TESSy - The European Surveillance System

Tuberculosis Reporting Protocol 2019

Surveillance data for 2018

February 2019

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Introduction

This reporting protocol is for the 2019 data call for tuberculosis surveillance data from 2018.

ECDC's Reporting Protocols are data collection guidelines for reporting countries' data managers, and are intended to:

- Introduce a uniform structure to make it easier for data managers to find data collection information across different subjects.
- Remove information not relevant to data managers.

The Reporting Protocols are supplemented by the *Technical Annex*, which contains updated generic information for each data collection.

Likewise, the Surveillance Protocol will contain some of the generic information previously contained in the Reporting Protocols.

Because reporting countries' data managers sometimes play multiple roles, it is relevant to distribute subject-specific material together with a Reporting Protocol. To maintain the uniform structure, this sort of material is now included in *Annex 2*.

How to use this document

This Reporting Protocol provides information for reporting countries' data managers in three main sections:

- *Reporting to TESSy* – contains general guidelines on how to prepare data for submission to TESSy, deadlines for data submission, subject-specific information (e.g. changes to metadata), and links to further information.
- *Annex 1* – contains:
    - A history of metadata changes for the subject(s) covered by this Reporting Protocol.
    - The metadata set for the subject(s) covered by this Reporting Protocol.
- *Annex 2* – contains subject-specific material relevant for distribution with the Reporting Protocol, for example:
    - Guidelines for data collection in the field.
    - Abbreviations.

Finding further information

 Paragraphs denoted by the information icon tell where you can find further information.

Updated links to all the schedules, documentation and training materials mentioned in this Reporting Protocol are included in the *Technical Annex*, including:

- Metadata sets and history.
- Tutorials for data transformation using respectively Excel and Access.
- TESSy user documentation.
- CSV and XML transport protocols.

Copyright

Reporting to TESSy

This section provides both an overview of the TESSy reporting process and tips on where you can find useful information[1].

The overall process is:

1. *Familiarise yourself with the data collection deadlines*.
2. *Prepare (export and transform) your data*.
3. *Check that your data comply with the metadata*.
4. *Check that your data source profile is up-to-date*.
5. *Submit your file(s) to TESSy.*
6. *Finalise and approve your submission.*

Checking the data collection schedule

An updated link to the current data collection schedule is provided in the *Technical Annex*. TB surveillance data should be reported to ECDC annually, but more frequent data submissions are possible. To be included in the annual report for 2018, data should be submitted by **1 September 2019**.

For inclusion of data in the WHO Global TB report 2019, Member State (MS) experts are requested to submit the surveillance data to TESSy and programme management data to WHO's global TB data collection system (https://extranet.who.int/tme/) by **1 June 2019**.

Preparing data

After you have exported the data from your national database, you need to ensure that the data are in a format that TESSy can accept. This applies both to the type of file submitted to TESSy (only CSV and XML files can be submitted) and to the format of the data in certain fields.

Tutorials covering how you can transform your data to the correct TESSy format using Excel or Access are available on the TESSy documents website. Information on the file formats is available in the CSV Transport Protocol and XML Transport Protocol.

Checking metadata

The TESSy metadata define the fields and data formats that are valid as input to TESSy for a given subject.

As requirements to the data to be shared among TESSy users change, the data changes needed to support the new requirements are identified and agreed upon between the National Surveillance Contact Points, the Network Coordination Groups and ECDC's Disease Experts, and then implemented as changes to the TESSy metadata.

In order to ensure that your data can be saved correctly in TESSy, you therefore need to check that your data are correctly formatted according to the most recent metadata set specifications.

Changes to the metadata for the subject of this Reporting Protocol are described in:

- *Changes to current metadata* – changes since the last Reporting Protocol.
- *Annex 1 Metadata change history* – all preceding changes.

It is especially important to focus on:

[1] For detailed information on access to TESSy, please read the *"Policy on data submission, access, and use of data within TESSy, 2015"*.

- **Field formats**

  Many fields require that data are formatted in a specific way. For example, dates must be in the YYYY-MM-DD format; dates in the DD/MM/YYYY format will be rejected.

- **Coded values**

  Some fields only permit the use of specific values (coded values). For example, **M**, **F**, **UNK**, or **Other** are the coded values for *Gender* and any other value in a *Gender* field will be rejected.

A single metadata set file contains all the definitions and rules you need to comply with to format your data correctly for every subject (usually a disease). The file can be downloaded as an Excel file from the TESSy documents website.

By filtering the fields in the file by subject, you can see the fields required for your subject and the rules applying to these fields.

The *Technical Annex* provides an overview of how you work with the metadata file, and the TESSy user documentation provides in-depth details on metadata.

Checking your data source profile

Before submitting your file(s), please review the profile for your data source(s) in TESSy (go to **Data Sources**), and update the information, if necessary.

Complete and up-to-date data source information for each subject is important for improving interpretation of data - each surveillance system has different features that need to be taken into account when comparing data at an international level.

If your data source information is out-of-date and you do not have access rights to update it, please request your National Focal Point for Surveillance or National Coordinator to do so.

In-depth information on the data source variables is available in the TESSy user documentation.

Submitting your data

Data are submitted through the TESSy web interface (go to **Upload**).

The *Technical Annex* provides an overview of how you submit files to TESSy, and the TESSy user documentation provides in-depth descriptions of all the upload methods.

Finalising your submission

The compliance of your data with the validation rules in the metadata is checked automatically during the data upload process.

The result of your upload – i.e. rejected or validated – is displayed immediately after the conclusion of the check in the **Validation details** webpage. Please review the result carefully:

- If your file has been rejected, there will be a message explaining each instance of non-compliance with the metadata that you need to correct.
- If your file has been validated, there might be warnings and remarks relating to possible data quality issues or to potential overwriting of existing records that you should consider.

When your file has been validated and you are satisfied that all corrections have been made, please ensure prompt approval – unapproved uploads can block the approval of other uploads.

See also *TESSy data validation*.

The TESSy user documentation provides information on reviewing validation results and adjusting reporting periods to avoid overwriting existing records.

TESSy HelpDesk contact details

Email:	*TESSy@ecdc.europa.eu*
Telephone number:	**+46-(0)8-5860 1601**
Availability:	9:00 – 16:00 Stockholm time, Monday to Friday (except ECDC holidays)

Changes to current Tuberculosis metadata

1. Removed two validation rules, one for DateOfDiagnosis and one for DateOfNotification. The rules were based on DateOfOnset and since DateOfOnset is not included in the metadata the validation rules were non-functional.
2. Clarification in the reporting protocol: for reporting of resistance to anti-TB drugs, the resistance pattern used at the initiation of the treatment should be reported to TESSy irrespectively of the method used for drug susceptibility testing or resistance prediction.

The previous metadata changes are described in *Annex 1*.

Information on changes to the metadata for other subjects is available on the *TESSy documentation website*.

Annex 1 Tuberculosis metadata

This section describes:

- *The tuberculosis metadata set*
- *Changes to the tuberculosis metadata*

Tuberculosis metadata set

All TB cases - confirmed, probable or possible - notified at country level for the year of interest should be included in the dataset and uploaded to TESSy. Cases should only be included once in a 12-month period (with the exception of relapses). Cases eligible for treatment but who never actually started treatment should also be included, as well as cases diagnosed post-mortem.

To facilitate data management, national data files should be organized in line with the data file specification described below – a complete description of each variable is available in the metadata set file released for each data collection.

Table 1: Tuberculosis metadata set overview

Variable	Description	Coded value list	Required
RecordId	Unique identifier for each record within and across the national surveillance system – MS selected and generated.		True (Error)
RecordType	Structure and format of the data (case based reporting and aggregate reporting).	'TUBE'	True (Error)
RecordTypeVersion	There may be more than one version of a RecordType. This element indicates which version the sender uses when generating the message. Required when no metadata set is provided at upload. See also *Record type version*.		False
Subject	Disease to report	[Subjects for TUBE]: TUBE = Tuberculosis	True (Error)
Status	Status of reporting NEW/UPDATE or DELETE (inactivate). Default if left out: NEW/UPDATE. If set to DELETE, the record with the given RecordId will be deleted from the TESSy database (or better stated, invalidated). If set to NEW/UPDATE or left empty, the record is newly entered into the database.	[Statuses]: DELETE = Delete a previously reported record. NEW/UPDATE = Report a new or update a previously reported record (default).	False
DataSource	The data source (surveillance system) that the record originates from.	[Data sources] (see *the coded values list*)	True (Error)
ReportingCountry	The country reporting the record.	[Countries] (see *the coded values list*)	True (Error)
DateUsedForStatistics	The reference date used for standard reports that is compared to the reporting period. The date used for statistics can be any date that the reporting country finds applicable, e.g. date of notification, date of diagnosis or any other date.	Date Allowed formats: yyyy, yyyy-Qq, yyyy-mm, yyyy-Www, yyyy-mm-dd	True (Error)

Variable	Description	Coded value list	Required
Age	Age corresponds to the age of the patient at start of treatment, otherwise age at diagnosis, or age at date of notification or DateUsedForStatistics.		True (Warning)
BeijingGenotype[2]	Optional variable. No need to be reported if the ”IsolateID” or “ECDCIsolateID” is provided.	BeijingGenotypeTB: BEIJING = Beijing NOBEIJING = Not Beijing POSSBEIJING = Possible Beijing Unk = Unknown	False
BornReportingCountry	If the origin of the patient cannot be recognized by the place of birth, then it should be recognized by the nationality.	YesNoUnk: N = No Unk = Unknown Y = Yes	True (Warning)
CountryOfBirth	Identifies the country where the patient was born. Countries are defined by their current borders. For patients born in countries that do not exist anymore, please use the code of the closest current country.	Country_Incl_HistCountries (see *the coded values list*)	True (Warning)
CountryOfNationality	This variable identifies the country of nationality of the patient at the time of notification as it is stated in the passport.	Country (see *the coded values list*)	True (Warning)
DateOfDiagnosis	The most complete date of diagnosis should be provided. Exact date is preferred.	Date: Allowed formats: yyyy, yyyy-Qq, yyyy-mm, yyyy-Www, yyyy-mm-dd, Unk	False
DateOfEntryToCountry	Entry date of TB cases of foreign origin (bornreportingcountry = 'N') to reporting country	Date: Allowed formats: yyyy, yyyy-Qq, yyyy-mm, yyyy-Www, yyyy-mm-dd, Unk, NA	False
DateOfNotification	Date of notification. If not available it should be coded as Unk.	Date: Allowed formats: yyyy, yyyy-Qq, yyyy-mm, yyyy-Www, yyyy-mm-dd, Unk	False
DiagnosedAnteMortem	If diagnosed ante-mortem, the case should be coded as "Yes". If diagnosed post-mortem, the case should be coded as "No".	YesNoUnk: N = No Unk = Unknown Y = Yes	False
ECDCIsolateID[2]	Identifier for each isolate record that is guaranteed to (i) be unique across countries/labs/pathogens, and (ii) does not contain additional encoded information.	Unk = strain not available for genotyping Isolate identifier provided by ECDC	False

[2] Variables related to molecular epidemiology, are recommended to be filled in for MDR TB cases (resistant at least to isoniazid and rifampicin), but data can be reported for other TB cases as well. The ECDC isolate **ID must be the same** as the ID that the national laboratory with reference function for molecular typing has obtained from ECDC after the submission of the isolate molecular typing data. The ECDC isolate ID cannot be changed within the country. Using this variable, the epidemiological and molecular data will be linked.

Variable	Description	Coded value list	Required
EnrolledToTreatment	Patient started appropriate TB treatment according to international recommendations. Note: For multidrug resistant TB (MDR TB) cases the start of anti-TB treatment with second-line drugs should be reported.	EnrolledToTreatmentTB: N = No, patient didn't start the treatment NA = Not applicable UNK = Unknown Y = Yes, treatment has been started	True (Warning)
Gender	Common variable. The gender of the TB patient. Transsexual should be coded as O – Other.	Sex: F = Female M = Male O = Other (e.g., transsexual) Unk = Unknown	True (Warning)
HIVStatus[3]	HIV status; previous positive test.	HIVStatusTB: NEG = Negative POS = Positive UNK = Unknown	False
IsolateID[2]	Unique identifier for each isolate within the data source / lab system related to the case.	Unk = strain not available for genotyping Position 1-2 = ISO two char's country code Position 3 = country lab. code (A-Z) Position 4-7 = 4-digit calendar year of specimen collection Position 8-12 = strain number attributed at country level	False
MajorSiteOfTB	Disseminated TB includes: TB of more than two organ systems, miliary TB, TB in which *M. tuberculosis* complex has been isolated from the blood. TB in children involving both the lung parenchyma and a lymphatic component should be coded as MajorSiteOfTB = PULMONARY (pulmonary) and MinorSiteOfTB = LYMPHEXTHOR (lymphatic intrathoracic). If one of the affected sites is the lung, such as in miliary TB, the case should be coded as MajorSiteOfTB = PULMONARY (pulmonary) and MinorSiteOfTB = DISSEM (disseminated). In all other cases, it should be coded as MajorSiteOfTB = DISSEM (disseminated) and MinorSiteOfTB = Unk (no minor site).	MajorSiteOfTB: BONEOTHER = Bone/joint other than spine CNSOTHER = Central nervous system other than meningitis DISSEM = Disseminated EXTRAPULMNOTSPEC = Extrapulmonary, exact site is unkown GASTROINTEST = Peritoneal/digestive LYMPHEXTHOR = Lymphatic extrathoracic LYMPHINTHOR = Lymphatic intrathoracic MENING = Meningitis O = Other PLEURAL = Pleural PULMONARY = Pulmonary (lung parenchyma, tracheobronchial tree, larynx) SPINE = Spine Unk = Unknown UROGEN = Genito-urinary	True (Error)

[3] Data are published in the surveillance reports if both the number of cases tested for HIV and the test results are reported.

Variable	Description	Coded value list	Required
MinorSiteOfTB	There is no code "PULMONARY" in MinorSiteOfTB since pulmonary TB is always a major site. Disseminated TB includes: TB of more than two organ systems, miliary TB, TB in which *M. tuberculosis* complex has been isolated from the blood.	MinorSiteOfTB: BONEOTHER = Bone/joint other than spine CNSOTHER = Central nervous system other than meningitis DISSEM = Disseminated EXTRAPULMNOTSPEC = Extrapulmonary, exact site is unknown GASTROINTEST = Peritoneal/digestive LYMPHEXTHOR = Lymphatic extrathoracic LYMPHINTHOR = Lymphatic intrathoracic MENING = Meningitis O = Other PLEURAL = Pleural SPINE = Spine Unk = Unknown UROGEN = Genito-urinary	True (Warning)
MiruCode[2, 4]	Optional variable. No need to be reported if the "IsolateID" or "ECDCIsolateID" is provided. If submitting 15 loci MIRU-VNTR results the missing loci should be coded as "x".		False
NationalityReportingCountry	Origin of the patient (based on citizenship). Be aware that nationality equals to citizenship.	YesNoUnk: N = No Unk = Unknown Y = Yes	True (Warning)
Outcome12Months	Patient first outcome at 12 months from the start of the treatment. Note: The outcome categories "CURED" and "COMPLETED" are very exceptional for M(X)DR TB cases at 12 months. Patients diagnosed post-mortem should be reported as DIEDTB, DIEDOTHER or DIEDUNK. The outcome should be reported as NA for the cases: - at the year of notification if outcome is still not determined	Outcome12MonthsTB: COMPLETED = Completed CURED = Cured DEFAULTED = Defaulted[5] DIEDOTHER = Died because of other cause DIEDTB = Died because of TB DIEDUNK = Cause of death unknown FAILED = Failed NA = Not Applicable STILLTREATMENT = Still on treatment TRANSFERRED = Transferred Unk = Unknown outcome	False

[4] Note: Please keep the order of MIRU loci in the submitted pattern. The correct order is:
MIRU 02 VNTR 42 VNTR 43 MIRU 04 MIRU 40 MIRU 10 MIRU 16 VNTR 1955
MIRU 20 VNTR QUB11b VNTR ETR-A VNTR 46 VNTR 47 VNTR 48 MIRU 23
MIRU 24 MIRU 26 MIRU 27 VNTR 49 MIRU 31 VNTR 52 VNTR QUB-26
VNTR 53 MIRU 39

[5] Currently classified as Lost to follow-up in the joint surveillance report

Variable	Description	Coded value list	Required
Outcome24Months	This variable should be coded for MDR TB or XDR TB cases. Note: This variable should be coded only for cases where Outcome12Months is coded as "STILLTREATMENT" and EnrolledToTreatment as "Y" (for MDR TB cases), otherwise it would be coded as NA. The outcome should be reported as NA for the cases: - if previously reported outcome (outcome12months) was other than STILLTREATMENT, or - if outcome after 24 months is not applicable (because 24 months have not elapsed).	Outcome24MonthsTB: COMPLETED = Completed CURED = Cured DEFAULTED = Defaulted[5] DIEDOTHER = Died because of other cause DIEDTB = Died because of TB DIEDUNK = Cause of death unknown FAILED = Failed NA = Not Applicable STILLTREATMENT = Still on treatment TRANSFERRED = Transferred Unk = Unknown outcome	False
Outcome36Months	This variable should be coded for MDR TB or XDR TB cases. Note: This variable should only be coded for cases where Outcome12Months and Outcome24Months is coded as "STILLTREATMENT" and EnrolledToTreatment as "Y". Outcome is mainly applicable for X(M)DR TB cases. The outcome should be reported as NA for the cases: - if previously reported outcome (outcome24months) was other than STILLTREATMENT, or - if outcome after 36 months is not applicable (because 36 months have not elapsed).	Outcome36MonthsTB: COMPLETED = Completed CURED = Cured DEFAULTED = Defaulted[5] DIEDOTHER = Died because of other cause DIEDTB = Died because of TB DIEDUNK = Cause of death unknown FAILED = Failed NA = Not Applicable TRANSFERRED = Transferred Unk = Unknown outcome	False
Pathogen	Species determination within *M. tuberculosis* complex. Cases of TB due to *M. bovis* BCG should not be notified.	PathogenTB: MAFRICA = *Mycobacterium africanum* MBOVIS = *Mycobacterium bovis* (except *M. bovis* BCG) MCAPRAE = *Mycobacterium caprae* MTUBE = *Mycobacterium tuberculosis* MTUBECOMPOTHER = Other member of *Mycobacterium* tuberculosis complex Unk = Unknown / Not Applicable	True (Warning)
PlaceOfNotification	Place of the first notification of the case to a regional authority. Select the most detailed NUTS level possible.	NUTS (see the coded values list in *the most recent TESSY metadata set*)	False

Variable	Description	Coded value list	Required
PlaceOfResidence	Place of residence of the case at the time of disease onset. Select the most detailed NUTS level possible.	NUTS (see the coded values list in *the most recent TESSY metadata set*)	False
PrevDiagnosis	Previous diagnosis of TB. The patient had TB in any previous calendar year.	YesNoUnk: N = No Unk = Unknown Y = Yes	True (Warning)
PrevDiagnosisYear	Year of previous diagnosis. If PrevDiagnosisYear is coded, then PrevDiagnosis = Y. PrevDiagnosisYear cannot be later than the DateUsedForStatistics. If PrevDiagnosisYear < 1951 then PrevTreatment = N & PrevTreatmentCompletion = NA.		False
PrevTreatment	Previous anti-TB drug treatment (at least one month of drug combination) If PrevDiagnosisYear < 1951 then PrevTreatment = N and PrevTreatmentCompletion = NA. If PrevDiagnosis = N then PrevTreatment = NA.	YesNoNAUnk: N = No NA = Not applicable Unk = Unknown Y = Yes	True (Warning)
PrevTreatmentCompletion	Previous treatment is defined here as treatment for active TB for 1 month or more with a combination of anti-TB drugs and excludes preventive chemotherapy. A patient is defined as having completed treatment if the course of treatment prescribed was completed and if the patient was officially discharged by the attending physician. It includes patients with both bacteriological proof of cure and patients with no culture or smear result available at the end of treatment. Default means interruption of treatment for 2 consecutive months. Failure means that bacteriology remained positive or became positive again at 5 months or later during the course of treatment for non-MDR TB cases with treatment for non-MDR TB cases. Failure for MDR TB cases: Treatment will be considered to have failed if two or more of the five cultures recorded in the final 12 months of therapy are positive, or if any one of the final three cultures is positive.	PrevTreatmentCompletionTB: NA = Not Applicable PREVTTCOMPL = Treatment of the previous TB episode completed PREVTTDEF = Lost to follow up from previous anti-TB treatment episode PREVTTFAIL = Failure of previous anti-TB treatment episode PREVTTNOCOMPL = Anti-TB treatment not completed in the previous episode (unspecified) Unk = Unknown	True (Warning)

Variable	Description	Coded value list	Required
ResultCulture	Indicates whether or not a culture test was carried out for diagnosis of the disease, and the result of the test. Culture done from any specimen should be reported.	ResultCultureTB: N = Negative for *Mycobacterium tuberculosis* complex P = Positive for *M. tuberculosis* complex Unk = Unknown	True (Error)
ResultMicroscopy	Microscopy result from any material investigated should be taken in account.	ResultMicroscopyTB: N = Negative for acid-fast bacilli (AFB) P = Positive for acid-fast bacilli (AFB) Unk = Unknown	True (Error)
ResultOtherTest	It should only be provided if the test was carried out. Else it should be coded as Unk.	ResultOtherTestTB: HISTOL = Detection of granulomata at histo-pathology NONUCLA = No detection of nucleic acid NUCLA = Detection of *M. tuberculosis* complex nucleic acid in any sample NUCLAHISTOL = Detection of both nucleic acid and granulomata Unk = Unknown	False
SIR_AMK[6]	Susceptibility to amikacin. Susceptibility testing of the second-line anti-TB drugs should usually be done for MDR-TB cases. Note: Any result from a CE-certified or accredited molecular diagnostic test/procedure/kit is accepted. The resistance pattern used at the initiation of the treatment should be reported irrespectively of the method used for drug susceptibility testing (DST) or resistance prediction.	SRUnk: NA = Not Applicable R = Resistant S = Susceptible Unk = Unknown	False
SIR_BDQ[6]	Susceptibility to bedaquiline. Susceptibility testing of the second-line anti-TB drugs should usually be done for MDR-TB cases. Note: Any result from a CE-certified or accredited molecular diagnostic test/procedure/kit is accepted. The resistance pattern used at the initiation of the treatment should be reported irrespectively of the method used for DST or resistance prediction.	SRUnk: NA = Not Applicable R = Resistant S = Susceptible Unk = Unknown	False

[6] Susceptibility testing of second-line anti-TB drugs should usually be done for MDR TB cases.

Variable	Description	Coded value list	Required
SIR_CAP[6]	Susceptibility to capreomycin. Susceptibility testing of the second-line anti-TB drugs should usually be done for MDR-TB cases. Note: Any result from a CE-certified or accredited molecular diagnostic test/procedure/kit is accepted. The resistance pattern used at the initiation of the treatment should be reported irrespectively of the method used for DST or resistance prediction.	SRUnk: NA = Not Applicable R = Resistant S = Susceptible Unk = Unknown	False
SIR_DLM[6]	Susceptibility to delamanid. Susceptibility testing of the second-line anti-TB drugs should usually be done for MDR-TB cases. Note: Any result from a CE-certified or accredited molecular diagnostic test/procedure/kit is accepted. The resistance pattern used at the initiation of the treatment should be reported irrespectively of the method used for DST or resistance prediction.	SRUnk: NA = Not Applicable R = Resistant S = Susceptible Unk = Unknown	False
SIR_ETH	Susceptibility to ethambutol. Note: Any result from a CE-certified or accredited molecular diagnostic test/procedure/kit is accepted. The resistance pattern used at the initiation of the treatment should be reported irrespectively of the method used for DST or resistance prediction.	SRUnk: NA = Not Applicable R = Resistant S = Susceptible Unk = Unknown	False
SIR_GAT[6]	Susceptibility to gatifloxacin. Susceptibility testing of the second-line anti-TB drugs should usually be done for MDR-TB cases. Note: Any result from a CE-certified or accredited molecular diagnostic test/procedure/kit is accepted. The resistance pattern used at the initiation of the treatment should be reported irrespectively of the method used for DST or resistance prediction.	SRUnk: NA = Not Applicable R = Resistant S = Susceptible Unk = Unknown	False
SIR_INH	Susceptibility to isoniazid. Note: Any result from a CE-certified or accredited molecular diagnostic test/procedure/kit is accepted. The resistance pattern used at the initiation of the treatment should be reported irrespectively of the method used for DST or resistance prediction.	SRUnk: NA = Not Applicable R = Resistant S = Susceptible Unk = Unknown	True (Warning)

Variable	Description	Coded value list	Required
SIR_KAN[6]	Susceptibility to kanamycin. Susceptibility testing of the second-line anti-TB drugs should usually be done for MDR-TB cases. Note: Any result from a CE-certified or accredited molecular diagnostic test/procedure/kit is accepted. The resistance pattern used at the initiation of the treatment should be reported irrespectively of the method used for DST or resistance prediction.	SRUnk: NA = Not Applicable R = Resistant S = Susceptible Unk = Unknown	False
SIR_LVX[6]	Susceptibility to levofloxacin. Susceptibility testing of the second-line anti-TB drugs should usually be done for MDR-TB cases. Note: Any result from a CE-certified or accredited molecular diagnostic test/procedure/kit is accepted. The resistance pattern used at the initiation of the treatment should be reported irrespectively of the method used for DST or resistance prediction.	SRUnk: NA = Not Applicable R = Resistant S = Susceptible Unk = Unknown	False
SIR_MFX[6]	Susceptibility to moxifloxacin. Susceptibility testing of the second-line anti-TB drugs should usually be done for MDR-TB cases. Note: Any result from a CE-certified or accredited molecular diagnostic test/procedure/kit is accepted. The resistance pattern used at the initiation of the treatment should be reported irrespectively of the method used for DST or resistance prediction.	SRUnk: NA = Not Applicable R = Resistant S = Susceptible Unk = Unknown	False
SIR_OFX[6]	Susceptibility to ofloxacin. Susceptibility testing of the second-line anti-TB drugs should usually be done for MDR-TB cases. Note: Any result from a CE-certified or accredited molecular diagnostic test/procedure/kit is accepted. The resistance pattern used at the initiation of the treatment should be reported irrespectively of the method used for DST or resistance prediction.	SRUnk: NA = Not Applicable R = Resistant S = Susceptible Unk = Unknown	False
SIR_PZA	Susceptibility to pyrazinamide. Susceptibility testing of the second-line anti-TB drugs should usually be done for MDR-TB cases. Note: Any result from a CE-certified or accredited molecular diagnostic test/procedure/kit is accepted. The resistance pattern used at the initiation of the treatment should be reported irrespectively of the method used for DST or resistance prediction.	SRUnk: NA = Not Applicable R = Resistant S = Susceptible Unk = Unknown	False

Variable	Description	Coded value list	Required
SIR_RIF	Susceptibility to rifampicin. Note: Any result from a CE-certified or accredited molecular diagnostic test/procedure/kit is accepted. The resistance pattern used at the initiation of the treatment should be reported irrespectively of the method used for DST or resistance prediction.	SRUnk: NA = Not Applicable R = Resistant S = Susceptible Unk = Unknown	True (Warning)
SIR_STR	Susceptibility to streptomycin. Note: Any result from a CE-certified or accredited molecular diagnostic test/procedure/kit is accepted. The resistance pattern used at the initiation of the treatment should be reported irrespectively of the method used for DST or resistance prediction.	SRUnk: NA = Not Applicable R = Resistant S = Susceptible Unk = Unknown	False
SpoligoCode	Optional variable. No need to be reported if the ”IsolateID” or “ECDCIsolateID” is provided.	15 digits binary code or UNK (Unknown / Not available).	False

Tuberculosis metadata change history

Table 2: Tuberculosis metadata changes 2010-2017, Changes to current Tuberculosis metadata *provides information on the most recent changes*

Year	Description
2017	Removed variables Classification, Laboratory result, SIR_CIP and RflpCode. Added new variables SIR_PZA and DateOfEntryToCountry. Added new code MCAPRAE to variable Pathogen. Updated or changed several TESSy data validation rules.
2016	Added new variable SIR_BDQ and SIR_DLM to collect drug susceptibility data for bedaquiline and delamanid. Changed description of variables BejingGenotype, EnrolledToTreatment, MiruCode, Outcome24Months, Outcome36Months, Pathogen, PrevDiagnosisYear. Updated coded value list for drug susceptibility reporting: NA – allowed when positive bacteriological result is missing. Deleted common variables: DateOfOnset, Epilinked and Outcome from TUBE variables list which are not applicable for TB data collection.
2015	In order to allow extrapulmonary TB cases to be classified according to the EU case definition, the validation rule severity was changed from error to warning in 2014. In 2015 the description of the ResultMicroscopy variable changed in the metadataset accordingly: the microscopy result from any material investigated should be taken into account.
2014	Decreased severity of a validation rule from error to warning including MajorSiteOfTB and ResultMicroscopy: Warning message for microscopy positive result if MajorSiteOfTB <> to Pulmonary: “The microscopic examination (ResultMicroscopy = P) should be usually reported for pulmonary case (MajorSiteOfTB = PULMONARY)”.
2014	Update NUTS codes according to the NUTS Codes 2010 classification from EUROSTAT
2013	Added variable EnrolledToTreatment for specifying the treatment cohorts. Added variables and SIR_LVX, SIR_GAT, SIR_MFX - collection of susceptibility data started for three fluoroquinolones (for defining XDR TB).
2012	Variable StrainNumber split into IsolateID and ECDCIsolateID in order to improve linkage of molecular typing data with epidemiological information of TB cases.
2011	Added variable HIVStatus, removed variable ClinicalCriteria and DOTS, variable SiteClassification incorporated to MajorSiteOfTB and MinorsiteOfTB and removed. Molecular typing data MiruCode changed to 24 digits MIRU-VNTR code.
2010	Revised and cleaned-up tuberculosis validation rules. Minor changes, and relaxation of severity of rules. Change of definition of code for TB pathogen "other TB complex".

Annex 2 Tuberculosis-specific material

Contact information

TB surveillance at ECDC:

Email: *tuberculosis@ecdc.europa.eu*

TB surveillance contact point at the WHO Regional Office for Europe

Email: *eurotb@who.int*

TME

Email: *tbdata@who.int*

Data to be submitted to TESSy

a. A dataset of TB cases (case-based) reported during 2018;
b. A dataset with updated information on treatment outcome:
   - Treatment outcome at 12 months for cases reported during 2017 (variable Outcome12Months);
   - Treatment outcome at 24 months for cases reported during 2016, if applicable (variable Outcome24Months – for M/XDR TB cases);
   - Treatment outcome at 36 months for cases reported during 2015, if applicable (variable Outcome36Months – for XDR TB cases);
c. Drug susceptibility testing (DST) results;
d. Molecular typing results should be reported using MYCOISO Recordtype and linked to the case-based data using the variables IsolateID or ECDCIsolateId (in the most recent record type version);
e. HIV testing results;
f. Information about TB control programme management, including budgets and expenditures.

Information on **a**, **b**, **c**, **d** and **e** should be reported through TESSy, and information on **f** through the *WHO global TB data collection system* (https://extranet.who.int/tme/).

Countries not yet able to provide case-based information on **c** and **e** through TESSy are kindly requested to fill in the joint TB data collection form in the WHO global TB data collection system, section 2.

All information for the joint TB data collection form that has already been reported in case-based format (**a** - **e**) will be extracted from TESSy and submitted to WHO. Therefore, there is no need to actively report to WHO for the respective sections.

Record type version

For the reporting of the 2018 case-based TB data, please use the most recent record type version that contains the changes approved by the National Focal Points for Surveillance.

For updating of the data reported before year 2012, record type versions TUBE.5 and 4 can be used. The definitions of the variables/codes for record type TUBE can be found in the metadata set file released for each data collection.

Preferred basis of data analysis

a) Origin

Patient origin should be reported based on place of birth (variable BornReportingCountry).

If the origin of the patient cannot be assessed from the place of birth, it must be coded as "Unk" and it should be assessed from the nationality (variable NationalityReportingCountry).

Please inform us which of these should be used for data analysis. Otherwise, we will choose the same variable as was used last year.

b) Previous TB history

The TB history of the case can be reported based on previous treatment history (variable PrevTreatment and PrevTreatmentCompletion) or, if not available, by previous diagnosis (variable PrevDiagnosis). **Please inform us which of these should be used for analysis. Otherwise, we will choose the same variable as was used last year.**

c) IsolateID or ECDCIsolateId

Molecular typing data on MDR TB have been collected in TESSy since January 2013. Every molecular typing record has two identifiers: "IsolateId" provided by the laboratory submitting data and "ECDCIsolateID" generated by TESSy. The same two variables are also part of the TUBE dataset. Reporting at least one of them to TESSy as part of the annual TB data call would therefore allow linking of molecular typing data to epidemiological surveillance data. Both "IsolateID" and "ECDCIsolateID" can be obtained from the national TB laboratory with reference function for molecular typing.

Updating historical (EuroTB) data

Data from the European Individual Tuberculosis Dataset (EITUD) have been migrated to TESSy. Updates are recommended for data from 1995-2006. After updating the historical data in TESSy, please contact the TESSY Helpdesk (*contact details*).

Reporting through the WHO global TB data collection system

As a European TB surveillance expert, you have also secured permission for data reporting in WHO's global TB data collection system (*https://extranet.who.int/tme/*). In case of any difficulties with logging in, please contact the WHO TB data helpdesk at *tbdata@who.int* or WHO/Europe at *eurotb@who.int*.

To help facilitate the submission of data to WHO, we would like to point out a few technical details:

a. Data submission to WHO will be performed directly via *https://extranet.who.int/tme*.
b. The joint TB data collection form has been slightly revised to reduce the amount of data requested.
c. EU/EEA countries reporting TB notification data via the TESSy data collection module of *the Joint European TB Surveillance System (http://www.ecdcwhosurveillance.org/)* do not have to duplicate their efforts by entering data into the WHO system section 2 (see *Data to be submitted to TESSy*).
d. Online data entry to WHO is an official channel for data submission. However, if you prefer to submit TB data using conventional offline methods, it is possible, after contacting WHO via email *eurotb@who.int*. The responsible officer from WHO/Europe or the WHO Country Office will guide and assist you.
e. Since a wide spectrum of information is requested in the form, you will need to contact the respective contact points in the National TB Programme body. It is therefore recommended to complete the form in steps, preferably by 1 June 2019, for the purposes of data to be published in the WHO's Global TB report, but no later than 1 September 2019.
f. The online validation rules will provide you with directions as to which data should be re-checked. Nevertheless, submitted data will be saved and ECDC will contact you to finalize the validation process and clear the country profile by the end of August 2019.
g. Via the WHO global TB data collection system, you will be able to view the content of the country profile as you submit/update the data.

TESSy data validation

Different logical checks per variable or across variables are carried out to identify impossible or improbable coding of the cases submitted to TESSy. If the checked file matches any of the criteria defined in the validation rules, online messages for each relevant record are returned to the user for review and action:

- Error messages: a validation issue of maximum importance/severity causes the submitted file to be automatically rejected by TESSy. The data provider is expected to review the message and the related data file, correct what triggers the validation error, and retest/resubmit the file to TESSy.
- Warning messages: while a warning does not prevent submitting the data file to TESSy, review of the message and appropriate follow-up action is expected in the interest of data quality.

Automatic checks during data upload

- All key fields are present and named according to the *TESSy metadata set 42*.
- Error messages:
    - If MajorSiteOfTB and MinorSiteOfTB are coded identically.
- Warning messages:
    - If BornReportingCountry = N and DateOfEntryToCountry is not reported.
    - If BornReportingCountry = Y and DateOfEntryToCountry is known.
    - If BornReportingCountry is 'UNK' and DateOfEntryToCountry is known.
    - If DateOfEntryToCountry is reported and is after DateUsedForStatistics.
    - If DiagnosedAnteMortem is 'N' and EnrolledToTreatment is 'UNK'.
    - If ECDCIsolateID does not match RegExp(([0-9a-fA-F]){8}-([0-9a-fA-F]){4}-([0-9a-fA-F]){4}-([0-9a-fA-F]){4}-([0-9a-fA-F]){12}).
    - If EnrolledToTreatment = Y or UNK and DiagnosedAnteMortem = N.
    - If MajorSiteOfTB is other than 'Pulmonary', and ResultMicroscopy is 'P'.
    - If PrevDiagnosis is not 'Y' and PrevDiagnosisYear is greater than 0.
    - If PrevDiagnosis is not 'Y' and PrevTreatment is 'Y'.
    - If PrevDiagnosis is 'N' and PrevTreatmentCompletion is not 'NA'.
    - If PrevDiagnosisYear is less than 1951 and PrevTreatment is 'Y'.
    - If PrevDiagnosisYear is less than 1951 and PrevTreatmentCompletion is not 'NA'.
    - If Pathogen is reported and ResultCulture is not 'P' or ResultOtherTest is not "NUCLA" or "Nuclahistol".
    - If Pathogen is reported and ResultCulture is not 'P' and ResultOtherTest is not reported.
    - If ResultCulture is not 'P' and or ResultOtherTest is not "NUCLA" or "Nuclahistol" and SIR_INH is 'R' or 'S' (the same rule is implemented for all DST variables: (SIR_AMK; SIR_BDQ; SIR_CAP; SIR_DLM; SIR_ETH; SIR_GAT; SIR_INH; SIR_KAN; SIR_LVX; SIR_MFX; SIR_OFX; SIR_PZA; SIR_RIF; SIR_STR).
    - If MajorSiteOfTB is not 'PULMONARY' and OutcomeXMonths is 'CURED'.
    - If MajorSiteOfTB = PULMONARY and OutcomeXMonths = CURED and ResultMicroscopy ≠ P and ResultCulture ≠ P – Microscopy positive or culture positive could reported as 'CURED'.
    - If DiagnosedAnteMortem = N and OutcomeXmonths ≠ (DIEDOTHER and DIEDTB and DIEDUNK and UNK and NA).
    - If BornReportingCountry is 'Unk' and NationalityReportingCountry is 'Unk' (Origin is not reported).
    - If BornReportingCountry is 'Unk' and CountryOfBirth is not 'Unk'.
    - If MajorSiteOfTB is not 'UNK' and MinorSiteOfTB is not reported.
    - If IsolateID is not reported and Molecular Surveillance information (SpoligoCode, MiruCode, Beijing GenoType) is reported.

Secondary validation by ECDC disease experts after upload

The expert approving the TB data receives an email and access to a sftp site with a validation report and feedback on the following:

- Country profile 2018 (notifications; laboratory confirmation and previous treatment; DST; treatment outcome).
- Completeness of main variables 2015 – 2018.
- Data consistency between 2017 and 2018.
- Separate information on inconsistencies concerning origin, laboratory test reporting and DST (Resultmicroscopy, ResultCulture, and SIR_INH, SIR_RIF), cured vs completed treatment, TOM reporting variables (Outcome12Months, Outcome24Months, Outcome36Months), previous treatment history, treatment enrolment, pathogen identification, and gender.

TB case definition for surveillance

Information from EU/EEA countries is collected to enable the classification of cases according to the case definition approved by the EU Member States and published by the European Commission. It classifies cases as 'possible', 'probable' or 'confirmed'. Possible cases meet clinical criteria only. Probable cases are defined by the additional detection of acid-fast bacilli (AFB) or *M. tuberculosis* nucleic acid or granulomata. Confirmed cases require a positive culture or detection of both AFB with microscopy and *M. tuberculosis* in nucleic acid amplification testing.

Cases discovered post-mortem, with gross pathological findings consistent with active TB that would have indicated anti-TB treatment, also fit the clinical criteria and should be reported.

Previous anti-TB treatment status

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

Previously treated patients have received one month or more of anti-TB drugs in the past. They are further classified by the outcome of their most recent course of treatment as follows:

> **Relapse:** patients have previously been treated for TB, were declared cured or to have completed their treatment 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 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 classified as 'treatment after default').
>
> **Other previous treatment:** patients 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 any of the categories listed above.

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

Site of disease

Pulmonary tuberculosis (PTB) refers to any bacteriologically confirmed or clinically diagnosed case of TB involving the lung parenchyma or larynx. 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, genito-urinary tract, skin, joints and bones, meninges.

Notes on the definitions

- The above definitions are in accordance with the European Commission's approved definitions for TB surveillance.
- All possible, probable and confirmed cases are reported to the joint European surveillance database. For countries with laboratory-based reporting where no clinical information is available, laboratory-confirmed cases should be reported.
- Cases should be notified only once in a given 12-month period. However, a case should be reported again if the diagnosis of confirmed tuberculosis is made following completion of anti-TB treatment (relapse), even if this occurs within 12 months of reporting the initial episode of disease.

Origin

The geographic origin of a TB case should be reported according to place of birth (born in the country/foreign origin) or citizenship (citizen/non-citizen) of the TB patient. Foreign origin refers to TB cases in individuals born in (or citizens of) a country different from the reporting country.

Drug resistance

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

Monoresistance: resistance to one first-line anti-TB drug only.

Multidrug resistance (MDR): resistance to at least isoniazid and rifampicin.

Note: Susceptibility testing of the second-line anti-TB drugs should usually be done for MDR TB cases.

Extensive drug resistance (XDR): resistance to (i) isoniazid and rifampicin (i.e. MDR), and (ii) resistance to at least one fluoroquinolone: gatifloxacin, moxifloxacin, ofloxacin or levofloxacin, and (iii) resistance to one or more of the following injectable drugs: amikacin, capreomycin, or kanamycin.

Rifampicin resistance: resistance to rifampicin detected using phenotypic or genotypic methods, with or without resistance to other anti-TB drugs. This includes any resistance to rifampicin, whether monoresistance, multidrug resistance, polydrug resistance or extensive drug resistance.

For reporting of resistance to anti-TB drugs, the resistance pattern used at the initiation of the treatment should be reported to TESSy irrespectively of the method used for DST or resistance prediction.

Treatment outcome

Cohort

All TB cases notified in the calendar year of interest, after exclusion of cases with a final diagnosis other than TB or cases found to have been reported more than once.

Note: 24-month outcome is collected for MDR TB cases notified in 2016 and 36-month outcome should be reported for XDR TB cases notified in 2015.

Period of observation

Cases are observed until the first outcome up to a maximum of 12 months after the start of treatment. For MDR TB cases in EU/EEA countries, treatment outcome after 24 months should be reported if treatment lasts longer than 12 months and the reported 12-month outcome should be coded as 'still on treatment'.

Treatment outcome categories

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.

Cured of MDR TB: Treatment completed as recommended under national policy without evidence of failure AND three or more consecutive cultures taken at least 30 days apart are negative after the intensive phase.

Completed: Treatment completed, but does not meet the criteria to be classified as cure or treatment failure.

Failed: A TB patient whose sputum smear or culture is positive five months or later into the treatment.

Treatment failed for MDR TB case: Treatment terminated or need for permanent regimen change of at least two anti-TB drugs due to:

- lack of conversion by the end of the intensive phase, or

- bacteriological reversion in the continuation phase after conversion to negative, or
- evidence of additional acquired resistance to fluoroquinolones or second-line injectable drugs, or
- adverse drug reactions (ADRs).

Died: A TB patient who dies for any reason before starting or during the course of treatment.

Defaulted: A patient whose treatment was interrupted for two consecutive months or more.

Still on treatment: A patient still on treatment at 12 months without any other outcome during treatment;

or

a patient reported as still on treatment at 12 months and still on treatment at 24 months without any other outcome.

Transferred: A patient referred to another clinical unit for treatment and information on outcome not available.

Unknown: A TB patient for whom information on treatment outcome is not available.