Report

European Antimicrobial Resistance Surveillance For Belgium (EARS-BE) -
Protocol 2021, including data call, case and data definitions, instructions for participating laboratories.

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Authors

Karl MERTENS, karl.mertens@sciensano.be T +32 2 642 57 95

Introduction

This document gives instructions to laboratories within Belgium (BE) to submit 2021 data to the Belgian network of the European antimicrobial resistance surveillance (EARS-NET, EARS-BE)[1,2]. EARS-Net is the main European epidemiologic surveillance system for Antimicrobial resistance (AMR), and its data serve as important indicators on the occurrence and spread of AMR in European countries[3].

On a yearly basis, EARS-Net collects and reports across European countries data on AMR against relevant agents within commonly occurring pathogens isolated from clinical invasive samples in humans. The Sciensano service "Healthcare-associated infections and antimicrobial resistance" coordinates the Belgian branch of EARS-Net (EARS-BE) and collects national data for Belgium to submit to Europe. In turn, ECDC shares EARS-NET annual data (including those of BE) with the Global Antimicrobial surveillance system (GLASS-WHO[4]). Of note, participation to EARS-BE 2021 is voluntary.

EARS-BE differs from EARS-Net in three major points :

(1) the additional collection of antimicrobial susceptibility tests (AST) on isolates collected from urine (next to blood/CSF samples);
(2) the inclusion of the pathogen *Proteus mirabilis*, a frequent cause of urinary tract infections[5];
(3) the distinction between all *Acinetobacter species* and the pathogen *Acinetobacter baumannii*, the predominant species of the genus comprised in the ESKAPE pathogens commonly associated with antimicrobial resistance[6].

This document relies on the standards and definitions that are laid out by EARS-Net[7] and summarizes these for participating laboratories, with additions specific for the Belgian network.

Following modifications with respect to the EARS-BE 2020 data collection[8] were added:

- Modification of required AST variable '**16 - ReferenceGuidelinesSIR**', indicating the EUCAST *version* used to interpret submitted ASTs (if EUCAST was used), **as well as possible exceptions** applicable to included ASTs;
- Organisation of the **2022 External Quality Assessment** is made provisional and pending on decision by ECDC;

This protocol further emphasizes on three major points :

- This surveillance includes **clinical invasive samples** (Blood/CSF) but also **clinical and screening urinary samples.** The variable 4 'Indication' to distinguish between clinical and screening samples is only used in the case of submission of samples from **urinary origin**, and if this information is available for extraction from the Laboratory information system.
- As a general rule, only results on **ASTs reported to the clinician** should be submitted as part of the EARSBE 2021 datafile. As an **exception** to this rule: results of ASTs *should* be submitted if these were **not included in the clinically reporting** with the objective of **guiding treatment choices** (so-called *masked results*).
- **No rules to avoid duplicate observations are defined** for the data submitted by the laboratory; these will be implemented by Sciensano/NSIH during preparation of national EARS-BE data. See also 'Validation and reporting'.

Of note, from the 2019 data collection onwards, EARS-Net (data on clinical invasive samples) will limit the analysis to data interpreted following EUCAST guidelines only. However, EARS-BE will continue to collect & report data of laboratories using other guidelines than EUCAST.

Also, starting from 2019 data collections, an AMR-EARS-BE harmonised protocol[10] will be proposed for implementation in a pilot phase. This protocol will give instructions to hospital laboratories in Belgium (BE) to submit annual surveillance data on antimicrobial resistance that correspond both to the Belgian national surveillances of methicillin resistant *Staphylococcus aureus* ("MRSA"), multi-resistant Gram-negative bacteria ("MRGN"), and vancomycin resistant enterococci ("VRE") as well as to the European Antimicrobial Resistance Surveillance Network for Belgium ("EARS-BE"). This protocol will be available on the Sciensano/NSIH website. Please contact EARS-BE or AMR coordinators for more information.

Case definition for AMR and inclusion criteria

Included sample types and pathogens. EARS-BE relies on the EU case definition for AMR as defined in the EARS-Net protocol[7]. The bacterial species under surveillance are *Streptococcus pneumoniae*, *Staphylococcus aureus*, *Enterococcus faecalis*, *Enterococcus faecium*, *Escherichia coli*, *Klebsiella pneumoniae*, *Pseudomonas aeruginosa* and *Acinetobacter spp.* EARS-BE further distinguishes *Acinetobacter baumannii* from other *Acinetobacter species*. Of these pathogens, all clinical isolates from blood and/or cerebrospinal fluid (CSF) samples taken in 2021 on an identified patient and for which an Antimicrobial Susceptibility Test (AST) has been performed, are included. EARS-BE uses the above inclusion criteria and additionally and optionally includes isolates originating from urine samples taken in 2021 from an identified patient (Table 3 variable 3 'Specimen'). Also, urine samples can be taken for clinical or screening purposes and are differentiated based on variable 4 'Indication' (Table 3). Included uropathogens are the pathogens stated above except for *S. aureus*, *S. pneumoniae and Acinetobacter spp* and supplemented with *Proteus mirabilis* (for which blood and CSF samples are not included)

Definition of antimicrobial resistance. The combinations of (microorganism x sample type x AST) that should be included in EARS-BE 2021 data are given in Table 1. Laboratories are eligible for participation to EARS-BE 2021 if they performed AST for at least one of these combinations on a sample taken in 2021 from an identified patient. These combinations serve the main set of microorganism/antimicrobial group combinations that are under surveillance by EARS-BE as displayed in Table 2.

Definitions of antimicrobial resistance follow those of the European Committee on Antimicrobial Susceptibility Testing (EUCAST) clinical breakpoints (latest EUCAST version for interpretation of 2021 ASTs: V11[9,10]). Antimicrobial resistance is to be encoded in required variable 15 'Result-lab' (Table 4) through categories S – I – R, the definitions of which were changed in EUCAST guidelines V9 (2019) as follows:

- **S** - *Susceptible, standard dosing regimen*: A microorganism is categorised as "Susceptible, standard dosing regimen", when there is a high likelihood of therapeutic success using a standard dosing regimen of the agent;
- **I** - *Susceptible, increased exposure*: A microorganism is categorised as "Susceptible, Increased exposure" when there is a high likelihood of therapeutic success because exposure to the agent is increased by adjusting the dosing regimen or by its concentration at the site of infection;
- **R** - *Resistant*: A microorganism is categorised as "Resistant" when there is a high likelihood of therapeutic failure even when there is increased exposure.

Detailed inclusion criteria. Following the above case definitions for AMR, the participating laboratory should prepare and submit EARS-BE data in the form of an electronic data file in which each individual observation holds info on a particular isolate x sample x AST result on a sample that was taken in 2021 from an identified patient and for which the result was reported to the clinician. Exception: results of ASTs should be still be submitted even if these were not included in the clinical reports with the objective of guiding treatment choices (so-called *masking of AST results*). All laboratories in BE (including non-hospital laboratories) that performed routine ASTs in 2021 corresponding to at least one combination of the sample types, isolates and tests defined above are invited to participate. EARS-BE defines no other inclusion criteria besides the ones above: annual exhaustive data according to at least one of the combinations under surveillance should be prepared, meaning no further selection is to be done on patient type, period, hospital site etc. Importantly, no restrictions are placed on the type of patients to include, but several variables are collected describing sample and patient characteristics such as a patient's hospitalization status or the ward in the hospital in which a sample was taken (see Table 3).

Data definition

The EARS-BE 2021 data file prepared by the laboratory will contain variables on the isolate and AMR test level. It will thus include the information on a particular AMR test result as a separate observation, and repeat all information on the level of the isolate, sample and patient over all included AMR tests. Tables 3 and 4 give the data collection definition for isolate and AMR test information, respectively. Participating laboratories should only submit data on variables for which information can be collected and submitted.

Variables 1 'LaboratoryCode', 2 'SampleDate', 3 'Specimen', 5 'PatientId', 13 'Pathogen', 14 'AMRtest', 15 'Result_lab' and 16 'ReferenceGuidelinesSIR' are mandatory variables (Required='Yes'); Observations without at least this info provided for these variables cannot be further processed by Sciensano/NSIH. Next to these, variables (8 'PatientType', 12 'IsolateId') are labelled 'recommended' (Required='No, but recommended') because they contain values needed for deduplication of raw data (see 'Reporting and validation of laboratory and national results' below) or calculation of specific indicators. The rest of the variables in Tables 3 and 4 specifying information on the hospitalization of the patient are optional.

Table 5 lists variables that are collected concerning the laboratory's participation, such as 17 'LaboratoryCode', 18 'LaboratoryAddress', 19 'ContactPerson' and 20 'Email'. The annual number of blood and urine culture sets performed by the laboratory (variables 21 and 22) are collected as well, these can be provided separately for each hospital associated with the laboratory if available. Variable 23 'LIMSSystem' was introduced in the 2019 data collection in order to identify the laboratory information management system (LIMS), and used to prioritize on projects for automation and validation of EARS-BE data exports from current LIMS.

No rules to avoid duplicate observations are defined for the data submitted by the laboratory; these will be implemented by Sciensano/NSIH during preparation of national EARS-BE data, and following the section 'Validation and reporting' (see below).

The data definition of Tables 3, 4 and 5 should be taken as a guideline, and does not need to be strictly followed. Possible deviations that are accepted:

- Participating laboratories are free to use own nomenclature if providing correspondence with this data definition. Sciensano/NSIH will establish *Laboratory-specific codebooks* documenting how each laboratory's specific nomenclature corresponds with EARS-BE codification. These codebooks will be included in the annual laboratory report; their validation by the laboratory is an essential step in obtaining correct results (see further Validation and reporting);
- The use of uppercase and lowercase characters in variable names and code values may be ignored;
- ASTs for which results are submitted don't need to be limited to the ones shown in Table 1; after conversion, Sciensano/NSIH will discard the ASTs not part of the inclusion criteria of Table 1.

Submitting data

AST data needs to be submitted to Sciensano/NSIH in the form of a flat-text data file, in Comma separated value (CSV) format or similar. If MS Excel is used, the use of formatting such as calculated fields or hiding of columns or rows should be avoided. MS Access files are not accepted. Submission of EARS-BE data in separate parts (for example by period, specimen, pathogen, etc.) is possible. Data files may not exceed 40Mb; data is to be spread over multiple files if this is the case.

Submitting EARS-BE data proceeds by sending an email with attachment to nsihdata@sciensano.be. The info on epidemiological variables at laboratory level of Table 5 is to be specified in the message body. A laboratory that tested zero isolates in 2021 for a particular pathogen or series of pathogens (for example no *Acinetobacter* spp isolates), is invited to report this in the mail message as well.

Please refer to the NSIH/EARS webpages (http://www.nsih.be, https://www.sciensano.be/) for the deadline of submitting laboratory data for 2021.

Validation and reporting of laboratory and national results

Conversion and standardization: Upon reception, laboratory data will be *converted* and *standardized* by Sciensano/NSIH unit to the EARS-BE 2021 data definition. In an intermediate step, the laboratory may be contacted for validation of unclear nomenclature or to provide missing information. Only laboratory data standardized towards the (13 'Pathogen', 3 'Specimen', 14 'Antimicrobial test') combinations of Table 1 are kept for further treatment and analysis.

De-duplication of laboratory data: For each laboratory, sample type (blood/CSF versus urine), pathogen (variables 1 'LaboratoryCode', 3 'Specimen', 13 'Pathogen') and AST, data de-duplication proceeds as follows:

- Aggregation of all test results (variable 15 'Result_lab') within the same patient, isolate and sample date (variables 2 'SampleDate', 5 'PatientId', 12 'IsolateId'), prioritizing test results as interpreted by the laboratory (variable 15 'Result_lab'), according to the most resistant result (R>I>S);
- In case of multiple samples (variable 3 'Specimen', variable 12 'IsolateId') on the same date (variable 2 'Sample date') for the same patient (variable 5 'Patient Id'), prioritization is done on sample type (CSF>BLOOD,), and then on test results (R>I>S, variable 15 'Result_lab');
- For each patient (variable 5 'PatientId'), results on the first occurring specimen (variable 2 'SampleDate') within the study year are then kept.

Reporting of laboratory results: De-duplicated annual laboratory data are then analysed, and reported in the form of a MS Excel (XLSX) laboratory report file. Analysis occurs always for a particular pathogen, results of which are given in the relevant worksheet of the report file. These pathogen-specific worksheets present the results for the sample types "Blood/CSF" and "Urine". Both indicators on sample or patient characteristics as well as on the antimicrobial resistance (or non-susceptibility) rate for included ASTs and antibiotic groups are presented. A guide for the interpretation of the EARS-BE laboratory report is available[11]. The laboratory report will be usually sent twice, a first time early in the year to inform the laboratory about its results and to allow their validation, and a second time with national results included once these became available.

Reporting of national results: Sciensano/NSIH will also produce national annual statistical and descriptive reports for 2021. Additionally, national 2021 data on blood/CSF isolates with anonymized laboratory, hospital and patient identifiers will be submitted to the European Centre for Disease prevention and Control (ECDC, Stockholm) for inclusion in the ECDC annual report on AMR. Note that, from 2019 onwards, ASTs results interpreted following non-EUCAST guidelines won't be included in the EARS-Net surveillance & report but will continue to be included & reported by EARS-BE surveillance.

External Quality Assessment (EQA)

All laboratories reporting EARS-BE 2021 data will be invited to participate in an annual external quality assessment (EQA). This is a service contracted by ECDC to an external contractor.

The annual procedure for this EQA is as follows:

- The contractor contacts the coordinator of EARS-BE at Sciensano/NSIH once a year, to update the contact details of participating laboratories and compile a list of addresses of laboratories to be included in the EQA for BE. In compliance with ECDC specifications, this list is based on laboratories that submitted data to EARS-BE 2021. A laboratory that is unable to submit data to the annual EARS-BE call but wants to participate to the annual EQA, should contact the EARS-BE coordinator to see what arrangements with ECDC are possible.
- The contractor then contacts the potential EQA participants with information on EQA reporting requirements and timelines, the provisions for intellectual property, data ownership and sharing, and planned post-EQA activities such as reports and publications.
- At the time of the actual EQA (most often early autumn), the contractor prepares one package for each laboratory, containing a set of at bacterial isolates, safety instructions, and detailed

information about routines for reporting of results. In addition to collection of EQA results, information on the use of methods (i.e. automated systems, disc diffusion, E-test etc.) and guidelines for clinical breakpoints as well as on the availability of and the requirement and/or obligation to participate to a national EQA scheme should be collected from the laboratories (type of EQA, mandatory, voluntary etc.). The packages (already labelled with the specific local laboratory address) are sent to the coordinator of EARS-BE who further forwards the packages to each participating local laboratory. Laboratories register their results in an on-line database provided by the contractor.

- The results will be compiled and analysed by the contractor, which will provide individual feed-back of the results to each participating laboratory and a country report to the national EQA coordinator compiling all EQA results from the laboratories in the country. The report should include the results from all participating laboratories (including a national summary) and include a short conclusion on the capacity of participating laboratories and if needed, recommendations for improvement.

Restrictions and confidentiality measures

Sciensano/NSIH applies the same restrictions and confidentiality measures to EARS-BE 2021 data of a particular laboratory and its contents as done with other Sciensano/NSIH surveillances. This means that a particular laboratory's data (or its contents) will only serve the objectives stated in the EARS-BE 2020 protocol. When institute (laboratory or hospital)-specific results are reported or presented, the identity of a particular institute will be only disclosed to the designated contact person(s) of the institute itself.

Table 1. EARS-BE 2021 microorganism, specimen source and antimicrobial resistance test combinations.

Microorganism	Specimen	Antimicrobial test
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) Penicillin meningitis (PEN_MENI)[1] Penicillin non-meningitis (PEN_NMEN)[2]
Staphylococcus aureus **(STAAUR)**	blood (BLOOD); cerebrospinal fluid (CSF);	Cefoxitin (FOX) Cloxacillin (CLO) Ciprofloxacin (CIP) Dicloxacillin (DIC) Flucloxacillin (FLC) Levofloxacin (LVX) Linezolid (LNZ) Meticillin (MET) Norfloxacin (NOR) Ofloxacin (OFX) Oxacillin (OXA) Rifampin (RIF) Trimethoprim/Sulfamethoxazole (SXT) Vancomycin (VAN)

Microorganism	Specimen	Antimicrobial test
Enterococcus faecalis **(ENCFAE)** ***Enterococcus faecium*** **(ENCFAI)**	blood (BLOOD); cerebrospinal fluid (CSF); urine (URI)	Ampicillin (AMP) Amoxicillin (AMX) Gentamicin-High (GEH) Linezolid (LNZ) Nitrofurantoin (NIT) (uncomplicated UTI only) Teicoplanin (TEC) Trimethoprim/Sulfamethoxazole (SXT) Vancomycin (VAN)
Escherichia coli **(ESCCOL)** ***Klebsiella pneumoniae*** **(KLEPNE)**	blood (BLOOD) ; cerebrospinal fluid (CSF); urine (URI)	Amikacin (AMK) Amoxicillin-clavulanic acid, systemic infection (AMC)[3] Amoxicillin-clavulanic acid, uncomplicated urinary tract infection (AMC_UC)[4] Amoxicillin (AMX) Ampicillin (AMP) (for ESCCOL only) Cefepime (FEP) Cefotaxime (CTX) Ceftazidime (CAZ) Ceftriaxone (CRO) Cefuroxime intravenous (CXM_IV)[5] Cefuroxime oral, uncomplicated urinary tract infection (CXM_PO)[6] Ciprofloxacin (CIP) Colistin (COL) Ertapenem (ERT) Fosfomycin (FOS_PO) (uncomplicated UTI only) Gentamicin (GEN) Imipenem (IPM) Levofloxacin (LVX) Meropenem (MEM) Moxifloxacin (MFX) Norfloxacin (NOR) Nitrofurantoin (NIT) (uncomplicated UTI only, *E coli* only) Ofloxacin (OFX) Piperacillin-tazobactam (TZP) Temocillin (TEM)[7] Tigecycline (TGC) Tobramycin (TOB) Trimethoprim, uncomplicated urinary tract infection (TRIM) Trimethoprim/Sulfamethoxazole (SXT)
Proteus mirabilis (PRTMIR)	urine (URI)	Amikacin (AMK) Amoxicillin-clavulanic acid, systemic infection (AMC)[3] Amoxicillin-clavulanic acid, uncomplicated urinary tract infection (AMC_UC)[4] Amoxicillin (AMX) Ampicillin (AMP) Cefotaxime (CTX) Ceftazidime (CAZ) Ceftriaxone (CRO) Cefuroxime intravenous (CXM_IV)[5] Cefuroxime oral, uncomplicated urinary tract infection (CXM_PO)[6] Ciprofloxacin (CIP) Fosfomycin (FOS_PO) (uncomplicated UTI only) Gentamicin (GEN) Imipenem (IPM) Levofloxacin (LVX) Meropenem (MEM) Norfloxacin (NOR) Ofloxacin (OFX) Piperacillin-tazobactam (TZP) Temocillin (TEM)[7] Tobramycin (TOB) Trimethoprim, uncomplicated urinary tract infection (TRIM) Trimethoprim/Sulfamethoxazole (SXT)

Microorganism	Specimen	Antimicrobial test
***Pseudomonas aeruginosa* (PSEAER)**	blood (BLOOD); cerebrospinal fluid (CSF); urine (URI)	Amikacin (AMK) Cefepime (FEP) Ceftazidime (CAZ) Ciprofloxacin (CIP) Colistin (COL) Gentamicin (GEN) Imipenem (IPM) Levofloxacin (LVX) Meropenem (MEM) Piperacillin (PIP) Piperacillin/Tazobactam (TZP) Tobramycin (TOB)
***Acinetobacter baumannii* (ACIBAU)** ***Acinetobacter spp., other than Acinetobacter baumannii* (ACINSP)**	blood (BLOOD); cerebrospinal fluid (CSF);	Amikacin (AMK) Ciprofloxacin (CIP) Colistin (COL) Gentamicin (GEN) Imipenem (IPM) Levofloxacin (LVX) Meropenem (MEM) Tobramycin (TOB)

[1] Penicillin meningitis (PEN_MENI): Susceptible (S) if MIC breakpoint ≤ 0.06 µg/mL; Resistant (R) if MIC breakpoint >0.06 µg/mL

[2] Penicillin non-meningitis (PEN_NMEN): S if MIC breakpoint ≤0.06 µg/mL; R if MIC breakpoint >2 µg/mL.

[3] Amoxicillin-clavulanic acid systemic infection (AMC) : S if MIC breakpoint ≤ 8 µg/mL ; R if MIC breakpoint >8 µg/mL.

[4] Amoxicillin-clavulanic acid uncomplicated urinary tract infection (AMC-UC) : S if MIC breakpoint ≤ 32 µg/mL; R if MIC breakpoint >32 µg/mL.

[5] Cefuroxime intravenous (CXM_IV): S if MIC breakpoint ≤ 0.0001 µg/mL; R if MIC breakpoint >8 µg/mL (definition EUCAST V10[8])

[6] Cefuroxime oral, uncomplicated urinary tract infection (CXM_PO): S if MIC breakpoint ≤ 8 µg/mL; R if MIC breakpoint >8 µg/ml (definition EUCAST V10[8]).

[7] Temocillin (TEM): EUCAST breakpoints were introduced in 2020[9]. Please make sure to indicate if other guidelines were used (e.g. BSAC).

Table 2. EARS-BE 2021 main antimicrobial group combinations under surveillance

Microorganism	Antimicrobial group	Antimicrobial tests
Escherichia coli **(ESCCOL)**	Aminopenicillins	AMX, AMP
	Fluoroquinolones	CIP, OFX, LVX, MFX, NOR
	Third-generation cephalosporins	CTX, CRO, CAZ
	Aminoglycosides (+ Amikacin)	GEN, TOB (,AMK)
	Carbapenems	IPM, MEM
	Polymyxins	COL
Klebsiella pneumoniae **(KLEPNE)**	Fluoroquinolones	CIP, OFX, LVX, MFX,NOR
	Third-generation cephalosporins	CTX, CRO, CAZ
	Aminoglycosides (+ Amikacin)	GEN, TOB (,AMK)
	Carbapenems	IPM, MEM
	Polymyxins	COL
Proteus mirabilis **(PRTMIR)**	Aminopenicillins	AMX, AMP
	Aminoglycosides (+Amikacin)	GEN, TOB (, AMK)
	Fluoroquinolones	CIP, OFL, LVX, NOR
	Third-generation cephalosporins	CTX, CRO, CAZ
	Carbapenems	IPM, MEM
Pseudomonas aeruginosa **(PSEAER)**	Piperacillin-tazobactam	TZP
	Ceftazidime	CAZ
	Fluoroquinolones	CIP, LVX
	Aminoglycosides (+ Amikacin)	GEN, TOB (,AMK)
	Carbapenems	IPM, MEM
	Polymyxins	COL
Acinetobacter baumannii **(ACIBAU)**	Fluoroquinolones	CIP, LVX
	Aminoglycosides (+ Amikacin)	GEN, TOB (,AMK)
	Carbapenems	IPM, MEM
Acinetobacter spp., other than Acinetobacter baumannii **(ACINSP)**	Polymyxins	COL
Streptococcus pneumoniae **(STRPNE)**	Penicillins	PEN, OXA
	Macrolides	ERY, CLR, AZM
	Fluoroquinolones	LVX, NOR, MFX
	Third-generation cephalosporins	CTX, CRO
Staphylococcus aureus **(STAAUR)**	MRSA	MET, OXA, FOX, FLC, CLO, DIC
	Fluoroquinolones	CIP, OFX, LVX, NOR
	Linezolid	LNZ
	Rifampicin	RIF
	Vancomycin	VAN
Enterococcus faecalis **(ENCFAE)** ***Enterococcus faecium*** **(ENCFAI)**	Aminopenicillins	AMX, AMP
	High-level aminoglycoside resistance	GEH
	Linezolid	LNZ
	Teicoplanin	TEC
	Vancomycin	VAN

Table 3. EARS-BE 2021 epidemiological variables at isolate level
(variables in grey are required, variables in light grey are recommended)

VariableName	**1 – LaboratoryCode**
Description	Laboratory code unique for the laboratory in which antimicrobial susceptibility testing is performed, assigned by national EARS-BE coordinator within SCIENSANO/NSIH. Note: this is not the SCIENSANO/NSIH hospital code; Contact the national EARS-Net coordinator within SCIENSANO if unknown. No need to provide this code if fixed for the entire file, in this case please provide the code as part of the email exchange For data submitted by a national reference laboratory: this is the code of the **local** laboratory that provided the sample.
Required	Yes
Data type	Coded Value
VariableName	**2 - SampleDate**
Description	Date when sample was taken. This date should fall in 2021
Required	Yes
Data type	Date
Code	Exact date only, "YYYY-MM-DD"
VariableName	**3 - Specimen**
Description	Isolate source The source of the isolate (i.e. blood/CSF/urine)
Required	Yes
Data type	Coded Value
Code	Enter data corresponding to the requested combination of "Pathogen", "Specimen" and "AMR test" in Table 1 '***EARS-BE 2021 microorganism, specimen source and antimicrobial resistance test combinations***'. BLOOD = Blood; CSF = Cerebrospinal fluid; URI = Urine
VariableName	**4 - Indication (only for urinary samples)**
Description	Indication for sampling : screening or clinical (e.g. diagnosis)
Required	No, but recommended for urinary samples.
Data type	Coded Value
Code	S = Screening; C = Clinical; UNK = Unknown.
VariableName	**5 - PatientId**
Description	Code used by the lab to uniquely identify a patient. Important note: a patient ID is crucial for the de-duplication of the data. This code should identify the patient, not the admission within a hospital. If there is no Patient ID available, SCIENSANO/NSIH will produce one based on the patient's personal information: Surname/First name/Date of birth /Postal code. These data are required, if there is no patient ID available. Due to the sensitive nature of this variable, the Patient ID will be converted by SCIENSANO/NSIH to an anonymous patient counter.

Required	Yes
Data type	Text
VariableName	**6 - Gender**
Description	Gender
Required	No
Data type	Coded Value
Code	M = Male F = Female O = Other UNK = Unknown
VariableName	**7 - Age** or **BirthDate**
Description	Age of the patient when the sample was taken, Alternatively, provide the patient's birth date.
Required	No
Data type	Numeric or Date
Code	Integer or Exact date "YYYY-MM-DD"
VariableName	**8 – PatientType**
Description	Origin of patient. Is the patient at the moment the sample is taken admitted in an acute care hospital (inpatient - INPAT), or not (outpatient-OUTPAT or other-O). 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".
Required	No, but recommended
Data type	Coded Value
Code	INPAT= Admitted (Inpatient) OUTPAT= Outpatient O = Other (e.g. emergency room) UNK=Unknown
VariableName	**9 – Hospital**
Description	Identifier for the acute care hospital where the sample was taken. Use a national hospital code (NSIH or RIZIV/INAMI for example), or the name of the hospital if unknown. Note: this is **not** the laboratory code!
Required	No
Data type	Text
VariableName	**10 - HospitalUnitType**
Description	Hospital department at time of sample collection.
Required	No
Data type	Coded Value
Code	ICU = Intensive Care Unit; O = non-ICU; UNK = Unknown.
VariableName	**11- DateOfHospitalisation**
Description	Date of admission in acute care hospital
Required	No
Data type	Date
Code	Exact date only, "YYYY-MM-DD"

VariableName	**12 - IsolateId**
Description	Code assigned by lab to uniquely specify an isolate. Will be used for data de-duplication.
Required	No, but recommended
Data type	Text
VariableName	**13 - Pathogen**
Description	Pathogen Species and genus of the pathogen which has been isolated from the sample.
Required	Yes
Data type	Coded Value
Code	Provide data corresponding to the requested combination of "Pathogen", "Specimen" and "AMR test" of Table 1 '***EARS-BE 2021 microorganism, specimen source and antimicrobial resistance test combinations***'. STRPNE = *Streptococcus pneumoniae* STAAUR = *Staphylococcus aureus* ENCFAE = *Enterococcus faecalis* ENCFAI = *Enterococcus faecium* ESCCOL = *Escherichia coli* KLEPNE = *Klebsiella pneumoniae* PRTMIR = *Proteus mirabilis* PSEAER = *Pseudomonas aeruginosa* ACIBAU = *Acinetobacter baumannii* ACINSP = *Acinetobacter spp.*, other than *Acinetobacter baumannii* spp.

Table 4. EARS-BE 2021 epidemiological variables at antimicrobial resistance test level (variables in grey are required)

VariableName	**14 – AMRtest**
Description	Code specifying the antimicrobial susceptibility test. Confirmation tests are restricted to following species:
Required	Yes
Data type	Coded Value,
Code	Provide data corresponding to the requested combination of "Pathogen", "Specimen" and "Antimicrobial Test" of Table 1 '***EARS-BE 2020 microorganism, specimen source and antimicrobial resistance test combinations***'
VariableName	**15 – Result_lab**
Description	Final interpretation result of all different susceptibility tests performed (SIR)
Required	Yes
Data type	Coded Value
Code	Final interpretation result of all different susceptibility tests performed, based on EUCAST breakpoints. Starting with data collected for 2019, the updated EUCAST definitions of susceptibility testing categories are used: **S - Susceptible**, standard dosing regimen: A microorganism is categorised as "Susceptible, standard dosing regimen", when there is a high likelihood of therapeutic success using a standard dosing regimen of the agent. **I - Susceptible, increased exposure**: A microorganism is categorised as "Susceptible, Increased exposure" when there is a high likelihood of therapeutic success because exposure to the agent is increased by adjusting the dosing regimen or by its concentration at the site of infection. **R - Resistant**: A microorganism is categorised as "Resistant" when there is a high likelihood of therapeutic failure even when there is increased exposure.
VariableName	**16 - ReferenceGuidelinesSIR**
Description	Guidelines for determining clinical breakpoint for antimicrobial susceptibility of the isolate. In case of EUCAST, provide the version used to interpret submitted ASTs. Eg « EUCASTV9 » , and add exceptions for the ASTs submitted
Required	Yes
Data type	text
Code	BSAC = British Society for Antimicrobial Chemotherapy EUCASTV*X.X* = European Committee on Antimicrobial Susceptibility Testing V*X.X* CLSI = Clinical and Laboratory Standards Institute NAT = National O = Other

Table 5. EARS-BE 2021 epidemiological variables at laboratory level
(variables in grey are required, variables in light grey are recommended)

VariableName	**17 - LaboratoryCode**
Description	Laboratory code unique for each laboratory BE, assigned by national EARS-Net BE coordinator within SCIENSANO/NSIH Note: this is not the SCIENSANO/NSIH hospital code; Contact the national EARS-Net coordinator within SCIENSANO if unknown. No need to provide this code if fixed for the entire file, in this case please provide the code as part of the email exchange For data submitted by a national reference laboratory: this is the code of the **local** laboratory that provided the sample.
Required	Yes
Data type	Coded Value
VariableName	**18 – LaboratoryAddress**
Description	Full laboratory name and address
Required	Yes
Data type	Text
VariableName	**19 – ContactPerson**
Description	Contact person in the laboratory
Required	Yes
Data type	Text
VariableName	**20 – Email**
Description	Email address of the contact person
Required	Yes
Data type	Text
VariableName	**21 – NumCultureSetsBlood**
Description	Annual number of blood culture sets performed in the laboratory. If possible, specify for any hospital (code) associated to the laboratory.
Required	Yes, when AST results on blood cultures were submitted
Data type	Numeric
Code	Exact number
VariableName	**22 – NumCulturesUrine**
Description	Annual number of urine cultures performed in the laboratory. If possible, specify for any hospital (code) associated to the laboratory.
Required	Yes, when AST results on urine cultures were submitted.
Data type	Numeric
Code	Exact number
VariableName	**23 – LIMSSystem**
Description	Laboratory Information Management System (LIMS) used in the laboratory
Required	No, but recommended
Data type	Code
Code	MOLIS, CORTEX, GLIMS, O=Other

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