

# Data Collection to Support Operational Research on All-Oral Shorter Regimens for RR-TB: A Practical Approach

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# Objectives

- Discuss types of forms used for data collection
- Consider adaptation of locally available forms
- Review principles of privacy and confidentiality in data collection, entry, and analysis
- Discuss variables to be used in data collection
- Review data flow, data entry, and data analysis
- Present “endTB” forms as one example

# Data Collection Forms

- Use what you have: initiation and follow-up forms, laboratory data for bacteriologic and safety monitoring, chest radiography report section.
- May want to add in additional variables for shorter regimens (i.e. assessment for recurrence)
- Simple is usually best: ensuring medical records are well-documented will not only make data collection easier but can also enhance patient care.
- How will “blank spaces” be handled (not asked? No? missing?)? How will free text be handled?

Form 01

**TB Control Programme**

Secondline Registration Number: \_\_\_\_\_

Date of second-line treatment registration: \_\_\_\_\_

Treatment Centre: \_\_\_\_\_

Patient Name: \_\_\_\_\_

Address & Telephone: \_\_\_\_\_

District: \_\_\_\_\_

Sex (circle one): M F

Age: DOB: \_\_\_\_\_

Initial weight (kg): \_\_\_\_\_

Height (cm): \_\_\_\_\_

Site (circle one or both): Pulmonary Extrapulmonary

If extrapulmonary, specify site: \_\_\_\_\_

**Second-line TB treatment card**

Registration Group	Choose one only
New	
Relapse	
After loss to follow-up	
After failure of first treatment with first-line drugs	
After failure of retreatment regimen with first-line drugs	
Other (previously treated without known outcome)	

Transfer in (from another second-line treatment programme) If yes name of centre: \_\_\_\_\_ Yes  
No

**HIV INFORMATION**

HIV Testing done (circle one): Y / N / Unknown

Date of test: \_\_\_\_\_ Result: \_\_\_\_\_

Started on ART (circle one): Y / N Date: \_\_\_\_\_

Started on CPT (circle one): Y / N Date: \_\_\_\_\_

**Meetings of review panel (medical commission, selection committee, consensus)**

Meetings of the review panel: dates and decisions		
Date	Decision	Next Date

**Previous Tuberculosis Treatment Episodes**

District TB Register No. (i.e. SMC register number)	Start Date (if unknown put year)	Regimen (write regimen in drug abbreviations)	Outcome

Previous use of second-line drugs for more than one month? Yes / No / Unknown

If Yes, indicate in Table above:

Drug Abbreviations			
First line drugs	second line drugs		
Isoniazid	An-ranibact	Pro-thiothamizide	Ble-bedaquiline
Rifampicin	Km-Kanamycin	Cl-cycloserine	Cl-cladribine
Pyrazinamide	cm-capreomycin	Cl-cycloserine	Cl-cladribine
Streptomycin	It-levofloxacin	Thp-pantoic acid	Des-desamides
2-Pyrazinamide	Mk-Mofloxacin	Amv (C-metaxolone)	Im-imipenem
	Of-ofloxacin	Amv (C-metaxolone)	Lzd-linezolid
	Gr-gatifloxacin		Mpm-moxifloxacin

Transfer in (from another secondline treatment programme) If yes name of centre: \_\_\_\_\_

# From Medical Records to Data Forms: Prioritizing Confidentiality

- Identifying information is necessary in the medical record for obvious reasons.
- Data forms with identifying information must be secured and accessible only to necessary personnel.
- Principles of privacy and confidentiality are essential in operational research.



# Study Variables

- Initial list can be made by reviewing initiation and follow-up forms.
- Additional variables can be added, especially those that may be associated with treatment outcomes (i.e. bilateral cavitory disease, baseline BMI, baseline Hb).
- Try to identify these prospectively, but can be added retrospectively if needed.
- Try not to collect too much data: a smaller number of variable that are of high quality

conf_mdr Notification	Number of laboratory-confirmed MDR-TB patients who started treatment for
conf_rrmd Notification	Number of laboratory-confirmed RR-TB or MDR-TB cases identified
conf_rrmd Notification	Number of laboratory-confirmed rifampicin-resistant (RR-TB) or multidrug-resistant
conf_xdr_1 Notification	Number of laboratory-confirmed XDR-TB patients who started treatment for
hiv_art Notification	HIV-positive TB patients started or continued on antiretroviral therapy (ART)
hiv_cpt Notification	HIV-positive TB patients started or continued on co-trimoxazole preventive therapy
hiv_ipt Notification	People living with HIV newly enrolled in HIV care who started treatment for TB
hiv_ipt_re Notification	People living with HIV currently enrolled in HIV care who started treatment for TB
hiv_reg Notification	Total number of people registered as HIV-positive regardless of year of diagnosis
hiv_reg_al Notification	Number of adults and children currently enrolled in HIV care during the year.
hiv_reg_ne Notification	Number of adults and children newly enrolled in HIV care during the year.
hiv_reg_nx Notification	Total number of adults and children newly enrolled in pre-ART care or on ART
hiv_tbdete Notification	Total number of adults and children newly enrolled in HIV care who are diagnosed
hiv_tbscr Notification	Number of adults and children enrolled in HIV care who had their TB status as
hivtest Notification	TB patients (new and re-treatment) with an HIV test result recorded in the TB
hivtest_po Notification	TB patients (new and re-treatment) recorded as HIV-positive
mdr_short Notification	Number of patients started on shorter MDR-TB treatment regimens during the
mdr_short Notificatio 0=No; 1=Y	Had any patients been started on shorter MDR-TB treatment regimens by the
mdr_tx_ac Notification	Number of patients on MDR-TB treatment who had adverse events registered
mdrxdr_bc Notification	Number of patients started on Bedaquiline during the reporting year
mdrxdr_bc Notificatio 0=No; 1=Y	Had any TB patients been started on Bedaquiline for the treatment of MDR-/
mdrxdr_dl Notification	Number of patients started on Delamanid during the reporting year



# Data flow, entry and analysis

- Identify electronic database that will be used for analysis (keep simple, utilize existing tools, ensure security).
- How will data be entered into the database? Who will enter it? When? How will quality entry be ensured? How can this be done and not interrupt patient care?
- Who will do the analysis? When? Could follow usual quarterly/twice yearly analysis of cohorts.
- Consider academic support for more complex analysis if needed



# Data Collection Tools: the endTB Example