

TESSy - The European Surveillance System

Antimicrobial resistance (AMR) reporting protocol 2018

European Antimicrobial Resistance Surveillance Network (EARS-Net) surveillance data for 2017

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Introduction

This reporting protocol is for the 2018 data call for antimicrobial resistance (AMR) surveillance data collected by the European Antimicrobial Resistance Surveillance Network (EARS-Net) for 2017.

The Reporting Protocols are data collection guidelines for reporting countries' data managers, and the new Reporting Protocol design is intended to improve user-friendliness by:

- Introducing a uniform structure to make it easier for data managers to find data collection information across different subjects.
- Removing 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 sometimes 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 guidelines on how to prepare data for submission to TESSy, deadlines, subject-specific information (e.g. new changes to metadata), and links to further information.
- Annex 1 contains:
 - o The metadata set for the subject(s) covered by this Reporting Protocol.
 - o A history of metadata changes for the subject(s) covered by this Reporting Protocol.
- Annex 2 contains subject-specific material relevant for distribution with the Reporting Protocol.

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 links to:

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

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Reporting to TESSy

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

The overall process is:

- 1. Familiarise yourself with the data collection deadlines.
- 2. Prepare (export and transform) your data.
- 3. Check that your data complies 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 collections schedule is provided in the *Technical Annex*.

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.

AMR-specific guidelines for data collection and preparation for TESSy are provided in *Annex 1* and *Annex 2*.

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.

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* preceding changes.

It is especially important to focus on:

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.

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

Submitting your data

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

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

TESSy HelpDesk

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 AMR metadata

No changes to AMR metadata have been made since 2014.

Previous metadata changes to AMRTEST are described in *Annex 1*.

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

Annex 1 AMR metadata

This section describes:

- The AMR metadata set
- Changes to the AMR metadata

AMR metadata set

The AMR metadata is described in two sections:

- Overview of EARS-Net AMR surveillance metadata
- Isolate-based reporting
- Laboratory and hospital activity denominator data

Overview of EARS-Net AMR surveillance metadata

The metadata set for **isolate based AMR reporting** (RecordType **AMRTEST**) consists of 8 technical variables and 29 epidemiological variables, which are further classified as variables at the patient/isolate level and variables at the AMR test level. The first level includes data referring to the isolate which are repeated in all records reporting the antimicrobial susceptibility tests performed for that isolate (See the following table).

The variables used for **reporting laboratory and hospital activity data** (RecordType **AMRDENOM**) according to aggregated format include: RecordType, RecordTypeVersion, Subject, DataSource, ReportingCountry, DateUsedForStatistics, LaboratoryCode, TownOfLaboratory, LaboratoryZIP, NumPopulationLab, FullYearReported, HospitalId, HospitalType, NumPopulationHosp, NumBedsHosp, NumBedsHospICU, NumPatDaysHosp, NumAnnualOccRateHosp, NumAdmissionsHosp, NumCultureSetsHosp.

The variables of **AMRTEST** and **AMRDENOM** RecordTypes are described in more detail, including the validation rules, in *Isolate-based reporting* on page 7 and *Laboratory and hospital activity* on page **Error! Bookmark not defined.**.

Current record type versions

Table 1 shows the record type versions to be used when reporting 2017 AMR surveillance data to TESSy.

Table 1: AMR record version types for 2017 data

| Record type | Record type version |
|-------------|---------------------|
| AMRDENOM | AMRDENOM.1 |
| AMRTEST | AMRTEST.2 |

Isolate-based reporting

The following set of variables applies for isolate-based reporting of AMR. The dataset is sub-divided into a common set of system related variables (technical variables) and epidemiological variables. The epidemiologic variables can be classified in two levels: isolate information and susceptibility test information. The first level includes data referring to the specific isolate, which are repeated for each antimicrobial agent for which the susceptibility of that isolate has been tested.

The variables are described in the following tables:

Table 2: Technical Variables

- Table 1: Epidemiological variables at isolate level
- Table 2: Epidemiological variables at AMR test level

Variables #1,2,4,5,6,7,9,10,11,18,25,26 are technically mandatory; TESSy will not accept the data submission unless these fields have been completed.

However, if you enter data that does not meet the requested combination of "Pathogen", "Specimen" and "Antibiotic", the record is ignored but the batch is NOT rejected. By ignored, TESSy does not insert the data for this record into the database. The ignored records are kept as original data but are not available for analysis or report.

Table 2: Technical Variables

| VariableName | 1 – RecordID |
|--|---|
| Description | Unique anonymised identifier for each record within and across the national surveillance system and subject – MS selected and generated. Recommended format: "[ReportingCountry][LaboratoryCode] [Patient Counter][Pathogen] [Specimen][Antibiotic][DateUsedForStatistics]" |
| Required (what happens if not submitted) | Yes (Error) |
| Data type | String (Max length: 80) |
| Corresponding variable in the previous EARSS Dataset (notes) | (new variable) |
| VariableName | 2 - RecordType |
| Description | Structure and format of the data. |
| Required (what happens if not submitted) | Yes (Error) |
| Data type | Coded Value |
| Code | AMRTEST |
| Corresponding variable in the previous EARSS Dataset (notes) | (new variable) |
| VariableName | 3 – RecordTypeVersion |
| Description | 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. |
| Required | No |
| Data type | Numeric |
| Code | See Metadata |
| Corresponding variable in the previous EARSS Dataset (notes) | (new variable) |
| VariableName | 4 - Subject |
| Description | Subject of the data to report. |
| Required (what happens if not submitted) | Yes (Error) |
| Data type | Coded Value |
| Code | AMR |
| Corresponding variable in the previous EARSS Dataset (notes) | (new variable) |

| VariableName | 5 - DataSource |
|--|--|
| Description | The data source (surveillance system) that the record originates from. |
| Required (what happens if not submitted) | Yes (Error) |
| Data type | Coded Value |
| Code | See Metadata |
| Corresponding variable in the previous EARSS Dataset (notes) | (new variable) |
| VariableName | 6 - ReportingCountry |
| Description | The country reporting the record. |
| Required (what happens if not submitted) | Yes (Error) |
| Data type | Coded Value |
| Code | See Metadata |
| Corresponding variable in the previous EARSS Dataset (notes) | (new variable) |
| VariableName | 7 - DateUsedForStatistics |
| Description | The reference date used for standard reports that is compared to the |
| Description | reporting period. Recommended: Date when sample was taken. |
| Required (what happens if not submitted) | Yes (Error) |
| Data type | Date |
| Code | Exact date only, "YYYY-MM-DD" |
| Corresponding variable in the previous EARSS Dataset (notes) | Date of sample collection (new format) |
| VariableName | 8 - Status |
| Description | 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. |
| Required | No |
| Data type | Coded Value |
| Code | NEW/UPDATE OR DELETE |
| Corresponding variable in the previous EARSS Dataset | (new variable) |

Table 1: Epidemiological variables at isolate level

| VariableName | 9 - LaboratoryCode |
|--|---|
| Description | Laboratory code unique for each laboratory within the country. |
| Required (what happens if not submitted) | Yes (Error) |
| Data type | Coded Value |
| Code | See Metadata If a country has a need for additional codes in the list, they must contact TESSy Helpdesk to get the code added. Recommended format: [ReportingCountry]-[code of three characters] |
| Corresponding variable in the previous EARSS Dataset | Laboratory code |
| VariableName | 10 - Specimen |
| Description | Isolate source The source of the isolate (i.e. blood) |
| Required | Yes (Ignore): data entry is required. However, if you enter data that does not meet the requested combination of "Pathogen", "Specimen" and "Antibiotic", the record is ignored but the batch is NOT rejected. By ignored, we mean that TESSy does not insert the data for this record into the database. The ignored records are kept as original data but are not available for analysis or report. |
| Data type | Coded Value |
| Code | BLOOD = blood CSF = Cerebrospinal fluid |
| Corresponding variable in the previous EARSS Dataset (notes) | Isolate source (new codes) |
| VariableName | 11 - PatientCounter |
| | |
| Description | Numeric Code for each patient, unique within lab. Anonymous code by lab to specify patient. |
| Required (what happens if not submitted) | Yes (Error) |
| Data type | Numeric |
| Code | Require that the labs anonymize the PatientCounter. |
| Corresponding variable in the previous EARSS Dataset (notes) | Patient ID / Code (it must be anonymous. It was a string now it is a number.) |
| VariableName | 12 - Gender |
| | |
| Description | Gender |
| Required (what happens if not submitted) | Yes (Warning) |
| Data type | Coded Value |
| Code | M = Male F = Female O = Other UNK = Unknown |

| Sex (new codes) |
|---|
| 13 - Age |
| Age of the patient when the sample was taken. |
| |
| Yes (Warning) |
| Numeric |
| Integer |
| (new variable) |
| 14 - IsolateId |
| |
| Isolate ID; Code for each isolate, unique within lab and year Text code assigned by lab to specify isolate |
| Yes (Warning) |
| Text |
| Isolate sample number |
| |
| 15 - Hospitalld |
| Unique identifier for the hospital within each laboratory. |
| Yes (Warning) |
| Text |
| Unique identifier for the hospital within each laboratory. Recommended format: [LaboratoryCode]-[letter assigned to a hospital – starting from A, B, C, etc.] |
| Hospital code (new recommended format) |
| |
| 16 - PatientType |
| Origin of patient. Is the patient at the moment the sample is taken admitted in a hospital (inpatient), or not (outpatient). Patients that go to the hospital for Dialysis, other Day Hospital Care and to Emergency room should be classified as "O" for the field "PatientType". All other patient that are admitted in the hospital as inpatients should be classified as "INPAT". |
| Yes (Warning) |
| Coded Value |
| INPAT= Admitted (Inpatient) OUTPAT= Outpatient O =Other (e.g. emergency room) UNK=Unknown |
| Origin of patient (new codes) |
| |

| VariableName | 17 - HospitalUnitType |
|--|--|
| | 1 |
| Description | Hospital department (at time of sample collection) |
| Required (what happens if not submitted) | Yes (Warning) |
| Data type | Coded Value |
| Code | INTMED =Internal Medicine PEDS =Paediatrics/neonatal PEDSICU=Paediatrics/neonatal ICU SURG =Surgery ONCOL=Haematology/Oncology OBGYN=Obstetrics/Gynaecology ICU=Intensive Care Unit ED=Emergency Department URO=Urology Ward |
| | INFECT=Infectious Disease Ward O =Other UNK=Unknown |
| Corresponding variable in the previous EARSS Dataset (notes) | Hospital department (new codes) |
| VariableName | 18 - Pathogen |
| Description | Pathogen Species and genus of the pathogen which has been isolated from the sample. |
| Required (what happens if not submitted) | Yes (Error) |
| Data type | Coded Value |
| Code | STRPNE=Streptococcus pneumoniae STAAUR=Staphylococcus aureus ENCFAE=Enterococcus faecalis ENCFAI=Enterococcus faecium ESCCOL=Escherichia coli KLEPNE=Klebsiella pneumoniae PSEAER=Pseudomonas aeruginosa ACISPP=Acinetobacter spp. |
| Corresponding variable in the previous EARSS Dataset (notes) | Pathogen code (new codes) |
| VariableName | 19 - DateOfHospitalisation |
| Description | Date of admission in hospital |
| Required | No |
| Data type | Date |
| Code | Exact date only, "YYYY-MM-DD" |
| Corresponding variable in the previous EARSS Dataset (notes) | Date of admission (new format) |
| VariableName | 20 - ResultPCRmec |
| Description | Detection of PCR mecA-gene |
| Required | No No |
| Data type | Coded Value |
| | <u> </u> |

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|--|---|--|
| Code | POS=positive NEG=negative UNK=unknown | |
| Corresponding variable in the previous EARSS Dataset (notes) | PCR mec-gene (new codes) | |
| Validation rule | To be reported only if Pathogen=STAAUR. | |
| | | |
| VariableName | 21 - ResultPbp2aAggl | |
| Description | Detection of PBP2a-agglutination | |
| Required | No | |
| Data type | Coded Value | |
| Code | POS=positive; NEG=negative; UNK=unknown | |
| Corresponding variable in the previous EARSS Dataset (notes) | PBP2a-agglutination (new codes) | |
| Validation rule | To be reported only if Pathogen=STAAUR. | |
| VariableName | 22 - Serotype | |
| Description | Serotype/group of the pathogen isolated from the sample. Reference: Danish Kauffman-Lund scheme from the WHO Collaborating Centre for Reference and Research on Pneumococci at the Danish Serum | |
| Required | Institute. | |
| Data type | Coded Value | |
| Code | See Metadata | |
| Corresponding variable in the previous EARSS Dataset (notes) | Serotype | |
| Validation rule | To be reported only if Pathogen=STRPNE. | |
| VariableName | 23 - ESBL | |
| | Detection of ESBL | |
| Description | | |
| Required | No Coded Value | |
| Data type | | |
| Code | POS=positive NEG=negative UNK=unknown | |
| Corresponding variable in the previous EARSS Dataset (notes) | ESBL present (new codes) | |
| Validation rule | To be reported only if Pathogen= ESCCOL or KLEPNE. | |
| VariableName | 24 - ResultCarbapenemases | |
| Description | Detection of Carbapenemases. This refers to phenotypic test for | |
| | carbapenemase activity (e.g. the Modified Hodge Test - MHT). | |
| Required | No | |
| Data type | Coded Value | |

| Code | POS=positive |
|--|---|
| | NEG=negative |
| | UNK=unknown |
| Corresponding variable in the previous EARSS Dataset (notes) | (new variable) |
| Validation rule | To be reported only if Pathogen= ESCCOL or KLEPNE or PSEAER or ACISPP |

Table 2: Epidemiological variables at AMR test level

| VariableName | 25 - Antibiotic |
|--|---|
| Description | Antimicrobial code |
| Required | Yes (Ignore): data entry is required. However, if you enter data that does not meet the requested combination of "Pathogen", "Specimen" and "Antibiotic", the record is ignored but the batch is NOT rejected. By ignored, we mean that TESSy does not insert the data for this record into the database. The ignored records are kept as original data but are not available for analysis or report. |
| Data type | Coded Value, |
| Code | See Implementation of AMR case definitions for TESSy where a list of all antimicrobial agent codes are provided |
| Corresponding variable in the previous EARSS Dataset | Antibiotic code |
| VariableName | 26 - SIR |
| Description | Final interpretation result of all different susceptibility tests performed |
| Required (what happens if not submitted) | Yes (Error) |
| Data type | Coded Value |
| Code | S=susceptible; I=intermediate; R=resistant |
| Corresponding variable in the previous EARSS Dataset | S/I/R |
| VariableName | 27 - ResultZoneSign |
| Description | Zone (> < =) This field can indicate if a value of the zone diameter of the disk test is "less than" (<); "equal to or less than" (< =); "equal to" (=); "equal to or greater than" (>=); or "greater than" (>) the value indicated in the following field. |
| Required | No |
| Data type | Coded Value |
| Code | < |
| Corresponding variable in the previous EARSS Dataset (notes) | Zone (> < =) (new codes) |
| VariableName | 29. Posult7onoValue |
| VariableName | 28 - ResultZoneValue |

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|--|---|--|
| Description | Zone (Value in mm) | |
| Required | No | |
| Data type | Numeric | |
| Code | Integer | |
| Corresponding variable in the previous EARSS Dataset (notes) | Zone (Value in mm) (only Zone diameter in millimetres; | |
| VariableName | 29 - ResultZoneSIR | |
| Description | Interpretation of the zone test. | |
| Required | No | |
| Data type | Coded Value | |
| Code | S=susceptible; | |
| Code | I=intermediate; R=resistant | |
| Corresponding variable in the previous EARSS Dataset (notes) | (new variable) | |
| VariableName | 30 - ResultMICSign | |
| Description | MIC (> < =) This field can indicate if a value of the zone diameter of the MIC test is "less than" (<); "equal to or less than" (< =); "equal to" (=); "equal to or greater than" (>=); or "greater than" (>) the value indicated in the following field. | |
| Required | No | |
| Data type | Coded Value | |
| Code | < | |
| Corresponding variable in the previous EARSS Dataset (notes) | MIC (> < =) (new codes) | |
| VariableName | 31 - ResultMICValue | |
| Description | MIC (Value in mg/l) | |
| · | No | |
| Required Data type | | |
| Data type | Text | |
| Code | If <1 then float, if >=1 then integer | |
| Corresponding variable in the previous EARSS Dataset (notes) | MIC (Value in mg/l) (only MIC values in mg/l; in the EARSS Dataset it also could contain the S/I/R results) | |
| | | |
| VariableName | 32 - ResultMICSIR | |
| VariableName Description | 32 - ResultMICSIR Interpretation of the MIC test. | |
| | | |

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|--|--|--|
| Code | S=susceptible; I=intermediate; R=resistant | |
| Corresponding variable in the previous EARSS Dataset (notes) | (new variable) | |
| | | |
| VariableName | 33 - ResultEtestSign | |
| Description | Gradient strip (> < =) This field can indicate if a value of the zone diameter of the gradient strip is "less than" (<); "equal to or less than" (< =); "equal to" (=); "equal to or greater than" (>=); or "greater than" (>) the value indicated in the following field. | |
| Required | No | |
| Data type | Coded Value | |
| Code | < | |
| Corresponding variable in the previous EARSS Dataset (notes) | E-test (> < =) (new codes) | |
| VariableName | 34 - ResultEtestValue | |
| Description | Gradient strip value (Value in mg/l) | |
| Required | No | |
| Data type | Text | |
| Code | If <1 then float, if >=1 then integer. The value 1.5 is also allowed. | |
| Corresponding variable in the previous EARSS Dataset (notes) | E-test (Value in mg/l) (only E-test values in mg/l; in the EARSS Dataset it also could contain the S/I/R results) | |
| | | |
| VariableName | 35 - ResultEtestSIR | |
| Description | Interpretation of the gradient strip test. | |
| Required | No | |
| Data type | Coded Value | |
| Code | S=susceptible; I=intermediate; R=resistant | |
| Corresponding variable in the previous EARSS Dataset (notes) | (new variable) | |
| VariableName | 36 - DiskLoad | |
| Description | Disk content (only if Zone) This field can be used to mention the load of the antimicrobial disk used. Please mention the value and the Units (e.g. mcg, Units or IU). | |
| Required | No | |
| Data type | Text | |
| Code | Value and units: i.e. UI, mcg. | |
| | <u> </u> | |

| Corresponding variable in the previous EARSS Dataset | Disk load |
|--|---|
| VariableName | 37 - ReferenceGuidelinesSIR |
| Description | To differentiate use of CSLI and EUCAST guidelines for determining clinical breakpoint for antimicrobial susceptibility of the isolate |
| Required | No |
| Data type | Coded value |
| Code | EUCAST = European Committee on Antimicrobial Susceptibility Testing CLSI = Clinical and Laboratory Standards Institute NAT = National O = Other |
| Corresponding variable in the previous EARSS Dataset | New variable 2012 |

AMR metadata change history

Metadata changes prior to 2014 can be found on the TESSy documents website.

Previous metadata changes

Table 3: Summary of implemented changes in case-based record types for Antimicrobial Resistance (AMR)

| Year | Subject | Description |
|-------|---------|---|
| 2015- | | No changes to AMR metadata. |
| 2016 | | |
| 2014 | AMRTEST | Addition of new codes to coded value list for antibiotics. |
| | AMRTEST | Update of validation rules associated to these new antibiotics. |
| | All | Update NUTS codes according to the NUTS Codes 2010 classification from EUROSTAT |

Annex 2 AMR-specific material

Contacts

Questions regarding coding, upload of data etc. should be directed to the *TESSy helpdesk* at *TESSy@ecdc.europa.eu*

Questions regarding the AMR reporting and contents will be dealt with by the ECDC AMR expert:

Liselotte Diaz Högberg:

E-mail: liselotte.diaz.hogberg@ecdc.europa.eu

Questions regarding the use of WHONET to prepare data for TESSy upload can be directed to ECDC contractor

John Stelling:

E-mail jstelling@whonet.org (keep liselotte.diaz.hogberg@ecdc.europa.eu in CC)

Microbiological guidelines for EARS-Net

EARS-Net encourages the use of The European Committee on Antimicrobial Susceptibility Testing (EUCAST) guidelines and breakpoints to determine clinical antimicrobial susceptibility (available at http://www.eucast.org/). In 2012, the EUCAST steering committee established a subcommittee for detection of resistance mechanisms and specific resistances of clinical and/or epidemiological importance. The sub-committee was established partly in response to frequently asked questions from users of EUCAST guidelines on this issue, and partly on request from the ECDC, as expert microbiology guidance was needed for EARS-Net participants.

The remit of the subcommittee was to develop practical guidelines for detection of specific antimicrobial resistance mechanisms of clinical and/or epidemiological importance. The document was developed by conducting systematic literature searches, and most recommendations are based on multi-centre studies, as these provide the best measure of robustness of the methods. Prior to publication of these guidelines, they were subjected to wide consultation through the EUCAST consultation contact lists, the EUCAST website and ECDC focal point contacts. An updated version of the result of this work can be found in the EUCAST guidelines for detection of resistance mechanisms and specific resistances of clinical and/or epidemiological importance¹. This document replaces the previous EARSS microbiology manual.

The guideline describes the definition of the mechanisms of resistances, an outline description of recommended methods of detection, and references to detailed descriptions of the methods for:

- 1. Carbapenemase-producing Enterobacteriaceae
- 2. Extended-spectrum β-lactamase (ESBL)-producing Enterobacteriaceae
- 3. Acquired AmpC β-lactamase-producing Enterobacteriaceae
- 4. Meticillin-resistant Staphylococcus aureus (MRSA)
- 5. Glycopeptide non-susceptible Staphylococcus aureus
- 6. Vancomycin resistant enterococci
- 7. Penicillin non-susceptible Streptococcus pneumoniae

¹. EUCAST. 2017. EUCAST guidelines for detection of resistance mechanisms and specific resistances of clinical and/or epidemiological importance. Version 2.0 of July 2017 Available at http://www.eucast.org/fileadmin/src/media/PDFs/EUCAST_files/Resistance_mechanisms/EUCAST_detection_of_resistance_mechanisms_170711.pdf

Implementation of AMR case definitions for TESSy

Given the typology of data for AMR surveillance, which refers to laboratory isolates rather than to cases of disease, the following case definition has been implemented in the RecordType "AMRTEST", for reporting to TESSy:

The bacterial species under surveillance are:

- Streptococcus pneumoniae (STRPNE)
- Staphylococcus aureus (STAAUR)
- Enterococcus faecalis (ENCFAE)
- Enterococcus faecium (ENCFAI)
- Escherichia coli (ESCCOL)
- Klebsiella pneumoniae (KLEPNE)
- Pseudomonas aeruginosa (PSEAER)
- Acinetobacter spp. (ACISPP).

All isolates from blood (STRPNE, STAAUR, ENCFAE, ENCFAI, ESCCOL, KLEPNE, PSEAER, ACISPP) and/or cerebrospinal fluid (STRPNE, ESCCOL, KLEPNE, PSEAER, ACISPP), for which a susceptibility test has been performed, have to be included.

The generic case definition of antibiotic resistance defined in the Commission implementing decision laying down case definitions for reporting communicable diseases to the Community network¹ states that "A pathogen is defined as clinically susceptible, clinically intermediate or clinically resistant to an antibiotic agent according to the EUCAST clinical breakpoints, i.e. clinical MIC breakpoints and their inhibition zone diameter correlates.

Clinically Susceptible (S)

- a micro-organism is defined as susceptible by a level of antibiotic activity associated with a high likelihood of therapeutic success
- a micro-organism is categorised as susceptible (S) by applying the appropriate breakpoint in a defined phenotypic test system
- this breakpoint may be altered with legitimate changes in circumstances

Clinically Intermediate (I)

- a micro-organism is defined as intermediate by a level of antibiotic agent activity associated with uncertain therapeutic effect. It implies that an infection due to the isolate may be appropriately treated in body sites where the antibiotics are physically concentrated or when a high dosage of antibiotic can be used; it also indicates a buffer zone that should prevent small, uncontrolled, technical factors from causing major discrepancies in interpretations
- a micro-organism is categorised as intermediate (I) by applying the appropriate breakpoints in a defined phenotypic test system
- these breakpoints may be altered with legitimate changes in circumstances

Clinically Resistant (R)

- a micro-organism is defined as resistant by a level of antibiotic activity associated with a high likelihood of therapeutic failure
- a micro-organism is categorised as resistant (R) by applying the appropriate breakpoint in a defined phenotypic test system
- this breakpoint may be altered with legitimate changes in circumstances.

 $^{^1}$ Commission Implementing Decision 2012/506/EU of 8 August 2012 amending Decision 2002/253/EC laying down case definitions for reporting communicable diseases to the Community network under Decision No 2119/98/EC of the European Parliament and of the Council. Available at

Although EARS-Net encourages the use of EUCAST clinical breakpoints in line with the EU case definitions, countries and laboratories using other guidelines are still welcome to report data if the use of clinical guidelines is specified under *Variable 37* (ReferenceGuidelinesSIR). Reporting of quantitative susceptibility data is strongly encouraged.

Duplicates from the same patients should be eliminated taking only the first by date of sample collection and isolate source. Table 4 lists all microorganism/source and antibiotic agent combinations under surveillance by EARS-Net.

If records referring to additional combinations are uploaded, they will be filtered out by the system - see *TESSy Filter 1*.

Table 4: Microorganism, specimen source and antimicrobial agent combinations under surveillance by EARS-Net

| Microorganism | Specimen source | Antimicrobial agent |
|-----------------------------------|---|---|
| Streptococcus pneumoniae (STRPNE) | blood (BLOOD); cerebrospinal fluid (CSF) | Azithromycin (AZM) Cefotaxime (CTX) Ceftriaxone (CRO) Clarithromycin (CLR) Erythromycin (ERY) Levofloxacin (LVX) Moxifloxacin (MFX) Norfloxacin (NOR) Oxacillin (OXA) |
| Staphylococcus aureus (STAAUR) | blood (BLOOD) | Penicillin (PEN) Cefoxitin (FOX) Cloxacillin (CLO) Ciprofloxacin (CIP) Daptomycin (DAP) Dicloxacillin (DIC) Flucloxacillin (FLC) Levofloxacin (LVX) Linezolid (LNZ) Meticillin (MET) Norfloxacin (NOR) Ofloxacin (OFX) Oxacillin (OXA) Rifampin (RIF) Vancomycin (VAN) |
| Enterococcus faecalis (ENCFAE) | blood (BLOOD) | Ampicillin (AMP) Amoxicillin (AMX) Gentamicin-High (GEH) Linezolid (LNZ) Teicoplanin (TEC) Vancomycin (VAN) |
| Enterococcus faecium (ENCFAI) | blood (BLOOD) | Ampicillin (AMP) Amoxicillin (AMX) Gentamicin-High (GEH) Linezolid (LNZ) Teicoplanin (TEC) Vancomycin (VAN) |
| Escherichia coli (ESCCOL) | blood (BLOOD); cerebrospinal fluid (CSF) | Amikacin (AMK) Amoxicillin-clavulanic acid (AMC) Ampicillin (AMP) Amoxicillin (AMX) Cefepime (FEP) Cefotaxime (CTX) Ceftazidime (CAZ) Ceftriaxone (CRO) Ciprofloxacin (CIP) Colistin (COL) Ertapenem (ETP) Gentamicin (GEN) Imipenem (IPM) |

| Microorganism | Specimen source | Antimicrobial agent |
|---------------------------------|---|---|
| inici corganism | Specimen source | Antimicrobial agent |
| | | Levofloxacin (LVX) Meropenem (MEM) |
| | | Moxifloxacin (MFX) Netilmicin (NET) |
| | | Norfloxacin (NOR) |
| | | Ofloxacin (OFX) Piperacillin-tazobactam (TZP) |
| | | Polymyxin B (POL) |
| | | Tigecycline (TCG) |
| Klebsiella pneumoniae (KLEPNE) | blood (BLOOD); | Tobramycin (TOB) Amikacin (AMK) |
| (, | cerebrospinal fluid (CSF) | Amoxicillin-clavulanic acid (AMC) |
| | | Cefepime (FEP) |
| | | Cefotaxime (CTX) Ceftazidime (CAZ) |
| | | Ceftriaxone (CRO) |
| | | Ciprofloxacin (CIP) |
| | | Colistin (COL) |
| | | Ertapenem (ETP) |
| | | Gentamicin (GEN) Imipenem (IPM) |
| | | Levofloxacin (LVX) |
| | | Meropenem (MEM) |
| | | Moxifloxacin (MFX) |
| | | Netilmicin (NET) |
| | | Norfloxacin (NOR) Ofloxacin (OFX) |
| | | Piperacillin-tazobactam (TZP) |
| | | Polymyxin B (POL) |
| | | Tigecycline (TCG) |
| (202222) | 11 1(2:002) | Tobramycin (TOB) |
| Pseudomonas aeruginosa (PSEAER) | blood (BLOOD); cerebrospinal fluid (CSF) | Amikacin (AMK) Cefepime (FEP) |
| | cerebrospinar naia (csr) | Ceftazidime (CAZ) |
| | | Ciprofloxacin (CIP) |
| | | Colistin (COL) |
| | | Gentamicin (GEN) |
| | | Imipenem (IPM) |
| | | Levofloxacin (LVX) Meropenem (MEM) |
| | | Netilmicin (NET) |
| | | Piperacillin (PIP) |
| | | Piperacillin/Tazobactam (TZP) |
| | | Polymyxin B (POL) Tobramycin (TOB) |
| Acinetobacter spp. (ACISPP) | blood (BLOOD); | Amikacin (AMK) |
| | cerebrospinal fluid (CSF) | Ciprofloxacin (CIP) |
| | | Colistin (COL) |
| | | Gentamicin (GEN) |
| | | Imipenem (IPM) Levofloxacin (LVX) |
| | | Meropenem (MEM) |
| | | Netilmicin (NET) |
| | | Polymyxin B (POL) |
| | | Tobramycin (TOB) |

Objectives for AMR surveillance

Surveillance of AMR within the European Union (EU) has been assured by European law: AMR is listed in decision no 1082/2013/EU of the European Parliament and of the Council on serious cross-border threats to health 1 , which in October 2013 replaced Decision 2119/98/EC on setting up a network for the epidemiological surveillance and control of communicable diseases in the EU. The case definitions to be followed when reporting data on infectious diseases, including antimicrobial resistance, to ECDC are described in Decision $2012/506/EU^2$.

The European Antimicrobial Resistance Surveillance Network (EARS-Net) is the continuation of the European Antimicrobial Resistance Surveillance System (EARSS), which was hosted by the Dutch National Institute for Public Health and the Environment (RIVM). Established in 1998, EARSS successfully created a multistate network for AMR surveillance and demonstrated how international AMR data could be provided to inform decisions and raise awareness among stakeholders and policy makers. By 1 January 2010, the management and administration of EARSS was transferred from RIVM to the European Centre for Disease Prevention and Control (ECDC), and the network was renamed EARS-Net. Data collected from EU Member States by the network since 1999 was transferred to The European Surveillance System (TESSy) database at ECDC.

EARS-Net is based on a network of representatives from the Member States collecting routine clinical antimicrobial susceptibility data from national AMR surveillance initiatives. Scientific guidance and support to the network is provided by the EARS-Net Coordination Committee. This group is composed of individual experts selected from among the nominated disease-specific contact points and experts from other organisations that are involved in surveillance of antimicrobial resistance.

The objectives of EARS-Net are to:

- collect comparable, representative and accurate AMR data;
- analyse temporal and spatial trends of AMR in Europe;
- provide timely AMR data that constitute a basis for policy decisions;
- encourage the implementation, maintenance and improvement of national AMR surveillance programmes; and
- support national systems in their efforts to improve diagnostic accuracy in the surveillance chain by offering an annual External Quality Assessment (EQA).

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 $^{^1}$ Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC.

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:293:0001:0015:EN:PDF

² Commission Implementing Decision 2012/506/EU of 8 August 2012 amending Decision 2002/253/EC laying down case definitions for reporting communicable diseases to the Community network under Decision No 2119/98/EC of the European Parliament and of the Council

Preparing national AMR datasets

The data collection at laboratory level can be performed both <u>electronically and manually</u> by filling out the corresponding Isolate Records Forms per pathogen (see <u>Isolate forms</u>). If the data collection at laboratory level has been performed manually by filling the Isolate Records, the Country Data Manager should create the fields "Age" and "PatientCounter" starting from the available information in the paper forms ("Year of birth" and "Patient ID / Code").

The data collection for EARS-Net is supported by WHONET (Microbiology Laboratory Database Software) which is a useful tool for processing and analysis of antimicrobial resistance data. It provides a routine procedure to perform data entry and to export data in EARS-Net exchange format and can be used locally by participating laboratories and centrally by country data managers. The software and manual can be downloaded from http://www.who.int/drugresistance/whonetsoftware/en/.

If a new laboratory joins the surveillance network the country disease specific contact points must communicate the new code of the new laboratory to the Helpdesk at tessy@ecdc.europa.eu by e-mail before uploading data; otherwise the system will not recognise the new code and will reject the entire file.

Checking for duplicate records

Before uploading a file to TESSy, the country data manager has to revise the laboratory data and check for duplicates (records with the same RecordId). If there are duplicates, TESSy will reject the upload. Duplicates should be eliminated by merging/selecting records.

Recommendations for merging and selecting records:

- In the TESSy metadata set the recommended format of the RecordId is the combination of the following fields: ReportingCountry; LaboratoryCode; PatientCounter; Pathogen; Specimen; Antibiotic; DateUsedForStatistics.
- Identify multiple isolates within the same day (using the field IsolateId when available) and select the first one per day (DateUsedForStatistics).
- If there are still duplicates, further merging/selection of records should be done according to the recommended method summarized in the following examples 1, 2 and 3.

Example 1 – Duplicates: same microorganism/antimicrobial agent combination but different microbiological tests

| Pathogen | Antibiotic | SIR | ResultZoneSIR | ResultMICValue | ResultMICSIR |
|----------|------------|-----|---------------|----------------|--------------|
| ESCCOL | СТХ | R | R | | |
| ESCCOL | СТХ | S | | 0.5 | S |

- The two records above refer to the same patient and the same microorganism/antimicrobial agent combination from the same source (blood) in the same day.
- According to the metadata set specifications, they are considered as duplicates and will
 generate an error in the uploading process to TESSy with the subsequent rejection of the
 entire batch of records.
- To avoid this unsuccessful outcome, it is possible to merge the reported data in one row.
- For the final interpretation of the susceptibility test (SIR), the MIC result will prevail.

| Pathogen | Antibiotic | SIR | ResultZoneSIR | ResultMICValue | ResultMICSIR |
|----------|------------|-----|---------------|----------------|--------------|
| ESCCOL | СТХ | S | R | 0.5 | S |

Example 2 – Duplicates: same microorganism/antimicrobial agent combination, same test, different SIR results

| Pathogen | Antibiotic | SIR | ResultZoneSIR | ResultMICValue | ResultMICSIR |
|----------|------------|-----|---------------|----------------|--------------|
| ESCCOL | СТХ | R | R | 8 | R |
| ESCCOL | СТХ | S | S | 0.5 | S |

Select the first in this order $R \rightarrow I \rightarrow S$ (therefore the most resistant is selected). This is a rare occurrence and this rule is implemented to have a standard algorithm for filtering the duplicates.

Example 3 – Duplicates: same microorganism/antimicrobial agent combination, same test, same SIR results

| Pathogen | Antibiotic | SIR | ResultZoneSIR | ResultMICValue | ResultMICSIR |
|----------|------------|-----|---------------|----------------|--------------|
| ESCCOL | СТХ | S | S | 0.5 | S |
| ESCCOL | СТХ | S | S | 0.5 | S |

If the records have the same SIR result (true duplicates) just select one of them, taking into account the completeness of the other variables.

Data management and analysis

TESSy filter 1 (case definition) and validation report

TESSy filters the uploaded records according to the list of Microorganism/Specimen/Antimicrobial agent combinations included in the AMR surveillance (the EARS-Net case definition for TESSy is described in more detail in *Implementation of AMR case definitions for TESSy*). Records referring to additional Microorganism/Specimen/Antimicrobial agent combinations are discharged.

Shortly after the data uploading, TESSy provides a validation report which should be assessed by the country user. The report shows summary statistics of the validated data from the uploaded batch.

TESSy filter 2 (preparing dataset for analysis)

This filter aims to obtain one record per patient/microorganism/specimen/antimicrobial agent combination and year.

| STEP 1 | Select all records that belong to the first date within the considered YEAR for each patient/microorganism combination. | Fields to identify the date: |
|--------|---|--|
| STEP 2 | If more than one source (BLOOD, CSF) is reported within the first date, select only one giving priority to the CSF. | Field to identify the source : • Specimen |
| STEP 3 | If the same antimicrobial is reported in more than one record within the first date, make a selection giving priority to records with results coming from the gradient strip test*. | Field to identify the antimicrobial: |
| STEP 4 | If the same antimicrobial is still reported in more than one record within the first date, make a selection giving priority to records with results coming from other MIC tests. | Fields to identify results coming from other MIC tests: ResultMICSIR* ResultMICVALUE* |

| STEP 5 | If the same antimicrobial is still reported in more than one record, make a selection according with the final interpretation of the susceptibility test (priority sequence $R \rightarrow I \rightarrow S$). | Field to identify the final interpretation of the susceptibility test : • SIR |
|--------|--|---|
| STEP 6 | If the same antimicrobial is still reported in more than one record, select the first one. | |

^{*} In the selection process gradient strip test results should prevail over other MIC results since, in the routine labs activity, the latter are likely to have been obtained through automated systems which are generally considered less reliable than gradient strip tests.

The TESSy filter includes two additional steps for meticillin-resistant *Staphylococcus aureus* (between Step 2 and Step 3 of the main algorithm).

| Conditions Pathogen="STA AND (Antibiotic="O | AAUR" KA" OR "MET" OR "FLC" OR "DIC" OR "CLO" OR "F | OX") |
|---|---|--|
| Additional STEP I | If the same antimicrobial is reported in more than one record within the first date, make a selection giving priority to records with the confirmation test results . | Field to identify the antimicrobial: • Antibiotic Fields to identify the confirmation test results: • ResultPCRmec*** • ResultPbp2aAggl*** |
| Additional STEP II | If the same antimicrobial is still reported in more than one record, make a selection according with the confirmation test result (priority to records with a positive result). | |

^{***}At least one among the two fields is not missing.

Data analysis and presentation

For the analysis, an isolate is considered resistant to an antimicrobial agent when tested and interpreted as resistant (R) in accordance with the clinical breakpoint criteria used by the local laboratory. An isolate is considered non-susceptible to an antimicrobial agent when tested and found resistant (R) or with intermediate susceptibility (I) using the same clinical breakpoints as interpretive criteria. EARS-Net encourages the use of EUCAST breakpoints, however, results based on other interpretive criteria used by the reporting countries are accepted for the analysis.

As a general rule, data are expressed as a resistance percentage, i.e. the percentage of R isolates out of all isolates with antimicrobial susceptibility testing (AST) information on that specific microorganism—antimicrobial agent combination, and for some bacteria as the percentage of non-susceptible (I+R) isolates out of all isolates with the relevant information. For selected analyses, a 95% confidence interval is determined for the resistance percentage by applying an exact confidence interval for binomial data.

In most cases, the percentage resistance is calculated considering an antimicrobial group (instead of a single antimicrobial agent), which needs other specifications to perform the analysis. The group often but not always represent an antimicrobial class. An example of an antimicrobial group is the third-generation cephalosporins for $E.\ coli.$ This group contains three antimicrobial agents: ceftriaxone (CRO), cefotaxime (CTX) and ceftazidime (CAZ). If two or more antimicrobials (records) are reported for the same "microorganism/antimicrobial group" combination, count only one of them; the choice has to be done according with the final interpretations of the susceptibility test (field=SIR; priority sequence $R \rightarrow I \rightarrow S$).

^{**} At least one among the two fields is not missing.

Specific rule for Streptococcus pneumoniae and non-susceptibility to penicillin

The antimicrobial considered for this resistance are penicillin (PEN) and oxacillin (OXA). If both are reported, give priority to penicillin.

Specific rule to define Meticillin-resistant Staphylococcus aureus (MRSA)

The antimicrobials considered for this resistance are: Oxacillin (OXA), Meticillin (MET), Flucloxacillin (FLC), Cloxacillin (CLO), Dicloxacillin (DIC) and Cefoxitin (FOX). Other tests (equivalents) are also considered as confirmation tests: PCR mecA or PBP2a detection.

| Hierarchical levels to assess the MRSA | Priority sequence of the results |
|--|----------------------------------|
| Confirmation test (PCR mecA and PBP2a) | POS→NEG |
| Gradient strip test (SIR result of OXA, MET, FLC, DIC, CLO, FOX) | R→S |
| Other MIC tests (SIR result of OXA, MET, FLC, DIC, CLO, FOX) | R→S |
| Other test (SIR result of OXA, MET, FLC, DIC, CLO, FOX) | $R \rightarrow S$ |

The definition of MRSA is based on the following criteria:

- I. If at least one between ResultPCRmec and ResultPbp2aAggl is positive then MRSA.
- II. If at least one between ResultPCRmec and ResultPbp2aAggl is negative and the other one is not positive then MSSA (Meticillin-sensitive *Staphylococcus aureus*)
- III. If both ResultPCRmec and ResultPbp2aAggl are missing then consider SIR to define susceptibility (if SIR=S then MSSA; if SIR=I or R then MRSA)

The full set of microorganism/antimicrobial group combinations that are under regular surveillance by EARS-Net (routinely presented in the EARS-Net annual report and the public EARS-Net database) is displayed in Table 8. In addition, additional analysis of other single or group of antimicrobial agents will be performed on an ad hoc basis.

If fewer than 10 isolates are reported for a specific organism—antimicrobial agent combination in a country, the results for this country are not displayed on the maps presented in the Annual Report and the interactive database.

The statistical significance of temporal trends of antimicrobial resistance percentages by country is calculated based on data from the last four years. Countries reporting fewer than 20 isolates per year, or not providing data for all years within the considered period, are not included in the analysis. Statistical significance of trends is assessed by the Cochran–Armitage test. An additional sensitivity analysis is performed by repeating the Cochran–Armitage test only including laboratories which consistently reported for the full four-year period in order to exclude selection bias when assessing the significance of the trends.

Table 5: Microorganism and antimicrobial group combinations under regular EARS-Net surveillance

| Microorganism | Antimicrobial group | Antimicrobial agents | | | |
|--------------------------------|--------------------------------------|------------------------------|--|--|--|
| Escherichia coli (ESCCOL) | Aminopenicillins | AMX, AMP | | | |
| | Fluoroquinolones | CIP, OFX, LVX | | | |
| | Third-generation cephalosporins | CTX, CRO, CAZ | | | |
| | Aminoglycosides | GEN, TOB, NET | | | |
| | Carbapenems | IPM, MEM | | | |
| | Polymyxins | POL, COL | | | |
| Klebsiella pneumoniae | Fluoroquinolones | CIP, OFX, LVX | | | |
| (KLEPNE) | Third-generation cephalosporins | CTX, CRO, CAZ | | | |
| | Aminoglycosides | GEN, TOB, NET | | | |
| | Carbapenems | IPM, MEM | | | |
| | Polymyxins | POL, COL | | | |
| Pseudomonas aeruginosa | Piperacillin+/- tazobactam | TZP, PIP | | | |
| (PSEAER) | Ceftazidime | CAZ | | | |
| | Fluoroquinolones | CIP, LVX | | | |
| | Aminoglycosides | GEN, TOB, NET | | | |
| | Carbapenems | IPM, MEM | | | |
| | Amikacin | AMK | | | |
| | Polymyxins | POL, COL | | | |
| Acinetobacter spp (ACISPP) | Fluoroquinolones | CIP, LVX | | | |
| | Aminoglycosides | GEN, TOB, NET | | | |
| | Carbapenems | IPM, MEM | | | |
| | Amikacin | AMK | | | |
| | Polymyxins | POL, COL | | | |
| Streptococcus pneumoniae | Penicillins | PEN, OXA | | | |
| (STRPNE) | Macrolides | ERY, CLR, AZM | | | |
| | Fluoroquinolones | LVX, NOR, MFX | | | |
| | Third-generation cephalosporins | CTX, CRO | | | |
| Staphylococcus aureus | MRSA | MET, OXA, FOX, FLC, CLO, DIC | | | |
| (STAAUR) | Rifampicin | RIF | | | |
| | Fluoroquinolones | CIP, OFX, LVX, NOR | | | |
| Enterococcus faecalis (ENCFAE) | High-level aminoglycoside resistance | GEH | | | |
| and Enterococcus faecium | Vancomycin | VAN | | | |
| (ENCFAI) | Aminopenicillins | AMX, AMP | | | |

Isolate forms

To be filled in by the laboratories without electronic system

The following isolate forms are included:

- Isolate Record Form *Streptococcus pneumoniae*
- Isolate Record Form *Staphylococcus aureus*
- Isolate Record Form Escherichia coli
- Isolate Record Form *Klebsiella pneumoniae*
- Isolate Record Form *Pseudomonas aeruginosa*
- Isolate Record Form

 Enterococcus faecium

 Enterococcus faecalis
- Isolate Record Form *Acinetobacter* spp.

Isolate Record Form Streptococcus pneumoniae

Instructions: Please send data of the first blood and/or cerebrospinal fluid isolate of every patient with an invasive *S. pneumoniae* infection. Send data on resistant and susceptible isolates; use 1 form per isolate.

[n] Indicates variable number in reporting protocol

| [9] Laboratory Code | | | | | | | | | |
|----------------------|---|--|--|--|--|--|--|--|--|
| [14] Isolate Id | [10] Specimen Blood CSF | [7] Date of sample collection (yyyy-mm-dd) | | | | | | | |
| [11] Patient counter | [12] Gender | [13] Age (years) | | | | | | | |
| [15] Hospital Id | [16] Patient type ☐ Inpatient ☐ Outpatient ☐ Other ☐ Unknown | [19] Date of Hospitalisation (yyyy-mm-dd) | | | | | | | |
| | ☐ Paediatrics/neonatal ICU ☐ Surgery ☐ Haematology/Ortment ☐ Urology department ☐ Infectious disease ward ☐ | | | | | | | | |

Antibiotic susceptibility testing (S/I/R, zone and/or MIC)

| | [26] SIR | | Zone diameter | | | MIC | | nt strip results | [37] Reference guidelines |
|--------------------|---|------------------------|---------------------------------|--------------------------------|--------------------------|---------------------------------|--------------------------|---------------------------------|---|
| [25] Antibiotic | (final interpretation result of all different susceptibility test performed) | [28] Result (mm) | [29] Interpretation (SIR) | [36] Disk load (specify unit)) | [31] Result (mg/l) | [32] Interpretation (SIR) | [34] Result (mg/l) | [35] Interpretation (SIR) | Fill in EUCAST, CLSI, National, Other |
| Oxacillin | | | | - | | | | | |
| Penicillin | | | | | | | | | |
| Erythromycin | | | | | | | | | |
| Clarithromycin | | | | | | | | | |
| Azithromycin | | | | | | | | | |
| Cefotaxime | | | | | | | | | |
| Ceftriaxone | | | | | | | | | |
| Norfloxacin | | | | | | | | | |
| Levofloxacin | | | | | | | | | |
| Moxifloxacin | | | | | | | | | |
| [22] Serotype: | | _ | | | | | _ | | |

Send this form to (Name/Institute/Contact details):

Isolate Record Form Staphylococcus aureus

Instructions: Please send data of the first blood and/or cerebrospinal fluid isolate of every patient with an invasive *S. pneumoniae* infection. Send data on resistant and susceptible isolates; use 1 form per isolate.

[n] Indicates variable number in reporting protocol

| [9] Laboratory Code | | | | | | | | | | | |
|---------------------|---|------------------------|--|---|--------------------------|---------------------------------|--------------------------|--|---|--|--|
| [14] Isolate Id | | [1 | [10] Specimen Blood CSF | | | | | [7] Date of sample collection (yyyy-mm-dd) | | | |
| [11] Patient coun | nter | [1 | [12] Gender | | | | | rears) | | | |
| [15] Hospital Id | | _ | [16] Patient type ☐ Inpatient ☐ Outpatient ☐ Other ☐ Unknown | | | | | of Hospitalisation | (yyyy-mm-dd) | | |
| | [17] Hospital Department Internal medicine Paediatrics/neonatal Paediatrics/neonatal ICU Surgery Haematology/Oncology Obstetrics/Gynaecology | | | | | | | | | | |
| | | | | | | | | • | iogy | | |
| ☐ Intensive care | e unit | cy departme | ent LUrology dep | artment LL Ir | nfectious di | sease ward \square | Other L U | nknown | | | |
| MRSA co | MRSA confirmation tests | | | | | | | | | | |
| [20] PCR mec | | | ☐ Positive ☐ Negative ☐ Unknown | | | | | | | | |
| [21] Pbp2a agg lu | utination | | ☐ Posit | ive 🗌 Nega | ative 🗌 U | nknown | | | | | |
| Antibioti | c susceptibility te | esting (S/ | I/R, zone and/or | MIC) | | | | | | | |
| | [26] SIR | | Zone diameter | | | MIC | | nt strip results | [37] Reference guidelines | | |
| [25] Antibiotic | (final interpretation result of all different susceptibility test performed) | [28] Result (mm) | [29] Interpretation (SIR) | [36] Disk load (specify unit)) | [31] Result (mg/l) | [32] Interpretation (SIR) | [34] Result (mg/l) | [35] Interpretation (SIR) | Fill in EUCAST, CLSI, National, Other | | |
| Cefoxitin | | | | | | | | | | | |
| Oxacillin | | | | | | | | | | | |
| Meticillin | | | | | | | | | | | |
| Flucloxacillin | | | | | | | | | | | |
| Cloxacillin | | | | | | | | | | | |
| Dicloxacillin | | | | | | | | | | | |
| Ciprofloxacin | | | | | | | | | | | |
| Ofloxacin | | | | | | | | | | | |
| Levofloxacin | | | | | | | | | | | |

Send this form to (Name/Institute/Contact details):

Norfloxacin
Rifampicin
Linezolid
Vancomycin
Daptomycin

Isolate Record Form Escherichia coli

Instructions: Please send data of the first blood and/or cerebrospinal fluid isolate of every patient with an invasive *S. pneumoniae* infection. Send data on resistant and susceptible isolates; use 1 form per isolate.

[n] Indicates variable number in reporting protocol

| F | | | | | | | | | | |
|--|--|----------------|---|-----------------------------|-------------|------------------|-------------------------|--------------------------|--------------------------------------|--|
| [9] Laboratory Code | | | | | | | | | | |
| [14] Isolate Id | | [1 | 10] Spe | cimen \square | Blood C | SF | | [7] Date of | sample collectio | n (yyyy-mm-dd) |
| [11] Patient coun | ter | [1 | [12] Gender | | | | | [13] Age (years) | | |
| [15] Hospital Id | | - | [16] Patient type ☐ Inpatient ☐ Outpatient ☐ Other☐ Unknown | | | | | [19] Date o | of Hospitalisation | (yyyy-mm-dd) |
| [17] Hospital Department Internal medicine Paediatrics/neonatal Paediatrics/neonatal ICU Surgery Haematology/Oncology Obstetrics/Gynaecology Intensive care unit Emergency department Urology department Infectious disease ward Other Unknown | | | | | | | | | | |
| Phenoty | oic detection of re | esistance | • | | | | | | | |
| [20] ESBL | | | | Positi | ve 🗌 Negat | ive 🗌 Unl | known | | | |
| [21] Carbapenem | ase | | | Positiv | ∕e □Negativ | ve Unkn | iown | | | |
| Antibioti | c susceptibility te | esting (S/ | /I/R, zc | one and/or | MIC) | | | | | |
| [25] Antibiotic | [26] SIR (final interpretation result of all different susceptibility test performed) | [28] Result | | ne diameter [29] rpretation | [36] | MIC [31] | | Gradie [34] Result | nt strip results [35] Interpretation | [37] Reference guidelines Fill in EUCAST, CLSI, National, |
| - | periormea) | (mm) | inte | (SIR) | Disk load | Result (mg/l) | Interpretation (SIR) | (mg/l) | (SIR) | Other |
| Amoxicillin | | | | | | | | | | |
| Ampicillin | | | | | | | | | | |
| Amoxicillin- clavulanic acid | | | | | | | | | | |
| Piperacillin - tazobactam | | | | | | | | | | |
| Gentamicin | | | | | | | | | | |
| Tobramycin | | | | | | | | | | |
| Netilmicin | | | | | | | | | | |
| Amikacin | | | | | | | | | | |
| Ciprofloxacin | | | | | | | | | | |
| Ofloxacin | | | | | | | | | | |
| Levofloxacin | | | | | | | | | | |
| Moxifloxacin | | | | | | | | | | |
| Cefotaxime | | | | | | | | | | |
| Ceftriaxone | | | | | | | | | | |
| Ceftazidime | | | | | | | | | | |
| Cefepime | | | | | | | | | | |
| Imipenem | | | | | | | | | | |
| Meropenem | | | | | | | | | | |
| Doripenem | | | | | | | | | | |
| Ertapenem Colistin | | | | | | | | | | |

Send this form to (Name/Institute/Contact details):

Tigecycline

Isolate Record Form Klebsiella pneumoniae

Instructions: Please send data of the first blood and/or cerebrospinal fluid isolate of every patient with an invasive *S. pneumoniae* infection. Send data on resistant and susceptible isolates; use 1 form per isolate.

* Mandatory variable, [n] Indicates variable number in reporting protocol

| [9] Laboratory Co | ode | | | | | | | | | |
|---|---|--|---------------|------------------------------|-------------------|--------------------------|---------------------------------|--------------------------|---------------------------------|---|
| [14] Isolate Id | | I | [10] Sp | ecimen \square | Blood C | SF | | [7] Date of | sample collectio | n (yyyy-mm-dd) |
| [11] Patient coun | iter | ı | [12] Gender | | | | [13] Age (years) | | | |
| [15] Hospital Id | | [16] Patient type ☐ Inpatient ☐ Outpatient ☐ Other ☐ Unknown | | | | [19] Date o | of Hospitalisation | (yyyy-mm-dd) | | |
| [17] Hospital Department ☐ Internal medicine ☐ Paediatrics/neonatal ☐ Paediatrics/neonatal ICU ☐ Surgery ☐ Haematology/Oncology ☐ Obstetrics/Gynaecology ☐ Intensive care unit ☐ Emergency department ☐ Urology department ☐ Infectious disease ward ☐ Other ☐ Unknown | | | | | | | | | | |
| Phenoty | pic detection of re | esistanc | е | | | | | | | |
| [20] ESBL | | | | ☐ Positiv | e 🗌 Negativ | ve 🗌 Unkr | nown | | | |
| [21] Carbapenem | iase | | | Positive | e Negative | e 🗆 Unkno | wn | | | |
| Antibioti | c susceptibility te | esting (S | 5/I/R, z | one and/or | MIC) | | | | | |
| | [26] SIR (final interpretation result of all different | | Zone diameter | | | MIC | Gradie | ent strip results | [37] Reference guidelines | |
| [25] Antibiotic | susceptibility test performed) | [28] Result (mm) | Int | [29] erpretation (SIR) | [36] Disk load | [31] Result (mg/l) | [32] Interpretation (SIR) | [34] Result (mg/l) | [35] Interpretation (SIR) | Fill in EUCAST, CLSI, National, Other |
| Amoxicillin clavulanic acid | | | | | | | | | | |
| Piperacillin - tazobactam | | | | | | | | | | |
| Gentamicin | | | | | | | | | | |
| Tobramycin | | | | | | | | | | |
| Amikacin | | | | | | | | | | |
| Netilmicin | | | | | | | | | | |
| Ciprofloxacin | | | | | | | | | | |
| Ofloxacin | | | | | | | | | | |
| Levofloxacin | | | | | | | | | | |
| Moxifloxacin | | | | | | | | | | |
| Nalidixic acid | | | | | | | | | | |
| Cefotaxime | | | | | | | | | | |
| Ceftriaxone | | | | | | | | | | |
| Ceftazidime | | | | | | | | | | |
| Cefepime | | | | | | | | | | |
| Imipenem | | | | | | | | | | |
| Meropenem | | | | | | | | | | |
| Doripenem | | | | | | | | | | |
| Ertapenem | | | | | | | | | | |
| Colistin | | | | | | Ī | | 1 | | |

Send this form to (Name/Institute/Contact details):

Tigecycline

Isolate Record Form Pseudomonas aeruginosa

Instructions: Please send data of the first blood and/or cerebrospinal fluid isolate of every patient with an invasive *S. pneumoniae* infection. Send data on resistant and susceptible isolates; use 1 form per isolate.

[n] Indicates variable number in reporting protocol

| [9] Laboratory Code | | | | | | | | | | |
|-----------------------------|--|------------------------|--|--------------------------------|--------------------------|---------------------------------|--|---------------------------------|---|--|
| [14] Isolate Id | | [1 | 0] Specimen \Box | Blood C | SF | | [7] Date of sample collection (yyyy-mm-dd) | | | |
| [11] Patient coun | iter | [1 | [12] Gender | | | | | /ears) | | |
| [15] Hospital Id | | l _ | [16] Patient type ☐ Inpatient ☐ Outpatient ☐ Other ☐ Unknown | | | | | of Hospitalisation | (yyyy-mm-dd) | |
| [17] Hospital Dep | [17] Hospital Department | | | | | | | | | |
| ☐ Internal medic | cine Paediatrics/n | eonatal 🗌 | Paediatrics/neona | atal ICU 🗆 s | Surgery \Box | Haematology/On | cology 🗆 C | Obstetrics/Gynaeco | logy | |
| ☐ Intensive care | unit Emergend | cy departme | ent Urology dep | oartment 🗌 li | nfectious di | sease ward | Other 🔲 U | nknown | | |
| Phenoty | pic detection of re | esistance | • | | | | | | | |
| [21] Carbapenem | [21] Carbapenemase Positive Negative Unknown | | | | | | | | | |
| Antibioti | c susceptibility te | esting (S/ | I/R, zone and/or | MIC) | | | | | | |
| | [26] SIR | | Zone diameter | | | MIC | | nt strip results | [37] Reference guidelines | |
| [25] Antibiotic | (final interpretation result of all different susceptibility test performed) | [28] Result (mm) | [29] Interpretation (SIR) | [36] Disk load (specify unit)) | [31] Result (mg/l) | [32] Interpretation (SIR) | [34] Result (mg/l) | [35] Interpretation (SIR) | Fill in EUCAST, CLSI, National, Other | |
| Piperacillin | | | | | | | | | | |
| Piperacillin- tazobactam | | | | | | | | | | |
| Gentamicin | | | | | | | | | | |
| Tobramycin | | | | | | | | | | |
| Netilmicin | | | | | | | | | | |
| Amikacin | | | | | | | | | | |
| Ciprofloxacin | | | | | | | | | | |
| Levofloxacin | | | | | | | | | | |
| Ceftazidime | | | | | | | | | | |
| Cefepime | | | | | | | | | | |
| Imipenem | | | | | | | | | | |
| Meropenem | | | | | | | | | | |
| Doripenem | | | | 1 | | | | | | |

Send this form to (Name/Institute/Contact details):

Colistin

Instructions: Please send data of the first blood and/or cerebrospinal fluid isolate of every patient with an invasive *S. pneumoniae* infection. Send data on resistant and susceptible isolates; use 1 form per isolate.

* Mandatory variable, [n] Indicates variable number in reporting protocol

| [9] Laboratory Code | | | | | | | | | | |
|--|--|------------------------|--|--------------------------------|--------------------------|---------------------------------|---|--|---|--|
| [14] Isolate Id | | [1 | [10] Specimen Blood CSF | | | | | [7] Date of sample collection (yyyy-mm-dd) | | |
| [11] Patient coun | nter | [1 | [12] Gender | | | | [13] Age () | vears) | | |
| [15] Hospital Id | | [1 | [16] Patient type ☐ Inpatient ☐ Outpatient ☐ Other ☐ Unknown | | | | [19] Date of Hospitalisation (yyyy-mm-dd) | | | |
| [17] Hospital Department Internal medicine Paediatrics/neonatal Paediatrics/neonatal ICU Surgery Haematology/Oncology Obstetrics/Gynaecology Intensive care unit Emergency department Urology department Infectious disease ward Other Unknown | | | | | | | | | | |
| Antibioti | c susceptibility te | esting (S/ | I/R, zone and/or | MIC) | | | | | | |
| | [26] SIR | | Zone diameter | | | MIC | Gradient strip results | | [37] Reference guidelines | |
| [25] Antibiotic | (final interpretation result of all different susceptibility test performed) | [28] Result (mm) | [29] Interpretation (SIR) | [36] Disk load (specify unit)) | [31] Result (mg/l) | [32] Interpretation (SIR) | [34] Result (mg/l) | [35] Interpretation (SIR) | Fill in EUCAST, CLSI, National, Other | |
| Amoxicillin | | | | | | | | | | |
| Ampicillin | | | | | | | | | | |
| Gentamicin - High | | | | | | | | | | |
| Vancomycin | | | | | | | | | | |
| Teicoplanin | | | | | | | | | | |

Send this form to (Name/Institute/Contact details):

Linezolid

Isolate Record Form Acinetobacter spp.

Instructions: Please send data of the first blood and/or cerebrospinal fluid isolate of every patient with an invasive *S. pneumoniae* infection. Send data on resistant and susceptible isolates; use 1 form per isolate.

* Mandatory variable, [n] Indicates variable number in reporting protocol

| managery randomy py manager random manager milapolitics | | | | | | | | | | |
|---|---|------------------------|--|--|--------------------------|---------------------------------|--|---------------------------------|---|--|
| [9] Laboratory Co | [9] Laboratory Code | | | | | | | | | |
| [14] Isolate Id | | [1 | 0] Specimen \Box | Blood C | SF | | [7] Date of sample collection (yyyy-mm-dd) | | | |
| [11] Patient coun | ter | [1 | [12] Gender | | | | | /ears) | | |
| [15] Hospital Id | | _ | [16] Patient type ☐ Inpatient ☐ Outpatient ☐ Other ☐ Unknown | | | | [19] Date of Hospitalisation (yyyy-mm-dd) | | | |
| Internal medic | [17] Hospital Department ☐ Internal medicine ☐ Paediatrics/neonatal ☐ Paediatrics/neonatal ICU ☐ Surgery ☐ Haematology/Oncology ☐ Obstetrics/Gynaecology ☐ Intensive care unit ☐ Emergency department ☐ Urology department ☐ Infectious disease ward ☐ Other ☐ Unknown | | | | | | | | | |
| Phenotypic detection of resistance | | | | | | | | | | |
| [21] Carbapenemase Positive Negative Unknown | | | | | | | | | | |
| Antibioti | c susceptibility te | esting (S/ | I/R, zone and/or | MIC) | | | | | | |
| | [26] SIR | | Zone diameter | | | MIC | | nt strip results | [37] Reference guidelines | |
| [25] Antibiotic | (final interpretation result of all different susceptibility test performed) | [28] Result (mm) | [29] Interpretation (SIR) | [36] Disk load (specify unit) | [31] Result (mg/l) | [32] Interpretation (SIR) | [34] Result (mg/l) | [35] Interpretation (SIR) | Fill in EUCAST, CLSI, National, Other | |
| Ciprofloxacin | | | | | | | | | | |
| Levofloxacin | | | | | | | | | | |
| Gentamicin | | | | | | | | | | |
| Tobramycin | | | | | | | | | | |
| Netilmicin | | | | | | | | | | |
| Amikacin | | | | | | | | | | |
| Imipenem | | | | | | | | | | |
| Meropenem | | | | | | | | | | |
| Doripenem | | | | | | | | | | |
| Colistin | | | | | | | | | | |

Send this form to (Name/Institute/Contact details):