Datacall

European Antimicrobial Resistance Surveillance For Belgium (EARSBE, EARSBE-URI, EARSBE-AMR) - Data call for 2023 data, including case and data definitions, and instructions for participating laboratories.

April 2024

Authors

Aline Vilain, aline.vilain@sciensano.be, T+32 2 642 51 71

Katrien Latour, katrien.latour@sciensano.be, T+32 2 642 57 62

Morgan Pearcy, morgan.pearcy@sciensano.be t+ 32 2 642 67 10

Contents

LIST OF ABREVIATIONS

AST	Antimicrobial susceptibility test
EARS-Net	European Antimicrobial Resistance Surveillance Network
EARS-BE	European Antimicrobial Resistance Surveillance : Belgium
ECDC	European Center of Disease Prevention and Control
EQA	External Quality Assessment
GLASS	Global Antimicrobial Resistance and Use Surveillance System
MRGN	Multidrug-resistant gram-negative bacteria
MRSA	Methicillin-resistant *Staphylococcus aureus*.
NSIH	Service of National Surveillance of Infections in Healthcare settings, Sciensano
NSIH-AMR	Mandatory national AMR surveillance (MRSA, MRGN, VRE) coordinated by NSIH.
VRE	Vancomycin- or linezolid-resistant enterococci.
WHO	World Health Organization

I. DESCRIPTION AND OBJECTIVES

This document provides laboratories of Belgium with instructions for the submission of 2023 data to EARS-BE[1], the Belgian branch of the European Antimicrobial Resistant Surveillance Network (EARS-Net[2]).

EARS-Net is the main European epidemiologic surveillance system for Antimicrobial resistance (AMR) and is coordinated by the European Centre of Disease Prevention and Control (ECDC).

On a yearly basis, EARS-Net collects and reports AMR data within commonly occurring pathogens isolated from human invasive specimens and provides important indicators on the occurrence and emergence of AMR in European countries.
The Sciensano service "Healthcare-associated infections and antimicrobial resistance" (NSIH) coordinates the EARS-BE surveillance and collects data for Belgium to submit to Europe. In turn, ECDC shares EARS-Net annual data with the Global Antimicrobial surveillance system of the World Health Organization (GLASS-WHO[3]). Participation in the EARS-BE surveillance is on a voluntary basis.

This document relies on the standards and definitions laid out by EARS-Net and summarizes these for the participating laboratories, with a few additions specific to the Belgian network.
Three types of data collection are proposed, differing from each other by the range of sample types included. Laboratories may choose to which one they wish to participate :

- **EARSBE**: annual antimicrobial susceptibility testing (AST) results of **blood and cerebrospinal fluid samples** positive for *Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa, Acinetobacter spp., Acinetobacter baumannii, Streptococcus pneumoniae, Staphylococcus aureus, Enterococcus faecalis* and *Enterococcus faecium*.
- **EARSBE-URI**: annual AST results according to **EARSBE data collection** and **additionally of urine samples** positive for *E. coli, Proteus mirabilis, K. pneumoniae, P. aeruginosa, E. faecalis* and *E. faecium*.
- **EARSBE-AMR** (hospital laboratories only): annual AST results according to **EARSBE and EARSBE-URI data collections** and **additionally of other clinical samples positive for** *E. coli, K. pneumoniae, P. aeruginosa, A. baumannii, S. aureus, E. faecalis and E. faecium* satisfying NSIH-AMR[4] inclusion criteria.

Data collection according to **EARSBE-AMR** is new since 2022, and invites laboratories associated to an acute care hospital to submit 2023 AST results from <u>all clinical isolates</u> for the specified pathogens, resulting in a common data collection for both EARSBE and the national NSIH-AMR surveillance[4] of methicillin resistant *Staphylococcus aureus* ("MRSA"), multi-resistant Gram-negative bacteria ("MRGN"), and vancomycin resistant enterococci ("VRE"). The objectives of such *harmonised EARSBE-AMR data collection* are to:

- Improve the quality of data for the NSIH-AMR surveillance by collecting detailed AST data instead of aggregated data.
- Increase the number of participants in the EARS-BE project by proposing an integrated data collection method.
- Prepare for further harmonization with national surveillances of Healthcare-associated infections, and for integration of such integrated national AMR surveillance in the Healthdata[5] (data collection and processing) and Healthstat (reporting) environments.

Hospital laboratory's EARSBE-AMR AST-level 2023 data will be used to reproduce the main NSIH-AMR indicators for resistance of included hospital sites, and to compare these with the indicator results as declared by the hospital as part of the annual NSIH-AMR surveillance registration. The main AMR indicators obtained from EARSBE-AMR 2023 data are those specified in the NSIH-AMR surveillance protocol[4], except for the ones on healthcare-associated MRSA and MRSA present at admission (as defined by the MRSA surveillance protocol). See sections IV. "Inclusion of laboratories, samples, pathogens and tests" and V. "Preparing and submitting data" for further details.

Note that participation to the EARSBE-AMR data collection still implies participation to annual AMR-MRSA, -MRGN and –VRE surveillances to enable comparison with indicators obtained through EARSBE-AMR AST data.

Participation to EARSBE(-URI/AMR) grants the inclusion of the laboratory in the ECDC 2024 External quality assessment (EQA) which is voluntary and free of charge. See section VII. "ECDC External quality assessment 2024".

II. CHANGES WITH REGARD TO THE PREVIOUS VERSION

INCLUSION OF NEW AST:

For *E.coli, K. pneumoniae P. aeruginosa* and *Acinetobacter* species, five new antimicrobials have been added to the surveillance:

- Cefiderocol,
- Ceftazidime-avibactam,
- Ceftolozane-tazobactam,
- Imipenem-relebactam,
- Meropenem-vaborbactam

III. DEFINITION OF ANTIMICROBIAL RESISTANCE

The microorganism/antimicrobial group combinations that are under surveillance in EARSBE, EARSBE-URI and/or EARSBE-AMR are displayed in Table 1 in Annex. These are derived from the list of followed AMR mechanisms as specified by EARS-NET[6] and EUCAST[7], and updated with specific antimicrobials used for treatment of UTI.

The definition of AMR follows the one of EUCAST. AMR is to be encoded in required variable '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.

IV. INCLUSION CRITERIA FOR LABORATORIES, SAMPLES, PATHOGENS, AND TESTS

1) LABORATORIES

All laboratories in BE, including non-hospital laboratories, are invited to participate.
Exception: the EARSBE-AMR data collection is restricted to laboratories associated to an acute care hospital.

2) SAMPLE TYPES AND PATHOGENS

For **EARSBE** data collection, included isolates are those positive for *E. coli, K. pneumonia, P. aeruginosa, Acinetobacter spp., Acinetobacter baumannii, Streptococcus pneumoniae, S. aureus, Enterococcus faecalis* and *Enterococcus faecium* from **blood** and **cerebrospinal fluid samples.**

For **EARSBE-URI** data collection, included isolates and sample types are those of **EARSBE** and additionally the isolates positive for *E. coli, K. pneumonia, P. aeruginosa, P. mirabilis, E. faecalis* and *E. faecium* from **urine samples**. If urine samples taken for screening purposes are included, these should be differentiated from clinical samples (variable 'Indication', see section V. 'Preparing and submitting data').

For laboratories associated to an acute care hospital, **EARSBE-AMR** data collection implies including isolates and sample types as for **EARSBE and EARSBE-URI** data collections above, and additionally the isolates obtained from **all other clinical samples**, specified as urine (for *S. aureus* and *A. baumannii*), faeces, and other clinical samples (other pathogens).

Figure 1: Sample types and pathogens included according to the data collections option.

Data collections	EARSBE	EARSBE-URI		EARSBE-AMR		
Sample types	Blood/CSF	Blood/CSF +	Urine	Blood/CSF +	Urine +	All other clinical samples
Pathogens	*E. coli,* *K. pneumoniae,* *P. aeruginosa,* *Acinetobacter spp.,* *A. baumannii,* *S. pneumoniae,* *S. aureus,* *E. faecalis* *E. faecium*	*E. coli,* *K. pneumoniae,* *P. aeruginosa,* *Acinetobacter spp.,* *A. baumannii,* *S. pneumoniae,* *S. aureus,* *E. faecalis* *E. faecium*	*E. coli,* *P. mirabilis,* *K.pneumoniae,* *P. aeruginosa,* *E. faecalis* *E. faecium.*	*E. coli,* *K. pneumoniae,* *P.aeruginosa,* *Acinetobacter spp.,* *A. baumannii,* *S. pneumoniae,* *S. aureus,* *E. faecalis* *E. faecium*	*E.coli,* *P.mirabilis,* *K.pneumoniae,* *P.aeruginosa,* *E.faecalis* *E.faecium*	*E. coli,* *K. pneumoniae,* *P. aeruginosa,* *A. baumannii,* *S. aureus,* *E. faecalis* *E. faecium*

3) AST

For all three data collections:

- Are included only the AST performed for the pathogen-test combinations listed in Table 2 (see Annex).
- Results must come from samples obtained in 2023.
- Only results for identified patients are included. Results from (external) quality assessments are excluded.
- Results coming from activities of the participating laboratory as a reference center (national or international referral of clinical isolates) are excluded.

- Only AST results reported to the clinician are accepted. Exception: AST results should be included if these were not included in the clinical reports with the objective of guiding treatment choices (so-called *masking or selective reporting of AST results*).
- ! For AST for which several breakpoints exist (intravenous vs oral ; meningitis vs non-meningitis) (see Table 2), laboratories must specify which are used, either directly in the data file, either in the participation_details form (see section V. 'Preparing and submitting data').

  Of note :

  - No further inclusion criteria are required:
    No further selection on patient type, hospital site, etc. should be performed.
    No deduplication rules are to be performed by the laboratory.
    These will be performed by Sciensano/NSIH.

  - For submission to ECDC in light of EARS-Net, only laboratories following the EUCAST guidelines are eligible since 2019.
    For the participation in any of the three EARS-BE data collections, no restriction on guidelines is performed.

V. PREPARING AND SUBMITTING DATA

1) AST RESULTS AND OTHER VARIABLES

The participating laboratory should prepare and submit annual 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.

The EARSBE(-URI/AMR) 2023 data file prepared by the laboratory will contain variables on patient, isolate and AST level. It will thus include information on a particular AST result as a separate observation, and repeat all information on the level of the isolate, sample and patient over all included ASTs. Tables 3 and 4 in Annex give the data collection definitions for isolate and AST information, respectively.

For **EARSBE data**, variables 'SampleDate', 'Specimen', 'PatientId', 'Pathogen', 'AMRtest', and 'Result_lab' are **mandatory variables** (Required='Yes'); Observations without at least this info cannot be further processed by Sciensano/NSIH. Next to these, variables ('PatientType', 'IsolateId') are labelled 'recommended' (Required='No, but recommended') because they contain values needed for deduplication of raw data (see section VI. '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.

For **EARSBE-URI data**, variable 'Indication' is additionally required if results from screening samples are included, and this to separate results from those of clinical samples.

For **EARSBE-AMR data**, apart from extended inclusion criteria (see previous section), variables "Indication", "Hospital", "PatientType", "IsolateId", "DateOfHospitalisation" are **additionally required** in order to calculate NSIH-AMR aggregated hospital indicators for 2023 using these data. Also, see section V.2) "Participation details" on additional variables describing how NSIH-AMR aggregated hospital indicator results for 2023 are obtained. Also, note that submitting 2023 results for the NSIH-AMR surveillance is still required when submitting EARSBE-AMR 2023 AST 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 EARSBE data, and following the section VI. 'Validation and reporting' (see below).

The data definitions of Tables 3 and 4 should be taken as a guideline, and do 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 EARSBE(-URI/AMR) codification. These codebooks will be included in the annual laboratory report; their validation by the laboratory is an essential step in obtaining qualitative 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 do not 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.

2) PARTICIPATION DETAILS

In addition to the data file, participating laboratories are requested to also submit the filled-in Excel form called **ParticipationDetails.xlsx**, providing info on the laboratory, the chosen data collection and the breakpoints used. Tables 5 and 6 describe the information requested in sheet 1 and 2 of the participation details form, respectively.

In the sheet1 of the participation details form, shown in Table 5, laboratories should specify the type of data collection, participation to the ECDC EQA, the annual numbers of blood and urine culture sets performed by the laboratory, and the laboratory information management system (LIMS) in place, which will be used to prioritize on projects for automation and validation of EARSBE data exports from current LIMS. Furthermore, if **EARSBE-AMR** AST data are submitted, the laboratory should also provide details on how AMR aggregated indicators for 2023 are (or will be) obtained, in order to interpret possible deviations between AMR indicators obtained from EARSBE-AMR data and those declared by the associated hospitals in light of the NSIH-AMR surveillance. See Table 5 for details.

In the sheet 2 of the form, shown in Table 6, laboratories are requested to specify, for each of the pathogen-test combination listed, the following information:

- Confirm that 2023 results of the mentioned pathogen x AST combination can be included in national reporting;
- Specify which guideline (EUCAST or other) was followed in 2023 for interpretation of the AST results;
- If EUCAST was followed, specify whether results were obtained using meningitis or non-meningitis breakpoints, or using intravenous or uncomplicated urinary tract breakpoints, for those ASTs where EUCAST specifies these breakpoints.

3) PROCEDURES FOR DATA EXTRACTION

To assist laboratories in extracting and preparing EARSBE(-URI/-AMR) AST-level data from their laboratory database(s), the following semi-automatic procedures are available:

- Procedures for extraction of annual AST data from GLIMS platforms using MISPL scripts;

- Procedure for periodic (including annual) extraction from INFECTIO platforms;

The EARSBE(-URI/-AMR) contact persons are available for further information on these procedures. We also invite laboratories to share procedures for extraction of EARSBE(URI/-AMR) from the above and other laboratory platforms.

4) SUBMITTING DATA

AST data need 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 EARSBE(-URI/-AMR) 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 EARSBE(-URI/-AMR) data proceeds by sending an email to the EARSBE coordinators at Sciensano/NSIH including the filled-in participation_details.xlsx form as attachment. A laboratory that tested zero isolates in 2023 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.

In order to ensure a secured data transfer of the annual AST results and upon reception of the mail with the participation_details.xlsx form, participants will receive a link to submit their data using the **Belnet Filesender platform** (https://www.belnet.be/nl/diensten/identity-mobility-federation/filesender).

Please refer to the NSIH/EARS webpage on https://www.sciensano.be/en/projects/european-antimicrobial-resistance-surveillance-belgium for the deadlines of submitting EARSBE(-URI/AMR) 2023 data, for confirming participation to the ECDC 2024 EQA, and for contact details of EARSBE coordinator(s) at Sciensano/NSIH.

VI. VALIDATION AND REPORTING OF LABORATORY AND NATIONAL RESULTS
(performed by Sciensano/NSIH)

1) EARSBE AND EARSBE-URI DATA

Conversion and standardization: Upon reception, laboratory data will be *converted* and *standardized* by Sciensano/NSIH to the EARS-BE 2023 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 ('Pathogen', 'Specimen', 'Antimicrobial test') combinations of Table 2 are kept for further treatment and analysis.

De-duplication of EARSBE(-URI) laboratory data: For each laboratory, sample type (blood/CSF versus urine), pathogen (variables 'LaboratoryCode', 'Specimen', '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 EARSBE laboratory report is available from the EARSBE coordinators at Sciensano/NSIH. 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 2023.

Sharing of standardized/deduplicated national EARSBE data with ECDC and WHO: Additionally, national 2023 data on blood/CSF isolates with pseudonymized laboratory, hospital and patient identifiers will be submitted to ECDCfor inclusion in theirannual report on AMR. Note that, from 2019 onwards, AST results interpreted following non-EUCAST guidelines are not included in the EARS-Net surveillance and report but will continue to be included & reported by EARSBE surveillance.

2) EARSBE-AMR DATA

The subset of EARSBE-AMR data corresponding to EARSBE and/or EARSBE-URI inclusion criteria will be reported following the procedures of the previous section.

Additionally, EARSBE-AMR data will be used to compare NSIH-AMR indicators for resistance obtained from these data for the included hospital site(s) with the declared NSIH-AMR indicators. Inclusion of patients, sample types, pathogens, ASTs differs from that of the EARSBE(-URI) AST data, and will be described at a later stage. Reporting of NSIH-AMR results using EARSBE-AMR data is restricted to the hospital level, no national results will be derived from these data.

VII. ECDC EXTERNAL QUALITY ASSESSMENT 2024

All laboratories reporting EARS-BE 2023 data are 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 laboratory wanting to be included into the 2024 EQA should confirm their participation by sending an email to the Sciensano/NSIH coordinator, and specify it in the

participation_details.xlsx form (See section V. Preparing and submitting data) The EARSBE Sciensano webpage (https://www.sciensano.be/en/projects/european-antimicrobial-resistance-surveillance-belgium) shows the final date for subscribing to the 2024 EQA (different from the final date for submitting EARSBE 2023 data).

- Starting from May 2024, the contractor contacts the coordinator of EARSBE at Sciensano/NSIH 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 submit data to EARSBE(-URI/AMR) 2023 and subscribed to the EQA.
- 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 summer or 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, disk 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 EARSBE 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.

VIII. RESTRICTIONS AND CONFIDENTIALITY MEASURES

Sciensano/NSIH applies the same restrictions and confidentiality measures to a particular laboratory's EARS-BE 2023 data and its contents as it does to other Sciensano/NSIH monitoring. This means that a particular laboratory’s data (or its contents) will only serve the objectives stated in the EARS-BE 2023 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.

IX. ANNEXES

TABLE 1. EARSBE(-URI) AND EARSBE-AMR 2023 ANTIMICROBIAL GROUP COMBINATIONS UNDER SURVEILLANCE

Microorganism	Antimicrobial group	Antimicrobial tests	EARSBE (-URI)*	EARSBE-AMR*
Escherichia coli ***Klebsiella pneumonia*** ***Proteus mirabilis***	Aminopenicillins (*E coli* and *P mirabilis* only)	Amoxicillin, Ampicillin	X	
	Penicillins, other	Amoxicillin-clavulanic acid, Piperacillin-tazobactam, Temocillin (urine samples only)	X	
	3rd-gen. cephalosporins	Cefotaxime, Ceftriaxone, Ceftazidime Ceftazidime-avibactam	X	X
		Cefepime, Cefuroxime Cefiderocol Ceftolozane-tazobactam	X	
	Carbapenems	Imipenem, Imipenem-relebactam, Meropenem, Meropenem-vaborbactam, Ertapenem	X	X
	Aminoglycosides	Gentamicin, Tobramycin, Amikacin	X	
	Fluoroquinolones	Ciprofloxacin, Ofloxacin, Levofloxacin	X	
	Fluoroquinolones, other	Norfloxacin, Ofloxacin	X	
	Tetracyclins	Tigecycline	X	
	Polymyxins (*E coli* and *K pneumoniae* only)	Colistin	X	
	Miscellaneous (urine samples only)	Fosfomycin, Nitrofurantoin, Trimethoprim, Trimethoprim-sulfamethoxazole	X	
Pseudomonas aeruginosa	Penicillins	Piperacillin-tazobactam	X	
	3rd-gen. cephalosporins	Ceftazidime Ceftazidime-avibactam	X	X
	Cephalosporins, other	Cefepime Cefiderocol Ceftolozane-tazobactam	X	X
	Carbapenems	Imipenem, Imipenem-relebactam, Meropenem, Meropenem-vaborbactam	X	X
	Aminoglycosides	Tobramycin, Amikacin	X	X
	Fluoroquinolones	Ciprofloxacin, Levofloxacin	X	X
	Polymyxins	Colistin	X	
Acinetobacter spp., ***Acinetobacter baumannii***	Cephalosporins	Ceftazidime-avibactam Cefiderocol Ceftolozane-tazobactam		
	Carbapenems	Imipenem, Imipenem-relebactam, Meropenem, Meropenem-vaborbactam	X (no URI)	X
	Aminoglycosides	Gentamicin, Tobramycin, Amikacin	X (no URI)	
	Fluoroquinolones	Ciprofloxacin, Levofloxacin	X (no URI)	
	Polymyxins	Colistin	X (no URI)	
Streptococcus pneumoniae	Penicillins	Penicillin (Oxacillin)	X (no URI)	
	3rd-gen. cephalosporins	Cefotaxime, Ceftriaxone	X (no URI)	
	Fluoroquinolones	Levofloxacin, Moxifloxacin (Norfloxacin)	X (no URI)	
	Macrolides	Erythromycin, Clarithromycin, Azithromycin	X (no URI)	
Staphylococcus aureus	MRSA	Cefoxitin, Oxacillin (Meticillin, Flucloxacillin, Cloxacillin, Dicloxacillin)	X (no URI)	X
	Fluoroquinolones	Ciprofloxacin, Ofloxacin, Levofloxacin (Norfloxacin)	X (no URI)	
	Glycopeptides	Vancomycin	X (no URI)	
	Oxazolidinones	Linezolid	X (no URI)	
	Miscellaneous	Rifampicin	X (no URI)	
Enterococcus faecalis	Aminopenicillins	Amoxicillin, Ampicillin	X	

Enterococcus faecium	Aminoglycosides	Gentamycine high level resistance	X	
	Glycopeptides	Vancomycin, Teicoplanin	X	X
	Oxazolidinones	Linezolid	X	X
	Miscellaneous (Urine samples only)	Nitrofurantoin, Trimethoprim-sulfamethoxazole	X	

* X = Pathogen – AST combination included

TABLE 2. EARSBE(-URI/AMR) 2023 SPECIMEN, MICROORGANISM, AND ANTIMICROBIAL RESISTANCE TEST COMBINATIONS.

Specimens	Microorganism	Antimicrobial test (EUCAST breakpoints if specified)
For **EARSBE**: • blood; • cerebrospinal fluid; For **EARSBE-URI**: EARSBE specimens and additionally: • Urine (optional); (see exceptions for each microorganism) For **EARSBE-AMR**: EARSBE-URI specimens and additionally: • faeces; • all other clinical samples; (see exceptions for each microorganism)	***Streptococcus pneumoniae*** Only results from **blood and/or CSF isolates** will be kept for analysis	Oxacillin (OXA) Penicillin (PEN): Meningitis or Non-meningitis breakpoints[1] Cefotaxime (CTX): Meningitis or Non-meningitis breakpoints[1] Ceftriaxone (CRO): Meningitis or Non-meningitis breakpoints[1] Azithromycin (AZM) Clarithromycin (CLR Erythromycin (ERY) Levofloxacin (LVX) Moxifloxacin (MFX) Norfloxacin (NOR)
	Staphylococcus aureus Only results from **blood and/or CSF**, and global results for **all clinical samples** (in case of EARSBE-AMR data) will be presented	Cefoxitin (FOX) Oxacillin (OXA) Cloxacillin (CLO), if OXA not reported Dicloxacillin (DIC), if OXA not reported Flucloxacillin (FLC), if OXA not reported Meticillin (MET), if OXA not reported Ciprofloxacin (CIP) Levofloxacin (LVX) Norfloxacin (NOR) Vancomycin (VAN) Rifampin (RIF) Linezolid (LNZ)
	Enterococcus faecalis ***Enterococcus faecium***	Ampicillin (AMP) Amoxicillin (AMX) Gentamicin-High (GEH) Vancomycin (VAN) Teicoplanin (TEC) Linezolid (LNZ) Nitrofurantoin (NIT): urine samples only Trimethoprim/Sulfamethoxazole (SXT): urine samples only
	Escherichia coli ***Klebsiella pneumoniae*** ***Proteus mirabilis*** For *P mirabilis*, only results from **urine samples** will be kept for analysis	Ampicillin (AMP): *E coli* and *P mirabilis* only Amoxicillin (AMX) Amoxicillin-clavulanic acid (AMC): Intravenous or Uncomplicated UTI breakpoints[2] Piperacillin-tazobactam (TZP) Temocillin (TEM): urine samples only Cefotaxime (CTX): Meningitis or Non-meningitis breakpoints[1] Ceftazidime (CAZ) Ceftazidime-avibactam (CZA) Ceftriaxone (CRO): Meningitis or Non-meningitis breakpoints[1] Cefuroxime (CXM), Intravenous or Uncomplicated UTI breakpoints[2] Cefepime (FEP) Cefiderocol (FDC) Ceftolozane-tazobactam (CZT) Imipenem (IPM) Imipenem-relebactam (IMR) Meropenem (MEM): Meningitis or Non-meningitis breakpoints[1] Meropenem-vaborbactam (MEV)

Specimens	Microorganism	Antimicrobial test (EUCAST breakpoints if specified)
		Ertapenem (ERT) Amikacin (AMK) Gentamicin (GEN) Tobramycin (TOB) Ciprofloxacin (CIP) Levofloxacin (LVX) Moxifloxacin (MFX) Norfloxacin (NOR): urine samples only Ofloxacin (OFX) Tigecycline (TGC): *E. coli* only Colistin (COL): *E coli* and *K pneumoniae* only Fosfomycin (FOS): Intravenous or Uncomplicated UTI breakpoints[2] Nitrofurantoin (NIT): *E coli* only, urine samples only Trimethoprim (TRIM): urine samples only Trimethoprim/Sulfamethoxazole (SXT): urine samples only
	Pseudomonas aeruginosa	Piperacillin/Tazobactam (TZP) Piperacillin (PIP) Ceftazidime (CAZ) Ceftazidime-avibactam (CZA) Cefepime (FEP) Cefiderocol (FDC) Ceftolozane-tazobactam (CZT) Imipenem (IPM) Imipenem-relebactam (IMR) Meropenem (MEM): Meningitis or Non-meningitis breakpoints[1]; Meropenem-vaborbactam (MEV) Amikacin (AMK) Gentamicin (GEN) Tobramycin (TOB) Ciprofloxacin (CIP) Levofloxacin (LVX); Colistin (COL)
	Acinetobacter baumannii ***Acinetobacter spp., other than Acinetobacter baumannii*** Only results from **blood and/or CSF**, and global results for **all clinical samples** (in case of EARSBE-AMR data) will be presented	Ceftazidime-avibactam (CZA) Cefiderocol (FDC) Ceftolozane-tazobactam (CZT) Imipenem (IPM) Imipenem-relebactam (IMR) Meropenem (MEM): Meningitis or Non-meningitis breakpoints[1] Meropenem-vaborbactam (MEV) Amikacin (AMK) Gentamicin (GEN) Tobramycin (TOB) Ciprofloxacin (CIP) Levofloxacin (LVX) Colistin (COL)

[1] for included AST, specify as AST_MEN (meningitis) and/or AST_NMEN (non-meningitis). If possible, provide results using non-meningitis breakpoints irrespective of sample type;

[2] for included AST, specify as AST_IV (intravenous) and/or AST_UTI (uncomplicated UTI). If possible, provide results using intravenous breakpoints irrespective of sample type;

TABLE 3. EARSBE 2023 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 EARSBE 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 2023
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	BLOOD = Blood; CSF = Cerebrospinal fluid; URI = Urine (only for EARSBE-URI and -AMR data collections); FAE = Faeces (only for EARSBE-AMR data collection); O = Other clinical samples (only for EARSBE-AMR data collection);
VariableName	**4 – Indication**
Description	Indication for sampling : screening or clinical (e.g. diagnosis)
Required	Only for EARSBE-URI and EARSBE-AMR data collections, and if results from screening samples are included;
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). If the sample is taken during a patients' hospital stay for dialysis or other day hospital care, PatientType should be classified as "O". If the sample is taken in the emergency room or during consultation in the hospital, PatientType should be classified as "OUTPAT". If the sample is taken during any other patient admission in the hospital as inpatients, PatientType should be classified as "INPAT".
Required	For EARSBE(-URI) data collection: not required, but **recommended**; For **EARSBE-AMR** data collection: **required**;
Data type	Coded Value
Code	INPAT= Admitted (Inpatient) OUTPAT= Outpatient O = Other 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	For EARSBE(-URI) data collection: not required; For **EARSBE-AMR** and multiple hospital sites data collection: **required**;
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	For EARSBE(-URI) data collection: not required; For **EARSBE-AMR** data collection: **required**;
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	For EARSBE(-URI) data collection: not required; For **EARSBE-AMR** data collection: **required**;
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 '***EARSBE 2023 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. EARSBE 2023 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 ‘***EARSBE 2023 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.

TABLE 5. EARSBE, EARSBE-URI, EARSBE-AMR 2023 PARTICIPATION DETAILS SHEET 1

(USE XLS TEMPLATE)

Laboratory code 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.
Laboratory name Full laboratory name
Laboratory address Full laboratory address
Contact person(s) Contact person(s) in the laboratory
Email address(es) Email address(es) of the contact person(s)
Participation Participation type Codes EARSBE = annual AST data of blood & CSF isolates; EARSBE-URI = annual AST data of blood, CSF & urine isolates (includes EARSBE); EARSBE-AMR = annual AST data of all clinical isolates (includes EARSBE-URI);
ECDC EQA 2023 Participation Participation to the voluntary and free-of –charge ECDC External quality assessment 2024 (Yes, No)
Results from screening samples included Specify if the data contains results from screening samples (Yes, No); Specify only if Participation = EARSBE-URI or EARSBE-AMR;
Hospital sites List of hospital codes (NSIH or other); Specify only if Participation EARSBE-AMR;
Number of blood culture sets Total number of blood culture sets performed in the laboratory in 2023.
Number of urine cultures Total number of urine cultures performed in the laboratory; Specify only if Participation = EARSBE-URI or EARSBE-AMR;
LIMSSystem Laboratory Information Management System (LIMS) used in the laboratory Codes CORTEX; MOLIS; GLIMS; Other;
Info on AMR aggregated indicators for 2023 Specify only if Participation = EARSBE-AMR; • **Date used for inclusion of isolates:** Codes Sample date; Other date (specify); • **Removal of Isolates from patients hospitalized during the previous year** (Yes, No):

- **Definition of hospitalized patients follows the EARSBE 'INPAT' definition**:
  Codes
  Yes;
  No, samples obtained in the emergency room from patients with subsequent hospitalization are marked as obtained from hospitalized patients;
  No (specify other differences);
- **Treatment of results of recurring ASTs from multiple isolates within a patient's hospitalization**:
  - Codes
  - Single AST result is kept (first occurring);
  - Single AST result is kept (most resistant);
  - Single AST result is kept (other criteria);

  Multiple AST results are kept (specify criteria);

TABLE 6. EARSBE, EARSBE-URI, EARSBE-AMR 2023 PARTICIPATION DETAILS SHEET2 (USE XLS TEMPLATE)

Details about included AST results:

For each Organism x AST combination of Table 2 and for which results are submitted, provide info as follows:

- **Include 2023 Results**: results for *organism_AST* to be included in the 2023 reporting, can be left to 'Yes' if all results are to be included, change to 'No' if submitted results of a particular *organism_AST* need to be removed
  Codes
  Yes;
  No;
- **Reference used in 2023**: Guideline used in 2023 for determining clinical breakpoint for antimicrobial susceptibility of the isolate against this antimicrobial. Can be provided globally (Organism&AST=ALL) with exceptions specified for a particular *organism_AST* only.
  Codes
  EUCAST,
  BSAC = British Society for Antimicrobial Chemotherapy,
  CLSI = Clinical and Laboratory Standards Institute,
  NAT = National,
  Other;
- **EUCAST version used in 2023:** Can be provided globally (Organism&AST=ALL) with exceptions specified for a particular *organism_AST* only.
  Codes
  - V12 = 2022;
  - V11 = 2021;
  - V10 = 2020;
  - V9 = 2019;

  Other;
- **EUCAST breakpoints used in 2023:**
  If Reference = EUCAST and for selected ASTs only (see Table 2 and XLS template);
  Specify the use of Non-meningitis or Intravenous breakpoints
  Codes

- NMEN = Non-meningitis for all sample types (preferred);
- MEN = Meningitis for CSF samples, Non-meningitis for other samples;
- IV = Intravenous for all samples types (preferred);
- UTI = (uncomplicated) UTI for urine samples, Intravenous for other;

  BOTH = Results of both breakpoints provided as separate ASTs;

  OTHER = Other use of breakpoints, please provide details in 'additional comments'

- **Additional comments:** free text, for example specify the date in case of change of guideline/method/breakpoint during the year;

X. REFERENCES

1. EARS-BE : European Antimicrobial Resistance Surveillance - Belgium. https://www.sciensano.be/en/projects/european-antimicrobial-resistance-surveillance-belgium

2. EARS-Net : European Antimicrobial Resistance Surveillance. ECDC https://www.ecdc.europa.eu/en/about-us/networks/disease-networks-and-laboratory-networks/ears-net-data

3. GLASS : Global Antimicrobial Resistance and Use Surveillance System. WHO. https://www.who.int/initiatives/glass

4. NSIH-AMR - National surveillance of antimicrobial resistance webpage. Sciensano. https://www.sciensano.be/en/projects/national-surveillance-antimicrobial-resistance.

5. Healthdata : https://healthdata.sciensano.be/fr/%C3%A1-propos-healthdatabe

6. European Centre for Disease Prevention and Control (ECDC). TESSy - The European Surveillance System. EARS-Net reporting protocol 2023. (2024). https://www.ecdc.europa.eu/en/publications-data/antimicrobial-resistance-amr-reporting-protocol-2024

7. EUCAST guidelines. The European Committee on Antimicrobial Susceptibility Testing. Breakpoint tables for interpretation of MICs and zone diameters. Version 12. (2022).