PATIENT MONITORING GUIDELINES FOR HIV CARE AND ANTIRETROVIRAL THERAPY (ART)

List of participating organizations

These guidelines reflect discussions at the WHO HIV patient ART monitoring meeting held at WHO/HQ, Geneva, Switzerland from 29-31 March 2004, and subsequent work by the subgroup reviewing the patient card and registers, discussions with stakeholders, initial ART patient monitoring experience, and further expert input. This document is a work in progress and will evolve in part determined by country experience and other relevant developments.

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A Word version of the card, Excel versions of the registers and reports, and training materials for filling out the forms are available at: http://www.who.int/hiv/toolkit/arv/en/index.jsp. To request country adaptation assistance please contact the imaimail@who.int or goves@who.int.

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Evaluation

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List of abbreviations

ADR	adverse drug reaction
AFRO	World Health Organization Regional Office for Africa
AIDS	acquired immunodeficiency syndrome
ARV	antiretroviral (drug)
ART	antiretroviral therapy
CBO	community based organization
CD4	human T-helper cells expressing CD4 antigen (T-helper cell)
DOB	date of birth
DOTS	directly observed therapy, short course
EMR	electronic medical record
FDC	fixed-dose combination
HAART	highly active antiretroviral therapy
HIV	human immunodeficiency virus
HIVDR	HIV drug resistance
HMIS	health management information system
ID	identification
IDU	injecting drug use
IMAI	integrated management of adolescent and adult illness
INH	isoniazid
LMIS	logistics management information system
M&E	monitoring and evaluation
MD	medical doctor
MOH	ministry of health
NGO	non-governmental organizations
OI	opportunistic infection
PDA	personal digital assistant
PLHA/PLWHA	people living with HIV/AIDS
PMTCT	prevention of mother-to-child transmission of HIV
SAM	service availability mapping
SEARO	World Health Organization Regional Office for South-East Asia
STI	sexually transmitted infection
TB	tuberculosis
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNGASS	United Nations General Assembly Special Session (on HIV/AIDS)
USAID	United States Agency for International Development
VCT	voluntary counselling and testing
WHO	World Health Organization

CHAPTER ONE

HIV PATIENT CARE AND ART INFORMATION SYSTEMS

A. Objectives and intended audience

Objectives of the Patient monitoring guidelines for HIV care and ART

These guidelines have been provided by the World Health Organization (WHO) and other international partners in order to aid in the development of an effective national HIV care and antiretroviral therapy (ART) patient monitoring system. Specific objectives include:

1. providing and facilitating national stakeholder consensus on a standardized minimum set of data elements to be included in patient monitoring tools;
2. helping to establish a functioning patient monitoring system so as to enable the rapid scale-up of effective chronic HIV care, ART and prevention;
3. providing considerations for HIV care and ART information systems design;
4. introducing the practice of a simple cohort analysis for HIV patients on ART;
5. mapping the standardized minimum set of data elements to the core ART programme indicators and other internationally agreed upon indicators; and
6. contributing to successful programme monitoring and global reporting and planning through the measurement of indicators at the district, national and international levels.

These guidelines reflect discussions at the WHO HIV patient ART monitoring meeting held at WHO/HQ, Geneva, Switzerland from 29 to 31 March 2004, and subsequent consultations with the subgroup reviewing the patient card and registers, discussions with stakeholders, and initial HIV care and ART patient monitoring experience.

Intended audience

These guidelines are intended for those involved at various levels of the development or revision of patient monitoring tools such as HIV care and ART patient and facility records, registers and reports, or electronic systems, including:

- national AIDS programme managers
- ministries of health
- monitoring and evaluation officers
- other providers of HIV care and ART who may be interested in the technical framework underlying the HIV care/ART patient monitoring system.

While the system described in these guidelines will be used by the clinical team providing chronic HIV care and ART, this document is aimed primarily at those involved in HIV/AIDS programmes at the district and national levels. There are training materials that are specifically targeted at people working at the facility level (see *Chapter 4, Section H*).

The "Three Ones" agreement[1] – one national HIV/AIDS action framework; one national HIV/AIDS coordinating authority; and one agreed country-level monitoring and evaluation system – should facilitate the cooperation of stakeholders in using standardized data elements and

[1] Joint United Nations Programme on HIV/AIDS (UNAIDS). *"Three Ones" key principles: coordination of National Responses to HIV/AIDS: guiding principles for national authorities and their partners.* Geneva, UNAIDS, 2004.

compatible patient monitoring systems in each country. At the global level, the harmonization of key elements of patient monitoring is one component of a global, coordinated HIV/AIDS monitoring and evaluation strategy.

B. Patient monitoring within efforts to scale-up HIV care, ART and prevention

The global emergency of HIV/AIDS has led to unprecedented attention and commitment from the international community to improve access to HIV care, ART and prevention. Many developing countries are currently designing and scaling-up large HIV care and ART programmes in order to save and improve the lives of those infected and affected by the disease and to reduce HIV transmission. In this context, the ability of countries to provide and sustain effective long term HIV care with ART and prevention is critical. This requires an effective patient monitoring system integrated with care, prevention and treatment at the health facility. Monitoring the programme by measuring key indicators and immediately feeding these back so as to improve programme activities are essential to success.

This large commitment by governments and international, bilateral and non-governmental agencies to providing access to ART requires the formation of clinical teams at multiple HIV care/ART sites. Equally as important is the creation of a system to support this care, both administratively, and with training, supervision, clinical mentoring, and other quality assurance inputs after training. A patient monitoring system forms the backbone of clinical care, treatment and prevention.

In many health facilities, most HIV care is currently episodic acute care with the exception of TB treatment. Establishing good chronic HIV care including ART requires forming and preparing a clinical team to provide continuity of HIV care. A key element of continuity of care is keeping a record which summarizes this care and allows each health worker or counselor to understand what has happened before: the patient's HIV clinical stage, weight and functional status; what prophylaxis, other medications, education, and psychosocial support have been provided on earlier visits; the patient's family, pregnancy, contraception, and TB status (checked at each visit); and a summary of the patient's ART over time. The core of these guidelines is an agreed list of essential minimum standard HIV care and ART patient monitoring data elements and their definitions (*Chapter 2* and *Annexes A* and *B*). These can be collected in a variety of ways with different formats of patient cards or records.

In addition to tracking important data for individual patient management, clinical teams need to summarize patient data from the group of patients they are responsible for, in order to manage their patients better, to plan, to order drugs, and to report these data. The growing number of patients in chronic HIV care and progressively on ART is a management challenge for clinical teams. A patient monitoring system based on chronic care registers helps clinical teams organize the care of groups of patients. Early in ART programme implementation, nurses in some facilities without formal chronic care registers, or before registers were printed, created their own by drawing columns to collect the necessary data elements on blank sheets of paper or exercise books. This demonstrates the inherent need for clinical teams providing chronic care to collect data on groups of patients in a timely manner despite the existing burden of record-keeping at many facilities. A small proportion of this aggregated data goes "up" and is also used for programme monitoring.

In a public health approach to making ART widely available in low-resource settings, patients are started on one of several first-line regimens, based on clinical staging and sometimes a CD4

count. The second-line regimens are limited and more expensive. The success of individual patient management (including survival) and of the ART programme depends on the ability to keep patients on a first-line regimen as long as possible. There must therefore be a serious commitment by the patient, treatment supporter, clinical team, and the community to almost perfect adherence and to remaining on a first-line regimen as long as possible. It is very important for clinical teams and the managers at district and national levels to monitor the proportion of patients who either remain on the original first-line regimen or have substituted to an alternative first-line regimen and the proportion who survive and remain on ART. This is recorded on the cohort analysis report form.

Simplified ART cohort analysis

Simplified cohort analysis is a key component of ART patient monitoring. It should not be confused with cohort studies which are a demanding research activity. In patient monitoring of ART, a cohort is an ART start-up group which in these guidelines (and the WHO illustrative system presented in *Chapter 4*) consists of all patients starting ART in the same month. Cohort analysis compares baseline characteristics of patients who started on ART, with their status at 6 and 12 months, then yearly. It allows comparison of the proportion of patients surviving on ART, remaining on the original first-line regimen (or substituting to an alternative first-line regimen), and returning to the functional status of working (or playing, for children). Where CD4 counts can be determined regularly, cohort analysis can show the improvement in the median CD4 count over time. The median CD4 count for a group of patient is a good measure of immunosuppression and predictor of mortality and serious opportunistic infections (OIs).

TB programmes have demonstrated the importance and feasibility of simplified cohort analysis based on data transferred from TB treatment cards to a register. Cohort analysis is a key organizational principle of TB monitoring. It is carried out routinely and successfully in all national TB programmes and is considered necessary to track trends in programme progress and determine treatment outcomes for patients. This is often based on a paper register maintained by the district TB coordinator; some countries are now entering the register data electronically in order to generate reports.

The simplified ART cohort analysis form can be filled out by most clinical teams and can provide important immediate feedback on success in keeping patients on first-line regimens. The district ART team, during on-site visits, needs to fully verify the data by going back to the register data for each monthly cohort.

Cross-sectional data on numbers of patients in HIV care and on ART

Efficient management of large numbers of patients and steady work towards national targets for the numbers of patients in HIV care and on ART require the ability to accurately keep track of these numbers and to avoid double-counting. The patient monitoring system allows clinical teams to tabulate and report on a monthly or quarterly basis on the numbers newly and cumulatively enrolled in HIV care, the numbers waiting for ART, and three ART numbers:

- new on ART (in the last month or quarter)
- cumulative ever started on ART at the facility
- currently on ART at the facility.

Success in reaching ART targets will be based both on cumulative ever started on ART and those currently on ART (subtracting those who have died, stopped ART, or been lost to follow-

up). These numbers are disaggregated by sex and age because of the importance of monitoring gender equity in access and assuring adequate attention to providing ART to children.

An effective patient monitoring system should be standardized and allow for continuity, referral and communication between all levels of care – from records kept by the patient, family or community treatment supporter; to the first-level facility, to the district hospital; to further referral to specialist physicians or for laboratory examinations. The system should be appropriate for adults, children and pregnant women.

C. Both patient and programme monitoring

Patient monitoring serves two main functions: first, it enables effective clinical management of patients; and second, patient monitoring data are used for programme monitoring and management, contributing to standardized indicators at the district, national and international levels for in-country and global reporting and planning.

At the national or international level, countries are developing ways to report on the set of internationally standardized indicators for monitoring national AIDS programmes' milestones[1] and the targets they have set working with large scale-up initiatives such as the "3 by 5" campaign[2] or the "2-7-10" targets defined by the United States President's Emergency Plan.[3]

Patient monitoring is the routine collection, compilation and analysis of data on patients over time and across service delivery points, using information either directly from paper forms or entered into a computer.

These data are best collected and stored at the health facility, and include basic patient demographic characteristics and contact information; information related to patient HIV care and ART history; and patient encounter information collected at each visit. Patient monitoring is often referred to as "patient tracking". Patient monitoring provides important information for patient management, both of individuals and groups of patients.

Patient management is the relationship between providers on a clinical team and the individual patient over time, assisted by written records. Patient management may also be referred to as "clinical management" or "clinical monitoring".

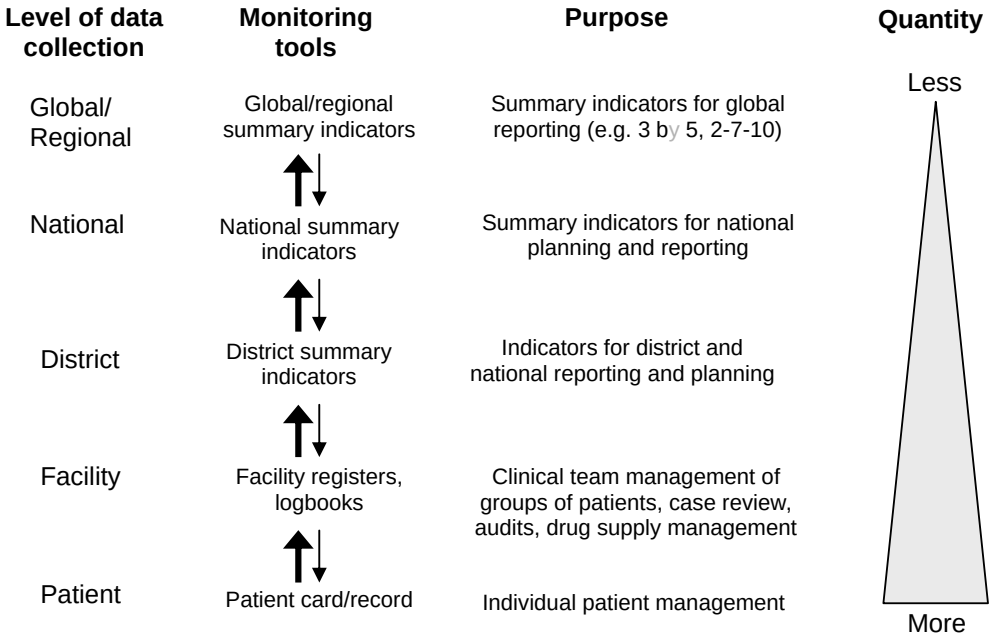
Programme monitoring is the routine tracking of priority information about a programme and its intended outcomes.[4] Monitoring at the facility, district and national level requires many types of information, including aggregated patient data.

Indicators are used at various levels and for different purposes as shown in *Fig. 1*. For example, as described above, the clinical team may use individual patient data for individual clinical management of a patient, while data on groups of patients may be collected and aggregated at the facility level as performance measures (for quality improvement) for the clinical team. Among the key information that may be used to calculate such indicators are: what regimens patients are on; whether or not they are dead or lost to follow-up while on ART (survival); weight,

[1] World Health Organization (WHO). *National AIDS programmes: a guide to indicators for monitoring and evaluating national antiretroviral programmes.* Geneva, WHO, 2005.
[2] WHO and UNAIDS. *"3 by 5" progress report.* Geneva, WHO and UNAIDS, 2004.
[3] Office of the Global AIDS Coordinator (OGAC). *The President's Emergency Plan for AIDS Relief: U.S. five-year global HIV/AIDS strategy.* Washington, D.C., OGAC, 2004.
[4] Joint United Nations Programme on HIV/AIDS (UNAIDS). *National AIDS programmes: a guide to monitoring and evaluation.* Geneva, UNAIDS, 2000.

functional status and clinical stage (quality of life and productivity); and adherence to ART, among others (see *Chapter 2*). Community-level monitoring systems, while not covered in these guidelines, play an important part in patient monitoring, and are currently in development.

Fig. 1. HIV/ART monitoring at different levels of the health care system[1]



An important distinction must be made from the outset between what data to collect and how to collect them. While there is international agreement on the core national-level HIV care/ART indicators[2], standardization as soon as possible of additional facility-level and district-level indicators for programme monitoring should also be done through national consensus-building. These guidelines provide a recommended set of data elements to collect for HIV care/ART patient monitoring. How these data are collected may vary between facilities but needs standardization nationally in order to ensure uniform reporting and national programme monitoring.

D. Organization of the guidelines

The focus of these guidelines is the list of essential minimum standard HIV care and ART patient monitoring data elements and how their collection facilitates clinical care and measurement of agreed indicators (*Chapter* 2 and *Annexes A* and *B*). The list is broken down into four categories: demographic information; HIV care and family status; ART summary; and patient-level encounter information. The definition and rationale for collection of each category of data are presented, along with examples of how they may be used in the context of patient management and programme monitoring and management.

[1] Adapted from: Health Metrics Network (HMN). *Statistics saves lives: strengthening country health information systems (Draft).* Geneva, HMN, 2005.
[2] World Health Organization (WHO). *National AIDS programmes: a guide to indicators for monitoring and evaluating national antiretroviral programmes.* Geneva, WHO, 2005.

Chapter 3 provides the broader context for the collection of these data relative to other facility-based information systems and discusses how paper and electronic systems are linked, the use of patient monitoring data to help management of the ARV drug supply, and the relationship to other monitoring and evaluation tools. Finally, the practical application of these guidelines is provided through presentation of the data elements using the WHO illustrative patient monitoring system *(Chapter 4)*, and other country and project examples *(Chapter 5)*.

E. How to adapt and operationalize the HIV/ART patient monitoring system

A patient monitoring system is a critical component of an integrated HIV care, ART and prevention programme. The development of an effective patient monitoring system should ideally occur in conjunction with the roll-out of the programme. Setting up or improving an HIV care/ART patient monitoring system is a multi-step process. While not providing a detailed methodology, the following are recommended actions to be taken (not necessarily in the order given) in adapting and operationalizing a patient monitoring system. More detailed guidance on adapting a generic system is currently in development.

- Gather key stakeholders to discuss the adaptation, development, revision, or strengthening (as appropriate) of the national HIV/ART patient monitoring system;
- Inventory current and potential patient monitoring tools and other information systems linked to HIV/ART patient monitoring;
- Obtain consensus on what indicators to measure and the corresponding minimum data elements to collect. Review and standardize definitions for each data element and indicator;
- Identify an appropriate system and tools to collect these data for each type of facility. Adapt tools based on country resources and information needs (for example, data on when cotrimoxazole prophylaxis is started or stopped may be omitted from registers if this information is not required for drug supply management);
- Obtain consensus on the patient monitoring tools from all key stakeholders;
- Plan who will carry out, supervise and support patient monitoring at facility, district, regional, and national levels;
- Develop (or adapt existing) training materials to prepare these staff at all levels on the use of patient monitoring tools, then train and retrain as necessary;
- Provide systematic follow-up after training and supportive supervision, to ensure quality data collection and effective use of the data at facility and district levels.

Experience in the field has demonstrated the tremendous importance of providing follow-up and supportive supervision after initial training. This supervision and follow-up may be provided by the district management team or by clinical mentors during site visits. These supervisors need to be prepared to effectively oversee, troubleshoot and solve problems. Smooth and accurate flow of data at the facility and from facility to district to central levels require regular facility visits by the district health information officer for data collection and analysis.

CHAPTER TWO

STANDARDIZED MINIMUM PATIENT MONITORING DATA

A. Essential minimum standard HIV care and ART patient monitoring data

This chapter presents the recommended **essential minimum standard HIV care and ART patient monitoring data** listed in more detail in *Annex A*. These data are broken down into four categories:

I. Demographic information

II. HIV care and family status

III. ART summary

IV. Patient encounter information.

The categorized list of data variables provided is for patients that are registered in HIV care and may or may not be on ART, and should be considered when designing records, registers and reports that monitor patients in HIV chronic care settings. Regardless of how the data are collected, it is essential to standardize variable definitions and codes in order to facilitate the accurate analysis of data across facilities, districts and countries.

It is important to identify, early on, which patient-level data are needed in order to manage individual facilities and to monitor and report on HIV service delivery activities. As noted in *Chapter 1*, patient monitoring data may also be relevant to managers for drug orders and supply forecasting, other planning, quality improvement, and reporting to the district and national level for programme monitoring and management.

A more complete description of the variables is provided in *Annex A: Standard HIV care and ART data variables and their coding*. In addition to the name of each variable, it includes a coding scheme and frequency of collection, and provides guidance on whether or not it is recommended that the variable be aggregated and used for programme monitoring at the facility level.

Table A provides a summary of the list of essential minimum standardized data elements by category. Following this, a more descriptive explanation of the data elements within each category is provided and includes:

- definition of key data elements
- rationale for collection of data
- examples of how data may be used.

Table A. Summary of minimum essential list of standardized data elements by category

I. Demographic information
• Name, sex, date of birth, age at registration, marital status • Unique ID number, patient clinic ID number • Address, telephone, contact information
II. HIV care and family status
• Date and location confirmed HIV-positive, HIV subtype • Entry point into HIV care • Current health facility, district, district clinician/team • Treatment supporter(s) name/address/contact information • If family members/partners: name, HIV status, HIV care status, unique ID number, date of birth/ age at registration • Drug allergies
III. ART summary

• ART history prior to entry
• ART START date/treatment cohort:
  • Date medically eligible to start ART
  • Why medically eligible; baseline CD4, clinical stage
  • Date medically eligible AND ready to start ART
  • Date medically eligible, ready AND selected to start ART
  • Functional status, clinical stage and weight at ART start
• First-line regimen
  • Original first-line regimen (list drugs)
  • If SUBSTITUTE within first-line regimen: dates, reasons, new regimens
• If SWITCH to or SUBSTITUTE within second-line regimen or higher: dates, reasons, new regimens
• ART interruptions: dates, reasons
  • STOP ART: dates, reasons
  • LOST (temporary): dates
  • RESTART: dates
• Transfer In, Transfer Out: date, facility transferred from or to
• DROP: dates
• DEAD: date

IV. Patient encounter information
• Encounter date, whether scheduled or not, next scheduled follow-up visit date • Months on current regimen • Current functional status, clinical stage, weight, height (for children) • TB status, TB treatment start/stop dates • Pregnancy status, EDD, family planning method(s), PMTCT referral/provision • Possible side-effects (including drug allergies), severity • New symptoms/diagnoses/OIs • Laboratory test dates and results • Prophylaxis: medication, dose dispensed, start/stop dates • ART dispensed: Regimen code, dose dispensed, (start/stop dates) • Adherence assessment (pill count, self-report, other) and reasons for both ART and prophylaxis non-adherence • Referral or link to other clinical or supportive care • Hospital days since last outpatient visit

I. Demographic information

- Name, sex, date of birth, age at registration, marital status
- Unique ID number, patient clinic ID number
- Address, telephone, contact information

Definition

Demographic information is collected once at baseline or enrolment and updated with changes.

Basic identifying data including **name, sex, date of birth, age, marital status, address, telephone number,** and other **contact information** are generally self-explanatory. It is important that this information be as complete as possible and that there be a consistent way to record each item, particularly the date of birth.

The **unique patient number** is a single identifier that is permanently assigned and cannot be reused once it has been created for a patient. Patients may already have unique numbers for general medical care or from receipt of other social services within a country. If unique identifiers are not pre-existing, they will need to be created and assigned at the start of HIV care or ART.

There are two parts to successfully administering lifelong unique numbers: 1) assigning a unique number; and 2) assigning only one unique number.

Avoiding the assignment of multiple unique IDs to a single patient who moves between facilities may be more challenging than unique number assignment. Even within a single facility, it is essential to be able to distinguish between a new patient and one who is already registered and returning for care or treatment in order to continuously link patients to their own records.

To avoid providing multiple unique numbers to one person, it is necessary to be able to match patients to their prior records and ID. This will require use of other identifying information such as **name, date of birth, telephone number, address, date ART was started**, etc. to be stored with the assigned unique number. When the unique number is not provided, these distinguishing fields must be used to find the assigned number, or, confirm that the patient was not previously assigned a unique number.

When matching patients to their records, there are several situations that may arise: a) patients have their unique number and you can look up prior records; b) patients provide identifying information and you can look up prior records; c) patients provide identifying information, but you fail to find prior records.

Failure to locate prior records may arise because: a) they do not exist; b) they do not exist at the facility in question; c) they exist at this facility but the identifying information provided was incorrect or insufficient, given the record retrieval system.

In order to provide continuity of care, it is therefore necessary to:

1. assign a unique number;
2. collect ancillary identifying information to be stored with the assigned number;
3. make this list of numbers and identifying information searchable at time of visit;
4. have this same list available at all sites of care used by same patient;
5. have capacity to match record fragments using ancillary information to reconstruct a single record if 3) or 4) fail at the time of visit; and
6. have capacity to prevent or detect use of false identifying information if necessary – usually done by use of ID verification in 1) or 2), or by use of a biometric identifier such as a finger or thumb print.

The patient clinic ID number is the patient record or chart number (non-unique) that most health facilities issue upon patient registration.

Rationale

Basic demographic information allows indicator data to be disaggregated (for example by age and sex) providing programmes with valuable data on coverage and equitable distribution of services.

Contact information is particularly important for follow-up of care and treatment when and if a patient does not show up for a clinic or pharmacy appointment and should be updated with changes.

Unique patient numbers allow programmes to identify and track patients as they move through different facilities and prevent duplication of patient counts. They also allow patient information concerning HIV care and ART to be accessed and, if possible, linked to other medical information at a higher level for analysis at the district or country level. In addition, unique patient numbers protect the privacy and confidentiality of patient information such as name, age, sex, address and telephone number, which may address concerns around stigma and discrimination. Specific guidelines addressing confidentiality of HIV/AIDS patient data are in development.

Examples of use

Several countries currently require facilities to fill out numbers of patients on HIV care and ART disaggregated by **sex** and **age** group (see *Chapter 5*). At a minimum, children (< 15 years) may be reported separately from adults. Youths 15–24 years may be separated out or children may be further broken down into 0–4 years and 5–14 years, depending on how data are used for programme monitoring.

Creating unique patient ID numbers
One way to assign and assure unique patient IDs (and avoid mislinking information from different patients) in the absence of immediate communications between every health facility, is to break the identifier into two parts. The first part of the patient ID is a unique code assigned to the original health facility (could be based on region, district, sub-district, etc.). There needs to be agreement on unique codes for facilities at the outset, but in most countries these codes exist. The second part is a unique serial number assigned to the patient by the health facility. The combination of these two parts both assures the uniqueness of the number, and allows for local assignment of this unique number.

In Zambia, for example, the proposed IDs include a district code DD, a unique facility code FFF within the district, and finally a unique block of six numbers NNNNNN that are assigned sequentially in the order each new patient is registered at the facility. Errors in ID transcription may occur at the time of registration, and may be addressed to some degree by the use of a single digit checksum "C" on the end of the number. This helps catch the problem before it causes too much trouble within the system. Zambia's proposed unique ID would thus have the format: DD-FFF-NNNNNN-C.

Unique identifiers may also be created using patient information. As in the first method, the way in which the ID will be formed needs to be agreed upon from the outset. However, while this enables any facility to create the same unique ID for one patient and validate it using identifying information, a major drawback of using this method is the potential breach of patient confidentiality.

II. HIV care and family status

- Date and location confirmed HIV-positive, HIV subtype
- Entry point into HIV care
- Current health facility, district, district clinician/team
- Treatment supporter(s) name/address/contact information
- If family members/partners: name, HIV status, HIV care status, unique ID number, date of birth/ age at registration
- Drug allergies

Definition

HIV care history is collected at baseline for all patients enrolled in HIV care whether or not they have started ART and is updated as information changes.

The information is generally related to how and why the patient entered into HIV care, and to details of the current facility providing care. This includes the date the patient tested HIV-positive (and subtype where available and needed), as well as the HIV status (if known) of immediate family members or partners, and their respective unique patient identifiers and ages or dates of birth.

For patients < 18 months, HIV antibody test results are not definitive; however, a negative test result is useful to exclude maternally acquired infection. Where available, more confirmatory polymerase chain reaction (PCR) test results may be recorded.

Other essential HIV care information includes how patients entered into care, i.e. where they were referred from (PMTCT, TB, STI, etc.), any treatment history including PMTCT participation, and the health unit and district of the facility where they are currently receiving HIV care. Additionally, the name of the medical officer or doctor at the first-level facility or clinical team overseeing the patient should be noted.

Contact information for the patient's treatment supporter should be collected. The treatment supporter's primary role is to assist with patient adherence. This may involve accompanying the patient to the clinic for appointments and drug pick-up, or providing assistance to ensure the patient takes the right drugs at the right time in the right way.

Finally, any drug allergies should be recorded in a visible place on the patient's chart either in a designated section on the patient card or near the top so that this information is easily identifiable by the clinical team.

Rationale

Treatment supporters may provide an additional means for contacting patients as well as adherence information.

Knowing the **HIV status** of family members and partners allows for cross-referencing of patients, particularly in a family-centred programme such as MTCT-plus which treats mothers, partners and children, or the integrated management of adolescent and adult illness (IMAI) approach.[1]

Identifying **entry points into HIV care** allows programme managers to assess the adequacy of linkages with other programmes and services. While this information may seem relatively simple to collect, patients may have been routed through several possible points of entry before reaching the HIV care facility and may not correctly identify the true referral unit. It is important to remember that VCT is the method of counselling and testing and that the entry point refers to how the patient arrived at VCT (or provider-initiated testing and counselling).

[1] http://www.who.int/hiv/toolkit/arv/en/index.jsp

Examples of use

This information may be used to ensure the quality and continuity of care, which may include: referring patients and HIV-positive family members to community-based or other services and support networks; engaging HIV-positive persons in prevention efforts; and enrolling HIV-positive family members into HIV care.

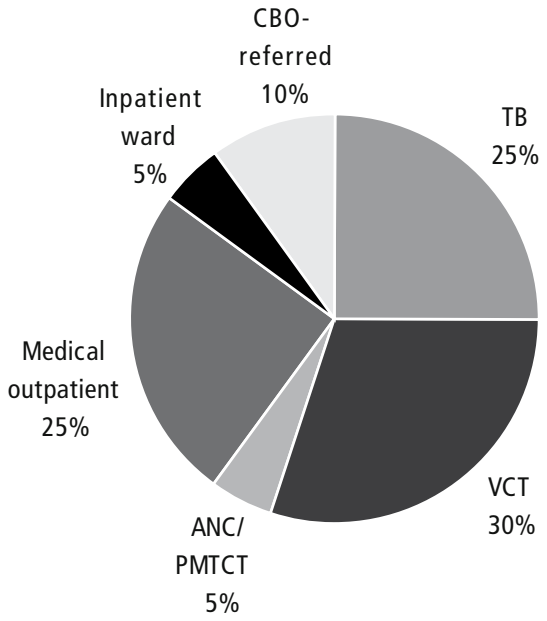
In addition, there are at least two indicators that may be generated from this category of data and used in programme monitoring:

- **Number of new and cumulative patients in HIV care**
  These numbers provide a cross-sectional summary of all patients who have ever enrolled in HIV care at each health facility. They do not account for any subsequent attrition or transfers into or out of the programme.

- **Distribution of entry points of patients enrolled in HIV care**

The pie chart and table below provide an example of how facility-level patient entry point data may be analysed. The pie chart graphs the proportions of HIV care patients by entry point, while the table contains a tally of the actual numbers of patients by entry point for the reporting period January to March, 2005.

Fig. 2. Distribution of entry points into HIV care at Health Facility A, January to March, 2005



Entry point into HIV care	# pts
TB	25
Sex worker outreach	0
Adolescent outreach	0
IDU outreach	0
Self-referred via VCT	30
Antenatal/PMTCT	5
Medical outpatient	25
Under 5 clinic	0
STI clinic	0
Inpatient ward	5
CBO-referred via VCT	10
Private doctor	0
Total	**100**

III. ART summary

- ART history prior to entry
- ART START date/treatment cohort:
  - date medically eligible to start ART
  - why medically eligible; baseline CD4, clinical stage
  - date medically eligible AND ready to start ART
  - date medically eligible, ready AND selected to start ART
  - functional status and weight at ART start
- First-line regimen
  - original first-line regimen (list drugs)
  - if SUBSTITUTE within first-line regimen: dates, reasons, new regimens
- If SWITCH to or SUBSTITUTE within second-line regimen or higher: dates, reasons, new regimens
- ART interruptions: dates, reasons
  - STOP ART: dates, reasons
  - LOST (temporary): dates
  - RESTART: dates
- Transfer In, Transfer Out: date, facility transferred from or to
- LOST (temporary): dates
- DROP: dates
- DEAD: date

Definition

The ART summary data are collected as information becomes available or relevant. They include the baseline clinical status of patients when they start ART; regimen changes and other status changes thereafter; interruptions with stop or lost and restart dates and reasons. The data cover the most important aspects of a patient's treatment history, and are critical for patients to receive continuous care, particularly when transferred to a new facility.

If a patient is not treatment-naive prior to starting ART at the health facility, it is important to determine, in as much detail as possible past ARV drug regimens and the duration the patient was on these regimens, including for PMTCT.

In addition, it is important to collect the date the patient is medically eligible to start ART, and why. Patients who are **medically eligible** to start ART have been clinically diagnosed using WHO clinical staging, immunologically diagnosed using CD4 count, or a combination of both according to programme guidelines. Patients who are medically eligible and **ready** to start ART have additionally been prepared for adherence. In systems where there is rationing of ART, patients who are medically eligible, ready and **selected** to start ART are those who have been chosen to receive ART based on certain criteria determined by the clinical team or special committee. A patient's **functional status** (working, ambulatory or bedridden (see definition under *Section IV Patient Encounter Information*)) and **weight** are also collected at ART start to be used as a baseline comparison for clinical progress through the programme.

There are several special terms and codes that are referred to throughout this document and are critical to ART patient monitoring. The codes and their definitions should be standardized nationally and ideally internationally to enable accurate data collection and analysis. *Table B* provides suggested standardized definitions and codes that may be customized to country programmes.

Rationale

Determining a patient's ART history prior to entry will enable the clinical team to better prescribe a suitable ARV regimen based on past ARV regimens. If the patient previously received monotherapy or dual therapy, was non-adherent, or stopped and restarted treatment, this may predict resistance to the first-line drug regimens.

Dates medically eligible, ready, selected, and started on ART can point to bottlenecks in the system, and may contribute to quality improvement and streamlining of certain procedures. In addition, recording the numbers of patients in each category may help clinical teams to predict patient load at each stage, and may help to prepare for appropriate care and treatment activities. Patients who are medically eligible but not yet started on ART comprise the "waiting list" for treatment.

Keeping track of substitutions and switches in drug regimens contributes to drug supply planning and assists in review of these clinical decisions by clinical mentors.

Recording stop, restart, temporary lost, and drop dates allows clinicians and programme managers to monitor adherence. Estimates of adherence on each visit and reasons for non-adherence are crucial for immediate intervention by the clinical team. Although the drug supply system and its logistics management system will strive to avoid stock-outs and provide alerts when these are about to occur, the patient monitoring system will also raise an alarm when the reason for patients stopping ART is listed as drugs being out of stock. As a special study, it would also be possible to link data on drug regimen switches with patient adherence patterns.

It is important to count transfers in and out so as to facilitate the transfer process and to determine the current cohort numbers, thereby avoiding double counting when aggregating data.

Recording deaths is extremely important as a clinical outcome, as is the reporting of when they occur in the programme (pre-ART or on ART). The calculation of mortality allows for the calculation of survival, a key impact indicator of a successful ART programme.

Examples of use

These data elements may be extracted for purposes of programme monitoring at the facility, district, national and international levels. For example, the data contribute directly to the measurement of three core national outcome and impact indicators as defined by the *Guide to indicators for monitoring and evaluating national antiretroviral programmes* (see *Chapter 2, Section B*):

- **Core 7:** percentage of people with advanced HIV infection receiving ARV combination therapy
- **Core 8:** continuation of first-line regimens at 6, 12 and 24 months after initiation
- **Core 9:** survival at 6, 12, 24, 36, etc. months after initiation of treatment.

See *Section B* in this chapter for other indicators that may be measured using these data elements.

Patient Transfer

In order to adequately manage a patient over time, a provider must know the patient's ART and clinical history and have access to the laboratory test results, as described above. When a patient is transferred to another facility, all records should ideally also be transferred to the receiving facility so that an optimum continuum of care can be provided.

The Western Cape's patient transfer form presented in *Chapter 5* is one example of information collected for patient transfer. The patient card including the summary sheet shown in *Annex D* could also be copied and used to facilitate easy transfer of information that has already been recorded.

It is important for countries to establish a national system for coordinating patient transfer between health facilities. A standardized verification process that facilitates effective and efficient patient transfer is essential, particularly in mobile populations and where ART is decentralized or decentralizing.

In order for successful patient transfer to occur, both patients and their records must be relocated from the current health facility to the receiving one. This process must take place in a timely manner in order to maintain continuous patient monitoring and management, above all to prevent any interruption in treatment. The transfer of patient records requires particular attention. In settings where there is a functioning electronic system, it may be possible to send the required documents electronically, including links to the drug supply system. Where this is not yet the case, there are several alternatives. The most convenient but perhaps most unreliable method is to have the patients physically transfer their own facility-based forms to the receiving health facility. However, in some countries, patient access to records is restricted. Patient files may also be mailed, faxed, delivered in person by health workers, or 'transferred' over the telephone by a clinician at the referring facility. In addition, the transferring facility should communicate with the receiving facility to alert it to the arrival of transferring patients, along with basic patient data variables, using the telephone or other means (see *Transfer In (TI)* under *Entering patient data in pre-ART and ART registers*). With any method, patients should be encouraged to have a personal copy of their transfer information so as to enhance expeditious continuity of care. Finally, keeping track of transferring patients will prevent double-counting of patients and thus ensure more accurate reporting (see *Creating unique patient ID numbers* above).

Similarly, if a patient is referred out for specialized services, it is important that any necessary information go with the patient (e.g. copy of the patient card and referral note) to the referral facility. Likewise, any relevant forms or notes containing important care and treatment information should be sent back to the referring facility either with the patient or via other modes of communication.

IV. Patient encounter information

- Encounter date, whether scheduled or not, next scheduled follow-up visit date
- Months on current regimen
- Current functional status, clinical stage, weight, height (for children)
- TB status, TB treatment start/stop dates
- Pregnancy status, family planning method(s), PMTCT referral/provision
- Possible side-effects (including drug allergies), severity
- New symptoms/diagnoses/OIs
- Laboratory test dates and results
- Prophylaxis: medication, dose, tablets dispensed, start/stop dates, reason for discontinuation
- ART dispensed: medication name, dose, number dispensed, (start/stop dates)
- Adherence assessment (pill count, self-report, other) and reasons for both ART and prophylaxis non-adherence
- Referral or link to other clinical or supportive care
- Hospital days since last outpatient visit

Definition

Patient encounter information is collected and updated every time a patient visits a health facility. In addition to the encounter date, information concerning the patient's clinical and follow-up status (lost, drop, transfer in/out, or dead) should be collected, including:

1. **Functional status** defined as:
   a) Working = able to perform usual work in or out of the house, harvest, go to school or, for children, normal activities or playing
   b) Ambulatory = able to perform activities of daily living but not able to work or play
   c) Bedridden = not able to perform activities of daily living

2. **WHO clinical stage** coded as 1, 2, 3, or 4 at any point if not on ART and T1, T2, T3, or T4 if on ART

3. **TB status** defined as:
   a) no signs or symptoms suggesting TB
   b) currently on INH prophylaxis, dose, adherence
   c) suspected TB, referred for evaluation (include referral date)
   d) sputum sample sent - date, sputum results and date received
   e) currently on TB treatment

4. **Possible side-effects (including drug allergies), new symptoms, diagnoses, or OIs**

5 **Laboratory results**
   If laboratory tests are conducted, test dates and results should be recorded.

6. **Specifics on ARV drugs, prophylaxis and other medications**
   If treatment or prophylaxis has been prescribed, it is important to monitor the doses dispensed and the start and stop dates for the duration on medication. This may be done either at the clinic or pharmacy. Standardized abbreviations for drug regimens should be implemented to facilitate data collection and analysis.

Finally, it is important to assess and record patient adherence to both treatment and prophylaxis at each encounter using a method or methods that have been agreed nationally. If non-adherence is reported, the reason(s) should also be noted.

Other patient encounter information may include the type of visit (scheduled/unscheduled), the next scheduled visit date, the number of months on the current ARV regimen, body weight, pregnancy status, and the use of family planning methods, referral to PMTCT or other programmes, and the number of hospital days since the last outpatient visit.

Rationale

In general, these data are important for tracking a patient's clinical status over time, which is critical for clinical management, and as a result may be needed for patient transfer (see above). These data are equally as important for tracking the status of a group of patients over time (through **cohort analysis**). This enables the measurement of clinical team performance and progress of the programme.

HIV care information is generally important for tracking patients in HIV care, both prior to enrolment in ART and while receiving ART. In many countries, patients receiving HIV care are treated as acute and episodic cases. Following patients through HIV care before starting ART allows providers to monitor and manage symptoms, make referrals to psychosocial, nutritional, and community support, and provide a direct link into treatment when the patient will benefit most from ART.

One of the main objectives of ART is to provide the opportunity for people to be productive in their work and daily life. Therefore, a measure of productivity may be used as one indicator of the success of an ART programme. **Functional status** and **weight** both serve this purpose.

Previously, **clinical stage** could only get higher or remain the same and therefore could only be used as a measure of a patient's stability or deterioration; however, the revised clinical staging is based on current clinical signs and it is therefore possible to go down in clinical stage, indicating an improvement with treatment. With ART, it will be common for a patient to move down in clinical stage.

Although ART can be started without a CD4 count, **CD4 counts (or CD4 percentages in young children)** are very valuable when available, particularly baseline CD4 to identify asymptomatic patients who are eligible for ART (especially useful during pregnancy and for identifying those at greater risk of nevirapine-related liver toxicity). Use of CD4 is additionally helpful to monitor response to ART, evaluate possible treatment failure, and make decisions on discontinuing prophylaxis. Finally, periodic monitoring of CD4 counts when there is ample laboratory capacity can be used to monitor disease progression prior to ART, and detect treatment failure.

TB status

It is important to check the TB status of patients at each HIV care visit. Between 5% and 15% of HIV patients will develop TB disease each year.[1] It is therefore essential to determine TB status at each HIV care visit, to send sputums or refer patients promptly for investigation when TB is suspected, and to make sure that these results are used, that treatment starts promptly, and that TB and HIV care are well coordinated. TB-ART co-treatment decisions require consulting a trained doctor or medical officer.

TB monitoring should be linked to HIV care/ART monitoring. The routine collection of data on the TB status of patients allows HIV care/ART patient monitoring data to be used to measure some components of several TB/HIV indicators (i.e. how many patients on ART are also on TB treatment; see *Section B* on measuring indicators).

[1] World Health Organization (WHO). *Guidelines for implementing collaborative TB and HIV programme activities.* Geneva, WHO, 2003 (WHO/CDS/TB/2003.319 and WHO/HIV/2003.01).

Checking the **pregnancy and family planning status** of women of childbearing age at each visit is essential in order to avoid the use of efavirenz (EFV) during the first trimester of pregnancy; and to provide PMTCT interventions, including contraception with dual protection (condoms), so as to avoid unwanted pregnancies and HIV transmission, and linkages with or direct provision of PMTCT interventions for women planning to become pregnant or already pregnant. Often there is a return to sexuality in patients on ART as they feel better and it is important to again discuss safer sex, condom use, dual protection, and plans for childbearing. A patient's desire to have children will invariably affect her contraceptive use. At each visit, counsellors may ask and record whether or not patients intend to become pregnant at each visit as an optional component of pregnancy and family planning status. An additional column may be used to report whether or not the most recent pregnancy was intended as an indicator of effectiveness of HIV prevention activities. Family planning status should be assessed and recorded at each patient visit for women, men and adolescents.

Side-effects (including drug allergies), new symptoms, diagnoses, or OIs
In general, monitoring side-effects, OIs and other symptoms and diagnoses is crucial for patient management. Recording side-effects and reporting new or unusual or unusually common reactions to the medical officer responsible for a clinical team, can initiate documentation of adverse drug reactions (ADRs) and toxicities, and may be useful for pharmacovigilance purposes (see *Chapter 3*). Any non-ARV drug allergies identified during initial or subsequent clinical reviews should also be clearly recorded on the patient's record. These are different from ADRs.

Monitoring adherence
The March 2004 patient monitoring meeting was unable to reach consensus on internationally standardized guidelines for measuring patient adherence, although there was full agreement on the importance of supporting and monitoring adherence. This was in part due to the absence of a gold standard for accurately determining true patient adherence, as all methods have their limitations. However, generic adherence assessment tools suitable for country adaptation are currently being developed by WHO.

Adherence assessment is generally recognized to be a key component of successful ART patient monitoring in slowing the development of resistance and predicting treatment outcomes.[1,2] Consequently, it is essential for each ART programme to decide on how adherence will be measured and to develop and monitor its own site-specific indicators that are both practical and feasible. Adherence should be counselled and monitored at **every** point of contact with a patient both inside and outside of the health facilities. Measurement of adherence may also serve as an early warning for the potential for HIV drug resistance to emerge rapidly.

Possible adaptations for higher resource settings
In programmes with greater resource capacity, it is possible to adapt or append the minimum essential data set with additional information such as viral load test results where they may be carried out and recorded on a regular basis. Viral load data may be increasingly necessary as more patients begin to fail first-line and second-line regimens, and may be used to measure treatment success.

[1] Harries DH, Gomani P, Teck R, et al. Monitoring the response to antiretroviral therapy in resource-poor settings: the Malawi model. *Transactions of the Royal Society of Tropical Medicine and Hygiene*, 2004, 98: 695-701.
[2] Paterson DL, Potoski B, Capitano B. Measurement of adherence to antiretroviral medications. *Journal of Acquired Immune Deficiency Syndromes*, 2002, 3:S103-6.

Examples of use

Clinical staging

Given the relative novelty of the revised clinical staging, there is presently no standardized method of recording the movement between stages. One suggestion is to differentiate the clinical stage for a patient on ART by the addition of a 'T' (for treatment) to the current coding method – T1, T2, T3 or T4. The clinical stage of a patient who is not currently on ART would therefore be recorded as 1, 2, 3, or 4. In contrast, once a patient is on ART, clinical staging could be recorded as T1, T2, T3 or T4 and could increase or decrease depending on the absence or presence of clinical signs or symptoms or CD4 count. Immunological stage is determined by CD4 alone and is always dynamic.

Monitoring adherence

There are many ways in which facilities may monitor patient adherence. These methods may differ according to the availability of resources. For example, the Centre for Infectious Disease Research in Zambia (CIDRZ) has created a special adherence form completed at each patient encounter, which documents missed doses, reasons for non-adherence and the presence of a treatment supporter. In Malawi, patients are given a 30-day supply of 60 ARV pills and a pill count is carried out at each patient visit (every 28 days) and recorded on the facility-based patient card. This information is transferred to the ART register, and patient adherence > 95% is defined as having 8 pills or fewer, left at each visit. In the quarterly cohort analysis, the proportion of patients achieving > 95% adherence is calculated and recorded and tracked over time.[1] Columbia University's MTCT-plus programme sites use a 7-day patient recall of number of pills taken and roughly categorize the response as none; very few; about half; most; and all of his/her pills.[2]

The following example is taken from the WHO Basic ART clinical training course.[3] In this course, considerable time is spent on adherence preparation, support and monitoring involving both the patient and his or her treatment supporter. An adherence estimate would depend on reports from both: "Use your best judgment to estimate the percentage of doses the patient takes, based on discussing with the patient (self-report) and counting the pills remaining. Record the percent of pills taken or categorize adherence as good, fair or poor based on the following: G (GOOD) ≥ 95% adherence, F (FAIR) 85–94% adherence and P (POOR) < 85% adherence."

To facilitate calculating percentages, on the back of Ethiopia's patient card encounter form (see *Chapter 5*), there is a table that provides a rough guide to estimating adherence using the number of missed doses per month based on a twice daily regimen. For example, missing ≤ 3 doses in a month is approximately ≥ 95% or GOOD adherence, 4–8 missed doses is about 85–94% or FAIR adherence, and ≥ 9 missed doses is about roughly < 85% or POOR adherence.

Other "low-tech" adherence methods include the use of a medication diary, pill identification and the use of a visual analogue scale. A recent study showed that self-report and use of a visual analogue scale overestimated adherence, while pill counts underestimated adherence.[4] Therefore, it would be best to combine at least two of these methods to more accurately estimate patient adherence. Successful clinical monitoring of adherence is based in part on good patient-provider relationships, which not only build rapport and trust between patient and provider, but may also enable more accurate monitoring of adherence. Treatment adherence has been shown to be associated with virologic suppression.[5]

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[1] Harries DH, Gomani P, Teck R, et al. Monitoring the response to antiretroviral therapy in resource-poor settings: the Malawi model. *Transactions of the Royal Society of Tropical Medicine and Hygiene*, 2004, 98: 695-701.
[2] MTCT-Plus Initiative. *MTCT-Plus patient data manual version 2.1*. New York, Columbia University Mailman School of Public Health, 2003.
[3] World Health Organization (WHO). *Participant manual for the WHO basic ART clinical training course*. Geneva, WHO, 2004.
[4] Maneesriwongul W, Williams A. Measuring medication adherence in AIDS patients in Thailand: a pilot study. XV International AIDS Conference, Bangkok, 2004. Abstract number, B12492.
[5] Paterson DL, Swindells S, Mohr J, et al. Adherence to protease inhibitor therapy and outcomes in patients with HIV infection. *Annals of Internal Medicine*, 2000, 133:21-30

Programmes that can afford to regularly carry out viral load tests may use undetectable viral load levels (< 400 copies/mL) as an approximation of adherence in addition to other assessment methods. This is done in the Western Cape. In their quarterly report, this is expressed as the percentage of patients who are on ART and have undetectable viral load levels by cohort (*Chapter 5*).

The WHO illustrative cohort analysis form that has been adapted by several countries (see *Chapter 5*) includes a rough measurement of adherence: patients who collected their drugs for 6 out of 6 months and 12 out of 12 months. While these indicators do not tell you how and if the patient took their drugs, they can serve as an early warning for the potential for HIV drug resistance to emerge rapidly (see *Table D*).

A patient scheduling system at either the clinic or pharmacy may also assist in the efficient determination of missed appointments, and identify potential adherence and drop-out problems. Some programmes may choose to dispense more than one month's worth of pills to allow for late pick-up due to potential travel difficulties (particularly in the rainy season) or other unforeseen circumstances which are outside of the patients' control. Programmes will have to take these allowances into consideration when reporting on adherence.

Whatever the method or methods used to monitor patient adherence, it is crucial that regular and standardized adherence monitoring be included in the design and implementation of any HIV care and ART patient monitoring system.

Hospital bed days

A potential outcome of ART is the reduced cost to the health care system and society as a whole. One measurement of this is the number of in-patient bed-days. A reduction in the number of bed-days should lead to a reduction in a portion of overall health care costs. This information may be collected in special studies.

Table B. Definitions of special patient monitoring terms and codes

Term/code	Definition
NEW	Refers to a patient who starts ART at any facility in the country or system (where a system refers to a single care and treatment programme, usually a national programme). NEW includes: 1) Treatment-naive patients with no prior ART; 2) Those who have received only short-course ARV prophylaxis for PMTCT; and 3) Non-naive patients with or without records who received ART from sources outside the system, and have not been counted as NEW in a system that is being monitored nationally (patient seen by private practitioner, self-purchasing or sent drugs). If a facility receives a non-naive patient without records who was previously treated at a facility that reports to the national programme (and therefore reported as NEW once already), an attempt should be made to retrieve the records and confirm that the patient was previously on treatment. In HIV care, NEW also refers to anyone who is registered in the system for the first time.
START	Refers to when a patient starts the first, original ART regimen in the system (or you can document when they started in any programme or under care of another practitioner if this date is known). For example, if a patient starts initial ART at clinic A, then transfers to clinic B, clinic A will record the patient as having started ART; clinic B will copy the date to the current clinic patient records, which precedes their first encounter date.
SUBSTITUTE	Refers to a substitution of drugs within first-line or second-line regimen.
SWITCH	Refers to a switch from first-line to second-line regimens (or second-line to third-line or salvage, etc.).
STOP	Refers to when a patient intentionally stops an ART regimen (usually but not always in discussion with the clinical team) through a planned interruption of ART or following poor adherence.
RESTART	Refers to when a patient who has stopped a previous ART regimen restarts ART. Guidelines for when and how to restart a patient on ART must be decided at national level.
LOST	Refers to temporary lost to follow-up of a patient who may have missed any clinical or drug pick-up appointment. Temporary lost is different from DROP as defined below. Both must be clearly defined nationally. Temporary lost to follow-up is also different from patient non-adherence. A patient may be non-adherent but not LOST.
DROP	Refers to a patient who has not responded to X number of follow-up contacts after X number of months of not being seen by a health worker (number and quality of follow-up contacts and duration of time to be agreed upon at the country level). If no national decision has been made, consider using three months initially. DROP or lost to follow-up is different from the temporary LOST in categorizing treatment interruptions (above). Patients categorized as DROP are dropped from the drug supply. LOST and DROP are only used in the context of ART and not chronic HIV care.
TRANSFER IN (TI)	Refers to when a patient who has been receiving ART at one facility in the country or system transfers into another in the same system with records. Transfer In is different from patients who have been receiving ART from sources outside of the system (see NEW). Patients who transfer in are **not** included in the number of cumulative ever started on ART at the facility (see definition on following page).

TRANSFER OUT (TO)	Refers to when a patient who has been receiving ART at one facility transfers out of that facility.
DEAD	Refers to when a patient dies anytime after being enrolled in HIV care or ART. DEAD patients can be separated as to whether the death occurred pre-ART, during ART or after ART is stopped.
Cumulative ever started on ART (at this facility)	Refers to the number of patients who have ever started on ART as NEW at that specific facility, and **does not** include patients who transfer in. Patients who transfer out, or are categorized as DROP, DEAD, LOST, or STOP, are not subtracted.
Current on ART (at this facility)	Refers to the number of patients who are currently on ART at a given facility and **does** include patients who transfer in. Patients who transfer out, or are categorized as DROP, DEAD, LOST, or STOP **are** subtracted.

B. Calculating indicators from the patient monitoring data

Keeping careful track of patient data is not only critical for monitoring individual patients, but is also essential in forming indicators for monitoring the progress of the HIV care/ART programme at the facility, district and national levels. An indicator is a measurable number, proportion, percentage, ratio, or rate that suggests the extent of achievement in delivering HIV care and ART of a programme, or summarizes the level of some condition in a district or facility's patient population. Six types of indicators can be calculated from the recommended patient monitoring data in these guidelines:

1. Indicators related to patients accessing HIV care and ART
2. Indicators related to success of ART
3. HIV drug resistance early warning indicators
4. Other indicators for programme monitoring at the facility level
5. TB/HIV indicators
6. Prevention indicators.

Many of these indicators are crucial for managing and adjusting ART programmes at facility and district level. A sub-set of core internationally agreed indicators provides a national picture of the progress of scaling up ART and allows comparisons with other countries, contributing to the global understanding of ART scale-up. These indicators are summarized in *Table C*.[1] Core 8 and 9, and the numerator of Core 7, originate directly from patient monitoring data, while Core 1 to 6 originate from other data sources. A more detailed description of Core indicators 7, 8 and 9 are provided in *Annex C*.

Table D presents the six categories of indicators and the rationale for their collection. The clinical team in each facility and the district management team which sums the reports from all facilities in their district should review important indicators on a monthly or quarterly basis. These results should be discussed during regular clinical team meetings and during supportive supervision visits by the district management team, the responsible medical officer, and by clinical mentors. A small subset of these indicators needs to be reported to the national level, and the core indicators should be reported internationally.

Table C. Core national ART programme indicators

Core 1	Existence of national policies, strategy and guidelines for ART programmes
Core 2	Percentage of districts or local health administration units with at least one health facility providing ART services in line with national standards
Core 3	Percentage of ARV storage and delivery points experiencing stock-outs in the preceding 6 months
Core 4	Number of health workers trained on ART delivery in accordance with national or international standards
Core 5	Percentage of health facilities with systems and items to provide ART services
Core 6	Percentage of health facilities with ART services that also provide comprehensive care, including prevention services, for HIV-positive clients
Core 7	**Percentage of people with advanced HIV infection receiving ARV combination therapy**
Core 8	**Continuation of first-line regimens at 6, 12 and 24 months after initiation**
Core 9	**Survival at 6, 12, 24, 36, etc. months after initiation of treatment**

[1] World Health Organization (WHO). *National AIDS programmes: a guide to indicators for monitoring and evaluating national antiretroviral programmes.* Geneva, WHO, 2005.

Table D. Patient monitoring indicators

Category	Indicator	Rationale
1. Indicators related to patient access to HIV care and ART	**a. New and cumulative number of persons enrolled in HIV care**	Identifies gross numbers of patients on HIV care/ART, contributing to 3 by 5 targets and progress of ART scale-up.
	b. New and cumulative number of persons enrolled on ART	
	c. Number of persons who are enrolled and eligible for ART but have not been started on ART	Identifies those waiting for ART.
	d. Percentage of those medically eligible for ART in clinic who have been started on ART	Identifies the reach and accessibility of ART during scale-up. Numerator for national core indicator 7, and UNGASS indicator: percentage of people
	e. Number currently receiving ART	
2. Indicators related to success of ART	**a. Survival at 6, 12 and 24 months after initiation of ART**	One of the goals of any ART programme should be to increase survival among infected individuals. National core indicator 9 and UNGASS indicator: survival at 12 months
	b. Percentage of individuals still on treatment and still prescribed a standard first-line regimen after 6, 12 and 24 months from initiation of ART	Unnecessary changes in regimen, treatment failure and intermittent ART are all associated with more rapid emergence of HIV drug resistance and may be used as indicators of programme performance and resource utilization. It is important to investigate the reason for higher or lower than average percentages of patients still on first-line treatment. This indicator is also important as an early warning signal for potential treatment failure. The inverse, percentage of patients on second-line and higher regimens could also be used in its place. National core indicator 8
	c. Percentage of people on ART whose functional status is working at 6, 12 and 24 months	This is an indicator of patient productivity, quality of life, and therefore ART success.
	d. Median CD4 and increase/ percentage CD4 ≥ 200 at 6 and at 12 months on ART compared to baseline	In facilities with CD4 testing capability, this may be a measure of ART success, with reduced risk to some OIs.

Category	Indicator	Rationale
3. HIV drug resistance early warning indicators **(See also 2b)**	**a. Percentage of patients who started ART 6 or 12 months ago who picked up ARV medications 6/6 or 12/12 months**	Provides a rough estimate of adherence.
	b. Percentage of patients with good adherence to ART	Good adherence (≥ 95%) is crucial to ART success. Identifying adherence rates is important for patient and programme management.
4. Other indicators for programme monitoring at the facility level	**a. Number on cotrimoxazole, fluconazole, INH prophylaxis at end of month**	May be used for non-ARV drug supply orders.
	b. Distribution of entry points of patients enrolled in HIV care	Identifies linkages between programmes and activities.
	c. Distribution of reasons for drug substitution, regimen switching, termination and interruption, and poor adherence	Helps clinical team to identify and respond to poor adherence; assists with quality assurance related to drug substitutions, regimen switches and interruptions.
	d. Distribution of patients not yet on ART by clinical stage	May help estimate resources to care for patients, drug supply for OI prophylaxis and treatment.
	e. Percentage of patients referred	Monitoring referral rates may enable facilities to manage referral systems more efficiently. Too high referral rates are difficult for patients and clinical teams to manage.
	f. Side-effects, OIs, other problems	Facilitates individual patient management and allows review of side-effects and new OIs.
5. Indicators of prevention activities integrated within HIV care and ART ***Prevention indicators are under review and in development.***	**a. Percentage of pregnant patients in HIV care pre-ART or on ART who are referred for or provided with PMTCT interventions**	This measures the effectiveness of linking HIV care and ART patients to PMTCT interventions. This can be calculated from the pre-ART and ART registers, using the entry for pregnancy and the indication whether or not PMTCT interventions were provided (or the same through card sorts for women only).
	b. Percentage of non-pregnant women in HIV care pre-ART or on ART who are using a contraception method	This may measure effectiveness of family planning counselling. This can be calculated through card sorts. It is possible to collect information on whether or not a patient intends to become pregnant, or if she is pregnant, whether or not her pregnancy was intended. If either is well reported and recorded, it will lead to a more accurate denominator for this indicator. These additions will be country-adapted and recorded on the patient card or record.

Category	Indicator	Rationale
6. TB/HIV indicators[1] (under review) *The indicator numbers are from the* TB/HIV indicator list; the "proxy" or partial indicators which can be measured by the HIV care/ ART patient monitoring system are listed below these.	**Number and percentage of ART patients simultaneously on TB treatment within last year**	The TB/HIV indicators measure commitment and capacity of TB services or HIV care/ART clinics to ensure that HIV-positive TB patients are able to access ART, and that HIV/AIDS patients are regularly screened, diagnosed and treated for TB. This can be measured in the ART register by adding up the number of patients with a TB treatment start day within the last year. This can be compared with TB/HIV indicator C.5.1. captured by the TB programme, the number and percentage of HIV-positive TB patients who are started on ART or continue previously initiated ART during or at the end of TB treatment.
	TB/HIV B.1.1. Number and proportion of all PLWHA attending for HIV testing and counselling or **HIV treatment and care services** who were **screened for TB symptoms** Measured as: proportion of patients in HIV care, before, during or after ART, whose TB status was screened at every visit.	Measures HIV care/ART clinical team performance in checking TB status at every visit. This could be measured by reviewing a sample of HIV care/ART cards during a visit by the TB or ART district coordinator.
	TB/HIV B.1.2. Number and proportion of all PLWHA attending for HIV testing and counselling or **HIV treatment and care services** who were screened for TB symptoms and **diagnosed with TB** Measured as: proportion of patients in HIV care (before, during or after ART) who were treated for TB disease.	This could be measured by: (a) card sorts from current patients; or (b) reviewing the pre-ART and ART registers yearly at the time of the cohort analysis. **Denominator:** number of patients on ART (from cohort analysis form) plus number of patients in HIV care who have not been started on ART (counted from pre-ART register). **Numerator:** number of patients started on TB treatment (from TB status column). This assumes that patients started on TB treatment have been diagnosed with TB disease through TB screening.
	TB/HIV B.2.1. Number and proportion of newly diagnosed HIV-positive patients who are given treatment for latent TB infection (**INH**) Measured as: proportion of patients in HIV care pre-ART or on ART who are on INH prophylaxis within 3 months of enrolling in HIV care.	Measures the performance of the HIV care team in treating latent TB infection among those with newly diagnosed HIV infection.

[1] World Health Organization (WHO). *A guide to monitoring and evaluation for collaborative TB/HIV activities*. Geneva, WHO, 2004 (WHO/HTM/TB/2004.342 and WHO/HIV/2004.09).

C. Paediatric indicators

Modifications have been made to the patient card to support its use for children including the addition of height. CD4 percentage may be added to the cohort analysis form to track paediatric patient treatment success as in the case of Ethiopia (see *Chapter 5*). The infant or young child's growth chart should be attached and referred to for detection of growth faltering. Additional paediatric indicators are under development.

D. Relationship to standardized TB monitoring and the new TB/HIV indicators

Standardized TB monitoring

TB patient (and programme) monitoring are based on a standardized treatment card; standardized registers and reports; globally standardized definitions; and deliberate limitation of the data collected.

Although the format of the forms and registers may vary between countries, the core data collected and the definitions are remarkably standardized. Almost all systems remain paper-based with hand summaries of data produced, usually quarterly, by the clinical team and the district coordinator. This is based on long experience. Recently, new TB/HIV indicators have been added [1] and electronic data entry of the registers has been introduced in several countries.[2]

The TB monitoring system is disease-specific. Chronic HIV care and ART also requires a simplified disease-specific system, with linkages to the patient's TB treatment card (when the HIV patient also requires treatment for TB) and eventual integration within the broader HMIS.

The illustrative HIV care/ART patient monitoring system presented in these guidelines builds on TB experience but with the following important differences required by HIV care and ART:

- HIV care and ART are life-long. HIV care is "true" chronic care whereas TB treatment is 6 to 8 months (or 18 to 24 months for multidrug-resistant (MDR)-TB cases).

- One row in the TB register is a course of treatment whereas one row in the ART register is a patient's lifelong treatment on ART, including changes in regimens and interruptions. A new episode of TB or a relapse will be recorded on a separate line in the TB register.

- TB outcomes are mutually exclusive and irrevocable events because they refer to a patient's experience on a time-limited TB regimen whereas the only irrevocable ART outcome is death, because ART patient monitoring tracks patients through regimen changes and interruptions.

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[1] World Health Organization (WHO). *A guide to monitoring and evaluation for collaborative TB/HIV activities.* Geneva, WHO, 2004 (WHO/HTM/TB/2004.342 and WHO/HIV/2004.09).

[2] Vranken R, Coulombier D, Kenyon T, et al. Use of a computerized tuberculosis register for automated generation of case finding, sputum conversion, and treatment outcome reports. *International Journal of Tuberculosis and Lung Disease*, 2002, 2:111-120..

- Default in TB monitoring (defined as > 60 days without treatment) is not the same as DROP or STOP in ART patient monitoring. Once a patient has defaulted on a TB regimen, this is an irrevocable event. If the patient restarts another course of TB treatment, a new row in the register is started for the patient.

- The "Transfer Out" outcome is a subset of TB cases. It is the responsibility of the initial facility to try to find and report the patient outcome in those who have transferred to another facility. The receiving facility registers the patient in order to manage and monitor their care but this patient record is disregarded when making cohort reports. In the ART experience, transfer patients are added and subtracted to the net current cohort and "Transfer Out" is not an outcome.

TB/HIV indicators

High co-morbidity between TB and HIV in many countries necessitates effective coordination, referral and communication between TB and HIV/AIDS programmes and co-management of TB/HIV by clinical teams to enable effective care and treatment of both diseases. Integrated monitoring and evaluation of TB and HIV programmes will capture how well HIV prevention, diagnosis and care or referral for HIV care take place within TB programmes and likewise, how well TB screening, prevention and treatment are occurring in HIV care/ART programmes.

There are four core TB/HIV indicators that are recommended in the *Guide to monitoring and evaluation of collaborative TB/HIV activities*[1] that require data collected by HIV care/ART programmes. These are summarized in the table above. The HIV care/ART patient monitoring data can only provide part of the denominator for several indicators (since the records are limited to patients enrolled in HIV care, which does not include all patients who test positive at various locations in the health system). Nevertheless, it may be useful to measure those patients in HIV care (with or without ART) who are on INH and who are treated for TB; the number of patients on TB/ART co-treatment; and the proportion of patients whose TB status is checked at each visit (based on a review of a sample of patient cards, looking at the TB status column).

To facilitate these measurements, a yearly tabulation sheet to be used by the TB or ART district coordinator during facility visits is in development.

These proposed proxy indicators and plans for data collection require further review and development.

[1] World Health Organization (WHO). *A guide to monitoring and evaluation for collaborative TB/HIV activities*. Geneva, WHO, 2004 (WHO/HTM/TB/2004.342 and WHO/HIV/2004.09).

CHAPTER THREE

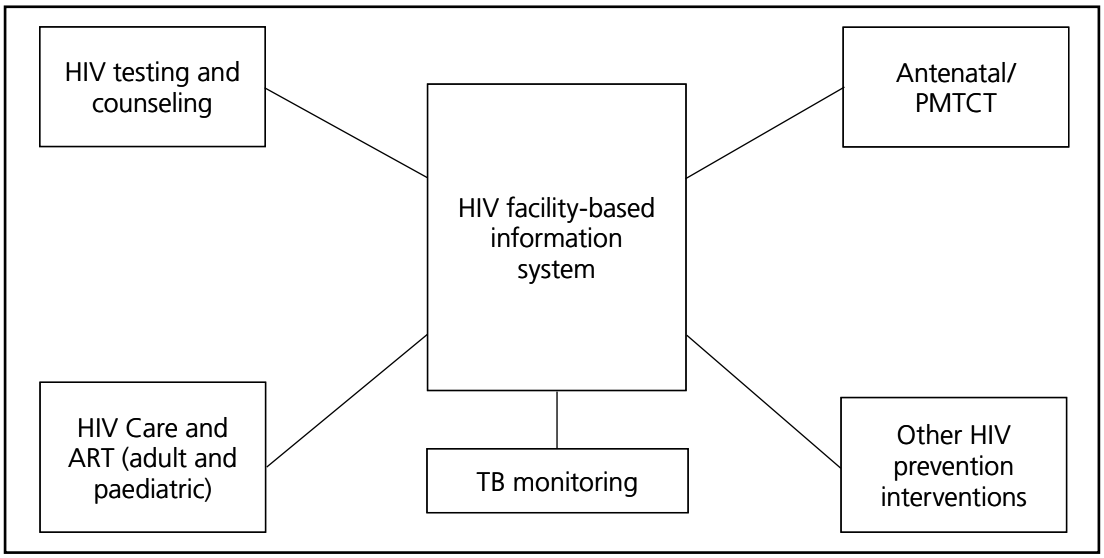
FACILITY-LEVEL DATA COLLECTION USE AND LINKAGES

A. Linkages with other facility-based systems

New data systems and approaches will be essential at the service delivery level to ensure that quality HIV care and ART services are rapidly made available and accessible and are linked with accelerated prevention interventions. These interventions are intimately linked to other existing services such as antenatal, obstetrical and STI care, PMTCT interventions, TB, family planning, and HIV testing and counselling, as well as HIV surveillance and HIV drug resistance surveillance and monitoring. A well-designed health management information system (HMIS) can provide information to support these linkages.

The following diagram illustrates a facility-based integrated HIV information system that includes both HIV care and ART data.

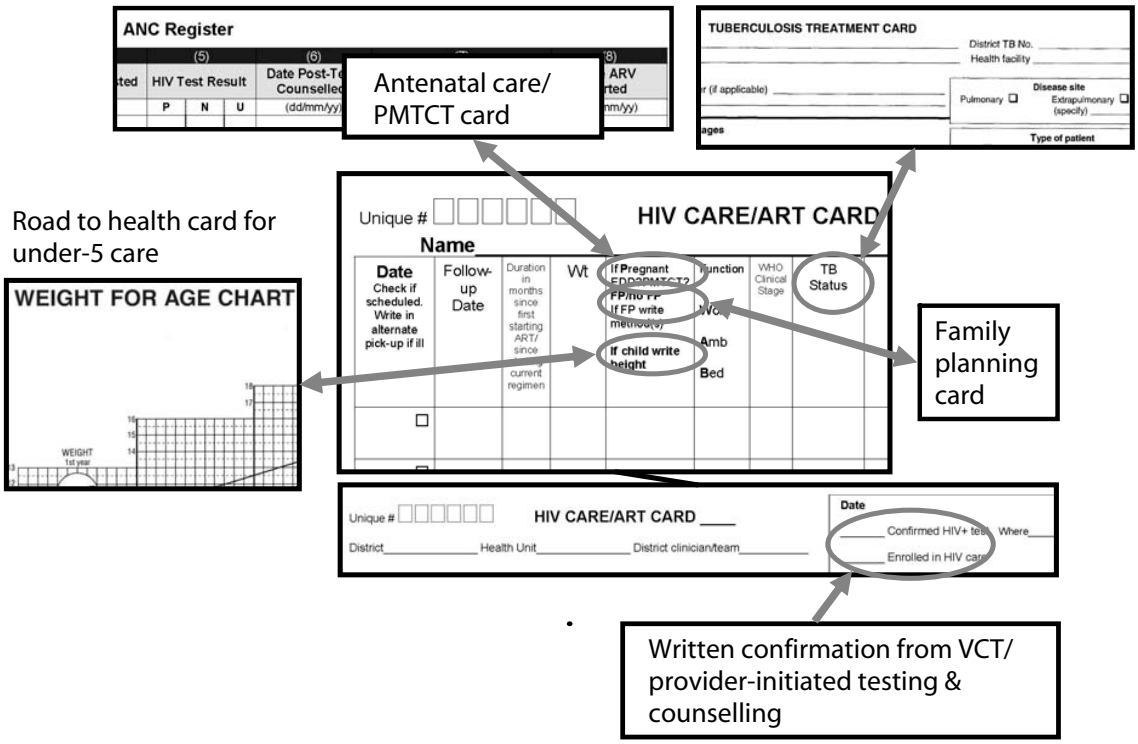
Fig. 3. Linkages between HIV/AIDS services



Patients may have more than one condition that requires tracking using several patient cards (one for each service). Linkages need to exist between information reported on an HIV care/ART patient card or record, and cards or records for family planning, TB treatment, antenatal care, PMTCT, and under-5 care. This should include transfer forms which facilitate referrals between services, as well as written confirmation of HIV-positive status from VCT and provider-initiated testing and counselling services.

The following diagram demonstrates the linkages which need to be developed:

Fig. 4. Linkages between HIV care/ART patient card or other record and records for TB treatment, antenatal care, family planning, VCT/provider-initiated testing and counselling, and under-5 care.



HIV care and ART information needs should be assessed and developed within the context of the overall facility-based health information system needs, especially other HIV services implemented in facilities. The HIV care/ART patient monitoring system should be planned and integrated whenever possible or feasible with these other HIV information systems and eventually integrated within the overall HMIS. However, this should not be allowed to delay the availability of a functional system as HIV care and ART are initiated and scaled-up. Modifying an HMIS system can sometimes require considerable time.

B. Linking paper and electronic systems

In many systems, data from patient monitoring will eventually be entered, analysed and transmitted electronically. Systems vary as to where the "paper to electronic" transition occurs. This may differ during initial ART scale-up, with an evolution towards earlier electronic entry over time. This may also differ between what can be done routinely at all sites and supported as a national system and what can be supported at facilities with special funding or research projects.

Electronic patient care information systems are currently being developed to interface with paper-based systems at different levels of data collection and analysis. Regardless of the data collection method, it is important that the definitions of essential data elements be standardized so that each system, whether paper or electronic, reports these data in a uniform way.

The following table shows the range of ways a paper-based system can link with district-level electronic reporting, from a minimal system of electronic entry of reports by the district or regional coordinator to a fully electronic system using an electronic medical record (EMR).

Table E. Paper-based and electronic patient monitoring systems

System type	Patient card or record	Register(s)	Quarterly cross-sectional and cohort reports	District or regional coordinator and up
Paper-based system with electronic entry of reports	Paper	Paper	Paper	Paper → electronic
Paper-based system with electronic entry of registers	Paper	Paper → electronic	Electronic	Electronic
Electronic medical record (EMR) with electronic entry of paper records	Paper → electronic	Electronic or may be printed from electronic database	Electronic	Electronic
EMR with direct electronic entry without paper when managing patients	Electronic	Electronic or n/a	Electronic	Electronic

Information collected and aggregated by first-level health facility clinical team

n/a – not applicable

Electronic data entry requires significant infrastructure including resources to capture and enter the data, reliable power and telecommunication sources, trained staff and support for technical assistance. Furthermore, as with any information system, persons who will be contributing to the electronic database must feel empowered to be able to use the data being generated, and understand and experience the benefits of such a system for it to succeed. Provided these inputs are available and can be sustained there are several potential advantages of moving towards an electronic system. These include significant labour-saving in reporting requirements, simplification of complex analyses, reduction of paper consumption (with financial savings potential in areas where paper is expensive), and greater ease in use of patient data for programme monitoring and evaluation. If done well, information can be quickly shared within facility and between teams and applied to patient care. Supporting an HIV care/ART electronic patient monitoring system can potentially contribute to strengthening the general primary care system.

However, it is important to consider the cost, time, and additional and sustainable resources (both physical and human) involved with the development of any type of electronic system, which may often be sizeable. A full EMR would take at least six months to more than a year to establish. Setting up electronic entry of the registers or reports can happen more quickly (over several months). In addition, the development or scaling up of an electronic system for an entire country may take significantly more time and resources than creating one for a single health facility. Regardless of the reach of an electronic system, it is important to stress that the development of such systems has a much greater likelihood of success where an effective paper system already exists. Many experts have emphasized that it is essential to have a solid "paper base".

Furthermore, the importance of having a minimalist and simplified electronic system should also be emphasized to address the back-log of paper forms for data entry and failed, excessively complicated systems that have been reported from the field.

Finally, there must be systems in place to back up the electronic system (by backing up the system hard drive on a regular basis, use of disks, etc.) if and when it fails, to ensure continuity of data flow and patient care.

Electronic entry of reports

This system employs a minimum level of electronic data entry. Data are collected and aggregated manually at the facility level. At the district (or regional) level, reports from several facilities are aggregated and then transmitted electronically to the national level. HealthMapper is a data management and mapping application developed by WHO that is currently supported in some capacity in 60 countries. It allows for data aggregation and indicator generation from the district level up; the reports in these guidelines can be entered into HealthMapper. Other software can also be adapted for this purpose.

Electronic entry of registers

It is important to differentiate between the acute or episodic care registers that are in use in most developing country health facilities, and chronic care registers. The standard episodic care registers log data for patients as they present at the clinic during the day. Each line represents a new encounter. In contrast, chronic care registers use one line per patient, and log information for all encounters with the patient on this line, rather than using a new line at each encounter. Electronic registers should mirror paper-based chronic care registers.

In countries with facilities both with and without on-site electronic data capability, it may be useful and more convenient to periodically enter the paper register data electronically in order to facilitate the generation of cross-sectional and cohort analysis reports. While this may be done by the clinical team or data entry clerk at a site with electronic capacity, at facilities without electronic capacity, electronic entry of registers may be carried out by district health information officers during site visits using a PDA or laptop. This allows more in-depth cohort analysis with disaggregation by sex and age. If a "register up" system (electronic entry of registers) is desired, it is important to use a compatible and standard data model to allow data sharing, aggregation, synthesis and the expansion of the system to the clinic level at a later date.

Electronic entry of registers is currently being carried out at BOTUSA sites to enter TB register data and produce TB reports electronically at the district level in several countries.[1] In Swaziland, an EpiInfo programme has been developed to enter the ART register electronically (http://hab.hrsa.gov/careware/). In the Masaka region of Uganda, a pilot study by WHO and SATELLIFE is experimenting with entering pre-ART and ART register information into a PDA (personal digital assistant) hand-held device and then transmitting the data via cell phone to a regional database.

When a paper register is periodically entered electronically from the 2004-2005 registers, it may be useful to print out computer-generated paper registers for continued care in 2006-2007.

[1] Vranken R, Coulombier D, Kenyon T, et al. Use of a computerized tuberculosis register for automated generation of case finding, sputum conversion, and treatment outcome reports. *International Journal of Tuberculosis and Lung Disease*, 2002, 2:111-120.

Electronic medical records (EMRs)

Electronic medical records may be created from data transferred from paper patient records, or directly input by providers in lieu of a paper record. If patient data can be electronically captured at the beginning of an encounter, multiple entry points of similar data can be removed (for example, the need for registers) and data can be used in everyday care, in addition to programme monitoring. However, it is important for any electronic system to be able to generate registers for patient monitoring purposes when necessary (e.g. to create patient lists with key data on their status).

Several projects in Africa[1] and Latin America[2] have shown that EMR systems in rural clinics are practical and can improve care, and with the tactical use of solar powered generators and relatively inexpensive satellite connections, such systems may soon become practical on a larger scale.

With the introduction of an electronic system, a patient monitoring system may vary between facilities within a country or over time, with a fully paper system initially and the gradual development of electronic entry from the reports or registers up. Initially, entering the subset of data which is aggregated in registers may be more feasible than entering all data on a patient record. It is important to make sure that the data captured on paper are compatible with the structure and eventual use of an electronic system. The electronic systems should be built upon a standardized paper-based system with simple transfer of data between the two if and when the electronic system is unable to function. If possible, the HIV care/ART electronic patient monitoring system may also be integrated into a broader health information system.

It is important to consider what system is feasible at all ART facilities and what can be introduced only in facilities with special projects or funding. Whatever is done must be compatible with a feasible, routine patient monitoring system that can be set up in all facilities delivering ART. Regardless of whether the system is paper-based or electronic, or a combination of the two, both the collection of data elements and subsequent analysis must be kept simple and minimal. For example, free text should be kept to a minimum, using instead check boxes and numerical data which can be easily transferred by a non-clinical person and into an electronic format and encoded to allow practical use within a database. Data dictionaries are now under development to ensure a "fixed taxonomy", which will greatly facilitate data sharing between systems and allow the possibility of multi-level data-mining. There is a working group actively seeking to define (HL7-based) specifications to support information transfer of ART data based on the minimum essential data set described in these guidelines.[3] However, the capturing of subjective observations is vital as relevant information can never be entirely predicted. It is from such direct observation that new hypotheses for better care are often discovered.

More information on EMR systems for HIV care in Africa is available from the August 2004 Nairobi Workshop on EMRs for HIV treatment and Care.[4] A companion electronic report with guidelines is in development and will be available later in 2005.

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[1] Rotich JK, Hannan TJ, Smith FE, et al. Installing and implementing a computer-based patient record system in sub-Saharan Africa: the Mosoriot medical record system. *Journal of the American Medical Information Association,* 2003, 10:295-303.

[2] Fraser HS, Jazayeri D, Nevil P, et al. An information system and medical record to support HIV treatment in rural Haiti. *British Medical Journal*, 2004, 329:1142-1146.

[3] HL7 ART working group draft documents can be accessed at: http://www.rhinonet.org/tikiwiki/tiki-index.php?page=HL7ART and email archives at http://list.who.int/archives/hl7art.html. For more technical information, or for information regarding the working group, contact: ehealth@who.int.

[4] World Health Organization (WHO). *Electronic Medical Record Meeting.* Kenya, WHO, 2004 (www.who.int).

Related discussions can be found at http://amrs.iukenya.org. Additionally, various examples of electronic systems are summarized on the RHINO Network.[1]

Other methods of data entry and transmission

In some middle-income countries such as China, electronic data management is enabled through the use of fax machines. For example, China uses the Data Fax System in which patient treatment data are faxed from the facilities and read into an electronic patient database at the national level. Transmission of data by fax allows for immediate transfer and receipt of timely data. However, use of a fax machine for data management necessitates having a dedicated and functioning telephone landline and electricity source at each data transfer site. In many research settings, more resource heavy and sophisticated systems may be used. For example, some of Columbia University's MTCT-plus project sites mail completed paper forms to a central information depot in the United States (John Snow Inc., Boston). These forms are then scanned and read into an electronic database under the supervision of dedicated staff.

C. Using patient monitoring data to help forecast and manage the ARV drug supply

Actual logistics or supply monitoring data related to the drug supply should be routinely collected and reported through the use of appropriate records and reports, comprising a logistics management information system (LMIS). These data should consist of:

- Actual Dispensed to User data (real consumption);
- Stock on Hand data; and
- Losses and Adjustments

and should form the basis for managing the drug supply.[2]

Patient monitoring data, while necessary or even crucial to managing the drug supply, cannot replace the need for logistics data or supply monitoring data.

Forecasting

Drug forecasting is the process of predicting drug consumption. Accurate drug forecasting is crucial for proper drug procurement. Underestimating drug needs leads to stock-outs. Overestimating drug needs leads to expired drugs and wasted money.

With a large number of patients on treatment, the relative ratios of patients receiving each regimen approximates a steady state. A snapshot of treatment for all patients for one day can then be used to estimate overall requirements.

Simple but effective forecasting can be done with minimal information: the number of patients (current and projected); and basic data about drug regimens used, such as the ratio of patients receiving first-line regimens versus second-line regimens. More detailed drug regimen data will improve the accuracy of the forecasting.

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[1] http://www.rhinonet.org/tikiwiki/tiki-index.php?page=ART+Inventory

[2] World Health Organization (WHO). *Management of drugs at health centre level.* Geneva, WHO, 2004 (WHO/AFR/EDP/04.3).

Cross-sectional data such as the distribution of patients receiving each first-line regimen, alternative first-line regimens, and second-line regimens can be obtained from the quarterly/monthly summary report.

Management of a restricted supply of drugs

During the initial phases of ART scale-up, the number of patients who are eligible and ready for ART will be very high. A small amount of ARVs may have been ordered, since health systems are starting to expand. If the demand for ARVs is much greater than the supply, this may cause stock-outs of drug supplies for continuing patients on ART.

Often, health facilities are restricted in the number of new patients they may enrol (rationing). It is essential to ensure that continuing patients have priority over new patients, in order to guard against treatment interruptions and the more rapid emergence of drug resistance.

Health facilities may dip into their buffer stocks to start new patients on ART, or they may be required to request the specific treatment regimens and wait for the next ARV delivery cycle to initiate treatment. In either case, health care providers must be carefully trained not to initiate treatment in more patients than they are allotted. Control over the number of new patients and the number of total patients will prevent stock-outs of ARVs at the health facility and nationally.

Verifying and auditing

Part of the regular supervision process for drug stores is to check for discrepancies between stock records and physical inventory. An additional safeguard is the ability to compare stock records and patient records.

This can be done at any time by reviewing the ART register and counting the number of patients receiving each regimen. For example, a typical programme may use six codes for all the possible first-line regimens:

1a(30)	=	d4T(30)-3TC-NVP
1a(40)	=	d4T(40)-3TC-NVP
1b(30)	=	d4T(30)-3TC-EFV
1b(40)	=	d4T(40)-3TC-EFV
1c	=	ZDV-3TC-NVP
1d	=	ZDV-3TC-EFV

The code of the regimen dispensed to the patient is recorded in the ART register. The exact number of patients receiving each regimen in the facility at any time can therefore be counted by reviewing the ART register.

The monthly consumption of each drug can then be estimated from the number of patients receiving each treatment regimen during the month. For example, in a typical programme using three fixed-dose regimens and three single-dose regimens:

Code	Treatment regimens	Patient Count
1a(30)	d4T-3TC-NVP (<60kg, fixed-dose)	A
1a(40)	d4T-3TC-NVP (≥60kg, fixed-dose)	B
1b(30)	d4T-3TC-EFV (<60kg, single-dose)	C
1b(40)	d4T-3TC-EFV (≥60kg, single-dose)	D
1c	ZDV-3TC-NVP (fixed-dose)	E
1d	ZDV-3TC-EFV (single-dose)	F

The number of patients taking each drug is the sum of number of patients taking each regimen that includes that drug. To calculate the monthly consumption of a drug, one must then multiply the patient count by 30 if the drug is taken once a day, and by 60 if the drug is taken morning and night.

Drugs	Patient Count	Monthly Consumption
d4T 30mg/3TC 150mg/NVP 200mg (fixed-dose)	A	60A
d4T 40mg/3TC 150mg/NVP 200mg (fixed-dose)	B	60B
ZDV 300mg/3TC 150mg/NVP 200mg (fixed-dose)	E	60E
d4T 30mg (single-dose)	C	60C
d4T 40mg (single-dose)	D	60D
3TC 150mg (single-dose)	C + D + F	60(C + D + F)
EFV 600mg (single-dose)	C + D + F	30(C + D + F)

Discrepancies between the monthly consumption as calculated from the numbers of patients and the monthly consumption as calculated from the stock records should be investigated carefully. Discrepancies may be due to arithmetic errors, recording errors in the stock cards or in the patient monitoring forms, or theft.

Electronic/computerized systems

Computerized systems that combine an EMR with logistics management form direct linkages between patient-level data and drug stock. These systems can greatly streamline the process of forecasting and stock management. Currently, however, these systems are not widely used in low-resource, decentralized systems of ART delivery.

Training modules are in development to:

- Teach the health facility team how to manage supplies of ARV drugs, drugs used to treat opportunistic infections, oral morphine and other drugs for symptom management (palliative care), as well as management of the routine health facility drug supply; and
- Teach the district coordinator how to estimate the drug needs of all the health facilities in the district; request a sufficient amount of ARV drugs for the entire district; distribute a sufficient amount of drugs to each health facility; and monitor drug supply management by the health facility team.

D. Using patient monitoring data for pharmacovigilance

Recording side-effects on the patient card and reporting new or unusual or unusually common reactions to the responsible medical officer on a clinical team, can initiate documentation of adverse drug reactions (ADRs) and toxicities for pharmacovigilance purposes. In many countries that are scaling up ART, an organized pharmacovigilance programme does not now exist.

Nurses or clinical officers trained in IMAI and many other ART curricula are already taught to consult or refer patients with any unusual or unexpected or serious side-effects; these would be noted under side-effects on the patient record but should also result in further action. When the medical officer or doctor on the clinical team are consulted on these problems or review cases, individual case report forms could be filled out. Inviting spontaneous reports, providing the report forms and an easy way to transmit them, educating medical officers, and integrating these reports into a clinical mentoring system could contribute to building a pharmacovigilance system. A clinical mentoring system which backs up medical officers or doctors at district level could provide the experienced ART physicians, paediatricians and an academic unit which make voluntary reporting more likely to be successful.

It may also be possible to use the aggregated patient monitoring data to get an estimate of the rates of substitutions and switches, or to do card sorts to estimate the frequency of certain side-effects during on-site visits.

E. Linkages with other monitoring and evaluation tools

With an effective patient monitoring system, it is possible to collect data that are useful and may feed into other M&E tools such as HIV/AIDS case surveillance and Service Availability Mapping (SAM). The outcomes of patient monitoring in conjunction with SAM, AIDS case surveillance and other HIV/AIDS M&E tools should be complementary and used together to make informed decisions at all levels.

HIV/AIDS case surveillance

The WHO HIV/AIDS case definitions have recently been reviewed and revised by WHO.[1] The new definitions seek to harmonize both clinical case definitions and surveillance definitions. In the present context of scaling up ART surveillance can be useful to monitor the burden of "advanced HIV disease" and allow estimates of the number of people who require or may shortly require ART. Revised case definitions facilitate this activity.

Advanced HIV/AIDS disease case is defined for surveillance as: any clinical stage 3 or 4 disease; or where CD4 is available, any clinical stage with CD4 < 350. This differs from the immunological criteria for initiating ART at CD4 < 200.

In the patient monitoring system, the patient's clinical stage can be obtained from the patient card or the pre-ART register.

[1] World Health Organization (WHO). *Interim WHO clinical staging of HIV/AIDS and HIV/AIDS case definitions for surveillance: African region.* WHO, 2005 (WHO/HIV/2005.02).

Routine patient monitoring contribution to HIV drug resistance surveillance and monitoring

Routine HIV drug resistance (HIVDR) testing is neither logistically feasible nor recommended in first-level health facilities in resource limited settings. While the emergence of HIV drug resistance is inevitable, it can be slowed by effective patient and drug supply management as well as HIVDR surveillance and monitoring.

WHO recommends that HIVDR surveillance and monitoring be carried out using either only existing routine patient monitoring data or these data in addition to laboratory specimens in a sample of patients.

Data from the routine patient monitoring system are used to calculate HIVDR early warning indicators (see *Table D*). These indicators cover factors that will influence the rapid emergence of HIV drug resistance (indicators may include drug stock-out rates, adherence assessment, high rates of treatment failure, and survival on ART). Adherence assessment may be obtained through periodic analysis of patient cards and on the cohort analysis form (where persons picking up ARV drugs 6/6 or 12/12 months are recorded), while treatment failure rates (patients who switch to a second-line regimen) and survival on ART are currently calculated at 6 months, 12 months and yearly thereafter on the cohort analysis form.

Data from the routine patient monitoring system with the addition of lab specimens in a sample of patients are used in the *HIVDR monitoring protocol*.[1] HIVDR monitoring measures and interprets rates of viral suppression and, in those who fail to achieve viral suppression 12-15 months after initiating a first-line regimen, specific HIVDR mutations and mutation patterns. It makes use of routinely captured data from patient cards or records including: documentation of prior ART; patient's ART summary including substitutions within first-line and switches to second-line; and the adherence assessments.

These methods contribute to a public health approach to limiting HIV drug resistance that should be standardized, sustainable, and institutionalized in countries.

[1] World Health Organization (WHO). *Monitoring of HIV viral suppression and HIV drug resistance in populations receiving ART in resource limited settings: protocol summary* (V.07-08-05). WHO, 2005.

CHAPTER FOUR

Practical application of patient monitoring tools: WHO illustrative system

A. Introduction

Collecting and analysing only what is needed for individual patient management and for clinic, district, and national programme management is an important principle for the design of HIV care and ART information systems. While the format of the forms may vary between countries, these guidelines encourage the use of a simplified standardized paper-based data collection process at clinic level as is used in TB monitoring. The WHO illustrative system presented in this chapter is based on the TB experience, where data elements are collected on a patient card or other record form during a clinical encounter and are transferred for data analysis, usually by entering into a paper register followed by manual or electronic entry to generate reports.

The system allows flexibility for additional data collection and analysis for clinic and programme needs and for research, but makes a clear distinction between what data are essential for ART programmes, what data are recommended for HIV care and ART delivery, and what should be reserved for separate data exercises by research staff. More is not better. The collection of data, if not simple and kept to a minimum, can impede effective service delivery and ART scale-up.

Implementing an HIV care/ART patient monitoring system helps clinical teams and the health system to make an effective transition from acute to chronic care delivery. The system described in these guidelines is based on the recommended set of standardized patient monitoring data presented in *Chapter Two: Standardized minimum patient monitoring data.* The data elements can be collected in a variety of ways, using different systems tailored to programme needs.

A routine patient monitoring system, based on the agreed minimum data elements, should be ongoing in all facilities delivering ART. Some facilities with extra funding and partner agency input will collect and analyse more data than others.

It is hoped that this chronic disease record system can pave the way for similar methods for diabetes and other chronic illnesses. A paper base is important for feasibility.

Standardized information systems should include the minimum data set, indicators calculated from cohort analyses, and quarterly (or monthly) cross-sectional reports of numbers of individuals in care and on ART.

The illustrative paper system presented in this chapter includes seven paper items, with items 2-6 included in *Annex D*, and the data flow between them illustrated in *Fig. 6*:

1. a short patient-held card (optional)
2. a facility-held HIV care/ART chronic care card or other patient record
3. an HIV care pre-ART register
4. an ART register
5. a quarterly (or monthly) cross-sectional report
6. an ART cohort analysis report
7. an appointment book to facilitate booking appointments and follow-up on ‘lost’ patients.

B. Patient card or other record

In many health facilities, most HIV care is currently episodic acute care with the exception of TB treatment which is followed using a TB treatment card. There may be an acute care register where each patient-visit is recorded and a notation made on either a patient-held record (commonly a school exercise book) or a facility-held chart. Establishing good chronic HIV care including ART requires forming and preparing a clinical team to provide continuity of HIV care. A key element of continuity of care is keeping a record which summarizes this care and allows each health worker or counsellor to understand what has happened on earlier visits.

When an HIV-positive patient enrols in HIV care, an HIV care patient card or other summary record should be started for that patient. Written documentation of a positive HIV test is required. This is called enrolling in HIV care. This does not happen automatically when the patient receives a positive HIV test result. Patients need to understand what is involved in HIV care and want to be cared for on an ongoing basis (with follow-up appointments). This is the first step in forming a partnership with the patient. Some patients will want to think about this for a while after learning that they are HIV-positive.

The HIV care patient card is started for patients when they register for chronic HIV care (not when they are HIV-positive as explained above). A country may choose to limit the card only to those about to receive ART, but this would be a country-specific adaptation of the system described in these guidelines.

There are many formats possible for the facility-held chronic care card or other patient record formats. This document presents an agreed list of the minimum variables to collect and suggested coding as presented in *Chapter 2*. As one example, this is included in the HIV care/ART card from the *WHO IMAI chronic HIV care with ARV therapy guidelines*[1] (see *Annex D*).

The format of the forms can vary. What is important is the standardization of the data elements and codes. Other formats which add additional data, expanding the card to a larger A3 size, spreading the content onto several pages, or electronic entry are all options (see *Chapter 5* for examples). For an A4 card which accommodates 16 encounters per page, several cards will be needed. Coloured cards should be considered; for example, a different colour would particularly make sense when the patient is on second-line treatment.

Detailed notes relevant to patient care and treatment may also be recorded on a separate clinical review form, which may already be used at many facilities. These forms would then be filed with the patient card. The *WHO IMAI chronic HIV care with ARV therapy guidelines*[2] provides a clinical review of symptoms and signs, medication use, side-effects, and complications in their patients. This may be laminated and kept at the facility as a reference to guide the patient assessment. If the clinician finds any abnormal signs, these are noted on the patient card in the appropriate column. The patient card therefore represents a summary of key positive findings from the clinical review.

There is often also a patient-held exercise book or facility-held patient chart, where detailed clinical notes on acute illnesses can be recorded (see *Fig. 5*).

[1] This card also appears in the *IMAI HIV care with ARV therapy* guidelines module and the guidelines and training materials teach health workers how to fill out the card correctly.
[2] http:// www.who.int/hiv/toolkit/arv/en/index.jsp

Many HIV care/ART systems will also issue a small patient-held card (see SEARO example in *Chapter 5*) which contains the unique patient ID number, a record of appointments, and drugs dispensed and taken.

Fig. 5. Patient information from the clinical review

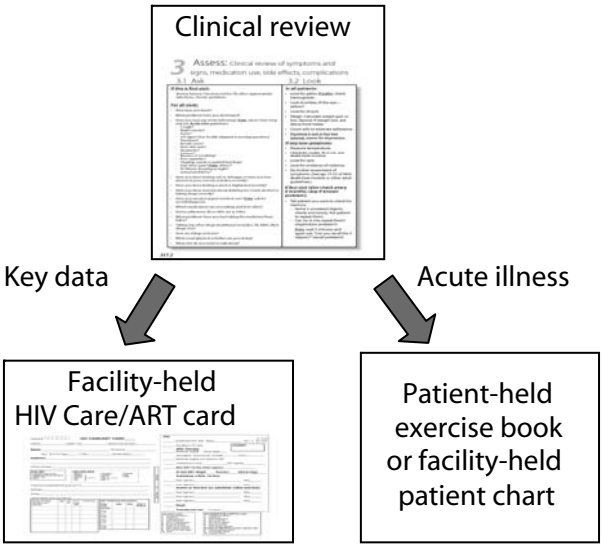
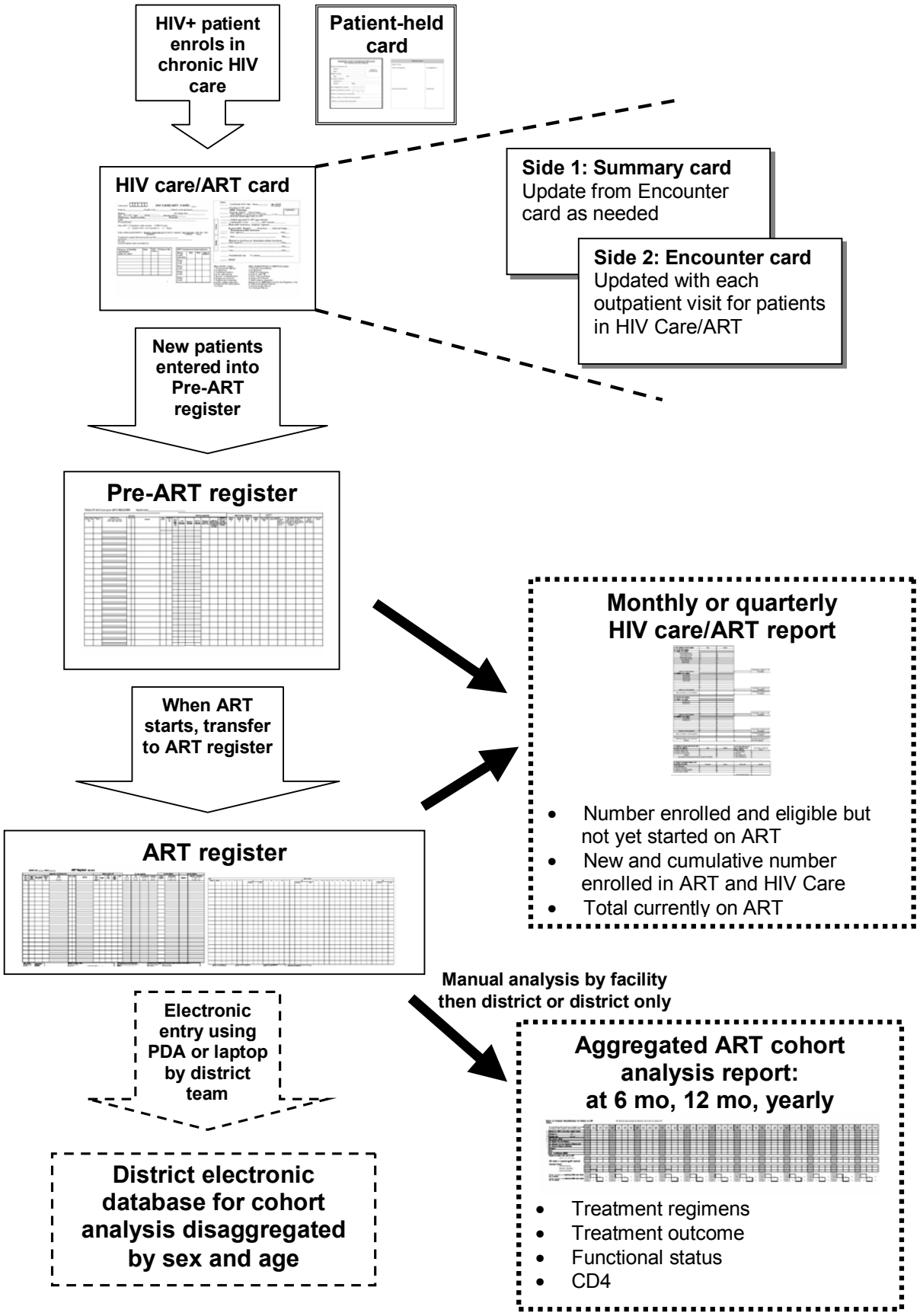


Fig. 6. Overview of data flow from patient card to the 2 registers to the 2 reports



C. Pre-ART and ART registers

Pre-ART register

Registration								Fill when applicapable							WHO Clinical Stage – insert date				ART						
Date enrolled in chronic HIV care	Patient clinic ID No.	NAME IN FULL Upper Space: surname Lower Space: given name	Age	Sex	Address	Entry point	Confirmed HIV+ date	*INH Start Date Stop date*	*CTX Start Date Stop date*	*Fluconazole Start date Stop date*	*TB Rx Start Date Stop date*	*Preg Due Date, PMTCT link*	If pt is DEAD before start ART, write DEAD and date	LOST TO FOLLOW-UP for X months or Transfer Out (TO) before starting ART and date	1	2	3	4	Date medically eligible for ART	Why medically eligible 1.Clinical only 2.CD4/% 3.TLC #	Date eligible & ready for ART	Date eligible, ready & selected by committee for ART	Date ART started (transfer to ART register)	Clinical stage at start of ART date	Unique ART number

Pre-ART register

All patients who first enrol in HIV care, whether they are on ART or not, are initially listed in the pre-ART register and counted as enrolled in HIV care. Data are recorded in the pre-ART register until the patient starts ART. Once the patient starts ART, then the ART register is used to collect and record the patient's history and ARV treatment. Even if a patient is already eligible for ART, s/he should be listed in the pre-ART register. Only patients who transfer in with records on ART (see below) will go straight into the facility ART register (these patients have already been entered into their original facility's pre-ART register).

In both registers, each row is one patient. The rows contain the names of patients, one patient per row. In the ART register, each row spans two A3 pages, whereas each pre-ART register row is on a single page.

ART register

Registration and Personal Information								Status at start ART					Fill when applicable				1st-line regimen		2nd-line regimen	
ART Start Date	Unique ART No	Why Eligible (Transfer In)	Patient Clinic ID	Name Surname Given name	Sex	Age	Address	Functional status	Wt	Child: Height	WHO clinical stage	CD4	INH Start date Stop date	CTX Start date Stop date	TB Rx Start date Stop date	Preg Due date PMTCT link	Original Regimen	Substitutions 1st: Reason/ Date 2nd: Reason/ Date	Regimen	Switches, substitutions 1st: Reason/Date 2nd: Reason/ Date

Year		Write in month																															
Month 0	Month 1	2	3	4	5	6				7	8	9	10	11	12				13	14	15	16	17	18	19	20	21	22	23	24			
							Function		*CD4*							*Function*		*CD4*													*Function*		CD4

ART register

The patient is entered in this register when he or she starts ART (*Fig. 5*). All patients who are prepared for ART adherence at the clinic will already have a single line entry in the pre-ART register. When the patient starts ART, the date of starting ART is recorded in both registers, as is the unique ART number. After this, no further entries are made into the pre-ART register. All subsequent entries are in the ART register.

ART start-up groups (ART cohorts). The ART register is organized by ART start-up groups or cohorts – designated by the month and year the patients start ART. For example, those patients who start ART between 1-31 March are entered on a page (or pages) and March is written under Month 0. In April, a new page is used and April is written under Month 0. Month 0 refers to the entire month during which the patients start ART. This facilitates analysing ART start-up group (cohort) outcomes at month 6, 12, and 24, etc.

At the end of each month, the follow-up status of the patient is recorded in the register. If a patient has come in more than once in the last month, the most recent event is recorded. This is also the case for Month 0.

When the patient has been on ART for a month, the entry is made in Month 1 (this numbering is done to keep consistency between the register and real duration on ART for clinical purposes). The "year" entry above the months applies to Month 0. When the year changes, the new year should be entered above January.

Transfer In (TI) patients are entered retrospectively in the ART register in the month they started ART. Transfer In requires that the records are transferred by some means, requiring that the patient has followed a Transfer Out procedure where they were previously cared for. This can be confirmed by phone to the place of care or via the district coordinator. Patients who are "Transfer In with records" are added in the register at the bottom of the list of clinic-originated patients started on ART in that month.

Although special cohort analyses can be done which separate the clinic-based patients in the cohort from the Transfer In patients in the same cohort, for the routine cohort analyses these patients are combined.

"Transfer In with records" will become an increasing proportion of patients over time, with patients returning to work and with increased mobility as patients improve clinically on ART, and with the expansion of ART services to a larger number and geographic distribution of facilities. An important reason for this approach is the expected substantial proportion of adult patients over time who move from the clinic where their ART was started to other clinics due to employment and other internal migration reasons.

Non-naive patient on ART from other sources (NOT the same as a Transfer In with records). National policy will dictate how these patients are handled. In general, this patient goes into the HIV care pre-ART register (into the queue in a rationed system). The patient must qualify (medical eligibility and any other requirements) and be prepared for adherence. These patients are not treated in the same way as a Transfer In with records where every effort and arrangement is made to make sure there is no interruption in therapy.

Monthly entries in the ART register

Current ARV regimen picked up last month. By using coded regimens, one can look at the current monthly column and tally up the regimens.

RESTART after treatment interruption. This is still somewhat unresolved and requires national adaptation and agreement as to when restart is permitted. Circumstances may differ; for example:

- Deliberate treatment interruption in first trimester pregnancy (STOP);

- Other planned treatment interruptions if these are recommended in the future (STOP);
- LOST or very poor adherence due to various reasons – these patients may or may not be restarted.

If the patient is restarted on ART, this should be recorded in the same line in the register. Given that death is the only irrevocable event, the patient always retains the same record throughout his or her liftetime on ART, as s/he may return after being determined LOST, STOP, DROP or Transfer Out. The number and weeks of each treatment interruption are retained on the card and appear in the ART register; these could be used in special analyses.

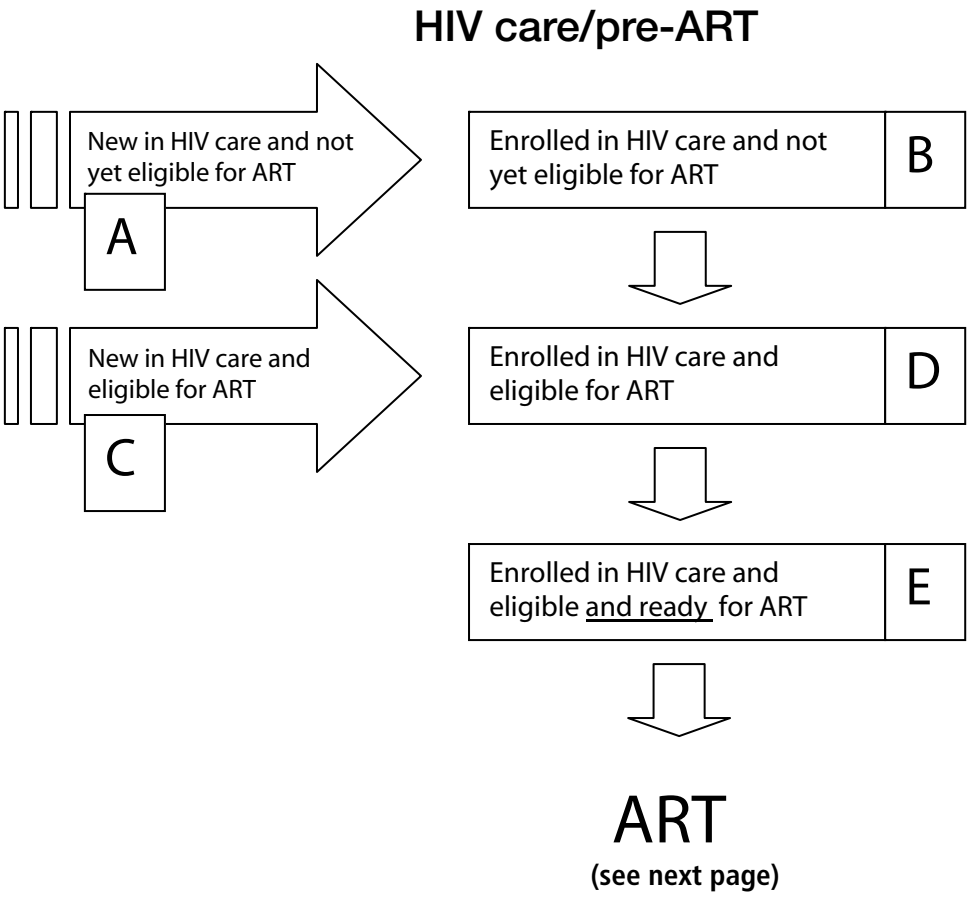
LOST or DROP. National decisions are required as to when LOST patients (temporary lost when patient misses an appointment or drug pick-up) become DROPped (patient did not show up for more than X months, after X attempts at contacting patient by health facility, and may be dropped from ARV drug orders). A default suggestion, pending a decision, could be 3 months.

Special entries for cohort analyses at 6 months, 12 months, then yearly

- **Functional status.** Enter W for Working, A for Ambulatory, and B for Bedridden. See Annex A for more detailed definition.
- **If CD4 counts** are available, enter the number or percentage (for children).
- **A blank column** is provided – an additional variable such as weight can be transferred from the card, as chosen by the clinical team or district coordinator.

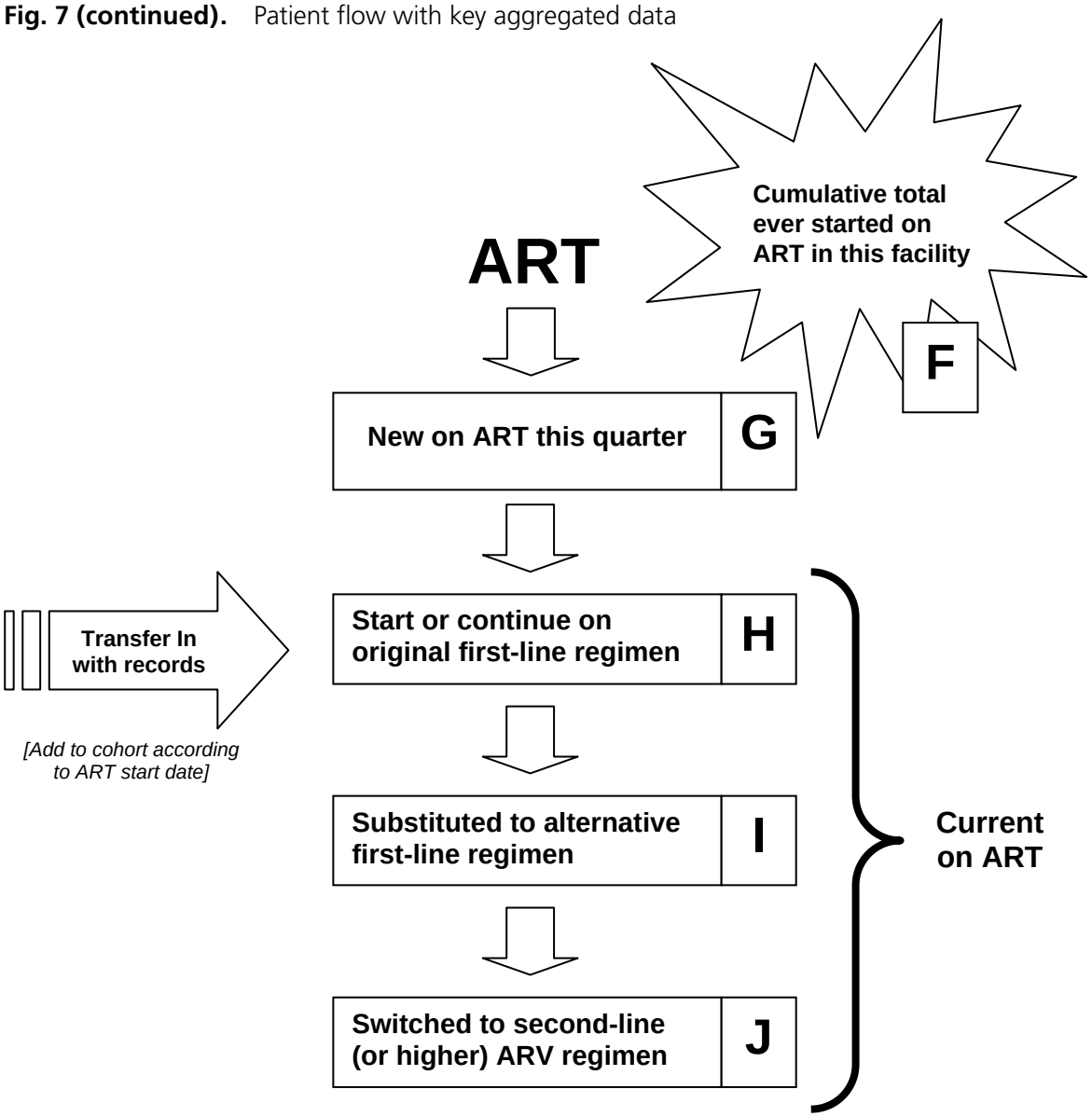
Fig. 7 demonstrates how the flow of data collection allows for the continuous monitoring of patient progress by capturing important information on patient status at each point of contact with the health facility.

Fig. 7. Patient flow with key aggregated data



When patients enroll in HIV care, they are either not yet eligible for ART (A) or already medically eligible for ART (C); both are included when counting the new patients enrolled in HIV care in the previous quarter (or month). Patients progress from not eligible for ART (A); to medically eligible for ART (D); to eligible **and ready** for ART, meaning they have been prepared for adherence (E); to new on ART in the previous quarter (or month) (G – see next page).

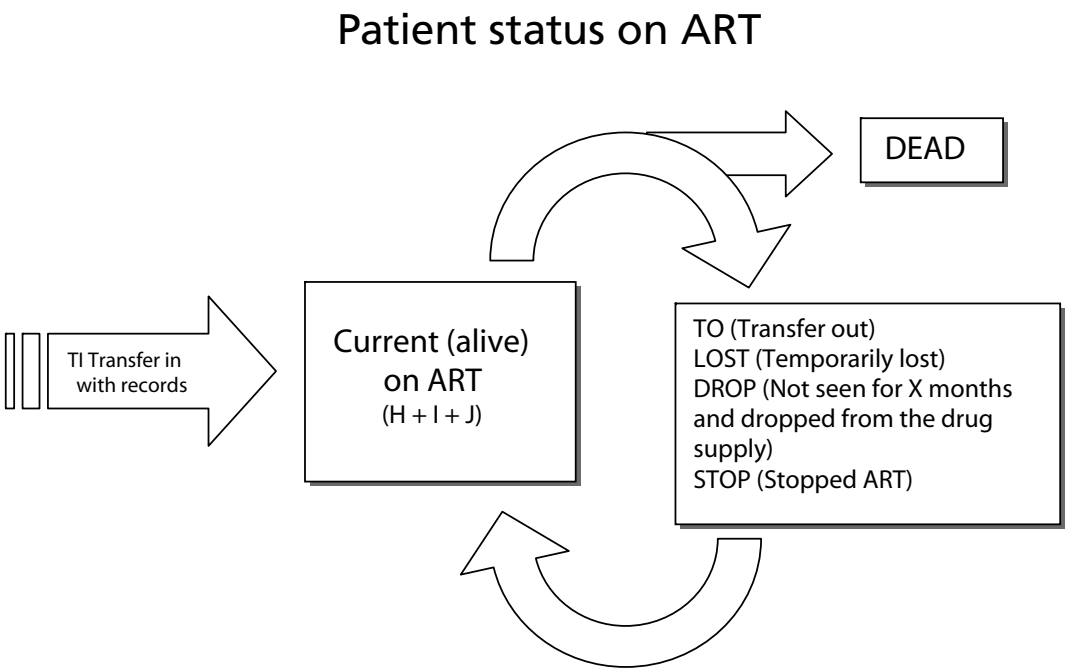
Fig. 7 (continued). Patient flow with key aggregated data



Those new on ART in the previous quarter (or month) are added to the cumulative total of those ever started on ART in the reporting facility (F). Even if the patient subsequently stops ART or dies, they are still included in the cumulative total (F).

Patients on ART **start** or continue on the original first-line regimen (H); they may have **substituted** to an alternative first-line regimen (I); or have **switched** to a second-line or higher ARV regimen (J). Adding H plus I plus J gives the number currently on ART at the reporting facility.

Fig. 7 (continued). Patient flow with key aggregated data



Prior to starting ART (pre-ART), patients can die, be lost to follow-up, or transfer out. These deaths and lost to follow-up patients need to be distinguished from those that occur after starting on ART. Patients on ART are either:

Still on ART (H or I or J)

DEAD

Transfer Out (TO)

LOST– temporarily (did not pick up ART for X months)

DROP (has not been seen at facility for X months, after X attempts at follow-up contact and dropped from drug supply)

STOP (stopped ART)

In addition to the ART start-up groups who started ART at the reporting facility, patients can Transfer In with their records. Patients who are lost or have stopped ART can sometimes be restarted. The only irrevocable category for patients on ART is death.

D. Quarterly (or monthly) facility-based HIV care/ART reporting form

The quarterly report is a cross-sectional report. The quarterly HIV care/ART reporting form is designed to report both on what has happened new in the previous quarter (or month), and to keep track of a cross-sectional summary of all patients currently on ART, as of the end of the previous quarter (or month). The report includes information both on enrolment in chronic HIV care and on ART from a single health facility (or from a single project within a large facility, each with its own registers). The report covers a three-month reporting period, that is, from the first to the last day of the quarter. The form can be adapted for use during a longer or shorter reporting period, such as monthly by replacing the word "quarter" with "month". The following tables are extracted from the full form in *Annex D: WHO quarterly (or monthly) report*.

Quarterly Report Table 1. HIV care (non-ART and ART) – new and cumulative number of persons enrolled

1. HIV care (non-ART and ART) - new and cumulative number of persons enrolled			
	Cumulative number of persons ever enrolled in HIV care at this facility from the quarter which ended 3 months ago	New persons enrolled in HIV care at this facility during the previous quarter	Cumulative number of persons ever enrolled in HIV care at this facility at end of the previous quarter
1. Males (>14 years)	a.	h.	o.
2. Non-pregnant females (>14 years)	b.	i.	p.
3. Pregnant females (>14 years)	c.	j.	q.
4. Males (0-14 years)	d.	k.	r.
5. Non-pregnant females (0-14 years)	e.	l.	s.
6. Pregnant females (0-14 years)	f.	m.	t.
Total	g.	n.	u.
	Total number of persons who are enrolled and eligible for ART but have not been started on ART		v.

This table is designed to report information about all of the HIV-infected patients enrolled in (which usually means "registered for") HIV care at a facility and includes both those eligible for ART and those not eligible for ART (non-ART) at the time of registration. This information is categorized by age group, sex and pregnancy status. Caution should be taken to not include the same woman twice in total counts – once as pregnant, and then again as non-pregnant after delivery. It is important to note the beginning and end dates of the quarter being referenced in the form.

Table 1 and Table 2 which follows use a simple principle that requires only counting once, those patients new in HIV care and new on ART.

Cumulative ever in HIV care or on ART (column on the right)	**=**	**Cumulative ever total (from the report of the quarter which ended 3 months ago)**	**+**	**New in the previous quarter**

The previous quarter refers to the quarter which has just ended and which the new patient data is being tallied from (also referred to as the "last" quarter). The term "previous" is used because the tally happens after the quarter is over (and to be consistent with the TB monitoring training materials). The new patients enrolled or started on ART in the previous quarter are added to the cumulative ever total taken from the report of the quarter which ended 3 months ago (this is the cumulative number of patients as the previous quarter began).

Each quarter it is only necessary to tally the **middle column**. The data in the left column comes from the previous quarter. The data in the right column comes from adding the left plus the middle column.

Quarterly Report Table 2. ART care – new and cumulative number of persons enrolled

2. ART care - new and cumulative number of persons enrolled			
	Cumulative number of persons ever started on ART at this facility from the quarter which ended 3 months ago	New persons started on ART at this facility during the previous quarter	Cumulative number of persons ever started on ART at this facility at end of the previous quarter
1. Males (>14 years)	a.	h.	o.
2. Non-pregnant females (>14 years)	b.	i.	p.
3. Pregnant females (>14 years)	c.	j.	q.
4. Males (0-14 years)	d.	k.	r.
5. Non-pregnant females (0-14 years)	e.	l.	s.
6. Pregnant females (0-14 years)	f.	m.	t.
Total	g.	n.	u.
	Number of persons on ART and already enrolled in programme who transferred into facility during the previous quarter		v.
	Number of baseline CD4+ counts for persons who started ART during the previous quarter (optional)		w.
	Median baseline CD4+ count for persons who started ART during the previous quarter (optional)		x.

This table is designed to report information about all patients started on ART at a facility. Similar to Table 1, this information is categorized by age group, sex and pregnancy status. Those "new

persons started on ART at the facility during the previous quarter" are added to the "cumulative number of persons ever started on ART at the facility at end of the quarter which ended 3 months ago," yielding the "cumulative number of persons ever started on ART at the facility at the end of the previous quarter".

Table 2 also includes information about the "number of persons on ART and already enrolled in the programme who transferred into the facility in the previous quarter". Those who are on ART and already enrolled in the programme at another facility should not be included in the "total number of persons ever started on ART at the facility," because those who transferred should have already been counted in the programme at another facility.

Finally, Table 2 includes the "number of baseline CD4 counts" and the "median baseline CD4 count " for persons who started ART in the previous quarter. For this reporting form, "baseline CD4 count" is defined as a CD4 count obtained anytime during the 3-month period prior to starting ART.

"Eligible for ART but not yet started" is an important number to total. These patients are enrolled in HIV care, have been assessed and found to be eligible, and are waiting for ART for various reasons. In rationed systems with insufficient ART, this number will grow and constitute a "waiting list". Although it is not on the generic quarterly report form at this time, it is possible to adapt the report form to keep track of deaths in patients waiting for ART, from the pre-ART register.

There are 3 ART numbers with important differences:

- **new on ART (started in the previous quarter; not transferred in)**
- **cumulative ever started on ART at this facility**
- **currently on ART at this facility**

Table 4 of the quarterly report provides a current tally or snapshot, at the end of the previous quarter, of how many patients are currently on ART and what proportion are on first- and second-line regimens, disaggregated by age and sex. The limitation of this cross-sectional report is that it combines patients who have been on ART for different durations. In the first quarters of actively scaling-up ART, the quarterly report will be dominated by patients newly on ART. This is a limitation of the data collected on the quarterly report form and a reason that it is important to also (although less often) use the cohort analysis report which allows comparison of outcomes of patients who have been on ART for approximately the same period of time but at different facilities or during different years of the programme.

Quarterly Report Table 4. ARV regimen at end of previous quarter

4. ARV regimen at end of quarter	Male	Female		
On 1st-line ARV regimen				
4.1 Adults (>14 years)				
1a d4t-3TC-NVP	a.	j.		
1b d4t-3TC-EFV	b.	k.		
1c ZDV-3TC-NVP	c.	l.		
1d ZDV-3TC-EFV	d.	m.		
Other	e.	n.		
Adults on 1st-line regimens	i.	r.	s.	Total number of adults on 1st-line regimen
4.2 Children (0-14 years)				
4a d4t-3TC-NVP	a.	k.		
4b d4t-3TC-EFV	b.	l.		
4c ZDV-3TC-NVP	c.	m.		
4d ZDV-3TC-EFV	d.	n.		
Other	e.	o.		
Children on 1st-line regimens	i.	s.	u.	Total number of children on 1st-line regimen
Adults and children on 1st-line regimens	j.	t.	v.	Total adults and children on 1st-line regimens
On 2nd-Line ARV regimen				
4.3 Adults (>14 years)				
2a ABC-ddI-LPV/r	a.	i.		
2b ABC-ddI-SQV/r	b.	j.		
2c TDF-ddI-LPV/r	c.	k.		
2b TDF-ddI-SQV/r	d.	l.		
Other	e.	m.		
Adults on 2nd-line regimens	h.	p.	q.	Total number of adults on 2nd-line regimen
4.4 Children (0-14 years)				
5a ABC-ddI-LPV/r	a.	k.		
5b ABC-ddI-NFV	b.	l.		
5c ABC-ddI-SQV/r	c.	m.		
Other	d.	n.		
Children on 2nd-line regimens	h.	r.	u.	Total number of children on 2nd-line regimen
Adults and children on 2nd-line regimens	i.	s.	v.	Total adults and children on 2nd-line regimens
Adults and children on 1st- and 2nd-line regimens	j.	t.	w.	Total adults and children on 1st- and 2nd-line regimens
				Total current on ART

Table 4 includes information about the number of persons on first- and second-line ART regimens at the end of the previous quarter and are sorted by age groups (adults >14 years versus children) and sex. This information is found in the ART register; the code of the regimen at the end of the previous quarter is listed under the last month of the quarter on page 2. For any quarter (or month), the ARV regimens from all of the ART register pages are tallied.

The quarterly report form can be enlarged to use it as a tally sheet. Put the regimen codes next to the drug abbreviations, for example d4T-3TC-NVP is 1a (30) and 1a (40). Since most adults will be on this regimen, it is possible to simply add the total for this regimen then put ticks for the other regimens. For accurate tallies with disaggregation by both sex and age, it can be helpful for one person to read the sex and age bracket then the regimen code from the register while another records these on the tally sheet.

Table 4 includes the WHO standard first-line ARV regimens and several second-line ARV regimens for adults and children and includes a number of blank cells (not shown), so that other regimens can be added, as needed.

After the tallies are done, convert the tally to numbers. Then add up the totals across the rows and vertically (for example, for adults on second-line regimens, add up the numbers in cells "i-o" and enter the total in cell "p").

Quarterly Report Table 5.1 Number of persons who did not pick up their ARV regimens (optional)

5.1 Number of persons who did not pick up their ARV regimens (optional)	Male	Female
1. For 1 month (only) in previous quarter	a.	e.
2. For 2 months (only) in previous quarter	b.	f.
3. For previous 3 or more months	c.	g.
Subtotal	d.	h.
Total number of persons who did not pick up their ART regimens		i.

This optional table provides a rough estimation of patient adherence to ARVs and may be an early warning indicator for the rapid appearance of HIV drug resistance. The table contains information about persons who started ART at the facility but did not pick up their ARVs for the entire 1 month (only), entire 2 months (only), and entire 3 months or more. This information comes from page 2 of the ART register or from pharmacy records at the facility. The tally of these data is only disaggregated by sex, not also by age. The rows are mutually exclusive. For example, if a man has not picked up drugs for two quarters, tally in the "b" only – do not also put a tick in "a".

Calculate subtotals for males and females (cells "d" and "h") and total these to determine the **total number of persons who did not pick up their ART regimens** (cell "i").

Quarterly Report Table 5.2 Of those who did not pick up regimen in previous 1 quarter (optional)

5.2 Of those who did not pick up regimen ever in previous quarter (optional)	Total number of adults and children
1. Lost to follow-up (dropped)	a.
2. Who died	b.
3. Who stopped ART	c.
4. Who transferred out	d.

This table contains information about why persons who started ART at the facility did not pick up their ARV regimens ever during the previous quarter. This may be useful for clinical management purposes. Note that filling in this table is optional because this information may not be readily available at some clinics and thus, may lead to underreporting. If this information is available at your clinic, count the number of adults and children who, **in the previous quarter**:

1. were **dropped** (lost to follow-up) - enter the total in cell "a" of column 5
2. had **died** - enter the total in cell "b" of column 5
3. had **stopped ART** - enter the total in cell "c" of column 5
4. had **transferred out** - enter the total in cell "d" of column 5

The data for the form can be compiled from information which is usually routinely collected at three sites at the facility: the clinic, the laboratory and the pharmacy. In a large facility, this information may be kept separately.

E. ART cohort analysis report form

Both cross-sectional and cohort analyses are useful in monitoring rapid scale-up of ART. Cohort analyses are usually a better indicator of programme activities than cross-sectional or cumulative analyses. Cohorts, also referred to as ART start-up groups, should be formed when patients start ART, not when they enter HIV care. Cohort analyses are important because they combine results from patients on ART for 6, 12, 24, etc. months. In contrast, the quarterly (or monthly) cross-sectional reports combine all patients, no matter what their duration on ART. During rapid scale-up of ART, most patients will have been started recently on ART and will still be on the first-line regimen; these patients will dominate the cross-sectional reports.

As described in *Chapter 1*, the **ART cohort analysis report form** (see *Fig. 8*) compares baseline characteristics of ART start-up groups (quarterly cohorts) with their status at 6 and 12 months then yearly. Key indicators for the clinical and district teams to see how well the programme is doing, such as the percentage of patients still on a first-line regimen or able to work at 6 and 12 months, are calculated using this report. It allows the teams, in a meaningful way, to compare success at 6 and 12 months of ART with earlier or later cohorts, or with other districts. This report does not have to be transmitted frequently – it can be reported every 6 months or even during a district or programme review on a yearly basis (see second column in *Table F*).

Cohort analysis allows comparison between groups of patients who have had equal duration of ART.

As in TB, the task of collating data for the cohort analysis is the responsibility of the district-level coordinators. The HIV care/ART patient monitoring guidelines encourage decentralizing registers to someone on the clinical team at each ART site. While it is also useful for the clinical team to fill out a cohort analysis report form (in Ethiopia, an enlarged copy will be posted on the wall), this will be dependent on the capacity to do so at each facility. However, because the data are of critical importance to programme monitoring, it is essential for the district coordinator or a designated person in charge of patient monitoring to fully verify the data. This requires going back to the registers and recalculating the results for each monthly cohort.

Where disaggregated cohort data (by sex and age) are required, the district coordinator will be responsible for transferring key data elements from the facility ART register electronically through the use of a PDA or laptop during regular site visits. These data are then transferred into an electronic database at the district level that allows more in-depth analysis of the cohort data.

Where CD4 counts are available, the quarterly report form may be adapted to include CD4 counts for cohorts which have completed 6 and 12 months of ART within the previous quarter. Additional cohort data should be reported on the *ART cohort analysis report form*.

The cohort analysis report supports the following analyses at 6 and 12 months on ART then yearly:

- percentage still on original first-line regimen, substituted to an alternative first-line regimen, switched to a second-line (or higher) regimen;
- functional status: percentage Working, Ambulatory and Bedridden;
- percentage of patients who have picked up their ARV drugs 6/6 months or 12/12 months (no gap in drug pick-up);
- optional: median CD4 count or percentage of CD4 counts done which are ≥ 200; and
- optional: percentage of viral loads which are below 400 copies/ml.

Fig. 8. Example of cohort analysis report form

Baseline data of cohort starting ART in January, 2005

6-month outcome data of cohort starting ART in January, 2005

Baseline data of cohort starting ART in February, 2005

	For cohort starting ART by month/ year: at baseline then results at 6 months on ART, 12 months on ART, 24 months on ART	Cohort Jan 05	6 mo- July05	12 mo- Jan06	24 mo- Jan07	Cohort Feb05	6 mo- Aug05	12 mo Feb06	24 mo- Feb07
G	Started on ART in this clinic- original cohort	13	13						
TI	Transfers In Add +	**x**	1			**x**			
TO	Transfers Out Subtract -	**x**	0			**x**			
N	Net current cohort	13	14						
H	On original 1st-line regimen	13	13						
I	On alternate 1st-line regimen (substituted)	0	1						
J	On 2nd-line regimen (switched)	0	0						
	Stopped	0	0						
	Died	0	0						
	DROP (Lost to follow-up)	0	0						
	Percent of cohort alive and on ART								
	[(H + I + J)/N * 100]	100%	100%						
	CD4 median or proportion ≥ 200 [of those with available CD4] (optional)	50	NA						
	Functional status								
	Number working	3	6						
	Number ambulatory	6	6						
	Number bedridden	4	2						
	Total W + A + B	13	14						
	Number of persons who picked up ARVs each month for 6 months	x	14	x	x	x		x	x
	Number of persons who picked up ARVs each month for 12 months	x	x		x	x	x		x

Table F. How the quarterly and cohort analysis reports measure HIV care/ART indicators

Indicator	Time frame for analysis	Which number or formula for calculating (numerator/denominator)	Sources of data
1. Indicators related to patients accessing HIV care and ART			
1a. Number enrolled in HIV care	Last quarter	- New in last month - Cumulative number of persons enrolled in HIV care by sex, age, pregnancy status	Quarterly report form –Table 1
1b. Number started on ART – new and cumulative ever	Last quarter	- New in last month - Cumulative number of persons ever started on ART at this facility by sex, age, pregnancy status	Quarterly report form – Table 2
1b. Number currently on ART	Cross-sectional – at end of last quarter	Total and disaggregated by sex, adult/ child, drug regimen	Quarterly report form – Table 4
1c. Number of persons who are enrolled and eligible for ART but have not been started on ART	Cross-sectional – at end of last quarter	Total number enrolled and eligible but not on ART	Quarterly report form – Table 1
1d. Percentage of those eligible for ART in clinic who have been started on ART	Cross-sectional – at end of last quarter	Cumulative number of persons ever started on ART at this facility ———————————————— Total number enrolled and eligible but not on ART plus cumulative number of persons ever started on ART at this facility	Quarterly report form – Table 1
1e. Core indicator 7 Percentage of people with advanced HIV infection receiving ARV combination therapy (UNGASS indicator)	Cross-sectional	Number currently on ART ———————————————— Denominator is an estimate based on HIV prevalence and expected percentage with advanced HIV infection (from HIV surveillance)	Quarterly report form ———————————— Estimate, HIV prevalence data
2. Indicators related to success of ART			
2a. Core indicator 9 Survival at 6, 12, 24, 36, etc. months after initiation of ART (UNGASS indicator)	6 and 12 months on ART and yearly thereafter	On any ARV regimen at 6 and 12 months and yearly thereafter ———————————————— Min = Original cohort + Transfers in Max = Net current cohort - patients dropped or stopped	Cohort analysis form ———————————— Cohort analysis form
2b. Core indicator 8 Continuation of first-line ARV regimen at 6, 12 and 24 months after initiating treatment	6 and 12 months on ART and yearly thereafter	On a first-line ARV regimen at 6 and 12 months and yearly thereafter ———————————————— Persons who started firstt-line ART for the first time during the time period under consideration.	Cohort analysis form ———————————— Cohort analysis form

Table F (continued). How the quarterly and cohort analysis reports measure HIV care/ART indicators

Indicator	Time frame for analysis	Which number or formula for calculating (numerator/denominator)	Sources of data
2c. Percentage of people on ART at 6, 12 and 24 months whose functional status is working	6 and 12 months on ART and yearly thereafter	Working ———————————————— Working + Ambulatory + Bedridden	Cohort analysis form
2d. Median CD4 at 6 and at 12 months on ART compared to baseline.	6 and 12 months on ART	Median CD4 at baseline, 6 and 12 months on ART	Cohort analysis form
3. HIV drug resistance early warning indicators			
3a. Percentage of patients who started ART 6 or 12 months ago who picked up ARV medications 6/6 or 12/12 months.	Cross-sectional – at end of last quarter	Persons who started ART 6 or 12 months ago who picked up ARV medications 6/6 or 12/12 months ————————————————. Persons who started ART 6 or 12 months ago and are still prescribed ART at the end of the time period	Cohort analysis form
3b. Percentage of patients with (good) adherence to ART	Cross-sectional every 3–12 months	Patients with adherence estimated as good ———————————————— Patients currently on ART	Patient card encounter form

Table G. Summary of minimum data elements by category and data source

	Patient card/record	Pre-ART register	ART register	Quarterly (monthly) report	Cohort analysis report
I. Demographic information	• Unique ID #, pt clinic #	• Pt clinic #/ unique ID #	• Pt clinic #/ unique ID #		
	• Name, address, phone	• Name, address	• Name, address		
	• Age, date of birth, sex, marital status	• Age, sex	• Age, sex	By sex, age, pregnancy status	
II. HIV care and family status	• Prior ART, care entry point	• Entry point			
	• Date, location confirmed HIV+ test, HIV subtype	• Confirmed HIV+ date			
	• Date enrolled in HIV care	• Date enrolled in HIV care		• New and cumulative persons enrolled in HIV care	
	• District, health Unit, district clinician/team				
	• Family members: Name, age, HIV status, unique ID #				
	• Home-based care provider				
	• Treatment supporter: Name, address, phone				
	• Drug allergies				
III. ART summary	• Date medically eligible for ART, why eligible	• Date medically eligible for ART, why eligible			
	• Date medically eligible and ready for ART	• Date medically eligible and ready			
	• Date medically eligible, ready, and selected for ART	• Date medically eligible, ready, and selected for ART			
	• ART start date	• ART start date	• ART start date	• New and cumulative persons enrolled in ART care	• # started on ART
	• ART start weight, height (for children), function, clinical stage, (CD4)			• (Median baseline CD4 count for persons who started ART) • (# of baseline CD4 counts for persons who started ART)	
	• Original ART regimen		• Original 1st-line regimen	• # on 1st-line ARV regimen by sex	• # on original 1st-line regimen
	• Substitute within 1st-, 2nd-line: Date, regimen, why		• Substitute/ switch regimen: Date, reason		• # on alternative 1st-line regimen

	Patient card/record	Pre-ART register	ART register	Quarterly (monthly) report	Cohort analysis report
	• Switch to 2nd-line+: Date, regimen, why			• # on 2nd-line ARV regimen by sex	• # on 2nd-line regimen
	• ART interrupted/stop/ Restart: Date, why				• # Stop on ART
	• Transfer in from xxx: Date				• # Transfer in
	• Transfer out to xxx: Date	• Date Transfer out before ART	• Date Transfer out		• # Transfer out
	• Date Dead, Lost, Drop	• Date Dead, Lost before ART	• Date Dead, Lost, Drop on ART		• # Dead, Lost, Drop on ART
IV. Patient encounter information	• Encounter date, whether scheduled, follow-up date				
	• Duration since first starting current regimen				
	• Weight – height (for children), function, clinical stage	• Clinical stage – date first seen in stage 1,2,3,4	• Weight (height) function, clinical stage at ART start		• Proportion working, ambulatory, bedridden
	• Pregnancy/family planning status	• Pregnancy expected due date/PMTCT link	• Pregnancy expected due date/PMTCT link		
	• TB status	• INH, TB Rx start/ stop dates	• INH, TB Rx start/ stop dates		
	• Side-effects (including drug allergies), OIs, other problems				
	• CTX, ARVs: adherence, dose dispensed	• CTX start/stop dates	• CTX start/stop dates	• # of persons who did not pick up their ARV regimens for 1,2,3 months/reason	• # of persons who picked up ARVs 6/6 and 12/12 months
	• Other medications dispensed	• Fluconazole start/stop dates	• Fluconazole start/stop dates		
	• CD4, other laboratory tests/ results				• (CD4 median/ proportion ≥ 200)
	• Refer/consult link				
	• # hospital days since last outpatient visit				
Other				• Total current on ART by age and sex	• Net current cohort
					• % cohort alive and on ART

F. Aggregating data

How the cross-sectional monthly or quarterly report is aggregated will differ depending on the reporting period. Aggregation is most straightforward if the reporting period is only one month for monthly reports or one quarter for quarterly reports. In this case, it is possible to sum all cells across facilities to compile the aggregate cross-sectional report for the district, region or country.

If the reporting period spans more than one month for monthly reports or one quarter for quarterly reports (for example, semi-annual or annual), it will be necessary to sum across facilities AND months/quarters for some cells, taking the numbers for the FIRST and LAST report in the reporting period (for example, taking the January-March (first quarter) and October-December, 2005 (last quarter) report when reporting for the January-December, 2005 period).

The following cells can be simply summed across facilities and across quarters:

Table 1

- New persons enrolled in HIV care at this facility during the previous quarter
- Number of persons enrolled for HIV care who transferred in from another facility during the previous quarter

Table 2

- New persons started on ART at this facility during the previous quarter
- Number of persons on ART and already enrolled in program who transferred into facility during the previous quarter
- Number of persons who restarted ART during the previous quarter, after stopping ART for at least 1 quarter
- Number of baseline CD4+ counts for persons who started ART during the previous quarter

* Median baseline CD4+ count for persons who started ART during the previous quarter -- this cannot be summed: the medians for all reporting periods will have to be averaged (or a median taken)

The following cells will be summed across facilities using the numbers from the FIRST quarter in the reporting period. For example, if the reporting period is January-December, 2005, numbers from the January-March, 2005 quarterly report forms will be summed in the aggregate report.

Table 1

- Cumulative number of persons ever enrolled in HIV care at this facility at beginning of previous quarter (left-hand column)

Table 2

- Cumulative number of persons ever started on ART at this facility at beginning of previous quarter (left-hand column)

Finally, the following cells will be summed across facilities for the LAST quarter in the reporting period. For example, if the reporting period is the quarter January-March, 2005, all cells will be summed across facilities for that quarter. If, however, the reporting period is one year – from January-December, 2005 – then the cells will be summed across facilities for the October-December, 2005 quarter (the LAST quarter in the reporting period). This includes:

Table 1

- Cumulative number of persons ever enrolled in HIV care at this facility at end of quarter (right-hand column)
- Total number of persons who are enrolled and eligible for ART but have not been started on ART

Table 2

- Cumulative number of persons ever started on ART at this facility at end of quarter (right-hand column)

Table 4

- All cells

Aggregating data from **Tables 5.1** and **5.2** may be difficult given that patients in these tables may be counted twice if the data are simply summed across facilities and months or quarters. Conversely, if the data are just taken from the last quarter or month in the reporting period, patients may be missing from the totals.

Using two people – one to read out the register data and the other to record and tally it – may facilitate the counts needed, disaggregated by sex, age and pregnancy status. To aggregate median CD4 count across facilities, it is possible to take the median or the mean.

Aggregation of the cohort analysis form generally requires simple addition, with the exception of any reported proportions and percentages (functional status, CD4 ≥ 200 and cohort alive and on ART). Having facilities report both the denominator and numerator for each proportion will facilitate aggregation. Aggregate proportions will thus be the total of all numerators across facilities over the total of all denominators across facilities.

G. Alternative approaches to calculating indicators

Many analyses are possible without a register or an electronic system. These can be done by simple tabulation methods such as card sorts or by stickers, flags or coloured paper clips on cards to indicate patients for review by the clinical team, etc. Patient monitoring should be used actively as a tool for quality improvement, both directly within the clinical team itself and with assistance from other teams, from the district or regional coordinators, or from mentors on follow-up visits after training. Motivation is important. Patient monitoring and the simple aggregation of data need to be satisfying, possibly even fun.

The fourth row in the table in *Annex B* describes summary data which can be derived directly from the patient card, for use only by the clinical team in individual patient management, for certain TB/HIV indicators, or for special studies. These data are not summarized by being transferred to the register. They can be analysed using card sorts or other methods. A special kanga (large piece of printed cloth common in Africa) has been designed to assist with certain card sorts.

H. Information collected on a yearly basis (in development)

It may be important to collect certain information for programmatic reasons, but may be difficult and impractical to do so routinely, particularly in low-resource settings. Some indicators are best done by on-site review of a sample of cards, while other methods include case review, key informant or exit interviews, and direct observation. These include: the percentage of ART patients treated for TB within the last year; adherence to ART; STI incidence; the percentage of pregnant patients referred to or provided with PMTCT; and the incidence of adverse reactions. A yearly report form and other tools are in development to assist with this type of data collection.

I. Roles and responsibilities within patient monitoring

Within an HIV care/ART patient monitoring system, there are several roles filled by different people and teams.

(**1) Clinical team** responsibilities include:

- Filling out patient card during individual patient management;
- Drug dispensing and adherence data collection and reporting;
- Regular clinical team review of cases (with medical officer when available);
- Consulting or referring to medical officer concerning unusual or serious patient outcomes and record on patient card;
- Carrying out facility-based data collection and reporting (up to district level) for patient monitoring; and
- Quality assurance through regular internal review or analysis of patient monitoring data.

In addition, someone on the clinical team or a trained data clerk or secretary should be responsible for updating the pre-ART and ART register, aggregating data for the quarterly cross-sectional and cohort analysis reports, and reviewing with the district ART coordinator on-site;

In a simplified system such as the WHO illustrative system, which limits what is kept on the paper record, a triage worker, receptionist or data clerk first interacts with the patient and retrieves the patient record, weighs the patient and records this on the card, and decides whether the patient needs to see a health worker or counsellor/patient educator (or both) on this visit.

An ART aid or other person trained to provide patient education and basic counselling would record data on the education and counselling summary form (this is neglected in some patient monitoring systems but is an essential component of care). S/he would also assess adherence and record this on the patient's card.

The health worker performs a full clinical review (often guided by a laminated form) but only records the key treatment data and pertinent positives on the patient card. Other details of an acute illness might be recorded in a patient-held exercise book or "patient passport" (for example, the Malawi health passport). A more elaborate recording system would retain and record all relevant events captured in the clinical review as well as detailed treatment data. This requires a full chart and space for chart storage with prompt retrieval for patient care.

The health worker would assess and record adherence to prophylaxis and ART and record the medications to be provided on the card with the number of doses dispensed, and, in larger

facilities, also on a prescription form which is taken to the pharmacy. On a small clinical team in a health centre, dispensing might also be done by a health worker who would also be responsible for stock card and other drug supply management notations.

If advice is sought by phone, a succinct summary of the case and problem would be prepared and information recorded in the phone consultation log.

If referral is necessary, the doctor/institution is consulted prior to referral if possible, a referral note is prepared (based on an agreed format), and a copy of the patient record or essential data from the patient record should accompany the patient or be sent electronically where feasible.

It is advisable to have a data clerk assisting the team to keep track of the patient cards, to update the registers and tabulate the reports. If not, this work needs to be done by a designated clinical team member who receives additional training. This person can often be trained to also greet patients, weigh them, retrieve their card, and help them meet with the appropriate person on the clinical team. Trained PLHAs can be particularly effective in this role. This team member should be able to:

- Enter data from paper forms to registers or transferring data from paper forms to electronic database at different stages of data aggregation; and
- File and retrieve patient cards and records; indicate patients who miss follow-up appointments and help arrange for tracing.

(2) Assistance from community-based workers and organizations. These can be very helpful in tracing lost patients, in treatment support, reporting on adherence, delivering medications, etc.

(3) District management team. This team is led by a district ART coordinator, and is overall responsible for aggregate data collection and reporting from facilities. While the coordinator may be a specific person with monitoring responsibility, the team will be comprised of a range of persons from various backgrounds including those with TB experience, statistical expertise, etc. The team should be able to:

- Enter data from paper forms to registers or transfer data from paper forms to electronic database at different stages of data aggregation;
- Enter ART register data on-site;
- Supervise and ensure proper HIV care/ART at health facilities in district;
- Conduct regular facility visits and periodic survey of patient monitoring system (clinical team performance, case management, TB monitoring);
- Supervise and assist with patient monitoring and facility-based data reporting (make sure cards and registers are appropriately filled out);
- Review, recalculate, finalize, and transmit facility-level cohort analysis forms;
- Aggregate facility-level data from all HIV care/ART facilities in the district and transmit;
- Analyse and report on district-level indicators to national level;
- Manage patient transfers within district and to other districts; and
- Manage the drug supply.

Quality assurance efforts after training are well served by a simple standardized patient monitoring system which can help clinical teams organize their work, and maintain a sense of the needs and status of their HIV patients as a group. Making sure specific clinical parameters are assessed on a routine basis can facilitate better clinical care and serve as a supervisory tool. Patient monitoring also includes a system to follow patients when they are referred to special services or transfer from one facility to another.

(4) Clinical mentor. An experienced clinician with expertise in chronic HIV care, ART and opportunistic infection management, as well as the patient monitoring system should be able to:

- Provide assistance and guidance to clinical team to facilitate individual patient management, both on-site and by distance communications (phone, email);
- Periodically participate on-site in clinical team case reviews. During these visits, review the patient registers and selected patient cards;
- Review reasons for substitutions and switches medical officers' case logs; and
- Review uncommon or unexpected side-effects and OIs.

J. Training materials

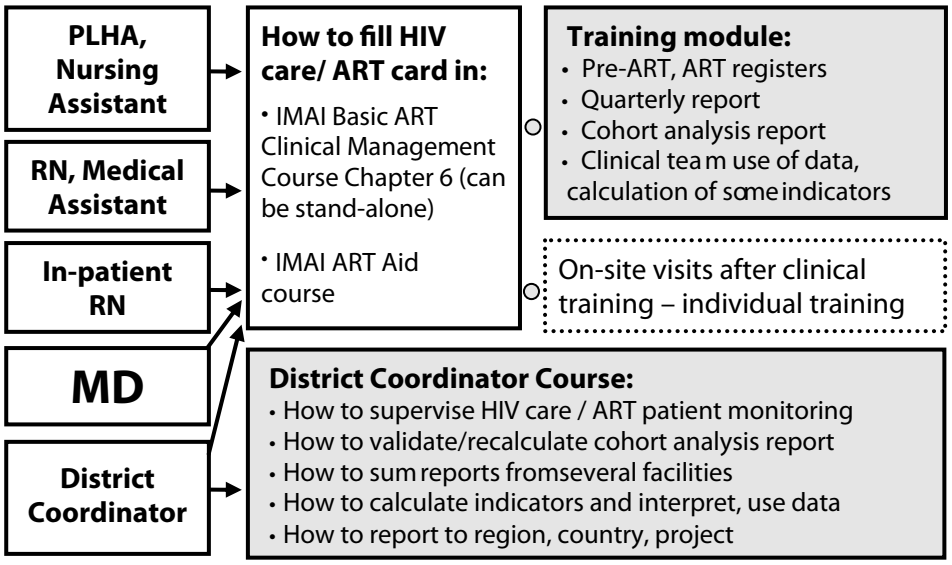
As shown in *Fig. 9*, training materials are available to:

- Teach health workers and counsellors how to fill out the HIV care/ART card. For the WHO version of the card, the WHO IMAI chronic HIV care with ART clinical guidelines explain how to fill out the HIV care ART card. Many of the variable definitions, explanations, and coding options are taught in the clinical training course.[1]
- Teach a health worker or a PLHA or other lay provider working with the clinical team to transfer data to the registers and complete the quarterly report and cohort analysis forms.
- Prepare the district ART coordinator and clinical team to use the data to calculate simple indicators and monitor care.

Guidelines and training materials are in development to guide the national and district ART programme manager to sum data from the quarterly and cohort reports and solve problems.

[1] World Health Organization. WHO basic ART clinical training course, based on IMAI HIV care with ARV therapy. Geneva, WHO, 2005 (http://www.who.int/3by5/capacity/en/).

Fig. 9. WHO HIV care/ART patient monitoring training



CHAPTER FIVE

Practical application of patient monitoring tools: country and project examples

Introduction

Many countries and projects have created their own versions of the patient cards, registers and reporting forms. While in general the examples presented in this chapter contain the same basic elements outlined in these guidelines, they differ in how and how often data are collected and in the format of the forms used. This reflects the varied data collection needs and resources.

There is obviously freedom to use different formats including a full patient chart; to collect additional data; and to adapt the forms to the country's clinical guidelines (for example, if no INH prophylaxis is routinely provided for HIV patients there should be no column on the card). It is important to standardize the system nationally with allowances for collecting more data or different formats for patient cards or charts. With the large resources available for some facilities, point-of-service flexibility is a good principle if a strong routine national system can still be built if there is standardization around collection and reporting based on the minimum data set and the internationally agreed indicators and definitions.

In a simplified system, which limits paper and health worker time required for data recording, there is often a laminated form to assist the clinical review; the health worker then records key treatment data and relevant information on a card. Other details of an acute illness might be recorded in a patient-held card or exercise book. A more elaborate recording system would retain and record all positives and negatives of clinical review and detailed treatment data. This requires a full chart and space for chart storage with prompt retrieval for patient care. A review of various patient record systems showed a wide range in the number of pages per patient visit from 0.05 (multiple visits on a single card) to 8 pages.

The following is a compilation of country and project examples of forms currently being used and adapted in the field, including a brief description of how these forms have been adapted.

Thyolo District, Malawi

These are monitoring tools that have been piloted and used in Thyolo District, Malawi since April 2003 and have now been introduced in all district outpatient ART clinics. This simple system focuses on patient outcomes and is based on the TB model of reporting and evaluating.

Patient master record card
Patients are issued personal identity cards and the facility keeps *patient master cards*, both carrying the same basic information. Regular follow-up of patients allows for monthly collection of information on the master cards monitoring weight, functional status, side-effects, adherence, and patient outcomes (alive, dead, defaulted, stopped, transfer out).

ART register
While the system does not currently make use of a pre-ART register, a simple *ART register* has been developed. For now, master cards are filed by the quarter in which the patient started on ART.

Quarterly cohort analysis
The system uses both cross-sectional and cohort analysis to monitor treatment outcomes: *Quarterly ARV cohort analysis* of patient master cards is carried out retrospectively. Treatment outcome, functional status and adherence rates are documented for the last month of the quarter as soon as the quarter ends. Outcome data for this cohort are analysed every three months.

Cumulative cohort analysis
Cumulative ARV quarterly analysis is a cross-sectional analysis of all cohorts. This is also carried out quarterly, but allows for an analysis of all patients who have ever started on treatment and yields information on patient outcome totals (described above). However, as the programme continues and the number cohorts increases, the cumulative analysis of these cohorts, particularly if paper-based, may become problematic. This could be solved by carrying out the cumulative analysis at 6 or 12 months, or transitioning to an electronic system.[1]

[1] Harries DH, Gomani P, Teck R, et al. Monitoring the response to antiretroviral therapy in resource-poor settings: the Malawi model. *Transactions of the Royal Society of Tropical Medicine and Hygiene*, 2004, 98: 695-701.

PATIENT MASTER RECORD CARD FOR ARV: Unique ARV Number CKW/ARV/01 Year 2004

Name: Mr Joshua Phiri Age: 34 Sex: M Initial Wt (Kg): 48 Transfer-In (Y/N): N

Address (physical/PO Box): TA Mtemba, near Chikwawa Boma, Chikwawa District

Name of identifiable guardian: Mr John Phiri

Date of starting 1st line ARV regimen (specify d4t/3TC/NVP formulation): Jul 14 -d4T-30mg Reason for ARV: Stage III (Pneumonia)

Date of starting alternative 1st line ARV regimen (specify) Date of starting 2nd line ARV regimen (specify)

yr	month	Date	WtKg	Outcome status					Of those alive			Ambulatory		Work/school		Side effects		No. Pills inBottle	ARVGiven		ARV notgi-ven
				A	D	DF	Stop	TO	Start	Sbs	Switch	Amb	Bed	Yes	No	Y	N		P	G	
200_	jan																				
	feb																				
	mar																				
	apr																				
	mai																				
	jun																				
2004	jul	14	48	x					x			x		x			x		x		
	aug	28	49	x					x			x		x			x	4	x		
	sep	26	50	x					x			x		x			x	2	x		
	oct	24	51	x					x			x		x		PN		4	x		
	nov																				
	dec																				

Outcome status: A=alive on ARV drugs; D=dead -whatever the cause; DF=default -not seen in three months; Stop=stopped treatment dueto side effects/other; TO=transfer-out to another ARV treatment unit
Of those alive: Start=on first line regimen; Sbs=substitute -changed to alternate first line regimen; Switch=changed to second line regimen

Ambulatory: Amb=able to walk to/at treatment unit and walks at home unaided; Bed=most of time in bed at home
Work/school: Yes=engaged in at previous work/employment or at school
Side effects: If Yes, specify – YES-PN=peripheral neuropathy; YES-HP=hepatitis; YES-SK=skin rash
No. Pills in bottle: If patient comes at 4 weeks count number of pills in bottle (8 pills or less = 95% adherent)
ARV given/not given: tick whether ARV therapy given in the appropriate column P=patient, G=guardian; if no ARV, then indicate why

Malawi ART register

ARV Registration Number	Year	Quarter	Date of registration	Name	Sex	Age	Address	Date first started ARV drugs	Reason for starting ARV drugs	Name/Address of Guardian	ARV Treatment Unit

Reason for starting ARV Drug: Stage III, Stage IV, CD4 count < 200/mm^3, Stage II with TLC < 1200/mm^3, Tuberculosis, Transfer-in

Quarters: 1 = January to March: 2 = April to June: 3 = July to September: 4 = October to December

Outcome (provide date when patient changes outcome from alive)					Of those alive (provide date when change from start)			Ambulant		At work or (in children at school)		Drug adherence > 95%		Remarks
Alive	Dead	Default	Stop	Transfer	Start	Substitute	Switch	Yes	No	Yes	No	Yes	No	

Alive - alive on ARV drugs: Dead - whatever the cause: Default - not seen in three months: Stop - stopped treatment due to side effects/other: Transfer - transfer-out to another ARV treatment unit

Start - on first line regimen: Substitute - changed to alternate first line regimen: Switch - changed to second line regimen
Ambulant - yes/no: At work or school - at previous or new employment for adults
Adherence > 95% - pill counts of 8 tablets or less when patient comes for review

ARV QUARTERLY COHORT ANALYSIS FORM*

NAME OF TREATMENT UNIT _____ **Thyolo DH**
COHORT [specify the year and the quarter] _____ 2003, Q2
Total number of patients initially registered for ARV in the cohort _____ 116
Year in which evaluation is taking place: _____ 2003
Date at which evaluation is taking place _____ July 10th

Of total number registered in the cohort:

Number Alive and on ARV therapy _____ 106 (91%)
[Alive and on First line regimen _____ 101]
[Alive and on Alternative first line regimen _____ 5]
[Alive and on Second line regimen _____ 0]
Dead _____ 6
Defaulted _____ 0
Stopped _____ 4
Transferred out to another treatment unit _____ 0

Of those Alive:

Number	Ambulatory	106
	At work	No information
	With side effects	14
	With Pill count in bottle 8 or less	63/63
	Note: Pill count in bottle 8 or less is equivalent to 95% adherence	

*Source: Harries AD. Scaling up ARV therapy: Integration of TB and HIV. HIV/AIDS Unit, Ministry of Health, Malawi.

The cumulative analysis needed of ten quarters registered for ARV therapy between April 2003 and September 2005*

Cohorts are numbered from 1 to 10, with first cohort being all patients registered for ARV therapy between April and June 2003, the second being patients registered between July and September, and so on	**Year and quarter in which each cohort is evaluated: based on Thyolo District Hospital predictions**									
	2003: q3	**2003: q4**	**2004: q1**	**2004: q2**	**2004: q3**	**2004: q4**	**2005: q1**	**2005: q2**	**2005: q3**	**2005: q4**
	Cohort 1	Cohort 1	Cohort1	Cohort 1	Cohort 1	Cohort 1	Cohort 1	Cohort 1	Cohort 1	Cohort 1
		Cohort 2	Cohort 2	Cohort 2	Cohort 2	Cohort 2	Cohort 2	Cohort 2	Cohort 2	Cohort 2
			Cohort 3	Cohort 3	Cohort 3	Cohort 3	Cohort 3	Cohort 3	Cohort 3	Cohort 3
				Cohort 4	Cohort 4	Cohort 4	Cohort 4	Cohort 4	Cohort 4	Cohort 4
					Cohort 5	Cohort 5	Cohort 5	Cohort 5	Cohort 5	Cohort 5
						Cohort 6	Cohort 6	Cohort 6	Cohort 6	Cohort 6
							Cohort 7	Cohort 7	Cohort 7	Cohort 7
								Cohort 8	Cohort 8	Cohort 8
									Cohort 9	Cohort 9
										Cohort 10
Cumulative analysis	Cohort 1	Cohorts 1+2	Cohorts 1+2+3	Cohorts 1+2+3+4	Cohorts 1+2+3+4+5	Cohorts 1+2+3+4 +5+6	Cohorts 1+2+3+4 +5+6+7	Cohorts 1+2+3+4 +5+6+7+8	Cohorts 1+2+3+4 +5+6+7 +8+9	Cohorts 1+2+3+4 +5+6+7 +8+9+10

*Source: Harries AD, et al. Cohort analysis for monitoring the response to antiretroviral therapy in resource-poor settings: the Malawi model2004. Draft.

Western Cape Province, South Africa

The system developed in the Western Cape, South Africa is based on three levels of information: individual patient management through clinical record-keeping using patient-held and facility-based patient cards; facility-based record-keeping through the use of registers; and cohort monitoring through quarterly treatment reports. For a complete list of monitoring tools and instructions, please refer to the Western Cape ART rollout resource website: http://www.epi.uct.ac.za/artrollout/.

Patient card encounter form
The patient encounter form is a different presentation of the summary page in the WHO HIV care/ART card and is the most successful and well-validated component of the system.

Pre-ART and ART registers
The pre-ART and ART registers are very similar to those presented in the WHO system, with the exception that the Western Cape pre-ART register also tracks CD4 count and the ART register tracks viral load and CD4 count.

Monthly report (including drug regimen breakdown)
The monthly report is a more simplified version of the WHO quarterly report, and the treatment cohort report, like the ART register, includes viral load and CD4 count summaries.

Treatment cohort report and completed report
The completed treatment cohort report form is based on pilot data collected from sites representing a 24-month history.

Patient transfer form
The patient transfer form presents an example of information that may be collected to transfer a patient between facilities.

Western Cape patient encounter form

Visit date	/ /			/ /			/ /			/ /			/ /		
Visit type	Nurse Doctor			Nurse Doctor			Nurse Doctor			Nurse Doctor			Nurse Doctor		
Date next visit	/ /			/ /			/ /			/ /			/ /		
Stage															
Weight															
Height / BSA (child)															
Bloods taken															
CD4 (CD4%)															
Viral Load															
HB															
PLT															
Neut															
TLC x 1000															
Triglycerides															
Cholesterol															
Glucose															
ALT															
Other results															
RPR															
Chest X-ray															
Referred / hospitalised															
FP / Condoms / Pap	FP	CON	PAP	FP	CON	PAP	FP	CON	PAP	FP	CON	PAP	FP	CON	PAP
HIV conditions / OI's / TB 1															
2															
3															
4															
5															
6															
TB symptoms															
Months on TB Rx															
TB M / C / S															
Months on ART															
Months on regimen															
Pill count	In	Out		In	Out		In	Out		In	Out		In	Out	
Medication, incl. ARVs and prophylaxis: ARV1															
ARV2															
ARV3															
ARV4 or other															
ARV5 or other															
ARV6 or other															
other															
other															
INH															
Cotrimoxazole															
Fluconazole															
Adverse event / grade															
Adverse event / grade															
Captured	Date			Date			Date			Date			Date		

ART 4

Western Cape pre-ART register

Month arriving at the clinic				Age & Gender																			
Page	Date started in care at clinic (DD/MM)	Patient's Name, Surname, folder number and ID number	Outcome Died/ Lost/ TFO/ ART / Date	Adult Female	Adult Male	Child < 14yo Fem	Child < 14yo Male	DOB -------- DD/MM/ YY	Date VCT -------- DD/MM/ YY	CD4 Value DD/MM/YY	CD4 Value DD/MM/YY	CD4 Value DD/MM/YY	CD4 Value DD/MM/YY	CD4 Value DD/MM/YY	CD4 Value DD/MM/YY	A	B	C	D	E	Comments	
1		Folder # ID	/ /							/ /	/ /	/ /	/ /	/ /	/ /						1	
2		Folder # ID	/ /							/ /	/ /	/ /	/ /	/ /	/ /						2	
3		Folder # ID	/ /							/ /	/ /	/ /	/ /	/ /	/ /						3	
4		Folder # ID	/ /							/ /	/ /	/ /	/ /	/ /	/ /						4	
5		Folder # ID	/ /							/ /	/ /	/ /	/ /	/ /	/ /						5	
6		Folder # ID	/ /							/ /	/ /	/ /	/ /	/ /	/ /						6	
7		Folder # ID	/ /							/ /	/ /	/ /	/ /	/ /	/ /						7	
8		Folder # ID	/ /							/ /	/ /	/ /	/ /	/ /	/ /						8	
9		Folder # ID	/ /							/ /	/ /	/ /	/ /	/ /	/ /						9	
10		Folder # ID	/ /							/ /	/ /	/ /	/ /	/ /	/ /						10	
11		Folder # ID	/ /							/ /	/ /	/ /	/ /	/ /	/ /						11	
12		Folder # ID	/ /							/ /	/ /	/ /	/ /	/ /	/ /						12	
13		Folder # ID	/ /							/ /	/ /	/ /	/ /	/ /	/ /						13	
14		Folder # ID	/ /							/ /	/ /	/ /	/ /	/ /	/ /						14	
15		Folder # ID	/ /							/ /	/ /	/ /	/ /	/ /	/ /						15	
16		Folder # ID	/ /							/ /	/ /	/ /	/ /	/ /	/ /						16	
17		Folder # ID	/ /							/ /	/ /	/ /	/ /	/ /	/ /						17	
18		Folder # ID	/ /							/ /	/ /	/ /	/ /	/ /	/ /						18	
19		Folder # ID	/ /							/ /	/ /	/ /	/ /	/ /	/ /						19	
20		Folder # ID	/ /							/ /	/ /	/ /	/ /	/ /	/ /						20	
			TOTALS																			

Western Cape ART register

Cohort				Outcome	Age & Gender																																						
																1	2	At 3 months: (Report on events between starting ARV's & 3 months)				4	5	At 6 months: (Report on events between 3 & 6 Months)					7	8	9	10	11	At 12 months: (Report on events between 6 & 12 months)					
Page	Date started (DD/MM)		Patient's Name, Surname, folder number and ID number	Died/ Lost/ TFO / Date	Adult Female	Adult Male	Child < 14yo Fem	Child < 14yo Male	Funding source: (S)tate / (O)ther	Prior ART (P)MTCT/ (H)AART	Pregnant when starting ART	WHO stage	Viral Load	CD 4 Count	Starting regimen			Regimen	Viral load	Outcome (R)IP/(L)TF/(T)FO	Transfer In			Regimen	Viral load	CD4	Outcome (R)IP/(L)TF/(T)FO	Transfer In						Regimen	Viral load	CD4	Outcome (R)IP/(L)TF/(T)FO	Transfer In	
1			Folder # ID Y Y M M D D	/ /																																							1
2			Folder # ID Y Y M M D D	/ /																																							2
3			Folder # ID Y Y M M D D	/ /																																							3
4			Folder # ID Y Y M M D D	/ /																																							4
5			Folder # ID Y Y M M D D	/ /																																							5
6			Folder # ID Y Y M M D D	/ /																																							6
7			Folder # ID Y Y M M D D	/ /																																							7
8			Folder # ID Y Y M M D D	/ /																																							8
9			Folder # ID Y Y M M D D	/ /																																							9
10			Folder # ID Y Y M M D D	/ /																																							10
11			Folder # ID Y Y M M D D	/ /																																							11
12			Folder # ID Y Y M M D D	/ /																																							12
13			Folder # ID Y Y M M D D	/ /																																							13
14			Folder # ID Y Y M M D D	/ /																																							14
15			Folder # ID Y Y M M D D	/ /																																							15
16			Folder # ID Y Y M M D D	/ /																																							16
17			Folder # ID Y Y M M D D	/ /																																							17
18			Folder # ID Y Y M M D D	/ /																																							18
19			Folder # ID Y Y M M D D	/ /																																							19
20			Folder # ID Y Y M M D D	/ /																																							20
				TOTALS																																							
TOT										EXP								FLR	VLD	VLS	RIP	TFI			FLR	VLD	VLS	CDD	CDA	RIP	TFI						FLR	VLD	VLS	CDD	CDA	RIP	TFI	
																		SLR			LTF				SLR					LTF							SLR					LTF		
																		STO			TFO				STO					TFO							STO					TFO		

Adult 1st Line Regimens

1a(30) = d4t(30)-3TC-EFV
1a(40) = d4t(40)-3TC-EFV
1b(30) = d4t(30)-3TC-NVP
1b(40) = d4t(40)-3TC-NVP
1c = AZT-3TC-NVP
1d = AZT-3TC-EFV
1e =
1N = non-standard regimen

Adult 2nd Line Regimens

2a = AZT-ddl-LPV/r (<60kg)
2a2 = AZT-ddl-LPV/r (>=60kg)
2b =
2c =
2d =
2N = non-standard regimen noted in comments

Paed. 1st Line Regimens

P1a = d4t-3TC-EFV
P1b = d4t-3TC-NVP
P1c = AZT-3TC-NVP
P1d = AZT-3TC-EFV
P1e = d4T-3TC-LPV/r
P1f = AZT-3TC-LPV/r
P1g = d4T-3TC-RTV
P1h = AZT-3TC-RTV
P1i =
P1N = non-standard

Paed. 2nd Line Regimens

P2a = AZT-ddl-LPV/r
P2b = AZT-ddl-NVP
P2c = AZT-ddl-EFV
P2d = ABC-ddl-LPV/r
P2e = ABC-ddl-NVP
P2f = ABC-ddl-EFV
P2g =
P2N = non-standard

Stop codes

S1 Toxicity/ side effects
S2 Contraindication - pregnancy
S3 Treatment failure
S4 Poor adherence
S5 Hospitalisation / too ill
S6 Drug out of stock
S7 Patient reason
S8 Other patient decision
S9 Planned interruption
S10 Other

ART 5a

	13	14	15	16	17	At 18 months: (Report on events between 12 & 18 months)					19	20	21	22	23	At 24 months: (Report on events between 18 & 24 months)					25	26	27	28	29	At 30 months: (Report on events between 24 & 30 Months)					31	32	33	34	35	36	Regimen changes		Comments	
						Regimen	Viral load	CD4	Outcome (R)IP/(L)TF(T)FO	Transfer In						Regimen	Viral load	CD4	Outcome (R)IP/(L)TF(T)FO	Transfer In						Regimen	Viral load	CD4	Outcome (R)IP/(L)TF(T)FO	Transfer In						Transfer to the follow-on register	New regimen / Reason for switch / Date	New regimen / Reason for switch / Date		
1																																					/ /	/ /	1	
2																																					/ /	/ /	2	
3																																					/ /	/ /	3	
4																																					/ /	/ /	4	
5																																					/ /	/ /	5	
6																																					/ /	/ /	6	
7																																					/ /	/ /	7	
8																																					/ /	/ /	8	
9																																					/ /	/ /	9	
10																																					/ /	/ /	10	
11																																					/ /	/ /	11	
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16																																					/ /	/ /	16	
17																																					/ /	/ /	17	
18																																					/ /	/ /	18	
19																																					/ /	/ /	19	
20																																					/ /	/ /	20	
																																					TOTALS			
						FLR	VLD	VLS	CDD	CDA	RIP	TFI				FLR	VLD	VLS	CDD	CDA	RIP	TFI						FLR	VLD	VLS	CDD	CDA	RIP	TFI						
						SLR					LTF					SLR					LTF							SLR					LTF							
						STO					TFO					STO					TFO							STO					TFO							

Reasons for regimen changes
(substitutions and switches)

1 Toxicity
2 Pregnancy
3 Risk of pregnancy
4 New TB
5 Change in protocol
6 Drug out of stock
7 Other patient reason
8 Clinical Treatment Failu
9 Immunological Treatme
10 Virological Treatment F

ART 5b

Monthly ART reporting form with regimen details

Year		District	
Month		Facility	
Date Reported		Completed by	

	Adults		Children		
	At end of month		At end of month		
	On ART	Due to start	On ART	Due to start	
d4T (30) / 3TC / EFV - 1a(30)					P1a
d4T (40) / 3TC / EFV - 1a(40)					
d4T (30) / 3TC / NVP - 1b(30)					P1b
d4T (40) / 3TC / NVP - 1b(40)					
AZT / 3TC / NVP - 1c					P1c
AZT / 3TC / EFV - 1d					P1d
Other first line ( )					
Other first line ( )					
AZT / ddI / LPV/r (<60kg) - 2a1					P2a
AZT / ddI / LPV/r (>=60kg) - 2a2					
Other second line ( )					
Other second line ( )					
Total remaining in care					

	Past month	Cumulative	Past month	Cumulative
Started on ART				
Cross-sectional % remaining in care Total remaining in care / Cummulative number started on ART x 100		%		%

Notes relating to drug availability and need for emergency procurement

General notes

ART 1

Western Cape quarterly treatment cohort report

Quarterly ART cohort reporting form

District: Facility: Adults or children:

	Treatment Cohort	Q1 '04	Q2 '04	Q3 '04	Q4 '04	2004	Q1 '05	Q2 '05	Q3 '05	Q4 '05	2005	Q1 '06	Q2 '06	Q3 '06	Q4 '06	2006	
Starting ART	Number non-naive commenced (EXP)																
	Number of ART-naive patients commenced (TOT)																
	Number of ART-naïve male																
	Number of ART-naïve female																
	Number with CD4 below 50/ul or 20% TLC																
After 3 months	Continuing first-line regimen (FLR)																
	On second line regimen (SLR)																
	Treatment discontinued (STO)																
	Viral load done (some projects) (VLD)																
	Viral load < 400 copies/mL (if applicable) (VLS)																
	Died (RIP)																
	Lost to follow-up (LTF)																
	Transferred out (TFO)																
	Transferred in (TFI)																
After 6 months	Continuing first-line regimen (FLR)																
	On second line regimen (SLR)																
	Treatment discontinued (STO)																
	CD4 counts done (CDD)																
	CD4 counts above 200 cells/ ?l or 20% TLC (CDA)																
	Viral load done (some projects) (VLD)																
	Viral load < 400 copies/mL (if applicable) (VLS)																
	Died between 3 and 6 months (RIP)																
	Lost to follow-up between 3 and 6 months (LTF)																
	Transferred out between 3 and 6 months (TFO)																
	Transferred in between 3 and 6 months (TFI)																
After 12 months	Continuing first-line regimen (FLR)																
	On second line regimen (SLR)																
	Treatment discontinued (STO)																
	CD4 counts done (CDD)																
	CD4 counts above 200 cells/ ?l or 20% TLC (CDA)																
	Viral load done (some projects) (VLD)																
	Viral load < 400 copies/mL (if applicable) (VLS)																
	Died between 6 and 12 months (RIP)																
	Lost to follow-up between 6 and 12 months (LTF)																
	Transferred out between 6 and 12 months (TFO)																
	Transferred in between 6 and 12 months (TFI)																
After 18 months	Continuing first-line regimen (FLR)																
	On second line regimen (SLR)																
	Treatment discontinued (STO)																
	CD4 counts done (CDD)																
	CD4 counts above 200 cells/ ?l or 20% TLC (CDA)																
	Viral load done (some projects) (VLD)																
	Viral load < 400 copies/mL (if applicable) (VLS)																
	Died between 12 and 18 months (RIP)																
	Lost to follow-up between 12 and 18 months (LTF)																
	Transferred out between 12 and 18 months (TFO)																
	Transferred in between 12 and 18 months (TFI)																
After 24 months	Continuing first-line regimen (FLR)																
	On second line regimen (SLR)																
	Treatment discontinued (STO)																
	CD4 counts done (CDD)																
	CD4 counts above 200 cells/ ?l or 20% TLC (CDA)																
	Viral load done (some projects) (VLD)																
	Viral load < 400 copies/mL (if applicable) (VLS)																
	Died between 18 and 24 months (RIP)																
	Lost to follow-up between 18 and 24 months (LTF)																
	Transferred out between 18 and 24 months (TFO)																
	Transferred in between 18 and 24 months (TFI)																

Western Cape example of completed treatment cohort report

Category	Data	2001 01_Q2	01_Q3	01_Q4	2001 Total	2002 02_Q1	02_Q2	02_Q3	02_Q4	2002 Total	2003 03_Q1	03_Q2	03_Q3	03_Q4	2003 Total	2004 04_Q1	04_Q2	04_Q3	2004 Total	Grand Total
Base																				
	Total	31	28	26	85	58	66	65	48	237	74	105	103	136	418	229				969
	CDD	31	28	24	83	58	65	65	48	236	74	101	103	132	410	217				
	%CD4<50	64.5%	42.9%	50.0%	53.0%	53.4%	40.0%	44.6%	58.3%	48.3%	45.9%	43.6%	29.1%	34.8%	37.6%	39.6%				
	Male%	32.3%	32.1%	26.9%	30.6%	31.0%	36.4%	32.3%	33.3%	33.3%	29.7%	31.4%	33.0%	35.3%	32.8%	29.7%				
	AIDS%	51.6%	35.7%	50.0%	45.9%	51.7%	37.9%	49.2%	52.1%	47.3%	39.2%	54.3%	39.8%	47.8%	45.9%	50.7%				

Category	Data	2001 01_Q2	01_Q3	01_Q4	2001 Total	2002 02_Q1	02_Q2	02_Q3	02_Q4	2002 Total	2003 03_Q1	03_Q2	03_Q3	03_Q4	2003 Total		
3 month																	
	FLR	27	25	22	74	55	55	59	44	213	71	91	90	122	374		
	SLR	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
	STO	1	0	0	1	1	0	0	1	2	1	2	2	1	6		
	VLD	25	24	22	71	45	49	49	38	181	58	75	74	108	315		
	VLS	21	21	18	60	41	44	46	30	161	44	70	69	86	269		
	CDD	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
	CDA	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
	RIP	3	2	4	9	2	9	6	3	20	2	10	8	11	31		
	LTF	0	0	0	0	0	1	0	0	1	0	1	2	2	5		
	TFO	0	1	0	1	0	1	0	0	1	0	0	1	0	1		
	Perc died	9.7%	7.4%	15.4%	10.7%	3.4%	14.1%	9.2%	6.3%	8.5%	2.7%	9.7%	8.0%	8.2%	7.5%		
	Perc ltf	0.0%	0.0%	0.0%	0.0%	0.0%	1.8%	0.0%	0.0%	0.5%	0.0%	1.1%	2.1%	1.6%	1.3%		
	Perc rip or ltf	9.7%	7.4%	15.4%	10.7%	3.4%	15.4%	9.2%	6.3%	8.9%	2.7%	10.6%	9.8%	9.6%	8.7%		
	Remaining in care	90.3%	89.3%	84.6%	88.2%	96.6%	83.3%	90.8%	93.8%	90.7%	97.3%	88.6%	89.3%	89.8%	90.7%		
	Perc stopped	3.6%	0.0%	0.0%	1.3%	1.8%	0.0%	0.0%	2.2%	0.9%	1.4%	2.2%	2.2%	0.8%	1.6%		
	Perc on SLR	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%		
	VL Completion	92.6%	96.0%	100.0%	95.9%	81.8%	89.1%	83.1%	86.4%	85.0%	81.7%	82.4%	82.2%	88.5%	84.2%		
	VLS%	84.0%	87.5%	81.8%	84.5%	91.1%	89.8%	93.9%	78.9%	89.0%	75.9%	93.3%	93.2%	79.6%	85.4%		
	ITT VL < 400	77.8%	84.0%	81.8%	81.1%	74.5%	80.0%	78.0%	68.2%	75.6%	62.0%	76.9%	76.7%	70.5%	71.9%		
6 month																	
	FLR	26	23	22	71	54	53	59	43	209	68	87	90				
	SLR	0	0	0	0	0	0	0	0	0	0	0	0				
	STO	2	0	0	2	0	0	0	1	1	1	4	2				
	VLD	25	23	21	69	53	49	54	36	192	59	74	83				
	VLS	22	22	17	61	47	44	48	32	171	56	69	69				
	CDD	25	23	20	68	50	49	54	34	187	59	72	88				
	CDA	9	15	11	35	23	22	28	16	89	28	41	47				
	RIP	0	2	0	2	2	2	0	1	5	3	3	0				
	LTF	0	0	0	0	0	0	0	0	0	0	0	0				
	TFO	0	0	0	0	0	0	0	0	0	0	0	0				
	Perc died	0.0%	8.0%	0.0%	2.7%	3.6%	3.6%	0.0%	2.2%	2.3%	4.2%	3.2%	0.0%				
	Perc ltf	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%				
	Perc rip or ltf	0.0%	8.0%	0.0%	2.7%	3.6%	3.6%	0.0%	2.2%	2.3%	4.2%	3.2%	0.0%				
	Remaining in care	90.3%	82.1%	84.6%	85.9%	93.1%	80.3%	90.8%	91.7%	88.6%	93.2%	86.7%	89.3%				
	Perc stopped	7.1%	0.0%	0.0%	2.7%	0.0%	0.0%	0.0%	2.3%	0.5%	1.4%	4.4%	2.2%				
	Perc on SLR	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%				
	VL Completion	96.2%	100.0%	95.5%	97.2%	98.1%	92.5%	91.5%	83.7%	91.9%	86.8%	85.1%	92.2%				
	VLS%	88.0%	95.7%	81.0%	88.4%	88.7%	89.8%	88.9%	88.9%	89.1%	94.9%	93.2%	83.1%				
	ITT VL < 400	84.6%	95.7%	77.3%	85.9%	87.0%	83.0%	81.4%	74.4%	81.8%	82.4%	79.3%	76.7%				
	CD4 Completion	89.3%	100.0%	90.9%	93.2%	92.6%	92.5%	91.5%	77.3%	89.0%	85.5%	79.1%	95.7%				
	CD4 > 200	36.0%	65.2%	55.0%	51.5%	46.0%	44.9%	51.9%	47.1%	47.6%	47.5%	56.9%	53.4%				
	ITT CD4 > 200	32.1%	65.2%	50.0%	47.9%	42.6%	41.5%	47.5%	36.4%	42.4%	40.6%	45.1%	51.1%				

FLR	On first line regimen	Perc died	Percentage of patients dying in the period
SLR	On second line regimen	Perc ltf	Percentage of patients lost to follow-up in the period
STO	Stopped ART but still in care	Perc rip or ltf	Percentage of patient who have either died or been lost to follow-up
VLD	Viral loads done	Remaining in care	Cumulative percentage of patients remaining in care
VLS	Viral load results under 400 cps/mL	Perc stopped	Percentage of patients who have stopped therapy at this duration on ART
CDD	CD4 counts done	Perc on SLR	Percentage of patients on second-line therapy at this duration on ART
CDA	CD4 counts above 200/ul	VL Completion	Percentage of viral loads done that should have been done
RIP	New deaths	VLS%	Of the viral loads done, the percentage below 400 cps/mL
LTF	New losses to followup	ITT VL < 400	Intention to test viral load below 400 cps/mL - i.e. not done is classified as being above 400 cps/mL
TFO	Transfers out	CD4 Completion	Percentage of CD4 counts done that should have been done
		CD4 > 200	Of those CD4 counts done, the percentage above 200/ul
		ITT CD4 > 200	Intention to test CD4 count above 200/ul, i.e. not done classified as being below 200/ul

Category	Data	Year 2001 01_Q2	01_Q3	01_Q4	2001 Total	2002 02_Q1	02_Q2	02_Q3	02_Q4	2002 Total	2003 03_Q1	03_Q2	03_Q3	03_Q4	2003 Total
12 month															
	FLR	25	23	20	68	53	50	56	38	197	67				
	SLR	1			1			3	2	5					
	STO	1			1				1	1	1				
	VLD	25	23	18	66	51	47	57	35	190	59				
	VLS	21	20	14	55	41	37	43	30	151	51				
	CDD	25	22	17	64	52	43	57	36	188	61				
	CDA	15	14	13	42	29	28	39	23	119	44				
	RIP	1		2	3	1	2		2	5					
	LTF								1	1	1				
	TFO						1			1					
	Perc died	3.6%		9.1%	4.1%	1.9%	3.8%		4.7%	2.4%					
	Perc ltf								2.4%	0.5%	1.4%				
	Perc rip or ltf	3.6%		9.1%	4.1%	1.9%	3.8%		6.8%	2.9%	1.4%				
	Remaining in care	87.1%	82.1%	76.9%	82.4%	91.4%	75.8%	90.8%	85.4%	85.7%	91.9%				
	Perc stopped	3.7%			1.4%				2.4%	0.5%	1.5%				
	Perc on SLR	3.8%			1.4%			5.1%	5.0%	2.5%					
	VL Completion	96.2%	100.0%	90.0%	95.7%	96.2%	94.0%	96.6%	87.5%	94.1%	88.1%				
	VLS%	84.0%	87.0%	77.8%	83.3%	80.4%	78.7%	75.4%	85.7%	79.5%	86.4%				
	ITT VL < 400	80.8%	87.0%	70.0%	79.7%	77.4%	74.0%	72.9%	75.0%	74.8%	76.1%				
	CD4 Completion	92.6%	95.7%	85.0%	91.4%	98.1%	86.0%	96.6%	87.8%	92.6%	89.7%				
	CD4 > 200	60.0%	63.6%	76.5%	65.6%	55.8%	65.1%	68.4%	63.9%	63.3%	72.1%				
	ITT CD4 > 200	55.6%	60.9%	65.0%	60.0%	54.7%	56.0%	66.1%	56.1%	58.6%	64.7%				
18 month															
	FLR	23	22	18	63	48	48	55							
	SLR	2	1		3	5	2	3							
	STO	1			1			1							
	VLD	22	22	16	60	49	47	47							
	VLS	16	18	12	46	38	43	29							
	CDD	21	20	16	57	48	46	43							
	CDA	15	16	13	44	38	32	29							
	RIP														
	LTF			2	2										
	TFO														
	Perc died														
	Perc ltf			10.0%	2.9%										
	Perc rip or ltf			10.0%	2.9%										
	Remaining in care	83.9%	82.1%	69.2%	78.8%	91.4%	75.8%	90.8%							
	Perc stopped	3.8%			1.5%			1.7%							
	Perc on SLR	8.0%	4.3%		4.5%	9.4%	4.0%	5.2%							
	VL Completion	88.0%	95.7%	88.9%	90.9%	92.5%	94.0%	81.0%							
	VLS%	72.7%	81.8%	75.0%	76.7%	77.6%	91.5%	61.7%							
	ITT VL < 400	64.0%	78.3%	66.7%	69.7%	71.7%	86.0%	50.0%							
	CD4 Completion	80.8%	87.0%	88.9%	85.1%	90.6%	92.0%	72.9%							
	CD4 > 200	71.4%	80.0%	81.3%	77.2%	79.2%	69.6%	67.4%							
	ITT CD4 > 200	57.7%	69.6%	72.2%	65.7%	71.7%	64.0%	49.2%							
24 month															
	FLR	23	21	16	60	43									
	SLR	2	2		4	6									
	STO	1		2	3	2									
	VLD	24	22	16	62	44									
	VLS	16	18	12	46	34									
	CDD	22	21	16	59	43									
	CDA	20	17	14	51	39									
	RIP					1									
	LTF														
	TFO					1									
	Perc died					1.9%									
	Perc ltf														
	Perc rip or ltf					1.9%									
	Remaining in care	83.9%	82.1%	69.2%	78.8%	87.9%									
	Perc stopped	3.8%		11.1%	4.5%	3.9%									
	Perc on SLR	8.0%	8.7%		6.3%	12.2%									
	VL Completion	96.0%	95.7%	100.0%	96.9%	89.8%									
	VLS%	66.7%	81.8%	75.0%	74.2%	77.3%									
	ITT VL < 400	64.0%	78.3%	75.0%	71.9%	69.4%									
	CD4 Completion	84.6%	91.3%	88.9%	88.1%	84.3%									
	CD4 > 200	90.9%	81.0%	87.5%	86.4%	90.7%									
	ITT CD4 > 200	76.9%	73.9%	77.8%	76.1%	76.5%									

Western Cape patient transfer form

NATIONAL COMPREHENSIVE HIV AND AIDS PROGRAMME

TRANSFER OF ART PATIENT TO OTHER ART SERVICE POINT

Transfer to:
ART Service Point: _____
District/Metro: _____
DC No.: _____ Province: _____
Tel: _____ Fax: _____

Transfer from: Public sector ☐
NGO/FBO/CBO ☐ GP ☐ Other non-public ☐
Facility Name: _____
District/Metro: _____
DC No.: _____ Province: _____
Tel: _____ Fax: _____
Mail address

Patient's contact details:

PATIENT IDENTIFIER

First Name: _____ Surname: _____ Date of birth ☐☐ ☐☐ ☐☐☐☐ (dd mm yy)

Sex M ☐ F ☐ Tel: _____ Current file No: _____ ID ☐☐☐☐☐☐☐☐☐☐☐☐☐

Parent/guardian: *(if applicable)* First Name: _____ Surname: _____ Tel: _____

PATIENT HISTORY

Baseline ART

ART start date ☐☐ ☐☐ ☐☐ (dd mm yy)
Regimen 1a ☐ Any child regimen ☐ *(if different to 1a or 1b)*
Regimen 1b ☐

Specify baseline ART regimen if not 1a or 1b:

Baseline Lab (at start of ART)

CD4 _____ % CD4 _____ cells/mm³

Baseline clinical status (at start of ART)

Weight (kg) ☐☐☐
Height (cm) ☐☐☐
WHO Clinical Stage Adult ☐
WHO Clinical Stage Child ☐
WHO Performance Scale ☐

Current ART

Current regimen since ☐☐ ☐☐ (mm yy)
Regimen 1a ☐ Regimen 2 ☐
Regimen 1b ☐ Any child regimen ☐ *(if different to 1a/b or 2)*

Specify current ART regimen if not 1a/b or 2:

ART drugs issued will last until ☐☐ ☐☐ ☐☐ (dd mm yy)

Most recent Lab

CD4 _____ % ☐☐ ☐☐ (mm yy)
CD4 _____ cells/mm³
VL _____ copies/ml ☐☐ ☐☐ (mm yy)
ALT _____ U/l Ery _____ x10¹²/l
Hb _____ g/dl HCT _____ l/l
Leuc _____ x10⁹/l Lymph _____ x10⁹/l
Neut _____ x10⁹/l Platlet _____ x10⁹/l
Gluc _____ mmol/l Cholest _____ mmol/l

Current clinical status

Weight (kg) ☐☐☐
WHO Clinical Stage Adult ☐
WHO Clinical Stage Child ☐
WHO Performance Scale ☐

Current prophylaxis:
Cotrimoxazole No ☐ Yes ☐
Fluconazole No ☐ Yes ☐

Prophylaxis issued will last until ☐☐ ☐☐ ☐☐ (dd mm yy)

REASON FOR TRANSFER / other relevant details: _____

Transfer date ☐☐ ☐☐ ☐☐ (dd mm yy)
First appointment made at receiving service point No ☐ Yes ☐
Appointment date ☐☐ ☐☐ ☐☐ (dd mm yy)

Clinician's name _____ Signature _____ Tel _____ Fax _____

ACKNOWLEDGEMENT OF TRANSFER (*to be completed by receiving ART service point*)

We have received the transfer notice. Received date: ☐☐ ☐☐ ☐☐ (dd mm yy)

Please fax☐ mail☐ to us:
Any previous Transfer forms ☐
ART Assessment and Baseline form ☐
ART Patient Follow Up forms/details ☐

Fax/send back copy of whole form to transferring ART service point immediately after receiving it!

Clinician's name _____ Tel _____ Fax _____

Patient has attended his/her first visit at our ART service point.

Date of visit: ☐☐ ☐☐ ☐☐ (dd mm yy)

Fax/send back copy of whole form to transferring ART service point immediately after first visit!

Clinician's name _____

Uganda

Monthly reporting form
Uganda has used the WHO forms described in these guidelines, with small modifications to adapt to country needs. The monthly reporting forms are bound and carbon-copied in triplicate to allow a copy to remain in the facility.

Uganda monthly report

THE REPUBLIC OF UGANDA

Comprehensive HIV Care including ART MONTHLY REPORTING FORM

Month:	Year: 2004
Facility Name:	Ownership: GOV / NGO / PRIVATE
District:_____HSD_____	Country: UGANDA

1. HIV care (non-ART and ART) - new and cumulative number of persons enrolled

	Cumulative number of persons ever enrolled in HIV care at this facility at beginning of month	New persons enrolled in HIV care at this facility Sduring the month	Cumulative number of persons ever enrolled in HIV care at this facility at end of month
1. Males (>14years)	a.	g.	m.
2. Non-pregnant females (>14years)	b.	h.	n.
3. Pregnant females	c.	i.	o.
4a. Boys under 5 years	d1.	j1.	p1.
4b. Boys 5-14 years)	d2.	j2.	p2.
5a. Girls under 5 years	e1.	k1.	q1.
5b. Girls (5 -s14 years)	e2.	k2.	q2.
Total	f.	l.	r.
	No. of persons on who are enrolled and eligible for ART but have not been started on ART		s1.
	Total number of persons who are enrolled and eligible for ART and ready but have not been started on ART		s2.
	No. of persons already enrolled for HIV care who transferred in from another facility.		t.

2. ART care - new and cumulative number of persons started

	Cumulative number of persons ever started on ART at this facility at beginning of month	New persons started on ART at this facility during the month	Cumulative number of persons ever started on ART at end of month
1. Males (>14years)	a.	g.	m.
2. Non-pregnant females (>14years)	b.	h.	n.
3. Pregnant females	c.	i.	o.
4. Boys (0-14) years	d.	j.	p.
5. Girls (0-14 years)	e.	k.	q.
Total	f.	l.	r.
	No. of persons on ART and already enrolled in program who transferred into facility in last month		s.
	Number of persons who restarted ART during the last month, after stopping ART for at least 1 month.		t.
	Number of baseline CD4+ counts for persons who started ART in the last month (optional)		u.
	Median baseline CD4+ count for persons who started ART in the last month (optional)		v.

THE REPUBLIC OF UGANDA

4. ARV regimen at end of month	Male	Female		
On 1st-line ARV regimen				
4.1 Adults (>14 years)				
d4T-3TC-NVP	a.	j.		
d4T-3TC-EFV	b.	k.		
ZDV-3TC-NVP	c.	l.		
ZDV-3TC-EFV	d.	m.		
	e.	n.		
	f.	o.		
	g.	p.		
	h.	q.		Total number of adults on 1st-line regimen
Adults on 1st-line regimens	i.	r.	s.	
4.2 Children (0-14 years)				
d4T-3TC-NVP	a.	k.		
d4T-3TC-EFV	b.	l.		
ZDV-3TC-NVP	c.	m.		
ZDV-3TC-EFV	d.	n.		
	e.	o.		
	f.	p.		
	g.	q.		
	h.	r.		Total number of Children on 1st-line regimen
Children on 1st-line regimens	i.	s.		
Adults and children on 1st-line regimens	j	t.	v.	Total adults and children on 1st-line regimens
On 2nd-Line ARV regimen				
4.3 Adults (14 years)				
ZDV-ddl-LPV/r	a.	i.		
d4T-ddl-LPV/r	b.	j.		
	c.	k.		
	d.	l.		
	e.	m.		
	f.	n.		
	g.	o.		Total number of adults on 2nd-line regimen
Adults on 2nd-line regimens	h.	p.	q.	
4.4 Children (0-14 years)				
d4T-ddl-NFV	a.	k.		
ZDV-ddl-LPV/r	b.	l.		
	c.	m.		
	d.	n.		
	e.	o.		
	f.	p.		
	g.	q.		Total number of children on 2nd-line regimen
Children on 2nd-Line regimens	h.	r.	u.	
Adults and children on 2nd-line regimens	i	s.	v.	Total adults and children on 2nd-line regimens
Adults and children on 1st-and 2nd-line regimens	j	t.		Total adults and children on 1st-2nd-line regimens

5.1 Number of persons who did not pick up their ARV regimens	Male	Female	5.2 Of those who did not pick up regimen in last 1 month (optional)	Total number of adults and children
1. For last 1 month (only)	a.	e.		
2. For last 2 months (only)	b.	f.	1. Lost to follow-up	a.
3. For last 3 or more months	c.	g.	2. Who died	b.
Subtotal	d.	h.	3. Who stopped ART	c.
Total number of persons who did not pick up their ART regimens		i.	4. Who transferred out	d.

6. Number of personnel trained in HIV care during the month	Physicians	Nurses	Other staff	Subtotal
1. ART clinical care	a.	e.	i.	m.
2. Non-ART clinical care	b.	f.	j.	n.
3. Adherence counseling/support	c.	g.	k.	o.
4. Other types of training	d.	h.	l.	p.
			Total personnel trained	q.

WHO South-East Asia Regional Office (SEARO)

SEARO has developed a training toolkit for HIV care and ART recording and reporting. The following forms are part of this package which also contains ARV drug registers and a cohort analysis report form.

Patient booklet
This is an example of a patient-held record that contains basic demographic information, the unique patient ID number, 12 pages of clinical notes (only 2 are shown), and the date of the next appointment.

The patient card, registers and monthly report forms are variations of the generic WHO tools.

Patient HIV care ART record
Pre-ART register
ART register
Monthly report form

Antiretroviral Treatment Record

(To retained by the patient)

Name of treatment unit: _____

District : _____

State: _____

Patient's photograph

Patient's name: _____

Age: _____ Sex: _____

Complete Address: _____

Village/town: _____

District: _____ State: _____

ART Registration number: ☐☐☐☐☐☐

Date of enrollment for ART: ☐☐ ☐☐ ☐☐
dd mm yy

Name of contact person/ guardian: _____

Phone number of contact person/guardian: _____

Address of contact person/guardian: _____

_____

_____

Clinical Notes	
Date of visit:	
Chief Complaints:	Investigations
Clinical examination:	Treatment

Clinical Notes	
Date of visit: Chief Complaints: Clinical examination:	Investigations Treatment

Remember

- Bring this booklet at each follow-up visit
- Take all medicines without missing any dose
- Take all medicines at the right time
- Take the full dose of medicines. DO NOT share medicines with family or friends
- Regular treatment can help you gain weight, feel better and resume normal activities
- Stick to a healthy and responsible life-style
- Bring empty blister packets/bottle at each follow-up visit

In case of emergency, contact : _____

(Name, address and phone number of hospital/health worker): _____

Come back on (Write date of next appointment)	
1.	6.
2.	7.
3.	8.
4.	9.
5.	10.

PATIENT HIV CARE and ANTIRETROVIRAL TREATMENT (ART) RECORD

(To be stored in a locked cabinet at the health centre and arranged serially by registration number)

1. Patient Identification Data (Write complete information)

Registration Number : ☐☐ ☐☐☐☐ code clinic (2#)-code patient (4#)

Name of Treatment Unit: _____ City: _____

District: _____ State/province: _____

Name of patient: _____

Age: _____ (date of birth: ☐☐/☐☐/☐☐ dd / mm / yy) Sex: ☐ Male ☐ Female

Patient's phone number: _____

Address: _____

City/village: _____ District: _____ State/province: _____

Distance from residence to clinic (km) _____

Treatment supporter's name (if applicable) _____

Treatment supporter's address: _____

Treatment supporter's phone number: _____

Date confirmed HIV+ test: ☐☐/☐☐/☐☐ dd / mm / yy **Place:**

Entry point (services referring the patient for HIV care): ☐ 1-VCT ☐ 2-TB ☐ 3-Outpatient ☐ 4-Inpatient ☐ 5-Paediatric ☐ 6-PMTCT ☐ 7-STI ☐ 8-Private ☐ 9-NGO ☐ 10-Self referred ☐ 11-IDU outreach ☐ 12- CSW outreach ☐ 13-other_____

☐ patient transferred in **on ART** from another HIV care/ART clinic from the national program

Name previous clinic: _____ Date transferred in : _____

2. Personal History (Tick one choice)

Mode of HIV trans-missio n
- ☐ 1 Commercial sex worker (CSW)
- ☐ 2 Other heterosexual route
- ☐ 3 Men having sex with men (MSM)
- ☐ 4 Injecting drug use (IDU)
- ☐ 5 Blood transfusion
- ☐ 6 Mother to child
- ☐ 7 Unknown

For IDUs Substitution therapy ☐ Y ☐ N
If yes, type:

Literate ☐ Yes ☐ No

Employed ☐ Yes ☐ No

Alcoholism ☐ Habitual ☐ Social ☐ No use

3. Family History (Tick one choice)

Marital status: ☐ Single ☐ Married ☐ Divorce/separate ☐ Widowed ☐ Not applicable

Estimated monthly household income:

Family members: partner/children	Age/ sex	HIV +/-/unknown	ART Y/N	Regist. No if in care

4. Antiretroviral treatment history

Was ART received before? ☐ Yes ☐ No

If yes ☐ PMTCT ☐ Earlier ART Place: ☐ Private ☐ Govt

Drugs and duration:

5. Clinical and Laboratory Investigations

	Date (dd/mm /yy)	WHO stage	Weight (kg)	Height (cm)	Perfor-mance A/B/C*	Total lymphocyte count	CD4 count (or % in children)
At 1st visit in clinic							
At ART medical eligibility				child			
At start of ART				child			
At 6 months ART				child			
At 12 months ART				child			
At 24 months ART				child			

6. Antiretroviral Treatment

Treatment Started
- ☐ D4T30+3TC+NVP
- ☐ D4T40+3TC+NVP
- ☐ D4T30+3TC+EFV
- ☐ D4T40+3TC+EFV
- ☐ ZDV+3TC+NVP
- ☐ ZDV+3TC+EFV

SUBSTITUTION within 1st line, SWITCH to 2nd line, STOP, RESTART

Date	Substitution, switch or stop	Reason (code)	Date restart	New regimen

Reasons SUBSTITUTE: 1 toxicity side effects, 2 pregnancy, 3 risk of pregnancy, 4 newly diagnosed TB, 5 new drug available, 6 drug out of stock, 7 other reason (specify)

Reasons for SWITCH: 1 clinical treatment failure, 2 immunological failure, 3 virologic failure

Reasons STOP: 1 toxicity side effects, 2 pregnancy, 3 treatment failure, 4 poor adherence, 5 illness hospitalization, 6 drug out of stock, 7 patient lack of finance, 8 patient decision, 9 planned treatment interruption, 10 others

7. Tuberculosis treatment during HIV care

Disease class (tick)
- ☐ Pulmonary TB
  - ☐ Smear-positive
  - ☐ Smear-negative
- ☐ Extrapulmonary site: _____

TB Regimen (tick)
- ☐ Category I
- ☐ Category II
- ☐ Other specify:

Date start TB Rx: ☐☐/☐☐/☐☐ dd / mm / yy

TB registration

District: _____

Health Centre: _____

TB number:

Treatment outcome: ☐ Cure ☐ Rx completed ☐ Rx failure ☐ Died ☐ Default ☐ Transfer out

Date: ☐☐/☐☐/☐☐) dd / mm / yy

8. End of Follow-up

☐ Death Date of death: ☐☐/☐☐/☐☐

☐ Lost to follow-up (>3 months) Date last visit: ☐☐/☐☐/☐☐

☐ Transferred out Date: ☐☐/☐☐/☐☐ dd / mm / yy New clinic:

* Performance scale: A- Normal activity; B- bedridden <50% of the day during last month; C- bedridden > 50% of the day during last month

9. PATIENT HIV CARE & ANTIRETROVIRAL TREATMENT FOLLOW-UP

Date of visit*	Date next visit	Weight (kg) & height for child	WHO stage	Perfor-mance scale*	pregnancy (y/n) or FP method*	opportunistic infections - code*	Drugs prescribed for prophylaxis of OIs	Antiretroviral drugs and dose prescribed	adherence to ART* - >95%, 80-95%, <80%	ART Side effects - code*	lab results when available	Cond-oms given y/n	Referred to specialist or hospit.

***Instructions and codes:**

Date: Write the date of actual visit starting from the 1st visit for HIV care – ALL DATES: **DD/MM/YY**

Performance scale: A- Normal activity; B- bedridden <50% of the day during last month; C- bedridden > 50% of the day during last monthj

FP: family planning; 1 condoms, 2 oral contraceptive pills, 3 injectable/implantable hormones, 4 diaphragm/cervical cap, 5 intrauterine device, 6 vasectomy/tubal ligation/hysterectomy

Opportunistic infections: Enter one or more codes − Tuberculosis (TB); Candidiasis (C); Diarrhea (D); Cryptococcal meningitis (M); Pneumocystis Carinii Pneumonia (PCP); Cytomegalovirus disease (CMV); Penicilliosis (P); Herpes zoster (Z); Genital herpes (H); Toxoplasmosis (T); Other-specify

Adherence: Check adherence by asking the patient if he/she has missed any doses. Also check the bottle/blister packet. Write the estimated level of adherence (e.g. >95% = < 3 doses missed in a period of 30 days; 80-95% = 3 to 12 doses missed in a period of 30 days; < 80% = >12 doses missed in a period of 30 days

Side effects: Enter one or more codes − S=Skin rash; Nau-nausea; V=Vomiting; D=Diarrhoea; N=Neuropathy;J=Jaundice; A=Anemia; F=Fatigue; H=Headache; Fev=Fever; Hyp=Hypersensitivity; Dep=Depression; P=Pancreatitis; L=Lipodystrophy; Drows=Drowsiness; O=Other− Specify

INFORMATION ABOUT ANTIRETROVIRAL DRUGS

Regimen	Dose	Major Toxicity	Drug Substitution
D4T/3TC/NVP (Stavudine Lamuvidine Nevirapine)	• d4T-3TC twice a day plus **NVP 200 mg once a day for 2 weeks** • d4T-3TC-NVP Fixed dose combination twice a day if patient tolerates first 2 weeks of NVP • d4T: 30 mg twice daily if <60kg, 40mg twice daily if >60 kgg	• d4T – related neuropathy or pancreatitis • d4T –related lipoatrophy • NVP –related severe hepatotoxicity • NVP – related severe rash (but not life threatening) • NVP –related life threatening rash (Stevens – Johnson syndrome)	• Substitute d4T to ZDV • Substitute d4T to TDF or ABC • Substitute NVP to EFV (except in pregnancy) • Substitute NVP to EFV (except in pregnancy) • Switch NVP to NFV
ZDV/3TC/NVP (Zidovudine Lamuvidine Nevirapine)	• ZDV-3TC twice a day plus **NVP 200 mg once a day for 2 weeks** • ZDV-3TC-NVP Fixed dose combination twice a day if patient tolerates first 2 weeks of NVP	• ZDV–related persistent GI intolerance or severe haemtological toxicity • NVP–related severe hepatoxicity • NVP–related severe rash (but not life threatening) • NVP–related life threatening rash (Stevens – Johnson syndrome)	• Substitute ZDV to d4T • Substitute NVP to EFV (except in pregnancy. In this situation switch to NFV, LPV/r or ABC) • Substitute NVP to EFV (except in pregnancy) • Substitute NVP to NFV
D4T/3TC/EFV (Stavudine Lamivudine Efavirenz)	• d4T/3TC as twice daily fixed dose combination plus EFV (600 mg) once per day • d4T: 30 mg twice daily if <60kg, 40mg twice daily if >60 kg	• d4T–related neuropathy or pancreatitis • d4T–related lipoatrophy • EFV–related persistent CNS toxicity	• Substitute d4T to ZDV • Substitute d4T to TDF or ABC • Substitute EFV to NVP
ZDV/3TC/EFV (Zidovudine Lamuvidine Efavirenz)	• ZDV-3TC twice a day as a fixed drug combination plus EFV (600 mg) once per day	• ZDV–related persistent GI intolerance or severe hematological toxicity • EFV–related persistent CNS toxicity	• Substitute ZDV to d4T • Substitute EFV to NVP

ABC= Abacavir; d4T= Stavudine; EFV=Efavirenz; LPV=Lopinavir; NFV=Nelfinavir
NVP= Nevirapine; TDF=Tenofovir; ZDV=Zidovudine; 3TC=Lamivudine

SEARO pre-ART register

HIV CARE- PRE ART REGISTER: Fill at first visit column 1 to 10 | Fill when applicable column 11 to 16

	1	2	3	4	5	6		7	8	9	10	11	12	13	14	15	16		
	DATE 1st visit at the clinic	Registration number	Patient's name and address	Age	Sex M/ F	Confirmed HIV+ test		Entry point - code 1 to 13*	risk factor - code 1 to 7**	Literate	Employed	CPT Date of Start	TB treatment Class/Regimen Date of start	DATE medically elligible for ART	Why medically elligible?	DATE ART started	End of follow-up before starting		
						Date	Place										Date of death	Date lost to FU (last visit)	Date transferred out
1										☐Y ☐N	☐Y ☐N				WHO stage CD4 #/% TLC#				
2										☐Y ☐N	☐Y ☐N				WHO stage CD4 #/% TLC#				
3										☐Y ☐N	☐Y ☐N				WHO stage CD4 #/% TLC#				
4										☐Y ☐N	☐Y ☐N				WHO stage CD4 #/% TLC#				
5										☐Y ☐N	☐Y ☐N				WHO stage CD4 #/% TLC#				
6										☐Y ☐N	☐Y ☐N				WHO stage CD4 #/% TLC#				
7										☐Y ☐N	☐Y ☐N				WHO stage CD4 #/% TLC#				
8										☐Y ☐N	☐Y ☐N				WHO stage CD4 #/% TLC#				
9										☐Y ☐N	☐Y ☐N				WHO stage CD4 #/% TLC#				
10										☐Y ☐N	☐Y ☐N				WHO stage CD4 #/% TLC#				
11										☐Y ☐N	☐Y ☐N				WHO stage CD4 #/% TLC#				
12										☐Y ☐N	☐Y ☐N				WHO stage CD4 #/% TLC#				
13										☐Y ☐N	☐Y ☐N				WHO stage CD4 #/% TLC#				
14										☐Y ☐N	☐Y ☐N				WHO stage CD4 #/% TLC#				
15										☐Y ☐N	☐Y ☐N				WHO stage CD4 #/% TLC#				

*Entry point: 1-VCT; 2-TB; 3-Outpatient; 4-Inpatient; 5-Paediatric; 6-PMTCT; 7-STI; 8-Private; 9-NGO; 10-Self referred; 11-IDU outreach; 12- CSW outreach; 13-other - **Write code TR if the patient was transferred in on ART**

**Mode of HIV transmission: 1-Commercial sex worker (CSW), 2-Other heterosexual route, 3-Men having sex with men (MSM), 4-Injecting drug use (IDU), 5-Blood transfusion, 6-Mother to child, 7-Unknown

CPT: Cotrimoxazole preventive therapy

SEARO ART register

ART REGISTER **Month:** **Year:**

	DATE of start of ART	Registration number	Patient's first name and surname	Age	Sex M/ F	Patient's address and contact number	Treatment supporter's name and contact number	Prior ARV history	WHO stage at start of Rx	Performance scale A-normal activity; B-bedridden<50%; C-Bedridden>50%	Weight (kg) at start, 6, 12,24 months of ART	CD4 count at start, 6, 12,24 months of ART (absolute number for adults and % for children)	TB treatment during ART Disease, Category Regimen Date Rx start	ART regimen started
1						…… ……	…… ……	☐ Y ☐ N		At start of Rx / At 6 months / At 12 months / At 24 months	At start of Rx / At 6 months / At 12 months / At 24 months	At start of Rx / At 6 months / At 12 months / At 24 months		
2						…… ……	…… ……	☐ Y ☐ N		At start of Rx / At 6 months / At 12 months / At 24 months	At start of Rx / At 6 months / At 12 months / At 24 months	At start of Rx / At 6 months / At 12 months / At 24 months		
3						…… ……	…… ……	☐ Y ☐ N		At start of Rx / At 6 months / At 12 months / At 24 months	At start of Rx / At 6 months / At 12 months / At 24 months	At start of Rx / At 6 months / At 12 months / At 24 months		
4						…… ……	…… ……	☐ Y ☐ N		At start of Rx / At 6 months / At 12 months / At 24 months	At start of Rx / At 6 months / At 12 months / At 24 months	At start of Rx / At 6 months / At 12 months / At 24 months		
5						…… ……	…… ……	☐ Y ☐ N		At start of Rx / At 6 months / At 12 months / At 24 months	At start of Rx / At 6 months / At 12 months / At 24 months	At start of Rx / At 6 months / At 12 months / At 24 months		
6						…… ……	…… ……	☐ Y ☐ N		At start of Rx / At 6 months / At 12 months / At 24 months	At start of Rx / At 6 months / At 12 months / At 24 months	At start of Rx / At 6 months / At 12 months / At 24 months		
7						…… ……	…… ……	☐ Y ☐ N		At start of Rx / At 6 months / At 12 months / At 24 months	At start of Rx / At 6 months / At 12 months / At 24 months	At start of Rx / At 6 months / At 12 months / At 24 months		
8						…… ……	…… ……	☐ Y ☐ N		At start of Rx / At 6 months / At 12 months / At 24 months	At start of Rx / At 6 months / At 12 months / At 24 months	At start of Rx / At 6 months / At 12 months / At 24 months		
9						…… ……	…… ……	☐ Y ☐ N		At start of Rx / At 6 months / At 12 months / At 24 months	At start of Rx / At 6 months / At 12 months / At 24 months	At start of Rx / At 6 months / At 12 months / At 24 months		
10						…… ……	…… ……	☐ Y ☐ N		At start of Rx / At 6 months / At 12 months / At 24 months	At start of Rx / At 6 months / At 12 months / At 24 months	At start of Rx / At 6 months / At 12 months / At 24 months		

ART REGISTER Month: Year:

Treatment substituted within 1st line drugs			Treatment switched to 2nd line			End of follow-up on ART			Monthly visits: ● 1st row, write patient outcome: on treatment **(OT)** if patient picked up ART drugs; stopped **(ST)** if ART was stopped by the doctor; missing **(MIS)** if the patient missed the scheduled visit; lost to follow-up **(LFU)** if the patient is missing for ≥3 months; restart **(RS)** if ART was restarted after an interruption; transferred out **(TR);** dead **(D); (NA)** if the patient was not scheduled to visit this month ● 2nd row: write adherence for the patients on treatment (A=>95%, B=80-95%, C=<80%)																							
Date substituted	Reason*	New Regimen	Date switched	Reason**	New Regimen	Date of death	Date lost to FU (last visit)	Date transfered Out on ART	Week 2	Month 1	mo.2	mo.3	mo.4	mo.5	mo.6	mo.7	mo.8	mo.9	mo. 10	mo. 11	mo.12	mo. 13	mo. 14	mo. 15	mo. 16	mo. 17	mo. 18	mo. 19	mo. 20	mo. 21	mo. 22	mo. 23	mo.24

*** Reasons for subsitution within first line treatment**:1-toxicity or side effects; 2-pregnancy;3-risk of pregnancy; 4-newly diagnosed TB; 5-new drug available; 6-drug out of stock; 7-other reason.

*** Reasons for switching to second line treatment**:1-toxicity or side effects; 2-pregnancy; 3-risk of pregnancy; 4-newly diagnosed TB; 5-new drug available; 6-drug out of stock; 7-other reason; 8-clinical treatment failure; 9-immunological failure; 10 -virological failure.

Reasons for stopping ART: 1- toxicity side effects; 2-pregnancy; 3-treatment failure; 4-poor adherence; 5-illness hospitalisation; 6-drug out of stock; 7-lack of finance; 8-patient's decision to stop; 9 other reason.

SEARO monthly report

Monthly HIV care/ Antiretroviral treatment (ART) Centre Report

1. Name of the Treatment Unit _____
2. Name of the District _____
3. Name of the State/province _____
4. Name of the Treatment Unit incharge _____

5. Report for the period [ ] month [ ] year

A- MEDICAL CARE

6. Enrollment in HIV care (PLWHA seeking care at the treatment center)	**adult male**	**adult female**	**child.<14 yo**	**total**
6.1 Cumulative no. of patients ever enrolled in HIV care at beginning of this month				
6.2 New patients enrolled in HIV care during this month				
6.3 Cumulative no. of patients ever enrolled in HIV care at the end of this month				
7. Medical eligibility for ART*	**adult male**	**adult female**	**child.<14 yo**	**total**
7.1 No. of patients medically eligible for ART but have not been started on ART at the end of this month				
8. Enrollment on ART	**adult male**	**adult female**	**child.<14 yo**	**total**
8.1 Cumulative no. of patients ever started on ARTat the beginning of this month				
8.2 New patients started on ART during this month				
8.3 No. of patients on ART transferred in this month				
8.4 Cumulative no. of patients ever started on ARTat the end of this month				
9. outcomes on ART	**adult male**	**adult female**	**child.<14 yo**	**total**
9.1 Cumulative no. of death reported at the end of this month				
9.2 Cumulative no. of patients transferred out under ARV at the end of this month				
9.3 No. of patients missing/lost to follow-up at the end of this month				
9.4 No. of patients stopping ART at the end of this month				
9.5 No. of patients on ART at the end of this month				
● 9.5.1 Among them, no. on original 1st line regimen				
● 9.5.2 No. on substituted 1st line regimen				
● 9.5.3 No. switched on 2nd line regimen				

* refers to the medical elligibility on clinical and/or laboratory criteriae, whether or not the patient is ready for ART

10. TREATMENT ADHERENCE		**Total**
10.1. No. of patients assessed for adherence during this month		
10.2. Of those assessed for adherence, level of adherence in the last month		
10.2.1. < 3 doses missed in a period of 30 days	**> 95%**	
10.2.2 =3 to 12 doses missed in a period of 30 days	**80-95%**	
10.2.3. >12 doses missed in a period of 30 days	**<80%**	

Monthly HIV care/ Antiretroviral treatment (ART) Centre Report

B- PHARMACY

11. REGIMEN AT THE END OF THE MONTH

Regimen	No. of patients on ART
D4T30/3TC/NEV	
D4T40/3TC/NEV	
ZDV/3TC/NEV	
ZDV/3TC/EFV	
D4T30/3TC/EFV	
D4T40/3TC/EFV	
Total= No. of patients on ART at the end of this month (=9.5)	

12. DRUG STOCKS

Was there a stock-out of antiretroviral drugs this month? **Yes** ☐ **No** ☐

Was there a stock-out of drugs for opportunistic infection this **Yes** ☐ **No** ☐

Name of the drug (list ARV and OI drugs)	Stock at the start of the month (A)	Stock received during the month (B)	Stock dispensed during the month (C)	Stock expired/ discarded during the month (D)	Stock at the end of the month (A+B)-(C+D)	Amount requested

Kenya

Quarterly integrated monitoring and evaluation report form
Kenya's MTCT+ programme is an example of one that links PMTCT to ART. Many of the same indicators and data can be collected in addition to PMTCT-specific information and should ideally be integrated and tracked on the same forms. The quarterly integrated monitoring form that is used in Kenya is a good example of how the linkage between PMTCT and ART may be accomplished.

MINISTRY OF HEALTH
INTEGRATED MONITORING AND EVALUATION REPORT FORM MOH 727
NASCOP

District_____**Province**_____**Quarter**_____**Year**_____

N/B: Indicate **N/S** where there is no service and **N/D** where there is service but no data

VCT: No. of expected reports_____ **No. reported**_____

	Measure			
Sex	**No of clients**	**No tested**	**No. +ve**	**%+ve**
Males				
Females				
Totals				

ARV. No. of expected reports_____ **No. reported** _____

	Measure		Children <13yrs		Adults. 13yrs		Totals		Grand Totals
			M	F	M	F	M	F	
A	No. of HIV+ve Patients receiving clinical care	New att.							
		Re-att							
B	No. of patients on prophylaxis **(New)**	Cotrimoxazole							
		Fluconazole							
C	No. of new attendance previously on ARVs								
D	No of patients who commenced ARV's within the month	**TOTAL**							
		PMCT mothers							
		PMCT spouse							
		TB patient							
		Health workers							
		Transfer in							
		Others (specify).....							
E	No. of patients starting ART by WHO	WHO stage 1							
		WHO stage 2							
		WHO stage 3							
		WHO stage 4							
F	No. of patients who changed therapy	Due to treatment failure							
		Due to toxicity							
		Due to cost							
		Sub-totals							
G	No of patients for whom ART treatment was discontinued	No known to have died							
		No of defaulters							
		No transfers out							
		Lost to follow up							
		No due to cost							
		Sub-totals							
H	Post exposure prophylaxis (PEP)	Sexual assault							
		Health workers							
		Sub-totals							

HIV Test Kits/ Blood safety/HIV Testing.

Test Kit	Received	Used	Expired	Balance
Determine				
Unigold				
Other rapid(specify) _____				
Vironostika				
Enzygnost				
Other long (specify)				

Blood safety

No of blood units screened for HIV_____ NO. HIV+_____

No. of blood units collected from Regional Blood Transfusion Centers_____

HIV Testing:

No. of patients tested for HIV_____No. tested HIV+_____

General Remarks_____

_____

_____

_____

PMCT: No. of expected reports_____ **No. reported**_____

	Measure		Number
A	No of new ANC clients		
B	No. of Revisits		
C	No. ANC counseled and tested		
D	ANC HIV +ve		
E	Mother NVP ANC		
F	Infant NVP ANC		
G	Maternity mothers counseled and tested		
H	Maternity HIV +ve		
I	Maternity NVP		
J	Maternity Infant NVP		
K	No of deliveries		
L	Choice of infant feeding	Breastfeeding	
		Alternative feeding	

STD's: No. of expected reports_____**No. reported**_____

	Syndrome	Type of visit	Totals
A	Urethral discharge	Initial visit	
		Re-att	
		Sub-total	
		Referrals	
B	Vaginal discharge	Initial visit	
		Re-att	
		Sub-total	
		Referrals	
C	Pelvic Inflammatory disease	Initial visit	
		Re-att	
		Sub-total	
		Referrals	
D	Genital ulcer disease(GUD) Males	Initial visit	
		Re-att	
		Sub-total	
		Referrals	
E	Genital ulcer disease(GUD) Females	Initial visit	
		Re-att	
		Sub-total	
		Referrals	
F	Ophthalmia Neonatorum	Initial visit	
		Re-att	
		Sub-total	
		Referrals	
G	Syphilis Serology	Male	
		Female	
		Sub-total	
	Grand Totals		

Homebased Care(HBC) : No. of expected reports_____
No. reported_____

	Activity	Females	Males	Totals
A	No. of new clients			
B	No. of patients enrolled in HBC			
C	No. of patients on ARV's			
D	No. of patients on TB Rx			
E	No. of deceased			
F	No. of CHW's providing HBC			
G	No. of support services available at support center			
H	No. of HBC Kits supplied			
I	No. of HBC Kits used			

Report compiled by.....**Design**..... **Date**.....**Sign**.....

N/B This form should be completed by all Districts to reach NASCOP and the PASCO by 21st of the following quarter. E.g. 1st quarter report of the year 2004 should reach by 21st of April 2004 etc.

US President's Emergency Plan Track 1.0 partners

Quarterly report form
The CDC has adapted the WHO quarterly report form for Track 1.0 partner organizations (grantees of centrally funded cooperative agreements and contracts through the Emergency Plan to implement HIV/AIDS programmes in 14 priority countries) to be able to collect indicators required by the US President's Emergency Plan. These include several cohort indicators collected at 6 and 12 months.

At the time of development, Track 1.0 reporting requirements included a definition of NEW that differed slightly from the one defined in *Table B*. In partner programmes, NEW referred to patients who initiated ART **during** the reporting period. This may include non-naïve patients such as those previously in PMTCT, or who may have received treatment in the past but not currently on ART when enrolling in the ART programme.

US President's Emergency Plan quarterly report form

Quarterly, Facility-Based HIV Care/ART Reporting Form

Quarter beginning (mm/dd/yy):	Quarter ending (mm/dd/yy):
Grantee:	Facility:
Location:	Country:

1. HIV Palliative Care (non-ART and ART care)

	Cumulative number enrolled in HIV care by the beginning of quarter	NEW enrollees in HIV care during the quarter	Cumulative number enrolled in HIV care by the end of the quarter		Total number who received HIV care during the quarter
1. Males (0-14 years)	a.	f.	k. 0		oo.
2. Males (>14years)	b.	g.	l. 0		pp.
3. Females (0-14 years)	c.	h.	m. 0		qq.
4. Females (>14 years)	d.	i.	n. 0		rr.
Total	e. 0	j. 0	o. 0		uu. 0
				Number in HIV care during the quarter & eligible for ART, but NOT started ART by the end of the quarter (subset of 1uu.)	vv.

2. ART Care

	Cumulative number started on ART by the beginning of the quarter	Number started on ART in program during the quarter (includes NEW and TRANSFERS)	Cumulative number started on ART by the end of the quarter	Number NEW on ART during the quarter (subset of 2h-2n)	Number on ART who TRANSFERRED in during the quarter (subset of 2h-2n)	Total number on ART at the end of the quarter
1. Males (0-14 years)	a.	g.	m. 0	aa.	gg.	mm.
2. Males (>14years)	b.	h.	n. 0	bb.	hh.	nn.
3. Females (0-14 years)	c.	i.	o. 0	cc.	ii.	oo.
4. Females (>14 years)	d.	j.	p. 0	dd.	jj.	pp.
Total	e. 0	k. 0	q. 0	ee. 0	kk. 0	qq. 0
5. Pregnant females (subset of total)	f.	l.	r. 0	ff.	ll.	rr.
				No. of persons on ART at the end of the quarter who were treated with USG-funded ART (subset of 2qq.)		ss.

7-Apr-05

3. Training in ART and HIV Care*	Physicians	Nurses	Other healthcare workers	Total
1. Number of persons trained in ART care during the quarter	a.	b.	c.	d. 0
2. No. trained in (non-ART) HIV palliative care during the quarter				e.

*Please provide training numbers by country, not by facility, for each grantee

4.1 Change in CD4+ count and adherence to ART for 6-month cohort (>6 years old)		
	Baseline	6 months
Months when cohort started ART	a.	
Number of persons in cohort	b.	e.
No. in cohort who have CD4+ counts	c.	f.
Median CD4+ count for cohort	d.	g.
No. in cohort who received ARVs for 6 out of 6 months		h.

4.2 Change in CD4+ count and adherence to ART for 12-month cohort (>6 years old)		
	Baseline	12 months
Months when cohort started ART	a.	
Number of persons in cohort	b.	e.
No. in cohort who have CD4+ counts	c.	f.
Median CD4+ count for cohort	d.	g.
No.of persons in cohort who received ARVs for 12 out of 12 months		h.

5. Number of patients on each regimen at the end of the quarter		
	Adults	Children (<14 years)
d4T-3TC-NVP	a.	aa.
d4T-3TC-EFV	b.	bb.
d4T-3TC-LPV/r	c.	cc.
ZDV-3TC-NVP	d.	dd,
ZDV-3TC-EFV	e.	ee.
ZDV-3TC-LPV/r	f.	ff.
ZDV-ddI-NVP	g.	gg.
ZDV-ddI-EFV	h.	hh.
ZDV-ddI-LPV/r	i.	ii
d4T-ddI-NVP	j.	jj.
d4T-ddI-EFV	k.	kk.
d4T-ddI-LPV/r	l.	ll.
	m.	mm.
	n.	nn.
	o.	oo.
	p.	pp.
	q.	qq.
	r.	rr.
	s.	ss.
	t.	tt.
	u.	uu.
	v.	vv.
	w.	ww.
Total	x. 0	xx. 0

LEGEND for Table 4		
Reporting Period patients being reported during the time quarter:	6-month cohorts patients who started on ART in the preceding months of:	12-month cohorts patients who started on ART in the previous year, during the months of:
October 1 - December 31	Feb, Mar, Apr	Aug, Sept, Oct
January 1 - March 31	May, June, July	Nov, Dec, Jan
April 1 - June 30	Aug, Sept, Oct	Feb, Mar, April
July 1 - September 30	Nov, Dec, Jan	May, June, July

6.1 Number of persons who started on ART at the facility in the EP program who were NOT on ART at the end of the quarter	Male	Female	Total
	a.	g.	m. 0
6.2 Reason			
1. Stopped ART	b.	h.	n. 0
2. Transferred out	c.	i.	o. 0
3. Death	d.	j.	p. 0
4. Lost to follow-up	e.	k.	q. 0
5. Unknown	f.	l.	r. 0

Multi-country Columbia Antiretroviral Programme (MCAP)

Columbia University Mailman School of Public Health is a Track 1.0 partner under the first phase of the US President's Emergency Plan. It is implementing HIV care and treatment at sites in Kenya, Mozambique, Rwanda, South Africa, and Tanzania, and must aggregate data using the Track 1.0 quarterly report form.

Adult enrolment and follow-up forms
These forms contain many of the same data elements on the Patient HIV care/ART cards presented previously; however, the information is collected over eight pages (four each) in a more user-friendly format. While check boxes and bubbles may reduce the incidence of reporting error, it ultimately results in a much larger volume of paper being used and stored. The storage of paper charts involves a more complex filing system, and the use of limited space and resources. The advantage of the card system is that it is a self-contained unit that can be filed, referenced, and transported relatively easily. Each programme must make its own decision, weighing the costs and benefits of each system.

Adult patient care flowsheet
This form functions in the same way as the summary sheet of the Patient HIV care/ART card shown in *Annex D*. Key information is transferred from the follow-up forms to allow providers a brief overview of a patient's clinical status.

Paediatric patient care flowsheet
This form is similar to the adult patient counterpart with two main differences: function has been replaced by milestones; and tuberculin skin test results and pregnancy status have been replaced by HIV test type and results (HIV status is more difficult to determine in infants who have been exposed to the virus in the womb and requires several tests to confirm positivity).

MCAP adult enrollment form

MCAP ADULT ENROLLMENT FORM

Patient Name: _____ **Patient ID Number:** [ ]

Enrollment Date: [ ][ ] / [ ][ ] / [ ][ ][ ][ ]
day month year

Site/Facility Code: [ ]
optional

Family Code: [ ]
optional

1. Date of birth: [ ][ ] / [ ][ ] / [ ][ ][ ][ ]
day month year
(Enter 99 if information is not known)

1a. Age at last birthday [ ][ ]
(Enter 99 if information is not known)

2. Sex: O Female O Male

3. Referred by: O VCT site O pMTCT site O family member enrolled in MCAP O self-referral
O TB clinic O STI clinic O inpatient hospital ward O outpatient clinic O other
O traditional healer O other HIV/AIDS treatment program (specify) :

4. Does the patient have a household member enrolled in MCAP? O Yes O No → Index Patient's MCAP ID #: [ ]

5. Is the patient a member of MCAP staff (health care worker) or family of MCAP staff? O Yes O No

6. Is the patient currently pregnant? O Yes O No → Expected Date of Delivery: [ ][ ] / [ ][ ] / [ ][ ][ ][ ]

7. Does the patient have a spouse, partner, household member(s) or child(ren) who might be eligible for MCAP? (e.g. known to be HIV-infected or at risk of HIV-infection?) O Yes O No → Provide referrals for VCT and/or MCAP enrollment as appropriate O Done

8. Is the patient employed outside the home? O Yes O No
9. Does the patient have electricity inside the home? O Yes O No
10. Does the patient have running (piped) water inside the home? O Yes O No

---

11. Within the last month, has the patient experienced any of the following symptoms? O Yes O No
If yes, fill in the 'o' to the right of each condition. If no, proceed to question 12.

Symptom	Yes	Symptom	Yes
Cough	O	Pain - Abdominal	O
Depression	O	Pain - Muscles	O
Diarrhea	O	Pain - Legs/feet	O
Difficulty breathing	O	Poor appetite	O
Fatigue	O	Rash	O
Fever	O	Thrush	O
Headache	O	Weakness	O
Memory problems	O	Weight gain	O
Nausea and/or vomiting	O	Weight loss	O
New visual problems	O	Other 1 (specify):	O
Night sweats	O	Other 2 (specify):	O
Numbness or tingling in legs and/or feet	O	Other 3 (specify):	O

12. Functional status (please select one):
O Working (able to perform usual work in or out of the house)
O Ambulatory (unable to work, but able to perform activities of daily living – e.g eating, bathing – without assistance)
O Bedridden (unable to perform activities of daily living – e.g. eating, bathing – without assistance)

13. Are the patient and/or his/her partner currently using any form of family planning? O Yes O No

If yes, fill in 'o' for all that apply:

O Condoms O Oral Contraceptive Pills O Injectable/ implanted hormones (e.g. Depo-provera, Norplant)
O Diaphragm / Cervical Cap O Intrauterine Device O Vasectomy/ tubal ligation/ hysterectomy
O Other: _____

14. Physical examination

Temperature [ ][ ].[ ] °C Height [ ][ ][ ] cm Weight [ ][ ][ ] kg

Examinations	Normal	**Abnormal**	Not Done	Comments / Descriptions
Ears, nose, throat	O	O	O	
Head and neck	O	O	O	
Cardiovascular	O	O	O	
Lungs	O	O	O	
Abdomen	O	O	O	
Lymph nodes	O	O	O	
Skin	O	O	O	
Urogenital	O	O	O	
Musculoskeletal	O	O	O	
Neurological	O	O	O	
Other 1 (specify):	O	O	O	
Other 2 (specify):	O	O	O	

15. Has the patient ever had, or does the patient currently have, any of the following conditions?

Fill in the 'o' to the right of each indicator condition

WHO Stage 1		**WHO Stage 4**	
Asymptomatic HIV Infection	O	Candidiasis (esophageal, bronchi, trachea, or lungs)	O
Persistent generalized lymphadenopathy	O	Cryptococcosis, extrapulmonary	O
WHO Stage 2		Cryptosporidiosis with diarrhea (> 1 month duration)	O
Herpes zoster (within last 5 years)	O	Cytomegalovirus disease (other than liver, spleen, lymph nodes)	O
Minor mucocutaneous manifestations	O	Herpes simplex (mucocutaneous >1month, or visceral any duration)	O
Recurrent upper respiratory tract infections	O	HIV encephalopathy	O
Weight loss ? 10% of body weight	O	HIV wasting syndrome	O
WHO Stage 3		Kaposi's sarcoma (KS)	O
Severe bacterial infections (i.e., pneumonia, pyomyositis)	O	Lymphoma	O
		Atypical mycobacteriosis, disseminated	O
Oral candidiasis (thrush)	O	Mycosis, disseminated endemic (i.e., Histoplasmosis, Coccidiodomycosis)	O
Unexplained chronic diarrhea (> 1 month)	O		
Unexplained prolonged fever (intermittent or constant, > 1 month)	O	Tuberculosis, extrapulmonary	O
		Pneumocystis carinii pneumonia (PCP)	O
Oral hairy leukoplakia	O	Progressive multifocal leukoencephalopathy (PML)	O
Tuberculosis, pulmonary (within previous year)	O	Salmonella septicemia, non-typhoid	O
Weight loss > 10% of body weight	O	Toxoplasmosis, CNS	O

16. Based on the table above, what is the highest WHO staging indicator condition the patient has experienced to date?

O WHO Stage **1** O WHO Stage **2** O WHO Stage **3** O WHO Stage **4**

17. What is the patient's most recent CD4 count?

[ ][ ][ ][ ] /mm^3 [ ][ ] %

Date specimen collected [ ][ ]/[ ][ ]/[ ][ ][ ][ ]

18. What medications is the patient currently taking?

O Isoniazid (INH) preventive therapy
O Cotrimoxazole prophylaxis
O Treatment for active TB disease
O Antiretroviral treatment (ART): please specify
O Other (please list all prescription, nonprescription, herbal, complementary, and traditional agents):

_____
_____
_____
_____

19. Has the patient previously been treated for tuberculosis? O Yes O No

20, Has the patient previously taken antiretroviral medication?

O No
O Yes, but only to prevent mother-to-child-transmission (pMTCT)
O Yes, patient was previously treated with antiretroviral medication (ART)

If the answer to Q 19 and/or Q 20 is yes, specify medications used and when treated:

21. If not on OI prophylaxis, indicate eligibility for OI prophylaxis as of this visit:

O Not yet determined/ awaiting other information

O Ineligible

O Eligible →
- O Newly eligible for prophylaxis by CD4 count ► CD4 count = ☐☐☐☐
- O Newly eligible for prophylaxis by WHO Stage ► WHO Stage = ☐
- O Previously eligible for prophylaxis (specify): _____

22. If not on antiretroviral treatment (ART), indicate eligibility for ART as of this visit:

O Not yet determined/ awaiting other information

O Ineligible

O Eligible →
- O Newly eligible for ART by CD4 count → CD4 count = ☐☐☐☐
- O Newly eligible for ART by WHO Stage → WHO Stage = ☐
- O Previously eligible for ART (specify): _____

23. List all medications being started, stopped, or continued (chart continues on next page):

Medication	**Recommendation** Start	Stop	Continue	Reasons for Discontinuation*	Dose and Comments
Cotrimoxazole	O	O	O		
Dapsone	O	O	O		
Zidovudine (AZT)	O	O	O		
Lamivudine (3TC)	O	O	O		
Stavudine (D4T)	O	O	O		
Didanosine (DDI)	O	O	O		
Abacavir (ABC)	O	O	O		
Nevirapine (NVP)	O	O	O		
Efavirenz (EFV)	O	O	O		
Nelfinavir (NFV)	O	O	O		
Lopinavir/ritonavir (LPV/r)	O	O	O		
Tenofovir (TDF)	O	O	O		

continued on next page…

Medication chart, continued…					
Medication	**Recommendation** start	stop	continue	Reasons for Discontinuation*	Dose and Comments
Isoniazid (INH):	O	O	O		
Rifampin (RIF):	O	O	O		
Ethambutol (ETH):	O	O	O		
Pyrazinamide (PZA):	O	O	O		
Streptomycin (STREP):	O	O	O		
Other (specify):	O	O	O		
Other (specify):	O	O	O		

* Reasons for Discontinuation:
1 = Side Effect / Toxicity / Drug interaction
2 = Disruption in Drug Supply / Stock out
3 = Patient non-adherence
4 = Treatment failure
5 = pMTCT prophylaxis complete
6 = Patient refused
7 = Other, specify

25. Patient Plan: _____

_____

_____

_____

_____

_____

26. What tests will be ordered for the patient?
Fill in 'o' for all that apply:

O None
O Complete Blood Count
O CD4 Count
O ALT (Alanine Aminotransferase)
O AST (Aspartate Aminotransferase)
O Creatinine
O Electrolytes
O Tuberculin skin test (TST using PPD)
O Sputum for AFB
O Pregnancy test
O Radiology test (specify): _____
O Other (specify): _____

27. What referrals will be made for the patient?
Fill in 'o' for all that apply:

O None
O Family planning services
O Nutritional support
O In-patient care / Hospitalization
O TB treatment / DOT program
O Adherence counseling
O Mental health services
O Psychosocial counseling
O Social support services
O Other referral (specify):
_____
_____

28. When is the patient's next appointment?

O 1 week
O 1 month
O 2 months
O 3 months
O 6 months
O Other (specify): _____

Appointment Date: __ __ / __ __ / __ __ __ __
day month year

Form Completed By: _____ **Provider Initials:** ___

MCAP adult follow-up form

MCAP ADULT FOLLOW-UP FORM

Patient Name: _____ **Patient ID Number:** [ ]

Visit Date:
[ ][ ] / [ ][ ] / [ ][ ][ ][ ]
day month year

1. Does the patient have a new medical problem, physical symptom, or concern today? O Yes O No
   If yes, please describe:

2. Within the last month, has the patient experienced any of the following symptoms? O Yes O No
   If yes, fill in the 'o' to the right of each condition. If no, proceed to question 3.

Symptom	Yes	Symptom	Yes
Cough	O	Pain - abdominal	O
Depression	O	Pain - muscles	O
Diarrhea	O	Pain - legs/feet	O
Difficulty breathing	O	Poor appetite	O
Fatigue	O	Rash	O
Fever	O	Thrush	O
Headache	O	Weakness	O
Memory problems	O	Weight gain	O
Nausea and/or vomiting	O	Weight loss	O
New visual problems	O	Other 1 (specify):	O
Night sweats	O	Other 2 (specify):	O
Numbness or tingling in legs and/or feet	O	Other 3 (specify):	O

3. Physical examination

Temperature [ ][ ].[ ] °C Height [ ][ ][ ] cm Weight [ ] kg Change in weight since last visit: [ ]

Examinations	Normal	Abnormal	Not Done	Comments / Descriptions
Ears, nose, throat	O	O	O	
Head and neck	O	O	O	
Cardiovascular	O	O	O	
Lungs	O	O	O	
Abdomen	O	O	O	
Lymph nodes	O	O	O	
Skin	O	O	O	
Urogenital	O	O	O	
Musculoskeletal	O	O	O	
Neurological	O	O	O	
Other 1 (specify):	O	O	O	
Other 2 (specify):	O	O	O	

4. Functional status (please select one):
   O Working (able to perform usual work in or out of the house)
   O Ambulatory (unable to work, but able to perform activities of daily living – e.g eating, bathing – without assistance)
   O Bedridden (unable to perform activities of daily living – e.g. eating, bathing – without assistance)

5. Are the patient and/or his/her partner currently using any form of family planning? O Yes O No

If yes, fill in 'o' for all that apply:

O Condoms O Oral Contraceptive Pills O Injectable/ implanted hormones (e.g. Depo-provera, Norplant)
O Diaphragm / Cervical Cap O Intrauterine Device O Vasectomy/ tubal ligation/ hysterectomy
O Other: _____

6. If the patient is female, is she pregnant?

O Yes, the patient is known to be pregnant. The expected date of delivery is ☐☐/☐☐/☐☐☐☐
day month year
O No, the patient is not known to be pregnant.
O The patient was pregnant; the pregnancy has ended since her last visit.
O Live birth O Pregnancy loss/ still birth O Pregnancy termination
→ Enrolled in MCAP? O Yes O No - if no, why not? (specify):

7. Since the last visit, has the patient been hospitalized for HIV-related reasons? O Yes O No
If so, briefly describe the reason for hospitalization:

_____
_____
_____
_____
_____

8. What is the highest WHO staging indicator condition the patient has experienced to date?

O WHO Stage 1 O WHO Stage 2 O WHO Stage 3 O WHO Stage 4

9. What is the patient's most recent CD4 count?

☐☐☐☐ /mm^3 ☐☐ %

Date specimen collected
☐☐/☐☐/☐☐☐☐
day month year

10. Since the last visit, has the patient had any other significant clinical or laboratory findings that will change his/ her medical management? If so, please detail here :

_____
_____
_____
_____
_____
_____
_____

11. If the patient is not on OI prophylaxis, indicate eligibility for OI prophylaxis as of this visit:

O Not yet determined/ awaiting other information

O Ineligible

O Eligible →
- O Newly eligible for prophylaxis by CD4 count → CD4 count = ☐☐☐☐
- O Newly eligible for prophylaxis by WHO Stage → WHO Stage = ☐
- O Previously eligible for prophylaxis (specify): _____

12. If the patient is not on antiretroviral treatment (ART), indicate ART eligibility as of this visit:

O Not yet determined/ awaiting other information

O Ineligible

O Eligible →
- O Newly eligible for ART by CD4 count → CD4 count = [ ][ ][ ][ ]
- O Newly eligible for ART by WHO Stage → WHO Stage = [ ]
- O Previously eligible for ART (specify): _____

13. If the patient is taking ARVs, during the last seven days, how many of her/his pills did the patient take?
(If not taking ARVs, skip to question 15)

Read list to patient, fill in only one 'o'

O None of her/his pills O Very few of her/his pills O About half of her/his pills

O Most of her/his pills O All of her/his pills every day → If all taken, skip to Question 15

14. If the patient missed any pills in the last seven days, what reason(s) did s/he provide?

Read list to patient, fill in 'o' for all that apply

O Forgot O Clinic ran out of medication O Patient ran out of pills

O Felt too ill O Lost her/his medication O Other reason: _____

O Side effects O Disclosure or privacy issues

15. List all medications being started, stopped, or continued:

Medication	**Recommendation** Start	Stop	Continue	Reasons for Stopping Med*	Dose and Comments
Cotrimoxazole	O	O	O		
Dapsone	O	O	O		
Zidovudine (AZT)	O	O	O		
Lamivudine (3TC)	O	O	O		
Stavudine (D4T)	O	O	O		
Didanosine (DDI)	O	O	O		
Abacavir (ABC)	O	O	O		
Nevirapine (NVP)	O	O	O		
Efavirenz (EFV)	O	O	O		
Nelfinavir (NFV)	O	O	O		
Lopinavir/ritonavir (LPV/r)	O	O	O		
Tenofovir (TDF)	O	O	O		
Isoniazid (INH):	O	O	O		
Rifampin (RIF):	O	O	O		
Ethambutol (ETH):	O	O	O		
Pyrazinamide (PZA):	O	O	O		
Streptomycin (STREP):	O	O	O		
Other (specify):	O	O	O		
Other (specify):	O	O	O		

* Reasons for Stopping Medication:
1 = Side Effect / Toxicity / Drug interaction
2 = Disruption in Drug Supply / Stock out
3 = Patient non-adherence
4 = Treatment failure
5 = pMTCT prophylaxis complete
6 = Patient refused
7 = Other, specify:

16. Patient Plan

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

17. What tests will be ordered for the patient? *Fill in 'o' for all that apply:*

O None
O Complete Blood Count
O CD4 Count Assay
O ALT (Alanine Aminotransferase)
O AST (Aspartate Aminotransferase)
O Creatinine
O Electrolytes
O Tuberculin skin test (TST using PPD)
O Sputum for AFB
O Pregnancy test
O Radiology test (specify): _____
O Other (specify): _____

18. What referrals will be made for the patient? *Fill in 'o' for all that apply:*

O None
O Family planning services
O Nutritional support
O In-patient care / Hospitalization
O TB treatment / DOT program
O Adherence counseling
O Mental health services
O Psychosocial counseling
O Social support services
O Other referral (specify):
_____
_____

19. When is the patient's next appointment?

O 1 week
O 1 month
O 2 months
O 3 months
O 6 months
O Other (specify): _____

→ Appointment Date: __ __ / __ __ / __ __ __ __
day month year

Form Completed By: _____ Provider Initials: ___

MCAP adult patient care flowsheet

MCAP Adult Patient Care Flowsheet

Patient Name: _____ Patient ID Number**:**

Date	Function (W, A, or B)	Wt (kgs)	WHO stage	CD4	TST (-/+)	Pregnant? (Y/N/NA)	INH? (Y/N)	CTX? (Y/N)	ART? (Y/N)	If on ARVs, list regimen

* W = able to work, A = ambulatory, B = bedbound

MCAP pediatric patient care flowsheet

MCAP Pediatric Patient Care Flowsheet

Patient Name: ______________________ Patient ID Number: | | | | | |

Date	Milestones (Y/N)	Wt (kgs)	WHO stage	CD4		HIV test (type & results)	INH? (Y/N)	CTX? (Y/N)	ART? (Y/N)	If on ARVs, list regimen
				#	%					

* Y = meeting developmental milestones, N = not meeting developmental milestones

MCAP Pediatric Patient Care Flowsheet – Version 1.0

International Center for AIDS
Care and Treatment Programs (ICAP)

Columbia University
Mailman School of Public Health

MCAP Pediatric Patient Care Flowsheet

Patient Name: _____ Patient ID Number**:** ☐☐☐☐☐

HIV test results:

Test #1: Type of test O HIV DNA PCR O HIV RNA PCR O Antibody test

Date of specimen: ☐☐ / ☐☐ / ☐☐☐☐ Age of child on date of test: ☐☐ O years O months

Test result: _____

Test #2: Type of test O HIV DNA PCR O HIV RNA PCR O Antibody test

Date of specimen: ☐☐ / ☐☐ / ☐☐☐☐ Age of child on date of test: ☐☐ O years O months

Test result: _____

Test #3: Type of test O HIV DNA PCR O HIV RNA PCR O Antibody test

Date of specimen: ☐☐ / ☐☐ / ☐☐☐☐ Age of child on date of test: ☐☐ O years O months

Test result: _____

Date	Milestones (Y/N)	Wt (kgs)	WHO stage	CD4		HIV test (type & results)	INH? (Y/N)	CTX? (Y/N)	ART? (Y/N)	If on ARVs, list regimen
				#	%					

* Y = meeting developmental milestones, N = not meeting developmental milestones

AIDSRelief Project (partners include: Catholic Relief Services, Catholic Medical Mission Board, Interchurch Medical Assistance, Futures Group, and University of Maryland)

The AIDSRelief Project is another Track 1.0 partner which has developed optional template forms for its project sites to use in the field. Some or all of the sites in Guyana, Haiti, Nigeria, South Africa, Tanzania, Uganda and Zambia have adapted or are in the process of adapting the forms.

Medical data card
The medical data form is another presentation of the HIV care/ART patient card presented in Annex D using bubbles rather than codes.

Home visit form
The home-based care forms were created at the request of project sites that wanted to capture basic information from established home-based care and adherence programmes.

AIDS Relief Project medical data card

MEDICAL DATA CARD

1. Patient Name _____ 2. Guardian's Name _____ 3. Contact Telephone Number _____

4. ID [ ][ ][ ] - [ ][ ][ ] - [ ][ ] - [ ][ ][ ][ ] 5. Hosp No. [ ] 6. Provider's Name _____

Country — CPOS# — Satellite # — Patient Enrolment #

7. Estimated Date of Birth_____/_____/_____ 8. Date of HIV diagnosis _____/_____ 9. Date Enrolled in AIDS Relief ____/___/___

10. Disclosed Status Yes ◯ 11. Treatment Preparation (date) _____/_____ 12. Date Initiated HAART ___/___/___

13. 1st Regimen_____/_____/_____/_____ 2nd Regimen_____/_____/_____/_____ 3rd Regimen_____/_____/_____/_____

Date started_____/_____ Date stopped_____/_____ Date started_____/_____ Date stopped_____/_____ Date started_____/_____ Date stopped_____/_____

14. Reasons for Change of Regimen

- ◯ Toxicity
- ◯ Treatment Failure
- ◯ Non-adherence
- ◯ Drug interaction
- ◯ Pregnancy
- ◯ Patient Preference
- ◯ Drugs not available
- ◯ Migratory patient, no follow up available
- ◯ Transfer to another program
- ◯ Inability to pay
- ◯ Other

Reasons for Change of Regimen

- ◯ Toxicity
- ◯ Treatment Failure
- ◯ Non-adherence
- ◯ Drug interaction
- ◯ Pregnancy
- ◯ Patient Preference
- ◯ Drugs not available
- ◯ Migratory patient, no follow up available
- ◯ Transfer to another program
- ◯ Inability to pay
- ◯ Other

Reasons for Change of Regimen

- ◯ Toxicity
- ◯ Treatment Failure
- ◯ Non-adherence
- ◯ Drug interaction
- ◯ Pregnancy
- ◯ Patient Preference
- ◯ Drugs not available
- ◯ Migratory patient, no follow up available
- ◯ Transfer to another program
- ◯ Inability to pay
- ◯ Other

15. ARV Mutations

NRTI:

NNRTI:

PI:

16. Past Medical History/Problem List

1_____ 4_____
2_____ 5_____
3_____ 6_____

17. OBGYN History

_____
_____
_____

Delivery date				Pap Smear	Stage
___/___	NVP ◯	HAART ◯		___/___	_____
___/___	NVP ◯	HAART ◯		___/___	_____

18. Opportunistic Infections

Date of:	Initial Dx	Confirmed	Recurrence	Confirmed
Pulmonary TB	___/___	◯	___/___	◯
Smear + ◯ Smear - ◯				
Extrapulmonary TB	___/___	◯	___/___	◯
Mycobacteria other	___/___	◯	___/___	◯
PCP	___/___	◯	___/___	◯
Cryptococcal meningitis	___/___	◯	___/___	◯
Oral Candidiasis	___/___	◯	___/___	◯
Candidial Esophogitis	___/___	◯	___/___	◯
Pneumonia	___/___	◯	___/___	◯
Herpes zoster	___/___	◯	___/___	◯
Herpes simplex	___/___	◯	___/___	◯

	Initial Dx	Confirmed	Recurrence	Confirmed
Genital ulcerative disease	___/___	◯	___/___	◯
Urethitis/cervicitis	___/___	◯	___/___	◯
PID	___/___	◯	___/___	◯
Neurological(Toxo, PML, lymph)	___/___	◯	___/___	◯
Encephalopathy	___/___	◯	___/___	◯
Cutaneous KS _____	___/___	◯	___/___	◯
Visceral KS _____	___/___	◯	___/___	◯
Lymphoma	___/___	◯	___/___	◯
Sepsis	___/___	◯	___/___	◯
Salmonellosis	___/___	◯	___/___	◯
Diarrhea/wasting	___/___	◯	___/___	◯

CD4 Nadir [ ]

19. WHO stage

[ ] At enrollment

[ ] At initiation of ARV

AIDS Relief Form 6
Medical Data Card; Page 1 of 2
November 2004

AIDS Relief Project home visit form

Home Visit Form

1. Patient Name _____ 3. Hosp/Facility # _____

2. ID ___ - ___ - ___ ____
Country POS # Satellite # Patient enrollment#

4. Caretaker/Guardian_____ 5. CHW/CHV/Nurse Team_____

5a. Alternative CHW/CHV Team #_____

6. How to Locate Patient:

Sublocation _____
Nearest Church _____
Primary School _____
Chief / Subchief _____
Telephone # _____

7. Dispensing Frequency: Duration:

- ◯ Directly observed therapy (DOT) ..... _____
- ◯ Weekly refills ..... _____
- ◯ Bi Monthly ..... _____
- ◯ Monthly ..... _____
- ◯ Other (please specify) ..... _____

Adherence codes:

1 Forgot	7 Delivery/ travel problems
2 Side effects	8 Dispensary out of stock
3 Feeling Sick	9 Program stopped
4 Illness in family	10 Unable to pay for meds
5 Perceived lack of need	11 Work conflict
6 Sharing medication	12 Other

	WEEK 1 __/__/__							WEEK 2 __/__/__							WEEK 3 __/__/__							WEEK 4 __/__/__						
	M	T	W	Th	F	S	S	M	T	W	Th	F	S	S	M	T	W	Th	F	S	S	M	T	W	Th	F	S	S
8 Number of Times You Saw The Patient (1-3)																												
9 Number of Times You Directly Observed Therapy (1-3)																												
10 Number of Times Caretaker Directly Observed Therapy (1-3)																												
11 Number of Missed doses per day (1-3)																												
12 Why Did Patient miss doses? (Fill in Adherence Reasons Code)																												
13 Was Adherence Explained And Encouraged? (Y or N)																												
14 Drugs Were Delivered To Patient (indicate with a tick mark)																												
15 Could Not Find (tick if unable to find patient/patient not home)																												
16 SYMPTOMS THIS WEEK: Cough																												
Diarrhea																												
Nausea/vomitting																												
Fever																												
Yellow eyes																												
Rash																												
Headache																												
Admitted to Hospital																												
Loss of appetite/abdominal pain																												
Other																												

Patient's next clinic appointment _____/_____/_____ _____/_____/_____ _____/_____/_____ _____/_____/_____

17 Actions Taken: Urgent Medical Referring Contact #_____ Supervisor Made Aware_____ Date _____/_____/_____

	Date	Daily Comments
Week 1	____/____/____	
	____/____/____	
	____/____/____	
	____/____/____	
	____/____/____	
Week 2	____/____/____	
	____/____/____	
	____/____/____	
	____/____/____	
	____/____/____	

	Date	Daily Comments
Week 3	____/____/____	
	____/____/____	
	____/____/____	
	____/____/____	
	____/____/____	
Week 4	____/____/____	
	____/____/____	
	____/____/____	
	____/____/____	
	____/____/____	

KwaZulu Natal province, South Africa

Adult visit summary form

KwaZulu Natal province in South Africa has developed a set of forms for both adults and children for its ARV rollout programme that may be accessed at: http://www.kznhealth.gov.za/arv/forms.htm. The adult visit summary form is an alternative presentation of a patient encounter form that is filled out at each patient visit.

Kwazulu Natal adult visit summary form

SA ID Number

Hospital File Number

ADULT VISIT SUMMARY FORM

KwaZulu Natal Department of Health
Comprehensive Care Programme

Visit Date		/ /		/ /		/ /		/ /		/ /	
Scheduled (X=No; Tick=Yes)											
Date of Next Visit		/ /		/ /		/ /		/ /		/ /	
WHO Staging											
WHO Performance											
Height (metres)											
Weight (kgs)											
BMI											
Temperature											
Blood Pressure (systolic/diastolic)		/		/		/		/		/	
Bloods Taken (X=No; Tick=Yes)											
Blood Results	CD4 Count										
	Viral Load										
	Hb										
	WCC										
	Plts										
	ALT										
	GGT										
	Alk Phos										
	Cholestrol										
Other Tests	Test Type										
	Result										
Treatment Regimen											
Months on Treatment											
Months on Regimen											
Substitutions											
Opportunistic Infections	1										
	2										
	3										
	4										
Adverse Events/ Side Effects	Event / Grade										
	Event / Grade										
	Event / Grade										
	Event / Grade										
Change in Treatment Regimen											
OI Prophy-laxis	Cotrimoxazole										
	Fluconazole										
No. of Missed Doses		In	Out	In	Out	In	Out	In	Out	In	Out
TB Symptoms (Tick=Yes)											
Months on TB Treatment											
Referrals (Tick=Yes)	Social Work										
	Counselling										
	TB Clinic										
	Inpatient/Hospital										
	Antenatal										
	Dietician										
	Specialist Clinic										
	Other *(specify)*										
Action											
Comments											
Captured By											

Ethiopia

ARV clinic patient record
Ethiopia has recently adapted the WHO forms to distribute nationally as it prepares to scale up ART. While the registers and aggregated data forms are almost identical for reporting reasons, the country has opted to include a set of clinical intake forms. The clinical form has the advantage of taking a clinician through the intake process, ensuring coverage of the major parts of a patient's clinical history and provides a comprehensive overview of the patient, including his or her social and economic circumstances. All but the two sections (E and F) of the form are filled out only once, at the initial visit (section G is filled out at the second visit). Section F gives an example of an adherence assessment form (to be filled out at each visit), which provides an estimate of self-reported adherence and reasons for poor or non-adherence.

HIV care/ART follow-up form
The follow-up form is similar to WHO's patient card encounter form. However, due to the lack of a patient summary form, it also incorporates information from clinical intake forms to facilitate data transfer to the pre-ART register. In addition the codes are more descriptive and provide users with a quick assessment of adherence.

Cohort analysis form
Ethiopia's cohort analysis form is a good example of a country-adapted form. While it is almost an exact replica of the generic WHO form, it has added mean CD4 % for children and replaced the months and years with those from the Ethiopian calendar. In addition to the regular A3 size presentation of the form, Ethiopia has created poster-size laminated cohort forms to be filled out and displayed at facilities to show progress of patients on treatment.

ARV CLINIC PATIENT RECORD

A. PATIENT REGISTRATION FORM

Health Facility Name:_____ Date:_____/_____/_____

PATIENT IDENTIFICATION

Name:_____ Father's Name:_____Grandfather's Name: _____

Date of Birth:_____/_____/_____ Age:_____ Gender: ○ Male ○ Female

ART Unique ID No.:_____ Patient Card No.: _____/_____

MARITAL STATUS:

- ○ Never Married
- ○ Married (incl. de facto)
- ○ Separated
- ○ Divorced
- ○ Widow/Widower

Occupation:_____

LEVEL OF EDUCATION:

- ○ No education
- ○ Primary
- ○ Secondary
- ○ Tertiary

RELIGION:

- ○ Muslim
- ○ Orthodox
- ○ Protestant
- ○ Catholic
- ○ Other

HUSBAND / WIFE AND DEPENDENT CHILDREN AT HOME

○ Husband/Wife Children ○ Yes ○ No

If Yes: Age _____,_____,_____,_____,_____,_____,

PATIENT ADDRESS

Region:_____Woreda/Kifle Ketema:_____

Kebele/Peasant Association: _____ House No.:_____

Telephone Number: Home_____ Mobile:_____ Work: _____

PATIENT REFERRAL INFORMATION

From with-in the hospital

○ In-patient ○ Medical Outpatient ○ TB Clinic ○ STI Clinic

○ PMTCT ○ General VCT ○ Pediatric Outpatient ○ Other Outpatient

Outside the Hospital

○ Health Centers ○ Public Hospital ○ Private Hospital ○ NGO/FBO Hospital

○ Private Clinic ○ Self-referred ○ Community Referred ○ Others ○ Unknown

CARE GIVER/EMERGENCY CONTACT INFORMATION:

Full Name: _____ Age: _____

Gender: ○ Male ○ Female

Relation: _____ ○ Other (Specify) _____

Address: ○ Same as patient's address

Region:_____Woreda/Kifle Ketema:_____

Kebele/Peasant Association: _____ House No.:_____

Telephone Number: Home _____ Mobile:_____ Work: _____

INSTRUCTIONS: A. PATIENT REGISTRATION FORM

Note: All fields must be filled in

Health Facility Name – Health Facility name as registered at the Ministry of Health

Date: - Use Ethiopian calendar and a format of DD/MM/YYYY

Name: - Enter patient's name.

Father's Name: - Enter patient's father's name. If not known enter NA.

Grandfather's Name: - Enter patient's grandfather's name. If not known enter NA

Patient Card Number- 6 digit number followed by year found on patient card to be issued to patient by

ART Unique ID No. –Patients should be assigned Unique ART number. This will be (region number/woreda/facility/patient assigned 5 digit number). The first patient to start ART in the clinic will be given 00001.

Date of Birth: -Use Ethiopian calendar and a format of DD/MM/YYYY. If only month and year are known then enter 00 for day, if only year is known than enter 00 for day and 00 for month.

Age: - Enter patient's current age in years. If patient is less than 5 years old, enter age in months.

Gender: -fill in the appropriate circle

Marital Status: - fill in appropriate circle

Level of Education: - fill in appropriate circle

Religion: - fill in appropriate circle

Occupation: Please fill in patient's job

Husband/Wife and dependent children at home: Please fill the appropriate circle (Husband or Wife). Fill in the appropriate circle for children. If there are children, please list all the ages in ascending order (eg 2, 5, 7 …)

Patient Address: - Enter address at which patient normally lives

a. **Region** – Enter one of the following number codes

1. Tigray (TG)	**6.** Benshangul .Gumuz (BG)
2. Afar (AF)	**7.** SNNPR (SN)
3. Amhara (AM)	**12.** Gambella (GA)
4. Oromia (OR)	**13.** Harar (HA)
5. Somali (SO)	**14.** Addis Ababa (AA)
	15. Dire Dawa (DD)

b. **Woreda/Kifle Ketema** – For Addis Ababa enter patient's Kifle ketema. For other regions enter patient's Woreda #.

c. **Kebele** – Enter patient's Kebele number

d. **House No.** – Enter patient's house number

e. **Home Telephone** – Enter patient's telephone number. If patient does not have a telephone enter NA.

f. **Mobile** – Enter patient's mobile (cell) telephone number. If patient does not have a mobile enter NA.

g. **Work** – Enter patient's work telephone number. If patient does not have a work telephone enter NA

Patient Referred From: - fill in appropriate circle. If patient is referred from Outside Clinic/Health Facility fill in the name of the Clinic/Health Facility. If patient is referred from other fill in name of the other facility.

Care giving Relative Information: Enter the name of family member that is aware of patient's serostatus to avoid unintended disclosure

a. **Name** – Enter name of next of kin

b. **Father's name** – Enter the father's name of next of kin

c. **Age** – Enter the age, in years, of the next of kin

d. **Relation** – fill in the appropriate circle that best describes the relationship between the patient

e. and the relative.

Care giving Relative Address: -If the relative's address is the same as the patient, fill in the appropriate circle. If it is different then fill in the spaces using the same codes as listed above for Patient Address fields.

a. **Region** – Enter one of the region number codes listed above under Patient Address Region field.

b. **Woreda/Kifle Ketema** – For Addis Ababa enter the Kifle ketema. For other regions enter the Woreda #.

c. **Kebele/Peasant Association** – Enter relative's Kebele//Peasant Association Number

d. **House No.** – Enter relative's house number

e. **Home Telephone** – Enter relative telephone number. If they do not have a telephone number enter NA.

f. **Mobile** – Enter relative's mobile (cell) telephone number. If they do not have a mobile enter NA.

Work – Enter relative's work telephone number. If they do not have a work telephone number enter NA.

ARV CLINIC PATIENT RECORD B. PAST MEDICAL /TREATMENT HISTORY FORM

Health Facility Name:_____ Date:_____/_____/_____

PATIENT IDENTIFICATION

Name:_____ Father's Name:_____Grandfather's Name: _____

ART Unique ID No.:_____ Patient Card No.: _____/_____

PAST OPPORTUNISTIC ILLNESS (MARK ALL THAT APPLY)

- ○ Candidiasis
- ○ Candidiasis (Oropharyngeal)
- ○ CMV
- ○ Cryptococcal Infection
- ○ Cryptococcal Meningitis
- ○ Cryptosporidiosis
- ○ Diarrhea (>1 month)
- ○ Disseminated Atypical Mycobacteriosis
- ○ Encephalopathy
- ○ Fever (>1 month; unexplained)
- ○ Herpes Simplex (>1 month)
- ○ Kaposi sarcoma
- ○ Minor Mucocutaneous Manifestations
- ○ Mycosis
- ○ PGL
- ○ PML
- ○ PneumocystisCarinii Pneumonia
- ○ Pneumonia (recurrent)
- ○ Recurrent URTIs
- ○ Salmonella Septicemia
- ○ TB-Extrapulmonary
- ○ Toxoplasmosis (brain)
- ○ Wasting Syndrome

Other (specify) _____

PAST TESTS/TREATMENT

TB

○ TB Smear Date: ____/_____/____ Site/Health facility:_____

Result: ○ Not Determined ○ Negative ○ Positive ○ Pos +1 ○ Pos +2 ○ Pos +3 ○ Unknown

TB Tx ○ Yes ○ No Completed Tx ○ Yes ○ No

Date Tx started _____/____/____ Date completed _____/_____/____

Regimen: ○ Not Determined ○ 2SRHZ/6EH ○ 2HRZES/1HRZE/5HRE ○ 2HRZE/6HE

Post Treatment smear: ○ Sputum smear + Date ___/___ /____ Smear negative Date ____/_____/___

HIV

HIV Test ○ Yes ○ No, if yes Date: ___/___ /____ Site/Health facility:_____

ARV Rx ○ Yes ○ No if yes Start: ___/___ /____ Length (weeks) _____ ○ Still on Treatment

Regimen: ○ d4t (30)-3TC-NVP ○ d4t (40)-3TC-NVP ○ d4t (30)-3TC-EFV

○ d4t (40)-3TC-EFV ○ AZT-3TC-NVP ○ 2nd line

○ PMTCT ○ Yes ○ No If Yes Site/Health facility:_____

Regimen: ○ Nevirapine ○ Non-Nevirapine _____ Baby Treated: _____

CD4

○ CD4+ ○ Yes ○ No, if yes Date: ___/___ /____ Site Health facility: _____Result___ ___/mm3

MEDICATIONS:

Cotrimoxazole ○ Yes ○ No **INH** ○ Yes ○ No **Fluconazole** ○ Yes ○ No

Other Medication/s (Specify): _____

Known Drug-related Allergies

○ Penicillium ○ Cephalosporin ○ Sulfonamides (Cotrimoxazole, etc.)

○ Amino glycosides (Streptomycin, etc) ○ Other_____(specify)

INSTRUCTIONS: B. PAST MEDICAL/TREATMENT HISTORY FORM

Note: All fields must be filled in

Health Facility name – Health Facility name as registered at the Ministry of Health
Date: - Use Ethiopian calendar and a format of DD/MM/YYYY
ART Unique ID No. –Patients should be assigned Unique ART number. This will be.(region number/woreda/facility/patient assigned 5 digit number). The first patient to start ART in the clinic will be given 00001.
Patient Card No. - 6 digit number followed by year found on patient card to be issued to patient by facility.
Past Opportunistic Illness – fill in all applicable circles. Note that this information can be obtained from both the patient and any available medical/lab records.
Past Tests/Treatment – If a patient has had more than one of these tests in the past, list only the most recent ones. Indicate the test date using Ethiopian calendar and a format of DD/MM/YYYY. The site refers to the facility at which the test was performed. If unknown enter NA in space. For CD4 test, if result is not available/unknown enter NA in result space.

a. **TB** – Enter date upon which patient initiated TB treatment and completed treatment using Ethiopian calendar and DD/MM/YYYY format.
b. **ARV** – Enter date on which patient initiated ARV treatment using Ethiopian calendar and DD/MM/YYYY format. Enter the length of treatment (in number of weeks) calculated from the start date to date the treatment ended. If patient is currently on ARV treatment, calculate length of treatment from start date to today. Fill in the appropriate circle for regimen and for outcome.
c. **PMTCT** – Same as with ARV

Prophylaxis – Same general instructions as Past Treatment fields.
Current Medications – Fill in all applicable circles. If 'Other' write in medications.

Known Drug Allergies – Fill in all applicable circles. If 'Other' write in drug name/ class

ARV CLINIC PATIENT RECORD

C. GENERAL CONDITION/PHYSICAL EXAM

Health Facility Name:_____ Date:_____/_____/_____

PATIENT IDENTIFICATION

Name: _____ Father's Name: _____ Grandfather's Name: _____

ART Unique ID No.: _____ Patient Card No.: _____/_____

VITAL SIGNS AND FUNCTIONAL LEVEL

Height (cm)	Weight (kg)	Temp (°C)	HR (b/m)	BP (s/d mmHg)	RR (R/m)
__ __ __	__ __ __	__ __	__ __ __	__ __ __ / __ __ __	__ __

SYMPTOM SCREEN

- ○ Chronic Cough
- ○ Dyspnea
- ○ Hemoptysis
- ○ Chronic Fatigue
- ○ Weight Loss ○ __% body wt
- ○ Flu-like (URTI)
- ○ Night Sweats
- ○ Fever > 1 month
- ○ Dysphagia and/or Odynophagia
- ○ Nausea and/or Vomiting
- ○ Abdominal Pain
- ○ Numbness/Tingling
- ○ Persistent Headaches
- ○ Mental Confusion
- ○ Chronic Diarrhea
- ○ STI Symptoms

PATIENT'S PREGNANCY STATUS

○ Pregnant EDD ____/____/____ ○ Not Pregnant ○ Not Applicable (male)

GENERAL APPEARANCE OF PATIENT AT PRESENTATION:

_____

_____

PHYSICAL EXAM

Physical Exam	Normal	Abnormal	Specify Abnormal Finding
HEENT			
Lymph nodes			
Chest			
Heart			
Abdomen			
Genitourinary System			
Musculo-skeletal system			
Skin			
Nervous System			

Other findings:

_____

_____

_____

_____

INSTRUCTIONS: C. GENERAL CONDITION/PHYSICAL EXAM

Note: All fields must be filled in

Health Facility Name – Health Facility name as registered at the Ministry of Health
Date: - Use Ethiopian calendar and a format of DD/MM/YYYY.
ART Unique ID No. –Patients should be assigned Unique ART number. This will be (region number/woreda/facility/patient assigned 5 digit number). The first patient to start ART in the clinic will be given 00001.
Patient Card No. - 6 digit number followed by year found on patient card to be issued to patient by facility
Functionalstatus–WorWork=working,AorAmb=ambulatory,BorBed=bedridden(Working=able to perform usualwork in or out of the house, harvest, go to school. Ambulatory=ambulatory but not able to work. Able to performactivities of daily living. Bedridden=not able to perform activities of daily living.
Vital Signs - Enter all the indicated vital signs. Symptoms – Fill in all applicable circles. Note the following:

a. For 'Cough' you can fill in duration and whether it is productive if applicable
b. For 'Fever' you can fill in duration if applicable
c. For 'Weight Loss' you can fill in if > than 10% of body weight
d. For 'Amenorrhea' you should enter the date of LMP using Ethiopian calendar and DD/MM/YYYY format
e. For 'Diarrhea' you can enter duration and if there is blood present

Patient's Pregnancy Status – fill in appropriate circle. If patient is currently pregnant indicate the Expected Delivery Date using Ethiopian calendar and a format of DD/MM/YYYY **Physical and Mental Examination** – fill in all applicable circles. Note that the left-hand column should be filled in if findings are normal. If findings are abnormal for any system, fill in applicable circles or spaces to the right.

ARV CLINIC PATIENT RECORD

D. CLINICAL REVIEW

Health Facility Name:_____ Date:_____/_____/_____

PATIENT IDENTIFICATION

Name:_____ Father's Name:_____Grandfather's Name: _____

ART Unique ID No.:_____ Patient Card No.: _____/_____

WHO STAGING

WHO Stage 1 Conditions

- ○ Persistent Generalized Lymphadenopathy (PGL)

WHO Stage 2 Conditions

- ○ Minor Mucocutaneous Manifestations
- ○ Weight Loss <10% of Body Weight
- ○ Herpes Zoster
- ○ Recurrent Upper Respiratory Tract Infections

WHO Stage 3 Conditions

- ○ Oral Candidiasis
- ○ Oral Hairy Leukoplakia
- ○ Unexplained Chronic Diarrhea (>1 month)
- ○ Unexplained Prolonged Fever (>1 month)
- ○ Weight Loss >10% of Body Weight
- ○ Bacterial Pneumonia
- ○ Other Severe Bacterial Infections (i.e. pyomyositis)
- ○ Pulmonary Tuberculosis

WHO Stage 4 Conditions

- ○ Extrapulmonary Tuberculosis
- ○ Atypical Mycobacteriosis
- ○ Crytococcosis Extrapulmonary
- ○ Herpes Simplex (mucocutaneous >1 month, or visceral
- ○ HIV Encephalopathy
- ○ Lymphoma
- ○ Mycosis, Disseminated (i.e. Histoplasma, Coccidioides)
- ○ Salmonella Septicemia, Non-typhoid
- ○ HIV Wasting Syndrome
- ○ Candidiasis (Esophagus, Trachea, Bronchi or Lungs)
- ○ Cryptosporidiosis with Diarrhea (>1 month duration)
- ○ CMV Disease (other than liver, spleen, lymph nodes)
- ○ Karposi's Sarcoma
- ○ PML
- ○ Pneumocystis Carinii Pneumonia (PCP)
- ○ Toxoplasmosis of the CNS

CLINICAL REVIEW

Does the Patient need evaluation for cough or TB?

○ No ○ Yes if Yes, Order: ○ TB sputum smear ○ Empiric Antibiotics ○ Chest X-Ray

Does the Patient need evaluation for diarrhea?

○ No ○ Yes Order: ○ Stool Examination ○ Empiric Antibiotics ○ Empiric Antiparasitics

Does the Patient need evaluation for fever?

○ No ○ Yes Order: ○ Urine Analysis ○ Malaria Slide ○ Hb, WBC, Diff

○ Blood Culture ○ Empiric Antibiotics ○ other (specify _____)

Does the Patient need prophylactic medication? ○ No ○ Yes

Does the Patient need evaluation for ARV treatment? ○ No ○ Yes

○ Start Education Sessions If Yes: ○ Hgb, WBC with differential ○ Liver function test (ALT) ○ CD4 count

INSTRUCTIONS: D. CLINICAL REVIEW

Note: All fields must be filled in

Health Facility name – Health Facility name as registered to the facility by the Ministry of Health
Date: - Use Ethiopian calendar and a format of DD/MM/YYYY
ART Unique ID No. –Patients should be assigned Unique ART number. This will be (region number/Woreda/facility/patient assigned 5 digit number). The first patient to start ART in the clinic will be given 00001.
Patient Card No. - 6 digit number followed by year found on patient card to be issued to patient by facility.
WHO Staging – fill in all applicable circles in each level. Note that a patient's WHO stage is the highest stage that has at least one circle filled in.
Clinical Review – The purpose of this section is to help the clinical provider develop an appropriate plan of care based on HIV/AIDS treatment guidelines. Any 'Order' circles filled in should be followed up with the appropriate laboratory/X-ray request form.

ARV CLINIC PATIENT RECORD

E. SOCIAL ASSESSMENT

Health Facility Name:_____ Date:_____/_____/_____

PATIENT IDENTIFICATION

Name:_____ Father's Name:_____Grandfather's Name: _____

ART Unique ID No.:_____ Patient Card No.: _____/_____

EMPLOYMENT

Current employment: ○ Working full time ○ Working part-time ○ Not working/Studying due to ill health
○ Unemployed

Other (Specify):_____

Employer's Name _____ Department _____ Position _____
Does/Did illness affect ability to carry out this employment/study? ○ Yes ○ No If yes how often_____

If No is there any impact due to illness?_____

LIVING CONDITIONS

Home: Number of rooms _____ ○ Running water ○ Electricity

Number of people in the household _____

RELIGIOUS/SUPPORTIVE CARE

Religious conviction
○ Muslim ○ Orthodox ○ Protestant ○ Catholic ○ Other

Spiritual caregiver_____

Community Support/HIV support groups ○ Yes ○ No

DISCLOSURE

Does anyone else know about your HIV Status?
Family ○ Wife/Husband ○ Own Child (ren) ○ Parent(s) ○ Brother(s)/Sister(s)
Others ○ Relatives ○ Friends

FAMILY MEMBERS – SPOUSE

Condition of wife/husband: ○ Healthy ○ Chronic Ill ○ Dead ○ Unknown
HIV tested Result ○ Not Asked ○ Negative ○ Positive ○ Unknown
TB Result ○ Not Asked ○ Negative ○ Positive ○ Unknown
Was/Is on ARV treatment Yes ○ No ○ **Was/Is on TB treatment** Yes ○ No ○

FAMILY MEMBERS – CHILDREN

Number of children alive____ Number HIV tested_____ Number positive____ Number chronically ill_____
Number of children died____ Number HIV tested_____ Number positive____ Number were chronically ill_____

ISSUES/CONCERNS IDENTIFIED

General

○ Concerns about financial issue within the family
○ Concerns about the children
○ Concerns regarding marital relationship
○ Concerns regarding family relations
○ Bereavement/grief
○ HIV status disclosure concerns
○ Adherence to treatment concerns
○ Dietary problems
○ Other concerns

INSTRUCTIONS: E. SOCIAL ASSESSMENT

Health Facility name – Health Facility name as registered at the Ministry of Health
Date: - Use Ethiopian calendar and a format of DD/MM/YYYY
ART Unique ID No. –Patients should be assigned Unique ART number. This will be.(region number/woreda/facility/patient assigned 5 digit number). The first patient to start ART in the clinic will be given 00001.
Employment Details (especially important if the clinic is workplace clinic)
Company – Fill in the name of the company where the patient words. If the patient is not working at this time enter NA.
Department – Fill in the department in which the patient works. If not known or not applicable enter NA
Employer's Working/Study: -

a. **Working full time** – If the patient is full time employee
b. **Working part-time** – If the patient works on part time base.
c. **Not Working/studying due to ill health.** – If the patient couldn't work/or study due to HIV/AIDS related problems
d. **Unemployed** – If the patient doesn't work due to not HIV/AIDS related problems but other factors
e. **Other (specify)**–Include students, housewives and other employment categories.

Disclosure: if any one knows the status of the patient/child at work place, school, family and other community members
Family Members:

a. **Family** : Spouse and/or children aware of the patient's serostatus
b. **Others:** other relatives, friends etc who are aware of the patient's serostatus

Family Member: spouse: please fill in the appropriate circle to indicate the health status of the spouse
Family Member: children: please fill in the appropriate circle to indicate the health status of the child
Issues/Concerns Identified: please fill in the appropriate circle to indicate the Issues/Concerns identified

Social assessment should be conducted whenever the patient comes to the Health facility by counselors or ART nurse

ARV CLINIC PATIENT RECORD

F. ART ADHERENCE COUNSELING

Health Facility Name:_____ Date:_____/_____/_____

PATIENT IDENTIFICATION

Name:_____ Father's Name:_____Grandfather's Name: _____

ART Unique ID No.:_____ Patient Card No.: _____/_____

HEALTH EDUCATION & KNOWLEDGE

○ Attended HIV related health education session(s) in the past

○ Attended HIV related counseling session(s) in the past

Understanding of HIV disease:	○ NA	○ -	○ +	○ ++	○ +++
Understanding of HIV transmission:	○ NA	○ -	○ +	○ ++	○ +++
Understanding of prophylaxis and treatment of OI:	○ NA	○ -	○ +	○ ++	○ +++
Understanding of ART medication adherence:	○ NA	○ -	○ +	○ ++	○ +++

RISK-BEHAVIOR

○ Has regular sexual partner

○ Has casual sexual partner(s) – Number of casual partners in last 3 months ○ 1 ○ 2 ○ 3 ○ >3

Condom use ○ NA ○ Never ○ Rarely ○ Sometimes ○ Mostly ○ Always ○ No response

Addictions:

Tobacco	○ NA	○ -	○ +	○ ++	○ +++	
Alcohol	○ NA	○ -	○ +	○ ++	○ +++	
Soft Drugs	○ NA	○ -	○ +	○ ++	○ +++	e.g., Khat, Shisha, pills, etc.
Hard Drugs	○ NA	○ -	○ +	○ ++	○ +++	e.g., cocaine, morphine, i.v.-drugs, etc.

Adherence: Concerns/barriers to ART:

○ Stigma (family and friends will find out) ○ Depressed/anxious

○ Afraid of medications (side effects; "poison") ○ Will forget to take medications

○ Doubt that medications will work ○ Other _____

GENERAL FEELING

Since your last visit , have you had any problems or complaints? ○ No ○ Yes

Have you been hospitalized? ○ No ○ Yes

How has your appetite been since your last visit? ○ Not Asked ○ Good ○ OK ○ Poor

How has your strength been since your last visit?

○ Normal ○ Weak, but not in bed ○ Very weak, often in bed ○ Extremely weak, mostly in bed

How many days have you been too sick to work?_____ ○ Lost job due to current illness

Evaluator's impression about mental condition

○ At ease ○ Confused ○ Depressed ○ Anxious ○ Suicidal

APPROPRIATE REFERRAL

○ Physician ○ Pharmacy ○ Social Services ○ Laboratory ○ Community Based Organizations

INSTRUCTIONS: F. ART ADHERENCE COUNSELING

Note: All fields must be filled in

This form must be completed each time a patient is seen at the ART clinic

Health Facility Name:- Health Facility name as registered at the Ministry of Health
Date: - Use Ethiopian calendar and a format of DD/MM/YYYY
ART Unique ID No. –Patients should be assigned Unique ART number. This will be. (Region number/Woreda/Facility/patient assigned 5 digit numbers). The first patient to start ART in the clinic will be given 00001.
Patient Card No. – 6 digit number followed by year found on patient card to be issued to patient by facility.
Health Education & Knowledge – fill in appropriate circles. Scale is from '- None' to '+++ A great deal'
Life Style – fill in appropriate circles. Scale is from '- No Use' to '+++ A great deal of use'
Issues Identified – fill all applicable circles, counsel and refer when necessary.
Adherence questions – fill in appropriate circle for each question. Educate patient re adherence at every visit.
General Feeling questions – fill in appropriate circles. Some questions may be more appropriate at follow-up.
Counsel patient accordingly
Appropriate referral: fill in appropriate circles and refer patient according to identified needs discovered during counseling

The Adherence counseling form need to be filled by the counselor or nurse every time the patient comes to clinic. This form should be copied.

ARV CLINIC PATIENT RECORD

G. ART ASSESSMENT AND PLAN

Health Facility Name:_____ Date:_____/_____/_____

PATIENT IDENTIFICATION

Name:_____ Father's Name:_____Grandfather's Name: _____

ART Unique ID No.:_____ Patient Card No.: _____/_____

ARV ELIGIBILITY CRITERIA

Clinical Criteria:

CD4 below 200	○ Yes	○ No
WHO Stage IV	○ Yes	○ No
WHO Stage II and III with TLC ≤ 1200	○ Yes	○ No

Social Criteria:

Resident of catchments area	○ Yes	○ No
No identified barriers for adherence	○ Yes	○ No

PLAN

1. **OI Prophylaxis (dd/mm/yy)**

Cotrimoxazole: Start_____/_____/_____Continue_____/_____/_____Discontinue_____/_____/_____Start at a later date_____/_____/_____

INH: Start_____/_____/_____Continue_____/_____/_____Discontinue_____/_____/_____Start at a later date_____/_____/_____

Fluconazole: Start_____/_____/_____Continue_____/_____/_____Discontinue_____/_____/_____Start at a later date_____/_____/_____

2. **Treatment for other conditions:** ○ **Yes** _____ ○ **No** _____

If Yes: Diagnosis: _____ Treatment: _____

If Yes: Diagnosis: _____ Treatment: _____

3. **Recommend ART:**

○ Yes _____ ○ No _____ ○ Deferred (State reason) _____

If yes, specify regimen:

- ○ 1a(30) = d4t (30)-3TC-NVP
- ○ 1a(40) = d4t (40)-3TC-NVP
- ○ 1b(30) = d4t (30)-3TC-EFV
- ○ 1b(40) = d4t (40)-3TC-EFV
- ○ 1c = AZT-3TC-NVP
- ○ 1d = AZT-3TC-EFV

INSTRUCTIONS : G. ART ASSESSMENT AND PLAN

Note: All fields must be filled in

Form G is to be completed at the second visit by the treating physician.

Health Facility Name:- Name as registered at the Ministry of Health
Date: - Use Ethiopian calendar and a format of DD/MM/YYYY
ART Unique ID No. –Patients should be assigned Unique ART number. This will be. (Region number/Woreda/Facility/patient assigned 5 digit numbers). The first patient to start ART in the clinic will be given 00001.
Patient Card No. – 6 digit number followed by year found on patient card to be issued to patient by facility.
ARV Eligibility Criteria- Clinical Criteria: fill in the appropriate circle to indicate the ARV Eligibility Clinical Criteria
ARV Eligibility Criteria- Social Criteria: fill in the appropriate circle to indicate the ARV Eligibility Social Criteria
Plan- OI Prophylaxis: please use the appropriate blank space to fill the appropriate date (dd/mm/yy)
Plan- Treatment for other conditions: fill in the appropriate circle
Plan- Recommend ART: please fill in the appropriate circle

Ethiopia HIV care/ART follow-up form

FEDERAL MINISTRY OF HEALTH OF ETHIOPIA

HIV CARE/ART FOLLOW-UP FORM

Patient Card No. _____ Unique ART No. _____ TB Card No. _____

Name: _____ Age: _____ years Sex: ____ M ____ F

Date confirmed HIV+ _____ (DD/MM/YY)

Address: Woreda/Kifle Ketema _____ Kebele/ Peasant Association: _____ H. No. _____ Tel.: _____

P/F	Follow up date (S/US)	Months on ART	Wt KG	Pregnant EDD PMTCT FP If FP, FP Method / For children: height	Function Work Amb Bed	WHO Stage	TB Status	Side effects	OIs	Cotrimoxazole		Other meds dispensed	ARV drugs				CD 4 cells/ mm3 or % if < 5	Hg, RPR, TLC, Other lab	Elig	Why Elig	Elig + Ready	Next visit date
										Adh	Dispense		Adh	why	Dispense (dose/reg code	why changed						

FOLART - Vr1/97

Follow-up date	Months on ART	Pregnancy/Family Planning	Functional status	TB status
S=Scheduled US=Unscheduled P=Paying F=Free	Duration in months since initiation of ART If PreART, leave blank 0 = ART initiation 1 week = 1 week 2 weeks = 2 weeks 3 weeks = 3 weeks 1 = 1 month … If pt changes regimen, add total no. of weeks since start of original regimen followed by '/' and the no. of weeks since start of new regimen	P = Pregnant If pregnant, give estimated due date (EDD) PMTCT = Referred to PMTCT FP = Not pregnant and on family planning If on FP, note methods (note: more than 1 method may be used): 1= condoms 2= oral contraceptive pills 3= injectable/implantable hormones (e.g. depo-provera) 4=Diaphragm/cervical cap 5=Intrauterine device 6=Vasectomy/tubal legation/hysterectomy	W=Working (able to perform usual work in or out of the house, harvest, go to school or, for children, normal activities or playing) A=Ambulatory (ambulatory but not able to work; able to perform activities of daily living) B=Bedridden (not able to perform activities of daily living)	No signs = no signs or symptoms of TB TB refer = TB suspected and referred for evaluation INH = currently on INH prophylaxis (IPT). TB Rx = currently on DOTS Sputum = TB suspected and sputum sample sent --, +, ++, or +++ = sputum results
Potential side effects	OIs or other problems (also use codes to left)	Adherence	Why poor/fair adherence	Dispense Dose/Regimen Code
Nausea Diarrhea Fatigue Headache BN burning/ numbness/ tingling Rash Anemia Abdominal pain Jaundice Fat changes CNS: dizzy, anxiety, nightmare, depression	Zoster BP, Bacterial Pneumonia PTB, Pulmonary Tuberculosis ETB, Extra pulmonary tuberculosis Thrush-oral, vaginal Ulcers-mouth, genital, DC or DA, Diarrhea Chronic/Acute PCP, Pneumocystis carinii pneumonia CT, CNS Toxoplasmosis CM, Cryptococcal Meningitis Other	Estimate adherence using the table below: Adherence / % / Missed doses G (good) / > 95% / ≤ 3 doses F (fair) / 85-94% / 4-8 doses P (poor) / < 85% / ≥ 9 doses STOP = Stopped ART If STOP, In why column, note reason why stopped: 1 Toxicity/side effects 2 Pregnancy 3 Treatment failure 4 Poor adherence 5 Illness, hospitalization 6 Drugs out of stock 7 Patient lack finances 8 Other patient decision 9 Planned treatment interruption 10 Other	1 Toxicity/side effects 2 Share with others 3 Forgot 4 Felt better 5 Too ill 6 Stigma, disclosure or privacy issues 7 Drug stock out – dispensary 8 Patient lost/ ran out of pills 9 Delivery/travel problems 10 Inability to pay 11 Alcohol 12 Depression 13 Other _____	Number of doses of treatment dispensed / Regimen code" Adult 1st Line Regimens: 1a(30)=d4t(30)-3TC-NVP 1a(40)=d4t(40)-3TC-NVP 1b(30)=d4t(30)-3TC-EFV 1b(40)=d4t(40)-3TC-EFV 1c = AZT-3TC-NVP 1d = AZT-3TC-EFV Adult 2nd Line Regimens: 2a = ABC-ddI-LPV/r 2b = ABC-ddI-NFV 2c= TDF-ddI-LPV/r 2d= TDF- ddI-NFV Child 1st Line Regimens 4a =d4T-3TC-NVP 4b = d4T-3TC-EFV 4c = AZT-3TC-NVP 4d = AZT-3TC-EFV Child 2nd Line Regimens 5a = ABC-ddI-LPV/r 5b = ABC-ddI-NFV 5c = TDF-ddI-LPV/r 5d = TDF-ddI-NFV
Eligible Check when patient is medically eligible for ART	Why Eligible 1 Clinical only 3 TLC 2 CD4 4 Transfer In (TI)	Eligible and ready Check when pt is medically eligible AND ready (counselled for adherence) for ART	Follow-up status After follow-up date, in second column, write: TO = transferred out LOST = not seen since … DEAD = died DROP = lost to follow-up, dropped from drug supply	

FOLART - Vr1/97

Ethiopia cohort analysis form

Report on Treatment Status/Outcomes for Cohorts on ART

Facility Name:_____

Cohorts are defined by month/year they started ART.

	For cohort starting ART by month/year: at baseline then results at 6 months on ART, 12 months on ART, 24 months on ART	Cohort Tire 97	6 mo-Hamle 97	12 mo-Tire 98	24 mo-Tire 99	Cohort Yekatit 97	6 mo-Nehase 97	12 mo Yekatit 98	24 mo-Yekatit 99	Cohort Megabit 97	6 mo-Meskrem 97	12 mo Megabit 98	24 mo-Megabit 99	Cohort Miazia 97	6 mo-Tikimete 98	12 mo Miazia 98	24 mo-miazia 99	Cohort Ginbote 97	6 mo-Hidare 98	12 mo-Ginbote 98	24 mo-Ginbote 99	Cohort Sene 97	6 mo-Tahesas 98	12 mo Sene 98	24 mo-Sene 99
A	Started on ART in this clinic- original cohort																								
B	Transfers In Add +	X				X				X				X				X				X			
C	Transfers Out Subtract -	X				X				X				X				X				X			
D	Net current cohort																								
E	On Original 1st Line Regimen																								
F	On Alternate 1st Line Regimen (Substituted)																								
G	On 2nd Line Regimen (Switched)																								
H	Stopped																								
I	Died																								
J	Transferred Out																								
K	Lost to Follow-up (DROP)																								
	Percent of cohort alive and on ART																								
	[(E+ F+G) / D * 100]																								
	CD4 % (for children)																								
	CD4 median or proportion ≥ 200 (optional)																								
	Functional Status																								
	Proportion Working																								
	Proportion Ambulatory																								
	Proportion Bedridden																								
	Number of persons who picked up ARVs each month for 6 months	x		x	x	x		x	x	x		x	x	x		x	x	x		x	x	x		x	x
	Number of persons who picked up ARVs each month for 12 months	x	x		x	x	x		x	x	x		x	x	x		x	x	x		x	x	x		x

	For cohort starting ART by month/year: at baseline then results at 6 months on ART, 12 months on ART, 24 months on ART	Cohort Hamle 97	6 mo- Tire 98	12 mo Hamle 98	24 mo- Hamle 99	Cohort Nehase 97	6 mo- Yekatit 98	12 mo Nehase 98	24 mo- Nehase 99	Cohort Meskerem 98	6 mo- Megabit 98	12 mo- Meskerem 99	24 mo- Meskerem 00	Cohort Tikimte 98	6 mo- Miazia 98	12 mo Tikimte 99	24 mo- Tikimte 00	Cohort Hidare 98	6 mo- Ginbot 98	12 mo Hidare 99	24 mo- Hidare 00	Cohort Tahisas 98	6 mo- Sene 98	12 mo Tahisas 99	24 mo- Tahisas 00
A	Started on ART in this clinic- original cohort																								
B	Transfers In Add +	X				X				X				X				X				X			
C	Transfers Out Subtract -	X				X				X				X				X				X			
D	Net current cohort																								
E	On Original 1st Line Regimen																								
F	On Alternate 1st Line Regimen (Substituted)																								
G	On 2nd Line Regimen (Switched)																								
H	Stopped																								
I	Died																								
J	Transferred Out																								
K	Lost to Follow-up (DROP)																								
	Percent of cohort alive and on ART																								
	[(E+ F+G) / D * 100]																								
	CD4 % (for children)																								
	CD4 median or proportion ≥200 (optional)																								
	Functional Status																								
	Proportion Working																								
	Proportion Ambulatory																								
	Proportion Bedridden																								
	Number of persons who picked up ARVs each month for 6 months	x		x	x	x		x	x	x		x	x	x		x	x	x		x	x	x		x	x
	Number of persons who picked up ARVs each month for 12 months	x	x		x	x	x		x	x	x		x	x	x		x	x	x		x	x	x		x

WHO European Regional Office (EURO)

Patient HIV care/ART card and Monthly report form

The EURO office has adapted the WHO forms to suit the specific characteristics of its target population. In many Eastern European countries, where these forms will be used, intravenous drug use (IDU) plays a role in HIV transmission. Hepatitis B and C and TB are also prevalent in this region and have accordingly been included on the monitoring forms. Identification of hepatitis is important as it may impact the adverse reactions from ART (on the liver). The EURO forms are currently being field-tested in Moldova and soon Ukraine.

EURO HIV care/ART card

Unique # ☐☐☐☐☐☐ HIV CARE/ART CARD____

District_____ **Health unit**___ **District physician/team**_____

Name_____ **Pt clinic no**_____

Sex: M ☐ F ☐ **Date of birth** _____ **Marital status**_____

Address_____

_____

Phone (whose)

Prior ART: ☐ **Transfer in with records** ☐ **PMTCT only**

☐ **Earlier ARV, not transfer in** ☐ **None**

Care entry point: (circle) **Hospital, TB clinic, STI clinic, IDU clinic, Out-patient clinic, HR program, AIDS Center, Women consultation Center, Other (specify):** _____

Treatment supporter/med pick-up if ill:_____

Address_____

Phone:

Home-based care provided by:

Date

_____ **Confirmed HIV + test** **Where**_____ **HIV 1 2** (circle) **Ab/PCR** **If < 18 mo**

_____ **Enrolled in HIV care**

ART

_____ **Medically eligible** **Clinical stage** _____

Why eligible: ☐**Clinical only** ☐**CD4#/%**___ ☐**VL**___

_____ **Medically eligible and ready for ART**

_____ **Transferred in from:**_____ **ART started:**_____

COHORT:

1st line

Start ART first-line initial regimen:_____

_____ * ****** ***** **IDU status**__**Weight**___

TB status___ **Hep B**___ **Hep C**__

_____ **Substitute within 1st line:**_____

_____ **New regimen**_____ **Why**___

_____ **New**_____ **Why**___

(use codes 1-7)

2nd line

Switch to 2nd line (or Substitute within 2nd line):_____

_____ **New regimen**_____ **Why**___

_____ **New**_____ **Why**___

_____ **New**_____ **Why**___

_____ **Dead** (use codes 8-10)

_____ **Transferred out** **To where:**_____

Names of family members or partners also in HIV care	Age	HIV status Date	Unique No

ART treatment interruptions

Stop Lost (circle)	Date	Why (use codes A-J)	Date if Restart:
Stop Lost			
Stop Lost			
Stop Lost			
Stop Lost			

Why STOP codes:

A Toxicity/side effects***
B Pregnancy
C Treatment failure
D Poor adherence****
E Illness, hospitalization
F Drugs out of stock
G Patient lacks finances
H Other patient decision
I Planned Rx interruption
J Other_____

Why SUBSTITUTE or SWITCH codes:

1 Toxicity/side effects
2 Pregnancy/risk of pregnancy
3 Due to identified Hepatitis
4 Due to new TB
5 New drug available
6 Drug out of Stock
7 Other reason (specify)_____

Reasons for SWITCH to 2nd line regimen only

8 Clinical treatment failure
9 Immunologic failure
10 Virologic failure

* Codes for TB status (check on each visit):	**IDU status	***Codes for potential Side Effects or Other Problems	****Codes for Why if poor/fair adherence	*****Codes for new OI or other diseases	****** Codes for Hepatitis B, Hepatitis C status
1. No TB treatment/prevention	1. Never injected dugs	1.Nausea	1. Toxicity/side effects	1. Generalised lymphoadenopathy	1. Unknown
2. Under TB preventative treatment	2. Injected drugs	2.Diarrhoea	2. Share with others	2. Herpes Zoster	2. Not infected
3. Under TB treatment	2a. last time injected drugs (date)	3. Fatigue	3. Forgot	3. Pneumonia	3. Infected (no need for treatment)
Please record the information below:	3. Inject drugs currently	4. Headache	4. Felt better	4. Candidiasis	4. Under treatment of Hep C
A). Skin test Date_____ Result +/-	3a. Everyday	5. BN burning/numb/tingling	5. Too ill	5. Recurrent bacterial infections	5. Under treatment of Hep B
B).Bacteriology Date_____ Result_____	3b. A few times a week	6. Rash	6. Stigma, disclosure or privacy issues	6. Oral hairy leukoplakia	
C). X-Ray Date_____ Result_____	3c. Less than once a week	7. Anaemia	7. Drug out of stock□dispensary	7. Persistent fever	
D). Preventative treatment Medication_____ Start date_____ Stop date_____	3d. Less than once a month	8. Abdominal pain	8. Patient lost/ran out of pills	8. Unexplained chronic diarrhoea	
E). TB treatment Start ate_____ Stop date_____	4. Under substitution treatment	9. Jaundice	9. Delivery/travel problems	9. Weight loss	
		10. Fat changes	10. Inability to pay	10. Cytomegalovirus retinitis	
		11. CNS: dizzy, anxiety, nightmare, depression	11. Alcohol	11. Lymphoma	
			12. Depression	12. Kaposi sarcoma	
			13. Injecting drugs_____	13. HIV encephalopathy	
			14. Other_____	14. Other (specify)	

Unique # ☐☐☐☐☐☐ HIV CARE/ART CARD ____ Name _____

Date Check if scheduled.(S) Unscheduled (U) Write in alternate pick-up if ill.	Follow-up date	Duration since first starting ART/ since starting current regimen?	Wt	Pregnant PMTCT? Due date or FP☐ no FP/yes: Methods	Function Work Amb Bed	WHO Clinical Stage	* TB Status	** IDU status	****** Hep C status	****** HepB status	*** SIDE EFFECTS related to ARV	***** New OI, Other PROBLEMS	Cotrimoxazole Adhere/ Dispense		**ARV drugs** Adhere/ Dispense		CD 4	VL	Syphilis	Hgb RPR, TLC, other lab	Refer or consult on link/ provide Hospital days - no
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Follow-up Education, Support and Preparation for ARV therapy

		Date/Comments	Date/Comments	Date/Comments
Educate on basics, prevention, disclosure	Basic HIV education, transmission			
	Prevention: abstinence, safer sex, condoms, Harm Reduction			
	Prevention: household precautions, what is safe			
	Post-test counselling: implications of results			
	Positive living			
	Testing partners			
	Disclosure			
	To whom disclosed (list)			
	Family/living situation			
	Shared confidentiality			
	Reproductive choices, prevention MTCT			
Progression, Rx	Child's blood test			
	Progression of disease			
	Available treatment/prophylaxis			
	Follow-up appointments, clinical team			
	CTX, INH prophylaxis			
ART preparation.....initiation.....support, monitor.....	ART□educate on essentials (locally adapted)			
	Why complete adherence needed			
	Adherence preparation, indicate visits			
	Indicate when READY for ART: DATE/result Clinical-team discussion			
	Explain dose, when to take			
	What can occur, how to manage side effects			
	What to do if one forgets dose			
	What to do when travelling			
	Adherence plan (schedule, aids, explain diary)			
	Treatment supporter preparation			
	Which doses, why missed			
	ARV support group			
	How to contact clinic			
Home-based care, support	Symptom management/palliative care at home			
	Caregiver Booklet			
	Home-based care□specify			
	Support groups			
	Community support			

Monthly, Facility-Based HIV Care/ART Reporting Form

Month:	Year:
MOH or Project or Grantee:	Facility:
Location:	City/oblast/Country:

1. HIV care (non-ART and ART) - new and cumulative number of persons enrolled			
	Cumulative number of persons ever enrolled in HIV care at this facility at beginning of month	New persons enrolled in HIV care at this facility during the month	Cumulative number of persons ever enrolled in HIV care at this facility at end of month
1. Males (>14 years)	a.	g.	m.
1a. Males IDUs (IDU code 3)			
1b. Males with active TB (TB code 3)			
1c. Males with active Hepatitis (codes for Hep 4 or 5)			
2. Non-pregnant females (>14 years)	b.	h.	n.
2a. Females IDUs (IDU code 3)			
2b. Females with active TB (TB code 3)			
2c. Females with active Hepatitis (codes for Hep 4 or 5)			
3. Pregnant females	c.	i.	o.
3a. Pregnant IDUs			
4. Boys (0-14 years)	d.	j.	p.
5. Girls (0-14 years)	e.	k.	q.
Total	f.	l.	r.
	Total number of persons who are enrolled and eligible for ART but have not been started on ART		s.
	No. of persons already enrolled for HIV care who transferred in from another facility		t.

2. ART care - new and cumulative number of persons started			
	Cumulative number of persons ever started on ART at this facility at beginning of month	New persons started on ART at this facility during the month	Cumulative number of persons ever started on ART at this facility at end of month
1. Males (>14 years)	a.	g.	m.
1a. Males IDUs (IDU code 3)			
1b. Males with active TB (TB code 3)			
1c. Males with active Hepatitis (codes for Hep 4 or 5)			
2. Non-pregnant females (>14 years)	b.	h.	n.
2a. Females IDUs (IDU code 3)			
2b. Females with active TB (TB code 3)			
2c. Females with active Hepatitis (codes for Hep 4 or 5)			
3. Pregnant females	c.	i.	o.
3a. Pregnant IDUs			
4. Boys (0-14 years)	d.	j.	p.
5. Girls (0-14 years)	e.	k.	q.
Total	f.	l.	r.
	No.of persons on ART and already enrolled in program who transferred into facility in last month		s.
	Number of persons who restarted ART during the last month, after stopping ART for at least 1 month		t.
	Number of baseline $CD4^+$ counts for persons who started ART in the last month (optional)		u.
	Median baseline $CD4^+$ count for persons who started ART in the last month (optional)		v.

Page 1

4. ARV regimen at end of month	Male	Female		
On 1st-line ARV regimen				
4.1 Adults (>14 years)				
AZT-3TC-EFV	a.	j.		
AZT-3TC-NVP	b.	k.		
d4T-3TC-EFV	c.	l.		
d4T-3TC-NVP	d.	m.		
	e.	n.		
	f.	o.		
	g.	p.		
	h.	q.		Total number of adults on 1st-line regimen
Adults on 1st-line regimens	i.	r.	s.	
4.2 Children (0-14 years)				
AZT-3TC-EFV	a.	k.		
AZT-3TC-NVP	b.	l.		
d4T-3TC-EFV	c.	m.		
d4T-3TC-NVP	d.	n.		
	e.	o.		
	f.	p.		
	g.	q.		
	h.	r.		Total number of children on 1st-line regimen
Children on 1st-line regimens	i.	s.	u.	
Adults and children on 1st-line regimens	j.	t.	v.	Total adults and children on 1st-line regimens
On 2nd-Line ARV regimen				
4.3 Adults (>14 years)				
ABC-ddI-LPV/r	a.	i.		
TDF-ddI-LPV/r	b.	j.		
ABC-ddI-SQV/r	c.	k.		
TDF-ddI-SQVr	d.	l.		
	e.	m.		
Another regimen (specify)	f.	n.		
	g.	o.		Total number of adults on 2nd-line regimen
Adults on 2nd-line regimens	h.	p.	q.	
4.4 Children (0-14 years)				
ABC-ddI-LPV/r	a.	k.		
ABC-ddI-NFV	b.	l.		
ABC-ddI-SQV/r	c.	m.		
	d.	n.		
Another regimen (specify)	e.	o.		
	f.	p.		
	g.	q.		Total number of children on 2nd line regimen
Children on 2nd-line regimens	h.	r.	u.	
Adults and children on 2nd-line regimens	i.	s.	v.	Total adults and children on 2nd line regimens
Adults and children on 1st- and 2nd-line regimens	j.	t.	w.	Total adults and children on 1st- and 2nd-line regimens

5.1 Number of persons who did not pick up their ARV regimens	Male	Female	5.2 Of those who did not pick up regimen in last 1 month (optional)	Total number of adults and children
1. For last 1 month (only)	a.	e.		
2. For last 2 months (only)	b.	f.	1. Lost to follow-up	a.
3. For last 3 or more months	c.	g.	2. Who died	b.
Subtotal	d.	h.	3. Who stopped ART	c.
Total number of persons who did not pick up their ART regimens		i.	4. Who transferred out	d.

6. Number of personnel trained in HIV care during the month	Physicians	Nurses	Other staff	Subtotal
1. ART clinical care	a.	e.	i.	m.
2. Non-ART clinical care	b.	f.	j.	n.
3. Adherence counseling/support	c.	g.	k.	o.
4. Other types of training	d.	h.	l.	p.
			Total personnel trained	q.

ANNEX A

Standard HIV care and ART data variables, periodicity and coding

This table is a more detailed version of the essential minimum standard HIV care and ART patient monitoring data listed in Table A. It includes the agreed variables and their coding and combines (and indicates where each is recorded), the variables on:

- the facility-held patient HIV care/ART card or other form of patient record;
- the pre-ART register;
- the ART register.

These are then used to produce the:

- quarterly (or monthly) facility-based HIV care/ART report form;
- ART cohort analysis report form.

The data which are aggregated (i.e. transferred to patient registers) are noted in the second column (periodicity of data collected and where recorded). Quarterly (or monthly) facility reports and cohort analysis reports may be generated from paper registers or directly from patient records using a card sort method or an electronic system. The participant training manual provides details of how data collected corresponds to items on the various forms used.

Annex A. Standard HIV care and ART data variables and their coding

Variable name	Periodicity of collection and where recorded	**Coding** (full words, abbreviations or coding numbers may be used)	Notes
I. Demographic information			
Collected at baseline/enrolment (update if changed)			
1. Last name	*Once* Card: copy to pre-ART register and ART register		
2. First name	*Once* Card: copy to pre-ART register and ART register		
3. Sex	*Once* Card: copy to pre-ART register and ART register	Female/male	
4. Date of birth	*Once* Card: copy to pre-ART register and ART register	dd/mm/yyyy	
5. Age at registration for HIV care	*Once* Card: copy to pre-ART register and ART register	Years	
6. Marital status	*Update as needed.* Card	**1** = single **2** = married **3** = divorced/separated **4** = widowed	
7. Unique ID number	*Once* Card: copy to pre-ART register and ART register	Combination of a facility-level code plus unique patient number (see *Chapter 2*)	This may be issued either at start of ART or when enrolling for HIV care.
8. Patient clinic ID number	*Once* Card: copy to pre-ART register and ART register		This is the usual pre-existing patient record or chart number.
9. Patient address	*Update* Card: copy to pre-ART register and ART register		
10. Telephone	*Update* Card	Phone number of patient or any contact	
11. Positive HIV test confirmed	*Once* Card	No/Yes	

Variable name	Periodicity of collection and where recorded	**Coding** (full words, abbreviations or coding numbers may be used)	Notes
II. HIV care and family status			
Collected at baseline/enrolment (update if changed)			
12. HIV subtype	*Once* Card	HIV-1 or HIV-2	This may be adapted to be removed where subtype determination is not feasible or a single subtype exists within a country.
13. Date positive HIV test confirmed	*Once* Card: copy to pre-ART register	dd/mm/yyyy	
14. Site where HIV test confirmed	*Once* Card	Free text box	
15. Entry point into HIV care	*Once* Card: copy to pre-ART register	**1** = PMTCT – from antenatal care clinic; detected by PMTCT programme testing of pregnant women **2** = medical outpatient **3** = outpatient – under 5/ paediatric **4** = STI outpatient **5** = TB treatment centre **6** = private provider or company/business **7** = inpatient **8** = IDU outreach/special services – IDU **9** = sex outreach/special services- Sex worker **10** = Outreach/special services – adolescent **11** = Self-referred (via VCT) **12** = CBO-referred (referred from a community-based organization, via VCT) **13** = other – write in. Police, military, etc. could be written in or added as code.	This may be adapted depending on the proximate or major referral sources.
16. District where facility is located providing HIV care currently	*Once* Card: copy to pre-ART register and ART register	Free text	
17. Health unit – facility where HIV care currently received	Card: copy to pre-ART register and ART register	Free text	

Variable name	Periodicity of collection and where recorded	**Coding** (full words, abbreviations or coding numbers may be used**)**	Notes
II. HIV care and family status (continued)			
18. District clinician/team	*Once* May need to be updated Card	Free text	Each clinical team requires a medical officer or doctor. If there is no doctor at the first-level facility, the responsible doctor or medical officer who is part of the clinical team should be listed here.
19. Name of treatment supporter	*Update* Card		To support patient adherence to care and treatment and assist patient for any care needs (e.g. pick up medications if ill, etc.).
20. Address of treatment supporter	*Update as needed Card*		
21. Family members/ partners also in care: names of children, partner(s), parent(s)	*Update* Card		Indicate as many children/ partners as necessary.
22. Child/partner/family member HIV status	Card		
23. Child/partner/family member unique ID	Card		
24. Child/partner/family member age at registration of date of birth	Card		
25. Drug allergies	*As applicable* Card	Record drug, type of reaction and date	A designated section for this should be included in a visible spot on the patient card.
III. ART summary			
Collected as information becomes available or relevant			
26. Antiretroviral treatment prior to enrolment	*Once* Card	**1** = currently being treated and transferred in with treatment records from within system **2** = PMTCT only **3** = prior ARV treatment but not transfer in with records; or client not able to provide treatment or referral information/ documentation **4** = none	

Variable name	Periodicity of collection and where recorded	Coding (full words, abbreviations or coding numbers may be used)	Notes
III. ART summary (continued)			
27. Date determined medically eligible to start ART	*Once* Card: copy to pre-ART register	dd/mm/yyyy	Based on CD4, WHO clinical staging, TLC, weight, or other national guidelines.
28. Why medically eligibility to start ARV therapy	*Once* Card: copy to pre-ART register and ART register	Choose one of the following based on the reason for medical eligibility for ART: 1 = clinical criteria only (not based on CD4 or TLC); 2 = CD4 with or without clinical criteria; 3 = clinical plus TLC	Determination of ART eligibility requires clinical and/or laboratory values (if CD4 or TLC available).
29. WHO clinical stage when medically eligible	*Once* Card: copy to pre-ART register	1, 2, 3, or 4	
30. CD4 count or % or TLC count if medically eligible based on CD4 or TLC	*Once* Card: copy to pre-ART register	If based on CD4 or TLC count, enter count or CD4 % in children.	
31. Date determined medically eligible and ready to start ART (prepared for adherence)	*Once* Card: copy to pre-ART register	dd/mm/yyyy	Ready means prepared for adherence as determined by country ARV programme criteria regarding required adherence preparation, clinical team meeting, and minimal essential patient education. More details on this are recorded on side 2 WHO HIV care/ART card. In paper system, entering date indicates patient is medically eligible and ready to start ART. (In electronic system, separate yes/no variable could be used.)
32. Date medically eligible and ready AND selected to begin ART at the facility	*Once* Card: copy to pre-ART register	dd/mm/yyyy	Country adaptation, for use where ART is rationed and a selection committee is used.
33. Date transferred in from another treatment facility on ART	*Once* Card: copy to ART register	dd/mm/yyyy	Patient must have medical record/documentation of treatment from original clinic.
34. Location transferred from	*Once* Card	Text box (health unit and district)	

Variable name	*Periodicity of collection and where recorded*	Coding (full words, abbreviations or coding numbers may be used)	Notes
III. ART summary (continued)			
35. Date ART started at original clinic	*Once* Card: copy to ART register	mm/yyyy	For patients who have transferred in from another facility within the system or a private facility. If start date is not known, leave blank.
36. ART cohort (start-up group)	*Once* Card: copy to ART register	Month, year (e.g. Jan 05 or Jan 2005 = started therapy in January 2005)	Month and year originally started ART at qualified health facility. Cohorts are formed by month of starting ART, when patients are entered in the ART register.
37. Functional status at start of ART	*Once* Card: copy to ART register	**W** or Work = Working **A** or Amb = Ambulatory **B** or Bed = Bedridden	**Working**: able to perform usual work in or out of the house, harvest, go to school or, for children, normal activities or playing. **Ambulatory**: Ambulatory but not able to work or play. Able to perform activities of daily living. **Bedridden**: Not able to perform activities of daily living. Functional status is independent of clinical staging.
38. Body weight at start of ART	*Once* Card: copy to ART register	kg	
39. Height at start of ART (for children)	*Once* Card: copy to ART register	cm	
40. First ARV regimen at this facility	*Once* Card: copy to ART register	**Adult 1st-line regimens:** **1a(30)** = d4T(30)-3TC-NVP **1a(40)** = d4T(40)-3TC-NVP **1b(30)** = d4T(30)-3TC-EFV **1b(40)** = d4T(40)-3TC-EFV **1c** = ZDV-3TC-NVP **1d** = ZDV-3TC-EFV For pts<60 kg use 30 mg For pts ≥60 kg use 40 mg **Children 1st-line regimens:** **4a** = d4T-3TC-NVP **4b** = d4T-3TC-EFV **4c** = ZDV-3TC-NVP **4d** = ZDV-3TC-EFV	ARV regimens listed here follow WHO recommendations. Adapt to country specific recommendations as needed and code accordingly.
41. Substitute ARVs within first-line regimen (first instance)	Card: copy to ART register	Enter date when first **substitution**	

Variable name	*Periodicity of collection and where recorded*	Coding (full words, abbreviations or coding numbers may be used)	Notes
III. ART summary (continued)			
42. Reason for substitution within first-line regimen	Card: copy to ART register	**1** = Toxicity/side-effects **2** = Pregnancy **3** = Risk of pregnancy **4** = Newly diagnosed TB **5** = New drug available **6** = Drug out of stock **7** = 0ther reason: (specify)	
43. ARV regimen after first substitution	Card: copy to ART register		
44. Substitute ARVs within first-line regimen (second instance)	Card: copy to ART register	Enter date if second **substitution**	Entering date means "yes" in paper system.
45. New first-line ARV regimen following second substitution	Card: copy to ART register	(See regimen codes above)	
46. Reason for second substitution	Card: copy to ART register	(Use substitution codes above)	
47. Switch to second line ARV regimen	Card: copy to ART register	Enter date if **switch** to second-line ARV regimen	
48. Reason for Switch to second-line regimen or substitution within second line regimen	Card: copy to ART register	**1** = Toxicity/side-effects **2** = Pregnancy **3** = Risk of pregnancy **4** = Newly diagnosed TB **5** = New drug available **6** = Drug out of stock **7** = 0ther reason: (specify) **8** = Clinical treatment failure **9** = Immunologic failure **10** = Virologic failure	Medical officer should also keep log with clinical summary and reasons for switch to second line, who consulted.
49. Second-line ARV regimen (first switch)	Card: copy to ART register. In ART register, record coded regimen patient is on at end of month	**Adult 2nd-line regimens** **2a(250)** = ABC-ddI(250)-LPV/r **2a(400)** = ABC-ddI(400)-LPV/r **2b(250)** = ABC-ddI(250)-SQV/r **2b(400)** = ABC-ddI(400)-SQV/r **2c(250)** = TDF-ddI(250)-LPV/r **2c(400)** = TDF-ddI(400)-LPV/r **2d(250)** = TDF-ddI(250)-SQV/r **2d(400)** = TDF-ddI(400)-SQV/r For pts<60 kg use 30 or 250 mg For pts ≥60 kg use 40 or 400 mg **Child 2nd-line regimens** **5a** = ABC-ddI-LPV/r **5b** = ABC-ddI-NFV **5c** = ABC-ddI-SQV/r (for pts ≥25kg)	Switch refers to switch to a second-line or salvage regimen.

Variable name	*Periodicity of collection and where recorded*	Coding (full words, abbreviations or coding numbers may be used)	Notes
III. ART summary (continued)			
50. Repeat switch or substitution within second-line regimens – as many times needed	Card-copy to ART register. In ART register, record coded regimen patient is on at end of month		Every month in ART register, record coded monthly regimen at end of that month.
51. When ART interrupted, stopped or lost	Card: copy to ART register. Record coded regimen patient is on at end of month.	Stop or Lost (temporary)	Patient who has missed an appointment or drug pick-up is considered LOST (temporary). That patient may reappear later and not be dropped from the drug supply.
52. If stopped ART, reason	Card: copy to ART register	**1** = Toxicity/side-effects **2** = Pregnancy: for example, planned treatment interruption in first trimester **3** =Treatment failure **4** = Poor adherence **5** = Illness, hospitalization **6** = Drug out of stock **7** = Patient lacked financial resources **8** = Other patient decision **9** = Other planned treatment interruption **10** = Other	STOP refers to when a patient intentionally stops an ART regimen (usually but not always in discussion with the clinical team) either through a planned interruption from ART or following poor adherence.
53. Date ART restarted	Card: In ART register, record coded regimen patient is on at end of month	dd/mm/yyyy	
54. Date ART interrupted second instance	Card: In ART register, record coded regimen patient is on at end of month coded	dd/mm/yyyy	
55. When ART interrupted- second instance-stopped or lost	Card: In ART register, record coded regimen patient is on at end of month.	Stop or Lost (temporary)	
56. If stopped (second instance), reason	Card: Copy to ART register		
57. Date ART restarted second instance	Card: In ART register, record coded regimen patient is on at end of month	dd/mm/yyyy	
58. Date Transferred Out with records (see codes)	*Once* Card: copy to ART register	dd/mm/yyyy	

Variable name	Periodicity of collection and where recorded	Coding (full words, abbreviations or coding numbers may be used)	Notes
III. ART summary (continued)			
59. Location transferred to	*Once* Card	Free text	For tracking transfer in and transfer out, between facilities within each system.
60. If temporarily LOST, indicate date	Card: In ART register	dd/mm/yyyy	Patient who has missed an appointment or drug pick-up is considered LOST (temporary).
61. If DROPped, indicate date	Card: In ART register, if drugs not picked up for the last x months, record "Lost to follow-up" or "DROP"	dd/mm/yyyy	Patient who has not been seen for X months after X number of follow-up attempts by health facility. This needs to be nationally adapted to indicate when patients are dropped from the facility's drug supply order (see *Table B*).
62. Date of death	*Once* Card: copy to ART register if on ART when died. Copy to pre-ART register if DEAD before starting ART	dd/mm/yyy	Death due to any cause, not just HIV. Need to separately add up deaths pre-ART and on ART or after stopping ART.
63. Outpatient encounter date	Card: Transfer first encounter date to ART summary section of the card and to pre-ART register as date patient enrolled in HIV care.	dd/mm/yyy	This date applies to all outpatient encounter data for that date. First visit is date patient enrolled in HIV care.
64. Visit type	*Each visit* Card	Scheduled or unscheduled visit	
65. Next scheduled outpatient visit date	*Each visit* Card	dd/mm/yyy	This may also be recorded in an appointment book and used for patient follow-up.
66. Months on current ARV regimen	*Each visit* Card	Months	Record number of months from start of original regimen, indicate new regimen with "/" and note number of months since start of new regimen and start of original regimen.
67. Functional status	*Each visit* Card: Transfer functional status at start ART to ART register	Work/ambulatory/ bedridden (see codes above)	

Variable name	Periodicity of collection and where recorded	Coding (full words, abbreviations or coding numbers may be used)	Notes
IV. Outpatient (clinic) encounter-level information			
69. Body weight	*Each visit* Card: Transfer weight at start ART to ART register	kg	
70. Height (for children)	*Each visit* Card: Transfer weight at start ART to ART register	cm	Check against height for age.
71. TB status	*Each visit* Card	**TB Rx** = currently on TB Treatment (follow by TB registry card number for reference) **INH** = currently on INH prophylaxis (IPT). If so, also enter dose dispensed and estimate of adherence. **Sputums** = TB suspected and sputums sent **–, +, ++, or +++** = sputum results **Refer TB**= suspected TB, referred for evaluation (include referral date) **No signs** = no signs or symptoms suggesting TB	In a paper system, if patient is on TB treatment, provide card number to crosslink the card. In an electronic system, enter the relevant TB card data.
72. TB treatment or INH start/stop date	*Each visit if applicable* Card: Transfer to pre-ART register if not yet on ART and to ART register if ART started	dd/mm/yyy	When applicable
73. Pregnancy/family planning in women of childbearing age	*Each visit if applicable* Card: Transfer to pre-ART register if not yet on ART and to ART register if ART started	**P** = pregnant (including those using condoms). If pregnant, report estimated due date **No FP** = not pregnant and not on FP **FP** = not pregnant and on FP. If on FP, note methods (more than one method may be used).	May code pregnancy as intended/unintended, or whether the patient intends to get pregnant. These adaptations will take place at the country level, and may include the addition of a column to the patient card.
74. Family planning method(s)	*Each visit if applicable* Card	Method codes: **1** = Condoms **2** = Oral contraceptive pills **3** = Injectable/implantable hormones (e.g. Depo-provera) **4** = Diaphragm/cervical cap **5** = Intrauterine device **6** = Vasectomy/tubal ligation/hysterectomy	Method codes adapted from Columbia MTCT-plus forms. Must be able to enter more than one method to indicate dual method. Recommended dual protection refers to use of condoms to prevent both HIV transmission and pregnancy.

Variable name	Periodicity of collection and where recorded	Coding (full words, abbreviations or coding numbers may be used)	Notes
IV. Outpatient (clinic) encounter-level information (continued)			
75. Refer for or link with other clinical care, PMTCT, supportive care	*Each visit if applicable* Card: Transfer to pre-ART register if not yet on ART and to ART register if ART started	Check if referred	Write in referral, reason and location.
76. Potential medication side-effects or other problems	*Each visit if applicable* Card	**Example of codes for potential side-effects or other problems, for nurses who have been taught to use the IMAI guidelines:** **Na**usea **Di**arrhoea **F**atigue **H**eachache **BN** burning/numb/tingling **R**ash **An**emia **AB**dominal pain **J**aundice **FAT** changes **CNS** (central nervous system): dizzy, anxiety, nightmare, depression Or write in others	Write the word or code, or check all that apply. These may be due to ARVs or other medications and have occurred at any time since the last visit. Laboratory values are recorded in another column. Alternative entry systems can be used. A simple system may be used by a nurse after training (the example presented is from IMAI) or a full doctor-based system. Substitute other recording systems for health workers with other training or more diagnostic resources.
77. Severity of side-effect(s)	Card if seen by MD	No problem, mild, moderate, severe. Give option to use standardized grading	Possible country adaptation- grade severity of side-effects.
78. New Symptoms/ Diagnoses/ Opportunistic Infections	Card	**Several options** **Example: IMAI2 codes for new OI or other Problems** (or write in or use codes from potential side-effect list): **Z**oster **P**neumonia **DE**mentia/**Encepha**litis **Thrush** – oral, vaginal **FEVER** **COUGH** **DB** difficult breathing **IRIS** Immune reconstitution inflammatory syndrome **W**eight Loss **UD** urethral discharge **PID** pelvic inflammatory disease **GUD** genital ulcer disease **Ulcers** – mouth or other__	Alternative entry systems can be used. A simple system may be used by a nurse after training (the example presented is from IMAI) or a full doctor-based system. In either case, a more detailed record of the illness and management plan would be kept in a patient-held or clinic-held record. This treatment card includes only an abbreviated summary.

Variable name	Periodicity of collection and where recorded	Coding (full words, abbreviations or coding numbers may be used)		Notes
IV. Outpatient (clinic) encounter-level information (continued)				
79. Prophylaxis medication name, dose and start date	*Each visit if applicable* Card: Transfer to pre-ART register if not yet on ART and to ART register if ART started	Cotrimoxazole, dapsone, fluconazole, isoniazid (INH) other	This may need several variables for dose, adherence (see **81 and 82**).	
80. Prophylaxis medications stop date	*Each visit if applicable* Card: Transfer to pre-ART register if not yet on ART and to ART register if ART started	dd/mm/yyyy		Either write abbreviations for the FDC (including indication of the stavudine dose in adults) or individual drug name or accepted abbreviation and the number dispensed Note: If the stavudine dose changes as the patient gains weight, s/he may still be on the original first-line regimen but with a higher stavudine dose.
81. Adherence to cotrimoxazole	Card	Estimates as for ART *(see **84**)*		
82. Reason for discontinuation of prophylaxis medication	Card	**1** = completed therapy **2** = improved immune function (e.g. CD4 count >200 cells for 6 months) **3** = side-effects/ toxicity **4** = stock out/drug supply disruption **5** = patient preference **6** = other, describe	Possible country adaptation to add reason for discontinuation.	Assessment and recording of adherence needs to be based on national adaptation. The March meeting did not agree on a single recommendation.

Variable name	Periodicity of collection and where recorded	Coding (full words, abbreviations or coding numbers may be used)	Notes
IV. Outpatient (clinic) encounter-level information (continued)			
85. Reason for missing ARV doses/adherence problems	*Each visit* Card	**Codes for why if poor/fair adherence:** **1** = toxicity/side-effects **2** = share with others **3** = forgot **4** = felt better **5** = too ill **6** = stigma, disclosure or privacy issues **7** = drug stock-out – dispensary **8** = patient lost/ran out of pills **9** = delivery/travel problems **10** = inability to pay **11** = alcohol **12** = depression **13** = pill burden **14** = other	
86. Laboratory test dates and names	*Each visit* Card: Transfer CD4 counts at baseline, 6 months, yearly to ART register. Use to calculate baseline and 6, 12 months on ART CD4 median on cohort analysis report.	Date specimen collected for laboratory test: dd/mm/yyyy Laboratory test: CD4 count (per mm^3) or % for children < 5 Total lymphocyte count Hemoglobin (g/dL) ALT/SGPT (U/L) AST/SGOT (U/L) Creatinine (mg/dL) Sodium (Na+) (meq/L) Potassium (K+)	CD4, where available, may also be collected to track immunological progress of patient on treatment. In higher-resource settings, viral load tests may be carried out regularly. It is possible to adapt the patient monitoring system to include viral load test results.
87. Number of hospital days since last outpatient visit	*As applicable* Card	Number of days	Hospitalization for any reason, not just HIV-related.

ANNEX B

Use of standard patient monitoring data elements by where and how aggregated

Annex B. Use of standard patient monitoring data elements by where and how aggregated

Agreed minimum essential data elements	What happens to the data	Indicators or other aggregated data
At baseline, **6, 12 months** then **yearly**; disaggregated by **sex** and **child/adult**: 1. On ART and: • ALIVE • DEAD • LOST/DROP/Transfer out 2. Current regimen • Original first-line • Substituted to alternative first-line • Second-line or higher 3. CD4 test results 4. Functional status 5. Regimen collected in last quarter **Source:** III. ART summary	Transfer to ART register then to **cohort analysis report**	Based on cohort analysis form, at **6, 12 months** then **yearly** and compared to **baseline**: **Indicators related to success of ART** ♦ **2a.** Percentage alive and on ART/Mortality on ART ♦ **2b.** Percentage still on a first-line regimen • **2c.** Percentage working, ambulatory, bedridden • **2d.** Median or mean CD4 counts (optional) **HIV drug resistance early warning indicators:** • Percentage switched to a second-line (or higher) regimen • **3a.** Percentage collected ARV drugs 6/6 or 12/12 months
1. When registered for HIV care 2. When medically eligible for ART 3. When medically eligible and ready for ART 4. When ART started 5. DEAD before ART 6. LOST or Transfer Out before ART **Source:** III. ART summary	Transfer to pre-ART or ART register then to **quarterly report**	**Indicators related to patients accessing HIV care and ART:** Disaggregated by adult, child, sex, pregnancy status: • **1a.** Number enrolled in HIV care: new and cumulative ever at the facility • **1b.** Number started on ART: new and cumulative ever started at the facility Disaggregated by adult, child, sex: • **1d.** Number currently on ART at the facility Not disaggregated: • **1c.** Number eligible for ART but not yet started

Agreed minimum essential data elements	What happens to the data	Indicators or other aggregated data
1. Entry point 2. Why eligible for ART 3. Reasons for: • Substitution within first-line • Switch/substitution to or within second-line • STOP ART 4. Number and weeks of each ART treatment interruption 5. Pregnancy status 6. Start/stop dates of prophylaxis: • Cotrimoxazole • Fluconazole • INH 7. TB treatment 8. Adherence on ART **Source:** II. HIV care and family status, III. ART summary, IV. Patient encounter information	Transferred to **pre-ART** or **ART register** but used only by clinical team/district ART coordinator – not transferred to quarterly report or cohort analysis	**Indicators for patient and programme management at the facility/district level:** • Distribution of entry points in patients enrolled in HIV care • Why eligible for ART: clinical only, CD4 or TLC • Distribution of patients not yet on ART by clinical stage • Distribution of reasons for substitute, switch, stop to investigate problems; whether substitutions and switches are appropriate (use in context reviewing medical officer log) • ART treatment interruptions: • Number/percentage of patients • Number weeks • Percentage of pregnant patients linked with PMTCT interventions (or simply use to generate lists to assure linkage) • Number on cotrimoxazole, fluconazole, INH prophylaxis at end of quarter (for ordering prophylaxis drugs) • Number/percentage of patients on both TB treatment and ART **3b.** Percentage patients with good adherence to ART
1. Date of each encounter 2. Weight (each visit; % gain or loss) 3. Adherence on CTX 4. Adherence on INH 5. Potential side-effects 6. New OIs, other problems 7. TB status (other than treatment or prophylaxis) 8. Referred or consulted with MD 9. Number inpatient days 10. If poor adherence on ART, reasons (coded) **Source:** IV. Patient encounter information	**Patient card** only. Not transferred to register	**Indicators for patient management at the facility- level or special studies:** • Percentage patients referred to MD ■ Common side-effects, OIs, other problems: ■ Patients with special problems ■ Identify patients for review at clinical team meetings ▲ Number/percentage patients hospitalized; number days ▲ Reasons for poor adherence

♦ National core indicators

■ These are used both for individual patient management and for medical officer or clinical mentor review on site visits. For potentially serious side-effects that result in a consultation or referral, medical officer needs to put in log and do further adverse event reporting.

▲ Tabulations for special studies

ANNEX C

Definitions of national-level and district-level indicators

Annex C. Definitions of national-level and district-level indicators (from *Chapter 2*)

The following indicators have been agreed upon internationally, may be extracted from the patient monitoring data elements presented, and are taken directly from the *Guide to indicators for monitoring and evaluating national ART programmes*.[1] However, they do not reflect the inclusion of paediatric data. Recommendations for the enhancement of the core indicators to better reflect paediatric outcomes are available.[2]

Core Indicator 7: Percentage of people with advanced HIV infection receiving antiretroviral combination therapy This is an UNGASS indicator.[3]	
Definition:	The percentage of people with advanced HIV infection who are currently receiving antiretroviral combination therapy.
Numerator:	Number of people with advanced HIV infection who receive antiretroviral combination therapy in accordance with the nationally approved treatment protocol (or WHO/UNAIDS standards); it is calculated as follows. Number of people receiving treatment at the start of the year plus Number of people who commenced treatment in the preceding 12 months minus Number of people for whom treatment was terminated in the preceding 12 months (including those who died)
Denominator:	Number of people with known advanced HIV infection (i.e. those in need of ART). The number of adults newly in need of ART is calculated by adding the number of adults newly in need of ART to the number who were on treatment in the previous year and survived to the current year. The number of adults newly in need of ART is estimated as the number developing advanced HIV disease who are not yet on treatment. Since some of the adults projected to develop advanced HIV disease may already have started treatment in the previous year, the number newly in need of ART is adjusted by subtracting people in this category. It is currently assumed that between 80% and 90% of adults on treatment will survive to the following year, depending on patients' adherence to treatment, resistance patterns, the quality of clinical management and other factors.
Rationale and what is measured:	As the HIV pandemic matures, increasing numbers of people are reaching advanced stages of HIV infection. ARV combination therapy has been shown to reduce mortality among infected people, and efforts are being made to make it more affordable in less developed countries. This indicator, introduced during the United Nations General Assembly Special Session on HIV/AIDS (and modified by UNAIDS in 2004), assesses progress in providing ARV combination therapy to every person with advanced HIV infection.
Measurement tools and how to measure the indicator:	This indicator can be compiled from programme monitoring data. The denominator is generated by estimating the number of people with advanced HIV infection requiring ARV combination therapy, most frequently on the basis of the latest sentinel surveillance data. The provision of ARVs in the private sector should be included in the calculation of the indicator wherever possible and the extent of such provision should be recorded separately. The start and end dates of the period for which ARV combination therapy is given should be stated. Overlaps between reporting periods should be avoided if possible.

[1] World Health Organization (WHO). *National AIDS programmes: a guide to indicators for monitoring and evaluating national antiretroviral programmes.* Geneva, WHO, 2005.
[2] Recommendations are available but not field-tested. Send requests to: 3by5help@who.int or crowleys@who.int.
[3] Joint United Nations Programme on HIV/AIDS (UNAIDS). *Monitoring the declaration of commitment on HIV/AIDS: guidelines on construction of core indicators: 2006 reporting.* Geneva, UNAIDS, 2005.

Frequency:	Data are collected continuously and aggregated in accordance with the required reporting period (e.g. every six months during scale-up, yearly thereafter).
Strengths and limitations:	This indicator allows trends to be monitored over time but does not distinguish between the different types of therapy available and does not measure the cost, quality or effectiveness of treatment. The proportion of people with advanced stages of HIV infection varies with the stage of the HIV epidemic and the cumulative coverage and effectiveness of ART among adults and children. Dynamic prevalence rates affect the accuracy of the estimate of the eligible population. Changing estimates of prevalence are not reflected in current prevalence rates. This specifically affects the denominator. The degree of utilization of ARV combination therapy depends on the cost relative to local incomes, service delivery infrastructure and quality, availability and uptake of VCT services, perceptions of effectiveness, possible side-effects of treatment, etc. ART for the prevention of MTCT or for post-exposure prophylaxis is not included in this indicator.

Core Indicator 8: Continuation of first-line regimen at 6, 12 and 24 months after initiating treatment This indicator is one of the **Drug Resistance Early Warning** indicators.	
Definition:	Percentage of individuals who are still on treatment and who are still prescribed a standard first-line regimen after 6, 12 and 24 months from the initiation of treatment.
Numerator:	Number of patients who are still on treatment and who are still prescribed a standard first-line regimen 12 months after initiating treatment.
Denominator:	Total number of individuals initiating treatment on a first-line regimen in the ART start-up group in the previous 6, 12 and 24 months.
Rationale and what is measured:	This indicator is important for tracking early warning signals of potential treatment failure. Unnecessary changes in regimen, treatment failure and intermittent ART are all associated with HIV drug resistance. The first year of treatment is most indicative of programme success in sustaining regimen continuity. Programmes in which > 80% of new patients are not on a first-line regimen after a year may be less likely to minimize the emergence of HIV drug resistance. This indicator measures the proportion of patients beginning first-line ART in a given cohort who are still on first-line therapy one year after ART begins.
Measurement tools and how to measure the indicator:	Patients beginning ART for the first time are identified through medical records. For each patient the drug regimen (drug list + dosage and frequency) is abstracted at the beginning of the first month and the last available prescriptions in the sixth, twelfth and twenty-fourth months are obtained from the treatment cards or medical records. Pharmacy records may also be used. If the person in question dies, is lost to follow-up, is transferred to another treatment programme, has stopped ART, or has no drugs prescribed in month 6, 12 or 24, this should also be recorded. Note: A person for whom a drug is substituted because of toxicity to a different first-line drug is still considered to be on a first-line regimen.
Frequency:	Abstractions take place monthly for each cohort that has begun ART 6, 12 and 24 months previously. The numerators and denominators are summed at the end of the calendar year in order to obtain annual percentages.
Strengths and limitations:	Because this indicator does not measure temporary interruptions in ART it may overestimate the continuity of first-line ART. Where possible, information should also be collected on whether the drugs were picked up each month. The quality of this indicator depends on the quality of the medical records and the patient registry.

Core indicator 9: Survival at 6, 12, 24, 36, etc. months after initiation of treatment This indicator is one of the **Drug Resistance Early Warning** indicators and an UNGASS indicator.[1]	
Definition:	Percentage of people alive and known to be on treatment at 6, 12, 24, 36, etc. months after initiation of treatment. The indicator can be constructed as a minimum and maximum estimate of survival, depending on the inclusion criteria for the denominator (see options (a) and (b) below).
Numerator:	Number of people continuously on ART at 6, 12, 24, 36, etc. months after initiation of treatment.
Denominator:	a) Minimum survival: Total number of individuals who initiated ART in the ART start-up group in the previous 6, 12, 24, 36, etc. months, ***including*** those who have stopped ART, those who have transferred out and people lost to follow-up. b) Maximum survival: Total number of individuals who initiated ART in the ART start-up group in the previous 6, 12, 24, 36, etc. months, ***excluding*** those who have stopped ART, those who have transferred out and people lost to follow-up.
Rationale and what is measured:	One of the goals of any ART programme should be to increase survival among infected individuals. This indicator measures the degree to which treatment can prolong a person's life by assessing how many individuals survive after receiving treatment for 6, 12, 24, 36, etc. months.
Measurement tools and how to measure the indicator:	Information on survival can be obtained from patient registers (HMIS) by tallying results for several monthly cohorts, each tabulated when on ART for 6 months, 12 months and yearly thereafter. For a comprehensive understanding of survival the following components must be measured. a) Number of people initiating ART and the start date. b) Number of people continuously on ART at 6, 12, 24, 36, etc. months after initiating treatment. c) Number of people who have stopped ART, those who have transferred out, people lost to follow-up, and those who died. A proportion of people who stopped treatment or were lost to follow-up may still be alive. As they are not continuously on treatment, however, they should not be included in the numerator. People who transfer between ART programmes and for whom a start date of treatment exists should be counted as continuously on treatment. These data should be presented for each time-specified period. It is recommended that, if feasible, programmes should follow patients throughout their time on treatment, as AIDS is a lifelong disease. Six-monthly tallies of new patients are necessary in order to measure this indicator.
Frequency:	Data are collected continuously and aggregated in accordance with the required reporting period.

[1] Joint United Nations Programme on HIV/AIDS (UNAIDS). *Monitoring the declaration of commitment on HIV/AIDS: guidelines on construction of core indicators: 2006 reporting*. Geneva, UNAIDS, 2005.

Strengths and limitations:	The strengths of this indicator lie in the ease of data collection, as any ART programme should monitor patients on treatment and determine the number of individuals who survive beyond specific periods in time. Patients records may not include mobile populations (e.g. refugees) or the status of the duration of their therapy. This indicator may only be obtained from a limited number of advanced care/referral facilities and/or designated cohort studies while HMISs are scaling up. As the latter become institutionalized and functional the data can be expected to become more comprehensive.

Further description of HIV drug resistance early warning indicators not included as core indicators listed in *Table F*:

Indicator 3a: Percentage of adults starting first-line ART who are prescribed a standard first-line ARV regimen This indicator is one of the **Drug Resistance Early Warning** indicators.	
Definition:	Percentage of individuals who are prescribed a standard first-line regimen, at initiation of treatment
Numerator:	Number of adults starting on first-line ART during the time period who are prescribed a standard first-line ARV regimen. Standard first-line ARV regimens are three (or four) drug HAART regimens that have been designated standard first-line regimens in national, provincial, district, or clinical centre guidelines.
Denominator:	Total number of adults first prescribed a first-line ART regimen during the time period.
Rationale and what is measured:	Monotherapy and dual therapy have been associated with HIV drug resistance in numerous studies; some "non-standard" combinations of three and four drugs are also associated with resistance. Although population-based studies linking prescribing practices and HIV drug resistance have not been performed for HIV, the emergence and transmission of drug resistance associated with tuberculosis in the 1960s and 1970s in the United States was linked to one-drug and two-drug regimens prescribed by physicians, and prescription of non-potent regimens has been associated with the emergence of resistance in several other diseases. Training for prescription of standard regimens, support for continuity of drug supply, support for continuing to take drugs despite short-term side-effects, and provision of alternative standard potent regimens are all interventions that can take place on a programme level to minimize the emergence of HIV drug resistance.
Measurement tools and how to measure the indicator:	Patients beginning ART for the first time are identified through medical records. For each, the drug regimen (drug list + dosage and frequency) is abstracted at the beginning of month 1 from the treatment card or medical record. Pharmacy records may also be used. Note: The substitution of one drug because of toxicity, so that the persons are on a "different" first-line regimen, still counts if it is a standard first-line regimen.
Frequency:	Data can be taken cross-sectionally each month or quarter. Alternatively, monthly cohort abstractions may provide a better trend analysis. Numerators and denominators are summed at the end of the calendar year to create an annual percentage.
Strengths and limitations:	The quality of this indicator will depend on the quality of the medical records and the patient registry.
Actions to be taken if target is not reached:	Investigate continuity of ARV drug supply (strengthen if necessary), provide additional training to clinical staff prescribing ARV drugs, consider regulating pharmacies so that only standard regimens can be dispensed, investigate whether acceptability/side-effects associated with particular regimens have influenced prescribing practices (provide support or alternative potent regimens).

Indicator 3b. Percentage of patients who started ART 6 or 12 months ago and picked up ARV medications 6/6 or 12/12 months This indicator is one of the **Drug Resistance Early Warning** indicators.	
Definition:	Percentage of individuals who are being prescribed ART and have picked up their drug regimens continuously for 6 and 12 months after initiating treatment.
Numerator:	Persons who started ART 6 or 12 months ago who picked up ARV medications 6/6 or 12/12 months.
Denominator:	Persons who started ART 6 or 12 months ago and are still prescribed ART at the end of the time period.
Rationale and what is measured:	Intermittent pick-up of ARV drugs, leading to intermittent ARV drug-taking, is highly associated with the emergence of HIV drug resistance. Although complex factors that may require individualized interventions may affect adherence, a failure to pick up drugs may also be associated with factors susceptible to intervention on a programme level. Experience in ARV and other treatment programmes has shown that lowering or abolishing medication costs, the provision of facilitators such as transport, meals while away from home, or childcare, home visits or other outreach measures, combining drug pick-up with other appointments, reduction of the pill burden, and better patient education may increase the regularity of drug pickup and adherence as a whole in a patient population.
Measurement tools and how to measure the indicator:	Patients beginning ART for the first time are identified through medical records. For each, the drug regimen (drug list + dosage and frequency) is abstracted at the beginning of each month for 6 months and 12 months from the treatment card or medical record. Pharmacy records may also be used. If the person dies, is lost to follow-up, is transferred to another treatment programme, has stopped ART, or has no drugs prescribed in during the 6-month or 12-month period, this should also be recorded.
Frequency:	Abstractions take place monthly for each cohort beginning ART 6 and 12 months previously. Numerators and denominators are summed at the end of the calendar year to create an annual percentage.
Strengths and limitations:	This indicator does not measure whether or not the patient was adherent to the drug regimen. It only measures whether the drug was picked up. Additional querying and counselling at each patient encounter to assess adherence is necessary to ensure successful treatment outcomes. The quality of this indicator will depend on the quality of the medical records and the patient registry.
Actions to be taken if target is not reached:	Investigate and address common reasons for missing drug pick-up. Provide targeted provider and patient education/counselling. Seek resources to supply programmatic facilitators (such as those listed above) to encourage regularity of pick-up. Monitor patient adherence and follow up on non-adherent patients.

ANNEX D

WHO ILLUSTRATIVE PATIENT MONITORING SYSTEM

Unique # ☐☐☐☐☐☐

HIV CARE/ART CARD ____

District_____ Health unit_____ District clinician/team_____

Name_____ Pt clinic #_____

Sex: M ☐ F ☐ Age_____ DOB_____ Marital status_____

Address_____

Telephone (whose):_____

Prior ART:
☐Transfer in with records
☐Earlier ARV but not a transfer in
☐PMTCT only
☐None

Care entry point:
☐PMTCT
☐Medical
☐Under5
☐TB
☐STI
} *Outpatient*
☐Private/Co
☐Inpatient
☐IDU
☐Adol
☐Sex
} *Outreach*
☐Self-refer
☐CBO
☐Other:

Treatment supporter/med pick-up if ill:_____

Address_____

Telephone:_____

Home-based care provided by:_____

Names of family members and partners	Age	HIV +/-	HIV care Y/N	Unique no.

ART treatment interruptions

Stop Lost (circle)	Date	Why	Date if Restart:
Stop Lost			
Stop Lost			
Stop Lost			
Stop Lost			
Stop Lost			
Stop Lost			

Drug allergies

1st-line

2nd-line

Date

_____ Confirmed HIV+ test Where_____ HIV 1 2 Ab / PCR *(if < 18 mo)*

_____ Enrolled in HIV care

COHORT:

ARV therapy

_____ Medically eligible Clinical stage_____

Why eligible: ☐Clinical only ☐CD4/%_____ ☐TLC_____

_____ Medically eligible *and* ready for ART

_____ Transferred in from_____ART started_____

_____ **Start ART 1st-line initial regimen:**_____

At start ART: Weight _____ Function_____ Clinical stage_____

Substitute within 1st-line:

_____ New regimen_____ Why_____

_____ New regimen_____ Why_____

Switch to 2nd-line (or substitute within 2nd-line):

_____ New regimen_____ Why_____

_____ New regimen_____ Why_____

_____ New regimen_____ Why_____

_____ **Dead**

_____ **Transferred out** To where:_____

Why STOP codes:
1 Toxicity/side effects
2 Pregnancy
3 Treatment failure
4 Poor adherence
5 Illness, hospitalization
6 Drugs out of stock
7 Patient lacks finances
8 Other patient decision
9 Planned Rx interruption
10 Other

Why SUBSTITUTE or SWITCH codes:
1 Toxicity/side effects
2 Pregnancy
3 Risk of pregnancy
4 Due to new TB
5 New drug available
6 Drug out of stock
7 Other reason (specify)
Reasons for SWITCH to 2nd-line regimen only:
8 Clinical treatment failure
9 Immunologic failure
10 Virologic failure

Unique # ☐☐☐☐☐☐

HIV CARE/ART CARD

Name_____

Date Check if scheduled. Write in alternate pick-up if ill	Follow-up date	Duration in months since first starting ART/ since starting current regimen	Wt	If **P**regnant EDD?PMTCT? **FP/no FP** If FP write method(s) **If child write height**	Function **W**ork **A**mb **B**ed	WHO clinical stage	TB status	Potential SIDE EFFECTS	New OI, Other PROBLEMS	Cotri-moxazole Adhere	Cotri-moxazole Dose	Other meds dispensed	**ARV drugs** Adhere/ Why	**ARV drugs** Regimen/ Dose dispensed	CD4	Hgb, RPR, TLC, other lab	Refer or consult or link/ provide If hospitalized, # of days
☐																	
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Pregnancy/family planning status if woman is of childbearing age:
P = Pregnant
If pregnant, give estimated due date (EDD) and write PMTCT if referred to PMTCT
FP= Not pregnant and on family planning
If using FP, note methods (note: more than 1 method may be recorded)
No FP = Not pregnant and not using FP

Codes for TB status (check on each visit):
No signs = no signs or symptoms of TB
TB refer = TB suspected and referred for evaluation
INH = currently on INH prophylaxis (IPT)
TB Rx = currently on TB treatment. Record TB card #
Sputum = TB suspected and sputums sample sent or results recorded

Codes for potential side effects or other problems:
Nausea
Diarrhoea
Fatigue
Headache
BN burning/numb/tingling
Rash
Anaemia
ABdominal pain
Jaundice
FAT changes
CNS: dizzy, anxiety, nightmare, depression

Codes for new OI or other problems:
Zoster
Pneumonia
DEmentia/**Enceph**
Thrush–oral/vaginal
FEVER
COUGH
DB difficult breathing
IRIS Immune reconstitution inflammatory syndrome
Weight loss
UD urethral discharge
PID pelvic inflammatory disease
GUD genital ulcer disease
Ulcers–mouth or other

Codes for why poor/ fair adherence:
1 Toxicity/side effects
2 Share with others
3 Forgot
4 Felt better
5 Too ill
6 Stigma, disclosure or privacy issues
7 Drug stock out—dispensary
8 Patient lost/ran out of pills
9 Delivery/travel problems
10 Inability to pay
11 Alcohol
12 Depression
13 Other_____

Codes for ART adherence. Estimate adherence for twice daily ART using the table below:

Adherence	%	Missed doses per month
G(good)	≥ 95%	≤ 3 doses
F(fair)	85-94%	4-8 doses
P(poor)	< 85%	≥ 9 doses

	Follow-up education, support and preparation for ARV therapy			
		Date/comments	Date/comments	Date/comments
Educate on basics, prevention, disclosure	Basic HIV education, transmission			
	Prevention: abstinence, safer sex, condoms			
	Prevention: household precautions, what is safe			
	Post-test counselling: implications of results			
	Positive living			
	Testing partners			
	Disclosure			
	To whom disclosed (list)			
	Family/living situation			
	Shared confidentiality			
	Reproductive choices, prevention MTCT			
	Child's blood test			
Progression, Rx	Progression of disease			
	Available treatment/prophylaxis			
	Follow-up appointments, clinical team			
	CTX, INH prophylaxis			
ART preparation.....initiation.....support, monitor....	ART -- educate on essentials (locally adapted)			
	Why complete adherence needed			
	Adherence preparation, indicate visits			
	Indicate when READY for ART: DATE/result Clinical team discussion			
	Explain dose, when to take			
	What can occur, how to manage side effects			
	What to do if one forgets dose			
	What to do when travelling			
	Adherence plan (schedule, aids, explain diary)			
	Treatment supporter preparation			
	Which doses, why missed			
	ARV support group			
Home-based care, support	How to contact clinic			
	Symptom management/palliative care at home			
	Caregiver booklet			
	Home-based care -- specify			
	Support groups			
	Community support			

Facility HIV care (pre- ART) register **Health unit_____**

Registration								Fill when applicable							Clinical stage- insert date				ART						
Date enrolled in chronic HIV care	Patient clinic ID No.	NAME IN FULL Upper space: surname Lower space: given name	Age	Sex	Address	Entry point	Confirmed HIV+ date	INH Start date Stop date	CTX Start date Stop date	Fluconazole Start date Stop date	TB Rx Start date Stop date	Pregnancy Due date, PMTCT link	If patient is DEAD before starting ART, write DEAD and date	Indicate if LOST TO FOLLOW-UP for more than X months or TO (Transfer out) before starting ART and date	Clinical stage 1	Clinical stage 2	Clinical stage 3	Clinical stage 4	Date medically eligible for ART	Why medically eligible: 1.Clinical only 2.CD4# /% 3.TLC #	Date eligible & ready for ART (after adherence preparation and clinical team meeting)	Date eligible & ready & selected by committee for ART	Date ART started (transfer to ART register)	Clinical stage at start of ART	Unique ART number

COHORT: Year _____ Month _____ **ART register 2006-2007**

Registration and personal information								Status at start ART					Fill when applicable				1st-line regimen		2nd-line regimen	
ART start date	**Unique ART number**	**Why eligible** *(Transfer in)*	**Patient's clinic ID**	**Name** *Surname* *Given name*	**Sex**	**Age**	**Address**	**Func-tional status**	**Weight**	**Child: Height**	**WHO clinical stage**	**CD4**	**INH** *Start date* *Stop date*	**CTX** *Start date* *Stop date*	**TB treatment** *Start date* *Stop date*	**Pregnancy** *Due date* *PMTCT link*	**Original regimen**	**Substitutions** *1st: Reason / Date* *2nd: Reason / Date*	**Regimen**	**Switches, substitution** *1st: Reason / Date* *2nd: Reason / Date*

Why eligible
1 **C**linical only
2 CD4
3 TLC
4 Transfer In (TI), where ART started

Functional status:
1 **W**ork
2 **A**mbulatory
3 **B**edridden

Reasons for regimen change
1 Toxicity/side effects
2 Pregnancy
3 Risk of pregnancy
4 Due to new TB
5 New drug available
6 Drug out of stock
7 Other reason (specify)

Reasons for switch to 2nd-line regimen:
8 Clinical treatment failure
9 Immunologic failure
10 Virologic failure

Follow-up status at end of each month:
On treatment (current regimen abbreviation)
DEAD
STOPped ART (continued on other care)
LOST (not seen in last month)
DROPped from drug supply
RESTART
Transferred **O**ut (**TO**)- if TO, transferred out to where

If follow-up status is **"STOP"**, then add reasons (and weeks of interruption if later restarted):
1Toxicity/side effects
2 Pregnancy
3 Treatment failure
4 Poor adherence
5 Illness, hospitalization
6 Drugs out of stock
7 Patient lack finances
8 Other patient decision
9 Planned treatment interruption
10 Other

ART register

Year																																	
Month 0	Month 1	2	3	4	5	6			7	8	9	10	11	12			13	14	15	16	17	18	19	20	21	22	23	24			
						Function		CD4						Function		*CD4*												Function		CD4

Adult 1st-line regimens
1a(30) = d4t(30)-3TC-NVP
1a(40) = d4t(40)-3TC-NVP
1b(30) = d4t(30)-3TC-EFV
1b(40) = d4t(40)-3TC-EFV
1c = AZT-3TC-NVP
1d = AZT-3TC-EFV

Adult 2nd-line regimens:
2a(250) = ABC-ddI(250)-LPV/r
2a(400) = ABC-ddI(400)-LPV/r
2b(250) = ABC-ddI(250)-SQV/r
2b(400) = ABC-ddI(400)-SQV/r
2c(250) = TDF-ddI(250)-LPV/r
2c(400) = TDF-ddI(400)-LPV/r
2d(250) = TDF-ddI(250)-SQV/r
2d(400) = TDF-ddI(400)-SQV/r

Child 1st-line regimens
4a = d4T-3TC-NVP
4b = d4T-3TC-EFV
4c = AZT-3TC-NVP
4d = AZT-3TC-EFV

Child 2nd-line regimens
5a = ABC-ddI-LPV/r
5b = ABC-ddI-NFV
5c = ABC-ddI-SQV/r

Quarterly, facility-based HIV care/ART reporting form

Patients registered during quarter (dd/mm/yyyy - dd/mm/yyyy):	
Date of completion of form (dd/mm/yyyy):	
MOH or Project or Grantee:	Facility:
Location:	Country:

1. HIV care (non-ART and ART) - new and cumulative number of persons enrolled			
	Cumulative number of persons ever enrolled in HIV care at this facility from the quarter which ended 3 months ago	New persons enrolled in HIV care at this facility during the previous quarter	Cumulative number of persons ever enrolled in HIV care at this facility at end of the previous quarter
1. Males (>14 years)	a.	h.	o.
2. Non-pregnant females (>14 years)	b.	i.	p.
3. Pregnant females (>14 years)	c.	j.	q.
4 Males (0-14 years)	d.	k.	r.
5. Non-pregnant females (0-14 years)	e.	l.	s.
6. Pregnant females (0-14 years)	f.	m.	t.
Total	g.	n.	u.
	Total number of persons who are enrolled and medically eligible for ART but have not been started on ART		v.

2. ART care - new and cumulative number of persons started			
	Cumulative number of persons ever started on ART at this facility from the quarter which ended 3 months ago	New persons started on ART at this facility during the previous quarter	Cumulative number of persons ever started on ART at this facility at end of the previous quarter
1. Males (>14 years)	a.	h.	o.
2. Non-pregnant females (>14 years)	b.	i.	p.
3. Pregnant females (>14 years)	c.	j.	q.
4. Males (0-14 years)	d.	k.	r.
5. Non-pregnant females (0-14 years)	e.	l.	s.
6. Pregnant females (0-14 years)	f.	m.	t.
Total	g.	n.	u.
	Number of persons on ART and already enrolled in program who transferred into facility during the previous quarter		v.
	Number of baseline CD4+ counts for persons who started ART during the previous quarter (optional)		w.
	Median baseline CD4+ count for persons who started ART during the previous quarter (optional)		x.

4. ARV regimen at end of quarter	Male	Female		
On 1st-line ARV regimen				
4.1 Adults (>14 years)				
d4T-3TC-NVP	a.	j.		
d4T-3TC-EFV	b.	k.		
ZDV-3TC-NVP	c.	l.		
ZDV-3TC-EFV	d.	m.		
	e.	n.		
	f.	o.		
	g.	p.		
	h.	q.		Total number of adults on 1st-line regimen
Adults on 1st-line regimens	i.	r.	s.	
4.2 Children (0-14 years)				
d4T-3TC-NVP	a.	k.		
d4T-3TC-EFV	b.	l.		
ZDV-3TC-NVP	c.	m.		
ZDV-3TC-EFV	d.	n.		
	e.	o.		
	f.	p.		
	g.	q.		
	h.	r.		Total number of children on 1st-line regimen
Children on 1st-line regimens	i.	s.	u.	
Adults and children on 1st-line regimens	j.	t.	v.	Total adults and children on 1st-line regimens
On 2nd-line ARV regimen				
4.3 Adults (>14 years)				
ABC-ddI-LPV/r	a.	i.		
ABC-ddI-SQV/r	b.	j.		
TDF-ddI-LPV/r	c.	k.		
TDF-ddI-SQV/r	d.	l.		
	e.	m.		
	f.	n.		
	g.	o.		Total number of adults on 2nd-line regimen
Adults on 2nd-line regimens	h.	p.	q.	
4.4 Children (0-14 years)				
ABC-ddI-LPV/r	a.	k.		
ABC-ddI-NFV	b.	l.		
ABC-ddI-SQV/r	c.	m.		
	d.	n.		
	e.	o.		
	f.	p.		
	g.	q.		Total number of children on 2nd-line regimen
Children on 2nd-line regimens	h.	r.	u.	
Adults and children on 2nd-line regimens	i.	s.	v.	Total adults and children on 2nd-line regimens
Adults and children on 1st- and 2nd-line regimens	j.	t.	w.	Total adults and children on 1st- and 2nd-line regimens
				Total current on ART

OPTIONAL

5.1 Number of persons who did not pick up their ARV regimens	Male	Female	**5.2 Of those who did not pick up regimen in previous 1 quarter**	Total number of adults and children
1. For previous 1 month (only)	a.	e.		
2. For previous 2 months (only)	b.	f.	1. Lost to follow-up	a.
3. For previous 3 or more months	c.	g.	2. Who died	b.
Subtotal	d.	h.	3. Who stopped ART	c.
Total number of persons who did not pick up their ART regimens		i.	4. Who transferred out	d.

Cohort analysis report

Report on treatment status/outcomes for cohorts on ART

ART start-up groups (cohorts) are defined by month/year they started ART.

Facility: _____

	For cohort starting ART by month/year: at baseline then results at 6 months on ART, 12 months on ART, 24 months on ART	Cohort Jan06	6 mo-July06	12 mo-Jan07	24 mo-Jan08	Cohort Feb06	6 mo-Aug06	12 mo-Feb07	24 mo-Feb08	Cohort Mar06	6 mo-Sep06	12 mo-Mar07	24 mo-Mar08	Cohort Apr06	6 mo-Oct06	12 mo-Apr07	24 mo-Apr08	Cohort May06	6 mo-Nov06	12 mo-May07	24 mo-May08	Cohort Jun06	6 mo-Dec06	12 mo-Jun07	24 mo-Jun08
G	**Started on ART in this clinic- original cohort**																								
TI	**Transfers in** Add +	x				x				x				x				x				x			
TO	**Transfers out** Subtract -	x				x				x				x				x				x			
N	**Net current cohort**																								
H	**On original 1st-line regimen**																								
I	**On alternate 1st-line regimen (substituted)**																								
J	**On 2nd-line regimen (switched)**																								
	Stopped																								
	Died																								
	Lost to follow-up (DROP)																								
	Percent of cohort alive and on ART																								
	[(H + I + J) / N * 100]																								
	CD4 median or fraction ≥ 200 [of those with available CD4] **(optional)**																								
	Functional status																								
	Number **W**orking																								
	Number **A**mbulatory																								
	Number **B**edridden																								
	Total **W+A+B**																								
	Number of persons who **picked up ARVs each month for 6 months**	x		x	x	x		x	x	x		x	x	x		x	x	x		x	x	x		x	x
	Number of persons who **picked up ARVs each month for 12 months**	x	x		x	x	x		x	x	x		x	x	x		x	x	x		x	x	x		x

For cohort starting ART by month/year: at baseline then results at 6 months on ART, 12 months on ART, 24 months on ART	Cohort Jul06	6 mo-Jan07	12 mo-Jul07	24 mo-Jul08	Cohort Aug06	6 mo-Feb07	12 mo-Aug08	24 mo-Aug08	Cohort Sep06	6 mo-Mar07	12 mo-Sep07	24 mo-Sep08	Cohort Oct06	6 mo-Apr07	12 mo-Oct07	24 mo-Oct08	Cohort Nov06	6 mo-May07	12 mo-Nov07	24 mo-Nov08	Cohort Dec06	6 mo-Jun07	12 mo-Dec07	24 mo-Dec08
Started on ART in this clinic- original cohort																								
Transfers in Add +	*x*				*x*				*x*				*x*				*x*				*x*			
Transfers out Subtract -	*x*				*x*				*x*				*x*				*x*				*x*			
Net current cohort																								
On original 1st-line regimen																								
On alternate 1st-line regimen (substituted)																								
On 2nd-line regimen (switched)																								
Stopped																								
Died																								
Lost to follow-up (DROP)																								
Percent of cohort alive and on ART																								
[(H + I + J) / N * 100]																								
CD4 median or proportion ≥ 200 [of those with available CD4] **(optional)**																								
Functional status																								
Number **W**orking																								
Number **A**mbulatory																								
Number **B**edridden																								
Total **W+A+B**																								
Number of persons who **picked up ARVs each month for 6 months**	x		x	x	x		x	x	x		x	x	x		x	x	x		x	x	x		x	x
Number of persons who **picked up ARVs each month for 12 months**	x	x		x	x	x		x	x	x		x	x	x		x	x	x		x	x	x		x