B. Revised recording and reporting forms

B.1 Paper-based or electronic recording and reporting

The forms, registers and reports presented in this document are designed for paper-based recording and reporting systems. They show how the revised case and outcome definitions can be incorporated into a country's TB recording and reporting system.

Countries using electronic systems for TB recording and reporting should adapt their software to incorporate the revised case and outcome definitions and to produce the indicator reports along the lines illustrated in this document.

B.2 Adaptation to local requirements

The forms, registers and reports presented in this document are intended to be illustrative rather than prescriptive and demonstrate how a minimum dataset for recording and reporting could be compiled. Each country will have its own particular requirements and will need to modify the forms, registers and reports to suit its needs.

Modifications could include:

- translating into local languages;
- adding new data items (e.g. identifiers, serial numbers, dates);
- in some countries, to comply with national confidentiality laws, removal of fields documenting the HIV status of TB cases;
- disaggregating existing data items into more detailed categories;
- adding format constraints (e.g. day/month/year fields for dates);
- adapting terminology to local usage;
- alternative reporting frequencies (e.g. monthly instead of quarterly);
- tailoring laboratory request and result forms to the types of tests provided by the laboratories;
- changing layout, including the arrangement of tables, size of fields, text of labels, white space, instructions, footnotes and the number of sheets needed for a given tool;
- adding official logos;
- removing the illustrative footnotes or converting them to short instructions within the body of forms;
- changing a field from one where a code is entered into multiple fields from which one is ticked (which is easier to use, but takes up more space), or vice versa, for example:

Treatment category (*Tick one option only*)		
Initial regimen with first-line drugs	Retreatment regimen with first-line drugs	Second-line treatment regimen
	✔	

or:

Enter treatment category (*Init/Retr/SL*)
Retr

It is important for NTPs to test their forms and registers before rolling them out, to make sure that they are usable and easy for NTP staff to read, understand and complete accurately. A few of the people who will eventually be using the forms should be observed filling them out using real data from their place of work; this will show which parts of the forms are clear and work well and which parts are unclear, do not work so well or are liable to misinterpretation. Discussions with people who have tested the forms can result in

valuable feedback on the layout and language of the forms and the instructions for their use. If the forms need to be modified as a result of the feedback, they should be tested again. Such testing will also provide useful ideas for the training and communication needed when the new forms are rolled out to the entire NTP.

B.3 The revised forms, registers and reports

Eight revised forms, registers and reports, as listed in the table below, are illustrated in this document. These focus on reporting tools and do not include tools for patient management (such as the TB treatment card) or resource management.

Section	Form name	Form no. in 2006 guide[a]	Form no. in 2008 guide[b]
B.3.1	Request for examination of biological specimen for TB	Form 1	Form 03
B.3.2	Basic management unit TB register	Form 5	Not in guide
B.3.3	Second-line TB treatment register	Not in guide	Form 02
B.3.4	Laboratory register for smear microscopy and Xpert MTB/RIF	Form 2	Form 04
B.3.5	Laboratory register for culture, Xpert MTB/RIF and drug susceptibility testing (DST)	Form 2	Form 04
B.3.6	Quarterly report on TB case registration in the basic management unit	Form 6	Not in guide
B.3.7	Quarterly report on TB treatment outcomes in the basic management unit	Form 7	Not in guide
B.3.8	Combined annual outcomes report for basic TB and for RR-/MDR-TB	Not in guide	Form 07

[a] *Revised TB recording and reporting forms and registers – version 2006.* Geneva, World Health Organization, 2006 (WHO/HTM/TB/2006.373; available at http://www.who.int/tb/dots/r_and_r_forms/).

[b] *Guidelines for the programmatic management of drug-resistant tuberculosis: emergency update 2008*. Geneva, World Health Organization, 2008 (WHO/HTM/TB/2008.402; available at http://whqlibdoc.who.int/publications/2008/9789241547581_eng.pdf).

Certainly, NTPs will want to monitor many other aspects of their work (e.g. stocks of pharmaceuticals, laboratory reagents, X-rays and other consumables; associated costs; human resources and training requirements), but these are outside the scope of this document.

The revised forms and reports for drug-resistant tuberculosis are discussed in greater detail in the *Companion handbook to the WHO guidelines for the programmatic management of drug-resistant tuberculosis.*[1]

[1] *Companion handbook to the WHO guidelines for the programmatic management of drug-resistant tuberculosis.*[1] Geneva, World Health Organization. 2014. (WHO/HTM/TB/2014.11; Available at: http://apps.who.int/iris/bitstream/10665/130918/1/9789241548809_eng.pdf)

B.3.1 Request for examination of biological specimen for TB

This is the standard form that accompanies a biological sample sent to a laboratory for smear microscopy, culture, Xpert MTB/RIF or DST (including line probe assay).

Requests for histopathology (including cytology) should be made with the standard forms currently in use at the health facility.

HIV status and previous treatment status are included so that the data required for assessing adherence to, and effectiveness of, testing algorithms can be collected.[1]

If analyses of several types of specimen (e.g. sputum and other fluids) are requested, a separate request form should be used for each specimen.

If multiple analyses (e.g. culture and DST on the same sputum sample) are requested, the results should be sent from the laboratory to the requestor as they become available, rather than waiting until all test results are confirmed. It may therefore be practical to produce the request forms in booklets with self-carbonated paper.

The requestor completes the upper portion of the form, including basic demographic and contact details of the patient being tested. Depending on the type of analysis required, the requestor also fills in the date of sample collection in the lower part of the form.

The lower part of the form is used to communicate results back to the facility that requested the tests, using a standardized notation. The person responsible for the test result must be clearly identified.

Notes for country customization

- HIV infection details can be omitted if necessary to comply with national confidentiality laws.
- Extra contact details (e.g. telephone number) for requestor and examiner could be added.
- Some countries use different scales for smear (e.g. /300 high-power fields (HPF)).
- Some countries may want to use separate request forms for smear, culture, Xpert MTB/RIF and DST.
- *Treatment unit* can also be a *referring facility*.

[1] See recommendations in *Rapid implementation of the Xpert MTB/RIF diagnostic test. Technical and operational 'how-to' – practical considerations*. Geneva, World Health Organization, 2011 (WHO/HTM/TB/2011.2; available at http://whqlibdoc.who.int/publications/2011/9789241501569_eng.pdf).

Request for examination of biological specimen for TB

Treatment unit: _____ Date of request: _____

Patient name: _____

Age (years): _____ Date of birth: _____ Sex: ☐ Male ☐ Female

Patient address: _____

_____ Telephone: _____

Reason for examination:

☐ Diagnosis. If diagnosis, presumptive RR-TB/MDR-TB?: ☐ Yes ☐ No

OR ☐ Follow-up. If follow-up, month of treatment: _____

HIV infection? ☐ Yes ☐ No ☐ Unknown

Previously treated for TB? ☐ Yes ☐ No ☐ Unknown

Specimen type: ☐ Sputum ☐ Other (specify):_____

Test(s) requested: ☐ Microscopy ☐ Xpert MTB/RIF

☐ Culture ☐ Drug susceptibility ☐ Line probe assay

Requested by (Name and signature): _____

_____

Microscopy results (*to be completed in the laboratory)*

Date sample collected *(filled by requestor)*	Specimen type	Laboratory serial number(s)	Visual appearance (blood-stained, mucopurulent or saliva)	**Result** (*tick one*)				
				Negative *(0 AFB/ 100 HPF)*	**1–9/100 HPF** *(scanty; report no. of AFB)*	**+** *(10–99 AFB /100 HPF)*	**++** *(1–10 AFB/ HPF)*	**+++** *(>10 AFB/ HPF)*

Examined by (name and signature): _____

Date of result: _____

Xpert MTB/RIF test result (*to be completed in the laboratory)*

Date sample collected: _____

M. tuberculosis: ☐ Detected ☐ Not detected ☐ Invalid / No result / Error

Rifampicin resistance: ☐ Detected ☐ Not detected ☐ Indeterminate result

Examined by (name and signature): _____

Date of result: _____

Culture results (*to be completed in the laboratory)*

Date sample collected *(filled by requestor)*	Media used (liquid or solid)	Laboratory serial number(s)	**Result** (*tick one*)						
			Negative *(0 colonies)*	**1–9** *(<10 colonies)*	**+** *(10–100 colonies)*	**++** *(>100 colonies)*	**+++** *(Innumer-able/ confluent growth)*	**NTM[1]**	**Contaminated**

Examined by (name and signature): _____

Date of result: _____

Drug susceptibility test (DST) and line probe assay (LPA) results (*to be completed in the laboratory)*

Date sample collected *(filled by requestor)*	Method[a]	Laboratory serial number(s)	**Results[b]** *(mark for each drug)*											
			H	R	E	S	Amk	Km	Cm	FQ: ___	Other: ___	Other: ___	Other: ___	Other: ___

[a] Specify: solid media DST; liquid media DST; direct LPA; indirect LPA

[b] Results codes: R = Resistant S = Susceptible C = Contaminated — = Not done

Examined by (name and signature): _____

Date of result: _____

[1] Non-tuberculous mycobacteria.

B.3.2 Basic management unit TB register

A basic management unit (BMU) is defined in terms of management, supervision and monitoring responsibility. A BMU for the TB programme may have several treatment facilities, one or more laboratories and one or more hospitals. The defining aspect is the presence of a manager or coordinator who oversees TB control activities for the unit and who maintains a master register of all TB patients being treated; this register is used to monitor the programme and report on indicators to higher administrative levels. Typically, the units correspond to the government's second subnational administrative division, which might be called, for example, a "district" or "county". It is internationally recommended that a BMU cover a population of between 50 000 and 150 000 or of up to 300 000 for large cities.[1]

A health facility is defined as any health institution with health care providers formally engaged in any of the following TB programme functions (DOTS): referring patients with presumptive TB or confirmed TB cases, laboratory diagnosis, TB treatment and patient support during treatment.

The BMU TB register (also sometimes called the district TB register) is intended primarily for recording the data needed to monitor BMU performance, using indicators and reports about TB patients. It is also commonly used to summarize testing results and treatment decisions in order to determine whether basic diagnostic and treatment guidelines are correctly implemented. No information that is beyond this monitoring scope should be included in the register.

The register should contain the records of all patients diagnosed with TB and eligible for TB treatment, including those diagnosed with RR-TB or MDR-TB, regardless of whether treatment was actually started. All of these cases are notifiable and should be included in the summary case notification reports sent to higher levels. The registration date is the date on which the BMU decides that a patient has TB and is eligible for treatment.

Bacteriological examination before the start of treatment ("month 0") now allows for the registration of results from an Xpert MTB/RIF test. Space is provided for recording whether the case is RR-TB or MDR-TB. Both smear and culture results can be recorded.

Notes for country customization

- The register illustrated in this section spans three pages for purposes of clarity. Countries that wish to retain the traditional BMU register format, spread across two pages, will need to design and test their register layout accordingly (for example by using a single coded column instead of multiple, mutually exclusive columns – see section B.2 above – or by using appropriate abbreviations in column headings).
- *Health facility* could be removed if the register covers only one facility.
- *Patient address* could be dropped if TB treatment cards are easily accessible – the address is not needed to generate standard reports and indicators.
- Alternative codes or full text could be used to indicate type of examination.
- For country-specific purposes, deaths due to TB and deaths due to other causes could be separated in the treatment outcomes section; however, the two need to be added together for outcome reporting.
- Numerators and denominators for calculating indicators to monitor community-based TB activities could be added. [2]

[1] See p. 10 of *Compendium of indicators for monitoring and evaluating national tuberculosis programs.* Geneva, World Health Organization, 2004 (WHO/HTM/TB/2004.344; available at http://whqlibdoc.who.int/hq/2004/WHO_HTM_TB_2004.344_chap1-2.pdf).

[2] See Annex 1 of: Getahun H et al. *ENGAGE-TB. Integrating community-based tuberculosis activities into the work of nongovernmental and other civil society organizations: operational guidance.* Geneva, World Health Organization, 2012 (WHO/HTM/TB/2012/8; available at http://apps.who.int/iris/bitstream/10665/75997/1/9789241504508_eng.pdf).

- *Laboratory serial numbers* for bacteriological examination could be added if needed for monitoring when TB treatment cards are not easily accessible.
- *History of previous treatment* is also known as *Patient registration group* and is also called *Type of patient* in earlier examples of the BMU TB register.[1]
- The footnotes shown are provided to explain the forms in this document and are not intended for inclusion in the country registers.
- Instead of two or three columns and a split row for a given period's bacteriological results, an alternative format could be used with the result prefixed by S, C or X, depending on the type of examination. For example:

Instead of:

Month 5	
S	C
Date	
++	+++
1/1/2013	14/1/2013

the following format could be used with results written as:

Month 5	
Result	Date
S:++	01/01/2013
C:+++	14/1/2013

[1] *Revised TB recording and reporting forms and registers – version 2006.* Geneva, World Health Organization, 2006 (WHO/HTM/TB/2006.373; available at http://www.who.int/tb/dots/r_and_r_forms/).

Basic management unit TB register (page 1 of 3)

Date of registration	BMU TB no.	Name	Sex (M/ F)	Age	Address	Health facility where treatment card is kept[a]	Date treatment started

[a] In case several copies are kept, the most peripheral facility should be entered.

Basic management unit TB register (page 2 of 3)

History of previous treatment (*choose one option only*)[b]						**Transfer in**[d]	**Site**		**Treatment category** (*choose one option only*)[c]			**TB/HIV activities**	
New	Previously treated patients				Previous treatment history unknown		Pulmonary	Extra-pulmonary	Initial regimen with first-line drugs	Retreatment regimen with first-line drugs	Second-line treatment regimen	ART (Y/N)	CPT (Y/N)
	Relapse	Treatment after failure	Treatment after loss to follow-up	Others previously treated									

[b] See definitions in section A.1.2.

[c] Tick the treatment category in which the patient is started:

- initial regimen with first line drugs (previously Category 1 or 3)
- retreatment regimen with first line drugs (previously Category 2)
- second-line treatment regimen (previously Category 4; if patient has been started directly on second-line treatment for RR-TB or MDR-TB, without being started on a first-line treatment in the episode registered here).

[d] Transferred-in patients have been transferred from another TB register to continue treatment. These patients are **not included** in the receiving unit's quarterly and annual reports of case registrations and treatment outcomes.

Basic management unit TB register (page 3 of 3)

Smear (S), culture (C) or Xpert MTB/RIF (X) results and other examinations[e]										**Treatment outcome and date outcome determined[f]**							**Remarks**
At the time of TB diagnosis					Month 2 or 3[g]		Month 5		End of treatment	Outcome						Moved to second-line treatment register[i]	
HIV infection (Y/ N/ unknown)[h]	Drug resistance (RR/MDR/ None/ unknown)[i]	S	C	X	S	C	S	C	S	C	Cured	Treatment completed	Treatment failure	Died	Lost to follow-up	Not evaluated		
		Date			Date		Date		Date									

[e] If more than one smear, culture or Xpert MTB/RIF test is done in a month, enter the most recent positive result.

Smear results reported as follows:

0	= no AFB
(1–9)	= exact number if 1–9 AFB/100 HPF (scanty)
+	= 10–99 AFB/100 HPF
++	= 1–10 AFB/HPF
+++	= >10 AFB/HPF

Culture result reported as follows:	0	= no growth reported
	(1–9)	= <10 colonies (report number of colonies)
	+	= 10–100 colonies
	++	= >100 colonies
	+++	= innumerable or confluent growth
Xpert MTB/RIF results reported as follows:	T	= MTB detected, rifampicin resistance not detected
	RR	= MTB detected, rifampicin resistance detected
	TI	= MTB detected, rifampicin resistance indeterminate
	N	= MTB not detected;
	I	= invalid / no result / error

Dates associated with the recorded examination results are dates of sample **collection**.

[f] See definitions in section A.2.1. Insert the date when outcome was met in the respective column**.** If patient "transfers out" to another BMU, make a note in the Remarks column. If no definitive outcome is obtained, record as *Not evaluated* or *Lost to follow-up* as appropriate.

[g] Patients on initial treatment have follow-up sputum smear microscopy examination at 2 months. Patients on retreatment regimen have follow-up sputum smear microscopy examination at 3 months. If the intensive phase of initial treatment is extended to 3 months, the results of follow-up sputum examinations at 2 **and** 3 months are registered in the same box.

[h] Insert HIV status at time of TB diagnosis:

Y	= Yes, HIV infection
N	= No HIV infection
Unk	= HIV status unknown.

[i] RR = rifampicin resistance only confirmed
MDR = multidrug resistance confirmed
None = neither detected;
Unk = unknown.
If DST is pending at time of registration, complete when the results become available.

[j] Tick this column if the patient was started on second-line treatment for RR-TB or MDR-TB. Before noting this in the BMU register, the BMU should receive confirmation from the unit providing second-line treatment that the patient has indeed started second-line treatment. These patients are excluded from first-line treatment outcome cohort calculations.

B.3.3 Second-line TB treatment register

The second-line TB treatment register is intended primarily to keep a record of those data that are important for generating indicators and reports of patients on second-line regimens for RR-TB or MDR-TB. In contrast to the BMU register, it is restricted to patients who have actually started on a second-line TB treatment regimen. This register is also commonly used to follow, at a glance, the adequacy of testing and treatment decisions. In its paper format, the register is quite large, its width reflecting the long treatment times commonly needed for second-line treatment regimens. It should not be burdened with information that is beyond its scope.

The second-line TB treatment register should be updated regularly from the individual second-line TB treatment cards and from laboratory registers. Patients are recorded in the register consecutively by *date of registration*. A patient's date of registration is the day when health staff enter him or her in the register; in some countries, however, it may be the date when the review panel decided to register the patient for second-line treatment.

Bacteriological examination before the start of treatment ("month 0") now allows for the registration of results from an Xpert MTB/RIF test.

Notes for country customization

- The register illustrated in this section spans four pages for purposes of clarity. Countries may want to redesign and test their register layout over a smaller number of pages.
- *Health facility* could be removed if the register covers only one facility.
- *Patient address, date of birth* and *Regimen (in drug initials)* could be dropped if TB treatment cards are easily accessible – these data items are not needed to generate standard reports and indicators.
- Alternative codes or full text could be used to indicate type of examination.
- For country-specific purposes, deaths due to TB and deaths due to other causes could be separated in the treatment outcomes section; however, the two need to be added together for outcome reporting.
- Instead of two or three columns and a split row for a given period's bacteriological results, an alternative format could be used with the result prefixed by S, C or X, depending on the type of examination. For example:

Instead of:

Month 5	
S	C
Date	
++	+++
1/1/2013	14/1/2013

The following format could be used with results written as:

Month 5	
Result	Date
S:++	01/01/2013
C:+++	14/1/2013

- *Final outcome* could be recorded using separate columns instead of a single column to keep the format consistent with BMU TB registers.
- *Registration group* is also known as *History of previous treatment* in the BMU TB register.
- The footnotes shown are provided to explain the forms in this document and are not intended for inclusion in the country registers.

Second-line TB treatment register (page 1 of 4)

Unique second-line TB treatment register no.	Date entered in second-line TB treatment register	Name	Sex (M/F)	Age	Address	BMU TB register number / Date entered in BMU TB register	Site of disease (P/EP)	Registration group[a]	Second-line drugs received previously (Y/N/Unk)	Date sample taken for DST	Result of drug susceptibility testing[b]										
											H	R	E	S	Amk / Km	Cm	FQ ___	Other ___	Other ___	Other ___	Other ___

[a] 1 = New; 2 = Relapse; 3 = After loss to follow-up; 4 = After failure of first treatment with first-line drugs; 5 = After failure of retreatment with first-line drugs; 6 = Transfer in (from another second-line treatment centre); 7 = Other

[b] Enter DST results that led to the patient being registered for second-line treatment. If DST is pending, complete when the results become available:
R = resistant; S = susceptible; C = contaminated; — = testing not done

First-line drug abbreviations: H = isoniazid; R = rifampicin; E = ethambutol; S = streptomycin; Z = pyrazinamide
Second-line drug abbreviations: Amk = amikacin; Km = kanamycin; Cm = capreomycin; FQ = fluoroquinolone; Lfx = levofloxacin; Mfx = moxifloxacin; Ofx = ofloxacin; Gfx = gatifloxacin; Eto = ethionamide; Pto = prothionamide; Cs = cycloserine; PAS = *p*-aminosalicylic acid; Amx/Clv = amoxicillin/clavulanate; Clr = clarithromycin; Cfz = clofazimine; Ipm = imipenem; Lzd = linezolid; T = thioacetazone

Second-line TB treatment register (page 2 of 4)

Reasons for entering in second-line TB treatment register		Regimen (in drug initials)	Smear (S), culture (C) or Xpert MTB/RIF (X) results[c]										Smear (S) and culture (C) results during treatment[d] (*continued*)															
RR-TB / MDR-TB confirmed	Presump-tive RR-TB/ MDR-TB[4]		Start of treatment Month 0			Month 1		Month 2		Month 3		Month 4		Month 5		Month 6		Month 7		Month 8		Month 9		Month 10		Month 11		Month 12	
			S	C	X	S	C	S	C	S	C	S	C	S	C	S	C	S	C	S	C	S	C	S	C	S	C	S	C
		Start date	Date			Date		Date		Date		Date		Date		Date		Date		Date		Date		Date		Date		Date	

[c] (If more than one smear or culture or Xpert test done in a month, enter in the most recent positive result. Dates associated with the results are dates of sample **collection**)

Smear results reported as follows:

- 0 = no AFB
- (1–9) = exact number if 1–9 AFB/100 HPF (scanty)
- \+ = 10–99 AFB/100 HPF
- ++ = 1–10 AFB/HPF
- +++ = >10 AFB/HPF

Culture results reported as follows:

- 0 = no growth reported
- (1–9) = <10 colonies (report number of colonies)
- \+ = 10–100 colonies
- ++ = >100 colonies
- +++ = innumerable or confluent growth

Xpert MTB/RIF results reported as follows :

- T = MTB detected, rifampicin resistance not detected
- RR = MTB detected, rifampicin resistance detected
- TI = MTB detected, rifampicin resistance indeterminate
- N = MTB not detected
- I = invalid / no result / error

[d] As per national policy.

Second-line TB treatment register (page 3 of 4)

Smear (S) and culture (C) results during treatment[d] (*continued*)																							
Month 13		Month 14		Month 15		Month 16		Month 17		Month 18		Month 19		Month 20		Month 21		Month 22		Month 23		Month 24		Month 25		Month 26		Month 27		Month 28	
S	C	S	C	S	C	S	C	S	C	S	C	S	C	S	C	S	C	S	C	S	C	S	C	S	C	S	C	S	C
Date		Date		Date		Date		Date		Date		Date		Date		Date		Date		Date		Date		Date		Date		Date	

[d] As per national policy.

Second-line TB treatment register (page 4 of 4)

Smear (S) and culture (C) results during treatment[d] (*continued*)																Final outcome (Cured, Treatment completed, Treatment failed, Lost to follow-up, Died, Not evaluated)[f]	TB/HIV activities[e]			Remarks
Month 29		Month 30		Month 31		Month 32		Month 33		Month 34		Month 35		Month 36			HIV infection (Y/N/Unk) [g]	On ART (Y/N)	On CPT (Y/N)	
S	C	S	C	S	C	S	C	S	C	S	C	S	C	S	C					
Date		Date		Date		Date		Date		Date		Date		Date		Date outcome assigned				

[d] As per national policy.

[e] TB/HIV data should also be copied back to the patient's record in the BMU TB register because that is the source document for compiling the BMU quarterly report on TB case management.

[f] Insert the outcome and the date when outcome was met. See definitions in section A.2.2. If patient "transfers out" make note in Remarks; if no definitive outcome is obtained indicate as *Not evaluated* or *Lost to follow-up* as appropriate.

[g] Insert HIV status at time of TB diagnosis:
Y = Yes, HIV infection
N = No HIV infection
Unk = HIV status unknown.

B.3.4 Laboratory register for smear microscopy and Xpert MTB/RIF

This register can be used for both sputum-smear microscopy and Xpert MTB/RIF examinations.

If more than one specimen is being tested in the course of investigation of the same patient, as is commonly the case when serial sputa are tested using by microscopy, the results **are recorded on the same line**. This also applies if both direct sputum smear microscopy and Xpert MTB/RIF examinations are carried out for the same patient with presumptive TB. If a patient is tested again during another diagnostic episode (e.g. if a patient with presumptive TB has a negative initial test and presents again with symptoms after a few months), the test results are registered in a new row. Results of tests undertaken for monitoring of patients on treatment are likewise entered in separate rows.

HIV status and previous treatment status are included so that adherence to, and effectiveness of, testing algorithms can be assessed.[1]

Notes for country customization

- Countries could choose to have separate registers for smear and Xpert MTB/RIF examinations rather than a combined register if these tests are performed in different locations. In such cases common fields should appear in both registers, and fields specific to each test should appear only in the relevant register.
- HIV infection details can be omitted if necessary to comply with national confidentiality laws.
- *Treatment unit* can also be called a *Referring facility*.
- The footnotes shown are provided to explain the forms in this document and are not intended for inclusion in the country registers.

[1] See recommendations in *Rapid implementation of the Xpert MTB/RIF diagnostic test. Technical and operational 'how-to' – practical considerations*. Geneva, World Health Organization, 2011 (WHO/HTM/TB/2011.2; available at http://whqlibdoc.who.int/publications/2011/9789241501569_eng.pdf).

Laboratory register for smear microscopy and Xpert MTB/RIF

Lab. serial no.	Date specimen received[a]	Patient name	Sex M/F	Age: Date of birth	Patient address	Treatment unit	BMU and TB register no.	HIV infection (Y/N/ Unk)[b]	Patient previously treated for TB[c]	Examination type (*tick one option*): Diagnosis	Examination type (*tick one option*): Follow-up Month[d]	Examination results: Xpert[e] Date	Examination results: Smear microscopy[f] 1 Date	Smear microscopy[f] 2 Date	Smear microscopy[f] 3 Date	Remarks[g]

[a] For diagnostic testing employing serial sputa or other specimens this is the date of receipt of the first set of specimens.

[b] Y = Yes; N = No; Unk = unknown

[c] Y = previously treated; N = not previously treated; Unk = unknown

[d] Patient on TB treatment; indicate month of treatment at which follow-up examination is performed.

[e] Xpert MTB/RIF test result reported as follows :

T	= MTB detected, rifampicin resistance not detected
RR	= MTB detected, rifampicin resistance detected
TI	= MTB detected, rifampicin resistance indeterminate
N	= MTB not detected
I	= invalid / no result / error

[f] Smear results reported as follows:

0	= no AFB
(1–9)	= exact number if 1–9 AFB/100 HPF (scanty)
+	= 10–99 AFB/100 HPF
++	= 1–10 AFB/HPF
+++	= >10 AFB/HPF

[g] If Xpert MTB/RIF indeterminate result, indicate error code or “invalid”.

B.3.5 Laboratory register for culture, Xpert MTB/RIF and drug susceptibility testing

This register is used for laboratories capable of undertaking more advanced specimen testing (culture, Xpert MTB/RIF, DST), such as reference laboratories. The method of diagnostic testing (culture or Xpert MTB/RIF) is indicated in the first two columns under "Type of examination".

If more than one specimen is being tested in the course of the investigation of the same patient, as is commonly the case when serial sputa are tested using by microscopy, the results **are recorded on the same line**. This also applies if both direct sputum smear microscopy and Xpert MTB/RIF examinations are carried out for the same patient with presumptive TB. If a patient is tested again during another diagnostic episode (e.g. if a patient with presumptive TB has a negative initial test and presents again with symptoms after a few months), the test results are registered in a new row. Results of tests undertaken for monitoring of patients on treatment are likewise entered in separate rows.

HIV status and previous treatment status are included so that adherence to, and effectiveness of, testing algorithms can be assessed from the laboratory register.[1]

Notes for country customization

- Countries could choose to have separate registers for culture, Xpert MTB/RIF and DST rather than a combined register. In such cases, common fields should appear in all three registers and fields specific to each test should appear only in the relevant register.
- Laboratories using different methods for DST may include a separate column to indicate details of the test (solid media DST, liquid media DST; direct LPA; indirect LPA) if they wish to compile reports based on test type.
- HIV infection details can be omitted if necessary to comply with national confidentiality laws.
- *Treatment unit* can also be called a *Referring facility*.
- The footnotes shown are provided to explain the forms in this document and are not intended for inclusion in the country registers.

[1] See recommendations in *Rapid implementation of the Xpert MTB/RIF diagnostic test. Technical and operational 'how-to' – practical considerations*. Geneva, World Health Organization, 2011 (WHO/HTM/TB/2011.2; available at http://whqlibdoc.who.int/publications/2011/9789241501569_eng.pdf).

Laboratory register for culture, Xpert MTB/RIF and drug susceptibility testing (page 1 of 3)

Lab. serial no.	Date specimen received	Patient name	Sex M/F	Age Date of birth	Patient address	Treatment unit	BMU and TB register no.	HIV infection (Y/N/ Unk)	Patient previously treated for TB (Y/N/ Unk)	Date specimen collected	Date specimen inoculated

Laboratory register for culture, Xpert MTB/RIF and drug susceptibility testing (page 2 of 3)

Examination results			Result of confirmatory test for *M. tuberculosis* (positive/ negative)	Culture sent for DST (Yes/No)	Name of person reporting culture or Xpert MTB/RIF results	Date results reported	Comments
Diagnosis		Follow-up					
Culture[a]	Xpert MTB/RIF[b]						
Date	Date	Month[c]					

[a] Culture result reported as follows:

0	= no growth reported
(1–9)	= <10 colonies (report number of colonies)
+	= 10–100 colonies
++	= >100 colonies
+++	= innumerable or confluent growth

[b] Xpert MTB/RIF test result reported as follows :

T	= MTB detected, rifampicin resistance not detected
RR	= MTB detected, rifampicin resistance detected
TI	= MTB detected, rifampicin resistance indeterminate
N	= MTB not detected
I	= invalid / no result / error

[c] Patient on TB treatment: indicate months of treatment at which follow-up examination is performed.

Laboratory register for culture, Xpert MTB/RIF and drug susceptibility testing (page 3 of 3)

Results of drug susceptibility testing (DST)[e]												Name of person reporting DST results	Date results reported	Comments
H	R	E	S	Amk	Km	Cm	FQ	Other _____	Other _____	Other _____	Other _____			

[e] Report results as S = susceptible, R = resistant, C = contaminated, — = Testing not done

First-line drug abbreviations:
H = isoniazid; R = rifampicin; E = ethambutol; S = streptomycin; Z = pyrazinamide

Second-line drug abbreviations:
Amk = amikacin; Km = kanamycin; Cm = capreomycin; FQ = fluoroquinolone; Lfx = levofloxacin; Mfx = moxifloxacin; Ofx = Ofloxacin; Gfx = gatifloxacin; Eto = ethionamide; Pto = prothionamide; Cs = cycloserine; PAS = *p*-aminosalicylic acid; Amx/Clv = amoxicillin/clavulanate; Clr = clarithromycin; Cfz = clofazimine; Ipm = imipenem; Lzd = linezolid; T = thioacetazone

B.3.6 Quarterly report on TB case registration in the basic management unit

This is the standard aggregated report of cases as recorded in the BMU TB register and of laboratory activity as recorded in the laboratory register.

A basic management unit (BMU) is defined in terms of management, supervision and monitoring responsibility. A BMU for the TB programme may have several treatment facilities, one or more laboratories and one or more hospitals. The defining aspect is the presence of a manager or coordinator who oversees TB control activities for the unit and who maintains a master register of all TB patients being treated; this register is used to monitor the programme and report on indicators to higher administrative levels. Typically, the units correspond to the government's second subnational administrative division, which might be called, for example, a "district" or "county". It is internationally recommended that a BMU cover a population of between 50 000 and 150 000 or up to 300 000 for large cities.[1]

The categories of cases in the report are stratified by whether they are bacteriologically confirmed or clinically diagnosed, by site of disease and by previous history of treatment. For all incident cases (new and relapses), a breakdown by age group and sex is requested. The form also captures the yield of bacteriological tests among patients with presumptive TB tested, and the yield of HIV testing among TB cases tested.

Among HIV-infected cases, the numbers on ART and CPT during the quarter are recorded. This is a change from the 2006 version of the forms and reports where ART and CPT coverage was compiled only in the treatment outcome report, meaning that assessment of ART and CPT coverage became available nationally a minimum of 12 months after registration.

Notes for country customization

- Some countries may use different quarters from those shown in the footnotes (Q1: 1 January – 31 March; Q2: 1 April – 30 June; Q3: 1 July – 30 September; Q4: 1 October – 31 December).
- NTPs may wish to monitor other indicators in their quarterly paper reports, but these are outside the scope of this document. Examples of other indicators include:
  - programmatic management of drug-resistant TB;[2]
  - public–private mix;
  - community-based activities;[3]
  - number of cases on various treatment regimens
- Block 1: extrapulmonary cases may be stratified separately by bacteriologically confirmed and clinically diagnosed (e.g. to have a more complete denominator for assessment of DST coverage).
- Block 3: laboratory diagnostic activity could be disaggregated by test type (smear, culture, Xpert MTB/RIF) if NTPs need this information.
- The footnotes shown are provided to explain the forms in this document and are not intended for inclusion in the country registers or reports.

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[1] See page 10 of *Compendium of indicators for monitoring and evaluating national tuberculosis programs.* Geneva, World Health Organization, 2004 (WHO/HTM/TB/2004.344; available at http://whqlibdoc.who.int/hq/2004/WHO_HTM_TB_2004.344_chap1-2.pdf).

[2] See *Companion handbook to the WHO guidelines for the programmatic management of drug-resistant tuberculosis.* Geneva, World Health Organization. 2014. *(WHO/HTM/TB/2014.11).* Available at: http://apps.who.int/iris/bitstream/10665/130918/1/9789241548809_eng.pdf)..

[3] See Annex 1 of: Getahun H et al. *ENGAGE-TB. Integrating community-based tuberculosis activities into the work of nongovernmental and other civil society organizations: operational guidance.* Geneva, World Health Organization, 2012 (WHO/HTM/TB/2012/8: available at http://apps.who.int/iris/bitstream/10665/75997/1/9789241504508_eng.pdf).