functionality
HIV.NFXNREQ.041	System requirements-General	Show the number of records that are not yet synchronised
HIV.NFXNREQ.042	System requirements-Scalability	Scalable to accommodate new demands
HIV.NFXNREQ.043	System requirements-Scalability	Be able to accommodate at least [x number of] health facilities
HIV.NFXNREQ.044	System requirements-Scalability	Be able to accommodate at least [x number of] concurrent users
HIV.NFXNREQ.045	System requirements-Scalability	Be able to accommodate more than [x number of] concurrent users
HIV.NFXNREQ.046	System requirements-Usability	Be user-friendly for people with low computer literacy
HIV.NFXNREQ.047	System requirements-Usability	Provide informative error messages and tooltips
HIV.NFXNREQ.048	System requirements-Usability	Alert the user when navigating away from the form without saving
HIV.NFXNREQ.049	System requirements-Usability	Support real time data entry validation and feedback to prevent data entry errors from being recorded
HIV.NFXNREQ.050	System requirements-Usability	Simplify data recording through predefined drop-down or searchable lists, radio buttons, check boxes
HIV.NFXNREQ.051	System requirements-Usability	Support multiple languages
HIV.NFXNREQ.052	System requirements-Usability	Use industry standard user interface practices and apply them in a consistent manner throughout the system
HIV.NFXNREQ.053	System requirements-Usability	Easy to learn and intuitive to enable user to navigate between pages
HIV.NFXNREQ.054	System requirements-Usability	Provide guidance to the users to better support clinical guidelines and best clinical practices
HIV.NFXNREQ.055	System requirements-Configuration	Configure the system centrally
HIV.NFXNREQ.056	System requirements-Configuration	Configure business rules in line with guidelines and SOPs
HIV.NFXNREQ.057	System requirements-Configuration	Configure error messages
HIV.NFXNREQ.058	System requirements-Configuration	Configure workflows and business rules to accommodate differences between facilities

Requirement ID	Category	Non-functional requirement
HIV.NFXNREQ.059	System requirements-Interoperability	Communicate with external systems through mediators
HIV.NFXNREQ.060	System requirements-Interoperability	Provide access to data through application programming interfaces (APIs)
HIV.NFXNREQ.061	System requirements-Interoperability	Be interoperable with external systems through mediators
HIV.NFXNREQ.062	System requirements-Interoperability	Link with insurance systems to verify eligibility and submit claims
HIV.NFXNREQ.063	System requirements-Interoperability	Exchange data with other approved systems
HIV.NFXNREQ.064	System requirements-Hardware & connectivity	Allow for data exchange and efficient synchronization across multiple facilities and points of service when internet is available, even when it is intermittent and slow

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ANNEX

ANNEX 1 ANC.B. ROUTINE ANTENATAL CARE (ANC) CONTACT, FROM THE WHO ANTENATAL CARE DIGITAL ADAPTATION KIT

Objective: As part of comprehensive and integrated ANC services, to counsel and provide HIV services to pregnant women, including testing services, prevention and linkage to care.

Notes: For HIV care and treatment, including ART initiation, for integrated care, the antenatal care process should follow tasks involved in updating of client history within the following larger processes (see the ANC DAK for complete business process, page 36[1]):

- HIV.B. HTS
- HIV.C. PrEP visit
- HIV.D. Care and treatment clinical visit.

ANC contact business process notes and annotation

General notes

Optimizing support for the nurturing care of children affected by HIV also means early identification and sustained care for families that are affected by HIV.

6. Collect woman's profile and history

- The pregnant woman's HIV status and recent testing details, including self-testing, are included.
- If HIV-positive, the woman's ART history, current usage, regimen, and recent viral load testing or viral suppression would be recorded.
- History-taking should also include partners' HIV statuses and whether the partners are on ART and whether they are virally suppressed.

9. Conduct laboratory tests and imaging

- All pregnant women should be tested for HIV, syphilis and hepatitis B surface antigen at least once and as early as possible, ideally during the first ANC contact. Dual HIV/syphilis RDTs can be considered as the first test in ANC settings.

10. Counselling, in-facility management and treatment:

- Check if an HIV test is needed. All pregnant women should be tested once as early as possible. The criteria to test are based on whether the woman already had a test during ANC, the HIV burden in the setting, a serodiscordant partner that is not virally suppressed, or other risk factors. Maternal retesting is not cost-effective in low HIV burden settings. If implemented, it should address only members of key populations or women with a sexual partner with HIV who is not virally suppressed on ART or who is from a key population.[2]

[1] Digital adaptation kit for Antenatal Care: Operational requirements for implementing WHO recommendations in digital systems. Geneva: World Health Organization; 2021 (https://www.who.int/publications/i/item/9789240020306, date accessed 20 July 2022).

[2] Consolidated guidelines on HIV testing services. Geneva: World Health Organization; 2019 (22). Table 1.1.

- **Retesting in pregnant and postpartum women, high HIV burden settings:** Retest all pregnant women with unknown or HIV-negative status in late pregnancy – at third trimester visit. If either the first test or retest is missed or delayed, "catch-up" testing is needed. An additional retest for women of unknown or HIV-negative status in the postpartum period can be considered. Countries could consider an additional postpartum test in specific districts or provinces with high HIV burden or incidence and among women from a key population or who have partners with HIV who are not virally suppressed.
- **Retesting in pregnant and postpartum women, low HIV burden settings:** Retest pregnant women with unknown or HIV-negative status who are in serodiscordant relationships, where the partner is not virally suppressed on ART, or who have other known ongoing HIV risk in late pregnancy – at a third trimester visit. If either the first test or retest is missed or delayed, "catch-up" testing is needed. An additional retest for women of unknown or HIV-negative status in the postpartum period can be considered among women from key populations or who have partners with HIV who are not virally suppressed. Countries could also consider an additional postpartum test in specific districts or provinces with high HIV burden or incidence. To verify HIV-positive diagnoses and prevent misdiagnosis of HIV, WHO recommends retesting all people with HIV prior to starting lifelong treatment. As confirmatory testing is only to verify an HIV-positive result, countries should use only the national HIV testing strategy and algorithm, which would not include dual HIV/syphilis RDTs.
- Decision logic:
  - HIV.DT.02 Test for HIV using testing algorithm
  - HIV.DT.03 Determine retest recommendation.
- Guidance and guidelines
  - *Consolidated guidelines on HIV testing services*. 2019. 8.4.2 Multiplex testing for HIV-1 and other infections: HIV and syphilis dual detection. Table 1.1.

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