FUCHIA 1.7 User Guide

Follow-Up and Care of HIV Infection and Aids

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Introduction

The "Follow-Up and Care of HIV Infection and Aids" software, otherwise known as FUCHIA, has been designed to facilitate the clinical, biological and therapeutic monitoring of HIV positive patients.

This guide is adapted from the original FUCHIA guide version 1.5, and follows the same pedagogical framework detailing the technical aspects of FUCHIA with reference to key activities related to monitoring of HIV patients and programs.

The guide is divided into 3 sections with part 1 containing the core elements addressing the process from program implementation, data collection, data entry and data analyses with a focus on data collected during a patients' first visit and subsequent follow-up visits. Part 2 includes two independent chapters for monitoring HIV and TB co-infections and the transmission of HIV from mother-to-child, whilst part 3 provides information to improve data quality and describes FUCHIA data exports and additional technical components of FUCHIA.

Guide Outline

The primary target audience for this guide are anyone delivering HIV care and involved in the process of monitoring HIV/AIDS programs, particularly program managers at the coordination level to practitioners (clinicians, nurses, counsellors) in direct contact with patients, to clerical staff entering data and data analysts.

Whilst trying to be as comprehensive as possible, this guide may not cover all areas of use. If additional help is required understanding a feature of the database, please feel free to contact the FUCHIA development team through fuchia@epicentre.msf.org.

This guide is a draft version, therefore hyperlinks to pages and cross-references within document are not yet available. Thanks for your patience.

The FUCHIA Team

1 – MONITORING HIV/ AIDS PROGRAMMES

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1.1 A monitoring system for HIV/AIDS programmes

1.1.1 Definition of a monitoring system

A disease monitoring system is a continuous process of gathering, analysing and reporting data on any given disease. It also allows such data to be collected in a standardised way.

The aims of this monitoring system are as follows:

- To describe the incidence, mortality and progression of the disease;
- To assess the impact of actions and measures taken;
- To detect anomalies and assess their significance;
- To assist in the allocation of resources in relation to short-term and long-term priorities;
- To assist in providing regular information to the populations concerned;
- To play a role in scientific research and expanding the frontiers of knowledge.

1.1.2 What is different about a HIV monitoring system?

It is able to accommodate the various constraints inherent in the type of infection caused by HIV:

- Numerous hospital visits per patient;
- Extremely long follow-up periods;
- Number and type of associated diseases;
- The number of antiretroviral drugs (ARVs) available and complexity of treatments
- The number of possible sites where patients are treated (out-patient, in-patient departments, health centres, etc…)

1.1.3 FUCHIA software, a monitoring tool

The "**F**ollow-**U**p and **C**are of **H**IV **I**nfection and **A**ids" software, otherwise known as **FUCHIA,** has been designed to facilitate the clinical, biological and therapeutic monitoring of HIV positive patients.

Beginning of 2000, a software prototype was created, in partnership with *MSF* [1] *France's* technical department and various medical teams working in the field. Since June 2001, a technical committee – made of members from five *MSF* operational centres (Belgium, France, Switzerland, the Netherlands and Spain) and Epicentre – has been involved in the process of developing FUCHIA. These five MSF divisions are also responsible for financing the development of this software.

More technically speaking, FUCHIA is a database interface operating in a standard Windows environment (95, 98, Millennium, NT4, 2000, XP, Vista, Windows 7), written in Object Pascal (Borland Delphi) and connected to an Access database.

Table 1: Development steps of FUCHIA over the years.

Versions	Year	Contents
v1.4.1.478	Dec. 2002	Forms: Patient, Follow-up, Pregnancy Reports: Standard, ARV, Patient Summary, Lists
v1.5.1.917	Feb. 2005	R software attached to generate reports and exports Tuberculosis form Exports: Tuberculosis, Pregnancy, Prescription, Free variables Lists: next appointments, Opportunistic infections Checklists: patient, follow up and treatment data
v1.5.2.86	Jul. 2005	Reports added: Outcome for patients on ARV, Patients followed on ARV (weight*treatment) Export added: blood collection data
v1.5.2.145	May 2006	Report added: cohort analysis of patients on ARV
v1.5.2.244	Sep. 2006	Export added: linearised export
v1.6.0.326	Mar. 2007	WHO staging: new WHO classification 2006 Variables added: creatinine, ALAT, Age Report added: tuberculosis
v1.6.1.467	Feb. 2008	Checklist for tuberculosis data
v1.6.2.508	Jun. 2008	Pregnancy form: variables added: referred by, date of admission, date of initiation of ARV (ART or prophylaxis) Patient Form: new variable for WHO staging, variable for decentralisation Follow up form: new variable for WHO staging Report added: PMTCT Checklist: PMTCT data
v1.6.2.526	Mar. 2009	Bugs corrected: WHO staging calculated, PMTCT baby prophylaxis
V1.7.0.844	Jan. 2011	Standard, ARV reports and patient summary: revised and moved under R – Exports in Stata format PMTCT: new variables in PMTCT and Child Follow up Form to account for the new 2009 WHO recommendations. Follow up form: new variables for TDF monitoring
1.7.1	March 2012	PMTCT: report & export & checklist updated

FUCHIA has two main functions:

[1] Médecins Sans Frontières

► ***Data collection***

Patient Form

Socio-demographic data

Medical history

Follow-up Form

Clinical, biological and therapeutic data

PMTCT Form

Clinical and therapeutic data

Tuberculosis Form

Clinical and therapeutic data

► ***Analyses***

FUCHIA Direct

- Database queries

Automatic Analyses with "R" statistical software

- Patient summary
- Description of patients
- Cohort and outcome reports
- PMTCT
- Tuberculosis
- Workload
- List of drug interruptions and intolerances
- Patient lists
- Check lists

Data exports

- Complete database
- Patient long export
- Patient wide export
- Tuberculosis
- PMTCT
- Prescription
- Lab results
- Free Variables

Export to other analysis software

1.2 How to organise the monitoring system?

Before implementing the FUCHIA monitoring system, prior authorisation must firstly be obtained from the Ministry of Health (MoH). The various healthcare structures involved in the patient and information flow process must also be identified:

For example:

Private consultations	Hospitalisation services	Ministry of Health
Screening centre	MSF Project Office	*MSF* Head Office
Referral locations	Pharmacy	*MSF* headquarters
Health centre	Laboratory	
	HIV care clinic	

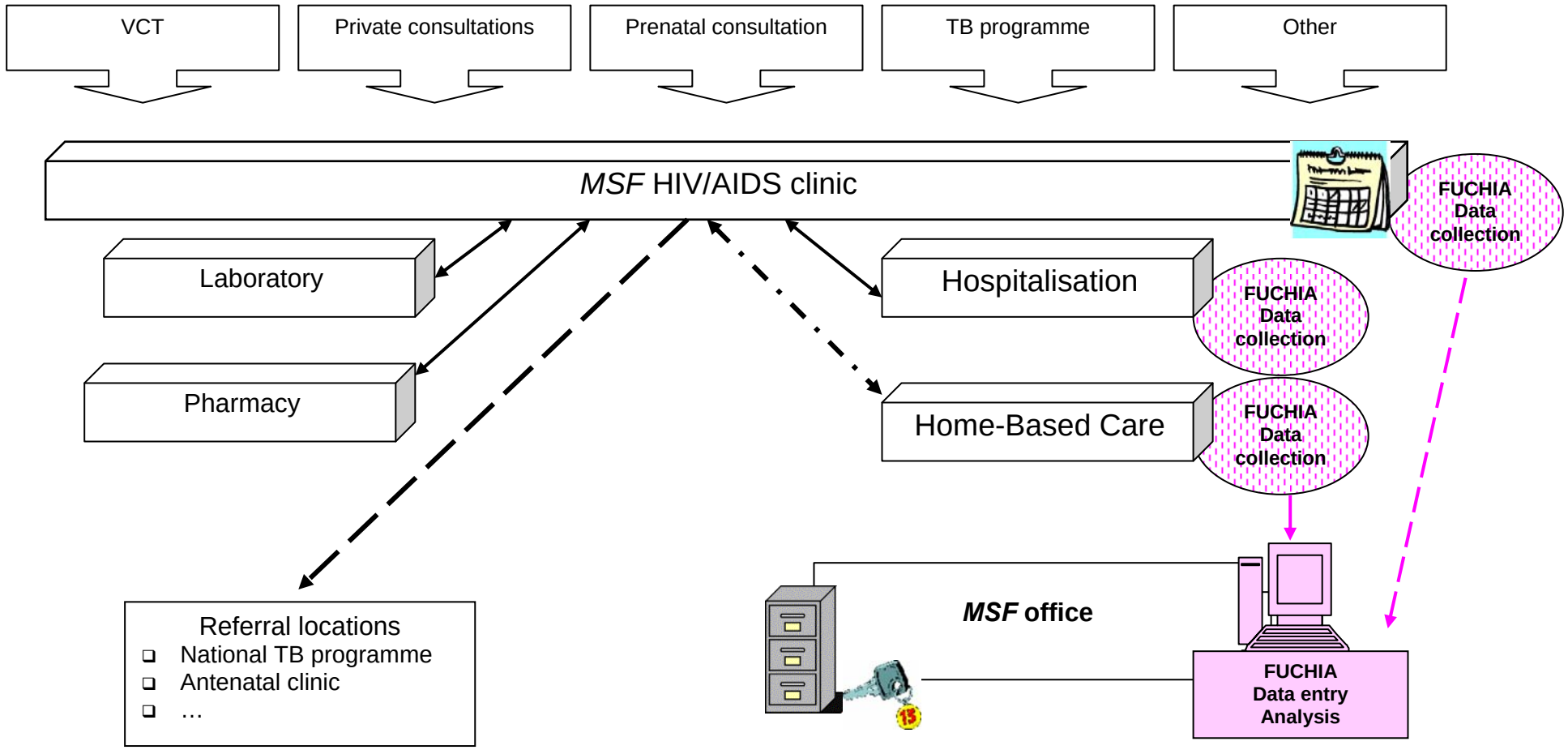
The table below will help you identify the resources required within each structure (human, materials, tools, etc…) via a list of questions per activity: data collection, transfer, data entry, filling and storage, back-up, analysis and reporting. It is important to respect the safety measures given in Chapter 11, thus protecting the patients and collected data and identifying training needs and manpower resources.

Next, the following flow criteria must be defined:
- The flow of information between the various structures
- The flow of patients

Table 2 : Implementing a monitoring system with FUCHIA – Questions

Activities	Where?	Who?	What? How?	When?
Data Collection	In which system structures does data collection take place?	By whom? Which skills are required? Who is responsible for the quality of data? Who is responsible for correcting data?	On which form? How are errors identified?	How often?
Transfer of forms	Between which structures are forms transferred? Where are transferred forms stored?	Who is responsible for this transfer?	Which data to transfer? Which form to use for transferring data between collection site and entry site?	How often? (Daily, weekly)
Data Entry	In which healthcare structure are data entered? Where is this computer located?	Who enters data? Which skills are required? Who is responsible for the quality of data entry? Who amends data entry errors?	Which data to enter? How are data entered? How to identify data entry errors?	How often are data entered? (Daily, weekly)
Filing and Storage following data entry	Where are data stored?	Who is responsible for storing data? Who supervises data storage?	Which documents to store? How is data filing organised? Where is the key kept and who is in charge of it?	When are the completed forms stored?
Data back-up	Where are database back-ups stored?	Who is responsible for data back-up?	On which support? (ZIP, USB key, CD ROM)	How often are data backed up?
Transfer of databases		For whom are transferred databases intended?	On which support? (ZIP, USB key, CD ROM)	How often?
Data analysis **&** **Usage**	Where are data analysed? (mission, head office, HQ, Epicentre…)	Who analyses the data and who interprets them? Which skills are required? Who uses the results from these analyses?	Which data to analyse? Which type of analysis? With which software package (s)? What is the purpose of these analyses?	How often are these analyses to be made?
Reporting	Where to report on data? (mission, head office, MoH, regional/ national workshops, international conferences)	For whom are the results intended? (MoH, partners, HQ, patients, public authorities…) Who is responsible for reporting data?	Which data to report on? In which format?	When to report data?

Figure 1: A monitoring system using FUCHIA – illustration



1.3 How to ensure the protection of patients and data?

In order to ensure the protection of patients and data, it is advisable to:

►a) Inform the local authorities and seek their approval.

FUCHIA, along with the monitoring system implemented by MSF for its programmes, must be submitted to the Ministry of Health and a local ethics committee. An agreement (known as a "memorandum of understanding") governing data collection, data entry and analysis must be clearly defined and concluded between local authorities and the partner(s) in charge of the project. This document must clearly stipulate that personal data is being collected for the purposes of monitoring the programme.

MSF missions are responsible for the protection of patients' data. MSF missions are responsible for data processing on a local level. Analysis and dissemination of results may only take place with the prior authorisation of MSF and with the approval of the Ministry of Health.

MSF activity reports must be regularly submitted to the authorities.

►b) Inform patients

Each patient taking part in the programme must be informed that computer data are being collected for patient and programme monitoring.

►c) Guarantee anonymity and respect patient confidentiality

Each patient is allocated an anonymous identification number (FUCHIA number). Data entry into the FUCHIA database is based on this identification number. The recommendation is that the first name and surname of patients should not appear anywhere in the database. The same applies to address and phone number.

►d) Take specific protection measures

MSF must take all the necessary precautions to ensure the security of installations and software equipment (computers, medical records, FUCHIA forms, printers, etc…).

The computer on which FUCHIA is installed must *not be used for other purposes.* If possible, no Internet servers or local computer networks should be connected to this computer, so as to avoid any unwanted access to the FUCHIA database or virus intrusion via local or remote networks.

At the end of each data entry session, all medical records and FUCHIA forms, together with all electronic support (disks, CD ROMs, USB keys) containing data, must be locked away.

The FUCHIA database is encrypted; it cannot be accessed via any other software. A password is required to access and use FUCHIA. Each mission has its own password, which must be changed on a regular basis. Persons allowed access to the software (and hence the password) must be identified in relation to their role within the programme. In most cases, these are: the head of mission, the doctor in charge of the HIV programme and data entry operators, all of whom are sworn to uphold the principles of professional secrecy.

2– IMPLEMENTING FUCHIA SOFTWARE

Once you have identified how the monitoring system is to be organised, you are now ready to implement the software. First, you will need to install the software. Next, you must set parameters for certain variables that are specific to the requirements of your project. In fact, certain variables are already predefined in FUCHIA (see Chap. III), but others (listed below) need to be defined at the time of installing the software.

2.1 Installing the software: See chapter 11

2.2 Existing variables to be coded

2.2.1 Patient identification

► ***Anonymous identification number (ID Number)*** (*mandatory*)

Each patient taking part in the programme is given an anonymous identification number, to ensure that data is collected anonymously. This number is:

- **Unique**: the same ID number may not be allocated to any other patient;
- **Personal**: the same ID number is used at each visit for the same patient, irrespective of the type of visit (consultation or hospitalisation).

Identification is to be alphanumeric and as straightforward as possible, e.g.:
- Project inclusion number
- Project inclusion number + mode of entry + year

For ID numbers, do not use medical record numbers allocated by hospital administration systems (risk of duplication).

► ***Other identification*** *(optional)*

This field allows other type of patient identification to be recorded (e.g. medical record numbers).

2.2.2 Socio-demographic variables and project variables

Options for certain socio-demographic variables (location, marital status, geographic origin, profession) and project variables (modes of entry, programmes, referred) must be defined once the software is installed.

See 💻 Coding of Variables § 2.6

Some rules on coding

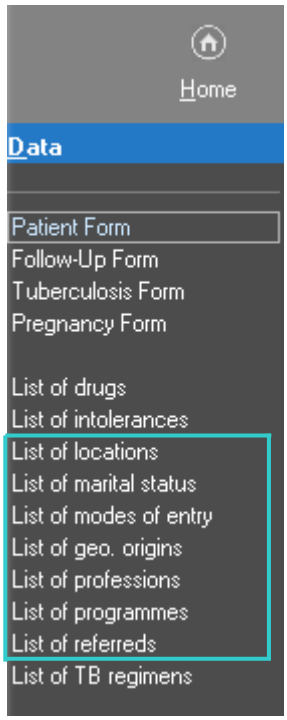
Codes must be defined at the time of installing the software

Codes must be programmed prior to any data entry

Avoid more than five codes per variable (too many codes make analysis more difficult).

Include a code “other” in the list of codes.

Here are some values to which codes may be given:



List of locations: (consultation and/or hospitalisation)
e.g.: home visits (Home-Based Case), hospitals, health centres

List of marital status
e.g.: married, widowed, divorced, single, other

List of modes of entry: modes of entry into the programme
e.g.: VCT, health centres, PMTCT, other

List of geographic origins
e.g.: districts, towns where patients reside

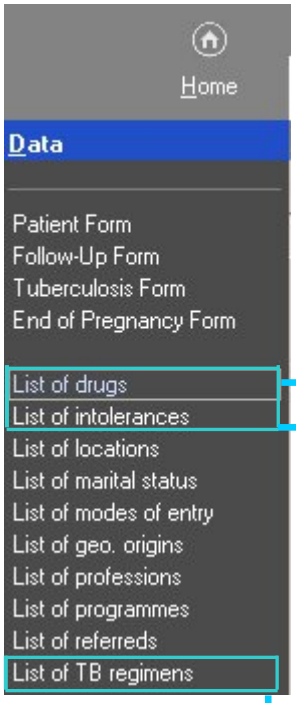
List of professions
e.g.: farmers, housewives, civil servants, doctors, other

List of programmes
e.g.: ARV MSF, ARV other

List of referred: Healthcare structure to which the patient is referred following consultation or hospitalisation.
e.g.: national tuberculosis programme, PMTCT, tertiary hospital, other

2.3 Existing variables to be adapted

For certain variables (drugs, intolerances and TB regimens), options are already predefined. However, it is possible to add codes to these variables.



2.3.1 List of drugs

The list given in FUCHIA has been created on the basis of treatments currently in use within the fields where MSF operates.
It consists of the following:

- Fixed Dose Combinations, adults & children formulations (FDC, FDCp, e.g.: AZT-3TC-NVP, AZT-3TC-NVPp),
- Dosage of regimens (e.g.: d4T 40mg and d4T 30mg)
- Paediatric formulations (e.g.: 3TCp, AZTp),
- Mother-to-child treatments (e.g.: AZT/MTC and NVP/MTC),
- Prophylactic treatments (e.g.: Cotrimoxazole, fluconazole)

It is possible to add another five free antiretroviral agents (AA1-AA5).

2.3.2 List of intolerances

This gives a list of different types of drug intolerance and grades of severity.
e.g.: Severe lipodystrophy, Grade 3 anaemia (Hb <6.5)

2.3.3 List of TB regimens

Five TB regimens are currently defined in the list:

- 2HRZE/4HR, 2HRZE/6HR, CAT2, 2SHRZ/2RH(Z)/3EH (Manyatta), DR TB regimen.
- Other regimens may be added to the list.

2.3.4 Adding codes to predefined variables

► ***Adding ARV drug codes***

- You may add ARV drug codes and only ARV drugs in these 5 lines only by changing the lookup.
- To avoid further problem when the added drug will be part of the standard list, rename the lookup such as: AA1 drug name.
- Do not change any other column but the lookup.
- Do not add any other line to the drug list.

Drag and drop header column here to group by this column.

Value	Lookup Short	Lookup	Code
440	AA1	Other ARV 1	AA1:A1:AA1
450	AA2	Other ARV 2	AA2:A1:AA2
460	AA3	Other ARV 3	AA3:A1:AA3
470	AA4	Other ARV 4	AA4:A1:AA4
480	AA5	Other ARV 5	AA5:A1:AA5

► ***Adding intolerance codes***

You may add a new code for an intolerance. This new code will be taken into account in the reports and exports

► ***Adding TB regimen codes***

You may add a new code for a TB regimen. This new code will be taken into account in the reports and exports

2.4 Variables to be created: free variables

Additional variables specific to one particular mission may be created in FUCHIA (see Naming for free variables § 2.7, in the knowledge that some data will be collected once only at the start of the follow-up period, whereas others will be gathered at each visit and are therefore likely to change over time:

► ***Free variables – Patient Form***
Data collected on one occasion only, during the patient's first visit
e.g.: Type of HIV, mode of transmission

► ***Free variables – Follow-up Form:***
Data gathered during various visits (consultation/ hospitalisation)
e.g.: Karnofsky score, CD8 cell count, community health worker

► ***Free variables – PMTCT Form:***
Gathered at the end of each pregnancy
e.g.: number of previous pregnancies, duration of pregnancy, infant weight

► ***Free variables – TB Form:***
Gathered during each new TB episode
e.g.: side effects.

Before deciding whether or not to collect variable data, you must determine:

Whether these variables are **relevant** for the whole cohort group**.**

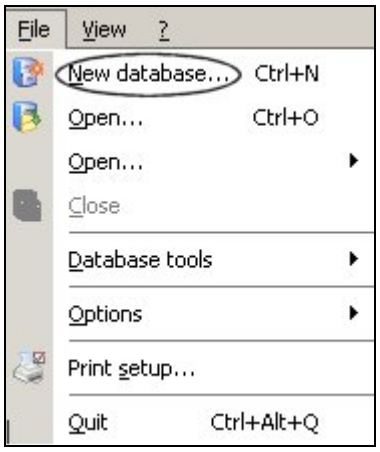
How heavy the **workload** will be (data entry)

Compliance with **ethical aspects** when handling personal information

How **available** this information will be with regard to the whole cohort group.

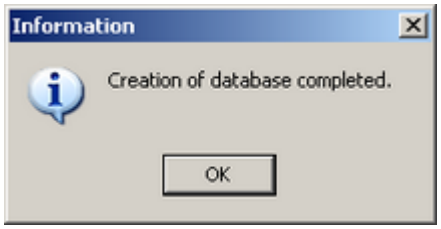
AND check that the free variable you will use has never been used = is empty

2.5 Creating a database

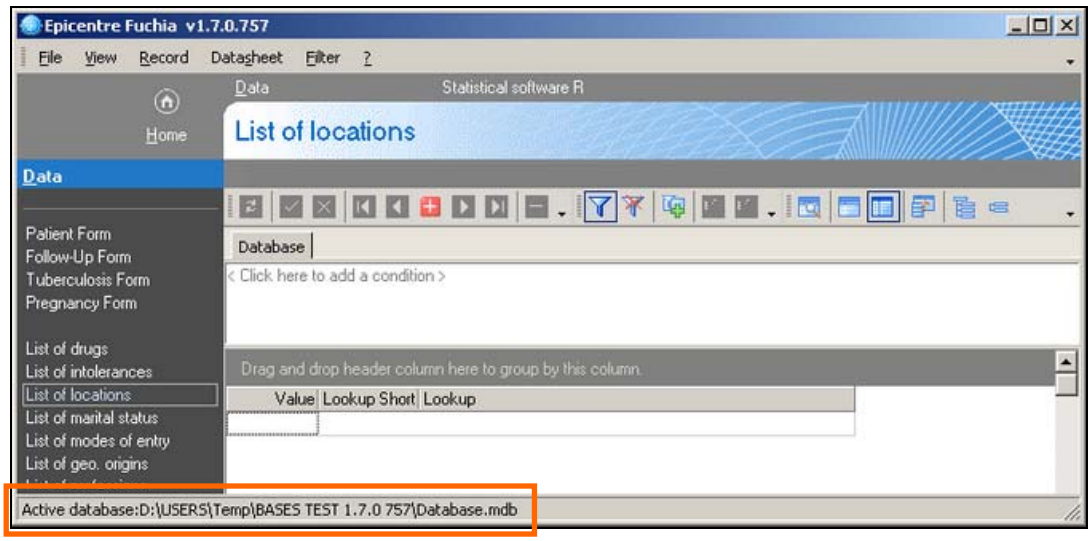


- FUCHIA datasets are named automatically with the extension .mdb as FUCHIA uses Microsoft Access software to store the data.
- If you are installing FUCHIA for the first time and therefore have no database, you will need to create one. To do this, go into “File\ New database”.
- You need to give your database a name and save it in a selected space on your hard-drive (e.g. **D:\users\Fuchia\database.mdb**). Make a note of the access path to this database.

When the database is created, you get the following message on the screen



Note: In the lower left corner of the FUCHIA screen, you find the name of the database and the path. FUCHIA will open automatically the last database open, unless you specify differently.



Next stage => cf. Coding of variables

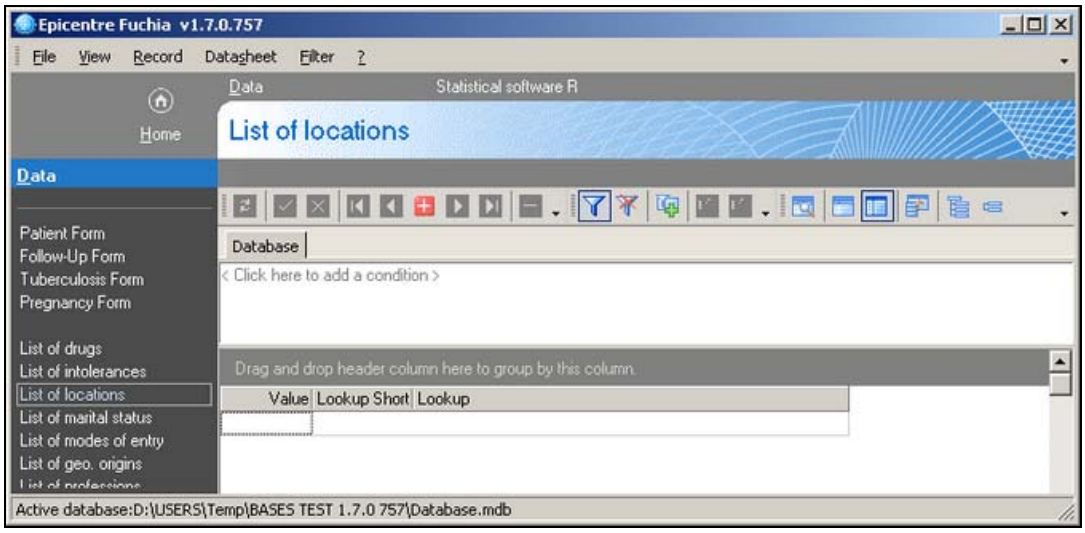
2.6 Coding of variables

► Existing variables to be coded

You have just created your FUCHIA database.

Next, you will need to code certain variables specific to your own particular programme: **locations, marital status, mode of entry, geographic origins, professions, programmes and referrals**. If you already had a database in FUCHIA 1.6, you need not recode these variables, as FUCHIA 1.7 will "re-use" the codes from the previous version).

To code these variables, click on the menu "Data" and again on the list to which you'd like to give a code, e.g. "Locations".



To give codes to the variable location, click on "New". Next, enter a value (1 for the first code, 2 for the second, etc…), and then give a code description (short/ long). For example:

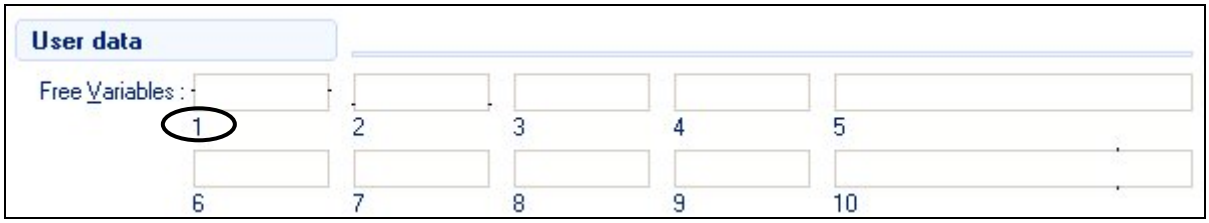
Next, click on "Save" to record your code. If you wish to add another code, click on "New". In case, you don't get an empty line, click on "New" a second time.

You can also modify or delete any code by clicking on "Modify" and "Delete".

2.7 Naming free variables

In **Patient, Follow up, PMTCT and Tuberculosis** forms**,** you have the option of entering new variables: ten for each form. As these variables are specific to each individual programme, they do not have a predefined title.

Here is an example of a Patient Form:



You can **give these variables** a name of your choice (so that their names will be displayed in FUCHIA). This will avoid any confusion during data entry. To do this, these names must be saved in the file **settings.ini.**

On computer operating with Windows XP, this file can be found at "C:\Documents and Settings\user\Local settings\Application Data\Epicentre\Fuchia\v1.7.1". With Windows 7, the file is found at "C:\Users\user\AppData\Local\Epicentre\Fuchia\v1.7.1". By clicking on **settings.ini**, the file will open in a notebook window, which shows the ten free variables available for each form. The Application Data folder might be hidden in your computer. To unhide it, in windows explorer, go to tools menu then File options. In display tab, tick "display the files and folders hidden".

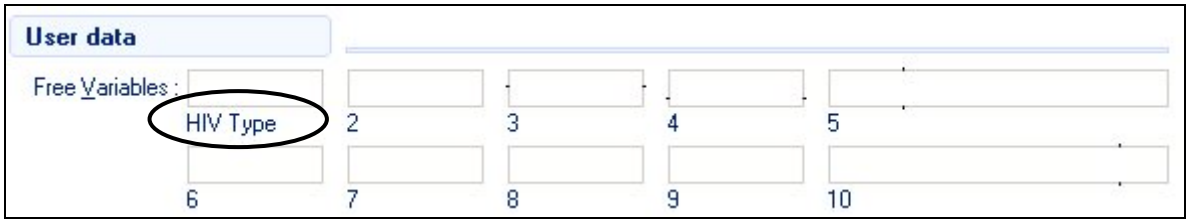
```
[Patient]
Description Free Variable 01=1
Description Free Variable 02=2
Description Free Variable 03=3
Description Free Variable 04=4
Description Free Variable 05=5
Description Free Variable 06=6
Description Free Variable 07=7
Description Free Variable 08=8
Description Free Variable 09=9
Description Free Variable 10=10
```

Note: The free variables of a given form appear in the settings.ini file only if you have opened FUCHIA and clicked on that form.

To give a name to any variable, replace the corresponding number (1, 2, 3 etc…) with the name you wish to allocate.

For example:

If, for Free Variable 1 of the Patient Form, you are collecting the type of HIV, and you would like to call this variable "HIV Type", just replace the line "Description Free Variable 01=1" with "Description Free Variable 01= HIV Type". Next, save the file. Close FUCHIA and re-open it and observe that the free variable 1 appears as below:



Each time you subsequently re-open FUCHIA, this variable name will appear in the Patient Form.

3 – DATA PROCESSING

List of tables

3.1. Introduction

FUCHIA is first and foremost a data-entry tool used to capture patient data collected prospectively using four standardised questionnaires: **Patient Form**, **Follow-up Form**, **Tuberculosis Form** and **PMTCT Form** for prevention of mother-to-child HIV transmission.

This chapter will focus on the Patient and Follow-up Forms and will outline the process by which the data is collected and entered. The procedures for tuberculosis and PMTCT will be dealt with in later chapters.

The patient form collects patient data at point of entry and exit of the cohort from the MSF program. Type of information collected:

- Socio-demographic data at entry: age, sex, profession, marital status, geographical origin
- Program data at entry, decentralisation and exit: mode of entry, referral
- Prior history: medical and treatment
- Exit data: death, discharge
- Patient movement: decentralisation

The Follow-up Form is the main tool used for patient monitoring and information collected at each visit from entry till discharge are recorded on this form. Type of information collected:

- Clinical: WHO staging, weight and height
- Laboratory: CD4, viral load, haemoglobin, ALAT and creatinine, Hepatitis B Antigen S, interim HIV test in PMTCT infants….
- Treatment: prescribed ARV and prophylactic drugs
- Intolerance and toxicities-related to ARV drugs
- Patient movement: program and location

Electronic versions of the FUCHIA forms in Word format can be found in the directory:

C:\Program Files\MSF\Fuchia\v1.7.1

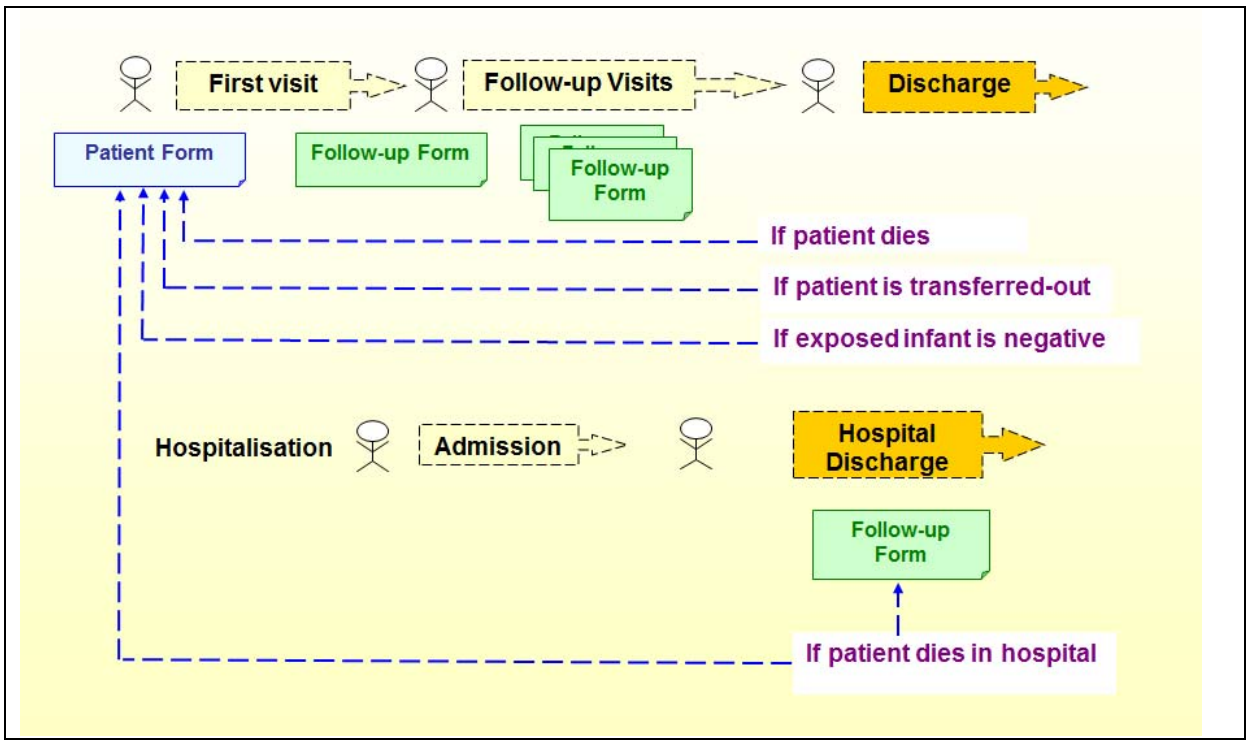
These FUCHIA forms may also be adapted to meet the needs of the field.

Note:

Standardisation of data collection is essential to allow computation of indicators and for comparisons over time and between programs.

3.2. Data collection

The flow chart describes the main points for data collection. To complete the Patient and Follow-up Forms, please refer to the section "Description of data collected" for detailed instructions.



The **first visit** is the point of entry for a patient. At this visit a patient is enrolled in the MSF program and is assigned a unique number (NID) and Patient and Follow-up Forms are completed.

At **subsequent visits** and hospitalisations a Follow-up Form is completed until a patient is discharged from the cohort.

Discharge is withdrawal of the patient from the MSF program, and can be either due to death or transfer-out or discharge of HIV negative infants born to PMTCT mothers. Patients are **not** discharged if they are lost-to-follow-up (LFU) or are decentralised during follow-up, as it is important to retain information on LFU and decentralisation for program monitoring purposes.

In the event of death, transfer-out or when an exposed baby is found HIV negative, always complete the discharge section on the "Patient" Form:

► For death, complete the variables “Death” and “Date of Death”.
► For transfer-out, complete the variables Cohort discharge” and “Cohort discharge Date”.
► For exposed baby with an HIV status negative, complete the variables Cohort discharge” and “Cohort discharge Date” and up date the HIV test and date on the patient form.

Hospitalisation: During follow-up, a patient may be admitted to hospital and may spend several days or even weeks in hospital. To record the information, do not record all in-patient consultations; instead complete one Follow-up Form immediately on patient discharge from hospital. The minimum information to record is date patient was admitted to hospital, date of discharge and status at discharge.

Further, any other changes (diagnosis, regimen) or laboratory results can also be recorded on the hospitalisation follow-up visit form at discharge.

► If death occurs whilst the patient is hospitalised, fill in a “Follow-up” Form, specifying the status at discharge (dead) and the date of discharge (date of death). Then, return to the “Patient” Form and enter the variables “Death” and “Date of Death”.

► If patient is transferred to an alternative hospital, fill in a “Follow-up” Form, specifying the status at discharge (transfer) and the date of discharge (date of transfer). At the next facility, complete a new “Follow-up” Form with the relevant information.

Note:

Transfer to another facility is **not** the same as transfer out from cohort, therefore the section on transfer out should not be completed on the “Patient” Form.

Further,

► If, during any visit, TB is diagnosed, a “Tuberculosis” Form must also be completed. See chapter Tuberculosis for further details.

► If during any visit, pregnancy is confirmed and a patient is admitted to a PMTCT programme, a “PMTCT” form is to be completed. See chapter PMTCT for further details.

► **If data are entered onsite at the same clinic where the HIV patient is being monitored**, data collection forms may be kept as part of the patient’s medical records.

► **If data entry is performed off site**, forms are to be completed in duplicate (original + carbon copy): The original is kept as part of the patient’s medical record. The copy is sent for data entry.

Decentralisation: During follow-up, patients may also be decentralised to other sites within the programme. To record this information, complete the section Discharge on the Patient form and tick the box “decentralised” to indicate patient is decentralised, the location patient was decentralised to and the date patient was decentralised. This date is the date when the decision is made to decentralise the patient and not the date the patient makes the first visit at the decentralised location.

Note:

Patients who are decentralised **are not** discharged from the cohort and are analysed as part of the cohort that is followed in the programme.

3.2.1. Description of data to be collected

Table 1: Patient Form

Name of Variable	Details	Comments
Identification		
Cohort Identification Number	Unique and personal number.	Ensures the link between patient information and follow-up visits.
Other Identification	Number or text enabling patient identification (e.g. medical record number, etc...)	
Admission		
Gender		
Date of birth	In dd/mm/yyyy format	If unknown, fill in the variables “Age”, “at date” and “Unit”.
Age & age unit	Age expressed in years/months/days. Tick the corresponding box.	If the date of birth is unknown, the patient’s age and the corresponding date must be recorded (e.g. the patient was 25 years old on 13/06/2002). This will allow an approximate date of birth to be calculated.
At date	In dd/mm/yyyy format	
Mode of Entry	Route in which the patient was enrolled in the program	Gives details on the link between the program and the relevant healthcare network. Codes to be defined at the time of creating database (cf. II.2.2)
Marital status	Marital status at the time of program inclusion	Codes to be defined at the time of creating database (cf. II.2.2)
Geographic origin	Address/ place of residence at the time of program inclusion	Give details on access to healthcare available within these geographical areas. Codes to be defined at the time of creating the database (cf. II.2.2)
Profession	Profession at the time of program inclusion	Codes to be defined at the time of creating the database (cf. II.2.2)
HIV	Negative / Positive / not specified	Defines the HIV status of a patient. HIV status of a PMTCT baby is not specified until the status can be ascertained by the clinician.
HIV test	Serology / PCR / not specified	Test used to define the HIV status
Date of HIV test result	In dd/mm/yyyy format	Date at which the status was defined
Clinical and treatment background		
Clinical background	Clinical background presented by the patient prior to program inclusion (WHO classification + 2 free spaces for other diagnoses)	
WHO	WHO clinical staging prior the first visit (1 / 2 / 3 / 4 / NS)	This field allows staging the patient without using the OI list.
Treatment background	Treatments administered to the patient prior to program inclusion: - Type of treatment - Initial prescription date - Length of treatment	Codes of PMTCT prophylaxis: see chapter 5, §5.2.2
Discharge		
Death	Variable to be ticked in the event of patient death	Deaths must always be recorded on the Patient Form **and again** on the Follow-up Form if patients were hospitalised at time of death.
Related to HIV	Yes/ no/ not specified	
Date of death	In dd/mm/yyyy format	
Cohort discharge	End of patient follow-up	Patients are classed as “discharged” (i.e. withdrawn from the cohort group), if they leave the program definitively (e.g. in the case of infants diagnosed as HIV negative, or if patients relocate geographically and are transferred elsewhere. NB: Do not record deaths under “transferred-out”; they must be recorded under “Deaths”.
Date of cohort discharge	In dd/mm/yyyy format	
Decentralized	Patient is followed in a decentralized location	Patients are classed as “decentralized” when they continue to be followed in the program and their follow ups are still entered in the same database but in a location identified as “decentralized”, ie: health centre.
Date of decentralization	In dd/mm/yyyy format	
Decentralized to	Location where patient has been decentralized	
User data		
Free variables	10 free variables giving other patient information.	Variables and codes to be defined at the time of creating the database (cf. II.2.3)
Notes	Free text	

Table 2: Follow-up Form

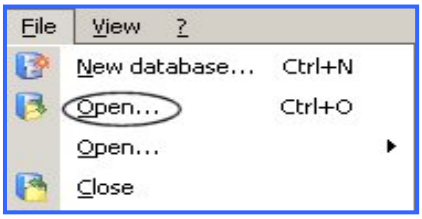
Name of Variable	Details	Comments
Patient Identification		
ID Cohort	Unique patient number	
ID Other	Number or text allowing patients to be identified by means other than the ID cohort number.	The recommendation for confidentiality reasons is that patient names are not used in FUCHIA.
Programme	Details to be given if the patient is included in a specific program (e.g. MSF ARV / non-MSF ARV).	Codes to be defined at the time of creating the database (cf. II.2.2).
Admission and follow-up		
Type	Consultation/ hospitalisation	To be filled in: - at each consultation - at each hospital discharge In case of hospitalisation, fill in one single form when the patient is discharged. Do not give details on various consultations given whilst the patient was hospitalised.
Location	Locations where visits take place	Codes to be defined at the time of installing the software (cf. II.2.2).
Date of visit / start of hospitalisation	In dd/mm/yyyy format	For consultations, this corresponds to the date when the consultation took place. For hospitalisation, this corresponds to the date when the patient was admitted.
Visit	On time, late, unplanned or not specified	Punctuality is measured by comparing the date current visit with the date of next appointment given on the previous visit.
Date of next appointment	Date of the next scheduled appointment following consultation/ discharge from hospital.	Allows FUCHIA to determine whether patients are lost to follow-up.
Referred to	Referral system in which patients, following hospital discharge / consultation, are referred outside the program.	Codes to be defined at the time of creating the database (cf. 2.2.2).
Discharge (if hospitalised)		
Status	Status on discharge: transferred, absconded, died, terminal stage or medical agreement	To be filled in only if the patient is hospitalised: If applicable, deaths are recorded on the Patient Form.
Date of discharge	In dd/mm/yyyy format	
Biological results		
Date of blood collection	In dd/mm/yyyy format	Blood test results must be recorded on the Follow-up Form nearest the date when the test was actually performed (i.e. the next visit). They are to be recorded once and only once.
Lymphocytes	/mm3	Those variables are seen under the tab “Lab tests”
CD4	/mm3	
CD4%	If not entered directly, will be calculated automatically based on total lymphocyte count and CD4	
Viral load	copies/ml	
HBsAg	Positive, negative, not done, not specified	
Glycosuria	0,1+,2+,3+ or NS	
Proteinuria	0,1+,2+,3+ or NS	
ALAT (SGPT)	UI/ml	
Creatinine		
Unit	Unit of creatinine: mg/dl or µmol/l	
Haemoglobin	g/dl	
Test	HIV test performed: DNA PCR, Ultra sensitive agP24, antibody test, RNA viral load, Immunocomb, NS	Those variables are seen under the tab “HIV tests (PMTCT follow up) and are exclusively for the follow up of babies born to PMTCT mothers.
Result	HIV test result: Negative / Positive / Invalid / Not done / NS	
Clinical conditions during this follow-up visit		
Diagnosis	Diagnosed WHO diseases: new/ ongoing/ recurrent: - New = new event that has never been previously diagnosed. - Recurrent = new episode of a disease previously diagnosed	Select from list on drop-down menu WHO stages are automatically calculated on the basis of clinical events diagnosed during patient visits. The cumulative WHO stage is also calculated automatically, and takes into account the current visit, all preceding visits and the patient’s medical history.

WHO	WHO clinical staging at visit (1 / 2 / 3 / 4 / NS)	This field allows staging the patient without using the OI list on a given visit.
Other diagnosis	Free text	
Weight	Kg	To be reported regularly if clinical progression is to be monitored over time.
Height	Cm	To be reported: For adults – on one occasion (first visit); For children – at each visit.
Active testing for TB	Sputum sample/ lung X-ray/ other/ not specified	To be completed each time active testing for TB is performed.
Mother to Child Program		
Mother to Child Program		To be ticked at the first visit when pregnancy is confirmed, then at every visit up until six months following delivery (or until mother stops breastfeeding).
Amenorrhoea	No. of weeks	
Breastfeeding	Type of feeding (Breast/bottle) : exclusive, replacement or mixed	
Treatment prescribed or stopped during the visit		
Drug	To be selected from the list of drugs.	Codes of PMTCT prophylaxis: see chapter 5, §5.2.2
Prescription	Codes are as follows: treatment begun, continued, continued with intolerance, restarted, stopped for intolerance, stopped for failure, stopped for non-compliance, stopped for patient reason, stopped for pregnancy stopped for end of treatment, stopped for TB regimen, stopped for other reason.	If treatment is ongoing, it must be systematically recorded as “continued”, regardless of the type of visit (consultation or hospitalisation) even if a continuation prescription is not given (because it is not yet needed). NB. The reason for treatment discontinuation must be specified, as, during analysis, the patient may only be considered for “treatment discontinuation”, if the reason for stopping treatment has been specified. <u>Stopped for non-compliance</u>: decision to stop taken by the doctor as a result of non-compliance <u>Stopped for patient reason</u>: on the patient’s request
Intolerance 1 Intolerance 2	To be selected from the list of intolerances. Two types of intolerance may be entered for each drug.	The type of intolerance must be recorded, regardless of whether or not a drug has been discontinued due to intolerance. See the case definition given in the Appendix
Intolerance	Any additional drug intolerances	
Supplementary nutrition program	Variable to be ticked if the patient has received food during the visit.	
Percentage of ARV missed	A set indicator within the program (e.g. % of capsules not taken)	Allows patient compliance to be measured. A clear definition should be written down by the programme medical coordinator to ensure that the same definition is used over time.
User data		
Free variables	10 free variables to be recorded at each follow-up, and which give other information on the patient.	Variables to be defined at the time of creating the database (cf. II.2.3)
Notes	Free text	

3.3. Data Entry

3.3.1 Opening the database

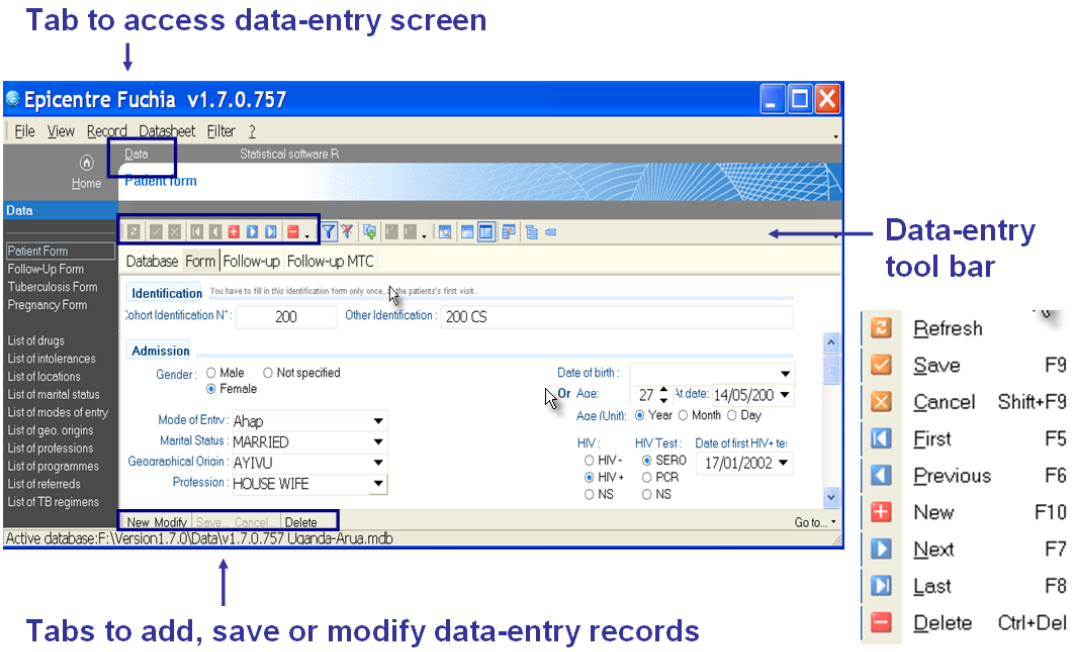
All FUCHIA databases are in an Access format and are named with the suffix (.mdb). These databases however, can only be opened in FUCHIA and not directly using Access, or by clicking the file using Windows Explorer. To open



Go to File\Open and select database using the browser. Once opened, the database name and access path will be displayed at the bottom of the screen. Each subsequent time FUCHIA is opened, this database will open automatically.

3.3.2 Accessing data entry screens

To enter data, go to menu "Data" at the top-left of the screen. This will give you access to the data entry screens of the four forms and the lists of pre-defined codes (see chapter 2, implementing FUCHIA). Click on the form required (e.g. Patient Form).



- ◊ The above input screen will appear with the tab "Form" highlighted. This is one of the options for data-entry and here the variables are displayed as it appears on the paper form.
- ◊ "Database" is the alternative data-entry screen and the variables and data are displayed as a spreadsheet.
- ◊ Switches can be made any time between the two options.
- ◊ For the patient form, two other tabs are shown, "Follow-up" to list the follow-up visits recorded on the "Follow-up" form of the patient selected and "Follow-up MTC" lists the data relating to PMTCT follow-up of the patient.
- ◊ The data-entry screen will be blank if no data had been entered previously.
- ◊ If data is entered, to view through records, use the arrow icons on the data entry tool bar.

3.3.3 Entering new data

1) To enter data related to a new patient, a new visit, a new episode of TB or a new admission to the PMTCT programme, go to the relevant form and click on "New" at the bottom of the screen and an empty data-entry screen will open. Specific instructions to complete data-entry of each form are given earlier in the chapter.

2) If the data is of a new patient, whose NID was not previously recorded in FUCHIA, first register the patient NID by opening a new patient form and entering and saving the NID on the input field “Cohort Identification n°”.

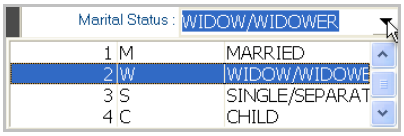
3) If data is of a new visit, a new TB episode or a new admission to the PMTCT programme, it is mandatory to first select the patient NID from the drop down list of previously recorded patient Ids. If the NID is not listed, then register the patient id as described above before further entry.

4) The following are general instructions for data-entry.

Date

When entering dates e.g. “Date of birth” a calendar will appear on screen. Select the month and year via the arrows at the top of the screen and then click on the relevant day, or enter the date directly using the format “dd/mm/yyyy” in the variable input field.

Drop-down list



Certain variables are pre-coded in FUCHIA (eg marital status, geographic origin, ARV drugs). When entering data on these variables, a drop-down list will appear listing the numeric as well as the short and long text codes. Using the arrows, move down the list to highlight the value required and left-click on the mouse.

Tick Box

Tick box entry is used to enter values for variables such as gender and HIV status. To enter, left-click the required option.

The default setting for these variables is “not specified”. If value is not known, leave input field as it is.

Free format

Combinations numeric and text can be entered

Free variables

The variables in the Free Variable section are free-format. The entries can be a combination of text and numeric. However, ensure the information is always entered in the correct entry field each time.

5) It is not mandatory to enter all the information of one form at one time. The minimum requirement for entry of each form are:-

Patient form	NID
Follow-up Form	NID, date of visit
TB form	NID, TB regimen prescribed, start date of TB regimen
PMTCT form	NID, date of admission to PMTCT program

Checks

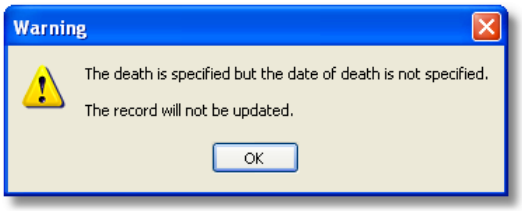
To ensure data quality at data entry, checks are in place within FUCHIA for certain variables. These checks come in the form of range or logical checks.

Further, certain sections (for example ARV treatment) have to be entered and saved before moving to other sections.

► When entering hospitalisation information in the Follow-up Form, FUCHIA obliges the user to enter all information relating to hospitalisation (type of visit, date of admission to hospital, date of discharge from hospital and reasons for discharge) at once.

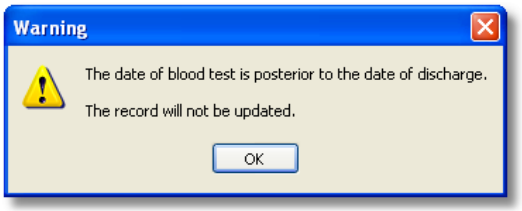
► FUCHIA prompts warning messages when a date is required:

- HIV test result
- Age at a given date
- Death, discharge, decentralised
- Laboratory results



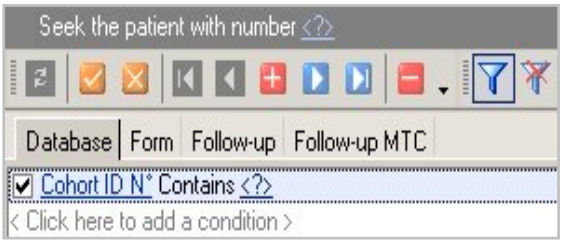
► As well as when a date is specified and

- no laboratory result is specified
- no HIV test result is specified
- the date of blood collection is after the date of visit or date of discharge from hospitalisation



3.3.4 Modifying data already entered

To modify an entry already entered in FUCHIA:



1) Find the record(s) of interest by entering the patient NID either on the statement "Seek the patient with number <?> or below Cohort ID No Contains <?>. Enter the NID in the space <?>, and FUCHIA will filter the database, and list all records relating to that NID.

In doing so, all forms except the Patient form, may have several entries (visits, TB episodes, PMTCT admissions) for the same patient. In this case, to move from one entry to the other, use the arrow icons on the data-entry tool bar.

2) Either click on the modify tab at the bottom of the screen and alter the entry or do so directly.

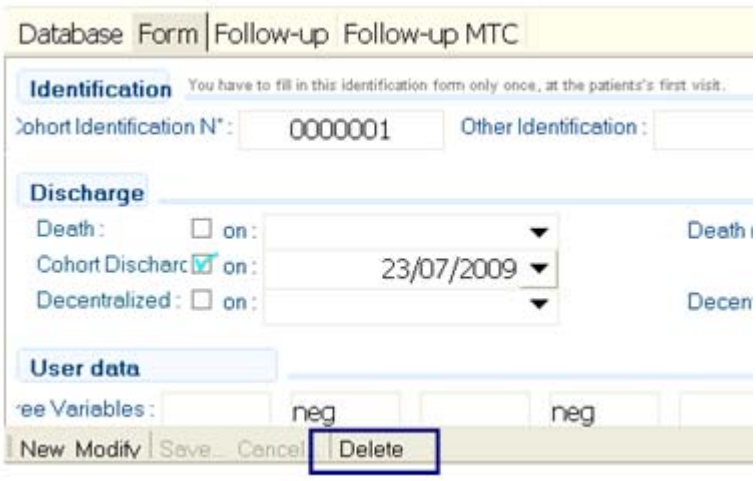
3) Click on the save tab to save the modifications or the cancel tab to return to the original data.

3.3.5 Saving

After entry click on “save” at the bottom of the screen to save the data.

1) When entering and saving a new patient NID, if the system detects any discrepancies in data entered in the first part of the form, an error message will be displayed. Before this record can be saved, these discrepancies must be corrected. If no discrepancies are identified, you will be asked to confirm the Patient ID number by re-typing the NID.

3.3.6 Deleting



To remove all information recorded on one patient from the database, go the patient form, identify the patient as shown above and click on the delete option at the bottom of the FUCHIA data-entry screen. Be careful as there is no undo option.

To remove all information from one patient visit, or one TB episode or one PMTCT admission, go to the specific form, identify the form and click on the delete option.

To remove some information from one patient visit, or one TB episode or one PMTCT admission, follow the instructions to modify data.

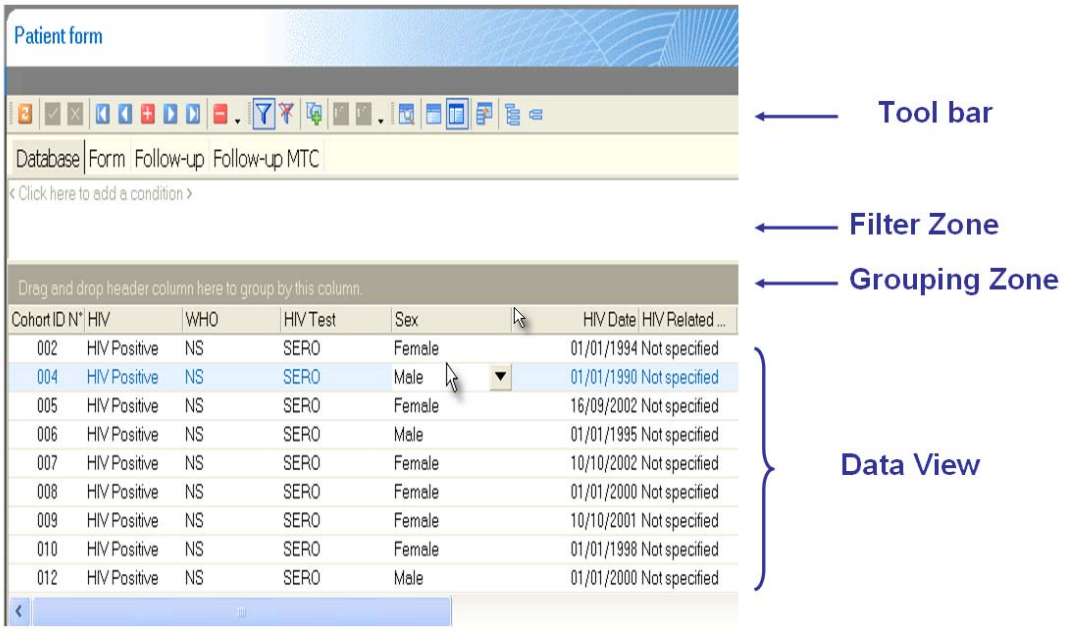
4 – FUCHIA DIRECT

FUCHIA direct enables the user to query the database and enables the user to view, list or tabulate data according to certain criteria. An example of a query can be to identify patients whose gender was not specified, to list visits between 01/04/2010 and 01/05/2010 or to count the number of admissions in the PMTCT programme over a certain period.

4.1. Accessing FUCHIA Direct

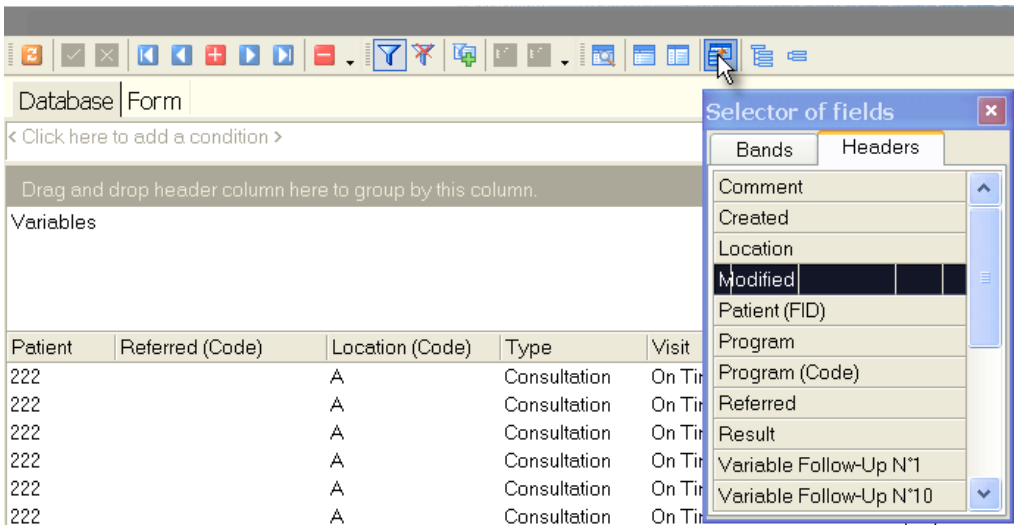
1) From the FUCHIA home page, go to Data and select data-entry screen (Patient, Follow-up, TB, PMTCT) of interest, and click on the "Database" tab to view the form in database mode. As shown below the data from each of the forms is organised as a spreadsheet with each column representing a variable.

2) At the top of the screen, is a tool bar, with icons for scrolling or filtering records. The white area beneath the tool bar is the filter zone and the dark grey area is the grouping zone. The functionality of these is explained later in the chapter.



4.2. Discard and Retrieve Variables

1) With the spreadsheet format, not all variables relating to the form are visible. This is particularly true for free variables. To identify these, go to the FUCHIA toolbar, click on the field selector, and a list of variables will appear. To include a variable in the data view, left-click with the mouse the variable of interest and drag it from the list to the light grey zone area where the variable headings are listed and insert between two variables by releasing the mouse.



NOTE: Not all variables can be viewed using this function. Data on treatment and diagnoses can only be viewed and analysed once the data is exported to another software (see chapter data exports).

2) To remove variables from the data view, left-click on the variable name heading and drag and drop the variable in the filter zone.

Note: This is only a display screen, so removing variables from the view will not delete the information from the database.

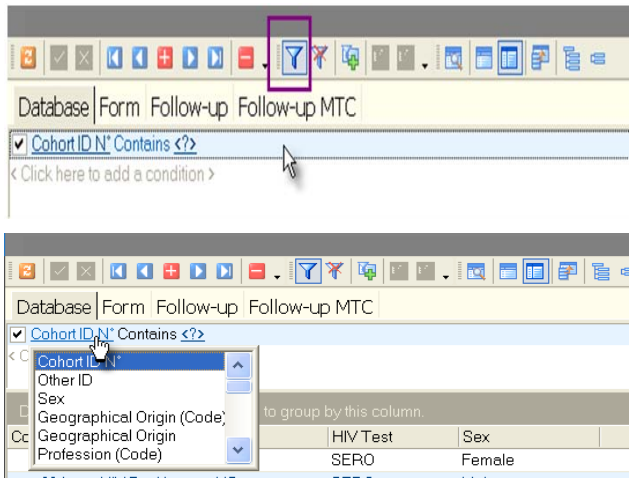
4.3. Header Column Manipulation

1) To change position of the variables in the data view, left-click column header and drag to the position you want to place the variable and release mouse.

2) To modify the size of the columns, left-click the space between two column headings and drag and release mouse to elongate or diminish the width of the column.

4.4. Data Selections

To search or select specific information with each form, the data filter has to be activated and a condition set by which to subset the data.



1) Activate filter by clicking on the funnel icon or directly by clicking on the area marked <click here to add a condition> in the filter zone.

2) A first filter will appear (shaded blue), with a tick box, and a statement "Cohort ID No" Contains <?>". This statement is the condition by which the data is to be selected. To complete this statement, just enter the patient NID in <?>, and the information specific to that person will be listed in the data view.

3) The filter statement consists of a variable name, followed by a condition containing an operator and a value or date, and can be adapted for different selections. Click on "Cohort Id No" to first select the variable and a drop down list of variables will appear. Select the variable of interest e.g. sex. Next select the operator, by clicking on "Contains". Another drop-down list will appear, with different options. These options will vary according to the format of the variable selected. See the list below. Highlight one of the options, and then click on <?> to get a list of values.

FUCHIA Data operators

Categorical Variables	Text Variables	Dates
Equal	Begins with	Between the
Is different of	Contains	Is empty
Is not specified	Does not contain	Is not empty
Is specified	Finishes with	Included in the last 7 days
	Is not specified	Included in the last month
	Is not specified or empty	Included in the last week
	Is specified	Included in the next 7 days
		Included in the next month
		Included in the next week
		the
		the or after the
		the or before the
		Included in the current month
		Included in the current week
		today
		tomorrow
		yesterday

Examples of FUCHIA Filter Statement

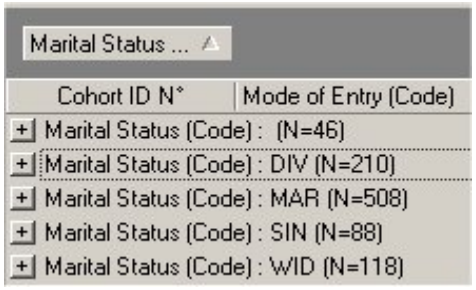
☑ Birth Between the Friday 01 January 2010 and Tuesday 10 August 2010
☑ HIV Equal HIV negative
☑ Sex Equal Male
☑ Cohort ID no Begins with 2

4) To include additional filters, re-click on the line <click here to add a condition> or click on the icon "append a filter"  .

5) To remove a filter, either click on the tick box next to each individual filter condition or click on the icon  to show all records.

4.5. Data tabulation

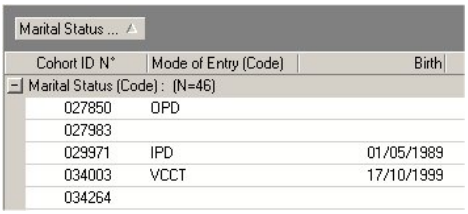
The other function in FUCHIA Direct is to group patients according to values of a selected set of variables. This is useful for knowing the number of patients with a certain condition and is far quicker than having to list them using the filter option and counting them by hand. However with very large databases, this option will take time, sometimes impossible.



1) Left-click on the column heading and drag the variable of interest for example marital status to the grouping zone and release.

2) This will give you the number of patients grouped according to marital status. In this example given, 46 patients' marital status was not specified, 210 were divorced, 508 were married, 88 were single and 118 were widowed.

3) The total is given at the bottom of the screen: N: string = 970



4) To obtain the list of the patients whose marital status is not known; click on the + sign to the left of marital status and this will display a list.

5) To return to the data summary, click on the – sign left of marital status.

6) To remove this calculation from your screen, left-click "Marital Status" (located in the grouping zone) and drag it from the grouping zone back to insert the variable between column headings.

4.6. Printing/Data Export

There are 2 ways for accessing the printing option. Either, go to the view menu and click on print or bring the printing icon to the tool bar by going to the view menu → toolbars → check the toolbar standard. It will bring the icons related to printing to the toolbar.

Printing directly selected list does not work. Instead an option is given to save the list as an Excel file.

5. R SOFTWARE

List of figures

List of tables

R is a programming language and an environment for statistical computing and graphics. It is distributed freely under the terms of the GNU Public Licence of the Free Software Foundation, and development and distribution of R are provided by several statisticians known as the "R Development Core Team" that has existed since mid-1997.

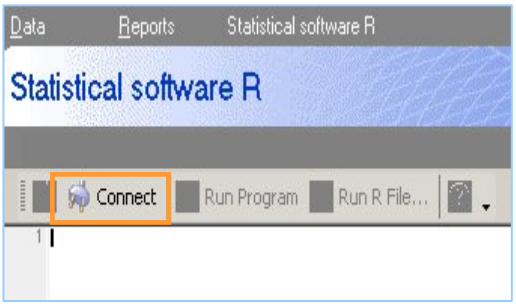
R was coupled with FUCHIA to allow greater flexibility in analysing FUCHIA data. With R it is possible to run standardised or user-written R programs or obtain ad-hoc information directly from the database using R interactively.

For further information go to **http://www.r-project.org/** The distribution of R is also accompanied by various manuals, and help is available from various "mailing lists" and R archives.

5.1. Accessing "R" software

1) Click on the tab "Statistical software R" on the FUCHIA home page.

2) The R software is automatically installed when FUCHIA is installed, However to execute R, the R software has to be actively connected to the current database opened in FUCHIA. To do so, click on the icon "Connect".



3) The following message will appear informing that the current database is connected to R and it indicates as well where the output directory and the database are located.

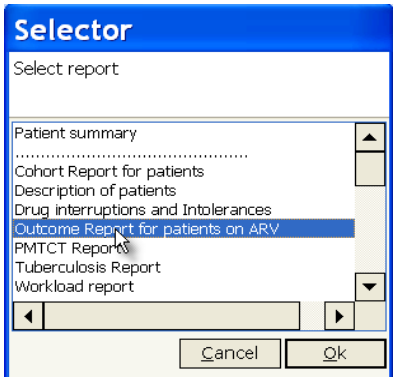
```
Dossier en cours (toutes les sorties ou fichiers sont envoyés dans ce dossier):
  > "C:/Epicentre/Fuchia/v1.7.0/Output"

>
>
>
Connection to database:
  >"D:\Users\Temp\BASES ORIGINALES\v1.7.0 844\v1.7.0 844 Résumé_test (backup 170844).mdb" Actived.
```

Note:

R is an interactive language, therefore always wait for the prompt ">" to execute new commands.

5.2. Running Standardised R Programmes

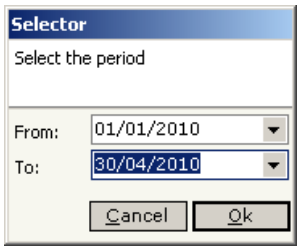


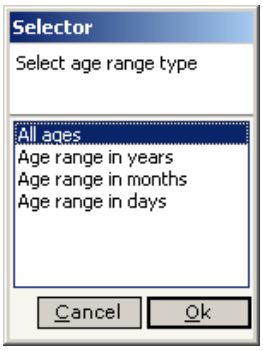
The standardised programs in R produce automated reports containing standard indicators, lists of patients or visits, check-lists for data verification and data exports.

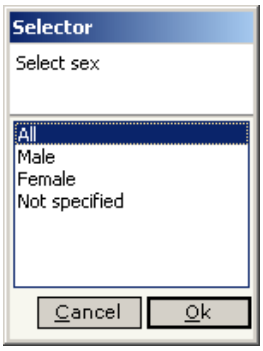
1) Once R is activated, click on "Run Program" to obtain the list of pre-written R programmes that generates reports, lists, checklists and exports.

2) To run a programme, select the relevant automated program and click OK.

3) Several dialogue boxes will open in succession, allowing you to specify data parameters for calculations and subgroup analysis. See 5.2.1 Data selection for further details.







4) Once selections are made, the entire R programme will run through on-screen. This may take some time, depending on the size of your database, the speed of your computer, and whether you are running on AC or battery power.

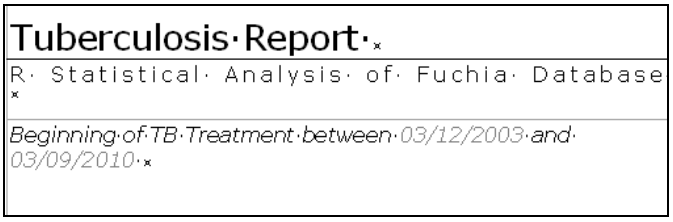
5) Whilst running R programmes, additional dialogue boxes may appear on screen or as minimised icons on the tool bar at the bottom of the screen. These require a response from the user (i.e. to specify analysis period, file name, etc…) and the program will not execute further without it.

To display click on the minimised icon and give a response to the question posed. The programme will now continue to run.

For example, certain reports also provide list of patients. If number of patients on list exceeds 100, the following message will appear, asking you to specify if the list should be added to the report.

6) The output (reports, exports, check-lists) are saved in the default output directory specified at the time when FUCHIA was installed (see chapter 11.3 Software Installation). In some instances, a browser window will open and the user will have the option of saving either in the default directory or in a user-specified directory.

7) The front page of each report will specify the name of the report, as well as the selections made to generate the report. For example, the following reports on all patients (both males and females of all ages) starting TB treatment between 03 December 2003 and 03 September 2010.



The selections are also displayed at the top of each table or figures given in each report. Please note that for example if you select a report for adults above 30 years of age, the standard tables will still report age group to be above or equal to 15 years of age, as shown below.

1.1 Distribution of patients by age group and HIV status

Patients who initiated ARV between 01/01/2008 and 01/02/2008, Sex Male, Age between 30 and 120 years

HIV	<12 months		≥12 to <18 months		≥18 to <60 months		≥5 to <15 years		≥15 years		Not Specified		Total	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
HIV Negative	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
HIV Positive	0	0.0	0	0.0	0	0.0	0	0.0	28	100.0	0	0.0	28	100.0
Not specified	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Total	0	0.0	0	0.0	0	0.0	0	0.0	28	100.0	0	0.0	28	100.0

5.2.1. Data selection

To generate automated reports (or produce lists or data exports), R will prompt the user for some information (data parameters); some parameters are required to produce information for the reports (report parameters) and others are required to subset the data for analysis or to export (patient parameters).

Report parameters

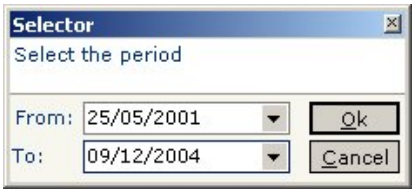
Table 1 lists the parameters requested by R for each of the reports. These are the report period, interval length, date of analysis and the definition for lost-to-follow-up (LFU).

If no selection is made, analyses will be performed of all patients over the whole period from the date of first recorded visit to date of last recorded visit in the database with a date of analysis set to the current date or the date of last recorded visit in the database.

Report period: defines either a cohort of patients or a span of visits. For example, in the cohort report for Pre-ART patients, the report period is selected from date of entry in the programme, whereas in the workload report, it is defined by the date of visit or date of hospital admission. For the list of patients by next visit, the report period is based on a period of dates of next appointment.

The report period will cover all dates from first visit recorded in the database up-to date of last recorded visit in the database. If dates are specified outside this range, FUCHIA will automatically take a period in the valid range.

For monthly analysis, ensure the start and end dates in the report period are given as the first day of the first month and the end date of the last complete month (i.e. 01/06/2009 and 30/11/2009).



To specify a period, either enter the date directly using the format “dd/mm/yyyy” in the input field From: and To: or click on the downward arrow to obtain a calendar.

Interval Length: indicates the interval by which the report period is to be divided for the cohort and workload report. The options are monthly, bi-monthly, three-monthly, six-monthly or yearly.

Ensure the selected period and reporting intervals correspond (you cannot request an analysis period of 3 months and a report interval of 2 months. If in doubt, select the option monthly.)

Table 1: List of report parameters by report type

Report parameters	Workload	Patient description	Cohort Report	Outcome Report	Drug interruptions / Intolerance	TB	PMTCT	List by next visit	List of OIs
Report period									
Date of visit or hospital admission	X			X	X			X	X
Date patient entered cohort		X	X						
Date patient initiated ART		X	X						
Date patient decentralised		X							
Date patient began TB treatment						X			
Date patient entered PMTCT programme							X		
Date of delivery							X		
Interval length	X			X					
Date of analysis			X				X		
Lost-to-follow-up definition			X	X					

LFU: This is to define when a followed patient becomes lost-to-follow-up. It is calculated using the date of next visit and the options of 1, 2, 3 or 6 months refer to those patients who did not attend their last scheduled appointment, and who are overdue by 1 month, 2 months, 3 months or 6 months. For further details on how LFU status is calculated, go to section 5.2.2 data calculations.

Date of analysis: is required for the cohort and the PMTCT report. This is the date of end of observation for a given report by which each patient's outcome is analysed. Note that for the outcome report, the date of analysis is defined automatically as the last date of the period selected.

Population parameters

R will prompt the user to specify the population parameters that permit the analyses of specific groups of patients. These population parameters are gender, age, programme and location. With the exception of gender, the other 3 parameters vary depending on the report that is generated. Table 2 outlines what they are.

Gender: Analysis can be restricted by gender with the options to generate reports or exports specifically for males, females or for those where sex is not specified.

Age: Generally speaking this refers to the age of the patient when a certain event occurs for example age at entry, age at ARV initiation or age at decentralisation. Therefore if "age>=15 years" is selected for the cohort report of pre-art patients, then this restricts the analysis to all those patients who were 15 years or more at programme entry. Similarly in the workload report, only those visits or hospitalisations where the patient matched the age criteria are reported.

Programme/Location: Selection of programme and location are similar to age. If selected, this refers to the programme or location where a certain event took place for example location at entry, location at ARV initiation or location patient decentralised to or visit location.

Note:

In order to perform accurate subgroup analyses, it is important that this information is complete and correctly entered in FUCHIA. Otherwise, when selecting certain subsets of data for example males entering in the MSF programme during 2007, those observations with missing gender or programme at date of visit would not be included.

Table 2: List of population parameters by report type

Population parameters	Workload	Patient description	Cohort Report	Outcome Report	Drug interruptions / Intolerance	TB	PMTCT	List by next visit	List of OIs
Gender	X	X	X	X	X	X			
Age									
Age at visit or Age at hospital admission	X				X				
Age at entry to cohort		X	X	X					
Age at ARV initiation		X	X	X					
Age at decentralisation		X							
Age start of TB treatment						X			
Programme / Location	1	1	2	2	1				
Drug interruption / intolerance recorded on a visit on that programme and location					X				
patient visited at least once in the period selected	X		X	X					
where patient entered the cohort	X	X	X	X					
where patient initiated ART		X	X	X					
where patient was decentralised from		X							
Opportunistic infection/illness									X

1 – Option for selection of programme and location, 2 – Option for selection of programme only

5.2.2. Data calculations

Description of key variables calculated in FUCHIA for R reports and R exports are given below.

Age

When date of birth is not known, the age of a patient at a specific date of visit is recorded and from this information FUCHIA calculates a date of birth and calculates the age of a patient at each visit and at each event (program entry, ART initiation, decentralisation, at last visit etc).

Age (in years) at each visit for example is calculated using the following formula from the date of birth and the date of visit

agev=(datvisit-datbirth)/365.25

Age (in years) at an event (e.g.) is calculated using the same formula from the date of birth and the date of entry in the program

age_entry=(dat_entry-datbirth)/365.25

ART variables

All variables relating to ART status (patients having initiated ART, date of ART initiation, ART period) are calculated using the information recorded in the section “ARV prescribed” either in the Patient or the Follow-up Form and FUCHIA considers any ARV regimen (mono, bi or tri therapy) as ART.

ART Naive/ART Experienced: Any patient with any recorded ARV history in the Patient Form are considered ART experienced at program entry and any patient with no recorded ARV history as ART naïve.

ART/Pre-ART patients: Patients who initiate any ARV regimen during follow-up in the programme are referred to as ART patients or ART initiated. Pre-ART patients are those that have not initiated an ARV regimen during their follow-up in the programme or by the data of analysis. Patients who are ARV experienced at programme entry will also be classified as Pre-ART up-to the time they initiate ART in the programme. Further, Pre-ART patients are also those who have never initiated ART.

ART/Pre-ART period: The period from programme entry up-to to ARV initiation is called the pre-ART period and the subsequent period from ARV initiation to end of follow-up or date of analysis is the ART period. Patients who never initiate ARV are also classified in the pre-ART period.

Note:

- Any ARV drug added in the drug list using the free “AA” variables will be taken into account in the reports.
- Any ARV drug added in the drug list not using the free “AA” variables will not be taken into account in the report.
- Any non-ARV drug added using the free “AA” variables will be analysed as an ARV drug.
- The 4 drugs “AZTMTC”, “NVPMTC”, “3TCMTC” and “NADMTC” are not considered as ARV used in ART. There were created for PMTCT when ARV drugs are given in a

short course (days or weeks). Patients prescribed one of these drugs are not considered on ART and therefore are not analysed in the reports analysing patients on ART. They are analysed in the reports analysing patients from entry.

Laboratory results

Laboratory results are entered in the Follow-up Form in FUCHIA once the test results are returned to the clinic. As a consequence the date of visit in which the information was entered might not match the corresponding date where the sample for the laboratory test was taken. When presenting or exporting laboratory results for a given date (e.g. date of visit, date of ART initiation, date of last visit), FUCHIA performs a search in the database to find laboratory test performed nearest to that date. A default of 90 days is used to perform the search, with the exception of the Patient Wide export where the user can specify 30, 60 or 90 days.

CD4% in description and cohort reports: CD4% value is taken if entered. If no data is entered, then the program calculates it using CD4 absolute count and total lymphocytes (CD4*100/Total Lc.).

Weight, Height, BMI

Weight and height are not available for every visit. Therefore when presenting or exporting this data at a specified date, FUCHIA orders by date of visit and takes the last recorded value for any subsequent visits with missing data for weight. With height, FUCHIA performs a similar task as to weight, but if a last recorded value is not available it searches subsequent visits and takes the first recorded value.

Once missing weight and height are imputed for every visit, body mass index for adult patients (age >=15 years) are calculated using the following formula.

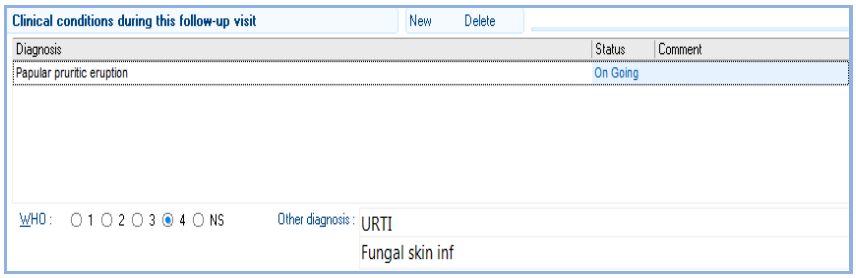
BMI (kg/m²) = (weight in kilograms) / (height in meters x height in meters)

WHO Staging

The clinical condition of the patient at each visit or prior to program entry is entered using a drop-down list of opportunistic infections (OIs) or entered directly (see below). From this information, the cumulative WHO staging is calculated, and takes into account the current visit, all preceding visits and the patient's medical history.

List of opportunistic infections

Direct entry of WHO staging



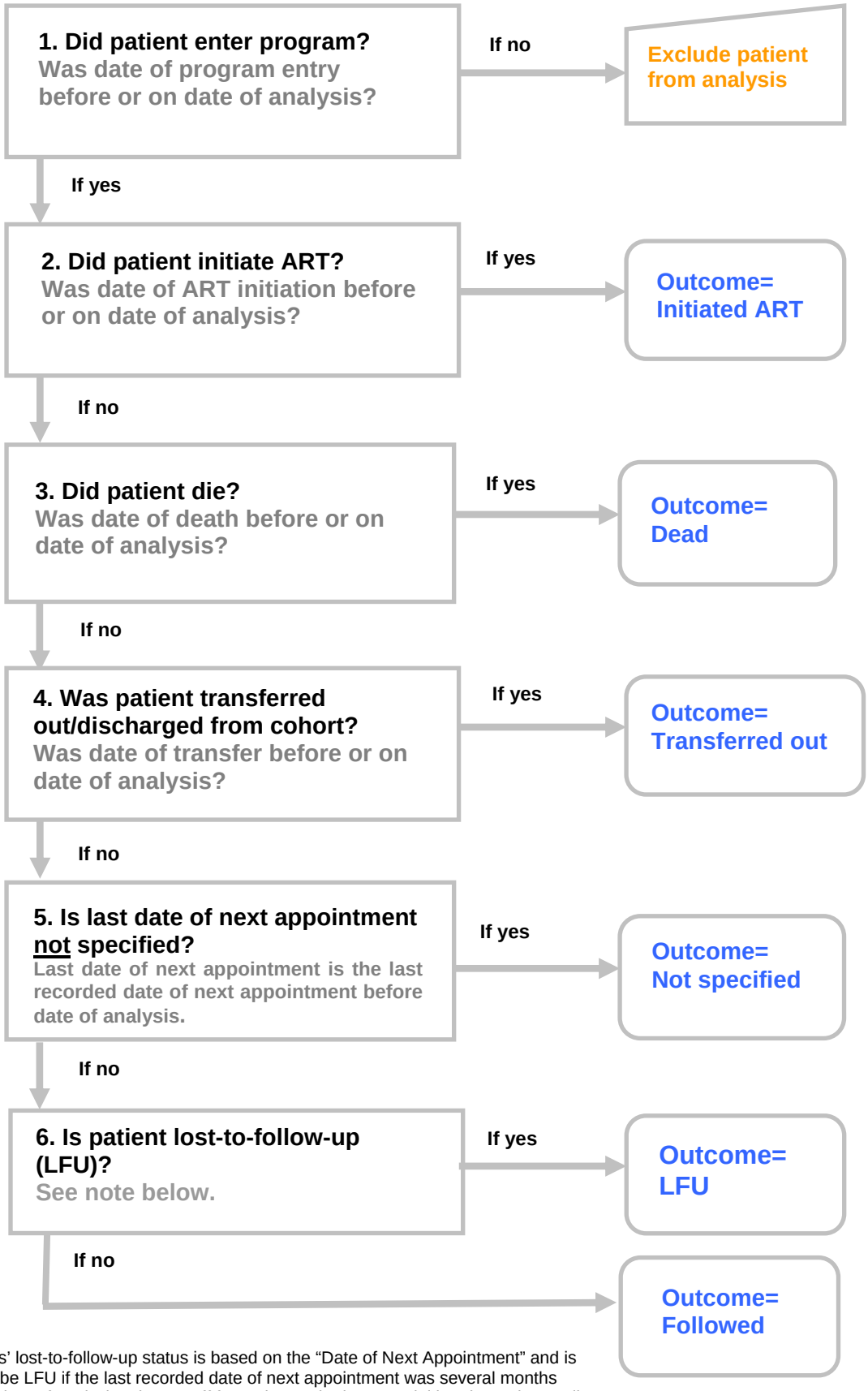
If at any visit, clinical condition is entered using both the direct field and the list of OIs, FUCHIA will then take the maximum value recorded to calculate the WHO staging at visit and the cumulative WHO staging.

Patient outcomes

Patient outcome is a key indicator for patient monitoring and programme evaluation. The variables required to define patient outcomes are date of analysis, date of death, date of discharge; last date of visit and last date of next visit prior to date of analysis, and a cut-off period to define lost-to-follow-up.

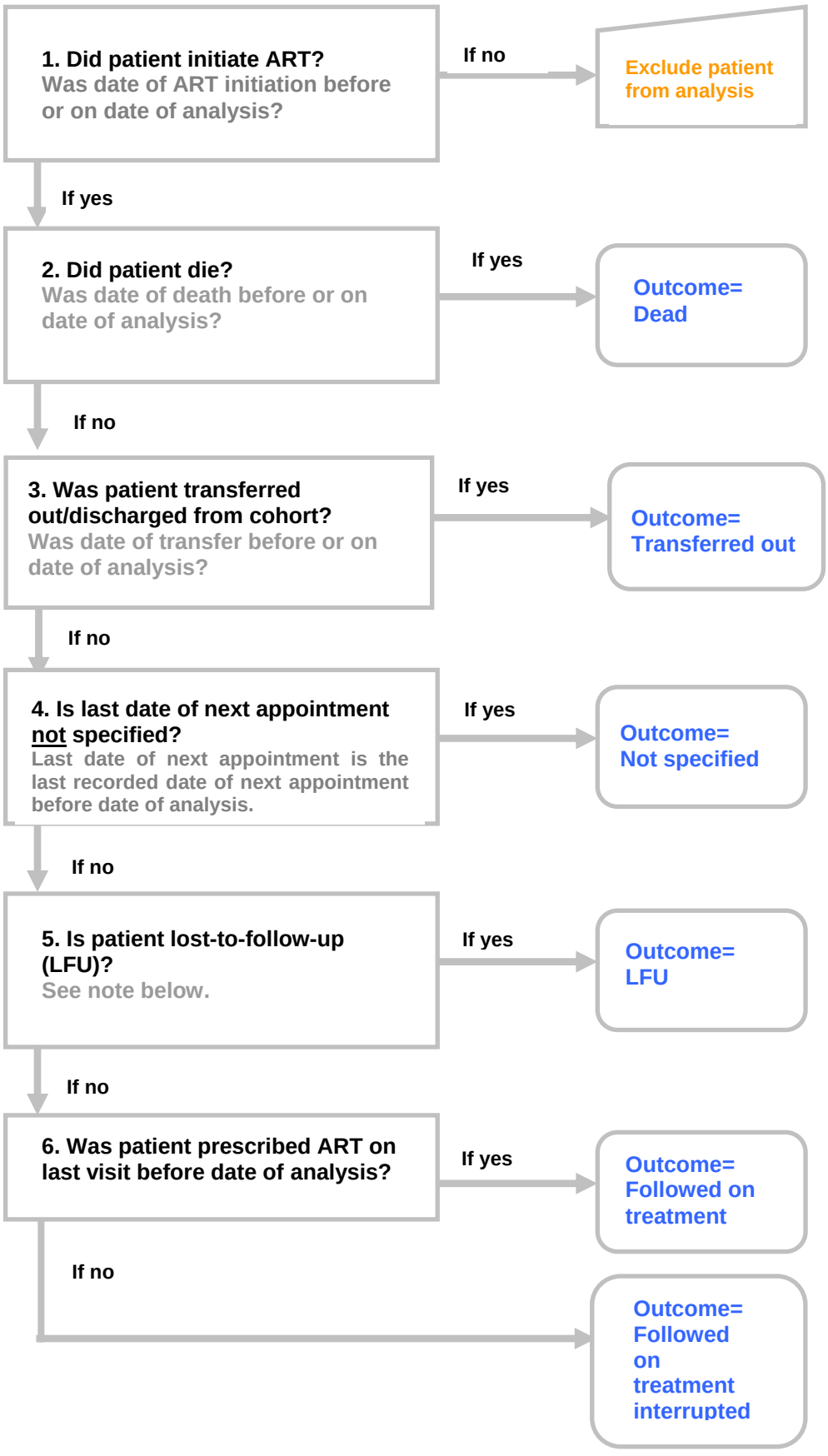
The following flow-charts (Figure1 and Figure 2) illustrate how patients are classified according to patient outcomes from programme entry or ART initiation at a specified date of analysis using the variables listed above.

Figure 1: Flow-Chart to illustrate patient outcomes from program entry



Patients' lost-to-follow-up status is based on the "Date of Next Appointment" and is said to be LFU if the last recorded date of next appointment was several months before date of analysis. The cut-off for patients who have not initiated ART is usually 6 months, therefore, if the date of analysis is 31/12/2009, a patient is said to be LFU if the last recorded date of next appointment was before 30/06/2009.

Figure 2: Flow-Chart to illustrate patient outcomes from ART initiation



Patients' lost-to-follow-up status is based on the "Date of Next Appointment" and is said to be LFU if the last recorded date of next appointment was several months before date of analysis. The cut-off for patients who have initiated ART is usually 2 months, therefore, if the date of analysis is 31/12/2009, a patient is said to be LFU if the last recorded date of next appointment was before 31/10/2009.

5.2.3. Programme running times

The programme **running times** (FUCHIA reports, "R" analyses, Exports) depend upon the size of the database being analysed and the complexity of the analyses or export and the speed and the power of the computer. As a guide, we have given the following examples.

Note:

For databases >= 100,000 KB, a 2 Gb ram is necessary to run "R" programmes.

Table 3: Programme running times

Database size (compressed)	Workload	Patient Description	Outcome Report	Cohort Report	Patient Wide Export*
5 MB (≈ 4,000 visits)	30 sec.	30 sec.	40 sec.	30 sec.	1 min.
20 MB (≈ 40,000 visits)	< 1 min.	< 2 min.	1 min.	2 min.	4 min.
30 MB (≈ 65,000 visits)	< 2 min.	3 min.	2 min.	3 min.	5 min.
60 MB (≈ 100,000 visits)	2 min.	5 min.	3 min.	6 min.	10 min.

*Patient wide export with exclusion of the background OI variables and the OI variables.

5.3. Using R interactively

The standardised reports in FUCHIA will meet the vast majority of needs. However, for ad-hoc questions, the data can be analysed either with the R exports, with FUCHIA direct or by interactive use of R. Although R is complex to learn and not a user friendly language for non specialists, the advantage is once the basics are mastered, many analysis and manipulations can be done without the need to export data.

In order to do so, it is important to first understand the structure of the database and then have a basic understanding of how to write R or SQL commands.

The following section aims to provide a brief overview of how R functions and an outline of how the user can use R to answer simple routine questions. For more advanced use, please refer to either the on-line help or the documents provided in the FUCHIA folder.

IF USING R INTERACTIVELY, ALWAYS MAKE A COPY OF THE DATABASE AND USE ONLY THE COPY FOR THE ANALYSIS TO AVOID LOSS OF DATA.

ALSO ENSURE ANY ANALYSIS PERFORMED IS VALIDATED.

5.3.1. The data model

FUCHIA is a relational database and the data are stored across multiple tables that are interlinked. In order to run R queries, it is important to first understand how to locate the stored information.

Refer to Chapter 5 Annex for an overview of the FUCHIA Access database and related tables**.** As this and Table 4 lists, there are 9 tables containing the information from the

patient, follow-up, PMTCT and TB forms. Each table is named beginning with “Tb”, and this simply refers to the fact that it is a table, followed by a text to indicate the type of data it contains (for example TbPatientDrug contains the drug prescription history recorded in the Patient Form. The table TbReference is similar to a dictionary file and contains the list of codes for all values coded in the database. The variables are named using the convention starting “Fdd” for dates, “Fds” for alphanumeric and “Fdn” for numeric.

Table 4: List of related tables in Access Database

Patient	Follow-Up	PMTCT	TB	
TbPatient TbPatientDrug TbPatientDiagnosis	TbFollowUp TbFollowUpDrug TbFollowUpDiagnosis	TbPregnancies TbBabies	TBFollowUpTb	TbReference

The arrows in the figure display how the tables link to each other. In most cases, the link matches the primary key from one table (which provides a unique identifier for each row), with an entry in the foreign key in another table. For example, each patient is linked by the FdxReference column in the table TbPatient (the primary key) and the FdxReferencePatient column (the foreign key) in either the TbFollowUp, TbFollowupTB or TbPregnancy tables.

The link can be one-to-one or one-to-many (∞). A one-to-many relationship is the most common and in this relationship, a row in table A can have many matching rows in table B, but a row in table B can have only one matching row in table A. For example, the TbPatient and TbPregnancy tables have a one-to-many relationship: each patient may have several admissions to the PMTCT program, but each PMTCT admission is related to only one patient. In a one-to-one relationship, a row in table A can have no more than one matching row in table B, and vice versa.

5.3.2. R basics

R objects

R is what is known as an "object-oriented" program where everything is treated as a type of object, including the results of analysis. The advantage being that the results can then be later displayed with other results or used for further manipulation.

For example, when performing a regression analysis with other statistical packages, a long line of output is displayed on screen. By contrast, the `lm()` regression function in R returns one object containing all the results: estimated coefficients, their standard errors, residuals, giving the user the choice to select which part of the object to extract.

To create and store an object, a name is assigned using the arrow-like signs `<-` and `->` as demonstrated in the example below. The sign used depends on whether the preference is to put the name first or last (it may be helpful to think of `->` as "put into" and `<-` as "set to"). The name used can consist of letters, numbers, and the "." character, but should not start with a number.

```
0.001 -> small.num                    #Stores 0.0001 under the name small.num
big.num <- 10 * 100                   #set big.num to 10000
big.num+small.num+1                   #big.num and small.num can now be treated
                                      as numbers, and used in a calculation
my.result <- big.num+small.num+2      #result of the calculation is stored in
                                      my.result
my.result                             #display result by typing name
```

R objects come in many forms. They can be variables (vector), arrays of numbers (matrices), character strings, lists, datasets (data frames) and functions. As a demonstration, type *ls()* from the R prompt in FUCHIA to list the objects currently in the workspace. The result is 2 columns giving the titles of the objects.

```
> ls()

 [1] "age.cut"                     "age.cut.labels"
 [3] "age.units"                   "analysis.at.art.initiation"
 [5] "analysis.at.decentralisation" "analysis.at.entry"
 [7] "analysis.times"              "blue.colors"
 [9] "blue.hue"                    "bmi.cut"
[11] "bmi.cut.labels"              "cd4.1.cut"
[13] "cd4.1.cut.labels"            "cd4.2.cut"
[15] "cd4.2.cut.labels"            "cd4tlc.1.cut"
[17] "cd4tlc.1.cut.labels"         "cd4tlc.2.cut"
[19] "cd4tlc.2.cut.labels"         "database"
[21] "database.is.dirty"           "database.last.modification"
[23] "date.fmt"                    "err"
[25] "interval.cut"                "interval.cut.labels"
[27] "intervals"                   "intervals.cd4"
[29] "intervals.flu"               "mt.filters"
[31] "n.day.by.month"              "n.day.by.year"
[33] "orientation.landscape"       "orientation.portrait"
[35] "orientations"                "patient.arts"
[37] "patient.naives"              "patient.periods"
[....]
```

To view an object, simply type the name at the R prompt.

```
> date.fmt
[1] "%d/%m/%Y"

> patient.naives
[1] "ARV Naive"     "ARV Non-Naive"

> database
RODBC Connection 1
Details:
  case=nochange
  DBQ=E:\Users\Temp\v1.7.0\Data\v1.7.0.725 Training.mdb
  Driver={Microsoft Access Driver (*.mdb)}
  DriverId=25
  FIL=MS Access
  MaxBufferSize=2048
  PageTimeout=5
  PWD=******
  UID=admin
```

As can be seen, `patient.naives` and `date.fmt` are character vectors containing 1 or 2 elements for labelling and formatting and `database` is the current FUCHIA database. Other useful commands for objects are:

```
attributes(object)              # Returns an object's attribute list.
length(object)                  # Provides length of object.
```

R functions

R Functions are used in almost any procedure and are also saved as objects. They contain lines of prewritten code and perform a specific task. For example the *plot()* function produces a scatter plot if applied to a simple list of numbers but if applied to the output of a regression analysis, will produce a series of plots on the various aspects of the regression output.

Many R functions produce results which differ depending on the **arguments** that are specified with them. Arguments are placed inside round brackets, separated by commas. Many functions have one or more *optional* arguments: that is, the user can choose whether or not to provide them. If an optional argument is not provided, there is usually an assumed default value.

```
plot(x, y = NULL, type = "p",  xlim = NULL, ylim = NULL,
log = "", main = NULL, sub = NULL, xlab = NULL, ylab = NULL,
ann = par("ann"), axes = TRUE, frame.plot = axes,
panel.first = NULL, panel.last = NULL, asp = NA, ...)
```

Most arguments to a function are named. For example, one of the arguments of the plot function is named type and the default is p for points. To switch to a line plot, simply replace `type="p"` with `type="l".`

To provide extra clarity, when using a function you can provide arguments in the longer form `name=value`.

R function can also be combined, with each one using the output of the last, resulting in a compound function. For example, consider the following

```
> nrow(subset(x03,z==1))
```

First the *subset()* function takes the data from the data frame `x03`, and extracts all those records for which the variable `z` has the value `1`. The resulting data is then fed into the *nrow()* function, which counts the number of rows. The net effect is to report the number of observations with *z* = 1 in the original frame.

R help

Almost all functions and objects automatically provided in R have a help page. To access the page type ? and the name of the object e.g.

```
> ?plot
```

or

```
> help(plot)
```

To see the examples posted on the bottom of the help page, type

```
> example(plot)
```

You can also access R help using the Help button on the R statistical software toolbar in FUCHIA.

R facts

R is case sensitive so care should be taken when naming or calling functions and variables.

Commands are entered in the command console and, are coloured red while results in the results console are shown in blue.

Once the database is connected to R, the command line prompt ">", will appear as an invitation to the user to start typing in commands. Commands can be cut and pasted from a text editor into the R prompt ">". The up arrow keys can also be used to scroll to previous commands.

5.3.3. A sample session

In this section, we will see how R can be used to make a data selection (query), recode a variable and produce some basic descriptive analysis.

Once R is connected to a FUCHIA database, the database itself is saved as an object named `database` in the R workspace (as shown earlier).

To retrieve information from the database, the function *`sqlquery()`* is used. For example to analyse age and sex distribution of patients in the database, the following command is required.

```
age.sex <- sqlQuery(database,'SELECT FdnGender, FdnAge FROM TbPatient')
```

The function `sqlquery()` extracts the age and sex of all patients in the database from the table containing the patient data (`TbPatient`). This data is then assigned to a new object called `age.sex`, which is a special form of R object, known as a data frame. Type in name of dataset at the command line prompt, to display the object to the screen:

```
age.sex
```

R will list the following.

```
  FdnGender FdnAge
1         1     30
2         0     30
3         1     27
4         1     44
5         1     33
6         0     29
 [....]
```

To obtain either the first or last lines of the listing, type `head(age.sex)` or `tail(age.sex).`

Information can be viewed or selected using indexing, for instance the age and sex of the 10th patient can be obtained by typing

```
age.sex[10,]
```

The square brackets are used for data selection. As we are viewing a data frame containing several rows and 2 columns, the comma in `age.sex[10,]` is required. As this informs R to display all columns of the data frame for the 10th observation. If the interest is only one column for example gender, this notation can be amended to

```
age.sex[10,1]
```

or

```
age.sex[10,'FdnGender']
```

Ensure the name of the variable is enclosed in single or double quotes. To obtain information of several patients, a vector can be included using the c(….) function, specifying a list of patients or a list of variables.

```
age.sex[c(3,5,10),c('FdnAge','FdnGender')]
```
and not `age.sex[3,5,10]`

If c(…) is omitted, R will be instructed to index a three-dimensional array, which in this case would be an error, as `age.sex` is a two-dimensional data frame. Another useful notation is a:b, so to display only the first five rows of the first two columns in the data frame.

```
age.sex[1:5,1:2]
```

Conditional selections can also be specified by inserting relational expressions.

```
age.sex[age.sex$FdnGender==1,]
```

Here, the observations that meet the condition `"FdnGender==1"` are displayed. In R, when specifying a variable in a data frame, it is necessary to insert a dollar sign between data frame and the variable of interest, as shown above. To save time, when working with mainly one data frame, the `attach()` function can be used, which allow you to directly reference the variable names. Note, however, that any type conversions you make to a data frame's variable will not be reflected in the attached version. Once you've finished using the data frame, you can remove it from the search path with `detach().`

```
attach(age.sex)
age.sex[FdnGender==1,]
```

For summary statistics of the retrieved data, type

```
summary(age.sex)
```

To obtain the number of cases by age and sex, the table command can be used.

```
table(age.sex)
```

R shows the number of patients for every age and sex combination. For example, There were 19 patients with sex=0 and 23 patients with sex=1 when age=1.

```
          FdnAge
FdnGender   0   1   2   3   4   5   6   7   8   9  10  11  12  13  14  15  16
       0    0  19  26  17  14  11  15  13  10   7   5   3   2   2   0   1   0
       1    1  23  16  16  13  13  10   9   7   7   6   1   2   4   1   6   8
       99   0   0   0   0   0   0   0   0   1   0   0   0   0   0   0   0   0
……..
```

To have the same information but grouped by age, the cut function can be incorporated.

```
age.sex[,'FdnAge']<-cut(age.sex[,'FdnAge' ], c(0,5,15,35,120))
```

Here, the variable "`FdnAge`" in the data frame `age.sex` is recoded to four categories: >0 to 5, >5 to 15, >15 to 35, and >=35 and the original `"FdnAge"` is replaced by the recoded `"FdnAge"` in the data frame.

```
head(age.sex)

  FdnGender   FdnAge
1         1  (15,35]
2         0  (15,35]
3         1  (15,35]
4         1 (35,120]
5         1  (15,35]
6         0  (15,35]

table(age.sex)

          FdnAge
FdnGender (0,5] (5,15] (15,35] (35,120]
       0     87     58     641      610
       1     81     53    1583      549
       99     0      1       1        0
```

Note:

Refer to chapter 5 Annex to obtain names of FUCHIA tables and variables.

In FUCHIA, a patient's age on date of visit is recorded when Date of birth is not known. Therefore, "FdnAge" may be incomplete or missing on some databases. See next section for further details.

5.3.4. FUCHIA R functions

To simplify the process of analysing data in R, several custom made functions were created. Of these, the functions to be familiar with and to use are:-

`init.report()`	`# To clear workspace. To be run at the start of every session.`
`exec.sql()`	`# Extracts data like the function sqlquery() but carries out some data management tasks: converting variable names and text entries to lower case, excluding duplication in query.`
`recodes()`	`# performs data recodes and essential transformations of the data (e.g. date calculations) and links value labels to value codes`
`save()`	`# save a data frame in either txt, tab, csv format or format for STATA or Epidata.`

To see how these functions can be incorporated in the analysis, the procedure described above is re-run with the new commands.

```
init.report()
age.sex <- exec.sql(database,'SELECT FdnGender, FdnAge FROM TbPatient')
age.sex  <- recodes(age.sex)
head(age.sex)
```

```
  fdngender fdnage
1    Female     37
2    Female     34
3      Male     36
4    Female     39
5    Female     26
```

```
age.sex[,'fdnage']<-cut(age.sex[,'fdnage' ], c(0,5,15,35,120))
table(age.sex)
```

```
               fdnage
fdngender       (0,5] (5,15] (15,35] (35,120]
  Male             87     58     641      610
  Female           81     53    1583      549
  Not specified     0      1       1        0
```

By using the `exec.sql()` and `recodes()` functions, the names of the two variables `"FdnAge"` and `"FdnGender"` have been changed to lower case and the distribution of sex by age are presented with value labels. In order for `exec.sql()` and `recodes()` to work, always enter `init.report()`beforehand.

To save the new data frame, the `save()` function can be used, where the file named "export" is saved in the usual FUCHIA output default directory as an Epidata file.

```
save(age.sex, filename="export", filter="rec")
```

As mentioned earlier, the variable `"fdnage"` is only recorded at a specific date of visit when date of birth is not known. For any analyses with age, the date of birth has to be re-calculated in-order to recuperate all the information recorded in the variables `"fddbirth"` or `"fdnage"`, `"fdnageunit"` and `"fdnagedate"`. FUCHIA automatically re-calculates this when the `recodes()` function is executed, providing all the variables are included in the data frame. Therefore if age is required and `"fddbirth"` is incomplete, the following procedure can be used prior to any analysis.

```
dob <- exec.sql(database,'SELECT FdxReference, FdsId, FdnGender, FddBirth, FdnAge,
FdnAgeunit, FddAgedate FROM  TbPatient')

dob <- recodes(exec.sql(database,'SELECT FdxReference, FdsId, FdnGender, FddBirth,
FdnAge, FdnAgeunit, FddAgedate FROM  TbPatient'))
dob <- recodes(dob)

head(dob)
```

```
     fdxreference fdsid fdngender fddbirth fdnage fdnageunit fddagedate
1           10231 10086    Female     <NA>     30    Year(s) 2007-05-09
       fdcbirth
1    1977-05-08
```

A new variable "`fdcbirth`" has been calculated, which can be used to derive age.

5.3.5. Extracting data from more than one table

To demonstrate how data from more than one table can be obtained, we are going to calculate the number of infants included in the PMTCT programme who had a confirmed HIV test result.

In order to do so, we need to obtain key information from several tables. From the Access table (`TbPatient`) containing Patient Form data, we extract the NID `"FdsId"` and HIV test result `"FdnHIV"` and from the Infant table (`TbBabies`), just the reference ID `"FdxReference",` as this is required to identify which of the patients are PMTCT infants and to merge the two tables together.

Note:

The following sequence will only work if there is information recorded in the PMTCT form in the FUCHIA database.

As before, the `exec.sql()` function will be used to extract the data from each table and then the `recodes()` function to recode the data.

```
# R session 2

init.report()

hiv <- exec.sql(database,'SELECT FdxReference, FdsId, FdnHiv  FROM  TbPatient')
hiv <- recodes(hiv)

baby <- exec.sql(database,'SELECT FdxReferencePatient as fdxreference FROM
TbBabies')
baby <- recodes(baby)
```

With the `merge()` function, the two data frames `hiv` and `baby` are combined into one data frame `data` , by linking together information in each using the join variable `"fdxreference".`

```
data <- merge(hiv, baby, by="fdxreference", all=F)
```

The `all=F` statement includes only those observations that have corresponding data in both tables. To obtain summary of all the data and to identify the number of infants with a final HIV test result, type

```
summary(data)
summary(data$fdnhiv)
```

To list the identities of infants whose final HIV status is not known, the data can be subsetted using a relational condition for a given list of variables with the c(…) notation.

```
data[data$fdnhiv=="Not specified", c('fdsid','fdcbirth','fddhiv')]
```

The condition `data$fdnhiv=="Not specified"` is specified using characters within double quotes, as the `recodes()`function recoded all numeric values to characters.

5.4. Running R in Batch Mode

All the above commands used in the interactive session can be simply placed together in a text document and executed at one time. This avoids having to manually enter the commands one by one. Here's how it can be done.

1) Go to a text editor and copy all the commands that worked. Save the document as sample**.R**,

```
# A sample R session

init.report()
age.sex <- exec.sql(database,'SELECT FdnGender, FdnAge FROM TbPatient')
age.sex  <- recodes(age.sex)
age.sex[,'fdnage']<-cut(age.sex[,'fdnage' ], c(0,5,15,35,120))
print(table(age.sex))
```

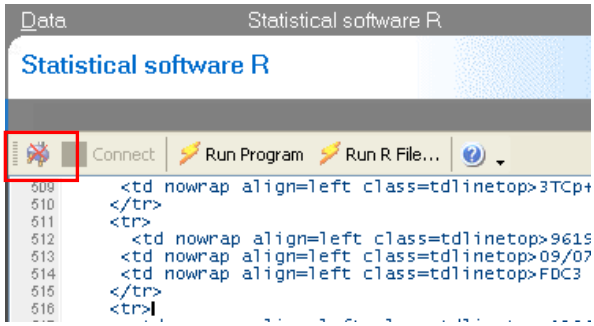
Note:

To display results using batch mode, use the print command, as shown above.

2) In FUCHIA, go to “R statistical software”, connect to the database and select “Run R file”. With the browser, search for sample.R file and click OK. R will execute the commands and display the results.

Further, this utility can be used to run additional “R” scripts developed by Epicentre which are currently not included in the list of automated reports/list/exports.

5.5. Disconnecting from “R"



- Always disconnect from the R software if you wish to switch to either data entry or FUCHIA direct.
- You can also disconnect from the R software if a programme takes too long to run and you wish to abort. To do so, click on the highlighted icon.

6 – R REPORTS

List of figures

List of tables

The main tool for data analysis is the automated reports in FUCHIA. These are predefined analyses and contain a basic set of indicators defined by the AIDS working group and used by the international office for monitoring and evaluation of HIV programmes, as well as other indicators necessary for reporting monthly and quarterly activities within HIV programmes. The reports are in the form of tables, figures or lists.

All reports are created using the R statistical software, and instructions on how to generate the reports and how to make pre-selections for analysis are presented in chapter 5.

All automatic reports are described below, with the exception of the TB and PMTCT reports which are dealt with in their respective chapters. For each report, a general outline is given followed by specific detail with examples of output and interpretation, and a summary of the reports utility.

6.1. Patient summary

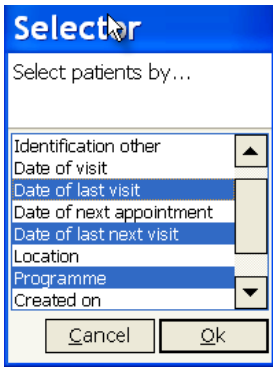
The Patient summary (see section 6.11) lists the key information recorded during patient visits, and gives the medical history of individual patients and describes the progression of their clinical and immunological status, from programme inclusion up until their last visit or over a selected period. This summary also describes treatment modifications and drug intolerances, and data from the TB and PMTCT forms are presented.

The patient summary can be generated for an individual or a group of patients by providing the patient's unique identifier (NID). To select a group of patients, the * character can be used.

Example

Enter "012*"	For all NID's starting with "012"
Enter "*012*"	For all NIDs that include "012" within the NID

FUCHIA will show a list of patients by sex, age (age on the date of the computer), NID and geographical origin for the selection specified. From here, the user can select all or some individuals by pressing ctrl key and left click mouse or a subgroup of individuals by pressing the ctrl key (to select the first patient) followed by the shift key and left click mouse (for the last patient in the group).



Other criteria are also available for patient selection, namely other identification, data of visit, date of last visit, date of next appointment, date of last next visit, location, programme, date created on, date updated on.

Selections can also be done using multiple combinations of the above criteria. At the selector window, press ctrl key and left click mouse to highlight the variables. Then click OK and FUCHIA will guide the user through the various selections.

The summary is obtainable for the whole period of patient follow-up or for a fixed period (e.g. the last 3 months) and can be saved in either portrait or landscape format. The landscape option displays also the laboratory results side by side with the clinical information on the follow-up visits (see figure below).

Once generated, the patient summary is saved in the usual output directory using the naming convention of "NID" and "NID other". For confidential reason, you may remove the "NID other" if the name is recorded in that variable.

Note:

If data on certain variables are not available for the patient selected, then this information is not displayed (i.e, if no creatinine values ever recorded, the graph on creatinine clearance will not be visible).

Useful for

- **Describing individual patient evolution**
- **Identifying missing values (e.g. absence of height, weight…)**

Laboratory results: portrait format

Examen	Laboratory test								
	Haemoglobinemia	ALAT	Creatinine	Glyc.	Prot.	Lymphocyte	CD4	CD4 (%)	Viral Load
21/07/2006				NS	NS		378		
25/10/2006				NS	NS		433		
30/11/2006				NS	NS		389		
29/03/2007	13.0			NS	NS	2092	421		
15/06/2007	11.6	11	94	NS	NS	4368			
03/07/2007	10.7	30	91	NS	NS				
23/08/2007	8.0		107	NS	NS		481		
24/09/2007			75	NS	NS	2580			
18/12/2007	14.8			NS	NS				

Laboratory results: landscape format

Visit				Obs.		Laboratory test								
TP	Adm.	TL	Sortie	Outc.	W	H	Hb	ALAT	Gl	PR	CR	LC	CD4	CD4%	VL	CL
C	27/06/2006	NS			45	158				NS	NS		378			
										NS	NS		378			
										NS	NS		378			
	03/07/2006	UP			42					NS	NS		378			
	27/07/2006	OT			46					NS	NS		378			
	25/10/2006	OT			50					NS	NS		433			
	30/11/2006	UP			47					NS	NS		389			
	14/12/2006	UP			46					NS	NS		389			
	29/12/2006	OT			47		13			NS	NS	2092	389			
	25/01/2007	UP			47		13			NS	NS	2092	389			
	08/02/2007	UP			45		13			NS	NS	2092	421			
	28/03/2007	OT			47		13	11	94	NS	NS	2092	421			57.9
	05/04/2007	OT			47		13	11	94	NS	NS	2092	421			57.8
	16/04/2007	OT			46		13	11	94	NS	NS	2092	421			56.6
	23/04/2007	OT			44		13	11	94	NS	NS	2092	421			54.1
	30/04/2007	OT			44		13	11	94	NS	NS	2092	421			54.1
	07/05/2007	OT			42		13	11	94	NS	NS	2092	421			51.6
	21/05/2007	OT			44		11.6	11	94	NS	NS	4368	421			54.1
	04/06/2007	OT			44	158	11.6	11	94	NS	NS	4368	421			54.1
	11/06/2007	OT			43		11.6	11	94	NS	NS	4368	481			52.8
	18/06/2007	OT			41		11.6	11	94	NS	NS	4368	481			50.4
									94	NS	NS	4368	481			50.4
	02/07/2007	OT			42		10.7	30	91	NS	NS	4368	481			52.6
	19/07/2007	DL			45		10.7	30	91	NS	NS	4368	481			57.1

Interpreting the output

◊ Laboratory results on portrait format are displayed by the date the sample for laboratory testing was taken (blood sample collection).

◊ Laboratory results on landscape format displays the data according to date of visit with the same test result sometimes appearing across several dates of visit. As explained in chapter 5.2.2 Laboratory results, the test results nearest to the date of visit by +/- 90 days will be displayed. For example, visits between 08/02/2007 and 04/06/2007 have a CD4 of 421, as these dates are within 90 days of the test done on 29/03/2007. However, the reading on 25/01/2007 is 389; as this date is nearest “blood collection” date 30/11/2006.

6.2. Patient description

Patient description generates 3 separate reports describing the demographic characteristics and clinical status of patients 1) at entry 2) at ART initiation and 3) at decentralisation.

Each report is defined by the period of analysis which is date of entry for patients enrolled, date ARV was first prescribed for those initiating ART and the date of decentralisation for those decentralised. Thus, for the period “01/03/2009” to “31/03/2009”, the report “patients at entry” includes only those who entered the programme during March 2009. Whereas the report “decentralised patients” only includes patients decentralised in this period.

Report can be generated for all patients or by sex, age, programme and location.

Note:

- In this and subsequent reports the term ART initiation refers to all patients who were initiated by the programme on any ARV (mono-, bi-, or tri- therapy).

- If programme and location are selected for the decentralisation report, then it refers to the location and programme where the patient was decentralised from, and not where the patient was decentralised to.

Useful for

- **Describing demographic and clinical characteristics of patients**
- **Describing programme activities in relation to patients recruited, patients initiating ARV and patients decentralised over fixed period of time.**

Patient description: an illustration

The following illustrates the first table (table 1.1) of the 3 different reports for the year 2007.

Entered the programme

1.1 Distribution of patients by age group and HIV status

Patients who entered into the program between 01/01/2007 and 31/12/2007

HIV	<12 months		≥12 to <18 months		≥18 to <60 months		≥5 to <15 years		≥15 years		Not Specified		Total	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
HIV Negative	2	9.1	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	0.6
HIV Positive	0	0.0	2	20.0	21	95.5	14	100.0	235	100.0	4	80.0	276	89.6
Not specified	20	90.9	8	80.0	1	4.5	0	0.0	0	0.0	1	20.0	30	9.7
Total	22	100.0	10	100.0	22	100.0	14	100.0	235	100.0	5	100.0	308	100.0

Initiated ART

1.1 Distribution of patients by age group and HIV status

Patients who initiated ARV between 01/01/2007 and 31/12/2007

HIV	<12 months		≥12 to <18 months		≥18 to <60 months		≥5 to <15 years		≥15 years		Not Specified		Total	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
HIV Negative	1	20.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	0.7
HIV Positive	0	0.0	0	0.0	20	100.0	5	100.0	105	100.0	2	100.0	132	94.3
Not specified	4	80.0	3	100.0	0	0.0	0	0.0	0	0.0	0	0.0	7	5.0
Total	5	100.0	3	100.0	20	100.0	5	100.0	105	100.0	2	100.0	140	100.0

Decentralised from

1.1 Distribution of patients by age group and HIV status

Patients who decentralized between 01/01/2007 and 31/12/2007

HIV	<12 months		≥12 to <18 months		≥18 to <60 months		≥5 to <15 years		≥15 years		Not Specified		Total	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%
HIV Negative	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	1	5.6
HIV Positive	0	0.0	0	0.0	1	100.0	0	0.0	16	100.0	0	0.0	17	94.4
Not specified	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Total	0	0.0	1	100.0	1	100.0	0	0.0	16	100.0	0	0.0	18	100.0

Interpreting the table

Table 1.1

- ◊ The text at the top of each table describes the population analysed. Therefore during 2007, 308 patients entered the program, 140 initiated ART and, 18 patients were decentralised.
- ◊ Majority of patients were adults (>=15 years of age) at the point of entry in the programme, at ART initiation and at decentralisation.
- ◊ HIV status was not specified for 9.7% of patients enrolled and 5.0% of patients initiating ART and they were less than 5 years of age.
- ◊ From the above tables, no assumption should be made that patients who initiate ART or were decentralised during 2007 were the same as those who were enrolled in 2007.
- ◊ If the reports were generated for specific age groups (for example adults above 20 years of age), ensure to interpret the age categories as >=20 years of age. In other words, the column with ">= 15 years" header will show the patients who are >= 20 years old and all the other columns will show "0".

Summary of the other data in the report

Some of the key results from the remaining tables of the above 3 reports are presented here (Table 1). Above each statistic in the below table, a report table number is given to identify where the information is located in the report.

Table 1: Summary of results in patient description report

	Programme Entry N=308	ARV initiation N=140	Decentralisation N=18
	Table 1.4	Table 1.5	Table 1.5
Women (%)	213 (69.2)	99 (70.7)	15 (83.3)
Median age in years [IQR]	30.1 [21.6 – 36.7]	30.9 [20.1 - 36.4]	31.8 [23.5 - 32.8]
	Table 1.9	Table 1.10	Table 1.10
ART naïve (%)	297 (96.4)	136 (97.1)	18 (100.0)
			Table 1.7
Pre-ART patients (%)	-	-	5 (33.3%)
		Table 1.15	
Decentralised (%)	-	1 (0.7)	-
	Table 1.2	Table 1.2	Table 1.2
Year of entry in programme (%)			
2005	-	1 (0.7)	2 (11.2)
2006	-	11 (7.9)	1 (5.6)
2007	308 (100.0)	128 (91.4)	15 (83.3)
		Table 1.3	Table 1.3
Median months since programme entry [IQR]	-	0.7 [0.5 - 1.1]	7.1 [4.0 – 9.6]
			Table 1.15
Median months since ART initiation [IQR]	-	-	3.7 [1.7 – 5.9]
	Table 1.6	Table 1.7	Table 1.7
Clinical WHO stage 3 or 4 (%)	124 (40.3)	63 (45.0)	7 (38.9)
	Table 1.5	Table 1.6	Table 1.6
BMI[1] (%)	N=235	N=101	N=12
>= 18.5 kg/m2	221 (94.0%)	93 (92.1%)	12 (100.0%)
	Table 1.7	Table 1.8	Table 1.8
CD4 count[2], cells/µl (%)	N=196	N=98	N=12
<50	16 (8.2)	12 (12.2)	1 (8.3)
50 – 199	71 (36.2)	65 (66.3)	4 (28.6)
200 – 349	40 (20.4)	16 (16.3)	0 (0.0)
≥ 350	69 (35.2)	5 (5.1)	7 (58.3)

		Table 1.13	Table 1.13
ARV regimen (%)	-		N=13
3TC+D4T+NVP	-	82 (58.6)	8 (61.5)
3TC+AZT+NVP	-	35 (25.0)	2 (15.4)
Other	-	23 (16.4)	3 (23.1)

[1]BMI applies only to patients >=15 years of age, [2]CD4 count applies to only patients >=5 years of age

◊ Note that the data are presented above side by side, but are not produced by FUCHIA like this. Comparisons should not be made across groups. Take for example the age profile of the three groups. Median age at entry, at ART initiation and at decentralisation is 30, but no inference should be made that patients who enter a programme, initiate ART and are decentralised shortly afterwards. In fact, median time between entry and ART initiation was 0.7 months in the program, and 7.1 months between entry and decentralisation. For those that had initiated ART before decentralisation, the time between ART initiation and decentralisation was 3.7 months.

◊ 5 of the 18 decentralised patients had not initiated ART prior to decentralisation and 1 of the 140 patients initiating ARV were decentralised when they initiated ARV.

◊ BMI and CD4 reported are the last recorded value within a 3-month window from date of enrolment, ART initiation or decentralisation.

◊ At ART initiation and at decentralisation, the most frequently prescribed ARV regimen was 3TC+D4T+NVP.

6.3. Workload report

The Workload Report provides the programme activity within a given period, and describes all consultations and hospital admissions recorded in this period.

Users are requested to specify a “start” and “end” date for the period of analysis and the interval (monthly, bi-monthly, quarterly, six-monthly and yearly) to summarise the visits. In addition, the report can be generated for specific age and gender categories and by programme and location.

Note:

The section on hospital discharges relates to hospital admissions during the selected period. It does not report discharges that occurred in the period but were associated with admissions prior to start of period.

If an individual programme or location is selected, the report summarises all consultations and hospitalisations of patients who were seen at least once in the specified programme or location during the period of analysis.

When age is specified, only those consultations or hospitalisations that match the age criteria will be taken into account. For example, a patient enters the MSF programme on 31/12/2009 and is 14.5 years of age. When creating the workload report for the year 2010 for adults (>=15 years), only visits after June 2010 will be included in the report for this patient.

Useful for

- **Monthly activity reports or**
- **Reports covering the entire period of the MSF programme.**

Workload Report table: an illustration

1 Description of patients seen during the period

1.1 Distribution of patient by patient status

Period between 01/01/2008 and 31/12/2008, Three month interval, Sex Male, Programme ZA Adults

Patient status in the period	Total	
	N	%
New (*)	53	65.4
Follow-up (**)	28	34.6
Total	81	100.0

* Patients coming for the first time during the period

** Patients followed from previous period

2 Description of visits during the period

2.1 Distribution of visits by interval

Period between 01/01/2008 and 31/12/2008, Three month interval, Sex Male, Programme ZA Adults

Interval between visit	Consultation		Hospitalisation		Total	
	n	%	n	%	n	%
2008-01	75	23.9	0	0.0	75	23.8
2008-04	103	32.8	1	100.0	104	33.0
2008-07	136	43.3	0	0.0	136	43.2
Total	314	100.0	1	100.0	315	100.0

* A patient with more than 1 consultation/hospitalisation/hospital discharge is only counted once

Interpreting the tables

Table 1.1

◊ By 31st December 2008, 81 male patients enrolled in the programme "ZA adults" came for at least 1 consultation or hospitalisation. 53 (65.4%) of these were new patients whose first visit occurred in the period of analysis (01/01/2008 to 31/12/2008). The remaining 28 were follow-up patients who had visits prior to January 2008 and had at least one visit recorded in the period of analysis.

Table 2.1

◊ 314 consultations and 1 hospitalisation occurred during the period specified, with 43.3% of consultations occurring in the third quarter of 2008 and 0 consultations were observed during the last quarter of 2008.

◊ One patient was hospitalised during the second quarter of 2008.

◊ From the data, we can estimate that each patient had an average of 3.9 visits during the period of analysis (314/81) and monthly consultations were on average 26 (314/12).

6.4. Outcome report for patients on ARV

This report displays the outcome of ART patients, where ART patients are those who have initiated ARVs (mono-, bi-, or tri- therapy) prior to or during the period analysed. The outcomes considered are:

- Deceased patients ("Dead"),
- Patients having left the cohort group ("Discharged"),
- Patients who are lost to follow up ("LFU").
- Patients who have initiated ART but were not prescribed ART at last visit prior to date of analysis ("Followed Ttt interrupt"),
- Patients who have initiated ART and were prescribed ART at last visit prior to date of analysis ("Followed On Ttt"),

- Patients who have initiated ART but was not scheduled a next visit ("Next appoint NS").

This report calculates the outcome of all ART patients at the end of the specified interval selected. Further details of how outcomes are calculated are given in Chapter 5.2.2 Data calculations.

The outcomes of ART patients are given at specified intervals (monthly, bi-monthly, three-monthly, six-monthly, etc…) over the period of analysis. The default setting for the period of analysis are the dates of first and last visit recorded in the database. These should correspond with the date a program opened and the current date for active programs or a date a program closed. There are instances however where the dates could be wrong due to date entry errors.

The date of analysis is the last date of the period selected. If the last date of the period is greater than the last date of visit recorded in the database, FUCHIA will automatically take the last date as no other information is available on patients after this date. This is also commonly known as the date of database update.

Useful for

- **Describing patient outcomes at specified intervals**
- **Describing programme evolution for example "scaling up of ART"**
- **Identifying the status of ART patients at a specified date.**
- **Identifying patients who are lost-to-follow up or those that have missed a recent appointment.**

Outcome Report table: an illustration

Table 1: Outcome Report for patients on ARV

Period between 01/01/2006 and 31/12/2006 • Monthly interval • Patients lost to follow-up for at least two months • Age between 15 and 120 years

Period	N		Dead		Transferred-out		LFU	Followed		Next appoint. NS
	n	Cum.	n	Cum.	n	Cum.		Ttt. interrupt.	On Ttt..	
01 janv. 2006 - 31 janv. 2006	0	1	0	0	0	0	1	0	0	0
01 févr. 2006 - 28 févr. 2006	3	4	0	0	0	0	1	0	3	0
01 mars 2006 - 31 mars 2006	3	7	0	0	0	0	1	0	6	0
01 avr. 2006 - 30 avr. 2006	17	24	0	0	0	0	1	1	22	0
01 mai 2006 - 31 mai 2006	24	48	0	0	0	0	1	1	46	0
01 juin 2006 - 30 juin 2006	31	79	1	1	0	0	1	0	76	1
01 juil. 2006 - 31 juil. 2006	17	96	1	2	0	0	2	2	89	1
01 août 2006 - 31 août 2006	43	139	1	3	0	0	2	2	132	0
01 sept. 2006 - 30 sept. 2006	70	209	1	4	0	0	1	0	203	1
01 oct. 2006 - 31 oct. 2006	50	259	2	6	0	0	2	1	249	1
01 nov. 2006 - 30 nov. 2006	31	290	4	10	0	0	4	2	274	0
01 déc. 2006 - 31 déc. 2006	36	326	2	12	1	1	8	2	303	0

Interpreting the table

Table 1

◊ The above report is for the period 01 Jan-06 to 31 Dec-06, and the selected period is analysed in monthly intervals.

- ◊ The column "N" (total patients) has 2 sub columns: "n" correspond to the patients initiated on ART during the specified month and the "cum" the cumulative number of patients initiated on ART by the end of that month. This applies also to the "Dead" & "Transferred out" column. Therefore by 30th June 2006, 79 patients had initiated ART and 31 in June 2006. 1 patient died and the death occurred in June 2006. Of those ART patients still alive (n=78), 1 was lost-to-follow-up and 1 had no date of next appointment.
- ◊ By the end of the period, 326 patients had initiated ART, 12 had died, 1 was transferred, 8 were lost-to-follow up. 2 of the 305 ART patients still followed were not prescribed ART at last visit prior to 31/12/2006.

6.5. Cohort Report

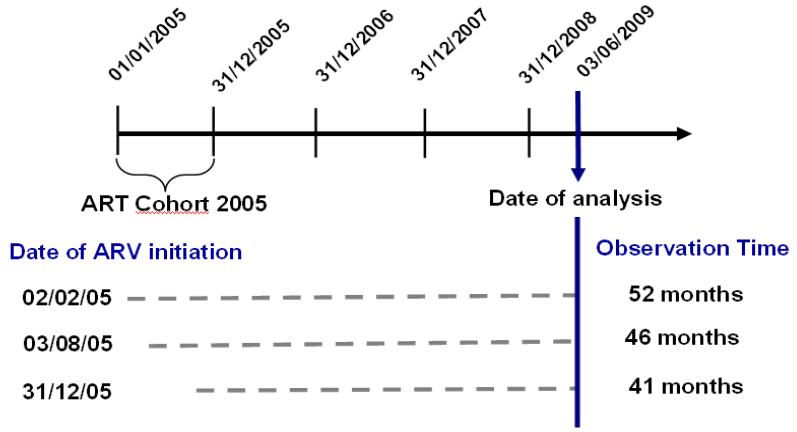
The cohort report describes the outcome of a cohort of patients who enter the programme (from entry or Pre-ART) or patients who initiate ART.

The cohort is defined by the date of entry in the programme or the date of ART initiation of ART patients, and the user is asked to specify a first and last date for the cohort selection.

Cohort outcomes are calculated at 6-month intervals from date of entry or date of ART initiation up-to date of analysis. The default for date of analysis is the last visit recorded in the database (end observation date), or the user can specify any date between last date specified for the cohort selection and the default date.

To ascertain who of the selected cohort is eligible for each 6-month analysis, FUCHIA calculates the maximum observation time an individual can be followed assuming the patient only exits the cohort after date of analysis.

Figure 1: Profile of three patients initiating ART



As an illustration, see the profile of the 3 patients in the above figure who were included in the cohort analysis for 2005 (results are presented later). All 3 patients initiated ART during 2005, and have 52, 46 and 41 months of observation by the date of analysis (03/06/2009).

Given there is almost a four year gap between ART initiation and date of analysis, the cohort report will produce a report of outcomes from 6 months since ART initiation up-to 48 months (see table 1.1). Patient 1, having 52 months of observation can therefore be eligible for all 6-month analysis, whereas patient 3 who initiated later in the year with only 41 months of observation will only contribute up-to the 36 month analysis.

Further, the cohort report provides description of patients still followed at the date of analysis and a list of patients by patient outcomes on this date.

Note:

- Calculation of CD4 and % CD4 are based on a window of 90 days around the date of analysis.

- Age group, ARV, prophylaxis, WHO staging are those recorded on the date of last visit before date of analysis.

- Weight is taken as the last recorded weight. If the date where weight was last recorded is more than 3 months before date of last visit, the date weight was taken is specified in the listing at the end of the report.

Useful for

- **Describing patient outcomes at 6-month intervals up to date of analysis**
- **Describing CD4 evolution over time**
- **Describing demographic and clinical characteristics of patients still followed**
- **Identifying current treatment regimens including 2nd Line / incorrect treatment regimen**
- **Preparation of ARV commands (consumption of ARV)**
- **Monitoring regimens according to weight (specially for children)**

Cohort Report: an illustration

1.1 → Cohort report of patients from their date of ARV initiation

Patients who initiated ARV between 01/01/2005 and 31/12/2005, Updated on 03/06/2009, Patients lost to follow-up for at least two months

Period	Total	ART initiated					
		Dead	Transferred	LFU	FU Tx. interrupt.	FU On Tx.	Next appoint. NS
At 6 months	835	66	71	85	1	597	15
At 12 months	835	84	127	109	2	503	10
At 18 months	835	95	150	119	1	460	10
At 24 months	835	101	163	125	4	431	11
At 30 months	835	104	166	139	1	418	7
At 36 months	835	107	170	141	2	409	6
At 42 months	807	108	161	153	1	378	6
At 48 months	478	77	71	88	2	234	6
At 03/06/2009	835	111	177	170	3	367	7

Lost to follow-up (LFU): Patients who did not attend their last visit which was planned more than 2 month(s) before the end of the period

Followed on treatment: Patients followed with ARV prescribed at the last visit

Followed Treatment Interrupted: Patients followed without ARV prescribed at the last visit

Interpreting the table

Table 1.1

◊ 835 patients initiated ART between 01/01/2005 and 31/12/2005.

◊ By date of analysis (03/06/2009):111 patients had died, 177 were transferred out (discharged), 170 were lost-to-follow-up and 7 had no scheduled date of next appointment. 370 of the 835 patients were still followed (3 without treatment and 367 with).

◊ The period refers to the number of observation months between ART initiation and date of analysis and is split by 6-month intervals. For this cohort the maximum observation time between ART initiation (2005) and date of analysis (3rd June 2009) is almost 4 years, all 835 patients had up-to 36 months of observation time, and within this time 107 patients died, 170 were transferred out, 141 were lost-to-follow-up, 6 had no scheduled date of next appointment, and 411 were followed.

◊ Only some of the patients initiating ART during 2005 can be "observed" for as long as 42 months (n=807), and 48 months (n=478). In other words, for the 48-month cohort, only 478 of the 835 patients have long enough follow-up, as they initiated ART between 01/01/2005 and 03/06/2005.

Last line of Table 1.1 of the cohort report identified 370 patients who initiated ART between 01/01/2005 and 31/12/2005 and who were still followed on the 03/06/2009. The remainder of the tables in the Cohort report displays information on these patients.

Descriptive tables, Cohort Report: an illustration

1.8 Immunocompetency: CD4

Patients who initiated ARV between 01/01/2005 and 31/12/2005, Updated on 03/06/2009, Patients lost to follow-up for at least two months

Period	Nb of patients with available follow-up	Nb of patients with available results (*)	Median CD4 [IQR]	Nb of patients with CD4 > 200
At ARV Initiation	370	114	161.5 [96.0-231.0]	40 (35.1 %)
At 6 months	354	10	300.5 [178.0-465.0]	7 (70.0 %)
At 12 months	359	231	327.0 [209.0-476.0]	178 (77.1 %)
At 18 months	360	107	272.0 [187.0-387.0]	77 (72.0 %)
At 24 months	359	239	410.0 [271.0-580.0]	218 (91.2 %)
At 30 months	358	148	396.5 [283.0-567.5]	132 (89.2 %)
At 36 months	364	262	408.5 [285.0-602.0]	238 (90.8 %)
At 42 months	355	99	417.0 [291.0-639.0]	91 (91.9 %)
At 48 months	227	39	420.0 [301.0-575.0]	35 (89.7 %)

Table 1.8

◊ This table describes the CD4 profile of patients who initiated ART during 01/01/2005 and 31/12/2005 and were still followed on the 03/06/2009 (n=370).

◊ Here the period refers to the actual months of follow-up in the cohort for the 370 patients, and these are split by 6-month intervals. For some intervals, not all 370 patients have a follow-up. For example 6 months after ARV initiation, 354 patients have a follow up visit recorded. The remaining 16 are excluded as they could have been lost-to-follow up or not have had a scheduled date of next appointment by their 6 month appointment.

◊ At ARV initiation, CD4 results were available for only 114 of the 370 patients.

◊ It appears CD4 tests are performed annually as more results are available at 12, 24 and 36 months than 6, 18 and 30months. CD4 tests are not available for the majority of patients followed after 42 months.

◊ At ARV initiation, 35% of those with a CD4 were above 200 cells/mm^3 and this percentage increases over treatment time.

6.6. Drug interruption/drug intolerance

This reports on drug prescription, drug discontinuation and drug intolerances over a specified report period. Information is given by number of patients and by type of ARV regimen with a list of patients who had an intolerance recorded.

Report: an illustration

1.1 Number of patients prescribed ARV during the period

Period between 01/06/2007 and 30/06/2007

Type	n
At least one prescription during the period	405
At least one interruption during the period	86
At least one intolerance during the period	14

1.3 List of patients with intolerance

Period between 01/06/2007 and 30/06/2007

Identification number	Date of last visit	Prescription	Treatment	Intolerance 1	Drug related to Int. 1	Intolerance 2	Drug related to Int. 2	Intolerance
7122	08/06/2007	Continued with Intolerance	FDC1					
7139	28/06/2007	Stopped for Intolerance	D4T30					
7313	22/06/2007	Stopped for Intolerance	FDC1			Neuropathy 3	D4T30	
7413	29/06/2007	Stopped for Intolerance	FDC1					
7586	29/06/2007	Stopped for Intolerance	FDC1			Neuropathy 3	D4T30	
7733	18/06/2007	Stopped for Intolerance	D4T30					
8147	18/06/2007	Stopped for Intolerance	FDC1			Neuropathy 3	D4T30	
8917	25/06/2007	Stopped for Intolerance	FDC1			Neuropathy 3	D4T30	
8958	20/06/2007	Stopped for Intolerance	FDC1			Neuropathy 3	D4T30	
9094	25/06/2007	Continued with Intolerance	FDC1					
9106	05/06/2007	Continued with Intolerance	FDC1					
9715	27/06/2007	Stopped for Intolerance	NVP				NVP	TOXICITY
9724	21/06/2007	Stopped for Intolerance	XXX-TB					
9937	11/06/2007	Stopped for Intolerance	EFV600					
9937	11/06/2007	Stopped for Intolerance	FDC5					
9937	11/06/2007	Stopped for Intolerance	XXX-TB					

◊ During June 2007, 405 patients were prescribed ARV at least once in the period. 86 patients interrupted their ARV treatment in the same period and 14 patients had drug intolerance.

◊ Number of patients listed (1.3) can be more than the number of patients reported to have at least one intolerance during the period (1.1), as the list contains all patients who have stopped or are continuing with intolerance or who have information recorded on any of the variables relating to intolerance.

Useful for

- **Describing the proportion of patients with drug interruption and drug intolerance**
- **Describing the proportion of reasons for stopping among the total prescriptions**
- **Getting the list of patients with an intolerance recorded**

6.7. List of patients by next visit: Patients expected to be seen

This creates a list of patients expected during a specified period. Calculations are based on the “date of next appointment” entered in the patient follow-up visit.

For example: The list of patients expected next week is obtainable by selecting next week’s “Next Appointment” dates. If your database is updated to 31/12/2009 and you wish to obtain a list of **patients expected** in the first week of January, ask for a list of Next Appointment dates between 01/01/2010 and 07/01/2010.

Patient lists are presented together with other information, such as “ARV prescribed Yes/No” (i.e. whether the patient is already on ARV therapy), “Date of last visit”, “Date of next Appointment”, and “Treatment” for patients on ARV.

Note:

This list is only useful for prospective analysis, as the list also includes those patients who died or were discharged.

Useful for

- **Identifying patients expected to be seen**
- **Identifying patients who had missed their appointment**

6.8. List of patients with an OI diagnosed

It gives a list of patients with an opportunistic infection (OI) within the selected period of time, regardless of whether patient is on ARV or not. The information is presented by OI and presents the date of the first visit during the report period where the selected OI had a status "New", "On Going" or "Recurrent" and subsequent visits during the report period where status "New" or "Recurrent" is recorded.

An illustration

OIs recorded in FUCHIA

OIs reported on OI list

	Report Period	Nid	Date	Status
1	Sep 1-Oct 3, 2003	121	13/09/2003	New
2	Dec 1-31, 2003	121	10/12/2003	On Going
3	Dec 2003 to Jan 2005	121 121	10/12/2003 03/01/2005	On Going Recurrent◊

◊ In the first report, as the period of selection was short, only one OI was listed. In the second report, as all TB events were ongoing episodes, only the first in the period is listed. Whereas, in report 3, as there was also a recurrent TB episode, this is listed with the first ongoing episode in the period.

Useful for

- **Identifying patients with an OI**

6.9. Other reports

The TB and PMTCT reports are described in the respective TB and PMTCT chapters.

6.10. Information available in the reports

Below is an overview of the information summarised in each automated report (Table 2).

Data on gender, HIV status, ARV history, period of entry, and mode of entry refer to the information recorded at programme entry for every report.

The remaining data (for example median age, BMI and CD4 measurements, WHO clinical staging) is given for the time specified for the report. For example ARV regimen, in the report "Patient description at ARV initiation" relates to the ARV prescribed on the date of ART initiation whereas in the "Patient description at decentralisation", it refers to the ARV prescribed on date of decentralisation.

Note:

The patient description reports provide a description of <u>all patients</u>

- At entry if "patient description at entry" has been selected
- At ART initiation if "patient description at ART initiation" has been selected

The cohort reports provide a description of the <u>patients still followed on the date of analysis</u>

- after entry in the programme if "cohort report from entry" has been selected
- after ART initiation if "cohort report from ART initiation" has been selected
- after decentralisation if "cohort report from decentralisation" has been selected

Table 2: Information available in the reports

	Patient Description at entry	Patient Description at ART initiation	Cohort report from entry	Cohort report from ART initiation	Cohort report from decentralisation	Drug interruptions/ Intolerance	Outcome report	Workload	List of OIs
Patient characteristics									
HIV status	X	X							
Gender	X	X	X	X	X				
Age group	X	X	X	X	X				
Patient outcomes									
Died			X	X	X		X		
transferred out			X	X	X		X		
lost-to-follow-up			X	X	X		X		
Followed			X	X	X		X		
Entry characteristics									
Programme								X	
Location								X	
Mode of entry	X	X	X	X	X				
Period of entry	X	X							
duration of follow-up since programme entry		X	X						
Clinical and immunological markers									
BMI	X	X							
CD4 cell count	X	X	X	X	X				
% CD4 cell count	X	X	X	X	X				
evolution of cd4 cell count			X	X	X				
WHO clinical staging	X	X	X	X	X				
opportunistic infections									X
ARV or prophylaxis									
ARV naïve status at programme entry	X	X							
ARV history (prescribed prior to programme entry)	X	X							
Period of ART initiation		X							
ART status		X							
ARV regimen	X		X	X	X	X			
Prophylaxis			X	X	X				
Duration of follow-up since ARV initiation				X	X				
Intolerance						X			
Reason for drug interruption						X			
Decentralisation									
Decentralisation status		X							
Period of Decentralisation		X							
Location Decentralised to		X							
Duration of follow-up since decentralization		X			X				
Admission and Follow-up									
Consultations / hospitalisations								X	
Time between successive visits								X	
hospital admissions								X	
hospital discharges								X	
reasons for discharge from hospital								X	
duration of stay in hospital								X	

6.11. Patient Summary

Patient Summary — **11138 BM | 7907**

General	
Sex	Female
Marital Status	WIDOW/WIDOWER
Profession	UNEMPLOYED
Origin	ARVILL
Mode of Entry	ABC

Clinical background	OMS 3
Weight loss	
Minor mucocutaneous manifestations	
Fever, unexplained	

Drt=Number of years of follow-up

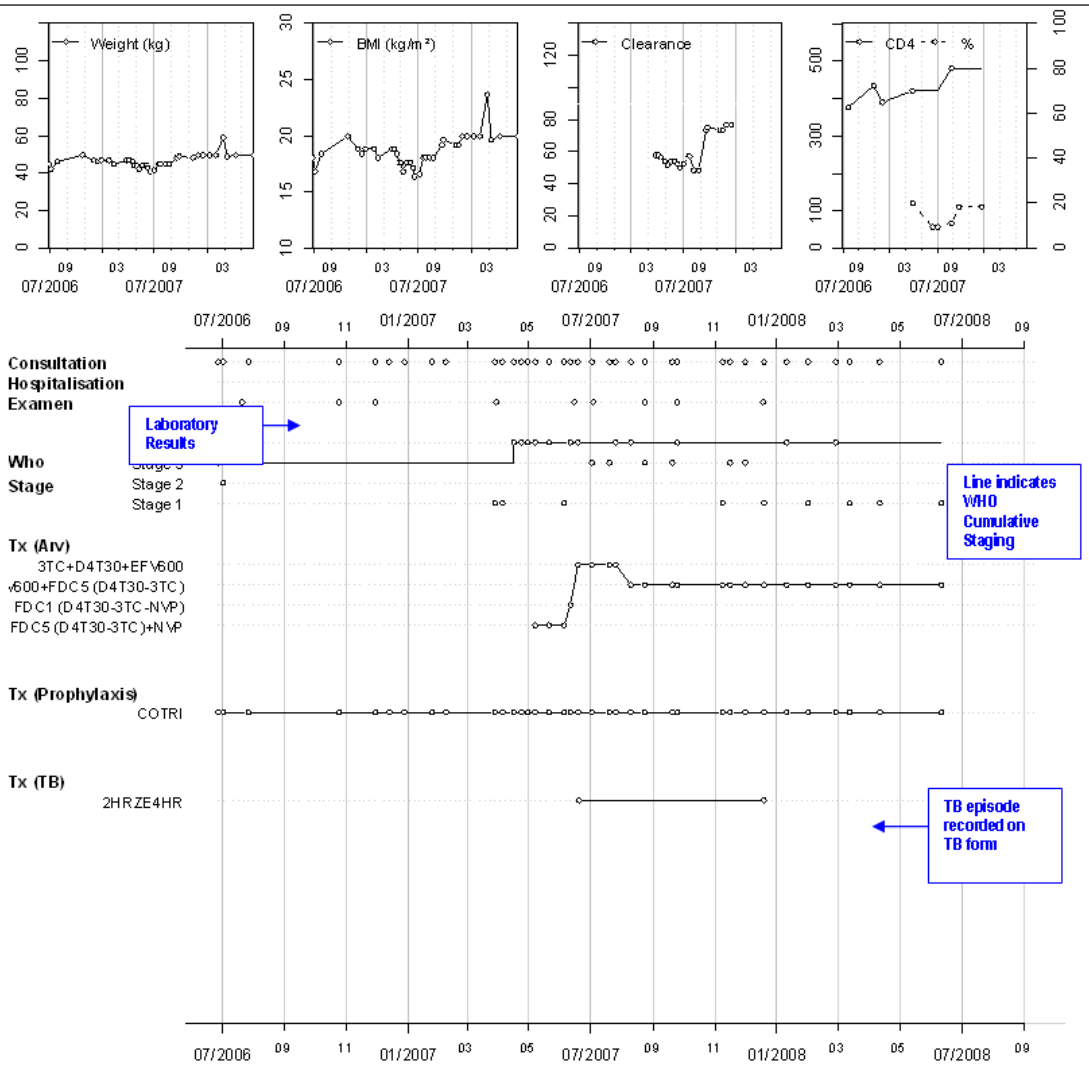
Remark= Programme

WHO Staging

At visit | Cumulative

Events	Date	Age	Drt.	Remark	RX	WHO
Birth	27/06/1978					
HIV Positive	26/06/2006	28				
First Visit	27/06/2006	28	0			3|3
First Visit (Under ARV)	07/05/2007	28.9	0.9	in MOH	FDC5 (D4T30-3TC)+NVP	4|4
Last Visit	12/06/2008	30	2	in MOH	EFV600+FDC5 (D4T30-3TC)	1|4

Timeline



Visit					Obs.		Tx	Diagnostic		
TP	Adm.	TL	Sortie	Outc.	W	H		WHO	Prct.	Diagnostic
C	27/06/2006	NS			45.0	158		3|3	N	Weight loss <10%
									N	Minor mucocutaneous ...
									N	Fever, unexplained
		UP			42.0			2|3	O	Minor mucocutaneous ...
		OT			46.0			0|3		
	25/10/2006	OT			50.0			0|3		
	30/11/2006	UP			47.0			0|3		
	14/12/2006	UP			46.0			0|3		
	29/12/2006	OT			47.0			0|3		
	25/01/2007	UP			47.0			0|3		
	08/02/2007	UP			45.0			0|3		
	28/03/2007	OT			47.0			1|3	N	Asymptomatic
	05/04/2007	OT			47.0			1|3	O	Asymptomatic
	16/04/2007	OT			46.0			4|4	N	Kaposi sarcoma
	.									

Visit Timeliness
UP=Unplanned
OT=On Time
LT=Late
NS=Not specified

Sortie=Date of discharge from hospital

Outc=Reason for discharge from hospital

Obs
W=Weight
H=Height

Prct=Status of OI
N=New,
O=Ongoing,
R=Recurrent

Examen	Laboratory test								
	Haemoglobinemia	ALAT	Creatinine	Glyc.	Prot.	Lymphocyte	CD4	CD4 (%)	Viral Load
21/07/2006				NS	NS		378		
25/10/2006				NS	NS		433		
30/11/2006				NS	NS		389		
29/03/2007	13.0			NS	NS	2092	421		
15/06/2007	11.6	11	94	NS	NS	4368			
03/07/2007	10.7	30	91	NS	NS				
23/08/2007	8.0		107	NS	NS		481		
24/09/2007			75	NS	NS	2580			
18/12/2007	14.8			NS	NS				

Visit about Tuberculosis						Treatment and Outcome		
Begin	Case	Type TB	Site EPTB	AFB	Culture	Protocol	End	Outcome
2007-06-19	N	P	NS	N	ND	2HRZE4HR	2007-12-19	TC

7 - TUBERCULOSIS

Liste of figures

7.1. TB/HIV co-infection

Tuberculosis (TB) is a common opportunistic infection amongst HIV patients and is associated with high mortality. The treatment of HIV-TB co-infected patients requires close monitoring because of possible drug interactions and drug intolerances.

For these reasons, data on TB is collected alongside HIV data and is recorded in FUCHIA for individual patient management and for the evaluation of TB and HIV services. Collection of information also facilitates the evaluation of service integration (e.g. one stop service, improved detection of both illnesses HIV and TB).

This chapter does not replace the tuberculosis clinical guidelines (TB definitions, regimens and duration), but will review how FUCHIA can be implemented in the management of tuberculosis in the context of HIV infection.

For further detailed information on TB/HIV co-infection, refer to the MSF TB guideline.

http://www.refbooks.msf.org/msf_docs/En/Tuberculosis/Tuberculosis_en.pdf

7.1.1. Essential data elements for TB/HIV evaluation

To correctly evaluate a programme, the following information is necessary:

- prior history of anti-tuberculosis treatment as an indicator of individual risk of poor adherence, resistance and loss-of-follow-up
- the site of disease to assess risk of TB transmission
- a bacteriological result obtained from performing an AFB search in sputum specimens
- the date of TB treatment starts and ends
- TB regimen
- TB outcome

It is essential that standardised definitions recommended by WHO are used for data collection. See TB guideline for further detail.

7.2. Data collection

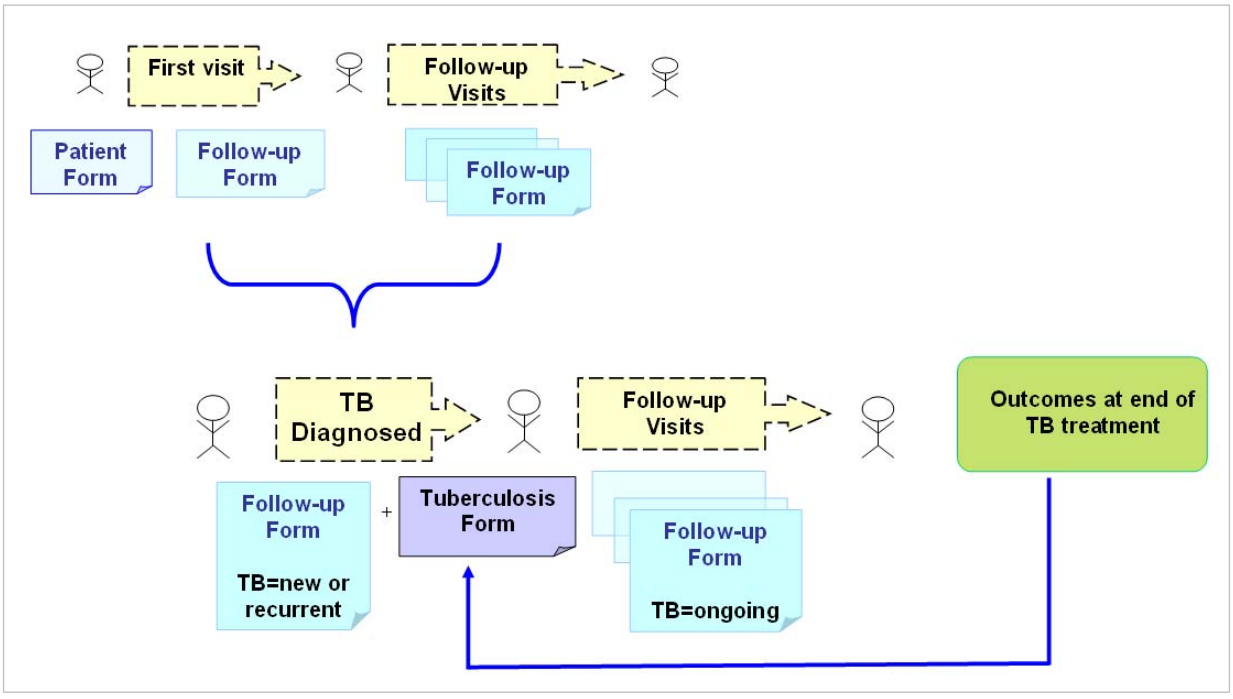
The FUCHIA TB database is to be used **only** to collect information on HIV infected patients co-infected with TB and not for all TB patients (including HIV uninfected) who are coming for TB treatment.

Figure 1 outlines the data collection flow-chart of how information on TB is to be recorded.

If during the first or a follow-up visit of an HIV patient a TB episode is diagnosed, a “Tuberculosis” form is completed, as well as the section on opportunistic infections on the ”Follow-up” form.

A single patient can have more than one TB episode, and one TB form is to be completed for every TB episode. A TB episode starts when the diagnosis is made and a date of treatment is fixed and ends on determination of the TB treatment outcome with a date of end of TB treatment. Please, refer to the MSF TB guidelines for definitions of TB outcomes and type of TB.

Figure 1: Data collection flow-chart



7.2.1. Steps in the data collection process

►On day of initiation of TB treatment:

Record on the "Follow-up" form of the "Clinical condition during follow-up visit" section either "new" or "recurrent" for the appropriate type of TB (PTB[1], EPTB[2]") diagnosed.

Complete a "Tuberculosis" form and record all the information with exception of the treatment outcome and the date of end of treatment. As for every form, the patient's unique id ("nid") is selected from the "Tuberculosis" Form. Full description of the variables included in the "Tuberculosis" form is provided in the next section.

►During any follow-up visits between date of initiation and completion of TB treatment:

Record on the "Follow-up" form of the "Clinical condition during follow-up visit" section "ongoing" for the type of TB (pulmonary, extra-pulmonary") treated.

►On day of completion of TB treatment:

Update the "Tuberculosis" form and enter the information on treatment outcome and date end of TB treatment.

Note:

If a patient is transferred into the HIV program during TB treatment, enter TB as background condition in Patient Form and enter TB "ongoing" in the "Follow-up" form. Also complete a "Tuberculosis" form for that patient and enter the start date of TB treatment as the actual date when treatment was started and not the date when the TB treatment was started in the MSF program or when the patient entered the MSF HIV program.

If a patient is transferred outside the HIV program during TB treatment, for program evaluation it is important to obtain the end treatment date and TB outcome of that patient from the clinic where the patient is transferred to.

[1] Pulmonary tuberculosis
[2] Extra pulmonary tuberculosis

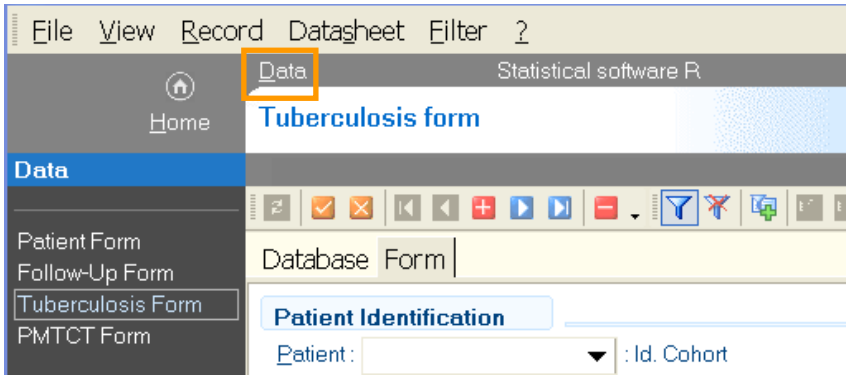
7.2.2. Description of data to be collected on Tuberculosis Form

Electronic version of the FUCHIA TB form in word format can be found in the directory: "C:\Program files\MSF\Fuchia\v1.7.1\doc\forms

Name of variable	Details	Comments
Patient Identification		
ID Cohort	Unique patient number	Defined in Patient Form
ID Other	Number or text allowing patients to be identified by means other than the cohort number.	Defined in Patient Form
Tuberculosis		
Sample for AFB search	Sputum / Other / Not specified	
AFB	(smear) Positive / Negative / Not done / Not specified	AFB = Acid-Fast Bacilli – Only sputum smear results should be recorded. Results of other specimen are not to be recorded.
Culture	Positive / Negative / Not done / Not specified	Only baseline culture result (before TB treatment start) should be recorded, even if such results are available few weeks after treatment start. If culture was performed on other specimen than sputum, the results can be recorded in culture. In case of sputum and other specimen, record only sputum culture results should be entered.
X-Ray	Suggestive / Not suggestive / Not done / Other / Not specified	Record only chest X-Ray
Type of TB	Pulmonary / Extra-pulmonary / Both / Not specified	If a patient has pulmonary (PTB) and extra-pulmonary TB (EPTB), "both" should be recorded.
EPTB Site	Pleural effusion, Disseminated or miliary, Meningitis, Bones and joints, Genito-urinary, Lymph nodes, Ascites, Digestive tract, Pericardial effusion, other or not specified	If a patient has more than 1 EPTB site, the clinician should record all sites on the FUCHIA paper. If lymph nodes are associated to another site, record only the other site. If there are 2 sites without lymph nodes or in addition to lymph nodes: record disseminated.
Case definition	New case, relapse, treatment after default, failure, transfer in, other, not specified	For list of definitions, please refer to the ***MSF* TB guide**.
Treatment		
Regimen	2HRZE/ 4HR 2HRZE/ 6HE 2SHRZE/ 1RHZE/ 5RHE2SHRZ/ 2RH(Z) 3EH (Manyatta) DR TB regimen	H isoniazid, R rifampicin, Z pyrazinamide, E ethambutol, S streptomycin Please refer to the ***MSF* TB guide** for a more detailed description of therapeutic regimens. Other regimens may be included by means of the TB Drug list.
SAT	Yes / No / Not specified	SAT stands for "Self-Administered Treatment". This refers to the intensive TB treatment phase only.
DOT	Yes / No / Not specified	DOT stands for "Directly Observed Treatment". This refers to the intensive TB treatment phase only.
Intermittent	Yes / No / Not specified	Twice or three times a week.
Start of treatment	Date given in "dd/mm/yyyy" format	Mandatory – can be before the date of opening of TB form or the first date of visit in FUCHIA.
End of treatment	Date given in "dd/mm/yyyy" format	Important to be recorded – date of TB treatment completed for patients with outcome "cured" or "treatment completed" – date of death, treatment interruption, transfer or failure for patients with death, defaulter, transfer out and failure outcomes, respectively.
Outcome	Cured, Failure, Treatment completed, Defaulter, Dead, Transferred-out, Adapted to DST, not specified	The standard definitions given in the ***MSF* TB guide** must be respected.
User Data		
Free variables	10 free variables that may be recorded for each TB episode.	E.g.: side effects, response to a course of non-specific antibiotics, clinical patient follow-up following end of treatment, result of culture that was performed during TB treatment…
Notes	Free text	

7.3. Data entry

The data from the “Tuberculosis” form are entered into FUCHIA. Click on Data (top panel), followed by Tuberculosis Form (left-hand side panel).



A common data-entry error found is a number of duplicate entries for the same TB episode. To avoid these, prior to entering a new TB episode, always check the database to see if there are other TB episodes recorded for that individual. If there are entries, then ensure that there are no entries already recorded for that episode. If a duplicate exists, then complete the information (e.g. end of treatment and outcome) on the available form. In case of doubt, please, check with the clinician.

Below is an outline of how the TB data should be entered in FUCHIA.

► *Entering Patient ID numbers*

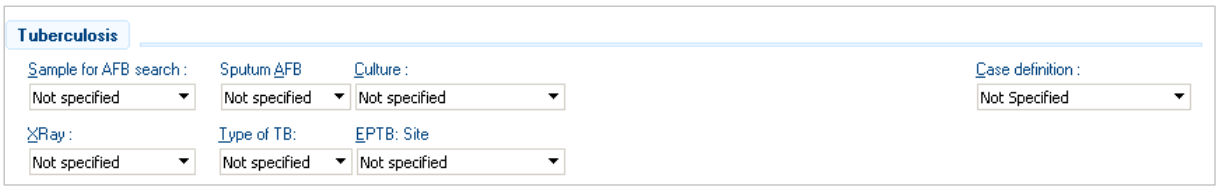
► *“ID. Cohort”*

Mandatory – *By clicking on the arrow shown above (right-hand side of entry field), a list of Patient IDs will appear. Select the ID number required. As with the “Follow-up” Form, the “TB” Form cannot be completed unless a Patient Form has been recorded beforehand (the ID number will not appear).*

► *“ID. Other”*

The other ID number (“ID. Other”) is linked to the “ID cohort” number and will appear automatically if it has been entered in the Patient Form.

► *Entering Tuberculosis data*



To enter these values, click on the arrow at the right-hand side of entry field and select the appropriate value.

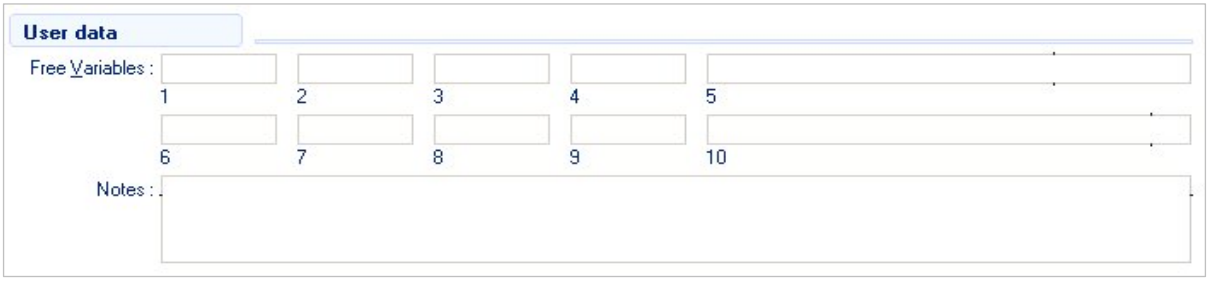
► *Entering treatment data:*

The variables "Regimen" and "Start of treatment" must be filled in.

The 5 most common TB regimens are pre-coded in the list of TB regimen in FUCHIA. If you want to record other regimens, you may do so by first creating new codes in the list of TB regimen, keeping in mind that the more regimens you add, the more complex the analysis will be.

The regimen to be recorded is the regimen prescribed at time of diagnosis and should not be modified during treatment ***even if the treatment is modified due to side effects****.* If you need this information, please use the free variables.

► *Entering user data:*



Data entry is in free-format. However, make sure that you: enter free variables in the correct entry fields, use standardised entries and document what is the information entered and when the process was started.

7.4. TB report

7.4.1. Overview

☛ TB programs are evaluated using cohort analysis. A TB cohort includes all patients started on TB treatment over a specified period of time. Classically, TB data collected allows producing 2 types of information:

- The case finding describes the characteristics of the patients of a cohort: number of patients, gender, age groups, sputum results, type of TB, and case definition…
- The cohort analysis provides the treatment results = outcome. The cohort is analysed when all patients of a cohort are likely to have completed their treatment. At the end of treatment, the status of each individual is defined: cured, deceased, defaulted etc…. From there, various rates are calculated for the cohort.

Note:

Traditionally, TB cohorts are analysed quarterly, 1 year after inclusion of the last patient of the cohort. For example, a cohort of patients initiating TB treatment during the first quarter of 2007 (01 Jan. – 31 Mar. 2007) will be evaluated at the end of the first quarter of 2008.

7.4.2. TB report generation

As for any R report, after connecting the database to the R software and selecting the TB report, additional selections are requested for period when treatment started, age, and sex.

As mentioned earlier, the duration of TB treatment depends on the regimen and to obtain treatment outcomes for all patients selected in the report, sufficient time must be given between the date when the report is generated (date of analysis) and the selection period of the report. For example, to obtain the outcomes of all patients starting TB treatment during the first quarter of 2008, the date for report generation should be after 31/03/2009.

The TB report is automatically saved in the default output directory defined when FUCHIA was installed (see chapter 11), under the name *"tuberculosis report.doc"*. In the event a TB report already exists, the newly run TB report will be named with an incremented digit in order to keep the existing TB report.

7.4.3. Contents of the TB report

☛ The TB report in FUCHIA provides both a description of the TB episodes treated and as well as a cohort analysis.

- Tables 1 to 4 of the report relate to **case finding** and provide a description of the patients diagnosed and started on TB treatment during the selected period.
- Tables 5 to 8 report **indicators related to TB/HIV co-infection** such as the number of patients who started cotrimoxazole prophylaxis and the number of patients started ART in relation to TB diagnosis and treatment.
- Table 9 is the **cohort analysis** which reports the treatment outcomes of TB episodes included in the selected cohort.

Note:

The tables report the total number of TB episodes diagnosed during the selected period. It does not necessarily give the total number of patients diagnosed with TB in the period, as one patient may have several episodes over that time (e.g. a re-infection or a TB relapse). The shorter the reporting period (e.g. by quarter to ensure one episode per patient), the more likely you will be to include a unique episode per patient.

As always, the front page displays the selections made for the report. The selections are reminded at the top of each table. Sex and age range will only be specified if these selections are made.

Tuberculosis Report

R Statistical Analysis of Fuchia Database

Beginning of TB Treatment between 01/01/2006 and 31/03/2006

Case finding

1 Distribution of tuberculosis types by sex and case definition

Beginning of TB Treatment between 01/01/2006 and 31/03/2006

	Smear positive pulmonary tuberculosis		Smear negative pulmonary tuberculosis		Extra-pulmonary tuberculosis		Not specified		Total	
	n	%	n	%	n	%	n	%	n	%
Sex										
Male	17	42.5	10	37.0	8	40	9	40.9	44	40.4
Female	23	57.5	17	63.0	12	60	13	59.1	65	59.6
Not specified	0	0.0	0	0.0	0	0	0	0.0	0	0.0
Case Definition										
New case	33	82.5	22	81.5	15	75	17	77.3	87	79.8
Relapse	6	15.0	5	18.5	4	20	3	13.6	18	16.5
Treatment after default	0	0.0	0	0.0	1	5	2	9.1	3	2.8
Failure	1	2.5	0	0.0	0	0	0	0.0	1	0.9
Transfer in	0	0.0	0	0.0	0	0	0	0.0	0	0.0
Other	0	0.0	0	0.0	0	0	0	0.0	0	0.0
Not specified	0	0.0	0	0.0	0	0	0	0.0	0	0.0
Total	40	100.0	27	100.0	20	100	22	100.0	109	100.0

New Cases: Patients never started on TB treatment or who took TB treatment in the past for less than one month

2 Distribution of tuberculosis types by age group

Beginning of TB Treatment between 01/01/2006 and 31/03/2006

TB type	<5 years		≥5 to <15 years		≥15 years		Not Specified		Total	
	n	%	n	%	n	%	n	%	n	%
Smear positive pulmonary tuberculosis	0	0.0	3	20.0	37	42.5	0	0.0	40	36.7
Smear negative pulmonary tuberculosis	1	14.3	2	13.3	24	27.6	0	0.0	27	24.8
Extra-pulmonary tuberculosis	1	14.3	2	13.3	17	19.5	0	0.0	20	18.3
Not specified	5	71.4	8	53.3	9	10.3	0	0.0	22	20.2
Total	7	100.0	15	100.0	87	100.0	0	0.0	109	100.0

3 Distribution of extra-pulmonary tuberculosis types by age group

Beginning of TB Treatment between 01/01/2006 and 31/03/2006

EPTB Type	<5 years		≥5 to <15 years		≥15 years		Not Specified		Total	
	n	%	n	%	n	%	n	%	n	%
Pleural effusion	0	0.0	1	50.0	7	41.2	0	0.0	8	40.0
Disseminated or miliary	1	100.0	1	50.0	3	17.6	0	0.0	5	25.0
Meningitis	0	0.0	0	0.0	1	5.9	0	0.0	1	5.0
Bones and joints	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Genito-urinary	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Lymph nodes	0	0.0	0	0.0	3	17.6	0	0.0	3	15.0
Ascitis	0	0.0	0	0.0	2	11.8	0	0.0	2	10.0
Digestive tract	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Pericardial effusion	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Other	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Not specified	0	0.0	0	0.0	1	5.9	0	0.0	1	5.0
Total	1	100.0	2	100.0	17	100.0	0	0.0	20	100.0

4 Distribution of treatments by case definition

Beginning of TB Treatment between 01/01/2006 and 31/03/2006

Case Definition	Regimen	Frequency	
		n	%
New case	2HRZE4HR	0	0.0
	2HRZE6HE	66	75.9
	2SHRZ/2RH(Z)/3EH (MANYATTA)	0	0.0
	Adult Cat II - MoH	0	0.0
	CAT2	0	0.0
	Children Cat I	19	21.8
	DR TB Regimen	2	2.3
	Multi Drug Resistant	0	0.0
	Other	0	0.0
	Poly Drug Resistant	0	0.0
	TB Meningitis/Cat II Paediatric	0	0.0

Interpreting the case finding tables:

Table 1

- During the 1st quarter 2006, 109 TB cases were diagnosed and TB treatment was started. 65 (59.6%) cases were diagnosed in female patients and 87 (79.8%) were new cases.
- Among the 109 cases, 40 (36.7%) were smear positive PTB. However, the type is not specified for 22 (20%) cases, showing that the database is not complete.

Table 2

- During the same period, of the 109 cases, 7 occurred in patients aged below 5 years, 15 in patients between 5 and 15 and 87 in patients aged 15 years and above.
- Of the 87 cases diagnosed in patients aged of 15 years and above, 37 (42.5%) were smear positive PTB, 24 (27.6%) smear negative PTB and 17 (19.5%) extra-pulmonary TB. For 9 (10.3%) cases, the type of TB is missing.

Table 3

- Overall, the 3 most frequent sites for EPTB are pleural effusion (40.0%), disseminated or miliary TB (25.0%) and lymph node TB (15.0%).

Table 4

◊ This is an extract of the table 4. Of the 87 new cases (table 1), none were prescribed a 6-month regimen (2HRZE/4HR), 66 (75.9%) received an 8-month regimen (2HRZE/6HE) and 19 (21.8%) received a category 1 regimen for children.

◊ The same information is displayed for each type of cases (relapse, treatment after default…) and for the whole cohort.

Indicators related to TB/HIV co-infection

5 Proportion of tuberculosis cases started on cotrimoxazole prophylaxis

Beginning of TB Treatment between 01/01/2006 and 31/03/2006

45% (49/109)

6 Description of duration of ART among patients who were on ART at the time of tuberculosis diagnosis

Beginning of TB Treatment between 01/01/2006 and 31/03/2006

Time between ART initiation and tuberculosis diagnosis	Frequency		Median CD4 at ART initiation (*)
	n	%	
<1 month	2	7.7	316.0
≥1 to <3 months	5	19.2	180.5
≥3 to <6 months	6	23.1	84.0
≥6 months	13	50.0	81.0
Total	26	100.0	107.5

(*) For patients >=5 years

7 Description of the treatment phases of tuberculosis for tuberculosis patients started on ART

Beginning of TB Treatment between 01/01/2006 and 31/03/2006

Phase of treatment	Frequency		Median CD4 at ART initiation (*)
	n	%	
Intensive phase of tuberculosis	18	31.6	69
Continuation phase of tuberculosis	35	61.4	84
In the month following end of treatment	4	7.0	419
Total	57	100.0	84

Exclusion of patients "Transferred in" and "Not specified"
(*) For patients >=5 years

8 Distribution of treatment duration for patients entered in the program after initiation of tuberculosis treatment

Beginning of TB Treatment between 01/01/2006 and 31/03/2006

Duration of TB treatment	Frequency	
	n	%
≤2 months	23	76.7
>2 months	7	23.3
Total	30	100.0

Interpreting the tables related to TB/HIV co-infection:

Table 5

◊ During the 1st quarter 2006, 49 of the 109 TB cases started cotrimoxazole (CTX) prophylaxis at the time of TB diagnosis.

◊ Note: it does not mean that 60 patients were not on CTX. Some could have been already on CTX before being diagnosed with TB.

Table 6

◊ 26 of the 109 TB cases were on ART at the time of TB diagnosis.
◊ 2 (7.7%) had been on ART for less than 1 month and 13 (50.0%) for 6 months or more.
◊ The last column displays the median CD4 at ART initiation for cases aged 5 years and above.

Table 7

◊ 57 TB cases initiated ART after TB treatment start.
◊ The ART initiation occurred during the intensive phase for 18 (31.6%) cases.
◊ As in the previous table, the last column displays the median CD4 at ART initiation for cases aged 5 years and above.

Table 8

◊ 30 TB cases entered the HIV program after initiation of TB treatment.
◊ 23 (76.7%) were enrolled within 2 months after TB treatment start.

Cohort analysis

9 Description of outcomes by type of tuberculosis and case definition

Beginning of TB Treatment between 01/01/2006 and 31/03/2006

TB type	Case Definition	Cured		Failure		Treatment completed		Defaulter		Dead		Transferred out		Adapted to DST		Treatment stopped for toxicity		Not specified		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Smear positive pulmonary TB	New case	19	57.6	1	3.0	0	0.0	4	12.1	6	18.2	3	9.1	0	0.0	0	0.0	0	0.0	33	100.0
	Relapse	4	66.7	0	0.0	0	0.0	1	16.7	0	0.0	0	0.0	0	0.0	0	0.0	1	16.7	6	100.0
	Treatment after default	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Failure	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	100.0
	Transfer in	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Other	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Not specified	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Total	24	60.0	1	2.5	0	0.0	5	12.5	6	15.0	3	7.5	0	0.0	0	0.0	1	2.5	40	100.0
	Total Retreatment	5	71.4	0	0.0	0	0.0	1	14.3	0	0.0	0	0.0	0	0.0	0	0.0	1	14.3	7	100.0

TB type	Case Definition	Cured		Failure		Treatment completed		Defaulter		Dead		Transferred out		Adapted to DST		Treatment stopped for toxicity		Not specified		Total	
		n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Total	New case	19	21.8	1	1.1	36	41.4	11	12.6	14	16.1	6	6.9	0	0.0	0	0.0	0	0.0	87	100.0
	Relapse	5	27.8	0	0.0	8	44.4	3	16.7	1	5.6	0	0.0	0	0.0	0	0.0	1	5.6	18	100.0
	Treatment after default	0	0.0	0	0.0	2	66.7	1	33.3	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	3	100.0
	Failure	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	100.0
	Transfer in	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Other	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Not specified	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
	Total	25	22.9	1	0.9	46	42.2	15	13.8	15	13.8	6	5.5	0	0.0	0	0.0	1	0.9	109	100.0
	Total Retreatment	6	27.3	0	0.0	10	45.5	4	18.2	1	4.5	0	0.0	0	0.0	0	0.0	1	4.5	22	100.0

Interpreting the cohort analysis table:

Table 9

◊ Here is an extract of the table 9, showing the outcomes of the smear positive PTB cases and of the entire cohort. The same information (not shown) is available for each TB type.
◊ Among the 40 smear positive PTB cases, 24 (60.0%) were declared cured, 1 (2.5%) failed, 5 (12.5%) defaulted and 6 (15.0%) died. For 1 case the outcome is not specified.
◊ The same information is shown for each case definition. Among the 33 new cases, 19 (57.6%) were declared cured, 1 (3.0%) failed, 4 (12.1%) defaulted, 6 (18.2%) died and 3 (9.1%) were transferred out.
◊ The last line shows the treatment outcomes for all cases receiving a retreatment regimen.
◊ The bottom part of the table (presented here) shows the outcomes of the entire selected cohort. Among the 109 TB cases, 25 (22.9%) were declared cured, 1 (0.9%) failed, 46 (42.2%) completed the treatment, 15 (13.8%) defaulted and 15 (13.8%) died.

7.5. TB indicators

This section presents some examples of the indicators that may be calculated with the FUCHIA TB data, provided that the number of data not specified is minimal. For interpretation, refer to the MSF TB guideline.

7.5.1. Inclusion

Indicator	Numerator	Denominator	Example
% of new cases (NC)	Number of NC	Total number of cases	87/109 = 79.8%
% of smear pos. cases among NC	Number of smear pos. among NC	Number of NC	33/87 = 37.9%
% of retreatment cases among total cases	Number of retreatment cases	Total number of cases	22/109 = 20.2%

7.5.2. Outcomes

Indicator	Numerator	Denominator	Example
Cure rate of smear pos. new cases	Number of smear + NC cured	Number of smear pos. NC	19/33 = 57.6%
Global cure rate (all smear pos. cases)	Number of smear + cured	Number of smear pos. cases	24/60 = 60.0%
Global success rate (cured & completed)	Number of cured & treatment completed	Total number of cases	(25+46)/109 = 61.5%
Global death rate	Number of death	Total number of cases	15/109 = 13.8%
Global defaulter rate	Number of defaulter cases	Total number of cases	15/109 = 13.8%
Global failure rate	Number of failure cases	Total number of cases	1/109 = 0.9%

7.5.3. TB/HIV co-infection

% of patients on ART at least one month after the end of TB treatment

= (patients on ART at time of TB diagnosis [table 6] + patients initiated during or within 1 month after TB treatment [table 7]) / number of TB cases

= (26 + 57) / 109

= 76.1%

8: PREVENTION OF MOTHER TO CHILD TRANSMISSION

List of figures

List of tables

8.1. Overview of the PMTCT intervention

Mother-to-child transmission (MTCT) is when an HIV-infected mother passes the HIV virus to her baby. This can occur during pregnancy, labour and delivery, or from breastfeeding.

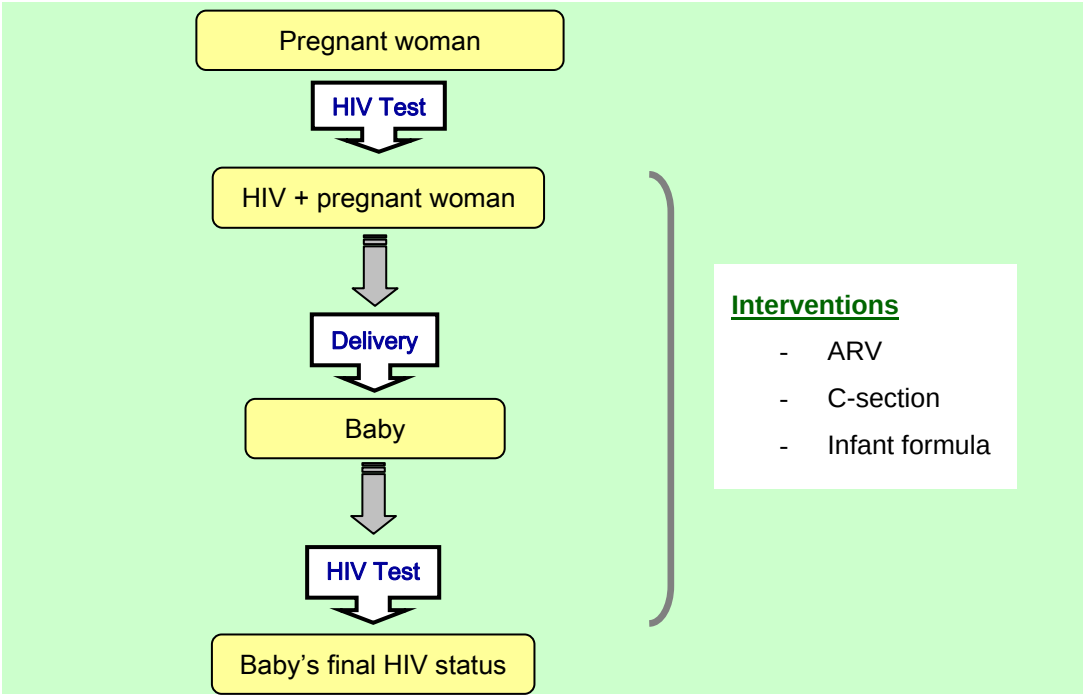
The ultimate objective of a PMTCT programme is to reduce the transmission of HIV from mother to child. In other words the aim of a PMTCT intervention is to ensure infants born to HIV+ mothers are HIV negative.

☛ **The transmission may occur at different time periods:**
- During pregnancy
- At birth
- Through breastfeeding

☛ **Interventions to reduce the mother to child HIV transmission include:**
- HIV testing
- ARV for the mother and the new born
- Selective caesarean section
- Infant formula feeding

☛ **For interventions to be feasible, one requires:**
- VCT, best if integrated in MCH services
- Access to ARV drugs
- Quality MCH services (ante & post-natal care, maternity, <5 clinic)

Figure 1: Diagram representing a PMTCT programme



8.2. Data collection

Information relating to PMTCT activities is collected to monitor and evaluate the program's PMTCT interventions. The guidelines and protocols have changed over time and FUCHIA version 1.7 incorporates the WHO recommendations of 2009 (see section 8.2.1).

Data collection commences at the point where the HIV+ mother's pregnancy status is confirmed and continues until the infant is discharged from the PMTCT cohort (i.e. when the HIV status of the infant is known and the infant is no longer exposed and at risk of HIV transmission). The time between these events could be long, therefore the PMTCT intervention is "divided" into 2 periods:

- The duration of the pregnancy until delivery and
- From birth of infant till discharge of infant from the PMTCT cohort

Data collection reflects these 2 periods, and figure 2 describes the process in detail. The main tools for data collection are the

- The PMTCT form which collects all information related to the pregnancy as early as 14 weeks of amenorrhea until delivery and includes the prophylaxis prescribed and its duration for the mother and the new born.
- The Baby Follow up form (see section 8.2.2) is adapted from the child follow up form and collects specific information related to the follow up of the baby born to an HIV+ mother (prophylaxis, end of breastfeeding, end of prophylaxis and HIV tests until the HIV status is determined).

Aside these, the FUCHIA patient and Follow-up Forms are required.

During PMTCT data collection
Forms to complete for the mother are: patient, follow-up (adult) and PMTCT forms
Forms to complete for the baby are: patient, follow-up (Baby or Child) and PMTCT forms
ONLY one PMTCT form to be completed during each pregnancy.

Electronic version of the FUCHIA forms in Word format can be found in the directory: "C:\Program Files\MSF\Fuchia\v1.7.1\doc\forms".

How to complete the PMTCT form and Baby Follow-up Form are described in section 8.2.3 and for information on completing the patient and Follow-up Form, go to chapter 3 Data Processing.

The data collection process in brief.

►At start of pregnancy	Complete Follow-up Form for the mother including the section on "Mother to child programme". If mother is **new** to the program, also complete a Patient Form for her.
►At admission of mother to PMTCT program	Start a new PMTCT form and complete the "admission" section.
►At initiation of Mother ARV protocol	Using the same PMTCT form as at admission, complete the "admission" section on mother ARV protocol. Complete the "ART & prophylaxis prescribed" section on mother's Follow-up Form for this and subsequent visits.
►At delivery	Using the same PMTCT form as at admission, complete "pregnancy outcome" section. For **every life birth,** Complete "children prophylaxis" section using the PMTCT form as at admission and a new line for each new born infant + Complete 1 Patient Form per new born infant + Complete 1 Baby Follow-up Form per new born infant. *For example, if 3 infants are born alive to one mother; 3 new patient and 3 new baby Follow-up Forms are to be completed with each infant assigned a unique NID.*
►Follow-up visit of exposed infants *	For **asymptomatic** infants, complete Baby Follow-up Form For **symptomatic** infants, complete standard child Follow-up Form on that visit and subsequent visits to record clinical conditions and ART prescription and complete a Baby Follow-up Form if any HIV test result or date end of breastfeeding or date end of prophylaxis are known.
►Discharge from PMTCT cohort **	For **HIV negative** infant, complete "discharge" section of the infant Patient Form. For **HIV positive** infant who is followed in the programme, follow standard procedures and complete Child Follow-up Form at visit and subsequent follow-up visits.

*Period where infant is exposed and is at risk of HIV transmission from the mother, and their HIV status is unknown

** Infant is discharged from PMTCT cohort when infant is no longer exposed and is no longer at risk of HIV transmission from the mother, and their HIV status is known

Assigning Unique IDs for the pregnant mother:

- If the mother is already followed in the programme, use the unique ID allocated to her on the PMTCT form.
- If the mother is a new HIV + patient and not yet registered in the programme, remember to fill a Patient Form so that she can be registered correctly in the FUCHIA database.

Assigning Unique ID for babies

- Each new born infant must be assigned a unique ID.
- Baby's ID can follow the numbering system in place in the programme or they can be allocated an ID based on the mother's ID.

  Ex: mother ID = 156 → baby ID (1st baby) = 156B1, baby ID (2nd baby) = 156B2.

It is essential that the baby ID is different from the mother ID.

8.2.1. 2009 WHO recommendations for PMTCT programmes

In late 2009, WHO published new recommendations for PMTCT programmes, and these revisions mainly concern the ARV protocols for mother and infant and the timing of infant HIV tests.

For more details, please refer to the Aids Working Group document and / or to the 2009 WHO recommendations.

Mother ARV protocol

For those pregnant women who meet the eligibility criteria for ART (i.e. has WHO staging of 3 or 4 or a CD4 count lower than 350 cells/mm3), the recommendation is that she starts and remains on combined antiretroviral therapy (cART), primarily to improve her health.

For those women who are not eligible for ART (i.e. WHO staging of 1 or 2 or CD4 >= 350 cells/mm3), there are two options and this intervention is primarily to prevent HIV transmission to the infant:

- **Option A:** Zidovudine (AZT) is given to the mother as early as 14 weeks of amenorrhea or for at least 4 weeks before delivery. If AZT is given for less than 4 weeks before delivery, then administration of a single dose of NVP at the beginning of labour and AZT/3TC during labour and delivery and for 7 days after delivery is also acceptable.

- **Option B:** Triple ARV prophylaxis is given to the mother as early as 14 weeks of amenorrhea and until delivery or until 1 week after cessation of breastfeeding, as applicable.

Option B is the WHO recommendation, and option A is an alternative for PMTCT programmes that cannot afford option B.

Baby ARV protocol

The recommendation is that all babies should receive a minimum of 6 weeks of ARV prophylaxis after birth.

Depending on the mother ARV protocol and in the case of breastfeeding, the baby ARV prophylaxis may be prescribed over the whole period of breastfeeding and until 1 week after breastfeeding has stopped.

Baby HIV testing

If relevant and reliable HIV tests are available on the field, baby HIV tests should be performed at 6 weeks since birth and at appropriate time points (whilst infant is exposed to breast milk and at risk of HIV transmission) in order to determine final HIV status of the infant.

8.2.2. Baby Follow-up Form

Baby Follow-up Form was created specifically to collect necessary information on babies born to mothers admitted to the PMTCT programme. The form differs in only two respects to the Child Follow-up Form: the section on clinical diagnosis ❶ has been shortened to allow space to record the information collected on interim HIV test results and to record when date end of breastfeeding or date end of ARV prophylaxis occurs❸.

We advise that you use this form from birth- until the final HIV status is determined. In this period the baby is to be followed regularly and the form completed at each visit. By completing the form, you will be able to monitor whether 1) baby remains asymptomatic, 2) mother/carer adheres to planned visits 3) ARV prophylaxis is prescribed to baby according to WHO recommendations and 4) HIV tests have been performed at certain times (from 6 weeks onward, depending on the tests available and the type of feeding).

Clinical conditions diagnosed during the current visit (codes: **N**ew, **O**ngoing, **R**ecurrent)

WHO stage 1 ❶	N	O	R
• Asymptomatic	O	O	O
• Persistent generalized lymphadenopathy	O	O	O

If the infant becomes sick (WHO stage 2 or above) ❷ please fill also a "regular" follow up form for children to allow the record of clinical conditions.

Other diagnosis 1: …… Other diagnosis 2: ……

Weight: …… (kg)
Height: …… (cm)

Active screening of TB: O Sputum / Sample O X-Ray O Other

Children HIV test results (only the final HIV status has to be recorded on child patient FUCHIA form) ❸

Age (months)	*Date (blood taken)*	*Test* [1]	*Result* [2]
……	……/……/……	……	……

[1]Test: DNA PCR, Up24Ag (Ultrasensitive AgP24), RT (antibody test), VL (RNA viral load), Immunocomb
[2]Results: Negative, Positive, Invalid, Not done, Not specified

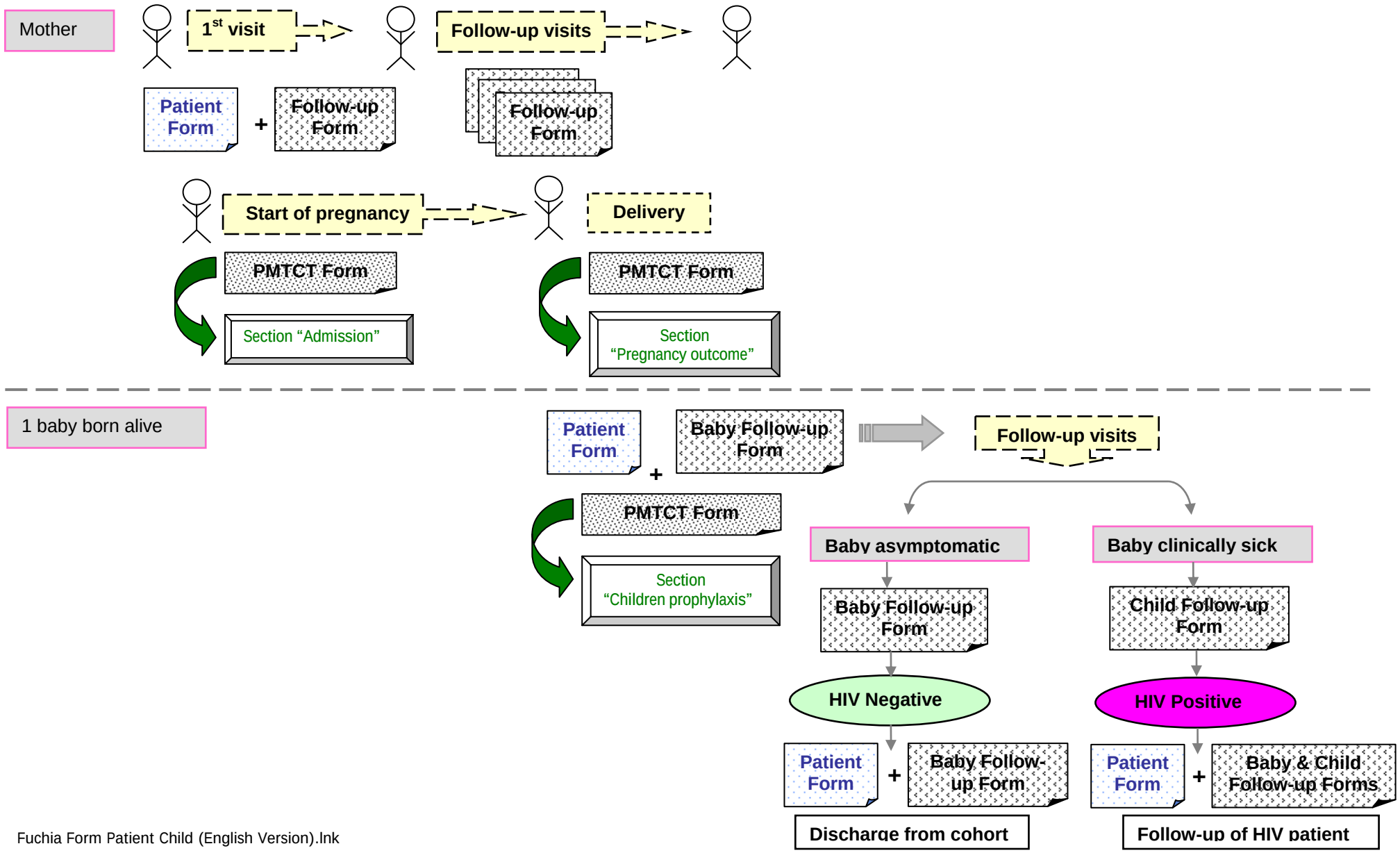
Date of end of breastfeeding: ……/……/…… Date of end of ARV prophylaxis: ……/……/……

◊ The Baby Follow-up Form is a template and we welcome any suggestions on how the additional information ❸ can be incorporated into the existing Follow-up Forms and reduce the number of paper forms.

◊ We expect the majority of PMTCT babies to be asymptomatic; therefore, only WHO stage 1 appears in the section clinical diagnosis on the Baby Follow-up Form. The "asymptomatic" box can be ticked at each visit when appropriate.

◊ As soon as the baby becomes "symptomatic", as mentioned on the form (❷), a standard Child Follow-up Form should also be completed on that visit and subsequent visits to record clinical conditions and ART prescription. However if by the date the child becomes "symptomatic", the final HIV status is not determined, or s/he is still breastfed or continue to be on ARV prophylaxis, then a Baby Follow-up Form should also be completed at each visit, such that the information (❸) is still collected.

Figure 2: Data collection flowchart for PMTCT data collection



Fuchia Form Patient Child (English Version).lnk

8.2.3. Description of the data to be collected

Table 1: PMTCT Form

Name of variable	Details	Comments
Mother Identification		
ID Cohort	Mother's unique cohort ID.	
ID other	Number or text allowing the mother to be identified by means other than the cohort number. (e.g.: medical record number…)	
Admission to PMTCT programme and Mother ARV protocol		**Section to be filled as soon as the mother enters the PMTCT programme**
Referred by	Facility referring the mother to the service	
Date of admission	Admission date in the PMTCT programme.	Admission recommended from 14 weeks of amenorrhea.
Mother ARV protocol	ARV protocol prescribed to the mother during the pregnancy: - cART - Prophylactic cART - AZT - AZT + NVP_{SD} + (AZT+3TC) - NVP_{SD} + (AZT+3TC) - NVP_{SD} - other - none - not specified	cART stands for combined Anti-retroviral therapy and is ticked when the mother is prescribed ART for her own health (i.e. her WHO staging is 3 or 4, or her cd4 count is below 350 cells/mm3). Prophylactic cART is ticked when the mother is prescribed ART primarily for the prevention of transmission of HIV to her infant. (her WHO staging is 1 or 2 and her cd4 count is above 350 cells/mm3). WHO recommended option B. Option A: AZT alone for at least 4 weeks before delivery, or AZT <4 weeks + NVP_{SD} during labour and AZT +3TC during labour and seven days after.
Date of initiation	Date mother initiated cART or the date mother started ARV prophylaxis.	If mother started ARV prophylaxis, enter the date prophylaxis was started for the current pregnancy.
Expected date of delivery	Delivery expected by that date	Good to enter, even if it is not a precise estimate, as this can help "detect" LFU mothers before delivery.
Pregnancy outcome		**Section to be filled soon after delivery** **See note below if outcome is miscarriage/abortion**
Date of delivery	Date of delivery / pregnancy outcome	The date will indicate the end of the pregnancy, regardless the outcome (miscarriage, abortion or baby born)
Type of delivery	Vaginal delivery, Caesarean section, NS	
Health facility	Hospital, Health centre, Home, Not specified	
Breastfeeding chosen at delivery	Yes / No / NS	
Number of babies born		**Enter** 0 if child is not viable or 0 to account for miscarriage and abortion (no baby "born") Or number of term or premature deliveries
Number of babies alive		**Enter** 0 to account for still birth or death during delivery Or number of babies born alive

Children prophylaxis (1 line per new born)		
Child Id. Cohort	Infant identification number	A Patient Form with a unique baby ID needs to be created and saved beforehand.
Id. Other	Number or text allowing the infant to be identified by means other than the cohort number. (e.g.: medical record number…)	
ARV	ARV drug(s) prescribed for prophylaxis	These variables will reflect what the intended protocol was at the time of delivery.
Duration	Prescribed duration of the ARV prophylaxis	
Comment	Free text	
User data		
Free variables	10 free variables to be entered at the end of pregnancy	Variables to be defined at the time of creating the database (cf. II.2.3)
Notes	Free text	

Note: There is no variable to record if the outcome of pregnancy is miscarriage or abortion. Therefore we propose that the information is collected the following way:

Date of delivery	Enter date of abortion or miscarriage.
Number of babies born	Enter 0 for miscarriage or abortion

Table 2: PMTCT Baby Follow-up Form

The following table displays the variables, details and comments that are important or specific to the follow-up of babies born to HIV + mothers. For details on the other variables, refer to chapter 3 – data processing.

Name of Variable	Details	Comments
Patient Identification		
ID Cohort	Unique patient number	See chapter 3 for complete comments
ID Other	Number or text allowing patients to be identified by means other than the ID cohort number.	See chapter 3 for complete comments
Admission and follow-up		
Type	Consultation/ hospitalisation	See chapter 3 for complete comments
Location	Locations where visits take place	See chapter 3 for complete comments
Date of visit / start of hospitalisation	In dd/mm/yyyy format	See chapter 3 for complete comments
Visit	On time, late, unplanned or not specified	See chapter 3 for complete comments
Date of next appointment	Date of the next scheduled appointment following consultation/ discharge from hospital.	See chapter 3 for complete comments
Referred to	Referral system in which patients, following hospital discharge / consultation, are referred outside the programme.	See chapter 3 for complete comments
Discharge (if hospitalised)		
Status	Status on discharge: transferred, absconded, died, terminal stage or medical agreement	**To be filled in only if the patient is hospitalised**
Date of discharge	In dd/mm/yyyy format	**If applicable, deaths are recorded on the Patient Form.**
Biological results		
Date of blood collection	In dd/mm/yyyy format	Blood test results must be recorded on the Follow-up Form nearest the date when the test was actually performed (i.e. the next visit). **They are to be recorded only once**.
Test	Lab technique used for HIV testing: DNA PCR, Ultra-sensitive agP24, antibody test, RNA viral load, Immunocomb, NS	Those variables are seen under the tab "HIV tests (PMTCT follow up)" and are exclusively for the follow up of babies born to PMTCT mothers.
Result	Negative / Positive / Invalid / Not done / NS	

Name of Variable	Details	Comments
Breastfeeding (Date end)	Date when the breastfeeding ended	Those dates are important for evaluation of the PMTCT intervention. Though collected on the Baby Follow-up Form, the data are entered in FUCHIA on the PMTCT form.
Prophylaxis (Date end)	Date when the baby ARV prophylaxis ended	
Clinical conditions during this follow-up visit		
WHO stage 1	"Asymptomatic" to be ticked as long as the baby remains asymptomatic.	We expect majority of PMTCT babies to be asymptomatic, therefore, only WHO stage 1 appears in the section clinical diagnosis on the Baby Follow-up Form. As soon as the baby becomes clinically sick (WHO stage 2 or above), please fill also a "regular" Follow-up Form for children to record the new clinical conditions.
Treatment prescribed or stopped during the visit		
Drug **Prescription**	To be selected from the list of drugs. Codes are as follows: • **treatment / prophylaxis begun,** • **continued,** • **continued with intolerance,** • **restarted,** • **stopped for intolerance,** • **stopped for failure,** • **stopped for non-compliance,** • **stopped for patient reason,** • **stopped for pregnancy** • **stopped for end of treatment,** • **stopped for TB regimen** • **stopped for other reason.**	If treatment / prophylaxis are on-going, it must be systematically recorded as "continued", regardless of the type of visit (consultation or hospitalisation). NB. **The reason for treatment discontinuation must be specified**, as, during analysis, the patient may only be considered for "treatment discontinuation", if the reason for stopping treatment has been specified. Stopped for non-compliance: decision to stop taken by the doctor as a result of non-compliance Stopped for patient reason: on the patient's request
Intolerance 1 **Intolerance 2**	To be selected from the list of intolerances. Two types of intolerance may be entered for each drug.	The type of intolerance must be recorded, regardless of whether or not a drug has been discontinued due to intolerance. See the case definition given in the Appendix
Intolerance	Any additional drug intolerances	

8.3. Data entry

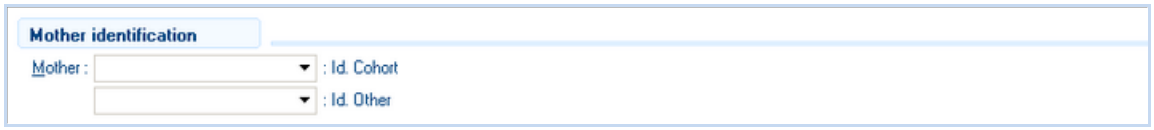
In FUCHIA, data related to PMTCT is mainly entered in the PMTCT data-entry form; however some information will have to be entered in the mother and infants' patient and follow-up data-entry forms.

Prior to entering any data in the FUCHIA PMTCT data-entry screen, ensure the unique ID of the mother exists in the FUCHIA database, or create a new Patient Form for her with her unique ID. Similarly, when entering data of the new born in the PMTCT form, a Patient Form for the infant has to be created prior to entry.

NOTE: To add a new patient, go to Chapter 3, section 3.3.3 Entering new data.

8.3.1. PMTCT form

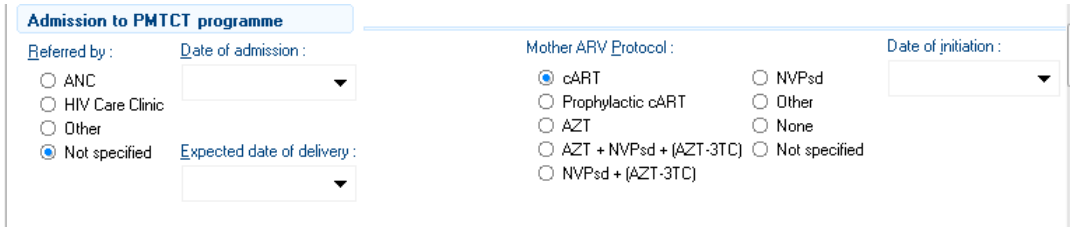
► *Entering Mother IDs*



Id Cohort (mandatory): Click on the arrow (right-hand side of entry field) for list of all Patient IDs to appear. Select the ID number required or enter the first digits to arrive nearer to the ID number required. If ID does not exist, create a new Patient Form for the mother with her ID.

Id Other: the Id Other is linked to the Id Cohort number and will automatically appear if it has been recorded and saved in the "Patient" Form.

► *Entering "Admission to PMTCT programme"*

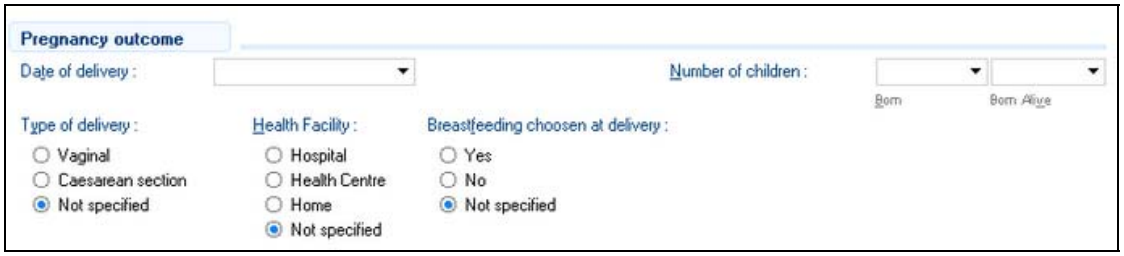


*Date of admission (**Mandatory**): Has to be entered for every pregnancy, as this variable is used to generate the PMTCT report.*

Date of initiation: Mandatory if the mother ARV protocol is different than "none" or "not specified" (see data entry checks).

Mother ARV Protocol, Date of Initiation and Expected date of delivery: See section 8.2.3 for details.

► *Entering "Pregnancy outcome"*



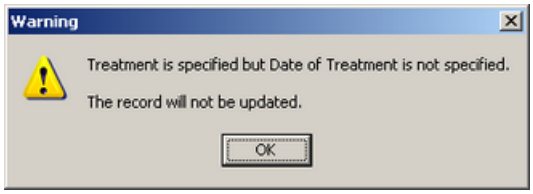
*Date of delivery & number of babies are **mandatory**. If a date of delivery is entered, the number of babies must be specified and vice-versa.*

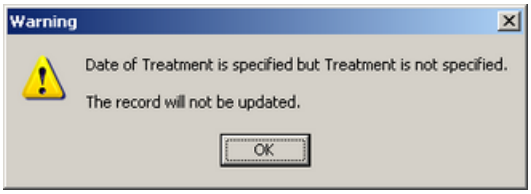
1 – Data entry check on dates of admission / of ART initiation / of delivery

- No check to oblige the date of delivery to be entered to avoid data entry to be stopped
- No check between those 3 dates
- This was a request of the Aids Working Group to allow post-delivery admission of an HIV+ mother who did not benefit from a PMTCT intervention during pregnancy or labour. In that case, her infant can now be proposed an ARV prophylaxis providing the infant is still asymptomatic.
- Therefore both, mother and infant need to be entered retrospectively in the FUCHIA database.

2 – Data entry check on date of initiation

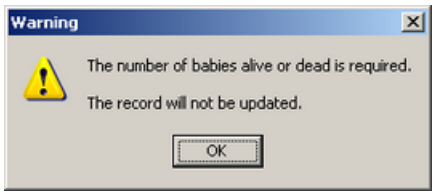
- FUCHIA will request a date of initiation if the mother ARV protocol is different than "none" or "not specified" *See below left screen copy*
- On the contrary, FUCHIA will request to specify a treatment if a date of initiation is specified. *See below right screen copy*





3 – Data entry check on number of babies born and born alive

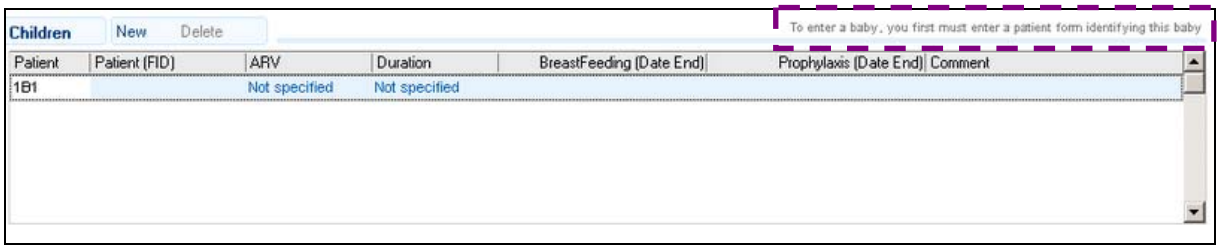
- Once a date of delivery is entered, the number of babies must be entered and vice-versa. The range for the number of babies born is 0 to 5. *See below left screen copy*
- The number of babies born alive must be equal or less than the number of babies born. A window will warn you if this condition is not respected. *See below right screen copy*



► *Entering data on new born infants*

To activate this section of the form, click on save at the bottom of the screen.

Data on infants are entered per row. Prior to entry ensure a unique ID is assigned to every new born infant and that a Patient Form exists in FUCHIA (see chapter 3 – data processing).



*Patient **(Mandatory):** From drop down list select unique ID of infant or enter first few digits to restrict list. Once selected, the other ID will appear if entered in the Patient Form.*

ARV & Duration: Two new variables added to allow separate entry of treatment and duration. By default, the fields "ARV" and "Duration" are "Not specified". It is now possible to enter the 2009 WHO recommendations for infant ARV prophylaxis: AZT or NVP for 6 weeks or "long PEP" during the period of breastfeeding until 1 week after end of breastfeeding and in any case, for at least 6 weeks.

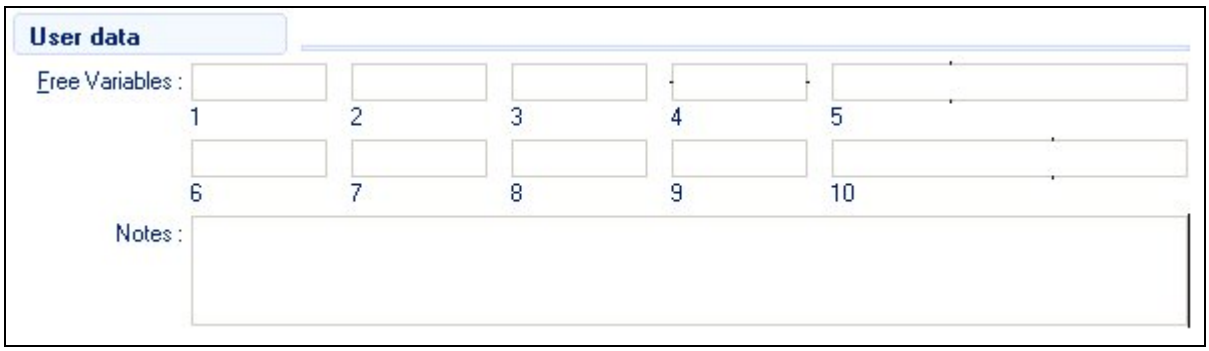
Date end of Breast feeding/Prophylaxis: This information is collected on the baby follow up form but entered in FUCHIA on the PMTCT form.

4 – Data entry check on ARV and duration

- Please ensure whilst entering this information that the correct ARV prophylaxis regimen is entered as currently there are no checks at entry.

► *Entering user data*

Data entry is in free-format. However, make sure that you enter free variables in the correct entry fields. Amend the section "Pregnancy" of the setting.ini file to see the label of the free variables you are entering. (See chapter 2, section 2.7 Naming free variables).



8.3.2. Data entry (other)

Not all PMTCT data collected are entered in the PMTCT form in FUCHIA. Some key PMTCT information is entered in the Patient and Follow-up Forms and here follows an overview.

Date of birth: Ensure this date is the same as the date of delivery

► *Entering Infant clinical condition*

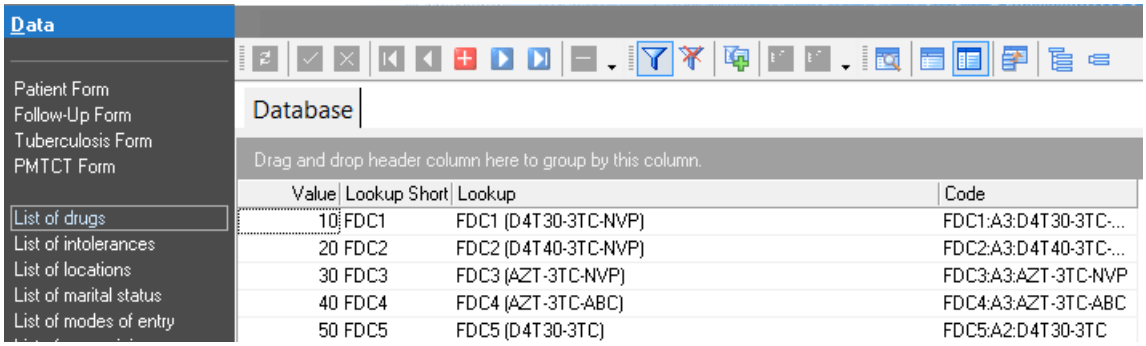
Although infants may be asymptomatic at first, it is important to collect this information at each visit.

The clinical background section in the Patient Form to be completed for those infants who have a clinical history and are enrolled in the program post-delivery. For infants who are followed in the program since birth, their clinical condition is to be entered in the Follow-up Form.

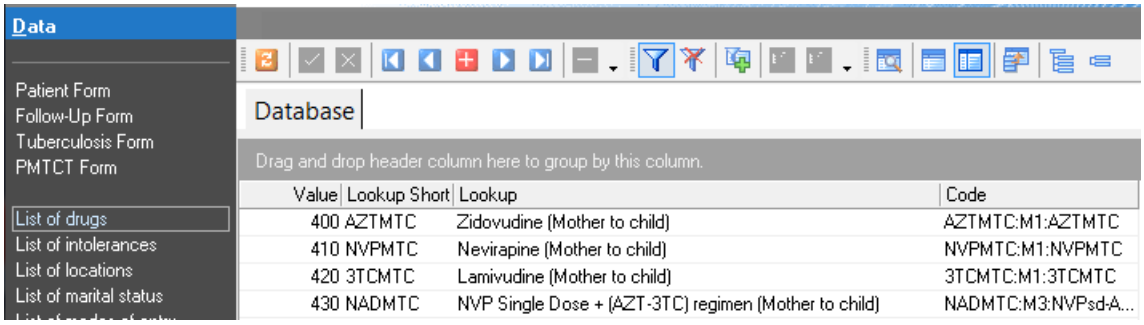
► *Entering Mother and Infant ARV prescription*

Similarly, from both patient management and PMTCT monitoring points of view, it is essential that any ARV prescribed or stopped and reason for stopping are clearly indicated. It is good practice therefore, to capture this information in the Follow-up Forms at each visit for both the mother and the infant and to enter this in FUCHIA for further analysis. For example, one can ascertain if ARV protocol are adhered to.

For mothers who are **prescribed cART**, use the appropriate codes for ARV drugs during data-entry. This way, the mother will be correctly considered as an ART patient in FUCHIA reports. For further explanation, refer to the chapter 5, section 5.2.2 Data calculations, ART variables.



For mothers and infants who are **prescribed ARV as prophylaxis**, the appropriate MTC codes (“AZTMTC”, “NVPMTC”, “3TCMTC” and “NADMTC) should be used during data-entry. This way these patients will be considered as pre-ART patients.

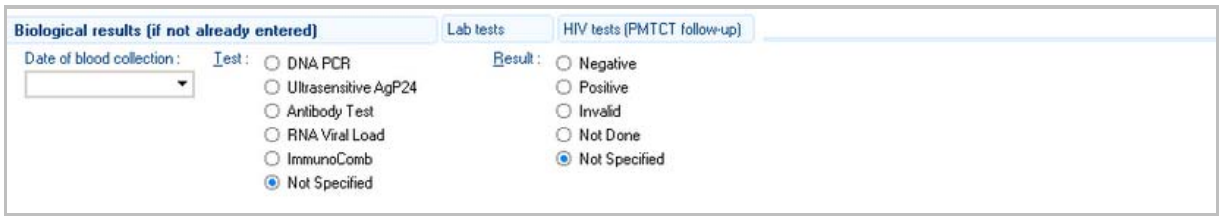


NOTE: History of ARV prescribed in the Patient Form relates to ARV prescribed by another programme. Do not use this to enter the ARV prophylaxis given by the PMTCT programme if this component is part of the package provided in the overall programme.

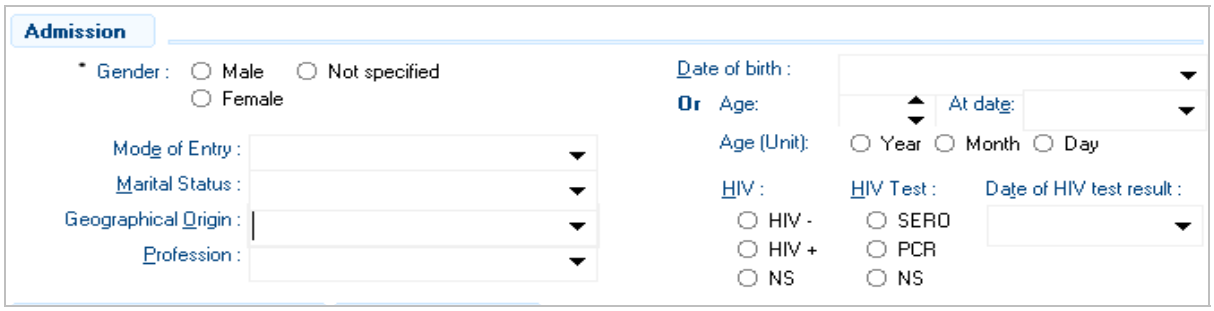
► *Entering Infant HIV test results*

Interim HIV tests are performed repeatedly from 6 weeks after birth of infant to 18 months. From these interim tests an HIV status is determined by the clinician and the infant is classified as either HIV positive (if tests are reliable) or HIV negative (providing the clinician is confident that the infant is no longer at risk of HIV transmission from the mother).

For any infant several interim test results may be available and this information is collected on the Baby Follow-up Form and is entered in FUCHIA in the Infant Follow-up Form. Click on the tab "HIV tests (PMTCT follow-up)" in the Follow-up Form, and enter the date of blood collection, the type of test performed (test) and the result.



Once the clinician has determined the HIV status of the infant, the HIV test result is entered in FUCHIA in the admission section of the Patient Form. Therefore, the fields "HIV result" and "test" remain "NS" and the field "date of HIV test" remain empty until that time.



5 – Data entry check on HIV tests for PMTCT baby follow-up

- As for any lab result, the date cannot be after the date of visit.
- As soon as a date is entered, "test" and "result" must be different than "not specified".
- If "test" is different than "not specified", then "result" must be different than "not specified" and vice-versa.

► *Entering Infant discharge from cohort*

Infants whose HIV status is confirmed negative will no longer be followed and should be discharged from the cohort. A PMTCT baby can also be discharged to another program before their HIV status is determined.

As with all other patients, the discharge section has to be updated in the event of death, transfer out or discharge of the infant, as this information is needed for both the PMTCT report and for other cohort reports. If section is not updated, infants will be wrongly considered as lost to follow-up.

In the Patient Form, section Discharge, tick cohort discharge and enter the date of discharge for infants discharged or transfer-out or tick death and date of death for infants who died.

8.4. PMTCT report

8.4.1. Overview

The report describes the various aspects of the PMTCT programme from admission of mother to the program, to delivery, to infant outcomes and their HIV status and provides a cohort analysis of the mother-infant pairs based on either

- the date of admission to the PMTCT program or
- the date of delivery

8.4.2. Report generation & Parameter selection

The PMTCT report is generated by specifying a period of analysis and a date of analysis.

The **period of analysis** defines the cohort of patients that will be analysed in the report. If date of admission is selected, the cohort consists of all pregnant women who were admitted to the PMTCT program over the period specified. If date of delivery is selected, the cohort consists of all infants born in the specified period.

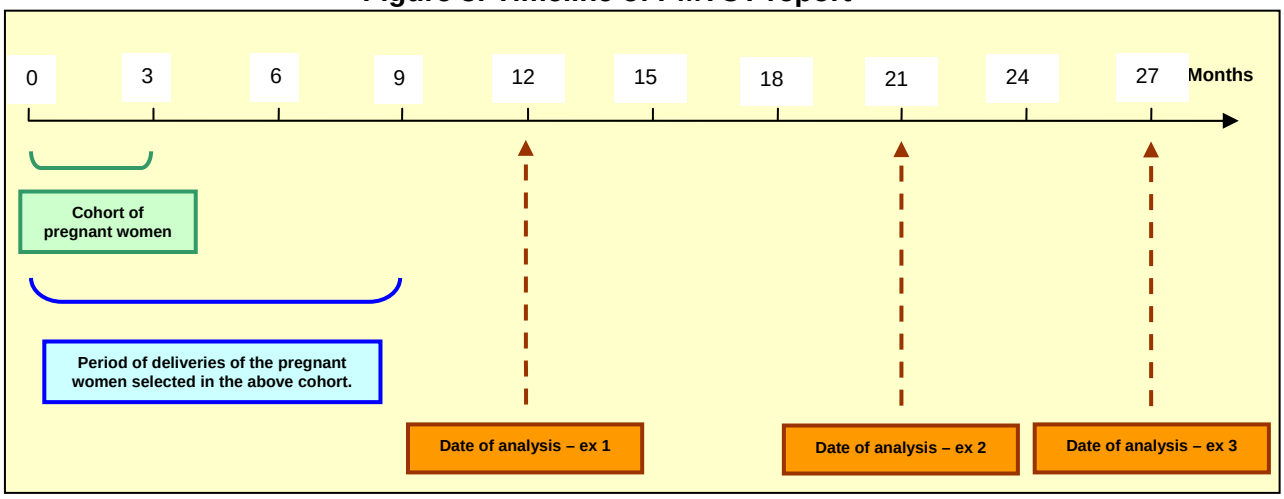
The **date of analysis** defines the date by which the PMTCT outcomes (delivery, infant HIV test results) are analysed. Therefore the choice of date is crucial in order to obtain the maximum amount of information for the report. For instance, a date of analysis close to period of admission to the PMTCT program may show that some pregnant women have not yet given birth. A date of analysis further away from this period may show all delivery outcomes but may not yet show the HIV status of all infants born. The general idea is to select a date of analysis further away from the period of selection in order to have as complete a report (with the maximum being 24 months after the last date in the period of selection).

The choice of date of analysis depends on many factors and what you want to analyse. Things to consider are

- Stage of pregnancy when mothers are admitted to PMTCT program. WHO recommends prescribing ARV prophylaxis to the mother as early as 14 weeks of amenorrhea. However, not all pregnant women will be admitted in the PMTCT programme at 14 weeks, more likely later and sometimes even after delivery.
- Lag time between admission of the mother in the programme and the determination of HIV status of the baby. At most, it may take 24 months if the mother is registered in the programme at 14 weeks: delivery 6 months later and HIV status determined at 18 months.
- The type of HIV tests available in the programme (i.e.DNA, RNA, serology).
- The type of feeding (breastfeeding or infant formula feeding) and the age of the infant when breastfeeding ends.

The diagram below shows the different aspects of PMTCT in relation to time and gives an example of a 3-month cohort of pregnant women.

Figure 3: Timeline of PMTCT report



The black line represents the calendar months, "0" is the beginning of the 1st month of a given period. Each interval corresponds to a 3-month period.

The green parenthesis defines the cohort of women. Here we consider a 3-month cohort, where pregnant women admitted to the programme between January and March (M0 – M3) are included in the analysis. Some of these women were admitted at about 14 weeks of amenorrhea (12 weeks of pregnancy) and others were admitted just before delivery.

The blue parenthesis corresponds to the period during which all the pregnant women selected in the above defined cohort will give birth. This period is much longer than the period that defined the cohort of mothers. The first delivery can theoretically occur at M0 if the pregnant woman is admitted and gives birth on the first day of the selection period. On the other extreme, a pregnant woman admitted on the last day of the selection period when she is at 14 weeks of amenorrhea will give birth 6 months later, i.e. at the end of M9. Hence the period of deliveries lasts from the first day of the selection period till the last day of M9.

Ex 1 Date of analysis is specified at the end of M12 (31st December).

All pregnant women would have given birth. All infants are at least 3 months old and should have an HIV test result done at 6 weeks if this option is feasible for the programme.

Ex.2: Date of analysis is specified at the end of M21.

All infants are 12 months old or older and if they have all stopped breastfeeding for more than 1 week, then theoretically their HIV status can be determined.

Ex.3: Date of analysis is specified at the end of M27

All infants are 18 months old or older and if all infants have stopped breastfeeding for more than 1 week (and probably more), then the HIV status can be determined.

8.4.3. Report Content

Section 1 of the report describes the number of pregnant women admitted in the programme.

Section 2 describes the pregnancy outcome, the type of delivery and the feeding choice at birth.

Section 3 describes the ARV protocols prescribed to the mothers and infants born alive.

Section 4 describes the early HIV testing results at 6-12 weeks post-partum.

Sections 5 and 6 describe the HIV testing results at 12 and 18 months respectively.

NOTE: The number of infants reported in the tables differs. Tables 2.2 and 2.3, the number of infants born and born alive correspond to the number recorded on the PMTCT form, section pregnancy outcome. From table 3 onwards, the number of infants corresponds to the infants who have been assigned a unique ID and have a Patient Form in the database.

The infant protocol must be recorded in the children section of the PMTCT form to be taken into account in the table 3.1

Front page

As always, the front page displays the selections made for the report. The same selections are displayed at the top of each table.

In the following example, the selection looks at the pregnant women admitted in the programme between 01/01/2010 and 31/12/2010 and their infants. The date of analysis is on the 19/12/2011.

Prevention of Mother To Child Transmission Program Report

R Statistical Analysis of Fuchia Database

Admission in PMTCT Program between 01/01/2010 and 31/12/2010, Analysis on 19/12/2011

Section: Activity

1 Activity report

1.1 Distribution of pregnant women by age group

Admission in PMTCT Program between 01/01/2010 and 31/12/2010, Analysis on 19/12/2011

Age group at admission		Data	
		n	%
<16 years		0	0.0
≥16 to <18 years		0	0.0
≥18 to <25 years		34	24.3
≥25 to <35 years		85	60.7
≥35 years		21	15.0
Not Specified		0	0.0
Total		140	100.0

1.2 Distribution of pregnant women by type of referral center

Admission in PMTCT Program between 01/01/2010 and 31/12/2010, Analysis on 19/12/2011

Referred by		Data	
		n	%
ANC		56	40.0
HIV Care Clinic		84	60.0
Peripheral HC		0	0.0
Other		0	0.0
Not specified		0	0.0
Total		140	100.0

Interpreting:

Table 1.1

◊ During the period selected, 140 pregnant women have been admitted in the PMTCT programme.
◊ Among the 140 pregnant women, 34 (24.3%) were 18 years old or more and less 25 years old.

Table 1.2

◊ During the period selected, 84 (60.0%) pregnant women were referred by the HIV care clinic.

Section: Pregnancy outcome, type of delivery and feeding choice

2 Pregnancy outcome, type of delivery and feeding choice

2.1 Outcomes of pregnancy at time of date of analysis

2.1.1 Distribution of mothers by pregnancy outcome at date of analysis

Admission in PMTCT Program between 01/01/2010 and 31/12/2010, Analysis on 19/12/2011

Pregnancy outcome		Data	
		n	%
Delivered		119	85.0
Not yet delivered*		0	0.0
Died		1	0.7
Transferred out		6	4.3
Other**		14	10.0
Total		140	100.0

* Not yet delivered: no date of delivery recorded and date of analysis <= date of expected delivery.

** Other: no date of delivery recorded and (date of analysis > date of expected delivery or date of analysis > 12 months after date of admission) .

2.1.2 Distribution of deliveries by type of delivery and type of health facility

Admission in PMTCT Program between 01/01/2010 and 31/12/2010, Analysis on 19/12/2011

Type of delivery		Hospital			Health Centre		Home			Not specified			Total	
		n	%		n	%	n	%		n	%		n	%
Vaginal		95	81.9		0	0.0	3	100.0		0	0.0		98	82.4
Caesarean section		21	18.1		0	0.0	0	0.0		0	0.0		21	17.6
Not specified		0	0.0		0	0.0	0	0.0		0	0.0		0	0.0
Total		116	100.0		0	0.0	3	100.0		0	0.0		119	100.0

2.1.3 Duration between admission and delivery

Admission in PMTCT Program between 01/01/2010 and 31/12/2010, Analysis on 19/12/2011

Duration (weeks)		Data	
		n	%
<0		0	0.0
≥0 and <4		10	8.4
≥4		109	91.6
Not Specified		0	0.0
Total		119	100.0

Interpreting:

Tables 2.1

◊ Table 2.1.1: Among the 140 pregnant women, 119 have delivered by the 19/12/2011 (date of analysis). 14 pregnant women are most probably lost to follow up for the PMTCT programme.

◊ Table 2.1.2: Among the 119 pregnant women who delivered, 116 delivered at the hospital and 21 had a caesarean section.

◊ Table 2.1.3: 109 pregnant women delivered 4 weeks or more after their PMTCT admission, 10 delivered within 4 weeks of their admission. No pregnant women were admitted after their delivery.

2.2 Proportion of infants born alive amongst total infants born

Admission in PMTCT Program between 01/01/2010 and 31/12/2010, Analysis on 19/12/2011

	N	No. alive babies	No. born babies
Mother ARV Protocol			
Treatment cART *	82	84	87
AZT + NVPsd + (AZT-3TC)	0		
NVPsd + (AZT-3TC)	0		
NVPsd	0		
Prophylactic cART **	35	34	35
AZT	0		
None	2	0	2
Other	0		
Not specified	0		
Overall	119	118	124

N Number of deliveries.

The number of babies born and born alive corresponds to the number of babies registered on the PMTCT form, pregnancy outcome section.

* Treatment cART: the mother is eligible for ART. The primary objective of ART is treating the mother.

** Prophylactic cART: the mother is not eligible for ART. The primary objective of ART is preventing the transmission of HIV to the baby.

2.3 Distribution of infants by feeding choice at birth

Admission in PMTCT Program between 01/01/2010 and 31/12/2010, Analysis on 19/12/2011

	N	No. alive babies
Breastfeeding		
No	33	37
Yes	81	81
Not specified	5	0
Overall	119	118

N Number of deliveries.

Interpreting:

Table 2.2

◊ 124 infants were born for the 119 deliveries and 118 were delivered alive.

Table 2.3

◊ At birth, the mothers of 81 infants alive have chosen to breastfeed.

◊ The mothers of 37 infants alive have chosen not to breastfeed. There are 37 infants for 33 deliveries; this means that some deliveries are twin or triplet deliveries.

Section: PMTCT protocols

3 PMTCT protocols

3.1 Distribution of infants born alive by mother and infant ARV protocols

Admission in PMTCT Program between 01/01/2010 and 31/12/2010, Analysis on 19/12/2011

Mother ARV Protocol	None		AZT 6 weeks		NVP 6 weeks		NVP Long PEP	
	n	%	n	%	n	%	n	%
Treatment cART *	3	100.0	0	0.0	0	0.0	0	0.0
AZT + NVPsd + (AZT-3TC)	0	0.0	0	0.0	0	0.0	0	0.0
NVPsd + (AZT-3TC)	0	0.0	0	0.0	0	0.0	0	0.0
NVPsd	0	0.0	0	0.0	0	0.0	0	0.0
Prophylactic cART **	0	0.0	0	0.0	0	0.0	0	0.0
AZT	0	0.0	0	0.0	0	0.0	0	0.0
None	0	0.0	0	0.0	0	0.0	0	0.0
Other	0	0.0	0	0.0	0	0.0	0	0.0
Not specified	0	0.0	0	0.0	0	0.0	0	0.0
Total	3	100.0	0	0.0	0	0.0	0	0.0

Mother ARV Protocol	Other		Not specified		Total	
	n	%	n	%	n	%
Treatment cART *	78	69.6	0	0.0	81	70.4
AZT + NVPsd + (AZT-3TC)	0	0.0	0	0.0	0	0.0
NVPsd + (AZT-3TC)	0	0.0	0	0.0	0	0.0
NVPsd	0	0.0	0	0.0	0	0.0
Prophylactic cART **	34	30.4	0	0.0	34	29.6
AZT	0	0.0	0	0.0	0	0.0
None	0	0.0	0	0.0	0	0.0
Other	0	0.0	0	0.0	0	0.0
Not specified	0	0.0	0	0.0	0	0.0
Total	112	100.0	0	0.0	115	100.0

The number of babies born alive corresponds to the number of babies with a Patient Form recorded.

Interpreting:

Table 3.1

- ◊ The report is able to give the protocol information for 115 infants only.
- ◊ 112 infants received a protocol different than AZT or NVP 6 weeks or NVP long PEP.
- ◊ The mothers of 81 infants were on “treatment cART”.
- ◊ Protocol information has not been recorded in the children section of the PMTCT form for 3 infants. Prior recording that information, a Patient Form must be filled to allocate an identification number to the infant. (see §8.2.2, table 1)

Section: Early HIV testing results between 6-12 weeks post-partum

4 Early HIV testing results between 6-12 weeks post-partum

4.1 Number of infants contributing to the 6-12 weeks period

Admission in PMTCT Program between 01/01/2010 and 31/12/2010, Analysis on 19/12/2011

PMTCT follow-up outcome at 3 m	Data	
	n	%
Followed	112	97.4
Transferred	0	0.0
Died	3	2.6
Lost to follow-up *	0	0.0
Unknown	0	0.0
No visit in the period	0	0.0
Total	115	100.0

4.2 Distribution of infant HIV testing results at 6- 12 weeks by mother ARV protocol (among those born >=6 weeks before analysis date)

Admission in PMTCT Program between 01/01/2010 and 31/12/2010, Analysis on 19/12/2011

Mother ARV Protocol	Positive		Positive (Confirmed)		Discordant		Negative		Invalid		Not done		Not specified		Total	
	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Treatment cART *	1	100.0	0	0.0	0	0.0	60	67.4	0	0.0	17	77.3	0	0.0	78	69.6
AZT + NVPsd + (AZT-3TC)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
NVPsd + (AZT-3TC)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
NVPsd	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Prophylactic cART **	0	0.0	0	0.0	0	0.0	29	32.6	0	0.0	5	22.7	0	0.0	34	30.4
AZT	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
None	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Other	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Not specified	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Total	1	100.0	0	0.0	0	0.0	89	100.0	0	0.0	22	100.0	0	0.0	112	100.0

¥ Discordant: the result of the repeated early testing is negative but the result of the first test done at 6 weeks was positive.

¥¥ Invalid: the laboratory could not determine the result.

Interpreting:

Table 4.1

- ◊ 6 weeks after birth, 112 infants are followed and 3 died before 6 weeks old.
- ◊ Infants who missed their date of appointment by more than one month are lost to follow up.
- ◊ Infants who have no follow up visit since birth are counted in the last row: “no visit in the period”.

Table 4.2

- ◊ Out of the 112 infants followed, 90 have an HIV test done between 6 to 12 weeks after birth.
- ◊ The HIV test result is negative for 89 infants and positive for 1.
- ◊ The positive result has not been confirmed.
- ◊ There is no result for 22 infants.

Section: HIV testing results at 12 months

5 HIV testing results at 12 months

5.1 Distribution of infants by PMTCT follow-up outcome and HIV test result at 12 months (among those born alive >=12 months before analysis date)

Admission in PMTCT Program between 01/01/2010 and 31/12/2010, Analysis on 19/12/2011

PMTCT follow-up outcome at 12 m	HIV Negative		HIV Positive		Not specified		Total	
	n	%	n	%	n	%	n	%
Followed	0	0.0	2	100.0	56	86.2	58	82.9
Transferred	2	66.7	0	0.0	2	3.1	4	5.7
Died	0	0.0	0	0.0	3	4.6	3	4.3
Lost to follow-up *	1	33.3	0	0.0	4	6.2	5	7.1
Unknown	0	0.0	0	0.0	0	0.0	0	0.0
No visit in the period	0	0.0	0	0.0	0	0.0	0	0.0
Total	3	100.0	2	100.0	65	100.0	70	100.0

* Lost to follow up: a child who has missed the last appointment for 1 month or more.

5.2 Distribution of infants' HIV status at 12 months by prescribed PMTCT protocol (among those born alive >=12 months before analysis date)

Admission in PMTCT Program between 01/01/2010 and 31/12/2010, Analysis on 19/12/2011

Infant HIV status at 12 m	None ***		Complete *		Partial **		Not specified		Total	
	n	%	n	%	n	%	n	%	n	%
HIV Negative	0	0.0	0	0.0	3	4.3	0	0.0	3	4.3
HIV Positive	0	0.0	0	0.0	2	2.9	0	0.0	2	2.9
Not specified	0	0.0	0	0.0	65	92.9	0	0.0	65	92.9
Total	0	0.0	0	0.0	70	100.0	0	0.0	70	100.0

* Protocol is complete if ARV prescribed is in perfect agreement with MSF recommendations.

** Protocol is partial if ARV prescribed for mother and/or child does not meet criteria for complete protocol.

*** None if ARV has not been prescribed to both mother and child.

5.3 Program outcome at 12 months of age among HIV+ infants by ART treatment status (among those born >=12 months before analysis date)

Admission in PMTCT Program between 01/01/2010 and 31/12/2010, Analysis on 19/12/2011

PMTCT follow-up outcome at 12 m	ART Initiated		ART Not initiated		Total	
	n	%	n	%	n	%
Followed	2	100.0	0	0.0	2	100.0
Transferred	0	0.0	0	0.0	0	0.0
Died	0	0.0	0	0.0	0	0.0
Lost to follow-up *	0	0.0	0	0.0	0	0.0
Unknown	0	0.0	0	0.0	0	0.0
No visit in the period	0	0.0	0	0.0	0	0.0
Total	2	100.0	0	0.0	2	100.0

* Lost to follow-up: has missed the last appointment by 1 month or more

Interpreting:

Table 5.1

- ◊ Out of the 115 infants who have an identification number, 70 can contribute to the 12-month analysis on the date of analysis (19/12/2011) = 70 are born 12 months or more before the date of analysis.
- ◊ Out of the 70 infants, 58 are followed, 4 are transferred, 3 died and 5 are lost to follow up.
- ◊ Out of the 70 infants, 3 are HIV negative, 2 are HIV positive and for 65, the HIV test result is not specified.
- ◊ The HIV test result is the result recorded on the infant Patient Form (HIV status).

Table 5.2

- ◊ A note below the table indicates what complete and partial protocol means.
- ◊ All 70 infants who contribute to the 12-month analysis are under the category "partial", meaning that either the infant or the mother was prescribed a protocol that does not meet the criteria of a complete protocol.

Table 5.3

- ◊ As shown in table 5.1, 2 infants are HIV positive.
- ◊ The 2 infants are followed and have been initiated on ART.

Section: HIV testing results at 18 months

6 HIV testing results at 18 months

6.1 Distribution of infants by PMTCT follow-up outcome and HIV test result at 18 months (among those born alive >=18 months before analysis date)

Admission in PMTCT Program between 01/01/2010 and 31/12/2010, Analysis on 19/12/2011

PMTCT follow-up outcome at 18 m	HIV Negative		HIV Positive		Not specified		Total	
	n	%	n	%	n	%	n	%
Followed	1	25.0	0	0.0	5	62.5	6	50.0
Transferred	2	50.0	0	0.0	0	0.0	2	16.7
Died	0	0.0	0	0.0	0	0.0	0	0.0
Lost to follow-up *	1	25.0	0	0.0	3	37.5	4	33.3
Unknown	0	0.0	0	0.0	0	0.0	0	0.0
No visit in the period	0	0.0	0	0.0	0	0.0	0	0.0
Total	4	100.0	0	0.0	8	100.0	12	100.0

* Lost to follow up: a child who has missed the last appointment for 1 month or more.

6.2 Distribution of infants' HIV status at 18 months by prescribed PMTCT protocol (among those born >=18 months before analysis date)

Admission in PMTCT Program between 01/01/2010 and 31/12/2010, Analysis on 19/12/2011

Infant HIV status at 18 m	None ***		Complete *		Partial **		Not specified		Total	
	n	%	n	%	n	%	n	%	n	%
HIV Negative	0	0.0	0	0.0	4	33.3	0	0.0	4	33.3
HIV Positive	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Not specified	0	0.0	0	0.0	8	66.7	0	0.0	8	66.7
Total	0	0.0	0	0.0	12	100.0	0	0.0	12	100.0

* Protocol is complete if ARV prescribed is in perfect agreement with MSF recommendations.

** Protocol is partial if ARV prescribed for mother and/or child does not meet criteria for complete protocol.

*** None if ARV has not been prescribed to both mother and child.

6.3 Follow-up outcome at 18 months of age among HIV+ infants by ART treatment status (among those born >= 18 months before analysis date)

Admission in PMTCT Program between 01/01/2010 and 31/12/2010, Analysis on 19/12/2011

PMTCT follow-up outcome at 18 m	ART Initiated		ART Not initiated		Total	
	n	%	n	%	n	%
Followed	0	0.0	0	0.0	0	0.0
Transferred	0	0.0	0	0.0	0	0.0
Died	0	0.0	0	0.0	0	0.0
Lost to follow-up *	0	0.0	0	0.0	0	0.0
Unknown	0	0.0	0	0.0	0	0.0
No visit in the period	0	0.0	0	0.0	0	0.0
Total	0	0.0	0	0.0	0	0.0

* Lost to follow up: has missed the last appointment by 1 month or more

Interpreting:

Table 6.1

- ◊ Out of the 115 infants who have an identification number, 12 can contribute to the 18-month analysis on the date of analysis (19/12/2011) = 12 are born 18 months or more before the date of analysis.
- ◊ Out of the 12 infants, 6 are followed, 2 are transferred and 4 are lost to follow up.
- ◊ Out of the 12 infants, 4 are HIV negative, 8 are HIV not specified.
- ◊ The HIV test result is the result recorded on the infant Patient Form (HIV status).

Table 6.2

- ◊ All 12 infants who contribute to the 18-month analysis are under the category "partial", meaning that either the infant or the mother was prescribed a protocol that does not meet the criteria of a complete protocol.

Table 6.3

- ◊ As shown in table 6.1, no infants are HIV positive.
- ◊ The infants who tested HIV positive at 12 months have not yet reached 18 months of follow up.

9 – DATA QUALITY

9.1 Introduction to Data Quality[1]

Data quality involves data collection, data entry and data verification.

Data quality, namely, accurate, reliable, precise, complete and timely data are imperative for the planning and provision of MSF HIV programmes and ultimately to decrease HIV morbidity and mortality.

High-quality data are needed at the local, state, national and international levels to effectively monitor and evaluate these programmes. Furthermore, the data must have integrity to be considered credible and should be produced ensuring standards of confidentiality.

Effective data management and cleaning require programmes to implement quality checks at multiple points in the data cycle to prevent errors, identify errors, and verify and correct data.

Data cleaning involves conducting standard methods for identifying and correcting missing, inaccurate, or out-of-range data values. Cleaning can be implemented during both the data entry and data management phases.

9.2 Data collection

Quality data collection can be obtained through a few measures:

- Regular team meetings and staff training
- Use of Standard Operating Procedures (SOPs) and other documentation materials
- Check randomly a set of forms against database content (e.g. 10% / month)

9.3 Data entry

Data input constitutes a major workload and requires skill and accuracy. It is therefore essential to recruit a data entry operator/clerk.

The time span between consultation and data input must be as short as possible, to allow for the true value of a current database capable of producing up-to-date reports.

[1] Refer to WHO Improving Data Quality, a guide for developing countries (2003).

FUCHIA gives warning messages for some data elements when it is essential to enter correct them at once. See chapter 3 – Data processing.

9.4 Data verification

Two methods are accessible to FUCHIA users to perform data verification.

FUCHIA direct, detailed in chapter 3 (data processing) is one “fast” way to check some data entry errors in small size datasets: missing data (age/date of birth, gender, date of next appointment) or aberrant dates (date of visit / birth / death…). In large size datasets, that method is not really feasible.

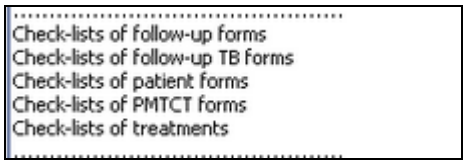
FUCHIA & R software give the possibility to run some checklists detailed below, which is useful for both large and small databases.

9.5 R checklists

See “Accessing "R" software”, in chapter 5, §5.1

Checklists are data management tools to identify data entry errors recorded in the FUCHIA database. The checks performed are generally for duplicate entries, missing data or potentially inconsistent entries.

In FUCHIA 1.7, 5 checklists are available:



☛ Checklist of follow-up forms detects the following errors

- Start and change in program and location
- Results of laboratory entered more than once with different values and the same date of sample collection.

☛ Checklist of TB form detects the following errors

- Duplicate: 2 TB episodes with the same starting date of treatment, patient with more than 1 TB episode recorded as “New Case”.
- Missing / wrong data: type of TB case, date of TB treatment end, TB treatment outcome, TB regimen, TB site, AFB search information, lab results.
- Inconsistencies: aberrant TB treatment dates, TB treatment duration >12 months, incoherent TB outcome for TB type, incoherent TB regimen for TB case, patient receives both SAT / DOT.

☛ Checklist of Patient Forms detects the following errors

- Missing data (never recorded): gender, HIV status, date of birth and agedate, height
- Errors in dates (in both patient and follow-up forms): more than 1 date of death in Follow-up Forms, patient dead or transferred before last follow up visit recorded, date of death recorded in Patient Form different than date of death recorded in Follow-up Form
- Patient Form has no follow-up visit recorded

☛ Checklist of PMTCT form (pregnancy) detects the following errors

Note: In FUCHIA 1.7.0, the PMTCT checklist has not been revised after the changes made in the PMTCT form. Therefore here it does not function but does with version 1.7.1.

- Data on mother and pregnancy:
  - Missing data: gender, HIV status, date of birth, date of admission, referral centre
  - Other potential errors: gender is male, HIV status is negative, age at admission <13 or >50, date of admission > date of delivery

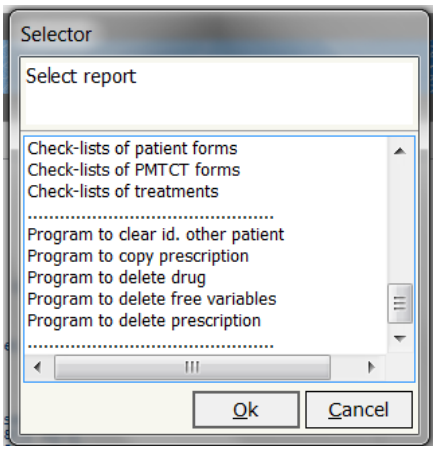
- Data on delivery
  - Missing data: date of delivery missing more than 9 months after admission to PMTCT programme, type of delivery, health facility, feeding choice, mother ARV protocol, date of initiation of mother ARV protocol
  - Other potential errors: 2 deliveries with a 10 month interval, feeding specified but no baby born alive, date of initiation of mother ARV protocol specified but protocol is none, date of initiation of mother ARV protocol posterior to date of delivery, number of baby born equals 0 or greater than 3, number of babies records different than the number of babies born alive.

- Data on babies
  - Missing data: gender, date of birth, HIV status 18 months old after delivery
  - Other potential errors: date of birth different than date of delivery, HIV status date before date of delivery or after date of death or date of transfer, number of babies born less than number of babies born alive.

☛ Checklist of treatment detects the following errors

- Treatment recorded without specifying prescription start
- Treatment ends without specifying prescription stop: a treatment has been started during a previous visit. In a subsequent visit, the treatment variable is empty, meaning that the treatment has not been recorded as “stopped”.
- Treatment recommences without specifying prescription restart

9.6 R programs to clean data



Specific R programs were written to copy or delete information of certain variables namely ID other, drugs and free variables.

To access, go to R software, connect R to database, click on "Run R program" and go to the end of the selector window to obtain the listing (below R checklists).

- 1 program to anonymise the database
- 1 program to delete free variable information
- 3 program to clean drug data

NOTE: These programmes are very useful but the process is **irreversible**. Therefore always make a back-up of the database before running the program. If you are not confident to use these programmes, contact the FUCHIA helpdesk at the following address: fuchia@epicentre.msf.org

To run

- Select program and click "ok".
- Make the necessary selections from the 'Selector' windows. These may appear at the bottom of the screen as a tab named 'Question' which you need to maximise.
- When the process ends, a message appears on the screen saying *"the database needs to be refreshed. Please restart FUCHIA".* Therefore, **it is essential** after executing the program; you immediately disconnect from R and close FUCHIA.
- You can then re-open FUCHIA and check if corrections have been recorded.

9.6.1 R programs to clean drug data

The R programs to clean drug data were written to remove duplication of pre-existing drugs or addition of non-ARV/non-prophylactic drugs from the list of predefined drugs in FUCHIA. Addition of new drugs results in new variables being added and this often blocked the production of automatic reports.

Common errors were:

- A new drug is added to the list, when a code already exists for that drug on the "list of drugs".

- A new ARV drug has been added to the list but is not coded in one of the ARV free variable (AA1-AA5),

- A non ARV drug has been added to the list, or the ARV variables (AA1-AA5) have been used to code NON ARV drugs.

In the first two scenarios patients prescribed these drugs are misclassified as pre-ART whereas in the last scenario, patients are misclassified as ART, and will be analysed as such in the reports. Please refer to chapter 5, section 5.2.2 ART Variables.

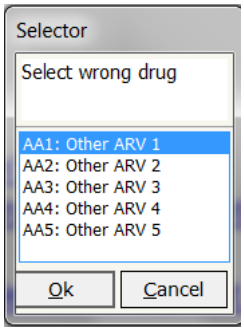
To clean the drug information, 3 R programs were written and are described below.

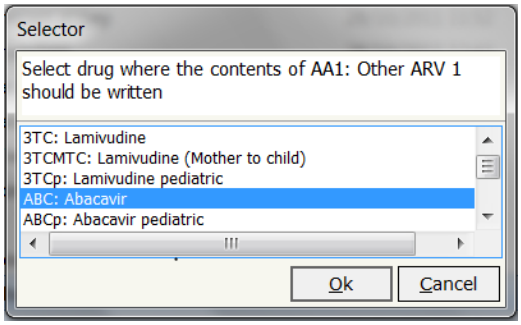
a) Copy prescription

This program automatically copies the content of new drug variable to one of the pre-existing FUCHIA drug variables.

It **does not** delete the new drug from the database and **does not** delete it from the listing of the FUCHIA list of drugs. This has to be done manually or by executing the delete drug programme.

Follow the instructions as above to run program. Several selector windows will open in sequence.





– At the first '**Selector**', select the drug that you want to copy the contents **from** (e.g. AA1) and click '**ok**'.
– On the second 'Selector', select the drug that you want to copy the contents to (eg ABC) and click 'ok.
– Reply "yes" to question '*Write the content of var1 in var2?'* displayed at the bottom of the screen if you wish to continue with the copy, or "no" to cancel.

If the variable that data is copied to contains information, then FUCHIA produces a listing of patients with their NID, date of visit, and the inconsistences found in the variables copied from and to. This listing will be automatically generated and saved in the output directory, and the changes will have to be made manually.

Useful for

- **Copying the prescriptions entered in a free ARV variable or a new variable to a pre-coded ARV drug existing in the FUCHIA list of drugs.**

b) Delete drug

This program automatically deletes the contents of a new drug from the patient and follow-up forms. It also deletes the variables associated with this new drug from the database and it updates the FUCHIA list of drugs, by removing the new drug from the list.

Follow the instructions as above to run program.

– On the 'Selector' menu: select the drug that you want to delete. You can either highlight one drug or all drugs or with the help of CTRL and ALT keys, select a subset of variables. Click "ok" to select.

– In situations where many drugs are listed, you will not be able to select all drugs. You have to select a subset and delete in batches.
– Reply "yes" to question '*Is it OK to delete drug(s): var1, var2, var3?*' if drugs listed are correct.

Useful for

- **Deleting non ARV drug added in a new variable which is not an ARV free variable.**

c) Delete prescription

This program deletes the content of a new drug from the patient and follow-up forms, as well as the content of the ARV free variables (AA1-AA5).

It **does not** however delete the variables associated with the new drug from the database and it does not update the FUCHIA list of drugs. This has to be done manually or by executing the delete drug program.

Follow the instructions specified above in delete drug.

Important note:

– If you have used 'delete prescription' instead of 'delete drug' to delete Non ARV drug entered as a new variable, you need to run delete drug variable to update the FUCHIA list of drugs.
– After running 'delete prescription' to delete Non ARV drug from free ARV variable (AA1-AA5), you need to update manually the free ARV variable Lookup ie to replace the Non ARV drug name by Other ARV 1, or Other ARV 2, ... or Other ARV 5.

Useful for

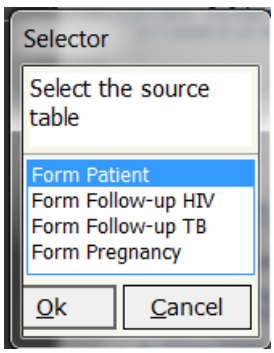
- **Deleting non ARV drug entered in ARV free variables (AA1-AA5).**

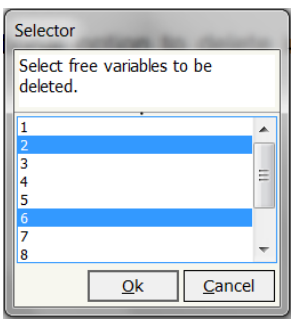
9.6.2 R program to delete free variables

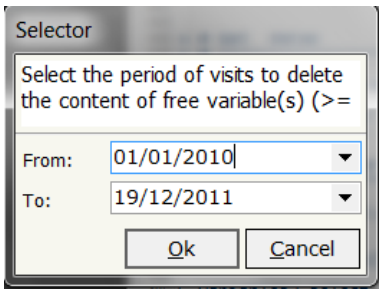
This program deletes the contents of the free variables from the Patient Form, the follow-up form, the TB form or the Pregnancy form.

Follow the instructions as above to run program.

– At the first 'Selector', select the source table from which you want to delete the contents of the free variables from and at the second selector the variables you want to delete.







With the follow-up form, there is an additional selector that allows you to delete information from the whole period over a specified period. In the selector shown here, all the data in the free variables between and including the dates shown are deleted.

- Say "yes" to the question *'Are you sure you want to delete the contents of free variables number: 1, 2, …n?',* after verifying it is correct.
- If the free variables deleted were labeled in the database, go to the settings.ini file and modify the free variable label accordingly.

9.6.3 R program to anonymise a database

Often patient names or other identifiable information are entered in the Patient Form in the variable "Other FUCHIA ID". The R program "clear id, other" deletes this information from the database. Follow the instructions as above to run program.

Useful for

- **Anonymising database before sending data**

10 – R EXPORTS

List of tables

For more detailed analyses users can export the data in FUCHIA to Excel or other statistical software packages such as Stata. The key purpose is to have additional flexibility to answer programme specific questions that are not readily available in the automatic reports.

The data are exported in either text or numeric format. The following choice is available:

Text format (data, variable names, labels)
- tab separated ascii file (*.txt)
- comma separated ascii file (*.csv)

Numeric format (data and variable names)
- tab separated ascii file (*.tab)

Numeric format for use in Stata (data + setup files) containing
space separated ascii file (*.raw)
dictionary file (*.dct)
commands for reading data, labelling variables and labelling values (*.do)

Numeric format for use in Epidata analysis or Epiinfo (data + setup files) containing
space separated dataset (*.rec)
check file containing values labels (*.chk)

The text formats contain only text, and are easier to use. They can be read directly into Excel or other software without the user having to have knowledge of how each variable is coded.

The numeric formats on the other hand are smaller in size but no information is available of how values are coded in the dataset. Therefore, the user will need to refer to the “contents” or the Stata (*.do) or the Epidata analysis/Epi-Info (*.rec) file.

When data are exported, other text files are also created:
* (contents).txt: contains a listing of the variables, their names, and a listing of codes.
* (describe).txt: gives a description of the variables contained in the export (n, missing)
* (rename).txt: exists only for the Stata and Epidata analysis/Epi-Info formats. It shows how some of the original variables have been renamed so that the software can read them.

Note:

All the above files can be examined using a standard text editor.

This chapter first describes each export, followed by how data is exported in FUCHIA, and how exports can be read into other software with a data dictionary of each export at the end.

10.1. Data from Patient and Follow-up Forms

Most of the information entered on the “Patient” and “Follow-up” forms are contained in the patient long export. In addition to that, there are also 3 other exports and these are:

Patient wide (one row per patient)
Blood collection data export
Prescription data

The data entered in the free variables in the Patient or Follow-up Forms are exported separately, as

Free variables Patient Form
Free variables

Each export is described briefly below.

10.1.1. Patient long export

Each line of the export corresponds to a visit made by a patient, resulting in several lines per patient. Data entered in the Patient Form (i.e. data that are entered only once) are copied throughout the database for each visit. By default (= if no selections are made), 298 variables are exported. In addition, if other codes have been added in the drug list out of the 5 AA free variables, these new codes will be exported under new variables (bkxxx, xxx).

Table 1: Illustration of the patient long export

Patient Form data ***Follow-up Form data***

nid	gender	marital status	date of visit	type of visit	weight
001	Female	Married	01/03/2004	Consultation	35
001	Female	Married	03/04/2004	Consultation	.
001	Female	Married	03/04/2004	Hospitalisation	.
002	Male	Not specified	27/04/2004	Consultation	45
003	Not specified	Single	17/08/2003	Consultation	.
003	Not specified	Single	31/10/2003	Consultation	.
003	Not specified	Single	23/12/2003	Consultation	58
003	Not specified	Single	08/01/2004	Consultation	.
003	Not specified	Single	15/04/2004	Consultation	58

Useful for

Detailed cohort analyses

10.1.2. Patient wide export

The patient wide export is a condensed form of the patient long data export, and was created to facilitate data analysis in the field without the need to use sophisticated statistical software such as Stata, SPSS or SAS.

It contains key information from the Patient Form and a selection of data from the Follow-up Form; namely ARV prescribed, ARV stopped due to intolerance, CD4, viral load, haemoglobin, opportunistic infections, lymphocytes, hepatitis B (HBSag), ALAT, creatinine, glycosuria, proteinuria, weight, height, prophylaxis and WHO stage.

Each row of the export contains information of each patient i.e. one line per patient. Hence, the data from the follow-up visits are restricted to those collected on the first and last patient visit for all patients and for those on ART, data is available on the date of ART initiation and at subsequent 6 monthly visits after ART initiation. The key variables on the Patient Forms will be exported automatically.

When data on opportunistic infections or drugs stopped for intolerance are requested, users will be asked to select one or more from a drop down list. To select more than one variable, hold down the Control key and select the variables required.

If there are no recorded laboratory results (CD4, viral load etc) or height and weight measurements for key dates (such as first and last visit, ART initiation and at 6 monthly visits), then FUCHIA will perform a search in the database to identify values recorded nearest to the key date and will ask the user to specify if the search is to be carried out within a 30 (or 60 or 90) day window. The last laboratory results in the patient wide export are however the **last ever recorded** and not the results recorded +/- 30 (or 60 or 90) days of the last recorded patient visit.

Note:

To identify the number of 6 monthly visits after ART initiation to export, FUCHIA calculates the difference between the first and last recorded visits on ART. If dates are wrongly recorded giving a long duration of follow up such several decades, the number of 6-monthly visits created will be too many to be read by Excel. To resolve the problem, check dates using FUCHIA direct and correct date errors, before exporting.

Useful for

Identification of mistakes in the database (abnormal values for laboratory data….)
Description of patients at ART initiation
Description of immunological recovery after ART start
Number of patients who stopped drugs for intolerance / drugs stopped
Description of OI after ART start
Number of active patients & number of patients on 2nd line
Eligibility of patients not on ART

10.1.3. Prescription data

The prescription data export contains the information recorded in the section ARV or prophylaxis prescribed or stopped during visits in the Follow-up Form. Each line of the export contains the information of one prescription, and lists if the treatment was started, stopped or continued during that visit, and if treatment was stopped due to intolerance, which intolerance and which drug contributed to the intolerance (for fixed drug combinations).

Note:

See § 10.5 if there are too many records to export all of them into Excel in one go,

Table 2: Illustration of data from prescription export

nid	datvisit	tttcode	ttttype	tttn	presctn	intolrc1	intlrd1	intolrc2
6769	09/03/2009	3TC	arv	1	Continued			
6769	09/03/2009	EFV600	arv	1	Started			
6769	09/03/2009	NVP	arv	1	Stopped for intolerance	Skin Eruption 3/4		
6769	09/03/2009	COTRI	pply	1	Continued			
6769	09/03/2009	D4T30	arv	1	Continued			

If a combination of drugs are prescribed using separated formulations (tttn = 1) during one visit, then several lines will be exported for that day, as in the example above; patient nid 6769, discontinued “NVP+3TC+D4T30” and started “EFV600+3TC+D4T30” on the 09 march 2009. The reason for stopping was intolerance due to skin eruption of grade 3/4.

If the treatment started or stopped is in a FDC form, the variable tttn will show a digit indicating the number of drugs contained in the FDC, as shown below.

nid	datvisit	Tttcode	ttttype	tttn	presctn	intolrc1	intolrc2
1	20/03/2009	FDC1 (D4T30-3TC-NVP)	arv	3	Stopped for TB regimen		
1	20/03/2009	FDC5 (D4T30-3TC)	arv	2	Begun		
1	20/03/2009	EFV600	arv	1	Begun		
1	20/03/2009	COTRI	pply	1	Continued		

Useful for

Identify patients with specific intolerances
Identify prescribed drugs over a period

10.1.4. Blood collection data

The blood collection data export is in a similar format to the patient wide data export, as each line corresponds to information of one patient. It contains all the laboratory results, and is organised by date of first, second, third and up-to the nth blood collection, where n refers to the maximum number of blood collection dates entered for a given patient.

Table 3: Illustration of the blood collection data export

Patient Form data — *1st, 2nd,3rd … Lab Results*

nid	gender	Hiv	fstdatv	fstdatva	exam1	cd41	Exam2	cd42	exam3	cd43
000301S	Female	HIV Positive	19/07/2007	14/08/2007						
000302S	Female	HIV Positive	19/07/2007	14/08/2007	24/07/2007	33	05/02/2008	189	28/08/2008	287
000303S	Female	HIV Positive	23/07/2007	14/08/2007	27/07/2007	24	25/06/2008	212		
000304S	Female	HIV Positive	24/07/2007		24/07/2007	361				

Above is an extract of the export of 4 HIV positive female patients who entered an MSF program during July 2007 (“fstdatv”). Three of the 4 had at least one blood sample taken for laboratory examination (“exam1”). The maximum number of results available was 3 and this was for patient NID=000302S, who had bloods taken on July 2007, February and August 2008, and CD4 values were recorded on all dates (“cd41”, “cd42” and “cd43”). Three of the 4 initiated ART on August 2007 (“fstdatva”), and one initiated without a CD4 value. Dates when blood was taken for the first time is approximately the same period, however the timing of the second blood test result is different.

Useful for

Reviewing the evolution of lab results

10.1.5. Free variables

All or some of the information of the free variables in the Patient and Follow-up Forms can be exported. The free variable patient export contains one line per patient, whereas the free variable follow-up export contains a line for every patient visit.

Note: In order to carry out a comprehensive analysis of the data, these exports would then have to be merged with either the patient long or patient wide data using a statistical software package. This can be done by matching the Patient nid, datvisit and type variables.

Useful for

Allows collection and analyses of programme specific information.

10.2. Data from TB form

All the information entered in the TB form including the 10 free variables is exported. Each line of the export corresponds to a recorded episode of tuberculosis.

Note: A single patient may have several TB episodes.

Useful for

Identify missing information
Describe TB episode according to type and TB case type

10.3. Data from PMTCT form

The pregnancy database export contains most of the information entered in the PMTCT form including the 10 free variables, alongside key information (nids, final HIV test result, and certain dates) of the mother and infant from Patient and Follow-up Forms.

The database structure is 1 line for every live birth (or 1 line for a delivery with zero live births). Therefore for multiple live births from 1 pregnancy, the information of the mother and the delivery replicates on several lines.

As shown below, we have 4 mothers. One of the mothers (nid=7185) had two deliveries, one January 2008 and another April 2009. Mother with NID=7182, had multiple deliveries on February 2008 and there were two live births (2 lines). Mother with nid=9156 delivered September 2007 but the infant was not born alive, hence information on infant is missing.

	A	B	C	D	E	F	G	H	I	J	K	L	W	X	Y	Z	AA	AB	AC	AD	AE
1	nidmother	refrb	datrefrb	delivery	datdeliv	issueexp	matern	bborn	balive	tttdv	dattttdv	feeding	rankmum	nidchild	arv	arvd	breastf	pplx	hiv	hivtest	hivdate
2	7041	HIV clinic	21/11/2007	Vaginal	04/02/2008		Not specified	1	1	Prophylactic cART	12/12/2007	Yes	1	7041B1	NVP+AZT	SD+4W			Not specified	Not specified	
3	7182	ANC	12/12/2007	Vaginal	08/02/2008		Not specified	2	2	Prophylactic cART	09/07/2007	Yes	1	7182B2	AZT	6W			HIV Negative	Serology	23/04/2008
4	7182	ANC	12/12/2007	Vaginal	08/02/2008		Not specified	2	2	Prophylactic cART	09/07/2007	Yes	1	7182B3	NVP	6W			HIV Negative	Serology	23/04/2008
5	7185	HIV clinic	16/07/2007	Vaginal	09/01/2008		Not specified	1	1	Prophylactic cART	15/05/2006	Yes	1	7185B1	NVP	Long PEP			HIV Negative	Serology	23/03/2008
6	7185	HIV clinic	30/10/2009	Vaginal	20/04/2009		Not specified	1	1	HAART	14/07/2009	Yes	2	7185B2	NVP	Long PEP					
7	9156	HIV clinic	20/09/2007	Vaginal	20/09/2007		Health centre	1	0	HAART	03/08/2007	Not specified	1								

The following is a summary of the data above.

nidmother	Number of Pregnancies	Deliveries	Alive births
7041	1	1	1
7182	1	1	2 (twins)
7185	2	2	2 (1 / delivery)
9156	1	1	0

Note:

When exporting to EXCEL, define “nidmum” and “nidchild” as text fields.

Useful for

Reporting on PMTCT indicators

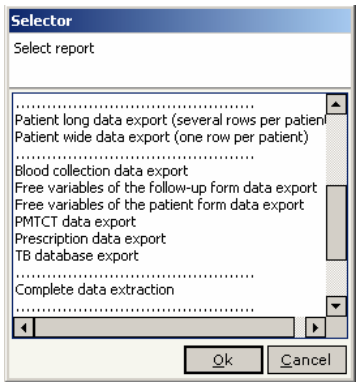
10.4. Exporting the whole database

The data within FUCHIA are stored in an Access database and contains a series of tables that are linked together by unique identifiers. If this option is selected, all the tables are exported. See the data model in chapter 5, § 5.3.1, figure 3

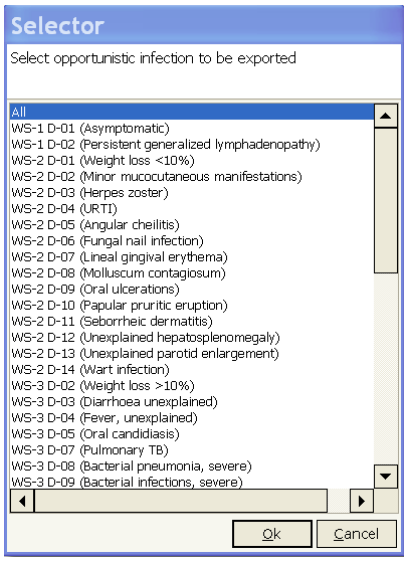
10.5. How to export data in FUCHIA

Data is exported via the R software (Chapter 5 R software):

1. Click on “Statistical Software R”
2. Click on “Connect”
3. When connected, click on “Run R Programme”
4. Select the type of export (patient long, patient wide etc.) to be exported and click OK.

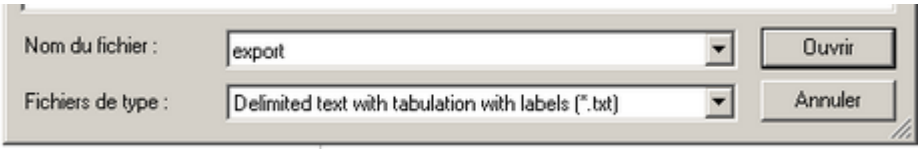


5. Too many variables for the number of columns available in Excel: For the larger exports (patient long, patient wide, prescription) additional selectors will be displayed to allow the user to create smaller datasets. Depending on the export, the selections can be period, age group, gender, opportunistic infections, intolerance or treatment. To select individual or several items on a list use the ctrl key followed by a left click. To select a group of items, press shift on the first item then left click on the last item.



6. Too many records for the number of rows available in Excel: Exported files containing more than 65,536 lines cannot be opened in Excel 2003 or earlier versions of Excel, but can be opened in Excel 2007. Therefore, if datasets are large, FUCHIA will give a warning message and the user will have the option to create smaller subsets of the data. For example for the patient long export, options for selection are programme, date of visit, type of visit, age at visit.

7. R will then create the export, and once finished will open a window for instructions to save the file. By default, FUCHIA saves all exports in the "txt" format using the name "export" in the default directory that was specified when FUCHIA was installed (See chapter 11 Technical details for further information).



8. You may change the name of the export by replacing "export" with your own selection, and also choose another type of export by using the drop down menu.

10.6. Reading FUCHIA data exports

Please follow the instructions below for opening the FUCHIA data exports using Excel, Epidata analysis/EPI-info or Stata.

10.6.1. In Excel

Most of the FUCHIA exports (*.txt, *.tab, *.csv, *.raw) can be opened in Excel. The fastest method is to go to the folder where the data is stored, right click on the name of the file and select the option open with Excel. However, as many programmes use the convention of using leading zeros when allocating a FUCHIA Nid to patients (eg NID="0005025"), we recommend that you use the method outlined below, otherwise in certain situation, Excel will remove the leading zeros, and the NID for patients with ids "000525" and "0525" will be listed as "525" for both.

1. Open Excel and go to "Open" from Excel's File menu, and browse to the folder that contains the data exports. Make sure that you have chosen the option "all file types" to view all files in the folder. Double-click the file and Excel will read in the data.

2. Excel will automatically open the "Text Import Wizard" window. Select "delimited" and click "next" to go the next window.

3. Select the delimiter that is used to separate the variables in the dataset. If you didn't know what the delimiter was before beginning the file import, you can usually scan the data and determine which character is being used. However, the FUCHIA exports are named using delimiter, so for example the CSV file is comma-delimited. After selecting the delimiter, click "Next" to proceed.

4. Assign the data format to each variable that you are importing. The default data format is "General," and this is the format you should keep unless any of your data fields contains dates or consists of data that you want to be read as text. As mentioned earlier, to keep the leading zeros, the "nid" should be changed to text. Therefore, at this step, highlight the column corresponding to the FUCHIA number ("nid", "nidmum" and "nidchild") and

change the format of the column to “text” by ticking the appropriate option. Please note in the PMTCT export, the FUCHIA numbers are called “nidmum” for mothers and “nidchild” for infants.

5. Click “Next” to finish the import, and save the resulting spreadsheet as an Excel file.

10.6.2. In Epi-Info/Epidata analysis

In FUCHIA, select option “Epi-Info (*.rec)“ for exporting data to be read into Epiinfo or Epidata analysis.

This option exports a data file with the extension *.rec together with a *.chk file containing the value labels of the variable in the rec file.

To execute in Epidata analysis/Epi-Info, right click the *.rec file and select “Open file with Epi-Info or Epidata analysis”.

This will automatically open the data in the programme that you requested. From here, you can start to analyse the data straight away.

Note:

Epidata analysis has a limitation that variable can be named only with a maximum of 10 characters. Therefore, some of the exported variables are renamed to comply with this. When an Epi-Info export is requested, FUCHIA also generates a text file that contains a list of the variables that were renamed. See example below.

“pwe export (rename).txt”

	vars	vars.orign
56	t6to12arvs	t6to12arvsi
57	t12datvisi	t12datvisit
71	t12to18arv	t12to18arvsi
72	t18datvisi	t18datvisit
86	t18to24arv	t18to24arvsi
87	t24datvisi	t24datvisit
101	t24to30arv	t24to30arvsi
102	t30datvisi	t30datvisit
116	t30to36arv	t30to36arvsi
117	t36datvisi	t36datvisit
131	t36to42arv	t36to42arvsi
132	t42datvisi	t42datvisit
146	t42to48arv	t42to48arvsi
147	t48datvisi	t48datvisit
181	lstdhemogl	lstdhemoglb
185	lstdhivloa	lstdhivload

Here, the original variables, such as t6to12arvsi and t12datvisit are renamed as t6to12arvs and t12datvisi for use in Epidata analysis/Epi-info.

10.6.3. In Stata

In FUCHIA, the selection is “Script Stata 7.0 (*.do)“ for exporting the data to Stata.

This option will export a data file with the extension *.raw together with a *.do Stata program file and a Stata dictionary file *;dct. The *.do file is the key file. It has two sections with instructions for Stata on how to read in the data and how the variables and values in the dataset should be labelled. From the *.do file, Stata will open the *.dct and *.raw files; therefore all three files should be stored in the same directory.

Note:

Some of the FUCHIA variables are named starting with a number or use the "/" character. These variables have been renamed for Stata use as they cannot be read into Stata. After exporting data, check the text file * (rename).txt to see if any variables were renamed.

To execute in Stata, go to correct folder and right click the *.do file and select "Open file with Stata".

This will automatically open Stata and read in the dataset and label the data. From here, the user will be able to start analysing the data. If the size of the database is beyond the memory allocated by default in Stata, Stata will not complete the process.

To resolve this problem; exit Stata and edit the .do file. Open the .do file with a data editor and insert two new lines at the top of the .do file and type the following and save the file.

clear
set mem 200m

The do file should now run. If the problem persists keep increasing the memory in the set mem command.

10.7. Data Dictionary – v1.7.1

The following sections outline the description of the variables found in each of the exports, and when required how some of the variables are calculated. In the longer exports, the variables are listed under common headings, whereas the variables in the shorter exports are listed according to how they ordered in the export.

10.7.1. Patient long data export v1.7.1

Socio-Demographic Information from Patient Form		
VARIABLE NAME	VARIABLE LABEL	CALCULATION METHOD/COMMENTS
nid	Cohort identification number	
keypatie	Cohort identification number	Calculated unique patient identifier in numeric format.
gender	Gender	
statut	Marital Status	
prof	Profession	
entry	Mode of entry	
origin	Geographical Origin	
birth	Date of birth	
age	Age	
ageunit	Unit (Year, Month, Day)	
agedate	Age corresponding date	Date (usually the day of first visit) at which the patient said his/her age was.
datbirth	Date of birth	Calculated variable, taking date of birth if specified in the variable "birth", or estimating date of birth by using the information in variables "age", "ageunit" and "agedate".
hiv	HIV Status of patient	
hivtest	HIV test type	
hivdate	HIV test date	
hivdead	Death related to HIV	
dead	Did patient die?	
datdeadp	Date patient died.	
trft	Was patient discharged (=transferred-out)?	
dattrft	Date patient discharged (=transferred-out)	
dctl	Was the patient decentralised?	
datdctl	Date patient decentralised	
dctlloc	Location patient decentralised to	

Information on Follow-Up Visits from Follow-up Form		
VARIABLE NAME	VARIABLE LABEL	CALCULATION METHOD/COMMENTS
keyfollo	Identification number of the visit	Unique ID for visit
refered	Referred to	
locat	Location of the visit	
program	Programme	
datvisit	Date of visit or start of hospitalisation	
datnext	Date of next appointment	
type	Visit type, consultation or hospitalisation	
visit	Visit on time or unplanned or delayed, NS	
datexit	Date of discharge	
exit	Status at discharge	
agev	Age at visit	Calculated from datbirth.
weight	Weight	
height	Height	
rank	Rank visit	Visits ranked according to date of visit
rankc	Rank consultation	Consultations ranked according to date of consultation
rankh	Rank hospitalisation	Hospitalisation ranked according to date of hospitalisation
Laboratory Data collected during Follow-Up visits on Follow-up and PMTCT Forms		
VARIABLE NAME	VARIABLE LABEL	CALCULATION METHOD/COMMENTS
examen	Date of blood collection	
alat	ALAT (SGPT) ui/L	
hbsag	Hepatitis B Antigen S	Added in 1.7.1
creat	Creatinine	In the recorded unit
creatui	Creatinine	In µmol/L (IU)
creatunt	Creatinine unit (mg/dL, µmol/L, ns)	Added in 1.7.0
glyco	Glycosuria	Added in 1.7.0
prote	Proteinuria	Added in 1.7.0
lc	Total Lymphocytes	
lccd4	Lymphocytes CD4	
lccd4tlc	Lymphocytes CD4 %	
hemoglb	Haemoglobin	
hivload	Viral load	
hivchl	Interim HIV test type of PMTCT babies	Added in 1.7.0
hivchlr	Interim HIV test result of PMTCT babies	Added in 1.7.0
Data on opportunistic illnesses (OIs) from Patient and Follow-up Form		
VARIABLE NAME	VARIABLE LABEL	CALCULATION METHOD/COMMENTS
OIs diagnosed during follow-up visits		
WHO Stage 1		
ws1d1	Asymptomatic	Adult – Child
ws1d2	Persistent generalized lymphadenopathy	Adult – Child
WHO Stage 2		
ws2d1	Weight loss <10%	Adult
ws2d2	Minor mucocutaneous manifestations	No longer an option since (WHO 2006)
ws2d3	Herpes zoster	Adult - Child
ws2d4	URTI	Adult - Child
ws2d5	Angular cheilitis	Adult
ws2d6	Fungal nail infection	Adult - Child
ws2d7	Lineal gingival erythema	Child
ws2d8	Molluscum contagiosum	Child
ws2d9	Oral ulcerations	Adult - Child
ws2d10	Papular pruritic eruption	Adult - Child
ws2d11	Seborrheic dermatitis	Adult
ws2d12	Unexplained hepatosplenomegaly	Child
ws2d13	Unexplained parotid enlargement	Child
ws2d14	Wart infection	Child
WHO Stage 3		
ws3d1	Bedridden <50% of the day during the last month	No longer an option since (WHO 2006)
ws3d2	Weight loss >10%, unexplained	Adult
ws3d3	Diarrhoea unexplained	Adult - Child
ws3d4	Fever, unexplained	Adult - Child
ws3d5	Oral candidiasis, persistant	Adult - Child
ws3d6	Vulvovaginal candidiasis >1 month	No longer an option since (WHO 2006)
ws3d7	Pulmonary TB	Adult - Child
ws3d8	Bacterial pneumonia, severe, recurrent	Adult (stage 4) – Child (stage 3)
ws3d9	Bacterial infections, severe, including pneumonia	Adult
ws3d10	Oral hairy leukoplakia	Adult - Child
ws3d11	Acute necrotizing ulcerative stomatitis	Adult - Child
ws3d12		No longer an option since (WHO 2006)
ws3d13	Lymph node TB	Child

ws3d14	Malnutrition moderate	Child
ws3d15	Unexplained anaemia/neutropenia/trombocytopenia	Adult - Child
ws3d16	HIV-associated chronic lung disease	Child
ws3d17	Lymphoid interstitial pneumonitis	Child
WHO Stage 4		
ws4d1	Bedridden >50% of the day during the last month	No longer an option since (WHO 2006)
ws4d2	Wasting syndrome by HIV/stunting/severe malnutrition	Adult - Child
ws4d3	Cryptococcosis extrapulmonary	Adult - Child
ws4d4	Pneumocystis pneumonia	Adult - Child
ws4d5	Toxoplasmosis of the brain	Adult - Child
ws4d6	Encephalopathy by HIV	Adult – Child
ws4d7	Penicillium marneffei infection	No longer an option (WHO 2006)
VARIABLE NAME	**VARIABLE LABEL**	**CALCULATION METHOD/COMMENTS**
ws4d8	Candidiasis oesophagus/trachea/bronchi /lungs	Adult – Child
ws4d9	Cryptosporidiosis	Adult – Child
ws4d10	Isosporiasis	Adult – Child
ws4d11	Extrapulmonary TB	Adult – Child
ws4d12	Lymphoma	Adult – Child
ws4d13	Herpes simplex infection	Adult – Child
ws4d14	Non-TB mycobacteria infection	Adult – Child
ws4d15	Septicaemia recurrent	Adult
ws4d16	Mycosis disseminated	Adult – Child
ws4d17	Kaposi sarcoma	Adult – Child
ws4d18	Cytomegalovirus infection	Adult – Child
ws4d19	Cervical carcinoma	Adult
ws4d20	HIV-associated cardiomyopathy	Adult – Child
ws4d21	HIV-associated nephropathy	Adult – Child
ws4d22	Progressive multifocal leukoencephalopathy	Adult – Child
ws4d23	Visceral leishmaniasis disseminated	Adult
bkwsxdx	History of OIs prior to programme entry	Variables named the same way as the OIs above, starting with the stem bk e.g. bkws1d1
Data on WHO staging from Patient and Follow-up Forms		
VARIABLE NAME	**VARIABLE LABEL**	**CALCULATION METHOD/COMMENTS**
whopd	WHO staging prior to programme entry entered using the direct field	
whopoi	WHO staging prior to programme entry based on OIs	Calculated variable using OI list
whop	Who staging prior to programme entry	Calculated variable using **whopd** & **whopoi**. If information is available from both, **whop** will take the maximum value recorded in whopd and whopoi.
whofd	WHO staging at visit entered using the direct field	
whofoi	WHO staging at visit based on OIs	Calculated variable using OI list
whof	WHO staging at visit	Calculated variable using **whofd** and **whofoi**. If, on the same visit, information is available from both, **whof** will take the maximum value recorded in whofd and whofoi.
whoc	Cumulative WHO staging	Calculated using **whop** and **whof.** At first visit, takes the maximum value recorded in either ***whop*** or ***whof***. On subsequent visits, takes the maximum value recorded either in the previous ***whoc*** or the current ***whof***.

Data on treatment prescribed on Patient and Follow-up Forms

VARIABLE NAME	VARIABLE LABEL	CALCULATION METHOD/COMMENTS
Treatment prescribed during follow-up visits		
3tc	Lamivudine	
3tcp	Lamivudine pediatric	
aa1	Other ARV 1	
aa2	Other ARV 2	
aa3	Other ARV 3	
aa4	Other ARV 4	
aa5	Other ARV 5	
abc	Abacavir	
abcp	Abacavir pediatric	
apv	Amprenavir	
atz	Atazanavir	
atzr	Atazanavir/ritonavir	
azt	Zidovudine	
aztp	Zidovudine pediatric	
d4t	Stavudine	
d4t30	Stavudine 30	
d4t40	Stavudine 40	
d4tp	Stavudine pediatric	
ddi400	Didanosine 400	
ddi250	Didanosine 250	
ddip	Didanosine pediatric	
drv	Darunavir	
efv600	Efavirenz 600	
efv800	Efavirenz 800	
efvp	Efavirenz pediatric	
etv	Etravirine	
fdc1	D4T30-3TC-NVP	
fdc2	D4T40-3TC-NVP	
fdc3	AZT-3TC-NVP	
fdc4	AZT-3TC-ABC	
fdc5	D4T30-3TC	
fdc6	D4T40-3TC	
fdc7	AZT-3TC	
fdc8	Tenofovir-FTC	
fdc9	EFV-TDF-FTC	
fdc10	D4T-3TC-NVP	
fdc11	TDF-3TC-EFV	
fdc12	TDF-3TC-NVP	
fdc1p	D4T30-3TC-NVPp	
fdc2p	AZT-3TC-NVPp	
fdc3p	D4T30-3TCp	
fdc4p	AZT-3TCp	
fdc5p	ABC-3TCp	
fdc6p	D4T-3TCp	
ftc	Emtricitabine	
idv	Indinavir	
lpvr	Kaletra (Lopinavir/Ritonavir)	
lpvrp	Kaletra (Lopinavir/Ritonavir) pediatric	
nfv	Nelfinavir	
nfvp	Nelfinavir pediatric	
nvp	Nevirapine	
nvpp	Nevirapine pediatric	
ral	Raltegravir	
rtv	Ritonavir	
sqv	Saquinavir	
tdf	Tenofovir	
aztmtc	Zidovudine (mother to child)	Code for PMTCT prophylaxis with AZT (mother or child)
nvpmtc	Nevirapine (mother to child)	Code for PMTCT prophylaxis with NVP (mother or child)
3tcmtc	Lamivudine (mother to child)	for PMTCT prophylaxis with du 3TC
nadmtc	NVP (single dose) + (AZT-3TC)	Code for PMTCT prophylaxis with NVPsd + (AZT+3TC)
cotri	Cotrimoxazole	
dap	Dapsone prophylaxis	
fluco1	Fluconazole primary prophylaxis	
fluco2	Fluconazole secondary prophylaxis	
inh	Isoniazid prophylaxis	
itr	Itraconazole prophylaxis	
myc	Treatment of atypical mycobacteriosis	
bkxxx	Prior history of ARV/Prophylaxis	Variables named the same way as above, starting with the stem bk e.g. bkfdc1

Data on ARV regimen		
VARIABLE NAME	VARIABLE LABEL	CALCULATION METHOD/COMMENTS
arv	Treatment	Calculated variable combining all ARV treatment prescribed during visit
narvp	Number of ARV prescribed	Calculated number of ARV prescribed during visit
narvs	Number of ARV stopped	Calculated number of ARV stopped during visit
arvpill	Percentage of ARV missed	
Data from Section on Mother-to-Child Transmission on Follow-up Form		
VARIABLE NAME	VARIABLE LABEL	CALCULATION METHOD/COMMENTS
pediat	Paediatric CDC staging	
mtc	Mother to child programme	
breastfd	Breastfeeding	
amrhea	Amenorrhoea	
tfc	Supplementary nutrition programme	
Other		
tb	AFB research for TB	New variable. Existed in FUCHIA version 1.6.2 but was not exported.

10.7.2. Patient Wide data export v1.7.1

General Info		
VARIABLE NAME	VARIABLE LABEL	CALCULATION METHOD/COMMENTS
datdb	date of the database	last date of visit entered on database
Data from Patient Form		
VARIABLE NAME	VARIABLE LABEL	CALCULATION METHOD/COMMENTS
nid	patient identification (FUCHIA number)	
gender	sex of patient	
hiv	HIV status	
origin	geographic origins	
entry	programme entry mode	
prof	profession	
statut	marital status	
datbirth	date of birth	calculated from the date of birth entered or the age (if there is no date of birth entered)
datdctl	Date patient decentralised	
dctlloc	Location patient decentralised to	
dattrft	transfer date	
datdead	date of death	
bkarv	ARV history	ARV+ARVmtc
bkwsXdX	history of opportunistic infections	
Data from first visit		
VARIABLE NAME	VARIABLE LABEL	CALCULATION METHOD/COMMENTS
fstdatv	date of first visit recorded	
fstpply	prophylaxis at first visit	at fstdatv
fstwhoc	Cumulative WHO stage at first visit	at fstdatv
fstwsXdX	opportunistic infections diagnosed at first visit	at fstdatv. Variables named the same way as the OIs above, starting with the stem fst
fstweight	weight at first visit	Measured either on fstdatv or +/- precision
fstheight	height at first visit	at fstdatv +/- precision
fstalat	alat at first visit	at fstdatv +/- precision
fsthbsag	HBsAg at first visit	at fstdatv +/- precision
fstcreatui	Creatinine in µmol/L (IU) at first visit	at fstdatv +/- precision
fstglyco	glycosuria at first visit	at fstdatv +/- precision
fstprote	proteinuria at first visit	at fstdatv +/- precision
fstlccd4	CD4 count at first visit	at fstdatv +/- precision
fstlccd4tlc	CD4 % at first visit	at fstdatv +/- precision
fsthemoglb	haemoglobin at first visit	at fstdatv +/- precision
fstlc	lymphocyte count at first visit	at fstdatv +/- precision
fsthivload	viral load at first visit	at fstdatv +/- precision

Data from Art initiation		
VARIABLE NAME	VARIABLE LABEL	CALCULATION METHOD/COMMENTS
t0datvisit	date of ART initiation	
t0arv	ARV prescribed at initiation	at t0datv
t0pply	prophylaxis at ART initiation	at t0datv
t0whoc	Cumulative WHO stage at ART initiation	at t0datv
t0wsXdX	opportunistic infections diagnosed at ART initiation	at t0datv. Variables named the same way as the OIs above, starting with the stem t0
t0weight	weight at ART initiation	at t0datv +/- precision
t0height	height at ART initiation	at t0datv +/- precision
t0alat	alat at ART initiation	at t0datv +/- precision
t0hbsag	HBsAg at ART initiation	at t0datv +/- precision
t0creatui	Creatinine in µmol/L (IU) at ART initiation	at t0datv +/- precision
t0glyco	glycosuria at ART initiation	at t0datv +/- precision
t0prote	proteinuria at ART initiation	at t0datv +/- precision
t0lccd4	CD4 count at ART initiation	at t0datv +/- precision
t0lccd4tlc	CD4% at ART initiation	at t0datv +/- precision
t0hemoglb	haemoglobin at ART initiation	at t0datv +/- precision
t0lc	lymphocyte count at ART initiation	at t0datv +/- precision
t0hivload	viral load at ART initiation	at t0datv +/- precision
t0to6wsxdx	OIs diagnosed between 0 and 6 months of ART initiation	> t0dat & ≤ t0dat+6months
t0arvsi	ARV stopped for intolerance at ART initiation	at t0dat
t0to6arvsi	ARV stopped for intolerance between 0 and 6 months	> t0dat & ≤ t0dat+6months
Data from six months after Art initiation		
VARIABLE NAME	VARIABLE LABEL	CALCULATION METHOD/COMMENTS
t6datvisit	date of visit nearest to 6 months after ART initiation	
t6arv	ARV prescribed at 6-month visit	at t6datv
t6pply	prophylaxis at 6-month visit	at t6datv
t6whoc	Cumulative WHO stage at 6-month visit	at t6datv
t6wsXdX	opportunistic infections diagnosed at 6-month visit	at t6datv. Variables named the same way as the OIs above, starting with the stem t6
t6weight	weight at 6-month visit	at t6datv +/- precision
t6height	height at 6-month visit	at t6datv +/- precision
t6alat	alat 6-month visit	at t6datv +/- precision
t6hbsag	HBsAg at 6-month visit	at t6datv +/- precision
t6creatui	Creatinine in µmol/L (IU) at 6-month visit	at t6datv +/- precision
t6glyco	glycosuria at 6-month visit	at t6datv +/- precision
t6prote	proteinuria at 6-month visit	at t6datv +/- precision
t6lccd4	CD4 count at 6-month visit	at t6datv +/- precision
t6lccd4tlc	CD4% at ART initiation	at t6datv +/- precision
t6hemoglb	haemoglobin at 6-month visit	at t6datv +/- precision
t6lc	lymphocyte count at 6-month visit	at t6datv +/- precision
t6hivload	viral load at 6-month visit	at t6datv +/- precision
t6to12wsxdx	OIs diagnosed between 6- and 12-month visit after ART initiation	> t6dat & ≤ t6dat+6months
t6to12arvsi	ARV stopped for intolerance between 6 and 12 month visit after ART initiation	> t6dat & ≤ t6dat+6months
Data from 12 months after Art initiation		
Data from 18 months after Art initiation		
Data from last visit		
VARIABLE NAME	VARIABLE LABEL	CALCULATION METHOD/COMMENTS
lstdatv	Last date of visit	
lstdatnext	Last date of next visit	
lstloc	Last Location	
lstdloc	Date location was last recorded	
lstarv	ARV at last visit	
lstpply	prophylaxis at last visit	at lstdatv
lstwhoc	Cumulative WHO stage at last visit	at lstdatv
lstwsXdX	Opportunistic infections diagnosed at last visit	at lstdatv. Variables named the same way as the OIs above, starting with the stem lst
lstweight	weight at last visit	at lstdatv +/- precision
lstheight	height at last visit	at lstdatv +/- precision

Laboratory data last ever recorded		
VARIABLE NAME	VARIABLE LABEL	CALCULATION METHOD/COMMENTS
lstalat	Last alat	Last alat ever recorded
lstdalat	Date alat last recorded	
lsthbsag	HBsAg last recorded	Last HBsAg ever recorded
lstdhbsag	Date HBsAg last recorded	
lstcreatui	Creatinine value in µmol/L (IU)	Last creatinine recorded
lstdcreatui	Date creatinine last recorded	
lstglyco	Last Glycosuria	Last glycosuria ever recorded
lstdglyco	Date glycosuria last recorded	
lstprote	Last proteinuria	Last proteinuria ever recorded
lstdprote	Date proteinuria last recorded	
lstlccd4	Last CD4 count	Last CD4 count ever recorded
lstdlccd4	Date CD4 count last recorded	
lstlccd4tlc	Last CD4%	Last CD4% ever recorded
lstdlccd4tlc	Date CD4% last recorded	
lsthemoglb	Last haemoglobin	Last haemoglobin ever recorded
lstdhemoglb	Date haemoglobin last recorded	
lstlc	Last lymphocyte count	Last lymphocyte count ever recorded
lstdlc	Date lymphocyte count last recorded	
lsthivload	Last viral load	Last viral load ever recorded
lstdhivload	Date viral load last recorded	

10.7.3. Prescription data export v1.7.1

Data from Patient Form		
VARIABLE NAME	VARIABLE LABEL	CALCULATION METHOD/COMMENTS
keypatie	Cohort identification number	Calculated variable containing unique numeric value for patient
nid	Cohort identification number	
Data from Follow-up Form		
VARIABLE NAME	VARIABLE LABEL	CALCULATION METHOD/COMMENTS
keyfollo	Identification number of the visit	Calculated variable containing unique numeric value for visit
datvisit	Date of visit or start of hospitalization	
type	Type of visit	
tttcode	Treatment	
ttttype	Type of treatment (ARV, prophylaxis, misc)	
tttn	Number of ARVs per regimen	Variable calculated
presctn	Prescription status (begun, continued, stopped….)	
intolrc1	Intolerance 1	
intolrd1	Drug related to intolerance 1	
intolrc2	Intolerance 2	
intolrd2	Drug related to intolerance 2	
intolrc	Other Intolerances	
comment		

10.7.4. Blood collection data export v1.7.1

Summary data from Patient and Follow-up Forms		
VARIABLE NAME	VARIABLE LABEL	CALCULATION METHOD/COMMENTS
keypatie	Cohort identification number	Variable calculated
nid	Cohort identification number	
gender	Gender	
hiv	HIV status	
dattrft	Date of transfer	
datbirth	Date of birth	
datdead	Date of death	
fstdatv	Date of first visit recorded on Follow-up Form	
lstdatv	Date of last visit recorded on Follow-up Form	
lstdatnext	Date of last next visit recorded on Follow-up Form	
fstdatva	Date of first arv visit	Calculated
whoc	Cumulative WHO Staging , when?	
Data from the 1st date, lab results were recorded		
VARIABLE NAME	VARIABLE LABEL	CALCULATION METHOD/COMMENTS
examen1	Date, where 1st lab sample was taken	
alat1	ALAT (SGPT) ui/L	
hbsag1	Hepatitis B Antigen S	
creatui1	Creatinine in µmol/L (UI)	
glyco1	Glycosuria	
lc1	Lymphocyte count cells	
lccd41	CD4 count cells	
lccd4tlc1	CD4%	
hemoglb1	Haemoglobinemia g/dl	
hivchl1	HIV Test (Interim test PMTCT)	
hivchlr1	HIV Test Result (Interim test PMTCT)	
hivload1	HIV Viral Load copies/ml	
prote1	Proteinuria	
Data from the 2nd , 3rd, 4th … date, lab results were recorded		
VARIABLE NAME	VARIABLE LABEL	CALCULATION METHOD/COMMENTS
examenX	Date, where 2nd, 3rd …. lab sample was taken	
alatX	ALAT (SGPT) ui/ml	
hbsagX	Hepatitis B Antigen S	
creatuiX	Creatinine in µmol/L (UI)	
glycoX.	Glycosuria	
lcX	Lymphocyte Count cells	
lccd4X	CD4 Count cells	
lccd4tlcX	CD4%	
hemoglbX	Haemoglobinemia g/dl	
hivchlX	HIV Test Child	
hivchlrX	HIV Test Child Result	
hivloadX	HIV Viral Load copies/ml	
proteX	Proteinuria	

10.7.5. Free variables of the Patient Form data export v1.7.1

VARIABLE NAME	VARIABLE LABEL	CALCULATION METHOD/COMMENTS
keypatie	Cohort identification number	Calculated variable containing unique numeric value for patient
nid	Cohort identification number	
dia1	Background Other diagnosis 1	
dia2	Background Other diagnosis 2	
varpt1	Free variable 1	
varpt2	Free variable 2	
varpt3	Free variable 3	
varpt4	Free variable 4	
varpt5	Free variable 5	
varpt6	Free variable 6	
varpt7	Free variable 7	
varpt8	Free variable 8	
varpt9	Free variable 9	
varpt10	Free variable 10	

10.7.6. Free variables of the Follow-up Form data export v1.7.1

VARIABLE NAME	VARIABLE LABEL	CALCULATION METHOD/COMMENTS
keyfollo	Identification number of the visit	Calculated variable containing unique numeric value for visit
keypatie	Cohort identification number	Calculated variable containing unique numeric value for patient
nid	Cohort identification number	
datvisit	Date of visit or start of hospitalization	
type	Type of visit	
dia1	Other diagnosis 1	
dia2	Other diagnosis 2	
varfu1	Free variable 1	
varfu2	Free variable 2	
varfu3	Free variable 3	
varfu4	Free variable 4	
varfu5	Free variable 5	
varfu6	Free variable 6	
varfu7	Free variable 7	
varfu8	Free variable 8	
varfu9	Free variable 9	
varfu10	Free variable 10	

10.7.7. Tuberculosis database export v1.7.1

Data from Patient Form		
VARIABLE NAME	VARIABLE LABEL	CALCULATION METHOD/COMMENTS
keypatie	Cohort identification number	Calculated variable containing unique numeric value for patient
nid	Cohort identification number	
Data on TB Episode		
VARIABLE NAME	VARIABLE LABEL	CALCULATION METHOD/COMMENTS
followtb	identification number of the tuberculosis record	Automatically created by FUCHIA
regime	Treatment	
tttfrom	Start of treatment	
tttto	End of treatment	
afbsearc	Sample for AFB search	
xray	Xray	
afb	AFB	
culture	Culture	
tbtyp	Type of TB	
tbtypext	EPTB : Sites	
case	Case definition	
sat	SAT	
dot	DOT	
intermit	Intermittent	
outcome	Outcome	
Data from TB Form – Free Variables		
VARIABLE NAME	VARIABLE LABEL	CALCULATION METHOD/COMMENTS
var1	Free variable 1	
var2	Free variable 2	
var3	Free variable 3	
var4	Free variable 4	
var5	Free variable 5	
var6	Free variable 6	
var7	Free variable 7	
var8	Free variable 8	
var9	Free variable 9	
var10	Free variable 10	
Rank	Rank of tuberculosis episode per patient	Calculated variable

10.7.8. PMTCT database export v1.7.1

Data from Patient Form – Mother & baby		
VARIABLE NAME	**VARIABLE LABEL**	**CALCULATION METHOD/COMMENTS**
nidmother	Cohort identification number of the mother	
nidchild	Cohort identification number of the baby	
hiv	Final HIV result of baby	
hivtest	Final type of HIV test of baby	
hivdate	Date of Final HIV test of baby	
Data from PMTCT form – Mother & Delivery		
VARIABLE NAME	**VARIABLE LABEL**	**CALCULATION METHOD/COMMENTS**
refrb	Referred by	
datrefrb	Admission date in the PMTCT programme	
delivery	Type of delivery	
datdeliv	Date of delivery	
issueexp	Expected date of delivery	
matern	Type of health structure facility	
bborn	Number of babies born	
balive	Number of babies born alive	
tttdv	Mother's ARV protocol	
dattttdv	Date when the mother started her ARV protocol	
feeding	Breastfeeding (choice at delivery)	New Variable replacing the variable "Feeding choice at delivery" of the previous version
rankmum	Rank of delivery per mother	Variable calculated
Data from PMTCT form – Infant		
VARIABLE NAME	**VARIABLE LABEL**	**CALCULATION METHOD/COMMENTS**
arv	ARV prophylaxis prescribed to the baby	New variable, replacing the variables AZT and NVP of the 1.6.2 version
arvd	Duration ARV prophylaxis prescribed to the baby	New variable, replacing the variables AZT and NVP of the 1.6.2 version
Data from Follow-up Form – Infant		
VARIABLE NAME	**VARIABLE LABEL**	**CALCULATION METHOD/COMMENTS**
breastf	Date breastfeeding ended	New variable
pplx	Date child ARV prophylaxis ended	New variable
examen1	Date of first HIV test recorded in Follow-up Form	
hivchl1	Type of test used on test 1	
hivchlr1	HIV test result performed for test 1	
examenX	Date of X HIV test recorded in Follow-up Form	
hivchlX	Type of test used on test X	
hivchlrX	HIV test result performed for test X	
Data from PMTCT form – Free Variables		
VARIABLE NAME	**VARIABLE LABEL**	**CALCULATION METHOD/COMMENTS**
var1	Free variable 1	
var2	Free variable 2	
var3	Free variable 3	
var4	Free variable 4	
var5	Free variable 5	
var6	Free variable 6	
var7	Free variable 7	
var8	Free variable 8	
var9	Free variable 9	
var10	Free variable 10	

11 – TECHNICAL FEATURES

11.1. FUCHIA helpdesk

The FUCHIA helpdesk can be contacted for any problems arising with the installation or implementation of FUCHIA. Please address any queries to **fuchia@epicentre.msf.org**.

If problems arise, please describe them with as much detail as possible, and if possible attach a screen copy for error messages shown on screen and email to the above address. To trouble-shoot the problem, information to include in the message are:

Mission/database	Computer environment
MSF section and country	Operating system (version + language)
Name of the mission	Hard drive capacity (GB) (total capacity if >1 partition)
Name of the database	Hard drive: free space (GB) (total free space)
Year database started	Processor

Language used in FUCHIA	RAM (MB) Size of the database before migration to the new version Size of the database after compacting with the new version Number of zip files after compression with the new version

11.2. Operating Platform

FUCHIA is a database interface operating in a standard Windows environment (95, 98, Millenium, NT4, 2000, XP, Vista, Windows 7), written in Object Pascal (Borland Delphi) and connected to an Access database.Therefore, all database filenames must have a ".mdb" suffix. The minimum requirements for configuration are:

Operating system: Microsoft Windows 2000, NT (SP3), XP, Vista, Windows 7
Office 2000 installed on PC
Recent PC (e.g. Pentium 3, 500MhZ)
256 MB random access memory (minimum)

The program may work on less powerful computers, but users may exceed system resources when working with large files. Databases can become large, and the computer environment must be able to work with large files. For example, a database containing fewer than 5000 patients a computer should have 1 Giga of RAM and 2 Giga if the database contains more than 5000 patients.

Further, anti-virus software with regular updates is also recommended, and a computer dedicated solely to FUCHIA use with no internet connection or email access.

11.2.1. Network

FUCHIA can be simultaneously used by multiple users allowing several FUCHIA applications to be performed on one database e.g. several data entry staff entering data.

For a network, it requires two or more computers, where one computer will be the “master” computer acting as the server and containing the FUCHIA database that is placed in a directory that can be shared by all computers. All computers should preferably be in the same room.

To set up a simple local network, contact a local IT specialist.

Once the network is set-up, it is good practice to allow **single use** for major tasks (such as database compaction, report generation or data export). For this one single person should be appointed to be responsible for these tasks. In other words, when these tasks are in progress, no data entry should be done.

11.3. Software installation

To obtain the software, write to the FUCHIA helpdesk address: fuchia@epicentre.msf.org
You will get a link to download the software.

MSF missions with inadequate access to internet can request a CD-ROM containing the FUCHIA installation with a password for installation from the FUCHIA helpdesk.

The software can be installed as described below.

1) Start-up computer in “administrator” mode.
2) Copy the FUCHIA set-up file onto the desktop, as FUCHIA cannot be directly installed from a CD ROM.
3) Double-click the FUCHIA set-up (Build v1.7.0).exe file on the desktop and follow the installation instructions.
4) The installation of FUCHIA involves files that can never be modified, files that can be modified by all users and files that can be modified by individual users in case a computer is shared by several users (e.g. account). The location of those files varies according to the operating system: Windows XP or Windows 7.
5) Some folders where those files are located are hidden. To unhide them, go to Windows explorer, file options, display and tick the option “unhide hidden files”.

Location of files if the operating system is Windows XP:

Type of files	Default location of files	
Protected	C:\Program Files\MSF[1]\Fuchia\v1.7.1	
Non-protected	C:\Documents and Settings\user\Local settings\Application Data\Epicentre\Fuchia\v1.7.1\R\fuchia\src	FUCHIA R packages
Non-protected	C:\Documents and Settings\user\Local settings\Application Data\Epicentre\Fuchia\v1.7.1	settings.ini

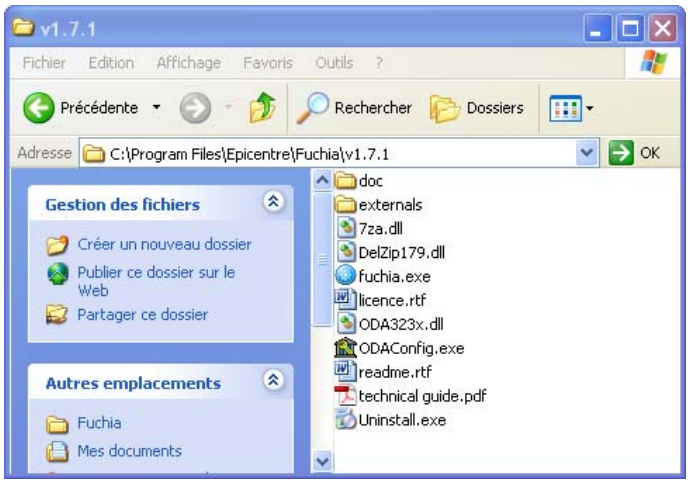
Location of files if the operating system is Windows 7:

Type of files	Default location of files	
Protected	C:\Program Files\MSF\Fuchia\v1.7.1	
Non-protected	C:\Users\user\AppData\Local\Epicentre\Fuchia\v1.7.1\R\fuchia\src	FUCHIA R packages
Non-protected	C:\Users\user\AppData\Local\Epicentre\Fuchia\v1.7.1	settings.ini

The screen copies shown below come from on a Windows XP computer:

[1] The default location of installation of FUCHIA used to be in C:\Program Files\Epicentre. From the version 1.7.1 the protected files of FUCHIA are now installed in “MSF” instead of “Epicentre”. Note that screen copies below have not been replaced.

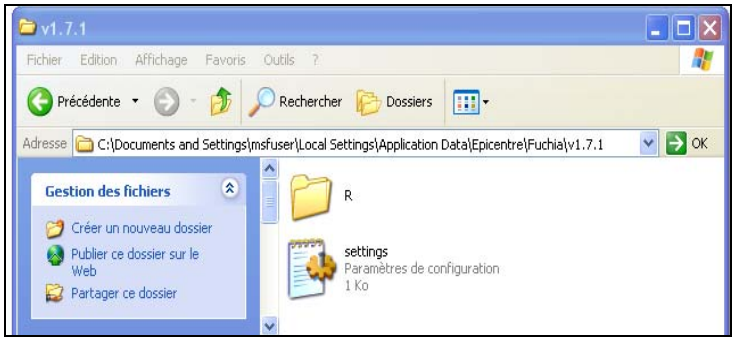
Protected files



Other resources are available in this directory including the PDF version of the guide and a folder (doc) containing the updated data collection forms.

The directory can be also accessed via the toolbar “start/all programs”. From there, look for the icon.

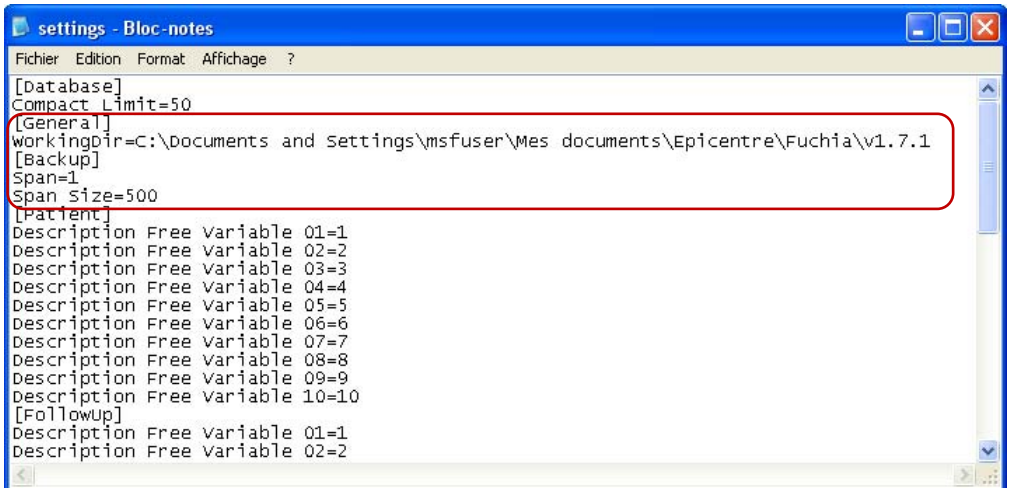
Non-protected files



The R folder contains the R files that are specific to FUCHIA and need to be accessible to be updated when necessary.

The settings.ini file has several functions:

- It indicates the default location of the working directory = where the output directory will be installed by default. This default location can be modified.
- It allows modifying the size of the zip files created by the compress function of FUCHIA. By default, the zip file size is 500 Ko.
- In this file, the label of each free variable can be written and the label will be visible on the screen. See chapter 2, §2.7.

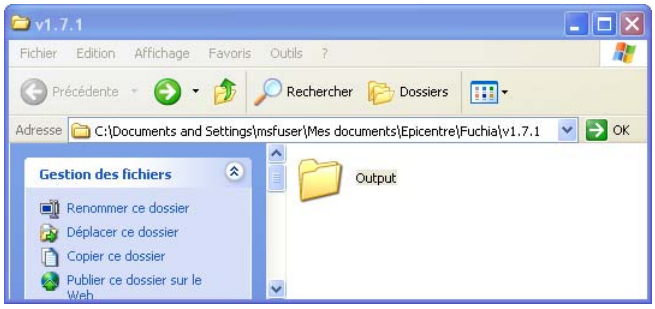


Note: To see the full content of the settings.ini file, you must:

- Open the database and go to each form to see the list of free variables in the settings.ini file
- Run a report or an export to see the path of the working directory
- Compress the database to see the option of changing the zip file size.

Easy access to the settings.ini file
The settings.ini can be accessed directly the via the toolbar “start/all programs/Fuchia 1.7.1” and be open with an editor software such as bloc-note.

Output directory in Windows XP



By default, it is located in C:\Documents and Settings\user\Epicentre\Fuchia\1.7.1. You may change the location through the settings.ini file (see above).

If you forget where it was installed, R reminds you its location when you connect R to the database.

6) Once installed, a shortcut will be created and installed on the desktop.

7) Close the software and switch computer back to “user” mode.

11.3.1. Updating FUCHIA

FUCHIA is regularly updated, partly to fix bugs found in the system, partly to include additional R programs and partly to upgrade the database in line with policy changes. At update, FUCHIA will convert the current database to align it with the new database. This conversion can involve addition/deletion or modification of variables and values.

For example, a major modification of FUCHIA from version 1.6.2 to version 1.7.0 was the incorporation of the 2009 WHO recommendations for monitoring PMTCT. As a consequence, several of the variables in the PMTCT form changed, for example the codes of variable Mother ARV protocol. Therefore, at the upgrade the values of the old variable are imported to the corresponding values of the updated variable.

Mother ARV protocol		
Version 1.6.2	→	Version 1.7.0
HAART		cART[1]
		Prophylactic cART[2]
AZT + NVPsd + (AZT-3TC)		AZT + NVPsd + (AZT-3TC)
NVPsd + (AZT-3TC)		NVPsd + (AZT-3TC)
NVPsd		NVPsd
Other		Other
None		None
Not specified		Not specified

[1] cART = combined Anti Retroviral Therapy. To be ticked if the mother is prescribed ART for her own health (WHO staging is 3 or 4, or cd4 count is below 350 cells/mm^3).

[2] is ticked if the mother is prescribed ART primarily for the prevention of transmission of HIV to her infant. (WHO staging is 1 or 2 and her cd4 count is above 350 cells/mm^3).

There are circumstances however if there is a bug or when there are no corresponding variables or codes, where the data of the current version may be lost. **Therefore always create a back-up copy of all existing databases in the current version of FUCHIA before upgrading.** See section "Data back-up and storage" for further details.

Note – FUCHIA can be upgraded to later versions. However, it is not possible to use earlier versions of FUCHIA to read databases that have been upgraded.

Prior to upgrade:

1) Ensure the FUCHIA set-up for the version currently used is accessible (either in the computer or on a CD) for reinstallation if necessary. If set-up is not available, request a link from the FUCHIA helpdesk (fuchia@epicentre.msf.org) to download it.

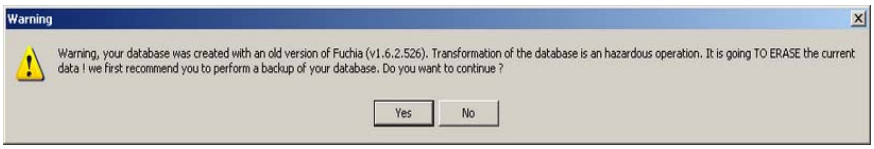
2) Create a back-up copy of all existing databases in the FUCHIA version currently in use. Ensure these copies are named appropriately and are located in an alternative environment to where the current database is stored.

3) Uninstall the current FUCHIA version (See section below).

4) Install the new version using the procedure detailed above.

For upgrade:

Double click on the new FUCHIA icon on the desktop and open the current database. FUCHIA will give a warning that the database will be converted to the new format.



At conversion, FUCHIA will save the new database and create a back-up of the database. The new database and the back-up will be named using the name of the current database. For example, if the current database was called "v1.6.2 MSF cohort.mdb", the new database will be called "v1.6.2 MSF cohort.mdb" and the back-up database "v1.6.2 MSF Cohort (backup 1.6.2 526).mdb".

To avoid any ambiguity, close FUCHIA and rename the database using the correct version.

v1.6.2 MSF cohort.mdb	→	v1.7.0 MSF cohort (insert date).mdb
v1.6.2 MSF Cohort (backup 162508).mdb	→	v1.6.2 MSF Cohort (insert date).mdb

If back-ups were performed prior to conversion, delete the back-up created at conversion.

11.3.2. Post installation: testing

After installation, a post-installation test should be performed to ensure that the software functions well within the computer environment without the risk of losing data. Three domains are listed for testing, and the idea is to start with the checklist for installation and then proceed through safeguarding and functionality.

Installation	Was back-up produced when FUCHIA was upgraded? Does the default password work? Can you change the password and re-open the database?
Safeguarding	Compact the database and check if *.bak file was created? Are you able to recover the database from the *.bak file Compress the database and check that the zip files are all in the same directory as the one of the database. Restore the zipped database and check that restored database is where the zip files are.
Functionality	Access to FUCHIA direct Functions of FUCHIA direct (click and drag, filter) Print function
Data entry	Create a new Patient Form Create a new Follow-up Form Test the "copy last treatment" function Create a new TB form Create a new PMTCT form with a least one baby alive Delete all the new forms that you have created (remember last one to be deleted should be the Patient Form) Modify an existing form
Access to R	Connect database to R. Disconnect database from R.
R reports	Re-Connect database to R. Run an R report. Check the report is saved in the default output directory.
R export	Run a frequently used R export in the format that is used in the mission (e.g. txt) Check the export can be read by the standard software used (e.g. Excel)

If problems arise, please describe them with as much detail as possible, and if possible attach a screen copy for error messages shown on screen and email to the FUCHIA address: fuchia@epicentre.msf.org.

If no major problems are identified, continue using the updated version of FUCHIA.

11.3.3. Uninstall FUCHIA[2]

To uninstall a version of FUCHIA, go to the default installation folder of that version and double click "uninstall.exe" and follow the instructions.
The folders and files corresponding to the version uninstalled must have been removed by the process: those located in C:\ Program Files\MSF\Fuchia\v1.7.1 and those located in

[2] Older versions of FUCHIA are installed in C:\Program Files\Epicentre\Fuchia\v1.x.x

C:\Documents and Settings\All Users\Application Data\Epicentre\Fuchia\v1.7.1. Only the output folder and the settings.ini file remain after uninstallation.

11.3.4. Password

FUCHIA is protected by a password.

Following installation, on opening a password is requested. This password is allocated by Epicentre and can be changed using "File\Options\ Change password"

11.3.5. Interface language options

English is the default language for the entire FUCHIA package. To change the language:

1) Go to "File\ Options" and select language.

2) To set the language, close FUCHIA and restart. Each subsequent time FUCHIA starts, the package will appear in the last selected language.

Note:

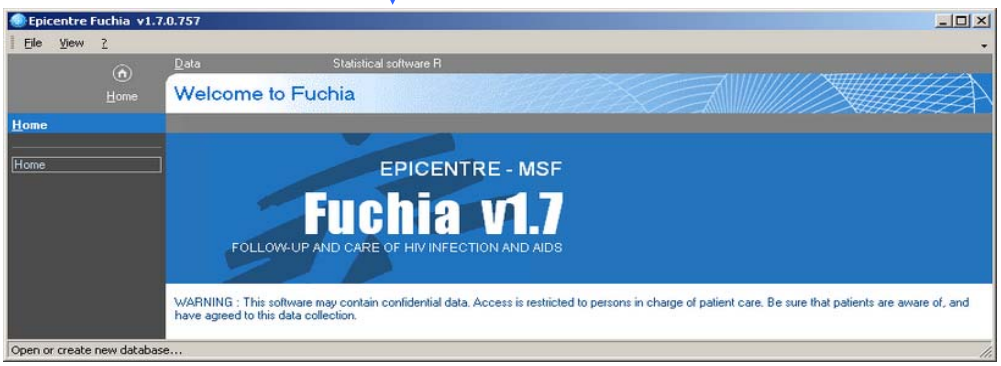
Spanish translation is no longer available in v1.7.

11.4. FUCHIA home page

On opening, the FUCHIA homepage will appear with two main icons.

Data for data entry

Statistical software R for data analysis, export and error reports



11.5. Creating database

For details, see Chapter 2 Implementation.

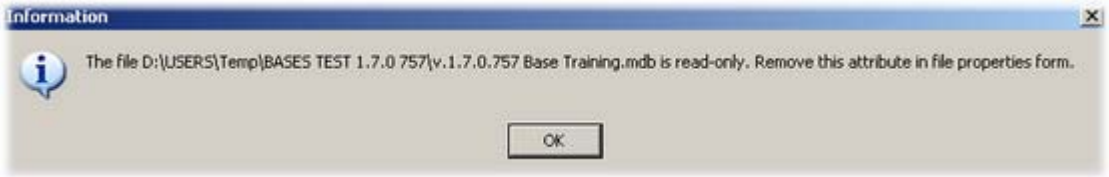
11.6. Opening a database

For details, see chapter 3 FUCHIA data processing.

11.6.1. Opening a CD-ROM database

If you wish to retrieve a database saved on a CD-ROM and copy it onto the hard drive, it will automatically copy itself as a read-only file. Before opening the database with FUCHIA, go to the properties of the database and uncheck the “read only”.

If you don’t do that when you open the database with FUCHIA, the following message will appear:



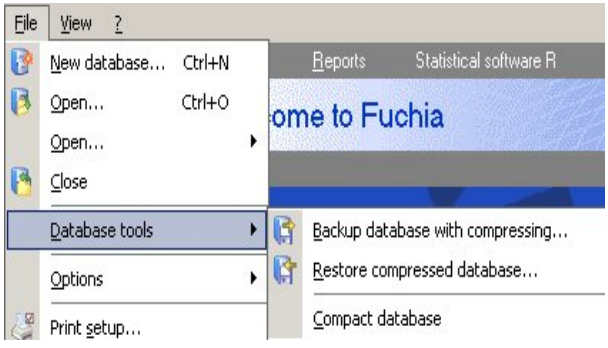
11.7. Closing a database

On exiting FUCHIA, the database is automatically closed. Use the option close to close current database in use and to open a new database.

11.8. Saving a database

There are three methods for saving data in FUCHIA, either 1) automatically when data is entered, modified or deleted, or 2) manually using the “Compress” and 3) “Compact” options. Compacting and compressing require sufficient space on the drive where the database is located.

To compress or compact data, go to Database Tools, and select “Backup database with compressing” or “Compact database”.



When saving, the user can specify the location where data will be stored (by default it is the desktop or the directory of last database opened). However, the name of the database **cannot be changed.** The database can only be renamed on exit from FUCHIA.

Note:

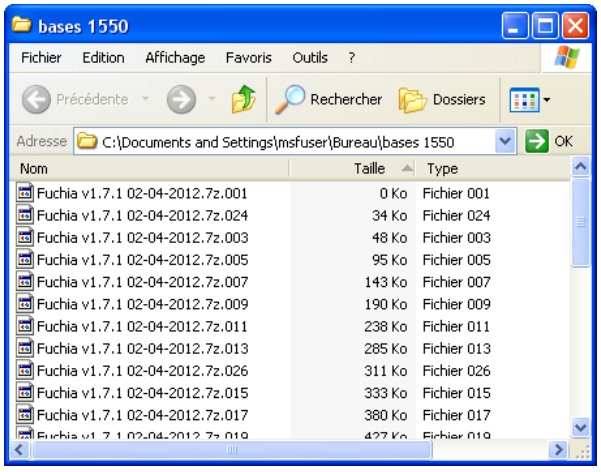
If the directory where a FUCHIA database is saved contains multiple sub-directories with long names, FUCHIA may have difficulty re-opening the database. Therefore, restrict the number and name of directories to a minimum.

11.8.1. Compact database

With FUCHIA versions prior to 1.7.0, the size of a database can increase dramatically as automatic reports are produced and temporary variables created. This prevents FUCHIA performing certain tasks or slows down the functioning of FUCHIA. Therefore, it is good practice to regularly compact the database and **every time** on exit of FUCHIA. On compacting, the unused space in the database is deleted thus reducing the file size and making it faster and more stable.

Compacting can be performed manually as described earlier or automatically if the size of the database gets larger than 50MB. A warning message will appear and the user will have to click OK to continue. The threshold of 50MB can be changed in the ini file.

11.8.2. Backup database with compressing



If the option back-up with compressing is selected, FUCHIA splits the database into several zipped files each reaching the maximum size defined in the settings.ini file (500 ko by default) to allow ease of sending files via email.

The default directory for storage of zipped files is the same as the unzipped database. Each zipped file is named as “FUCHIA v.1.7.1 + date of back-up” and numbered 001 to the maximum number of zipped files.

All files must be kept together in order to restore the database, therefore ensure none of the files are missing when copying the files for storage or back-up or when sending.

Note: **Do not change the name at the point of saving.**

11.9. Data back-up and storage

11.9.1. Hardcopy forms

The filing method for hardcopy forms varies from program to program; all methods should allow MSF staff to trace back the forms easily. Filing according to ID numbers and visit dates would seem to be the most suitable. The filing can be done either within the patient’s medical records or in appropriate folders.

11.9.2. Data back-ups

As with other applications, it is strongly recommended that users copy FUCHIA databases to securely stored external back-up locations (Zip disk, CD, USB key) in order to retrieve data when problems arise with a database. The frequency of data back-ups will depend on the level of mission activity. The more active a MSF program, the more forms will have to be re-entered if the data is lost, thus creating the need to back up data on a more regular basis. Frequent data back-ups (eg. Daily) will avoid operators having to re-enter forms in the event of data loss, a computer virus infection, damaged hard drive, etc. See “Chapter 1 Data Protection Measures” for further details.

Back-up of a FUCHIA database can be done:

By copying the database to a back-up location and renaming the database using the name of the database + date of back-up and changing the suffix from .MDB to .BAK.

By “compacting” or “compressing” the database, a back-up database is automatically created using the name of the database and the suffix .BAK. Copy this file to the back-up location and rename as specified above.

Note: If using .zip files as back-up ensure .zip files are named with the date of back-up.

11.9.3. Restoring a backup copy and a compressed database

Copy the back-up files from back-up location to a temporary location. To restore back-up file with the suffix .BAK, simply change the suffix from .BAK to .MDB.

To restore .ZIP files, first ensure ALL zip files are present and then

1) Open FUCHIA and select the option “Database Tools / Restore compressed database” in the file menu.

2) Go to the folder where the zipped files are located if it does not show it automatically.

3) By default, the only visible file is the 001 zip file. Select it (ex: Fuchia v1.7.1.02.04-2012.7z.001) and open it.

4) You get a message saying “restore of database completed”. Click OK and the database will appear in the directory where the zip files were located. If .zip filenames are similar to current database, then at restoration current database is deleted and replaced by the restored zipped file.

5) A compressed FUCHIA database can be restored only by the version of FUCHIA used for the compression.

11.10. Sending FUCHIA database

To send FUCHIA databases via email, ftp server, CD-ROM or floppy disk.

Anonymise database if patient names are recorded in the variable “Other FUCHIA ID” in the Patient Form (see section 11.10.2).

“Compact” or “Compress” database depending on size. In general, compress the database for sending by email or ftp, and compact if sending a CD-ROM or flash drive.

Ensure to copy the .BAK file in a “read-only” mode to avoid inadvertent changes to database.

Ensure all .zip files are copied or sent.

11.10.1. Send zipped file by email

First send an email informing that a database is to be sent specifying the number of zipped files to be sent. Each subsequent mail should contain a maximum of 2 zipped files and the heading of each mail should specify the name of project + country + number of zips sent. e.g. “country-mission 2 of 12”.

Note: If one file is missing, it will be impossible to restore the database. When you send the last message, indicate clearly it is the last mail with the highest file number.

If there is a problem sending the zipped files, replace the “zip” suffix of the first file by “zzz”.

11.10.2. Anonymise database

A specific R programme exists to delete patient names (or other information) entered in the Patient Form in the variable “Other FUCHIA ID”. See chapter 9, § 9.6.3 (clear ID other)