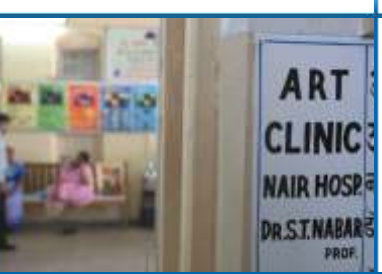
Training Toolkit

HIV Care and Antiretroviral Treatment Recording and Reporting System



PARTICIPANT MANUAL

2006

World Health Organization
Regional Office for South-East Asia
New Delhi

Further publications can be obtained from the HIV/AIDS Unit,
Department of Communicable Diseases, World Health Organization,
Regional Office for South-East Asia, World Health House, Indraprastha Estate,
Mahatma Gandhi Road,New Delhi 110002, India.
Fax +91-11-23370197, 23379395, 23379507
Email: hiv@searo.who.int
Library support: library@searo.who.int

Designed and Printed in India by: Macro Graphics Pvt. Ltd., www.macrographics.com

Document No.: SEA/AIDS/161
ISBN No.: 92 9022 268.9

Participant Manual

HIV Care and ART Recording and Reporting System

Sub module 1

Sub Module 1

1. Overview of HIV care/ART recording and reporting system

1.1. Session objectives

At the end of this session the participants will be able to:

- understand the importance of standard recording and reporting tools;
- list key information collected; and
- identify the different forms to be used in a paper based recording and reporting system.

Terms used

- *Patient management* is the relationship between a provider (and clinical team) and the individual patient over time assisted by written records.
- *Patient monitoring* is the practice of capturing data on patients over time and across clinical sites, as well as using information either directly from paper forms or from those entered into a computer.
- *Programme monitoring* is the routine tracking of priority information about a programme and its intended outcomes. Monitoring at the facility, district and national levels requires many types of information, including aggregated patient data.

1.2. Objectives of programme monitoring

With the increasing access to antiretroviral treatment (ART), a strong monitoring system is required at facility, district, provincial, national and international levels.

At facility level, the objectives of programme monitoring are to:

- support patient management by regularly recording and storing of key individual information for lifelong care and follow-up;
- facilitate an accurate patient tracking system to identify those missing or lost to follow-up; and
- support drug supply management at the facility.

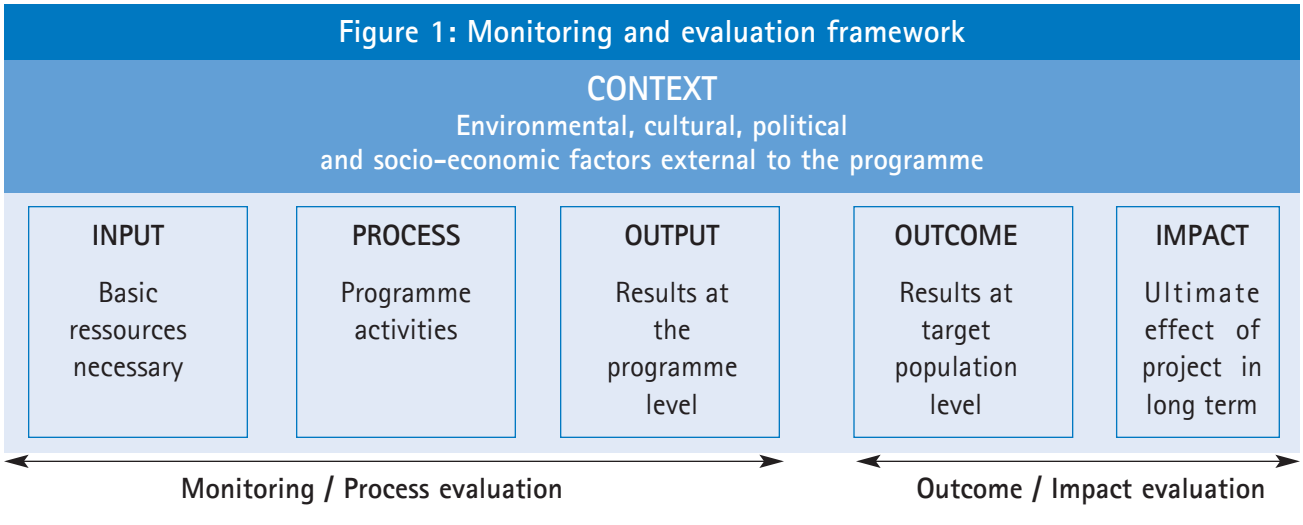
At all levels, programme monitoring will help to:

- document the progress in equitable access to HIV care and ART programmes; and
- identify the successes and gaps over time and modify the programmes accordingly.

1.3. Indicators at national/international levels

Ten indicators, based on the monitoring and evaluation framework (Figure 1), were developed for national programmes to demonstrate progress in scaling up ART programmes.

Figure 1: Monitoring and evaluation framework



Input
1. Existence of national policies, strategy and guidelines for ART programmes.

Process
2. Percentage of districts or local health administration units with at least one health facility providing ART services in line with national standards.

3. Percentage of ARV storage and delivery points experiencing stock-outs in the preceding 6 months.

4. Number of health workers trained on ART delivery in accordance with national or international standards.

Output
5. Percentage of health facilities with systems and items to provide ART services.

6. Percentage of health facilities with ART services that also provide comprehensive care, including prevention services, for HIV-positive clients.

Outcome
7. Percentage of people with advanced HIV infection receiving ARV combination therapy.

8. Continuation of first-line regimens at 6, 12 and 24 months after initiation.

Impact
9. Survival at 6, 12, 24, 36 etc. months after initiation of treatment.

These indicators are recommended to be used during the evaluation phase of the national programmes. Some indicators (7,8,9) need to be obtained from programme monitoring at facility level.

1.4. Indicators at the facility level

The following indicators are recommended to be produced at the facility level.

Indicator	Level of detail	Recommended reporting frequency
1. Cumulative number ever enrolled for HIV care	By sex, age	Monthly
2. Number started on ART during the reporting period	By sex, age	Monthly
3. Cumulative number ever started on ART	By sex, age	Monthly
4. Cumulative number medically eligible for ART but have not been started on ART	By sex, age	Monthly
5. Cumulative number on ART		Monthly
6. Cumulative number on substituted 1st line regimen		Monthly
7. Cumulative number switched to 2nd line regimen		Monthly
8. Proportion of patients with >95% adherence		Monthly
9. Proportion of patients alive and on treatment 6, 12, and 24 months after start of treatment		Bi-annual or annual
10. Proportion of patients continuing initial 1st line regimen, substituting 1st line, switched to 2nd line at 6, 12, 24 months of ART		Bi-annual or annual
11. Proportion of patients with >200 mm3 CD4 cells after 6, 12, 24 months of ART		Bi-annual or annual
12. Proportion of patients on ART whose performance scale at 6, 12, 24 months is "normal activity."		Bi-annual or annual
13. Proportion of patients who have picked up their ARV drugs 6/6 months or 12/12 months		Bi-annual or annual

1.5. Standardized recording and reporting system

To generate the above listed indicators, it is important to have a uniform data collection and reporting system.

Standard recording and reporting ensures that key information gets stored. This helps in:

- easily retrieval by care providers to get an overview of the patient's progress over time;
- exchange of information between the different health care providers (such as, doctor, nurse, counselor, psychologist) as well as with other ART centres when the patient is referred or transferred to another clinic; and
- facilitate compilation and comparison of indicators at province, national and international levels.

1.6. List of records and reports at the facility

A paper based system is preferred at the initial stage of programme monitoring because it:

- prevents delay in implementation of monitoring and evaluation;
- allows easy implementation in particular at the peripheral level;
- allows easy adaptation and revision to the local situation; and
- requires low technical support.

An adequately tested paper-based system also will greatly facilitate the development of a computer-based system.

The WHO recommended paper based system consists of 5 recording forms and 2 reporting forms. These recording and reporting tools are briefly described below.

Recording forms

1. Patient HIV Care and Antiretroviral Treatment (ART) Record **(Patient HIV Care/ART Record)**
2. **Pre-ART Register**
3. **ART Register**
4. **ARV Drug Dispensing Register**
5. **ARV Drug Stock Register.**

The **Patient HIV Care/ART Record** is maintained for each patient under HIV care whether or not they started on ART. In this record standard information is noted under four categories.

i. *Demographic information*, collected at first visit or on enrollment which is updated if the information has changed.
ii. *HIV care history*, collected for all patients enrolled in HIV care whether or not they have started ART.
iii. *ART summary*, collected at start and change in treatment as well as at 6 months and yearly follow-up.
iv. *Patient follow-up information,* collected every time the patient visits the facility.

In the **Pre-ART Register** and **ART Register** there is one row per patient to record key individual information from the Patient HIV Care/ART Record. These registers will facilitate the calculation of indicators for programme monitoring.

The *Pre-ART Register* is filled in at the patient's first visit to the clinic with subsequent key information up to the beginning of ART.

The *ART Register* is filled in at the start of ART and at each follow-up visit up to 24 months.

Ideally, both these registers should be filled in by the health care providers immediately following the patient visits. They can also be filled in by trained staff (such as, nurses, secretaries) based on information recorded in the HIV Care/ART Card some time after the visits.

The **ARV Drug Dispensing Register** and **Drug Stock Register** are designed to support monitoring of drug requirements, such as to record the number of ARV tablets dispensed to the patients and to report drug consumption, and available drug stocks.

Reporting forms

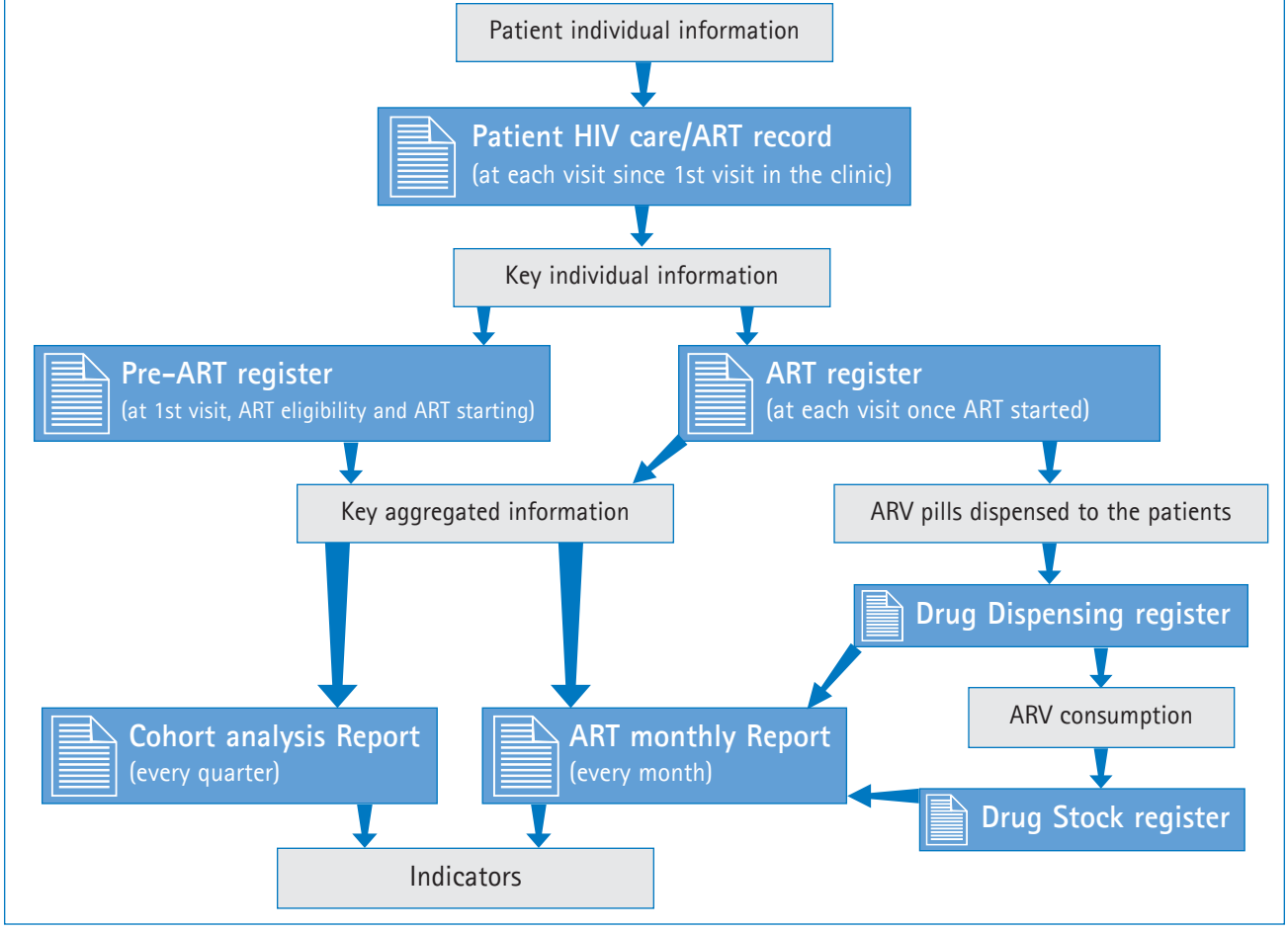
1. The Monthly HIV Care/Antriteroviral Treatment (ART) Centre Report **(ART Monthly Report)**
2. Treatment Outcomes for Cohorts on ART **(Cohort Analysis Report).**

The **ART Monthly Report** and **Cohort Analysis Report** are designed to record aggregated information extracted from the Pre-ART and ART Registers and the Drug Dispensing and Drug Stock Registers. This aggregated information will be used to calculate indicators at the facility, district, provincial and national levels. Both forms should be filled in by the facility manager or trained staff under his/her supervision.

Cohort indicator analysis may be done on a quarterly basis.

The above records and reports help in patient and programme monitoring and in generating the required indicators listed under section 1.4. As shown in Figure 2, individual patient information is recorded in the HIV Care/ART Patient Record at the time of the consultation and subsequent follow-up. This is the key record and a source for information for the Pre-ART and ART registers. The Pre-ART and ART registers in turn help in preparing the monthly and cohort reports. The Drug Dispensing Register is used for recording the information at the time each patient is dispensed medicines. The Drug Stock Register uses information

Figure 2. Recording and reporting forms in a paper based monitoring system



from the Drug Dispensing Register and is used to prepare the ART Monthly Report. The use of these forms is listed in Table 1.

Table 1: Use of the forms in a paper based monitoring system

Form	What information?	For what purpose?	When to complete?	Who will complete?
Patient HIV Care / ART Record	Demographic, HIV care, antiretroviral treatment and monthly follow-up clinical information	✦ Patient management: to ensure appropriate lifelong follow-up ✦ Patient monitoring: to obtain key individual variables for future analysis	✦ At each patient visit, starting from the 1st visit to the clinic	✦ Health care providers during each patient visit
Pre-ART Register	Standardized and systematic key variables on each patient before ART started	✦ Patient monitoring: to report key variables on each patient ✦ Programme monitoring: to facilitate calculation of indicators	✦ At the 1st visit ✦ At start of tuberculosis treatment and cotrimoxazole prophylaxis ✦ At ART eligibility ✦ At start of ART ✦ At end of follow-up, if needed	✦ Health care providers during each patient visit or ✦ Trained staff using patient record after the visit
ART Register	Standardized and systematic key variables on each patient under ART	✦ Patient monitoring: to report key variables on each patient ✦ Programme monitoring: to facilitate calculation of indicators	✦ At each visit once ART is started	✦ Health care providers during each patient visit or ✦ Trained staff using patient record after the visit
ARV Drug Dispensing and Stock Registers	Drugs and no. of tablets dispensed Drug stocks	✦ Patient monitoring: accounting for no. of tablets dispensed ✦ Programme monitoring: drug consumption and available stocks	✦ At the time of drug dispensing to each patient ✦ Daily basis	✦ Pharmacist or officer in charge of dispensing drugs
Monthly ART Report	Indicators	✦ Programme monitoring: to calculate and analyse indicators	✦ Every month	✦ Facility manager or ✦ Trained staff under supervision of the facility manager
Cohort Analysis Report	Indicators	✦ Programme monitoring: to calculate and analyse indicators at 6,12, 24 months of start of ART	✦ Every 6 months or during yearly assessment	✦ Facility manager or ✦ Trained staff under supervision of the facility manager

1.7. Storage of records and reports

Correct storage of records and reports is important and ensures:

- that forms are available at each next visit; and
- the confidentiality and security of the forms.

In numerous settings, records are transferred from outpatient services to the administrative section in charge of storage. This system is often not suitable for the lifelong follow-up required in HIV care because of the elaborate procedures and efforts required in requesting and obtaining the patients' records on time, as well as the possibility of difficulty in finding or losing records.

The best method is to store patient records within the clinic. Ensure that:

- Records are kept in a locked cabinet with access limited to authorized staff.
- Records are arranged serially by registration number. Alternatively, they may be arranged by name, or date/month of next appointment. This will help in quickly locating the medical records just before the consultation, as well as in identifying those patients who missed an appointment.

1.8. Confidentiality and security

Confidentiality is the assurance that medical information will be used only for appropriate care and treatment of the individual.

Security is defined as the protections that assure that no breaches in confidentiality will occur.

Stigma and discrimination regarding HIV/AIDS still remain very high in most of the countries. Lack of confidentiality within health services is often a major obstacle in access to care for people who need it. Strict rules of confidentiality between the patients and their health care providers have to be developed to protect patients' rights. Protecting confidentiality is part of the professional code of conduct for doctors, in the form of the Hippocratic Oath, and indeed of all other members of the medical team (health care providers and supporting staff, e.g. the secretary for programme monitoring).

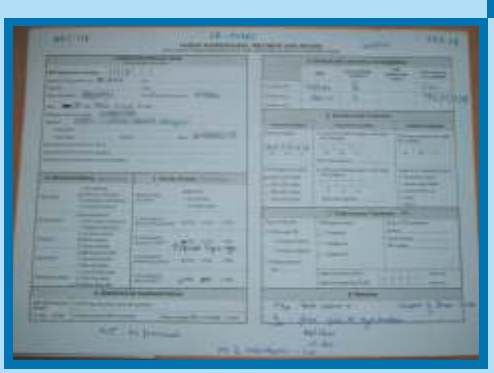
When recording and compiling individual information ART clinic managers should ensure that confidentiality of records is maintained. Breaches in confidentiality may easily occur if the patients' records are not stored properly (as these may be accessed by unauthorized persons, like friends or family members). In establishing the monitoring system all aspects of confidentiality should be addressed, such as:

- Has the medical team, including the non-technical staff, handling patient information (e.g. secretary) been briefed on the principles of confidentiality?
- Where will the patient records be stored and who are the designated persons authorized to access the records?
- Who will be in charge of the registers and where will these registers be stored?
- How will the medical information be transferred between services, such as for blood samples and laboratory results?

In a paper based system, the most sensitive documents are the Patient HIV Care/ART Record and the registers, because they include patient information. Usually, only one copy should be available directly under the responsibility of the facility manager. The registers should be kept in a locked cabinet after the day's activity is over or when the clinic closes.

Computerization of individual patient information represents an even higher risk for breaches in confidentiality as electronic files can be easily reproduced and shared. Besides all the protection required for securing the database (such as computers dedicated for this purpose only, access limited to authorized persons, regular change of password), individual patient information should be computerized by registration number to maintain anonymity.

Sub module 2



2. How to use the Patient HIV Care/ART Record

Sub Module 2

2.1. Session objectives

At the end of the session the participants will be able to:

- understand how the Patient HIV Care/ART Record is used; and
- how to correctly fill out the Patient HIV Care/ART Record.

2.2. What is the Patient HIV Care/ART Record?

Effective lifelong HIV care, including ART, requires keeping track of the patient's baseline and follow-up care and treatment history. Any health care provider in the medical team (such as doctor, nurse, counsellor, psychologist) needs to know key clinical details and what was done on previous visits.

In this chapter you will learn to use a Patient HIV Care/ART Record which should be retained at the clinic and updated at every patient visit. This Record is designed to be used from the time an HIV-positive patient registers for lifelong HIV care, regardless of whether he (she) needs ART at the start.

The Patient HIV Care/ART Record contains key individual information to be recorded uniformly for all registered patients. Additional loose pages may be inserted in a prepared docket of the Record for writing more information gathered during the visits.

The patient may also be given a **patient booklet** (not shown here) which includes key diagnostic and treatment details.

The Patient HIV Care/ART Record has two pages for entering key information:

- Page 1 is a summary of key identification, socio-demographic, clinical and therapeutical information. This includes mostly one-time information.
- Page 2 is a table for follow-up visits, where one row is filled out for each visit.

2.3. Who should complete the Patient HIV Care/ART Record?

HIV/ART care is provided by a team including nurses, counselors, and physicians. Therefore, different items in the record are completed by different members of the team. For example, the identification data may be filled by a nurse, the social data by a counselor and clinical data by a physician.

2.4. When should the Patient HIV Care/ART Record be started?

When an HIV-positive patient, whether symptomatic or not, decides that he (she) wants to avail of ongoing care at your clinic, fill-out a Patient HIV Care/ART Record for this new patient. This is called enrolling the HIV-infected person in HIV care. Patients need to understand that HIV care implies the desire to be cared for on an ongoing basis with follow-up.

2.5. What information should be recorded?

This section explains in detail the variables, information as well as details of when and who fills up each of the 9 sections of the Patient HIV Care/ART Record (see Forms).

Page 1 of Patient HIV Care/ART Record: Summary Information

Part 1. PATIENT IDENTIFICATION DATA

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_____

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

Name previous clinic: _____ Date transferred in: _____

Information to be recorded	Instructions for recording	When to record	Who will record
Registration Number	**Write the registration number allocated to a new patient (according to the system chosen in the national programme).This registration number should be unique, i.e. the same number cannot be attributed to more than one patient.** **The assigning of a registration number should be as simple as possible and decided at the country level. An easy way is to allocate a two-letter code for each ART clinic (e.g. for clinic A, XA where X refers to district or sub-district code) and a serial number for the patients (e.g. the first patient in clinic A in district X will be allocated the number XA001).** **For a** transferred **in patient under ART from another clinic you should keep the same registration number as that at the previous clinic.**	1st visit to your clinic	**nurse**
Name of treatment unit, city, district, state or province	**Write the name and address of your clinic, including the city or village, district and province or state where it is situated.**	1st visit	**nurse**

Information to be recorded	Instructions for recording	When to record	Who will record
Name of patient	Write the name and surname of the patient, and other names (father/husband name) if required.	1st visit	nurse
Age Sex	Write the age of the patient in years and for babies write the date of birth in the boxes in dd/mm/yy format and the corresponding age. Tick the appropriate box to indicate sex of the patient.	1st visit	nurse
Patient's phone numer and address	Write as accurately as possible the phone number and detailed contact address of the patient.	1st visit	nurse
Distance from residence to clinic (km)	Estimate and write the distance from the patient's home to the clinic in kilometres.	1st visit	nurse
Treatment supporter's name, address, phone number	Write the treatment supporter's name, address and phone number, if applicable and possible (the patient should not face confidentiality problems because of the treatment supporter). It is useful to have a treatment supporter who can help in ensuring adherence and can be contacted to trace the patient if the patient misses an appointment.	1st visit	nurse
Date and Place of confirmed HIV+ test	Write the date when the HIV-positive test result was available (in dd/mm/yy format) and the place it was performed. For babies less than 18 months old, write if the test is an antibody test (ELISA, rapid test) or PCR. For antibody test, you might have to reconfirm HIV-positivity after 18 months.	1st visit	nurse
Entry point	When a patient enrols for HIV care, it is useful to know from where in the health care system the patient has come. Tick the appropriate box to indicate the name of the service which referred the patient to the clinic (entry point). It may be from: 1. VCT-Voluntary counselling and testing services 2. TB-Tuberculosis control programme 3. Outpatient services 4. Inpatient services 5. Paediatric services 6. PMTCT-Prevention of mother-to-child transmission services 7. STI-Sexually transmitted infections services 8. Private health services 9. NGO-Non-government organizations 10. Self referred 11. Outreach/special services for IDUs 12. Outreach/special services for commercial sex worker 13. Other (to be specified).	1st visit 1st visit	nurse nurse
Patient transferred in on ART	Tick the box if the patient started ART at another HIV care/ART clinic under the national programme and was transferred in for continuation of treatment at your clinic. Write the name of the previous clinic and the date of transfer in. Ideally, the patient should be transferred in with his (her) Patient HIV care/ART Record (or a copy) without the need for you to open a new one. For a patient not started on ART and transferred from one clinic to another, it is more simple to register the patient as a new patient in the clinic transferred in. However, a copy of his (her) past Patient HIV Care/ART Record should be with the patient when he/ she relocates.		

Part 2. PERSONAL HISTORY

2. Personal History (Tick one choice)	
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
For IDUs If yes, type:	Substitution therapy ☐ Y ☐ N
Literate	☐ Yes ☐ No
Employed	☐ Yes ☐ No
Alcoholism	☐ Habitual ☐ Social ☐ No use

Information to be recorded	Instructions for recording	When to record	Who will record
Mode of HIV transmission	Tick one choice for the most probable way the person was HIV infected: 1 Commercial sex worker 2 Other heterosexual route 3 Men who have sex with men 4 Injecting drug use 5 Blood transfusion 6 Mother to child 7 Unknown.	1st visit	doctor
For IDUs Substitution therapy Y/N If yes, type:	For injecting drug users, tick Y if the person is currently under substitution therapy (e.g. methadone) and if not, tick N. Write the type of substitution therapy the patient is taking.	1st visit	doctor
Literate	Tick Yes if the patient is literate, i.e. can read and write. Tick No, if the patient cannot read or write.	1st visit	nurse
Employed	Tick Yes if the patient has a regular employment or activity (such as a farmer), otherwise tick No.	1st visit	nurse
Alcoholism	Try to assess the patient's drinking habit as this is important for the adherence to medications. Tick Habitual, if he drinks alcohol every day. Tick Social if he drinks alcohol only for social reasons. Tick No use if the patient occasionally never drinks.	1st visit	nurse

Part 3. FAMILY HISTORY

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

Information to be recorded	Instructions for recording	When to record	Who will record
Marital status	Record the marital status of the patient, whether single, married, divorced/separated, widowed or not applicable (e.g. transgender).	1st visit	nurse
Estimated monthly household income	If possible, try to get an estimate of the income of all household members during a month.	1st visit	nurse
Family members partner/children	For close family members (husband, wife, regular partner if not married, children) record their name, age, relationship to the patient, their HIV status (+ or - or unknown), any family member currently receiving ART, and their registration number if they are also in HIV care.	1st visit	nurse

Part 4. ANTIRETROVIRAL TREATMENT HISTORY

4. Antiretroviral treatment history		
Was ART received before? ☐ Yes ☐ No	If yes ☐ PMTCT ☐ Earlier ART	Place: ☐ Private ☐ Govt
	Drugs and duration:	

Information to be recorded	Instructions for recording	When to record	Who will record
Was ART received before?	Tick Yes if the patient ever took ARV drugs. If yes, tick the appropriate box in the next column to indicate whether it was: ✦ *PMTCT* refers to women who received ARV during pregnancy/delivery to prevent mother to child transmission. ✦ *Earlier ART* refers to those patients who took some ARV for treatment before either as self prescription, private services, etc., whatever the type of regimen and the duration, outside of the national ART programme.	1st visit	doctor
Place:	Tick the appropriate box where the patient received previous ART-in a private facility (including self prescription) or in a government facility.	1st visit	doctor
Drugs and duration	For patients who ever took ARV drugs in the past write the names of the drugs and duration of treatment.	1st visit	doctor

Part 5. CLINICAL AND LABORATORY INVESTIGATIONS

5. Clinical and Laboratory Investigations							
	Date (dd/mm/yy)	**WHO stage**	**Weight** (kg)	**Height** (cm)	**Performance 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			

This part is a summary of the most important dates and clinical/laboratory investigations during HIV care and ART follow up.

Information to be recorded		**Instructions for recording**	**When to record**	**Who will record**
Date dd/mm/yy	At 1st visit in clinic	This is the day of enrollment at your clinic, it is the day of 1st contact.	1st visit	nurse
	At ART medical eligibility	This is the date when the patient was considered eligible for ART and refers exclusively to medical criteria (i.e. clinical stage, CD4, total lymphocyte count). If a patient is enrolled at stage IV, the date of 1st visit (enrollment in HIV care) and the date of eligibility for ART, will be similar.	when applicable	doctor
	At start of ART	It is the exact date ART was started through the national programme. For a patient "transferred in" under ART, it is the date the patient started ART at the previous clinic. The date of starting ART through the national programme is a definitive date and should not change for a patient whatever subsequent interruptions and transfers from clinics may occur.	when applicable	doctor
	At 6 months ART	This date of visit corresponds to 6 months follow-up after starting ART. If the patient was lost to follow-up, died or transferred out before 6 months after start of ART (i.e. no visit at 6 months), then write the exact reason in this cell. Do not forget to record and secure this information in part 8: end of follow-up. If the patient did not visit exactly at 6 months, record the next follow-up visit that occurred after 6 months.	when applicable	nurse/ doctor
	At 12 months ART	This date of visit corresponds to 12 months follow-up after starting ART even if the patient has stopped *ART*. If the patient was lost to follow-up, died or *transferred out* before 12 months (i.e. no visit at 12 months), write the exact reason in this cell. Do not forget to record and secure this information in part 8: end of follow-up. If the patient did not visit exactly at 12 months, record the next follow-up visit that occurred after 12 months.	when applicable	nurse/ doctor
	At 24 months ART	This date of the visit corresponds to 24 months follow-up after starting ART even if the patient has stopped ART. If the patient was lost to follow-up, died or transferred out before 24 months (i.e. no visit at 24 months), write the exact reason in this cell. Do not	when applicable	nurse/ doctor

Information to be recorded	Instructions for recording	When to record	Who will record
	forget to record and secure this information in part 8: end of follow-up. If the patient did not visit exactly at 24 months, record the next follow-up visit that occurred after 24 months.		
WHO stage	Write the WHO clinical stage of the patient at each of these time points (refer to the exact classification of signs and symptoms from WHO guidelines).	1st visit and when applicable	doctor
Weight (kg)	Write down the weight of the patient in kilogram at each of these time points.		nurse/ doctor
Height	Write down the height in centimeters at 1st visit for adults, and at each of these time points for children.		
Performance A/B/C	Write the appropriate performance scale (A, B or C) at each of these time points. A is for a normally active patient. B is for a patient who was bedridden for less than half of the day during last month. C is for a patient who was bedridden for more than half of the day during last month.		
Total lymphocyte count or CD4 (mm3)	Write the exact total lymphocyte count or CD4 count corresponding to these time points. For children, report the percent of CD4 among total lymphocyte count.		

Part 6. ANTIRETROVIRAL TREATMENT

6. Antiretroviral Treatment					
Treatment Started	SUBSTITUTION within 1st line, SWITCH to 2nd line, STOP, RESTART				
☐ D4T30+3TC+NVP ☐ D4T40+3TC+NVP ☐ D4T30+3TC+EFV ☐ D4T40+3TC+EFV ☐ ZDV+3TC+NVP ☐ ZDV+3TC+EFV	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

Information to be recorded	Instructions for recording	When to record	Who will record
Treatment started	Tick the appropriate ART regimen the patient is started on: ✦ D4T/3TC/NVP (Stavudine/Lamuvidine/Nevirapine)- (D4T30 and D4T40 are 30 mg and 40 mg of Stavudine) ✦ ZDV/3TC/NVP (Zidovudine/Lamuvidine/Nevirapine) ✦ D4T/3TC/EFV (Stavudine/Lamivudine/Efavirenz) ✦ ZDV/3TC/EFV (Zidovudine/Lamuvidine/Efavirenz).	Day of starting ART	doctor
Substitution	Substitution refers to the change in regimen within the recommended 1st line regimen to counter side-effects or for intermittent conditions (such as tuberculosis and pregnancy) and should not be considered due to treatment failure. Write the Date of substitution, the Code 'substitute', the corresponding number code for the Reason, the Date of restart and the New regimen started.	Day of 1st line substitution	doctor
Switch	Switch refers to the change from 1st line recommended regimen to 2nd line recommended regimen. Write the Date of switch, the Code 'switch', the corresponding number code for the Reason, the Date of restart and the New regimen started.	Day of switch to 2nd line	doctor
Stop	Stop corresponds to a medical decision to interrupt ART during a patient visit, whatever the duration irrespective of whether or not the patient will restart in the future. ART is no more prescribed at this visit. Write the Date of stop, the Code 'stop' and the corresponding number code for the Reason. If ART is restarted later, write the Date of restart and the New regimen in the same row you wrote for stop.	Day of stopping treatment Day of restarting	doctor

Part 7. TUBERCULOSIS TREATMENT DURING HIV CARE

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

This part refers to tuberculosis (TB) treatment at the time of enrolment or during follow-up. Do not record here history of TB before follow-up at the clinic.

Information to be recorded	Instructions for recording	When to record	Who will record
Disease class	Tick the appropriate box corresponding to pulmonary or extra-pulmonary TB. For pulmonary TB tick the appropriate box to indicate sputum status, smear-positive or smear-negative. If the patient has extrapulmonary TB, write the affected site on the line provided at the bottom of this box.	1st visit/ TB diagnosis	doctor
TB Regimen	Tick the recommended treatment category (I , II, other) started by the patient.	1st visit/ TB diagnosis	doctor
TB registration	Write the name of the district, health centre and TB number of the TB clinic in charge of follow-up of the patient for TB.	1st visit/ TB diagnosis	doctor
Date start TB Rx	Write the date of start of TB treatment in dd/mm/yy format. ✦ It may be before the 1st visit to your clinic if the patient is enrolled for TB treatment. ✦ It may be during follow-up at your clinic if TB is diagnosed during HIV care/ ART follow-up. ✦ Do not record past history of TB treatment received before enrollment in HIV care.	1st visit/ TB diagnosis	doctor
Treatment outcome	Tick the appropriate treatment outcome as recorded in the TB programme register (i.e. cure, completed, failure, died, default or transfer out), and the date of outcome in dd/mm/yy format.	End of TB treatment	doctor

Part 8. END OF FOLLOW-UP

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:

Whenever the patient does not return for follow up for HIV care this part should be completed. This closes the Patient HIV Care/ART Record.

Information to be recorded	Instructions for recording	When to record	Who will record
Death and Date of death	If the patient dies, you should try and get the exact date of death. This is important for getting an idea of the duration of follow-up from the time the patient was enrolled, started on ART and died. If you do not have the day, write the month and year. Sometimes, this information may become available a long time after the patient dies. For example, when a patient was lost to follow-up and you were informed about his (her) death 6 months later. Complete the information whenever it is known to you.	When applicable	nurse/ doctor/ counsellor (all who have the information)
Lost to follow-up (> 3 months) and Date last visit	A patient is lost to follow-up when he (she) misses 3 scheduled appointments. Tick and write the date (dd/mm/yy) of the last visit to your clinic. If the patient returns thereafter and restarts HIV care and follow-up at your clinic, erase the date of lost to follow-up and continue recording subsequent information.	When applicable	nurse doctor counsellor

Information to be recorded	Instructions for recording	When to record	Who will record
	If the patient was reported dead thereafter, record the date of death if the death was within 3 months of last visit (erase "date lost to follow-up" and record date of death).		
Transferred out Date New clinic	Tick and write the date of transfer out (dd/mm/yy) and the name of the new clinic where the patient is transferred in, if the patient is referred to a new clinic due to reasons of personal convenience.	When applicable	doctor

Page 2 of Patient HIV Care/ART Record: Information on Follow-Up

Part 9. PATIENT HIV CARE & ANTIRETROVIRAL TREATMENT FOLLOW-UP

9. Patient HIV Care & Antiretroviral Treatment Follow-up													
Date of visit	Date next visit	Weight (kg) & height for child	WHO stage	Performance scale*	Pregnancy (y/h) 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	Condoms given y/h	Referred to specialist or hospital

One row should be completed for each visit starting from the 1st visit to the clinic.

Information to be recorded	Instructions for recording	When to record
Date of visit	Write the date of current visit (dd/mm/yy). Refer to the instructions and codes given at the end of the form.	nurse
Date next visit	Write the date of the next scheduled appointment given during current visit.	nurse/ doctor
Weight (kg) & height for child	Record the weight in kilograms. For babies/children also record the height. Do not forget to write this information on page 1 of the record, part 5, at 1st visit, ART eligibility, ART start, and ART 6, 12 and 24 months.	nurse
WHO stage	Write the WHO clinical stage of the patient at each visit (refer to WHO guidelines). Do not forget to report this information on page 1 of the card, part 5 at 1st visit, ART eligibility, ART start, and ART 6, 12 and 24 months.	doctor
Performance scale	Write the appropriate performance scale at each of these time points. A is for a normally active patient. B is for a patient who was bedridden for less than half of the day during last month. C is for a patient who was bedridden for more than half of the day during last month. Do not forget to report this information on page 1 of the card, part 5 at 1st visit, ART eligibility, ART start, and ART 6, 12 and 24 months.	nurse / doctor
Pregnancy (y/n) or FP method	For women of child-bearing age, systematically write at each visit the pregnancy status (y/n). If the patient is not pregnant, the family planning (FP) method employed is written using the codes specified in the footnote on this page of the record under FP.	nurse / doctor
Opportunistic infections	Make a note of the opportunistic infections treated during the current visit, such as TB, candidiasis, diarrhea, cryptococcal meningitis among others. Use the codes in	doctor

Information to be recorded	Instructions for recording	When to record
Code	the footnote on this page of the record under Opportunistic Infections to complete this box. For TB diagnosis and treatment do not forget to record specific information on page 1, part 7.	
Drugs prescribed for prophylaxis of OIs	Write the drugs prescribed for prophylaxis of OI (primary or secondary) in this box: ✦ cotrimoxazole for Pneumocystis carinii pneumonia, and toxoplasmosis prophylaxis ✦ fluconazole for cryptococcosis prophylaxis ✦ isoniazide or other regimen for prevention of TB.	doctor
Antiretroviral drugs and dose prescribed	Write the regimen and dose prescribed at current visit. If ART was stopped at this visit write stop. If ART was substituted or switched, write the new regimen and dose. If treatment was stop(ped), substitute(d) or switch(ed) do not forget to complete the corresponding row on page 1, part 6.	doctor
Adherence to ART >95%, 80-95%, <80%	Write the level of adherence to ART for those who were prescribed ART at the previous visit. If less that 3 doses are missed in a period of 30 days, it means more than 95% adherence; 3 to 12 doses missed in a period of 30 days means 80-95%. More than 12 doses missed in a period of 30 days means less than 80% adherence. Refer to the footnote on page 2 of the record for details on checking adherence.	counselor
ART Side effects Code	Write any side effects currently reported by the patient and attributed to ART. Use the codes specified in the footnote on page 2 of the record for details.	doctor
Lab results when available	This box is used to record important laboratory test results at the date of visit the blood sample was collected.	nurse/ doctor
Condoms given Y/N	Mention in this box if condoms were given to the patient during the visit. Write Y or N. This allows us to review strengthening prevention activities during medical care.	counselor
Refer to specialist or hospital	Write in this box if after the patient visit you have to refer the patient to a specialist (example a TB clinic for on suspicion for TB) or if the patient needs hospitalization.	doctor

2.6 Check list on when to record information

When	Part	Information
1st visit	Summary part 1 Summary part 2 Summary part 3 Summary part 4 Summary part 5 Summary part 7	✦ Patient Identification Data ✦ Personal History ✦ Family History ✦ Antiretroviral treatment history ✦ Clinical and Laboratory Investigations: complete the 1st row of the table. ✦ Tuberculosis treatment during HIV care: if the patient is enrolled on TB treatment.
1st visit	Part 9, page 2 table	✦ 1st row corresponds to the 1st visit by the patient for HIV care enrollment.
At each following visit	Part 9, page 2, table	✦ One row per visit ✦ Correct also information in the summary part when applicable (example new family member enrolled in care).

When	Part	Information
At ART medical eligibility	Summary part 5	✦ Clinical and Laboratory investigation: complete the 2nd line of the table.
At start of ART	Summary part 5 Summary part 6	✦ Clinical and Laboratory investigation: complete the 3rd line of the table ✦ Antiretroviral treatment: write the ART regimen started.
At each ART stop or change in regimen	Summary part 6	✦ Antiretroviral treatment: complete one row of the table.
At 6, 12, 24 months after start of ART	Summary part 5	✦ Clinical and Laboratory investigation: complete respectively the 4th, 5th and 6th rows of the table.
At TB diagnosis/ treatment made during HIV care	Summary part 7	✦ Tuberculosis treatment during HIV care: record specific information on affected TB site and treatment.
At time of transfer out of the clinic	Summary part 8	✦ End of follow up: tick box, transferred out and write the date and place of transfer out.
When the patient is not seen for more than 3 months	Summary part 8	✦ End of follow-up: tick box, lost to follow-up and write the date of last visit to the clinic.
When you get information that the patient died	Summary part 8	✦ End of follow-up: tick box, death and write the date of death as accurately as possible (at least month and year).

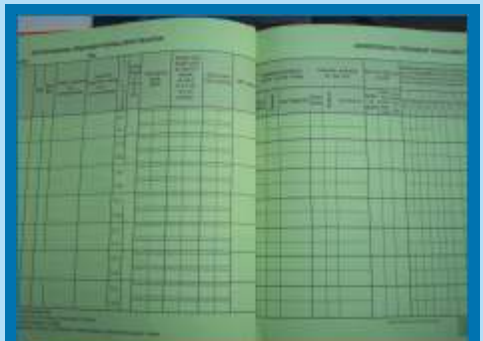
EXERCISE 1 - PATIENT RECORD

Refer to exercise 1 and complete question 1. This exercise will help you in understanding how to complete the patient record. The medical history of 2 patients is developed in 2 case studies. Refer to their medical history and complete their patient record accordingly.

Sub module 3

3. How to use the Pre-ART and ART Registers

Sub Module 3



3.1. Session objectives

At the end of this session the participants will be able to:

- understand how the Pre-ART and ART Registers are used; and
- correctly fill out the Pre-ART and ART Registers.

3.2. What are the Pre-ART and ART Registers for?

In a paper based monitoring system, registers are convenient tools to facilitate the aggregation of individual information from the Patient HIV Care/ART Records for obtaining programme indicators. Without registers, each patient record would need to be checked one by one to calculate the required indicators.

Registers are used to record key information (in column) for patients (one row for each patient) from patient records. All information in the registers is obtained from the Patient HIV Care/ART Record. The information in the registers is then used to compile ART Monthly Reports and Cohort Analysis Reports.

The registers do not contain all the information recorded in the Patient HIV Care/ART Record, but only minimum selected indicators for programme monitoring.

3.3. When should the registers be filled in?

Registers should be filled on time, ideally just after the patient visit (by doctors, nurses, counselors) or before the Patient HIV Care/ART Record is stored (by trained supporting staff, such as nurses, secretaries).

It is important for the registers to be updated on time for enabling patients tracking (to identify who did not come) and for ensuring the accuracy of monthly indicators.

3.4. Initial entry in the registers

In the registers, patients are recorded:

- by date of first visit in the clinic (enrollment) in the Pre-ART Register; and
- by date of start of ART in the ART Register.

In both the registers, it is recommended to separate the groups of patients by the month in which they were enrolled (Pre-ART Register) or started ART (ART Register). This can be done by starting a new page each month.

By this approach, patients are registered by the month in which they were enrolled or started on ART (monthly cohort) which will facilitate the analysis of the outcomes.

3.5. Pre-ART Register

The purposes of the pre-ART Register are to document:

Routine performance indicators

- The cumulative enrolment in HIV care, by sex and age;
- The cumulative number medically eligible for ART but have not been started on ART, by sex and age;

More in-depth analysis

- Socio economic profile of people accessing HIV care and starting ART;
- Services which refer the patients for HIV care and in particular, the number and proportion of patients referred from TB services;
- Access to care and ART for the most vulnerable high risk groups (sex work and injecting drug use);
- Occurrence of TB among patients enrolled and not started on ART;

- Criteria routinely used for medical eligibility to ART; and
- Profile of persons who died or were lost to follow-up before starting ART.

The pre-ART Register has to be completed:

- at the first visit for most of the information (column 1 to 10);
- at the start of cotrimoxazole preventive therapy (column 11);
- at the start of TB treatment (column 12);
- at medical eligibility for ART (column 13-14);
- at start of ART (column 15); and
- whenever follow-up was ended before ART was started (columns 16).

For a patient starting ART, the Pre-ART Register does not have to be used once the date of start has been recorded; all their information will now be recorded in the ART Register.

At the 1st visit

✦ Date of 1st visit at the clinic	From Patient HIV Care/ART Record part 5
✦ Registration number	From Patient HIV Care/ART Record part 1
✦ Name / address	From Patient HIV Care/ART Record part 1
✦ Age and Sex (M/F)	From Patient HIV Care/ART Record part 1
✦ Date and place of HIV+ test	From Patient HIV Care/ART Record part 1
✦ Entry point	From Patient HIV Care/ART Record part 1
✦ Mode of HIV transmission	From Patient HIV Care/ART Record part 2
✦ Literate	From Patient HIV Care/ART Record part 2
✦ Employed	From Patient HIV Care/ART Record part 2

At start of CPT (cotrimoxazole preventive treatment)

✦ Date of start	From Patient HIV Care/ART Record part 9, page 2

At TB diagnosis and treatment

✦ Class/Regimen and Date of start	From Patient HIV Care/ART Record part 7

At medical eligibility for ART

✦ Date medically eligible for ART	From Patient HIV Care/ART Record part 5
✦ Why medically eligible?	From Patient HIV Care/ART Record part 5 Report WHO stage, CD4 and TLC whenever available at date of eligibility

At start of ART

✦ Date ART started	From Patient HIV Care/ART Record part 5

When applicable

✦ End of follow-up before starting ART	Report date of death or lost to follow-up or transferred out as in Patient HIV Care/ART Record part 8. This should be recorded only for the patient who did not start ARV.

3.6. ART Register

The purposes of the ART Register are to document the following:

(a) Routine performance indicators

- The number started on ART during the period, by sex and age;
- The cumulative number ever started on ART, by sex and age;
- The cumulative number on treatment, by sex and age;
- The time point outcomes of the cohort of patients who started ART (stop, lost to follow-up, transferred out, dead);
- The cumulative number on substituted 1st line regimen;
- The cumulative number on 2nd line regimen;
- Regimen prescribed at the end of a period;
- The proportion of people with more than 95% adherence;
- The proportion of people alive and on treatment at 6, 12 and 24 months after start of treatment;
- The change in CD4 count at 6,12, 24 months of ART;
- The proportion of people whose performance status at 6, 12, 24 months is "normal working";

(b) Patient management

- Identification of patients lost to follow-up;
- Identification of patients who missed appointments;

(c) In-depth analysis

- Survival on treatment according to sex, age, initial regimen and prior exposure to ARV;
- Occurrence of TB among patients on ART;
- Reasons for substituting and switching regimen; and
- Frequency of substituting and switching according to initial regimen started, gender, age and prior exposure to ARV.

The ART Register has to be completed for all patients starting ART, during all monthly follow-up visits since the date of starting treatment to the end of follow-up on ART.

At the 1st visit

✦ Date of start of ART	From Patient HIV Care/ART Record part 5
✦ Registration number	From Patient HIV Care/ART Record part 1
✦ Patient's first name and surname and address	From Patient HIV Care/ART Record part 1
✦ Age and Sex (M/F)	From Patient HIV Care/ART Record part 1
✦ Treatment supporter's name and contact number	From Patient HIV Care/ART Record part 1
✦ Previous ARV history	From Patient HIV Care/ART Record part 4
✦ Performance scale at start	From Patient HIV Care/ART Record part 5
✦ Weight (kg) at start, height at start	From Patient HIV Care/ART Record part 5
✦ CD4 count at start	From Patient HIV Care/ART Record part 5, for children report the %CD4
✦ TB treatment during ART	From Patient HIV Care/ART Record part 7: inform the type of TB, the regimen category and date of start of TB treatment
✦ ART regimen started	From Patient HIV Care/ART Record part 6

At any substitution or switch in ART regimen

✦ Treatment substitute within 1st line regimen ✦ Treatment switched for 2nd line regimen	✦ Write the date of substitution or switch, the reason (code) and the new regimen started

	as in the Patient HIV Care/ART Record part 6. ✦ The Register contains space to enter two substitutions and two switches (1st and 2nd row). ✦ For a patient who restarted after a stop, first complete the monthly follow-up visit as indicated above; stop (ST) at the visit ART was stopped and subsequent visits and on treatment (OT) at the visit ART was restarted. If the patient restarted the same regimen, do not add more information. If the patient started a new regimen inform the switch/substitution in this part. The date of switch/substitution will be the date the patient restarted.

At the end of follow-up under ART

✦ Date of death	✦ Report the date of death systematically when you get this information, as in the Patient HIV Care/ART Record part 8.
✦ Date of lost to follow-up (date of last visit)	✦ Once a patient is missing for more than 3 months, report the date of last visit as date lost to follow-up as in the Patient HIV Care/ART Record part 8. ✦ Write in pencil. If a patient lost to follow-up came back for care and ART, you can erase this information.
✦ Date of transferred out under ART	✦ Report the date of transferred out as in the Patient HIV Care/ART Record part 8.

At each monthly follow-up visit up to 24 months

✦ Patient status	On the first row write the patient status at current visit. To complete this part you need to check the table of follow-up visits, part 9, page 2 and part 8 (end of follow-up) in the Patient HIV Care/ART Record: ✦ **On treatment (OT)** when the patient still continues ART at this visit and picks up his (her) drugs; ✦ **Stopped (ST)** when the patient came for the appointed visit but ART was not prescribed because it was stopped at this visit or at a

	previous visit and was not restarted (e.g. because of TB treatment); ✦ **Missing (MIS)** when the patient did not come for the current monthly scheduled visit; ✦ **Lost to follow-up (LFU)** when the patient is missing for more than 3 months; ✦ **Restart (RS)** when the patient is restarting ART after a period of stop or after 3 or more missed appointments; ✦ **Transferred out (TR)** if the patient is definitely transferred to an other ART clinic after this visit; ✦ **Death (D)** when the patient is reported dead; and ✦ **Not expected (NA)** patient was not due for a visit at the clinic. This will differentiate patients missing an appointed visit from those who are not due to visit during the month. NOTE: If a patient came twice during a month, only record the details at the last visit in the Register (except for the two-week visit after starting that has to be recorded in the specific column). For patients who are deceased, missing for more than 3 months or transferred out, do not forget to complete the part 'End of follow-up on ART'.
✦ Adherence	On the second row write the levels of adherence for the patient on treatment, as in the Patient HIV Care/ART Record table of follow-up part 9 (adherence column).

3.7. Patients transferred in

Sometimes, patients followed-up for HIV care at one clinic as part of the national programme may move and be referred to another new clinic also under the national programme. These patients are said to be **'transferred out'** from the previous clinic and **'transferred in'** the new clinic. The Patient HIV Care/ART Record should be also sent with the patient to the new clinic so that the same record gets used ensuring continuum of care at the new clinic.

If the Record is not sent with the patient when he (she) relocates, it will be necessary to open a new Patient HIV Care/ART Record at the new clinic.

If the patient did not start ART at the time of transfer, it is easier to register and consider the person as a new patient at the new clinic.

If the patient was on ART at the time of transfer, you should maintain his (her) original ART history.

- ✦ Keeping his (her) previous registration number at the earlier clinic, also add a new registration number at this clinic. Complete as much as possible your ART Register according to the information available (if the patient transferred with a copy of the medical record) on his (her) follow-up under ART.

- Registering this patient in the monthly cohort he (she) was started on ART at the previous clinic (e.g. a patient started on ART in October 2004, transferred in on ART in January 2005, should be registered with the group of patients started on ART in October 2004 and not with the group of patients started on ART in January 2005) (an example is given in the next section).
- DO NOT change the date of start of ART recorded at the previous clinic.
- Recording the mode of entry in the pre-ART register as transferred in (code TR) and the date of 1st visit to your clinic (new clinic) which is the date of transfer in.
- Recording the date of starting ART and all information related to outcomes at 6, 12, and 24 months (whatever the duration of ART follow-up).
- Considering his (her) first visit at your clinic as a follow-up under ART and completing the monthly visit part accordingly (e.g. for the example above, the first visit at the new clinic will be at 3 month follow-up visit).

An example of a transferred in patient is given in Section 3.9 below.

3.8. Identification of patients missing or lost to follow-up in the ART Register

Patients are registered by the date they started ART. On the same page, all patients would have started on the same month and have the same duration of follow-up under ART. Consequently, they should have the same number of monthly visits and outcomes recorded. So those missing would be easily identified.

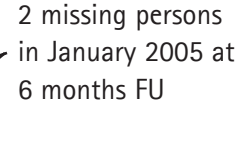
Figure 3 is an example of a page of the ART Register for the patients who started ART in July 2004. Two patients who missed their visits at 6 months (in January 2005) and are easily identified as those cells are empty. One of the patients was missing for 3 months and should also be recorded as lost to follow-up.

Figure 3: Using the ART Register for identifying patients missing monthly visits or lost to follow-up on ART

MONTH: July **Year: 2004**

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 appointed visit, lost to follow-up (LFU) if the patient is missing >3 months restart (RS) if ART

we.2	mo.1	mo.2	mo.3	mo.4	mo.5	mo.6	mo.7	mo.8
OT	OT	OT	OT	OT	OT	OT		
A	A	A	A	A	A	A		
OT	OT	ST	ST	ST	RS	OT		
A	A	A				A		
OT	OT	OT	OT	OT	OT	OT		
A	B	B	A	A	B	B		
OT	OT	OT	MIS	OT	OT			
A	A	A		C	C			
OT	OT	OT	OT	OT	OT	OT		
A	A	A	A	A	A	A		
OT	OT	OT	OT	MIS	MIS			
A	A	C	C					



EXERCISE 1 - PRE-ART AND ART REGISTERS

Refer to exercise 1 and complete question 2. This exercise will help you in understanding how to complete the pre-ART and the ART registers using the patient record. Using the patient records you have completed for these 2 case studies, complete now the pre-ART and ART register.

3.9 Examples

The following ART Register gives examples on how to record follow-up under ART (up to December 2004) (1) in a usual situation, (2) for a patient transferred in, (3) for a patient who substitute first line regimen after a period of interruption, (4) or a patient lost to follow-up.

Register study 1: Ms A (registration number TL 124), is 24 years old and started D4T/3TC/NVP on 12th December 2003. At this time she had stage IV disease, and was bedridden more than half of the day during the previous month. Her weight was 41 kg for a height of 163 cm. TLC was 800 cells/mm3. She had never received ART before and no CD4 tests were performed. She came every month during 2004 and reported more than 95% adherence always. After 6 months on treatment she was able to work again, and her weight increased to 45 kg. She had 156 CD4 cell count on investigation at 6 months. In December 2004, for the visit at 12 months, she was still working and the CD4 examination showed 208 cells. Her weight was 47 kg. She did not miss any doses and the same treatment was continued.

Register study 2: Mr B, who is 33 years old, was transferred out on 5th December 2004 to clinic TL for follow-up under ART. He started ART in the national programme at clinic BA, 7 months ago on 1st May 2004 (registration number BA 256). At the start of ART he was in stage III disease, and weighed 65 kg for a height of 175 cm. He had 145 CD4, and was working. He had been taking ART before starting treatment in the national programme (he was able to afford 3 months dual therapy ddC/AZT in 2003). He was started on D4T/3TC/NVP and was followed-up every month with more than 95% adherence. At 6 months on examination he was found to have 210 CD4 and his weight was 66 kg. The 1st visit to clinic TL was his 7th month follow-up visit. He reported having missed more than 3 doses of ART (he missed 5 days ART because of moving). The same regimen was continued at clinic TL.

Register study 3: Mr C is 40 years old (registration number TL 2698) and was started on ART 3 months ago on 6th September 2004. He had stage IV disease and CD4 at 32. His weight was 54 kg for a height of 169 cm. He was bedridden for less than half part of the day. He had not previously taken ARVs and was started on D4T/3TC/NVP. On the 2nd follow-up visit for ART, he reported not having missed any doses. He complained about productive cough, asthenia, and night sweats. He was referred to the TB centre, where a diagnosis of smear-positive pulmonary TB was made. ART treatment was stopped and TB treatment started on 17th October (regimen category I). He came for monthly appointments and ART was restarted in December 2004 with D4T/3TC/EFV, once the TB treatment was well-tolerated.

Register study 4: Ms D is 36 years old (registration number TL 820) and started ART on 15th June 2004. She had stage III disease with CD4 at 79. Her weight was 56 kg for a height of 162 cm. She was working. She had taken NVP for PMTCT a year ago. She lives quite far (2 hours drive from the clinic), has lost her husband and has to take charge of two children (HIV negative) alone. On the visit at 2 weeks, she said not having missed any ART doses. At one month she missed more than 3 doses of ARV, because she came late for her scheduled appointment as one child was sick. The month after, she reported poor adherence (<80%) due to gastro intestinal side effects. Since 15th August 2004, she had not returned to clinic TL and has been reported as lost to FU in December 2004 as she has been missing for more than 3 months.

	DATE of start of ART	Registration number	Name	Age	Sex M/ F	Received ARV before starting	WHO stage at start	Performance scale A-normal activity; B-bedridden<50%; C-Bedridden>50%				Weight (kg) & height (cm) at start for adults, at start, 6, 12,24 mo. for children				CD4 count (% for children)				TB treatment during ART Type Regimen Date ttt start	Antiretroviral treatment regimen started	Treatment substitute within 1st line drugs			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 appointed visit, lost to follow-up (LFU) if the patient is missing														
								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			Date subst.	Reason	New Regimen	Date of death	Date of definite stop*	Date lost to FU* (last visit)	Date transfer. Out on ART	we. 2	mo. 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
1	12/12/ 2003	TL-0124	A	24	F	☐ Y ☐ N	4	C	A	A		41 / 163	45	47		not done	156	208			D4T 30/ 3TC/ NVP								OT	OT	OT	OT	OT	OT	OT	OT	OT	OT	OT	OT	
																													A	A	A	A	A	A	A	A	A	A	A	A	
2	1/8/ 2004	BA-0256	B	30	M	☐ Y ☐ N	3	A	A			65 / 175	66			145	210				D4T 40/ 3TC/ NVP								TRANSFERRED IN 5/12/2004							OT						
																													A	A	A	A	A	A	A	B						
3	1/9/ 2004	TL-2698	C	40	M	☐ Y ☐ N	4	B				54/169				32				PTBsm+ Cat I 17/10/04	D4T 30/ 3TC/ NVP	5/12/04		4 D4T30/3TC/EFV					OT	ST	ST	RS									
																													A	A												
4	15/6/ 2004	TL-0820	D	36	F	☐ Y ☐ N	3	A				56/165				79					D4T 30/ 3TC/ NVP						15/8/ 2004		OT	OT	OT	MIS	MIS	LFU							
																													A	B	C											

Sub module 4

Sub Module 4

4. How to use drug dispensing and stock registers

4.1 Session objectives

This session is primarily for pharmacists or drug dispensing officers in charge of dispensing drugs and maintaining drug stocks. At the end of the session the participants will be able to:

- fill out the ARV Drug Dispensing Register and Drug Stock Register.

4.2 Objectives of drug dispensing and stock management

The objectives of monitoring drug dispension and stock records are:

- to document the regimen prescribed to the patients and the number of tablets given at each follow-up visit; and
- to ensure an uninterrupted supply of drugs by maintaining adequate drug stocks monitoring.

4.3 What is the purpose of drug dispensing and stock registers?

For monitoring of drug dispensing and stock management two registers are to be maintained at the pharmacy;

- the ARV Drug Dispensing Register to record the number of tablets of each drug given to the patients at each follow-up visit; and
- the ARV Drug Stock Register to record the daily consumption of ARV drugs.

From these two registers, indicators will be compiled and reported every month in the ART Monthly Report. Part B of the Monthly Report records the drugs dispensed and stock. Two indicators will be produced from Part B.

1. **The regimen at the end of the month** will describe the distribution of the patients according to the type of regimen they received during the month (last prescription). It gives information about the most frequent prescriptions and will identify the patients already receiving 2nd line regimen.
2. The **drug stocks** will describe the consumption of each drug during the month.

Both pieces of information are necessary for drug stock maintenance.

4.4 ARV Drug Dispensing Register

This Register must be maintained by the pharmacist/drug dispenser in the HIV care/ART facility. The purpose of this Register is two-fold:

- to document and account for every tablet of each drug by obtaining the patient's signature against the number of tablets given; and
- to calculate the daily consumption of each drug.

The list of drugs in this Register should be adapted according to the ARV drugs available in the national programme.

After writing the registration number and the patient's name, write under the corresponding columns, the number of tablets dispensed. For e.g. If the patient was given Virolis 30 mg and Nevipan for one month, then enter 60 under Virolis 30 mg and 60 under Nevipan. Leave the other cells blank. Ask the patient to sign or make a thumb impression if the patient is illiterate.

Maintain a separate page for each day. In other words, for every new day, start on a fresh page. This may, however, be adapted to the activity level of the clinic, i.e. if only a few patients are enrolled on ART you can start a separate page each week instead of a separate page every day.

At the end of the day, add up the number of tablets for each drug. This represents the daily consumption of each drug. Use this information to complete the ARV Drug Stock Register.

This Register contains information on patients on ART and is submitted to the same ethical and confidential rules applied to the Pre-ART and ART Registers at the clinic.

- Access to the ARV Drug Dispensing Register should be limited to authorized staff identified in advance.
- All persons accessing the ARV Drug Dispensing Register, including administrative staff (e.g. to support compilation of statistics), are required to comply with the professional codes of conduct to protect patient confidentiality.
- Only one copy of the Register should be made available directly under the responsibility of the pharmacy manager. The ARV Drug Dispensing Register should be kept in a locked cabinet when the pharmacy is closed.

4.5 ARV Drug Stock Register

This Register must be maintained by the pharmacist/drug dispenser at the HIV care/ART facility.

Divide the Register into different sections grouping at least 12 pages and dedicate one section for each drug.

On each page, drug stock details can be maintained for a period of one month. Thus each section can maintain drug stock details of one drug for one year.

- **Name of the drug:** Write the name of the drug, e.g. Virolans. All the details on this page should then relate to Virolans.
- **Date:** Write the date in dd/mm/yy format.
- **Opening stock (A):** Write the number of tablets available at the start of the day.
- **Stock received (B):** If new stock was received, then write the number of tablets received, otherwise write '0'.
- **Stock dispensed (C):** Write the total number of tablets dispensed to patients during the day. Obtain this information from the ARV Drug Dispensing Register.
- **Stock expired (D):** Write the total number of tablets that were beyond the expiry date or were discarded due to any reason.
- **Balance Stock:** Calculate the balance number of tablets at the end of the day using the formula: Balance stock = (A+B) - (C+D).

At the end of each month, complete the monthly summary. Use this summary for preparing the ART Monthly Report.

EXERCISE 2 - DRUG DISPENSING AND STOCK REGISTERS

Complete exercise 2. This exercise will help you in understanding how to maintain the drug dispensing and drug stock registers and how to transfer this information in the monthly report at the end of the month.

Sub module 5

5. How to complete the monthly report

5.1 Session objectives

At the end of this session the participants will be able to:

- understand how the ART Monthly Report is used;
- fill out indicators in the monthly report by checking the Pre-ART and ART Registers; and
- analyse the indicators and trends over time.

5.2 What is the ART Monthly Report for?

The ART Monthly Report documents the main indicators for monitoring access to HIV care, access to ART and the continuation of ART. The following core indicators are internationally recommended at the facility level and are obtained from this report:

1. Cumulative number enrolled in HIV care
2. Number started on ART during the reporting period
3. Cumulative number ever started on ART
4. Number medically eligible for ART but have not been started on ART
5. Cumulative number on ART
6. Cumulative number on substituted 1st line regimen
7. Cumulative number switched to 2nd line regimen
8. Proportion of people with more than 95% adherence.

The ART Monthly Report is a cross-sectional approach to document the programme performance. Cross-sectional means that the indicators are compiled at one time point (at the end of each month) without taking into account the duration of follow-up of the patients. In other words it gives a one-time snapshot. The indicator "cumulative number on ART", indicates how many patients are continuing ART at the end of the month, but does not convey for how long these patients have been under ART.

ART follow-up is a lifelong dynamic process. This is why it is useful to have "longitudinal" indicators (i.e. information for a period of time), which takes into account the duration of follow-up, such as how many patients have been on treatment for 6 months, 12 months and 24 months. This is the purpose of the Cohort Analysis Report, presented in the next chapter.

Cross-sectional indicators require only counting at one time point and are easier to calculate than the longitudinal indicators that will require calculations over a period of time (6 months, 12 months, 24 months or more).

5.3 When and how will the ART Monthly Report be completed?

The ART Monthly Report has to be completed each month in the week following the end of the month, and sent without delay to the province/state programme (e.g. the monthly report for January 2005 will be completed during the first week of February 2005).

The ART Monthly Report will be completed by the facility manager or trained staff under his (her) supervision.

The documents necessary to complete the ART Monthly Report are:

- the ART Monthly Report from the previous month (e.g. for the January 2005 report you will need the December 2004 report); and
- the Pre-ART Register and ART Register provided that these registers are being updated every day up to the end of the month (all new patients registered and all patient necessary information recorded). For example for the January 2004 report, the registers should include registration of all patients who accessed care or started ART in January 2004, registration of all stops, substitutions, switches that occurred in January 2004 and registration of monthly visits of patients under ART.

Not all indicators need to be calculated each month; some are reported from the previous report adding to information from the current month. For example, the cumulative number of persons enrolled in HIV care at the end of the month is equal to the total from the previous month plus the new patients enrolled in HIV care during this month.

5.4 How to calculate indicators?

Indicators to be calculated each month are highlighted in bold. Others will be obtained from the previous ART Monthly Report or by addition.

Indicators on enrollment in HIV care, eligibility for ART, enrollment on ART (parts 6, 7, 8) have to be calculated separately for women, men and children. Indicators on treatment outcomes need not be disaggregated by age and sex (table 2).

5.5 How to analyse the ART Monthly Reports?

The ART Monthly Reports give indicators at one time point. These indicators require a month by month analysis for a clear picture of trends over time.

Analysis should be performed at the facility level by:

- reporting indicators in a monthly table; and
- figures showing the trends over time.

The following is an example from a clinic which started HIV care and ART programme at the same time in September 2003. Indicators are presented in monthly tables and figures, updated up to December 2004.

Two core indicators are calculated:

- Proportion of patients eligible, but who did not start treatment

$$= \frac{\text{No. of patients eligible for ART have not been started on ART}}{\text{Cumulative no. of patients who started ART} + \text{no. of patients eligible for ART who have not been started on ART}} \times 100$$

- Proportion still on ART among those who started treatment

$$= \frac{\text{Cumulative no. of patients still on ART}}{\text{Cumulative no. of patients who started ART}} \times 100$$

Such analysis can be done for all patients, and also disaggregated by age and sex.

It is also possible to calculate the above indicators for a specific period, for example the last trimester, the first trimester, the whole calendar year, etc. For example in this facility during the year 2004 (Table 3):

- 914 new patients were enrolled in HIV care. This number is obtained by substracting 206 (total entrolled at end December 2003) from 1120 (total enrolled at end December 2003).

Similarly, 317 were found eligible for ART (388 - 71) and 180 patients were started on ART (236 - 56).

Similarly, it is possible to compile and analyse the outcomes of treatment (Table 4).

Table 2: Indicators in the monthly report

Indicator No.	Indicator	Where is this information?	How to calculate?
Part 6. Enrolment in HIV care			
6.1	Cumulative no. of patients ever enrolled in HIV care at the beginning of the month	✦ Previous ART Monthly Report, indicator 6.3	It is the same result as indicator 6.3 from the previous month (cumulative no. of persons ever enrolled in HIV care at the end of the month). For example for Jan. 05 note numbers 6.3 from the Dec. 04 report.
6.2	**New patients enrolled in HIV care during this month**	✦ Pre-ART Register ✦ Column "Date of 1st visit"	Check the Pre-ART Register for those who have a date of 1st visit in the current month. As patients are registered in chronological order, so you will have to check only the last pages. For example, for the Jan. 05 report, it is all patients who have a date of 1st visit between 1st and 31st January 2005.
6.3	Cumulative no. of patients ever enrolled in HIV care	✦ Addition 6.1 + 6.2	This is obtained by adding 6.1+ 6.2. You will also report these numbers in the next ART Monthly Report part 6.1.
Part 7. Medical eligibility for ART			
7.1	**No. of patients medically eligible for ART but have not been started on ART at the end of this month***	✦ Pre-ART Register ✦ Columns ◗ "Date medical eligible for ART" ◗ "Date ART started"	This information is in the pre-ART register, by checking 'date medical eligible for ART' and 'date ART started'. Count the number of patients whose ✦ "date medical eligible for ART" is entered/known BUT ✦ "date of ART started" is empty, whatever the period that the patient was eligible. Note that you will have to rapidly check the whole Pre-ART Register as patients are registered by date of 1st visit and not by date of eligibility. That means that an old patient entering HIV care long time ago at an asymptomatic stage might be eligible much later. Details of such a patient will be on the initial pages of the Register.
Part 8. Enrollment on ART			
8.1	Cumulative no. of patients ever started on ART at the beginning of this month	✦ Previous ART Monthly Report, indicator 8.4	It is the same result as indicator 8.4 from the previous month (cumulative no. of persons ever started on ART at the end of the month). For example for Jan. 05 pick up numbers 8.4 from the Dec. 04 report.

Indicator No.	Indicator	Where is this information?	How to calculate?
8.2	**New patients started on ART during this month**	✦ ART Register, column "date of start of ART" ✦ Double check with Pre-ART Register column "date ART started"	This information is in the ART Register. Count the number of patients whose date ART start was during the reporting month. For example for the January 05 report, report the number of patients whose date of starting ART was between 1st and 31st January 2005. In the ART Register, as patients are registered in chronological order of starting, you will have to check only the last pages. Double check this information with the Pre-ART Register, column "date ART started", to check that both registers are updated.
8.3	**Number of patients on ART transferred in this month**	✦ ART Register	Count the no. of persons who were transferred in under ART during the month. You will need to check the whole ART Register, as patients transferred in are registered (added) in the pages corresponding to the month they have started ART (and not in the month they are transferred in).
8.4	Cumulative no. of patients ever started on ART at the end of this month	✦ Addition 8.1 + 8.2 + 8.3	This is obtained by adding 8.1+ 8.2 + 8.3. You will also report these numbers in the next ART Monthly Report part 8.1.
Part 9. Outcomes on ART			
9.1	**Cumulative no. of deaths reported at the end of the month**	✦ ART Register ✦ Column "End of Follow-up on ART" ✦ Date of death	Count the total deaths registered. You have to check the whole Register. Be careful, this information is not always present at the time of preparing the ART Monthly Report. Information about which patient was missing, or died may be delayed. However, when you get this information, the patient should not be considered as missing any more but as deceased. For this reason, it is necessary to check the whole Register every month for new report of death. To help in this rigorous counting every month, once you have counted a patient dead you can tick in red the cell corresponding to his (her) date of death. So that the next time, you can easily count patients who are dead but not already reported. And then, simply add this number, to the cumulative reported number in the previous month in 9.1.
9.2	**Cumulative no. of patients transferred out under ART at the end of this month**	✦ ART Register ✦ Column "End of Follow-up on ART" ✦ Date of transfer out	Count the total transferred out on the ART Register. You have to check the whole Register. To help in this rigorous counting every month, once you have counted a patient as transferred out, you can tick in red the cell corresponding to his (her) date of

Indicator No.	Indicator	Where is this information?	How to calculate?
			transfer out. So that the next time, you can easily count the patients transferred out but not already reported. And then, simply add this number to the cumulative reported the previous month in 9.2.
9.3	**Number of patients missing/lost to follow-up at the end of this month**	✦ ART Register ✦ Part on Monthly visit ✦ 1st row	Count the number of patients whose last reported outcome on the 1st row was Missing/Lost to follow-up (codes MIS or LFU).
9.4	**Number of patients stopping ART at the end of this month**	✦ ART Register ✦ Part on Monthly visit ✦ 1st row	Count the number of patients whose last reported outcome on the 1st row was Stop (code ST).
9.5	Cumulative no. of patients on ART at the end of this month	✦ Calculation from above indicators ✦ ART Register ✦ Part on Monthly visit/ 1st row	The cumulative no. of persons on ART at the end of the month will be = 8.4 - 9.1 - 9.2 - 9.3 - 9.4. Also you can count the number of patients whose last reported outcome was On Treatment (OT) and Restart (RS).
9.5.1	No. on original 1st line regimen among those on ART	✦ By calculation from indicators below	This indicator can be obtained by calculation once the number on substituted 1st line and on 2nd line regimen have been identified = 9.5 - 9.5.2 - 9.5.3.
9.5.2	**No. on substituted 1st line regimen among those on treatment**	✦ ART Register ✦ Columns "Treatment substitute"	Among those on treatment or restarting, count the number who substitute 1st line regimen. You have to check the whole Register. Note that column "treatment switch" should be empty (otherwise the patient is on 2nd line regimen and should be counted in the indicator below). To help in this rigorous counting every month, once you have counted a patient who substituted, you can tick in red the cell corresponding to his(her) date of substitute. So that the next time, you can easily count patients substituted and not already reported. Simply add this number, to the cumulative reported the previous month in 9.5.2.
9.5.3	**No on 2nd line regimen among those on treatment**	✦ ART Register ✦ Columns "Treatment switches"	Among those on treatment or restarting, count the number who switched to 2nd line regimen. You have to check the whole Register. To help in this rigorous counting every month, once you have counted a patient who switched, you can tick in red the cell corresponding to his (her) date of switch. So that the next time, you can easily count patients who switched and not yet reported. And then, simply add this number, to the cumulative reported the previous month in 9.5.3.

Indicator No.	Indicator	Where is this information?	How to calculate?
Part 10. Treatment adherence			
10.1	No. of patients assessed for adherence	✦ Register ✦ Part Monthly visits ✦ 2nd row	In the table of monthly visits, count how many have a LAST record of adherence. While counting the numbers, you can tick the LAST record of adherence. So that the month after you can easily identify which cell is the last record of adherence.
10.2	Level of adherence at the end of this month	✦ ART Register ✦ Part Monthly visits ✦ 1st row	Among those who have a last record of adherence count and report how many are A (>95%), B (80-95%), and C (<80%). The total of A+B+C should be equal to 10.1.
Part 11. Regimen at the end of the month (see sub- module 4)			
11.	Add as many rows as the number of different ART regimen dispensed	✦ Drug Dispensing Register ✦ All daily dispensing sheets related to the month	In the Drug Dispensing Register, check all pages related to the month. Count the number of the different regimens dispensed and report it in the table. If a patient came twice and was dispensed ART twice during a month (e.g. visit at 2 weeks) count this patient and the regimen dispensed only once at the last visit during the month. Separate adult drug doses and pediatric formulations meant for children. Add as many rows as the number of different type of ART regimen dispensed. The total of regimen dispensed (total of the column) should be equal to the number of patients on ART at the end of the month (indicator 9.5). These indicators can also be obtained from the ART Register by checking the regimen of the patients whose columns "end of treatment" are empty (patients with a date of "end of treatment" recorded are not any more on treatment and are not included in this indicator).
Part 12. Drug stock			
12.	Add as many rows as drugs you have in stock	✦ Drug Stock Register ✦ All drug-month sheets	Report the monthly summary consumption for each drug. Note if there was a stock out in ARV or OI drugs during the month.

* Medical eligibility. Medical eligibility refers to the clinical and immunological (CD4 or TLC) criteria that make the patient in need of ART.

Table 3: Cumulative enrolment in HIV care and ART in clinic A since the beginning of the programme

enrolment	Sep-03	Oct-03	Nov-03	Dec-03	Jan-04	Feb-04	Mar-04	Apr-04	May-04	Jun-04	Jul-04	Aug-04	Sep-04	Oct-04	Nov-04	Dec-04
cumulative no. of patients starting ART	6	25	41	56	71	86	103	118	133	148	162	176	191	206	221	236
no. of patients medically eligible for ART but have not been started on ART	6	7	11	15	12	10	9	10	17	30	33	45	77	99	127	152
no. of persons enrolled in HIV care not elligible for ART	25	59	101	135	185	219	256	293	329	358	396	428	482	564	641	732
cumulative no. of patients enrolled in HIV care	37	91	153	206	268	315	368	421	479	536	591	649	750	869	989	1120
Proportion eligible who did not start treatment	**50.0**	**21.9**	**21.2**	**21.1**	**14.5**	**10.4**	**8.0**	**7.8**	**11.3**	**16.9**	**16.9**	**20.4**	**28.7**	**32.5**	**36.5**	**39.2**

Table 4: Outcomes of patients who started ART in clinic A since the beginning of the programme

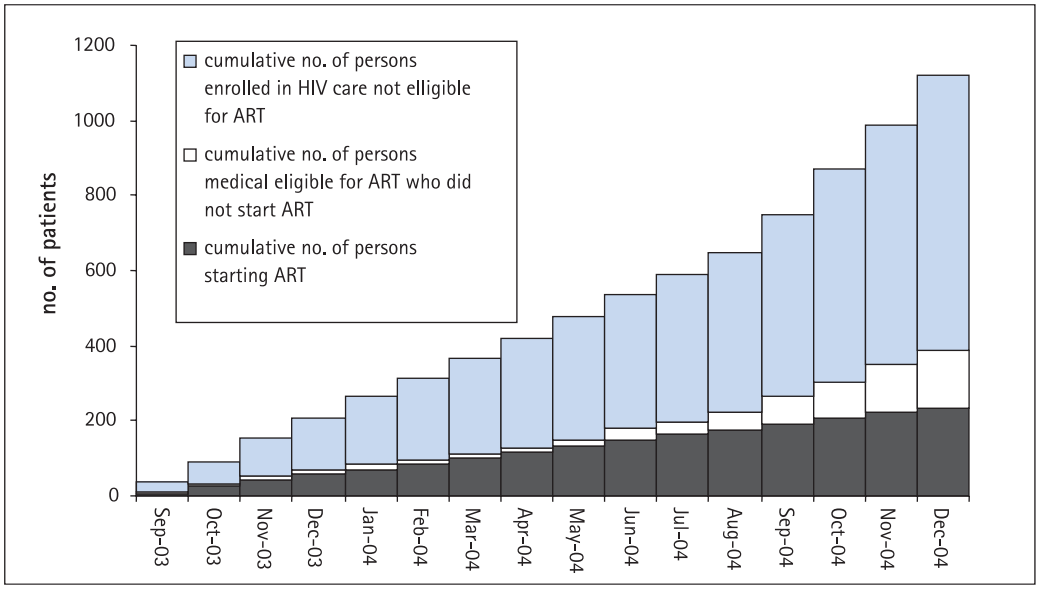
outcomes on ART	Sep-03	Oct-03	Nov-03	Dec-03	Jan-04	Feb-04	Mar-04	Apr-04	May-04	Jun-04	Jul-04	Aug-04	Sep-04	Oct-04	Nov-04	Dec-04
cumulative no.of death	1	2	2	5	5	6	6	8	8	8	10	11	11	11	12	14
cumulative no. transferred out	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
no. missing/lost to follow-up	0	0	2	3	2	3	3	5	4	6	4	6	8	12	9	12
no. stopping ART	0	0	0	1	1	0	1	2	3	2	2	3	2	2	1	2
Cumulative no. on ART	5	23	37	47	63	77	93	103	118	132	146	156	170	181	199	208
Proportion on ART	**83.3**	**92.0**	**90.2**	**83.9**	**88.7**	**89.5**	**90.3**	**87.3**	**88.7**	**89.2**	**90.1**	**88.6**	**89.0**	**87.9**	**90.0**	**88.1**

The data in the above tables can be depicted by figures.

In Figure 5, the total of the bar is the cumulative number of patients enrolled in HIV care at the end of the month.

- The smaller black bar is the cumulative number of patients who started ART at the end of the month.
- The white bar is the cumulative number of patients who were found eligible for ART, but not started on treatment.

Figure 5. Cumulative enrolment in HIV care and ART at clinic A (September 03–December 04)

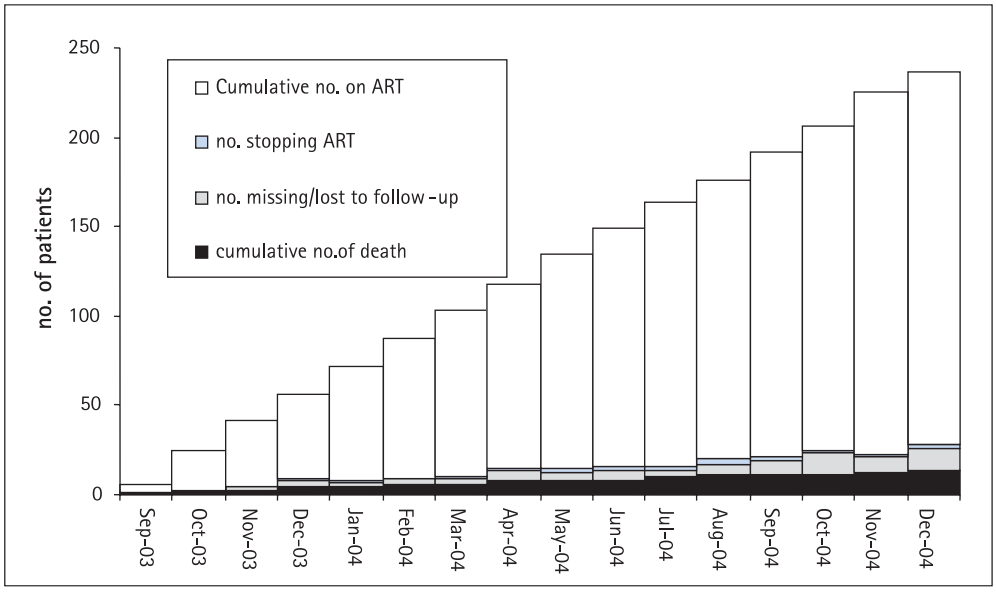


The interpretation of this data is that the enrollment in HIV care accelerated during the last months in 2004 (more patient accessing HIV care than before). But the rate of starting patients for ART remained constant. This led to an increase in the number of people eligible for ART but who did not start it, i.e. patients on waiting list for starting treatment.

In Figure 6, the total of the bar is the cumulative number of patients who ever started ART at the end of the month.

- The black bars at the bottom end show patients who died.
- The grey bars are patients who are missing/lost to follow-up at the end of the month.
- The thin black areas above the grey bars are patients who are stopping ART at the end of the month.
- The white bars are those actively on ART (including those who restarted).

Figure 6. Treatment outcome of ART among patients who started in clinic A (September 03-December 04)



This figure is a cumulative representation of inclusion and outcomes on ART. It clearly shows that whereas the case fatality rate remains fairly high under ART, the vast majority of patients remained on ART in the clinic A programme.

However, these indicators and this representation do not give any indication of the duration for which each patient was on ART. In other words, after how many months of ART did the patients die or were lost to follow-up? It does not indicate for those starting 12 months ago, how many are still on treatment?

Therefore, it is necessary to add to the ART Monthly Report, a periodical Cohort Analysis Report, with the main objective to describe the outcomes on ART according to the individual duration of treatment.

EXERCISE 3 - MONTHLY REPORT

Complete exercise 3. This exercise will help you in compiling a monthly report. Using the last monthly report, the pre-ART and the ART registers, you will have to complete the new monthly report.

Sub module 6

Sub Module 6

6. How to complete the cohort report

6.1 Session objectives

At the end of this session the participants will be able to:

- understand how the Cohort Analysis Report is used; and
- fill out the Cohort Analysis Report by obtaining information from the ART Register.

6.2 What is the Cohort Analysis Report for?

Both cross-sectional and cohort analyses are useful in monitoring rapid scale-up of ART. Cohort analyses are usually better indicators of programme activities than cross-sectional or cumulative analyses. Cohorts should be formed when patients start ART, not when they enter HIV care. Cohorts can be formed according to the month/year the patients started ART.

The ART Cohort Analysis Report compares baseline clinical characteristics of groups of patients during a month (monthly cohorts) with their status at 6 months and subsequently yearly intervals. Key indicators for the clinical and district team to see how well the programme is doing, such as proportion of patients still on a first-line regimen or with normal activity at 6 and 12 months, are calculated using this report. It allows the team to compare success at 6 and 12 months of ART in a meaningful way with earlier or later cohorts, or with other districts.

Cohort analysis is a key monitoring approach used under DOTS. It is carried out routinely and considered necessary to track trends in programme progress and determine treatment outcomes for patients given the fixed treatment period usually 6-9 months. Although ART is lifelong, the same approach of cohort analysis can be applied to ART monitoring. Cohort analysis allows comparison between groups of patients who have had for a similar duration of ART.

Whereas in TB, the task of culminating data for the cohort analysis has generally been designated to the district level coordinators, the HIV care/ART patient monitoring guidelines encourage decentralizing registers to someone on the clinical team at each ART site. Under supervision of the district or state coordinator, the simplified Cohort Analysis Report can be filled out at the facility with further analysis and supervision by the district ART coordinator on visits to the facility.

The Cohort Analysis Report supports the following analyses at 6 and 12 months on ART, and then yearly:

- proportion still on original 1st line regimen, substituted to an alternative 1st line regimen, switched to a 2nd line regimen/ among patients alive and on ART at the end of the period (6 months, 12 months and yearly);
- proportion of patients showing normal activity, bedridden < 50%, bedridden >50%/ among patients alive and on ART at the end of the period (6 months, 12 months and yearly);
- proportion of patients who have picked up their ARV drugs 6/6 months or 12/12 months/ among patients alive and on ART at the end of the period (6 months, 12 months and yearly);
- optional: median CD4 count or proportion of CD4 counts done which are >200 mm3 among patients controlled for CD4; and
- optional: proportion of viral loads which are below 400 copies/ml.

6.3 When will the Cohort Analysis Report be completed?

This Report does not have to be completed frequently. It can be reported every 6 months or even on a yearly basis during a district or programme review.

6.4 How to calculate indicators?

To compile the Cohort Analysis Report you need the ART Register only. All patients (even those transferred in after starting in another clinic) are registered by month/year they have started (monthly cohort) and grouped in the same pages of the Register.

For each of the monthly cohorts you need to check and report:

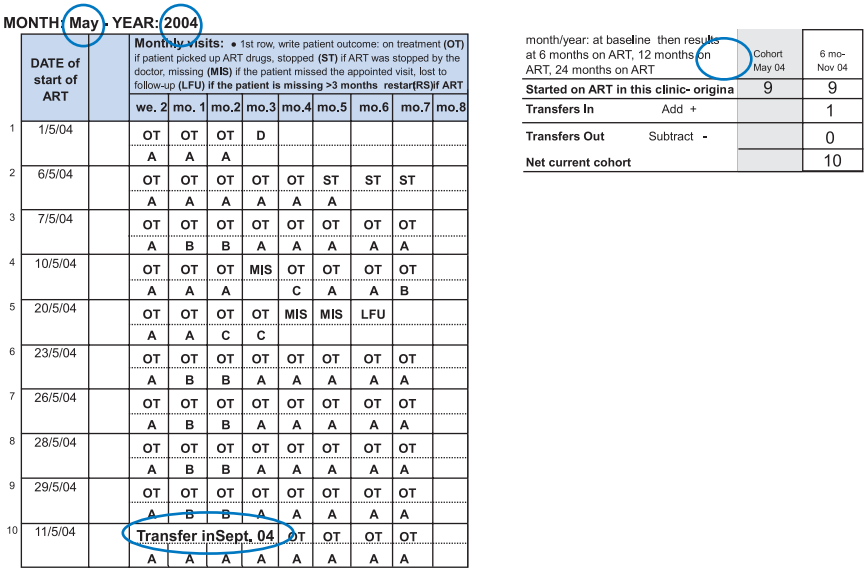
- How many patients are included in a given monthly cohort (main denominator)?
- What are their outcomes at 6 months and then every year?

In the following example, the May 2004 cohort is assessed for outcomes at 6 months (November 2004) during December 2004, and indicators are compiled in the cohort form.

The following figures highlight step-by-step information you have to look for and:

- Where is this information in the ART register?
- What are the results you have to report in the Cohort Analysis Report?

1: How many patients have started ART in May 04?



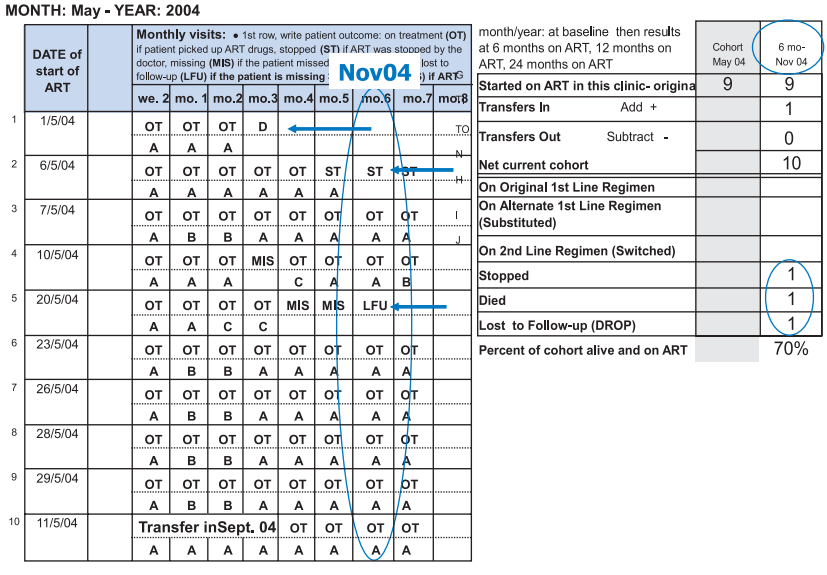
MONTH: May - YEAR: 2004

	DATE of start of 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 appointed visit, lost to follow-up (LFU) if the patient is missing >3 months restar(RS)if ART								
			we. 2	mo. 1	mo.2	mo.3	mo.4	mo.5	mo.6	mo.7	mo.8
1	1/5/04		OT	OT	OT	D					
			A	A	A						
2	6/5/04		OT	OT	OT	OT	OT	ST	ST	ST	
			A	A	A	A	A	A			
3	7/5/04		OT	OT	OT	OT	OT	OT	OT	OT	
			A	B	B	A	A	A	A	A	
4	10/5/04		OT	OT	OT	MIS	OT	OT	OT	OT	
			A	A	A		C	A	A	B	
5	20/5/04		OT	OT	OT	OT	MIS	MIS	LFU		
			A	A	C	C					
6	23/5/04		OT	OT	OT	OT	OT	OT	OT	OT	
			A	B	B	A	A	A	A	A	
7	26/5/04		OT	OT	OT	OT	OT	OT	OT	OT	
			A	B	B	A	A	A	A	A	
8	28/5/04		OT	OT	OT	OT	OT	OT	OT	OT	
			A	B	B	A	A	A	A	A	
9	29/5/04		OT	OT	OT	OT	OT	OT	OT	OT	
			A	B	B	A	A	A	A	A	
10	11/5/04		Transfer inSept. 04				OT	OT	OT	OT	
			A	A	A	A	A	A	A	A	

month/year: at baseline then results at 6 months on ART, 12 months on ART, 24 months on ART		Cohort May 04	6 mo- Nov 04
Started on ART in this clinic- origina		9	9
Transfers In	Add +		1
Transfers Out	Subtract -		0
Net current cohort			10

At this clinic, 9 patients started ART in May 2004, and one patient who also started in May 2004 at another clinic was transferred in during Sept 2004. Among them, no patients were transferred out before 6 months. Thus the net cohort who can be assessed at 6 months is 10.

2: How many are alive and on treatment at 6 months?



MONTH: May - YEAR: 2004

	DATE of start of 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 Nov04 lost to follow-up (LFU) if the patient is missing i) if ART								
			we. 2	mo. 1	mo.2	mo.3	mo.4	mo.5	mo.6	mo.7	mo.8
1	1/5/04		OT	OT	OT	D					
			A	A	A						
2	6/5/04		OT	OT	OT	OT	OT	ST	ST	ST	
			A	A	A	A	A	A			
3	7/5/04		OT	OT	OT	OT	OT	OT	OT	OT	
			A	B	B	A	A	A	A	A	
4	10/5/04		OT	OT	OT	MIS	OT	OT	OT	OT	
			A	A	A		C	A	A	B	
5	20/5/04		OT	OT	OT	OT	MIS	MIS	LFU		
			A	A	C	C					
6	23/5/04		OT	OT	OT	OT	OT	OT	OT	OT	
			A	B	B	A	A	A	A	A	
7	26/5/04		OT	OT	OT	OT	OT	OT	OT	OT	
			A	B	B	A	A	A	A	A	
8	28/5/04		OT	OT	OT	OT	OT	OT	OT	OT	
			A	B	B	A	A	A	A	A	
9	29/5/04		OT	OT	OT	OT	OT	OT	OT	OT	
			A	B	B	A	A	A	A	A	
10	11/5/04		Transfer inSept. 04				OT	OT	OT	OT	
			A	A	A	A	A	A	A	A	

month/year: at baseline then results at 6 months on ART, 12 months on ART, 24 months on ART		Cohort May 04	6 mo- Nov 04
Started on ART in this clinic- origina		9	9
Transfers In	Add +		1
Transfers Out	Subtract -		0
Net current cohort			10
On Original 1st Line Regimen			
On Alternate 1st Line Regimen (Substituted)			
On 2nd Line Regimen (Switched)			
Stopped			1
Died			1
Lost to Follow-up (DROP)			1
Percent of cohort alive and on ART			70%

Under column no. 6 you may note that there are 7 patients on treatment (OT), one patient died during the 3rd month, one patient is currently stopping ART and one patient is lost to follow-up. In total 7/10 (70%) are alive and on ART at 6 months.

3: Among those on treatment at 6 months, how many are on original, substitute, switched regimen?

	Treatment substitute within 1st line drugs			Treatment switched for 2nd line		
	Date subst.	Reason	New Regimen	Date switch	Reason	New Regimen
1						
2						
3	1/7/04	4	D4T/3TC/EFV			
4						
5						
6						
7	5/6/04	1	D4T/3TC/NEV			
8						
9						
10						

month/year: at baseline then results at 6 months on ART, 12 months on ART, 24 months on ART	Cohort May 04	6 mo- Nov 04
Started on ART in this clinic- origina	9	9
Transfers In Add +		1
Transfers Out Subtract -		0
Net current cohort		10
On Original 1st Line Regimen		5
On Alternate 1st Line Regimen (Substituted)		2
On 2nd Line Regimen (Switched)		0
Stopped		1
Died		1
Lost to Follow-up (DROP)		1
Percent of cohort alive and on ART		70%

Under the column, treatment substitution and switch, check how many patients changed regimen before 6 months. Among the 7 patients alive and on ART, 2 substituted regimen before 6 months, and none switched to 2nd line regimen. Note that the denominator is only those patients who are alive and on treatment.

4: Proportion with CD4> 200 at baseline & 6 months?

	CD4 count (% for children)	
1	start: 86	6 mo:
	12 mo:	24 mo:
2	start: 45	6 mo:
	12 mo:	24 mo:
3	start: 86	6 mo: 200
	12 mo:	24 mo:
4	start: 68	6 mo: 118
	12 mo:	24 mo:
5	start: 110	6 mo:
	12 mo:	24 mo:
6	start: 105	6 mo: 160
	12 mo:	24 mo:
7	start: 90	6 mo: 150
	12 mo:	24 mo:
8	start: 35	6 mo: 80
	12 mo:	24 mo:
9	start: 60	6 mo: 120
	12 mo:	24 mo:
10	start: 147	6 mo: 210
	12 mo:	24 mo:

month/year: at baseline then results at 6 months on ART, 12 months on ART, 24 months on ART	Cohort May 04	6 mo- Nov 04
Started on ART in this clinic- origina	9	9
Transfers In Add +		1
Transfers Out Subtract -		0
Net current cohort		10
On Original 1st Line Regimen		5
On Alternate 1st Line Regimen (Substituted)		2
On 2nd Line Regimen (Switched)		0
Stopped		1
Died		1
Lost to Follow-up (DROP)		1
Percent of cohort alive and on ART		70%
CD4: proportion ≥ 200	0/10	2/7

In the CD4 column, count how many patients were tested and how many have a result >200 cells, at baseline and at 6 months. In the above example, no one had CD4 >200 at baseline, but at 6 months 2 of 7 had CD4 >200.

5: Performance scale at baseline & 6 months?

	Performance scale A-normal activity; B-bedridden<50%; C-Bedridden>50%	
1	start: C	6 mo:
	12 mo:	24 mo:
2	start: B	6 mo:
	12 mo:	24 mo:
3	start: C	6 mo: A
	12 mo:	24 mo:
4	start: C	6 mo: B
	12 mo:	24 mo:
5	start: B	6 mo:
	12 mo:	24 mo:
6	start: B	6 mo: B
	12 mo:	24 mo:
7	start: A	6 mo: A
	12 mo:	24 mo:
8	start: C	6 mo: B
	12 mo:	24 mo:
9	start: C	6 mo: B
	12 mo:	24 mo:
10	start: A	6 mo:A
	12 mo:	24 mo:

month/year: at baseline then results at 6 months on ART, 12 months on ART, 24 months on ART	Cohort May 04	6 mo- Nov 04
Started on ART in this clinic- origina	9	9
Transfers In Add +		1
Transfers Out Subtract -		0
Net current cohort		10
On Original 1st Line Regimen		5
On Alternate 1st Line Regimen (Substituted)		2
On 2nd Line Regimen (Switched)		0
Stopped		1
Died		1
Lost to Follow-up (DROP)		1
Percent of cohort alive and on ART		70%
CD4: proportion > 200	0/10	2/7
Performance scale		
A Proportion normal activity	2/10	3/7
B Proportion bedridden <50%	3/10	4/7
C Proportion bedridden >50%	5/10	0/7

In the performance scale column, check the performance scale at baseline and at 6 months.

6: How many picked up ARV each month for 6 months?

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 appointed visit, lost to follow-up **(LFU) if the patient is missing >3 months restart (RS) if ART**

we. 2	mo. 1	mo.2	mo.3	mo.4	mo.5	mo.6	mo.7	mo.8
OT	OT	OT	D					
A	A	A						
OT	OT	OT	OT	OT	ST	ST	ST	
A	A	A	A	A	A			
OT	OT	OT	OT	OT	OT	OT	OT	
A	B	B	A	A	A	A	A	
OT	OT	OT	MIS	OT	OT	OT	OT	
A	A	A		C	A	A	B	
OT	OT	OT	OT	MIS	MIS	LFU		
A	A	C	C					
OT	OT	OT	OT	OT	OT	OT	OT	
A	B	B	A	A	A	A	A	
OT	OT	OT	OT	OT	OT	OT	OT	
A	B	B	A	A	A	A	A	
OT	OT	OT	OT	OT	OT	OT	OT	
A	B	B	A	A	A	A	A	
OT	OT	OT	OT	OT	OT	OT	OT	
A	B	B	A	A	A	A	A	
Transfer in Sept. 04		OT	OT	OT	OT			
A	A	A	A	A	A	A	A	

month/year: at baseline then results at 6 months on ART, 12 months on ART, 24 months on ART	Cohort May 04	6 mo- Nov 04
Started on ART in this clinic- origina	9	9
Transfers In Add +		1
Transfers Out Subtract -		0
Net current cohort		10
On Original 1st Line Regimen		5
On Alternate 1st Line Regimen (Substituted)		2
On 2nd Line Regimen (Switched)		0
Stopped		1
Died		1
Lost to Follow-up (DROP)		1
Percent of cohort alive and on ART		70%
CD4: proportion > 200	0/10	2/7
Performance scale		
A Proportion normal activity	2/10	3/7
B Proportion bedridden <50%	3/10	4/7
C Proportion bedridden >50%	5/10	0/7
Number of persons who **picked up ARVs each month for 6 months**	x	6
Number of persons who **picked up ARVs each month for 12 months**	x	x

Under the columns of monthly visits, check those patients alive and on treatment at 6 months who picked up their drugs every month. Here you see that one patient missed one monthly appointment. Only 6 picked up drugs for 6/6 months.

EXERCISE 4 - COHORT REPORT

Complete exercise 4. This exercise will help you in understanding how to complete a cohort report at 6 months and at 12 months. Using the ART register, you will have to compile the information available in the cohort report.

EXERCISE 5 - COHORT INTERPRETATION

Complete exercise 5. This exercise will help you in understanding how to analyse a cohort report at 6 months and at 12 months. Using a completed cohort report, you will have to compile all the results, present the results in graphs and prepare a short presentation.

Sub module 7

7. Data flow and use of data at each level

Sub Module 7

7.1 Data flow

Patient HIV Care/ART Records and the Pre-ART and ART Registers have to be kept at the clinic. They might be used during programme review at the facility level to obtain additional indicators.

The Cohort Analysis Report is not to be forwarded to the next level above every month but is a tally sheet to be completed for the outcomes at 6, 12 and 24 months for the monthly cohorts of patients starting ART. This report has to be kept at the clinic. The frequency to transmit the indicators from the cohort report will be decided by the national AIDS programme. For example, it may be decided not to transmit the indicators but to collect them actively during supervision or programme review.

The **ART Monthly Report** should be forwarded to the level above without delay at the beginning of the following month, with continuity between the different levels of the AIDS programme:

- National AIDS programme manager

  Monthly facility reports + Monthly compilation of facilities reports

- State/Province AIDS programme manager

  Monthly facility reports + Monthly compilation of facilities reports

- District AIDS programme manager

  Monthly facility report

- Facility/treatment unit manager

At the district, state/province and national levels, the ART Monthly Reports from the different HIV care/ART treatment units can be compiled, in a tally sheet, assigning one row per facility and the total computed.

In the early stage of the programme, it is recommended to forward the date up to the national level a copy of each treatment unit report as well as the monthly compilation of all treatment units.

7.2 Use of data

At the district, state or province and national levels, ART Monthly Reports from the various treatment units should be compiled and totaled. Key indicators should be selected for this analysis.

The key indicators to compile per facility and in total and analyse every month are the following:

- completeness of monthly reporting: no. of facility reports expected/no. received;
- cumulative no. of patients enrolled in HIV care at the end of the month, by sex, age;
- No. of patients eligible for ART and have not been started on ART at the end of the month, by sex, age;
- cumulative no. of patients ever started on ART at the end of the month, by sex, age;
- cumulative no. of deaths reported at the end of the month;
- No. of patients on ART at the end of the month;
- No. of patients on substituted 1st line regimen at the end of the month;

- No. of patients who switched to 2nd line regimen at the end of the month;
- No. of patients assessed for adherence and no. with adherence >95% this month;
- was there a stock out of ARV drugs this month Y/N; and
- was there a stock out of drugs for OI this month Y/N.

For all facilities, the same figures developed in chapter 4.5 (how to analyse the monthly reports) can be produced to analyse the trends of the programme over time.

An example of a monthly compilation sheet to forward to the upper level is presented below.

A simple data-entry system (excel-EpiInfo) might be developed to computerize the monthly reports from the various treatment units (1 row per facility - month report). This will facilitate in comparing performance of different ART facilities and also monitoring trends over time.

Example of compilation form at district, state/province, national level

HIV care/ART programme: monthly compilation form for monthly reports from treatment units

Month: **Year:**

How many facility reports were expected this month? /_____/ How many facility reports were received? /_____/

			Cumulative no. ever enrolled in HIV care at the end of the month				No. eligible for ART but not have been started on ART at the end of the month				Cumulative no. ever started on ART at the end of the month				Cumulative no. of deaths reported at the end of this month	No. of patients on ART at the end of this month	No. of patients on substituted 1st line regimen at the end of the month	No. of patients on switched 2nd line regimen at the end of the month	No. of patients assessed for adherence during this month	No. of patients with >95% adherence	Stock out of ARV drugs this month (Y/N)	Stock out of drugs for OI this month (Y/N)
Name of the treatment unit	District	State/ Province	no. of adults male	no. of adults female	no. of children	Total patients	no. of adults male	no. of adults female	no. of children	Total patients	no. of adults male	no. of adults female	no. of children	Total patients								
TOTAL																						

World Health Organization
Regional Office for South-East Asia
New Delhi