EURL-PH-AMR

EU Reference Laboratory for public health on Antimicrobial Resistance

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Document overview

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Deliverable name	Plan for External quality assessment (EQA) exercise of performance of laboratories participating in European Antimicrobial Resistance Surveillance Network (EARS-Net)
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Project website	-

Introduction

The European Antimicrobial Resistance Surveillance Network (EARS-Net) is the largest publicly funded system for antimicrobial resistance (AMR) surveillance in Europe. Data from EARS-Net play an important role in raising awareness at the political level, among publihjælprc health officials, in the scientific community, and among the general public (https://www.ecdc.europa.eu/en/about-us/networks/disease-networks-and-laboratory-networks/ears-net-data). EARS-Net performs surveillance of antimicrobial susceptibility of eight bacterial pathogens commonly causing infections in humans:

- *Escherichia coli*
- *Klebsiella pneumoniae*
- *Pseudomonas aeruginosa*
- *Acinetobacter species*
- *Streptococcus pneumoniae*
- *Staphylococcus aureus*
- *Enterococcus faecalis*
- *Enterococcus faecium*

The EARS-Net reporting protocol defines the panels of antimicrobial agent combinations under surveillance for each species. In addition, the EUCAST guidelines for the detection of resistance mechanisms and specific types of resistance of clinical and/or epidemiological importance explain the mechanisms of resistance and describe the recommended methods of detection for key species–antimicrobial group combinations.

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 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 by offering annual external quality assessments (EQA).

The overall scope of the EARS-Net EQA is to assess the quality of species identification and the accuracy of the interpretation of phenotypic antimicrobial susceptibility testing (AST) results, and to evaluate the overall comparability of routinely collected AST results between European laboratories. Laboratories reporting EARS-Net Surveillance data to ECDC can participate in the EARS-Net EQA.

Annually ECDC publish a summary report on the *External quality assessment (EQA) of the performance of laboratories participating in the European Antimicrobial Resistance Surveillance Network (EARS-Net)*.

DTU Food has organised the annual EARS-Net EQA exercises since 2021 and will lead the planning and conduction of the annual EARS-Net EQAs under the EURL-PH-AMR contract. The annual EQA preparation (e.g. written materials and communication, procedures and protocols, selection of bacterial strains for the EQA, preparation of expected results and scoring) will be coordinated with and approved by ECDC. The strains will primarily originate from DTU Food, SSI and EDL biobanks. Expected results and associated scoring will be determined by analysing AST results obtained by

DTU Food and two external reference laboratories. The list of national EARS-Net EQA Coordinators (NEC) and participating laboratories will be compiled by DTU Food with input from ECDC. The consensus phenotypic AST profile will be compared with detection of acquired antimicrobial resistance genes and chromosomal point mutations from whole-genome sequencing data. DTU Food will prepare up to 1,200 packages containing live cultures of six strains, shipped to the NECs for further distribution. The EQA protocol and a manual on how to use the EQA webtool to report results will be available on a dedicated website. DTU Food developed and hosts a password-protected webtool for submission of results. Individual evaluation reports and certificates will be available through the webtool. Country reports will be shared with NECs and ECDC. A survey will be conducted to recover participant feedback. A comprehensive summary report for the EQA exercise using the ECDC technical report template will be produced.

The EARS-Net EQAs will be conducted in compliance with recommendations in internationally recognised guidelines and standards such as ISO 17025:2017 (equivalent to ISO 15189:2022), ISO 20776-1:2020 and ISO 17043:2023. DTU Food is accredited according to the three above standards with concrete plans to have the EARS-Net EQA covered by this accreditation.

The present document is giving a timeline for the different activities to be carried out during the 2025 EARS-Net EQA.

Timeline and descriptions of activities

Activity 1: List of National EARS-Net EQA coordinators for the 2025 EARS-Net EQA - due 31 March 2025
After ECDC approval the invitation material will be sent to the National Focal Points for Antimicrobial Resistance (NFPs for AMR) and the 'Operational Contact Points for microbiology – Diseases Caused by Antimicrobial-Resistant Microorganisms (AMR)' (OCPs), to identify the national coordinator for the EQA exercise. The contact information of the NFPs and OCPs for AMR (name, address, telephone number and email address) will be provided by ECDC by 1 February 2025.

Activity 2: List of potential participating laboratories – due 30 May 2025
After ECDC approval the invitation material will be sent to the National EQA Coordinator (NEC), with the NFPs in copy, with information about the rationale and objectives of the EQA exercise, the expected activities for the NEC, the reporting requirements and timelines, including the minimum requirements for obtaining an EQA certificate, the provisions for intellectual property, data ownership and sharing, and planned post-EQA activities such as reports, scoring, publications and participant feedback survey.
With the help of the appointed NEC, compile a list of potential participating laboratories with official contact information (clearly identifiable: LabID, name, address, telephone number and email address). The list of participating laboratories from the 2024 EARS-Net EQA will be used as a starting point. The National Coordinator will be given the option of sending out the information letter to the laboratories instead of DTU Food.

Activity 3: Contact the potential participating laboratories – due 30 May 2025
After ECDC approval of an information letter drafted by DTU Food, the laboratories, with the National EARS-Net Coordinators in copy, will receive an information letter indicating the rationale and objectives of the EQA exercise, the reporting requirements and timelines, including the minimum requirements for obtaining an EQA certificate of participation (laboratories acquire a 'certificate for participation' if they report interpretation of AST results for the six strains included in the EQA), the provisions for intellectual property, data ownership and sharing, and planned post-EQA activities such as reports, scoring, publications and participant feedback survey. The material should also indicate any participation requirement, e.g. for the participating laboratories to be reporting data to EARS-Net.

Activity 4: Agreement of selected bacterial strains to be included in the EQA - due 30 January 2025
In collaboration with ECDC, select the bacterial strains to be included in the EQA exercise.

Activity 5: Draft protocol – due 30 April 2025
Provide the protocol to be used in the EQA exercise for ECDC approval.

Activity 6: Final protocol – due 31 May 2025
Share the final protocol with ECDC. The protocol, after agreement with ECDC, will be uploaded to the EURL-PH-AMR website and a link will be provided to the participants.

Activity 7: Consensus results of the selected strains – due 31 May 2025
The AST results from two external reference laboratories will be used together with results obtained at DTU Food to prepare the consensus results for the panel of selected bacterial strains and

antimicrobials. Results should include non-truncated MIC values, disc diffusion results and intended scoring taking the “level of difficulty” and “severity of error” into account for each organism-antimicrobial combination to be shared with ECDC for agreement on consensus results.

Activity 8: Prepare the selected specimen panel – due 30 June 2025
DTU Food will prepare the selected specimen panel including associated quality assurance procedures to guarantee the viability of the samples.

Activity 9: Prepare all EQA specimens and prepare one package for every participating laboratory – due 30 June 2025
DTU Food will prepare the individual packages for each participating laboratory (maximum 1200 laboratories).

Activity 10 (Milestone 18): Shipment of material – due 30 June 2025
Send packages with EQA samples (already labelled with the specific local laboratory address) in overpacks to the NECs in a secure manner. Each package will include a cover letter, approved by ECDC, with safety instructions on how to handle the EQA samples.

Activity 11: EQA results and codebook – due 30 August 2025
Collect the EQA results including replies to questions on e.g. routine AST methods and guideline for clinical breakpoints, compile and share the resulting database, anonymised, with ECDC. The questions is developed in collaboration with ECDC. A codebook describing the variables in the database will be shared as well. The national EQA results will be shared with the NEC.

Activity 12: Produce and send individual feedback of the results to each participating laboratory – due 31 October 2025
The participants will receive email information that the individual laboratory reports can be downloaded via the secure webtool provided by DTU Food. The individual reports include, for each strain-antimicrobial combination, the expected and reported AST results and respective interpretations and the evaluation score, as well as explanations, after approval by ECDC, on the difficulty of AST interpretations. A copy of the reports will be shared with the NEC.

Activity 13: Prepare and distribute ECDC certificates of participation in the EQA exercise – due 30 November 2025
The participants will receive email information that the certificate approved and signed by ECDC is available for download via the secure webtool provided by DTU Food. Submission of interpretation of all 6 bacterial samples is a minimum requirement of participation. A copy of the certificates will be shared with the NEC.

Activity 14: Produce and distribute country reports to each national EQA coordinator – due 31 January 2026
Share a country report with the NEC and the respective NFP in copy providing all EQA results including scoring, from the participating laboratories using anonymised laboratory identifiers. The report should include the results from all participating laboratories (including a national summary and results for each individual laboratory) and include a short conclusion on the capacity of participating laboratories and, if needed, recommendations for improvement, to the NEC. A copy of the national reports will be shared with ECDC.

Activity 15: Prepare and distribute the ECDC EQA participant feedback survey – due 15 November 2025

The questions for the feedback survey are provided by ECDC by 30 August 2025 and will be shared in the form of a web-based electronic questionnaire on a secure platform. Participation will be anonymised.

Activity 16: Collect the survey data and share the database with ECDC – due 15 December 2025

The results from the feedback survey will be extracted from the survey platform and shared with ECDC.

Activity 17 (Deliverable 7.2): Produce a comprehensive summary report for the whole EQA exercise using the ECDC technical report template – due 31 January 2026

Produce an EU level report providing a summary of all EQA results, including scoring. The report should include a short conclusion on the capacity of participating laboratories and, if needed, recommendations for improvement.

Activity 18 (Milestone 19): Present the results of the EQA exercise at a webinar – due 28 February 2026

A webinar on the 2025 results of the EARS-Net EQA will be organised and all participating laboratories, National EARS-Net EQA Coordinators, NFPs for AMR, OCPs for microbiology - AMR, ECDC, HaDEA and the European Commission will be invited.