Definitions and reporting framework for tuberculosis – 2013 revision

(updated December 2014)

World Health Organization

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Abbreviations and acronyms

ADR	adverse drug reaction
AFB	acid-fast bacilli
ART	antiretroviral therapy
BMU	basic management unit
CPT	co-trimoxazole preventive therapy
DR-TB	drug-resistant TB
DST	drug susceptibility testing
EPTB	extrapulmonary TB
HIV	human immunodeficiency syndrome
HPF	high-power field
MDR-TB	multidrug-resistant TB
NTP	national tuberculosis programme
PTB	pulmonary TB
RR-TB	rifampicin-resistant TB
TB	tuberculosis
STAG-TB	Strategic and Technical Advisory Group on TB
WHO	World Health Organization
WRD	WHO-approved rapid diagnostics
XDR-TB	extensively drug-resistant TB

Background

Collection of tuberculosis (TB) data forms part of the general health information system, which aims to:

- ensure *high-quality patient care*, a continuum of care, information-sharing with patients and transfer of information between health facilities;
- *aid staff* in providing adequate services to individual patients;
- allow managers at different levels in the national TB programme (NTP) to *monitor programme performance* in a standardized and internationally comparable way;
- provide the basis for programmatic and *policy development*.

For data to be comparable within and between NTPs, standard definitions of key concepts captured by NTP information systems need to be used.

This document revises previous WHO standard case definitions[1] for TB and drug-resistant TB, the categories used to assign outcomes, and the standard reporting framework for TB.

The main reasons for these revisions are the following:

- WHO-approved rapid diagnostics (WRD) such as Xpert MTB/RIF,[2] which employ molecular techniques for the diagnosis of TB, are being introduced globally and are expected to replace conventional bacteriology for diagnosis in many settings. However, WRD results do not always fit with the previous case definitions and treatment outcomes as envisaged by the 2006 WHO revision of paper-based reporting. Patients diagnosed with rifampicin-resistant TB using Xpert MTB/RIF need to be enumerated separately and the standard laboratory and TB treatment registers make no provision for this. Similarly, the standard laboratory test request form does not include these tests and makes no provision for reporting their results.
- The definition of a bacteriologically confirmed case needs to be more flexible to allow the incorporation of results from WRD.
- The definitions need to use less judgemental language, so the terms “defaulter” and “TB suspect” have been replaced by “lost to follow-up” and “presumptive TB”, respectively.
- The current treatment outcome definitions of “cured” and “treatment failed” in multidrug-resistant TB (MDR-TB) cohorts need simplification to allow their wider application to patients still on treatment.

The recording and reporting forms for paper-based systems needed revision to bring them into line with the revised case and treatment outcome definitions, as well as to address the following:

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[1] Previous definitions and recording and reporting formats were defined in:
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/).
Guidelines for treatment of tuberculosis, 4th ed. Geneva, World Health Organization, 2009 (WHO/HTM/TB/2009.420; available at http://whqlibdoc.who.int/publications/2010/9789241547833_eng.pdf).
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).
Those earlier definitions are now superseded by the definitions presented in this document.

[2] In this document, Xpert MTB/RIF refers to the currently available methodology that employs an automated real-time nucleic acid amplification technology for rapid and simultaneous detection of TB and rifampicin resistance. See*: Automated real-time nucleic acid amplification technology for rapid and simultaneous detection of tuberculosis and rifampicin resistance: Xpert MTB/RIF system. Policy statement.* Geneva, World Health Organization, 2011 (WHO/HTM/TB/2011.4; available at http://whqlibdoc.who.int/publications/2011/9789241501545_eng.pdf).

- Outcome reporting for drug-sensitive and drug-resistant TB (DR-TB) needs to be combined for countries where programmatic management of DR-TB is incorporated ("mainstreamed") in the NTP.
- Childhood TB reporting using paper-based systems was incomplete because age disaggregations were previously limited to sputum smear-positive TB, which is uncommon in children
- Using paper-based systems, there was a delay of two calendar years in the reporting of co-trimoxazole preventive therapy (CPT) and antiretroviral therapy (ART) because these were collected only in the treatment outcome reports and not in the case registration reports.

Revision process and acknowledgements

The revision of the definitions and reporting framework represents the collaborative work of staff at different levels of the World Health Organization (WHO) and its technical partners. The following milestones in the finalization of the process are highlighted:

- May 2011: expert consultation on updates to definitions of TB cases and treatment outcomes, Geneva, Switzerland.
- June 2011: WHO's Strategic and Technical Advisory Group on TB (STAG-TB), Geneva.
- July 2011: presentations and discussions with WHO regional and country staff, Geneva, and subsequent further consultation with WHO staff .
- October 2011: meeting of the DOTS Expansion Working Group, Lille, France.
- Extensive e-mail consultation with a wide range of countries and technical partners between November 2011 and March 2013.
- Twelve countries invited to test the definitions and forms in the second half of 2012, of which seven agreed (Belarus, Brazil, Cambodia, Djibouti, Estonia, Pakistan, Philippines); the definitions and forms were revised in the light of feedback received from these countries.
- December 2014: The reporting of TB/HIV (Block 4 of the "Quarterly report on TB case registration in the basic management unit" and Blocks 1 and 2 of the "Quarterly report on TB treatment outcomes in the basic management unit") was changed to focus on new and relapse TB cases only. This is to ensure consistency with the forthcoming 2015 revision of the guide to monitoring and evaluation for collaborative TB/HIV activities.

A. Revised definitions

This section describes the revised definitions of TB cases, their classification and the treatment outcome categories.

Presumptive TB refers to a patient who presents with symptoms or signs suggestive of TB (previously known as a *TB suspect*).

A.1 Case definitions

- A **bacteriologically confirmed TB case** is one from whom a biological specimen is positive by smear microscopy, culture or WRD (such as Xpert MTB/RIF). All such cases should be notified, regardless of whether TB treatment has started.
- A **clinically diagnosed TB case** is one who does not fulfil the criteria for bacteriological confirmation but has been diagnosed with active TB by a clinician or other medical practitioner who has decided to give the patient a full course of TB treatment. This definition includes cases diagnosed on the basis of X-ray abnormalities or suggestive histology and extrapulmonary cases without laboratory confirmation. Clinically diagnosed cases subsequently found to be bacteriologically positive (before or after starting treatment) should be reclassified as bacteriologically confirmed.

Bacteriologically confirmed or clinically diagnosed cases of TB are also classified according to:

- anatomical site of disease;
- history of previous treatment;
- drug resistance;
- HIV status.

A.1.1 Classification based on anatomical site of disease

Pulmonary tuberculosis (PTB) refers to any bacteriologically confirmed or clinically diagnosed case of TB involving the lung parenchyma or the tracheobronchial tree. Miliary TB is classified as PTB because there are lesions in the lungs. Tuberculous intra-thoracic lymphadenopathy (mediastinal and/or hilar) or tuberculous pleural effusion, without radiographic abnormalities in the lungs, constitutes a case of extrapulmonary TB. A patient with both pulmonary and extrapulmonary TB should be classified as a case of PTB.

Extrapulmonary tuberculosis (EPTB) refers to any bacteriologically confirmed or clinically diagnosed case of TB involving organs other than the lungs, e.g. pleura, lymph nodes, abdomen, genitourinary tract, skin, joints and bones, meninges.

A.1.2 Classification based on history of previous TB treatment (patient registration group)

Classifications based on history of previous TB treatment are slightly different from those previously published.[1] They focus only on history of previous treatment and are independent of bacteriological confirmation or site of disease. Note also that the registration groups for DR-TB are slightly different and are described in the *Companion handbook to the WHO guidelines for the programmatic management of drug-resistant tuberculosis.*[2]

New patients have never been treated for TB or have taken anti-TB drugs for less than 1 month.

Previously treated patients have received 1 month or more of anti-TB drugs in the past. They are further classified by the outcome of their most recent course of treatment (see table in section A.2.1) as follows:

> **Relapse patients** have previously been treated for TB, were declared *cured* or *treatment completed* at the end of their most recent course of treatment, and are now diagnosed with a recurrent episode of TB (either a true relapse or a new episode of TB caused by reinfection).
>
> **Treatment after failure patients** are those who have previously been treated for TB and whose *treatment failed* at the end of their most recent course of treatment.
>
> **Treatment after loss to follow-up patients** have previously been treated for TB and were declared *lost to follow-up* at the end of their most recent course of treatment. (These were previously known as *treatment after default* patients.)
>
> **Other previously treated patients** are those who have previously been treated for TB but whose outcome after their most recent course of treatment is unknown or undocumented.

Patients with unknown previous TB treatment history do not fit into any of the categories listed above.

New and relapse cases of TB are **incident** TB cases.

A.1.3 Classification based on HIV status

HIV-positive TB patient refers to any bacteriologically confirmed or clinically diagnosed case of TB who has a positive result from HIV testing conducted at the time of TB diagnosis or other documented evidence of enrolment in HIV care, such as enrolment in the pre-ART register or in the ART register once ART has been started.

HIV-negative TB patient refers to any bacteriologically confirmed or clinically diagnosed case of TB who has a negative result from HIV testing conducted at the time of TB diagnosis. Any HIV-negative TB patient subsequently found to be HIV-positive should be reclassified accordingly.

HIV status unknown TB patient refers to any bacteriologically confirmed or clinically diagnosed case of TB who has no result of HIV testing and no other documented evidence of enrolment in HIV care. If the patient's HIV status is subsequently determined, he or she should be reclassified accordingly.

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[1] See section 2.4 of *Guidelines for treatment of tuberculosis,* 4th ed. Geneva, World Health Organization, 2009 (WHO/HTM/TB/2009.420; available at http://whqlibdoc.who.int/publications/2010/9789241547833_eng.pdf).

[2] *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)

A.1.4 Classification based on drug resistance

Cases are classified in categories based on drug susceptibility testing (DST) of clinical isolates confirmed to be *M. tuberculosis*:

- **Monoresistance:** resistance to one first-line anti-TB drug only.
- **Polydrug resistance:** resistance to more than one first-line anti-TB drug (other than both isoniazid and rifampicin).
- **Multidrug resistance:** resistance to at least both isoniazid and rifampicin.
- **Extensive drug resistance:** resistance to any fluoroquinolone and to at least one of three second-line injectable drugs (capreomycin, kanamycin and amikacin), in addition to multidrug resistance.
- **Rifampicin resistance:**[1] resistance to rifampicin detected using phenotypic or genotypic methods, with or without resistance to other anti-TB drugs. It includes any resistance to rifampicin, whether monoresistance, multidrug resistance, polydrug resistance or extensive drug resistance.

These categories are not all mutually exclusive. When enumerating rifampicin-resistant TB (RR-TB), for instance, multidrug-resistant TB (MDR-TB) and extensively drug-resistant TB (XDR-TB) are also included. While it has been the practice until now to limit the definitions of monoresistance and polydrug resistance to first-line drugs only, future drug regimens may make it important to classify patients by their strain resistance patterns to fluoroquinolones, second-line injectable agents and any other anti-TB drug for which reliable DST becomes available.

A.2 Treatment outcome definitions

The new treatment outcome definitions make a clear distinction between two types of patients:

- patients treated for drug-susceptible TB;[2]
- patients treated for drug-resistant TB using second-line treatment (defined as combination chemotherapy for drug-resistant tuberculosis which includes drugs other than those in Group 1[3]).

The two groups are mutually exclusive. Any patient found to have drug-resistant TB and placed on second-line treatment is removed from the drug-susceptible TB outcome cohort. This means that management of the standard TB register and of the second-line TB treatment register needs to be coordinated to ensure proper accounting of the outcomes of treatment.

[1] New definition, introduced in this document.

[2] Drug-susceptible in this section refers to patients who do not have evidence of infection with strains resistant to rifampicin (i.e. not rifampicin-resistant or multidrug-resistant TB).

[3] See Table 7.1 in: *Guidelines for treatment of tuberculosis,* 4th ed. Geneva, World Health Organization, 2009 (WHO/HTM/TB/2009.420; available at http://whqlibdoc.who.int/publications/2010/9789241547833_eng.pdf).

A.2.1 Treatment outcomes for TB patients (excluding patients treated for RR-TB or MDR-TB)

All bacteriologically confirmed and clinically diagnosed TB cases should be assigned an outcome from this list **except** those with RR-TB or MDR-TB, who are placed on a second-line drug regimen (see section A.2.2).

Outcome	**Definition**
Cured	A pulmonary TB patient with bacteriologically confirmed TB at the beginning of treatment who was smear- or culture-negative in the last month of treatment and on at least one previous occasion.
Treatment completed	A TB patient who completed treatment without evidence of failure BUT with no record to show that sputum smear or culture results in the last month of treatment and on at least one previous occasion were negative, either because tests were not done or because results are unavailable.
Treatment failed	A TB patient whose sputum smear or culture is positive at month 5 or later during treatment.
Died	A TB patient who dies for any reason before starting or during the course of treatment.
Lost to follow-up	A TB patient who did not start treatment or whose treatment was interrupted for 2 consecutive months or more.
Not evaluated	A TB patient for whom no treatment outcome is assigned. This includes cases "transferred out" to another treatment unit as well as cases for whom the treatment outcome is unknown to the reporting unit.
Treatment success	The sum of *cured* and *treatment completed.*

Patients found to have an RR-TB or MDR-TB TB strain at any point in time should be started on an adequate second-line drug regimen. These cases are **excluded** from the main TB cohort when calculating treatment outcomes[1] and included only in the second-line TB treatment cohort analysis (section A.2.2). If treatment with a second-line drug regimen is not possible, the patient is kept in the main TB cohort and assigned an outcome from among those in table in section A.2.1 above.

[1] This is a change from previous practice; such cases used to be classified as *Treatment failed.*

A.2.2 Outcomes for RR-TB/MDR-TB/XDR-TB patients treated using second-line treatment

Outcome	Definition
Cured	Treatment completed as recommended by the national policy without evidence of failure AND three or more consecutive cultures taken at least 30 days apart are negative after the intensive phase.[a]
Treatment completed	Treatment completed as recommended by the national policy without evidence of failure BUT no record that three or more consecutive cultures taken at least 30 days apart are negative after the intensive phase.[a]
Treatment failed	Treatment terminated or need for permanent regimen change of at least two anti-TB drugs because of: – lack of conversion[b] by the end of the intensive phase[a], *or* – bacteriological reversion[b] in the continuation phase after conversion[b] to negative, *or* – evidence of additional acquired resistance to fluoroquinolones or second-line injectable drugs, *or* – adverse drug reactions (ADRs).
Died	A patient who dies for any reason during the course of treatment.
Lost to follow-up	A patient whose treatment was interrupted for 2 consecutive months or more.
Not evaluated	A patient for whom no treatment outcome is assigned. (This includes cases "transferred out" to another treatment unit and whose treatment outcome is unknown)
Treatment success	The sum of *cured* and *treatment completed*

[a] For *Treatment failed*, lack of conversion by the end of the intensive phase implies that the patient does not convert within the maximum duration of intensive phase applied by the programme. If no maximum duration is defined, an 8-month cut-off is proposed. For regimens without a clear distinction between intensive and continuation phases, a cut-off 8 months after the start of treatment is suggested to determine when the criteria for *Cured*, *Treatment completed* and *Treatment failed* start to apply.

[b] The terms "conversion" and "reversion" of culture as used here are defined as follows:

Conversion (to negative): culture is considered to have converted to negative when two consecutive cultures, taken at least 30 days apart, are found to be negative. In such a case, the specimen collection date of the first negative culture is used as the date of conversion.

Reversion (to positive): culture is considered to have reverted to positive when, after an initial conversion, two consecutive cultures, taken at least 30 days apart, are found to be positive. For the purpose of defining *Treatment failed*, reversion is considered only when it occurs in the continuation phase.

The revised definitions should be applied by the NTP at a set changeover date (e.g. 1 January): all cases on treatment on that date will be assigned outcomes according to the revised definitions. This means that patients started on treatment in the previous year may be assigned outcomes according to two different definitions of *cured* or *treatment failed*, depending on whether they completed treatment before or after the changeover date. This may be the most practical option for the transition period, given that retrospective reassignment of outcomes is not always feasible.

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[j]	
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	
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	

Smear (S) and culture (C) results during treatment[d] (*continued*)																			
Month 23		Month 24		Month 25		Month 26		Month 27		Month 28									
S	C	S	C	S	C	S	C	S	C	S	C								
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)*		Examination results				Remarks[g]
										Diagnosis	Follow-up Month[d]	Xpert[e] Date	Smear microscopy[f] 1 Date	2 Date	3 Date	

[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.

[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).

Quarterly report on TB case registration in the basic management unit

Name of BMU: _____ Facility:_____	Patients registered during[a] _____ quarter of year_____
Name of TB Coordinator:_____ Signature: _____	Date of completion of this form: _____

Block 1: All TB cases registered during the quarter[b]

	New	Relapse	Previously treated (excluding relapse)	Previous treatment history unknown	Total
Pulmonary, bacteriologically confirmed					
Pulmonary, clinically diagnosed					
Extrapulmonary, bacteriologically confirmed or clinically diagnosed					

Block 2. All new and relapse cases (bacteriologically confirmed or clinically diagnosed) registered during the quarter by age group and sex

	0–4	5–14	15–24	25–34	35–44	45–54	55–64	>65	Total
Male									
Female									

Block 3: Laboratory diagnostic activity[c]

Patients with presumptive TB undergoing bacteriological examination	Patients with presumptive TB with positive bacteriological examination result

Block 4: TB/HIV activities (all new and relapse TB cases registered during the quarter)

Patients tested for HIV at the time of TB diagnosis or with known HIV status[d] at the time of TB diagnosis	HIV-positive TB patients	HIV-positive TB patients on ART	HIV-positive TB patients on CPT

[a] Registration period is based on date of registration of cases in the TB register, following the start of treatment. Q1: 1 January – 31 March; Q2:1 April – 30 June; Q3: 1 July – 30 September; Q4:1 October – 31 December.

[b] "Transferred in" cases are excluded.

[c] Data aggregated from the TB laboratory register based on *Date specimen received,* and **excluding** patients examined for follow-up. .

[d] Include all TB patients previously known to be HIV-positive (e.g. documented evidence of enrolment in HIV care such as enrolment in the pre-ART register or in the ART register once started on ART) or with a documented negative HIV test conducted at the time of TB diagnosis.

B.3.7 Quarterly report on TB treatment outcomes in the basic management unit

This is the standard quarterly report used to monitor treatment outcomes for all TB cases that have not been started on second-line treatment. Treatment outcomes for RR-TB, MDR-TB and XDR-TB cases placed on second-line treatment are usually compiled annually rather than quarterly (see "Combined annual treatment outcomes report for basic TB and for RR-/MDR-TB").

The report enumerates the treatment outcomes of patients registered (i.e. recorded in the BMU TB register) in the quarter that ended 12 months previously. For example, if this report is completed at the close of the second quarter, data are compiled on patients registered in the second quarter of the previous calendar year.

This report **excludes**:

- patients who were transferred in from another BMU;
- patients who were found to have RR-TB or MDR-TB and who were started on a full MDR-TB treatment regimen (i.e. were moved to the second-line treatment register).

The report **includes** TB/HIV activities as this allows the NTP to update the data it has previously collected in the quarterly report on TB case registration in the basic management unit (section B.3.7).

Notes for country customization

- Some countries may use different quarters instead of the standard ones (Q1: 1 January – 31 March; Q2: 1 April – 30 June; Q3: 1 July – 30 September; Q4: 1 October – 31 December).
- 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 treatment outcome monitoring).
- The footnotes shown are provided to explain the forms in this document and are not intended for inclusion in the country registers or reports.
- NTPs may wish to monitor treatment outcomes for patients whose treatment is supported by community health workers or community volunteers.[1]

[1] 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).

Quarterly report on TB treatment outcomes in the basic management unit

Name of BMU: _____ Facility:_____ Name of TB Coordinator:_____ Signature: _____	Patients registered during[a] _____ quarter of year_____ Date of completion of this form: _____

Block 1: All TB cases registered during the quarter (except for TB cases moved to the second-line treatment register)

TB patient type	Number of cases registered	Treatment outcomes					
		Cured	Treatment completed	Treatment failed	Died	Lost to follow-up	Not evaluated
Bacteriologically confirmed, new and relapse							
Clinically diagnosed, new and relapse							
Retreatment (excluding relapse)							
HIV-positive, new and relapse							

Block 2: TB/HIV activities (all new and relapse TB cases registered during the quarter)

HIV-positive TB patients	HIV-positive TB patients on ART	HIV-positive TB patients on CPT

[a] Registration period is based on date of registration of cases in the TB register, following the start of treatment. Q1: 1 January – 31 March; Q2:1 April – 30 June; Q3: 1 July – 30 September; Q4:1 October – 31 December.

B.3.8 Combined annual treatment outcomes report for basic TB and for RR-TB/MDR-TB

This form captures on one sheet the outcomes for patients on first-line and second-line TB treatment. It is a new form that targets sites where both types of treatment are available (e.g. decentralized MDR-TB treatment sites).

Block 1 is the standard DOTS treatment cohort annual report for the year **minus 2** (e.g. the 2011 cohort is assessed in 2013), with four separate patient groups.

The following are excluded from Block 1:

- patients who were transferred in from another BMU;
- patients who were found to have RR-TB or MDR-TB and who were started on a full MDR-TB treatment regimen (i.e. were moved to the second-line treatment register).

Patients found to have RR-TB or MDR-TB but **not** moved to the second-line treatment register are included in Block 1 and are classified as per the outcomes defined in A.2.1.

Block 2 is intended for the second-line treatment outcome cohort of the year before that of Block 1 (i.e. year **minus 3**; e.g. the 2010 RR-TB/MDR-TB cohort is assessed in 2013).

The examples in section C illustrate the distinction between Block 1 and Block 2.

Block 2 is similar to that published in *Multidrug-resistant tuberculosis (MDR-TB) indicators: a minimum set of indicators for the programmatic management of MDR-TB in national tuberculosis control programmes*,[1] except that it also aggregates RR-TB cases with MDR-TB cases if such patients are treated with a full MDR-TB regimen.

If a case is assigned an outcome of *Treatment failure* and the patient is restarted on a revised regimen **within the same year** then, for the purposes of reporting treatment outcomes **in Block 2**, the case is not assigned another outcome. In other words, only the first outcome met is recorded for outcome monitoring. The same principle is followed for any patient whose treatment is interrupted for two months or more (*Lost to follow-up*) and who then starts treatment again **within the same year**. Outcomes assessed in this manner thus tend to be more conservative, given that a proportion of patients who restart a new regimen after a *Treatment failure or Loss to follow-up* would ultimately be cured. A more realistic assessment of long-term outcomes would be possible if a patient-based register, preferably in electronic format, were maintained to record events following the first outcome, including relapses.

In Block 2, NTPs able to differentiate XDR-TB from other MDR-TB cases, particularly those where XDR-TB cases represent >5% of MDR-TB, should report outcomes for non-XDR MDR-TB (including other RR-TB) and XDR-TB cases separately. (The conditions under which it is recommended that outcomes for HIV-infected cases and XDR-TB cases be shown separately are detailed elsewhere.[1]) MDR-TB patients found to have XDR-TB at any time in the course of their second-line TB treatment would be excluded from the non-XDR MDR-TB cohort and included in the XDR-TB treatment cohort. In addition, NTPs in high-HIV settings should enumerate outcomes for HIV-positive RR-TB/MDR-TB cases as a separate line.

[1] *Multidrug-resistant tuberculosis (MDR-TB) indicators: a minimum set of indicators for the programmatic management of MDR-TB in national tuberculosis control programmes*. Geneva, World Health Organization, 2010 (WHO/HTM/TB/2010.11; available at http://www.who.int/tb/challenges/mdr/programmatic_guidelines_for_mdrtb/).

Notes for country customization

- Countries with a low XDR-TB burden could drop the separate line in Block 2 for XDR-TB outcomes.
- Countries with a low HIV burden could drop the separate line in Block 2 for HIV-positive RR-TB/MDR-TB outcomes.
- For country-specific purposes, deaths due to TB and deaths due to other causes could be separated in the treatment outcomes section.
- Block 2 assumes cases with RR-TB are treated with a full MDR-TB regime. If this is not the case, outcomes for RR-TB cases could be reported separately from those for MDR-TB cases.
- Other indicators not included in Block 2 to monitor RR-/MDR-TB treatment are described in Chapter 2 of *Companion handbook to the WHO guidelines for the programmatic management of drug-resistant tuberculosis.*[1]
- The footnotes shown are provided to explain the forms in this document and are not intended for inclusion in the country registers or reports.

[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)

Combined annual treatment outcomes report for basic TB and for RR-TB/MDR-TB

Name of BMU: _____ Facility:_____ Date of completion of this form: _____

Block 1. All TB cases (except for TB cases moved to the second-line treatment register) registered in calendar year:[a] _____

TB patient type	No. of cases registered	Treatment outcomes					
		Cured	Treatment completed	Treatment failed	Died	Lost to follow-up	Not evaluated
Bacteriologically confirmed, new and relapse							
Clinically diagnosed, new and relapse							
Retreatment (excluding relapse)							
HIV-positive, new and relapse							

Block 2. TB cases started on a second-line TB drug regimen in calendar year:[b] _____

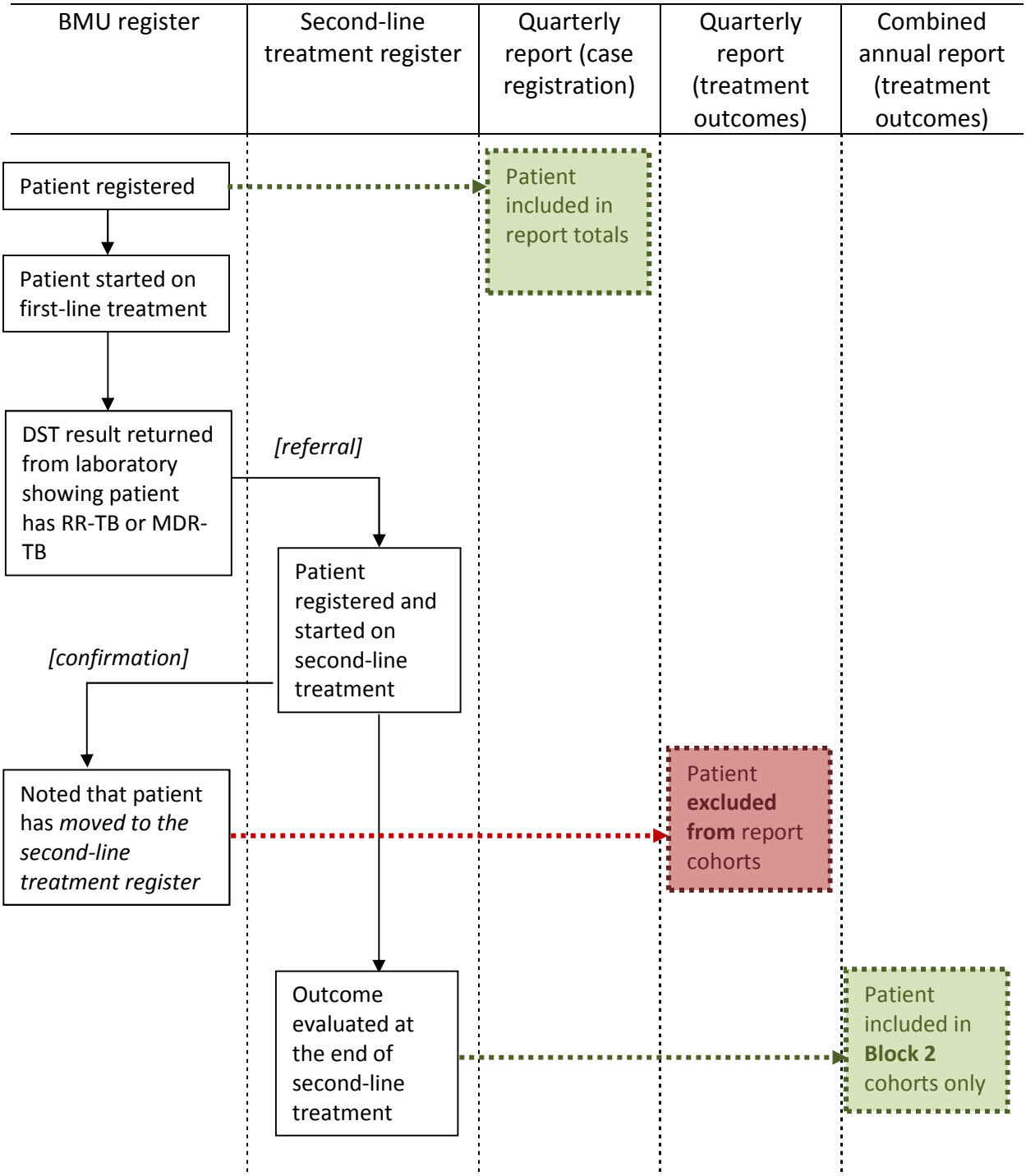
TB patient type	No. of cases started on second-line TB treatment	Treatment outcomes					
		Cured	Treatment completed	Treatment failed	Died	Lost to follow-up	Not evaluated
All confirmed RR-TB/MDR-TB cases							
HIV-positive RR-TB/MDR-TB cases[c]							
All confirmed XDR-TB cases[c]							

[a] Patients to be assessed are all those registered in the current calendar year **minus two** (excluding those moved to a second-line treatment). Thus, if the current calendar year is 2013, the outcomes collated will be for the cohort registered in calendar year 2011.
[b] Patients on a second-line drug regimen to be assessed are those started on second-line drugs in the current calendar year **minus three**. Thus, if the current calendar year is 2013, the outcomes collated will be for the cohort started on second-line drugs in calendar year 2010.
[c] See **Notes for country customization** for when outcome reporting by these sub-groups is required.

C. Examples

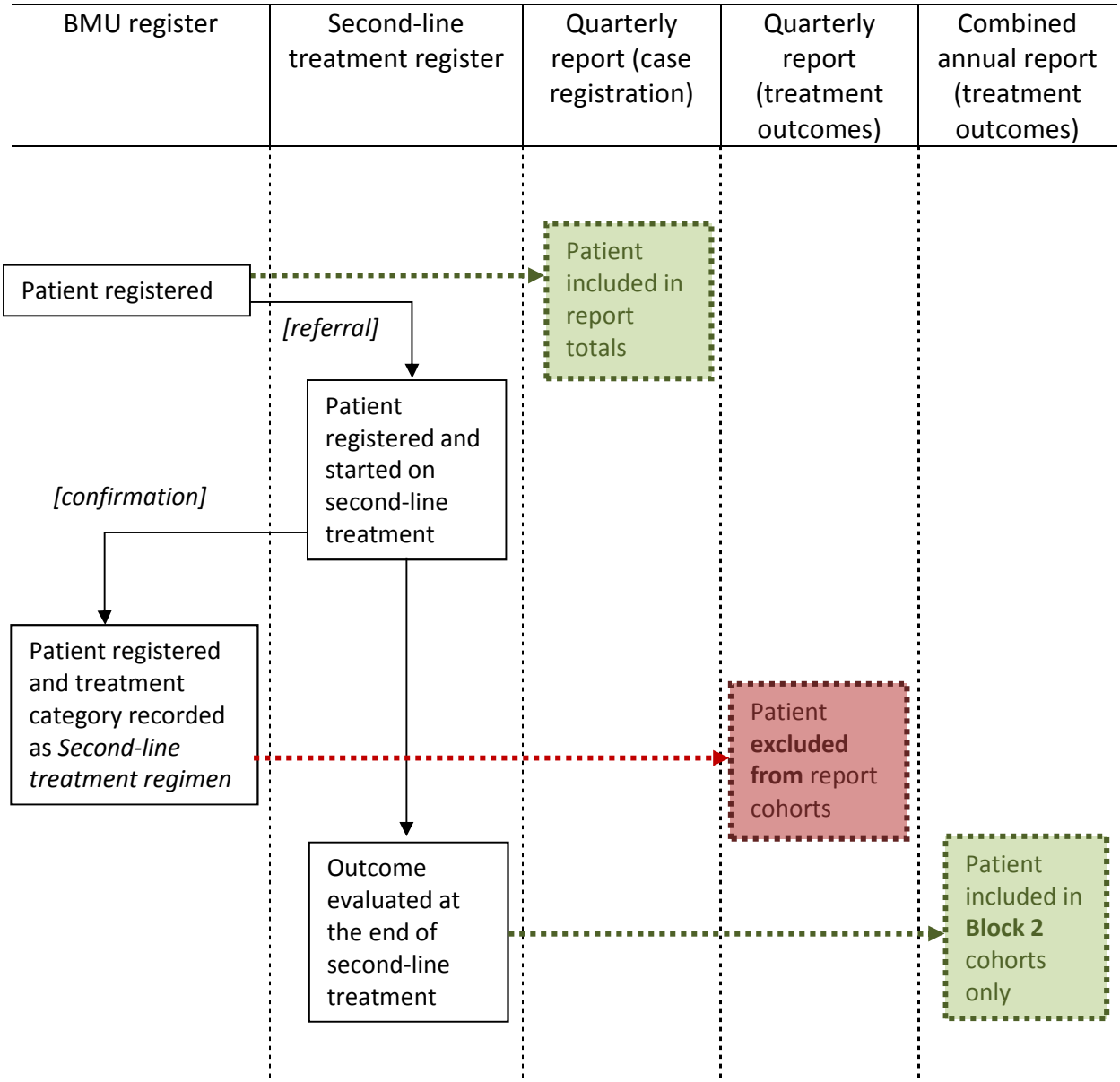
The following examples are not clinical algorithms but are intended as **illustrations** of how the paper-based registers described in section B can be used to identify separate treatment cohorts as defined in section A.2.

C.1 A patient was started on first-line treatment, drug resistance was then detected and the patient was transferred to second-line treatment

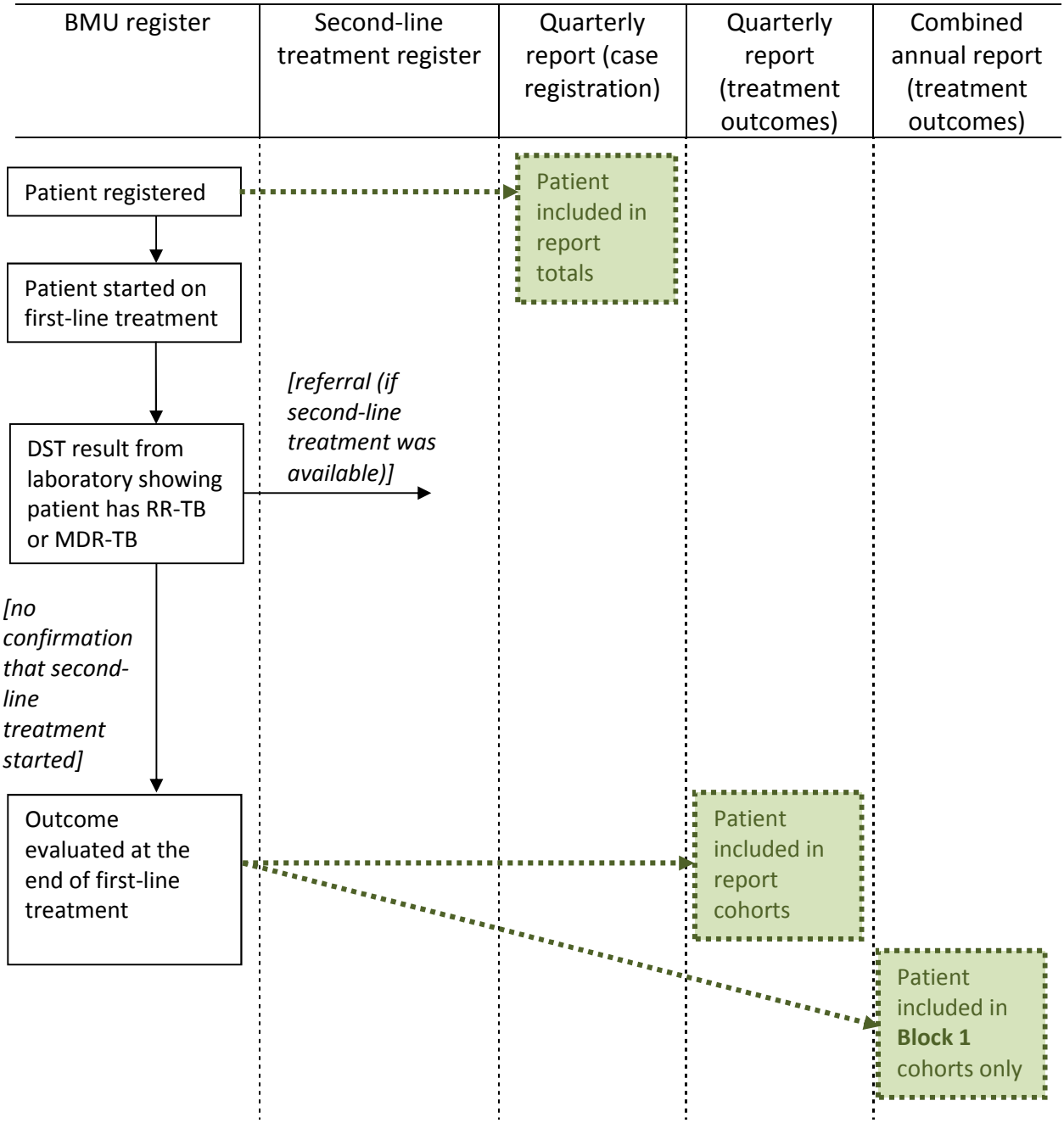


Note that the BMU should receive confirmation, from the unit providing second-line treatment, that the patient has indeed started second-line treatment before noting this in the BMU register (see example C.3 for a situation in which confirmation was not received).

C.2 A patient was started immediately on second-line treatment because RR-TB was detected using Xpert MTB/RIF at the time of diagnosis



C.3 A patient was started on first-line treatment, drug resistance was then detected but the patient never started second-line treatment (because it was unavailable, the patient died or the patient was lost to follow-up)



Note that if second-line treatment becomes available after the outcome of first-line treatment is recorded, the second-line treatment needs to be treated as a separate registration episode; the new episode would then be similar to example C.2 above.

Standardization of definitions and reporting structures has permitted uniformity in the reporting of indicators of performance of national TB control programmes for many years. This document revises previous WHO standard case definitions for TB and drug-resistant TB, the categories used to assign outcomes, and the standard reporting framework for TB. WHO-approved rapid molecular diagnostics have been widely introduced since the previous definitions and reporting framework were published, and the treatment of drug-resistant TB has been scaled up, necessitating adjustments in the way cases and outcomes are now defined and reported.

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