

# Minutes of Meeting

# Meeting of the EARS-Net Disease Network Coordination Committee

Meeting called by	Hanna MERK, Pete KINROSS, Dominique MONNET		
Facilitator	Hanna MERK, Pete KINROSS		
Note taker	Hanna MERK		
	<b>DNCC Members:</b> Arjana TAMBIĆ, Dorota ŻABICKA, Gunnar SKOV SIMONSEN (DNCC Chair), Helena RIBIČ, Helena ŽEMLIČKOVÁ (Deputy Chair), Jos MONEN, Marie-Cécile PLOY, Stephen MURCHAN, Tim ECKMANNS; <b>DNCC Observers:</b> Carlo GAGLIOTTI (ECDC contractor), Danilo LO FO WONG (WHO/Europe), Thierry NAAS (ESGARS)		
Attendees	<b>ECDC (presenters):</b> Hanna MERK ( <u>Chair and Minutes</u> ), Pete KINROSS, Dominique MONNET		
	ECDC (other attendees): Angelo D'AMBROSIO, Holger HASTÉN ( <u>Support</u> ), Tommi KÄRKI		

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## Scope and purpose

The purpose of this meeting was to update and ask the members of the European Antimicrobial Resistance Surveillance Network (EARS-Net) Disease Network Coordination Committee (DNCC) for advice on activities that were conducted in 2023 and that are planned for 2024 and onward; including the annual epidemiological report (AER), the EARS-Net reporting protocol and analysis, the upcoming EARS-Net network meeting, the upcoming EARS-Net External Quality Assessment (EQA) exercises, EU reference laboratory for public health on AMR in bacteria (EURL AMR) and the further development of EARS-Net surveillance.

### Agenda

10:00 - 10:10	Welcome and housekeeping (Hanna MERK, ECDC)
10:10 - 10:30	Update on ECDC and ARHAI (Dominique MONNET, ECDC)
10:30 - 11:15	EARS-Net update (Hanna MERK, Pete KINROSS, ECDC)
11:15 – 11:45	Resistance to new antibiotics - surveillance plans (Hanna MERK, Pete KINROSS, ECDC)
11:45 - 12:00	EARS-Net reporting protocol (Hanna MERK, ECDC)
12:00 - 13:00	Lunch break
13:00 - 13:30	Estimated incidence of bloodstream infections with resistant bacteria - plans (Hanna MERK, ECDC; Carlo GAGLIOTTI)
13:30 - 14:15	Cerebrospinal fluid specimens in EARS-Net (Hanna MERK, Pete KINROSS, ECDC; Carlo GAGLIOTTI)
14:15 – 14:35	EARS-Net EQA EURL and reports (Pete KINROSS, ECDC)
14:35 – 14:45	EARS-Net network meeting (Pete KINROSS, ECDC)
14:45 – 14:55	AOB (Hanna MERK, ECDC)
14:55 – 15:00	Closing of meeting (Hanna MERK, ECDC)

# Agenda items

### Welcome and housekeeping

### Attachment 1: A - EARS-Net\_DNCC\_meeting\_20240417.pdf

ECDC opened the meeting. No objections were raised to the **recording** of the meeting for minutes taking purposes. The meeting scope, which was to provide updates and seek advice from the EARS-Net DNCC members on the activities conducted in 2023 and those planned for 2024 and onwards, was presented. Then the meeting **agenda** was presented. Several DNCC members/observers submitted **annual declarations of interest** (ADoIs) that contained potential conflicts of interest (CoIs). Prior to the meeting, when advised by ECDC Legal Services, ECDC requested clarifying information from the DNCC member/observer. The meeting participants were asked to raise if, given the agenda there was anything from their ADoI that they wished to raise or highlight, and whether there had been any relevant updates to their ADoI. None were raised by the participants. ECDC informed that declared interests do not automatically imply a CoI. However, the presence of a CoI always leads to mitigation measures. For example, these measures might include not inviting a participant to attend the entire meeting or a particular agenda item, and/or inviting a meeting participant to state their CoIs at the start of the meeting.

### Update on ECDC and ARHAI

### Attachment 2: B - EARS-Net DNCC\_2024\_Update on ECDC and ARHAI.pdf

Dominique MONNET (DoMo), Head of the Antimicrobial Resistance (AMR) and Healthcare-Associated Infections (HAI) (ARHAI) Section and Acting Group Leader AMR/antimicrobial consumption (AMC), provided an update on the activities and EU legislation relevant to the EARS-Net DNCC.

On 20 February 2024, Dr Pamela RENDI-WAGNER was nominated as the **new Director of ECDC**. Her hearing by the European Parliament Committee on Environment, Public Health and Food Safety (ENVI) took place on 19 March 2024. Dr RENDI-WAGNER's planned start at ECDC is mid-June 2024.

Several **additional organisational changes** had taken place at ECDC in 2024, including: (a) DoMo is now Acting Group Leader AMR/AMC (in addition to Head of Section ARHAI); (b) Piotr KRAMARZ is Acting Chief Scientist; (c) Ines STEFFENS is Acting Head of Unit for the Scientific Methods and Standards Unit (SMS). In addition, the following upcoming changes were planned for before July 2024: (a) an Acting Head of the Executive Office in the Director's Office; (b) Antje DAUME as Acting Head of Section in Human Resources; and (c) an Acting Head of the Disease Programmes Unit. The information will be updated on the <u>ECDC webpage</u> as the changes are implemented.

From the **new EU regulations** that came into effect in November 2022 and amended (a) the regulation establishing the ECDC and (b) repealed a previous decision on serious cross-border threats to health, three articles were highlighted. (1) The work related to Article 7 of the Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU, which pertains to **Member States' reporting on prevention, preparedness, and response planning**. The reporting had been completed and compiled into a draft report.

(2) Concerning Article 8, which involves **the assessment of the reporting through country visits** with AMR and HAIs being a priority area, a methodology was developed and up to eight visits are planned for 2024 (Belgium, 11-13 May; Finland, 10-14 June; Estonia, 1-4 October; Spain, 14-18 October; Sweden, 21-25 October; Malta, 24-29 November; Luxembourg, December TBC; Portugal TBC). DoMo also raised that each country visit was expected to require 15 working-days per ECDC staff conducting the visit.

(3) Regarding Article 13, which calls for **strengthened data collection and the definition of disease-specific European surveillance standards**, it was highlighted that, as per the Regulation, data should be reported at the NUTS2 level when available, and the list of communicable diseases and related special health issues, case definitions and procedures for the operation of the surveillance network was going to be updated. So far, it looks like the corresponding implementing acts will not include the distinction between case-based and event-based surveillance as originally proposed by ECDC, but that this distinction will most likely be made in a delegated act on "surveillance standards" under Article 14 "Digital platform for surveillance". Moreover, the adoption of the implementing and delegated acts was foreseen for early 2025.

Regarding the establishment of an **EU reference laboratory (EURL) for AMR in bacteria**, a consortium led by Statens Serum Institut (SSI, Denmark) and also composed of Danmarks Tekniske Universitet (DTU, Denmark) and the Clinical Microbiology Region Kronoberg (Sweden) has been designated by the European Commission.

Additionally, it was mentioned that the recent **Council Recommendation on stepping up EU actions to combat AMR in a One Health approach**,

- encourages Member States to close surveillance and monitoring gaps by 2030. This included ensuring inclusion
  of not only invasive isolates but also other isolates in reporting to ECDC.
- welcomes action to

- develop EU infection prevention and control (IPC) guidelines in human health. This work was foreseen to be carried out in coordination with ECDC. Moreover, this work was expected to start in 2025, while avoiding overlap with 2nd EU Joint Action on Antimicrobial Resistance and Healthcare-Associated Infections (EU-JAMRAI 2).
- work on developing EU guidelines for the treatment of major common infections in humans and for perioperative prophylaxis. ECDC expects to be asked to contribute to this work.
- included recommended targets for AMC and AMR. This work also involved setting up indicators and sharing best
  practice on their use, that would support the attainment of the recommended targets. ECDC will be involved in
  this work.

Regarding investments under EU4Health for 2021-2027 the following were highlighted:

- a) The EU-JAMRAI 2 with an EU budget of € 50 million and a budget from Member States of € 12.5 million started in January 2024.
- b) AMR Interventions and Projections, for which the Organisation for Economic Co-operation and Development (OECD) will receive € 600 000. The disease burden work previously carried out by ECDC was foreseen as work that would possibly be carried out by OECD in the future, on an annual basis.
- c) AMR and HAIs work by WHO/Europe will receive € 1 million for 2024. Discussion to achieve complementary actions by ECDC and WHO/Europe rather than overlap is ongoing.

It was also raised that the **ECDC ARHAI team has several large outputs already achieved or planned for 2024** (a) the already published 4th Joint Interagency Antimicrobial Consumption and Resistance Analysis (JIACRA) report (2019-2020-2021 data); (b) the Report on the 3rd point prevalence survey (PPS) of HAIs and antimicrobial use in acute care hospitals (2022-2023 data); (c) the EARS-Net AER, November 2024 (2023 data); (d) the European Surveillance of Antimicrobial Consumption Network (ESAC-Net) AER, November 2024 (2023 data); (e) the European Antimicrobial Resistance Genes Surveillance Network (EURGen-Net) report on genomic-based surveillance of carbapenem resistant and/or colistin-resistant Enterobacterales at EU level (CCRE survey of EURGen-Net); (f) the AER on surgical site infections (SSIs); (g) the AER on HAIs in intensive care units (ICUs); (h) the AER on *Clostridoides difficile* infections; (i) the Expert Opinion on "Colonisation by multidrug-resistant Enterobacterales after international travel: risk factors and implications for surveillance, infection prevention and control, and patient"; (j) the Scientific Report on the impact of the use of azole fungicides, other than as human medicines, on the development of azole-resistant *Aspergillus* sp..

Moreover, **several ARHAI meetings/events are scheduled for 2024**, in addition to the ongoing EARS-Net DNCC meeting. Some have already occurred. These were the Healthcare-associated Infections Surveillance Network (HAI-Net) SSI meeting, the HAI-Net ICU meeting, the HAI-Net *C. difficile* infection meeting, and the EURGen-Net Expert Meeting for the carbapenem-resistant *Acinetobacter baumannii* (CRAb) survey Expert Group. The upcoming meetings are the ESAC-Net DNCC meeting, the Joint HAI-Net/Sciensano meeting, followed by the EU Presidency AMR high-level meeting, the EURGen-Net Network Meeting (CRAb survey protocol), the EARS-Net network meeting, the HAI-Net DNCC meeting, the EURGen-Net network meeting, the multi-drug resistant organisms (MDRO) course, another EARS-Net DNCC meeting, the ESAC-Net network meeting, and European Antibiotic Awareness Day (EAAD). There are also the ongoing and planned country visits under Article 8 (see below), and 'standard' visits to Greece, Sweden, North Macedonia, and Montenegro, with one additional country visit yet to be scheduled.

In conclusion it was mentioned that **AMR remains a priority for ECDC**, although there is an ongoing overall priority exercise at ECDC for 2025 and onwards. DoMo also considered strengthening of EARS-Net essential because of new indicators, targets and health burden estimates (including achieving better country representativeness and better completion of epidemiological variables). Moreover, integration/harmonisation with EURGen-Net was also essential, and the expansion of EARS-Net for example, towards new antibiotics, new pathogens, new sample types, new epidemiological variables, and structure and process indicators deserved discussion.

### **DNCC feedback**

The DNCC Chair expressed concern at the volume of ECDC ARHAI/EARS-Net resources spent on repetitive resource intense work such as JIACRA and country visits. Moreover, the DNCC Chair advised to highlight to the European Commission (EC) that this meant having to spend less resources on improving surveillance. In reply, ECDC clarified that as these were requests the EC, the requests could be negotiated but not rejected by ECDC.

The DNCC Chair also expressed concern regarding (a) the EURL for AMR in bacteria having a public health focus rather than focus on the clinical microbiology laboratories that participate in EARS-Net, and (b) the work on treatment guidelines. Similarly, Marie-Cécile PLOY (MCPI) expressed that work related to treatment guidelines was also conducted within EU-JAMRAI 2. ECDC clarified that the EURL would be discussed at upcoming DNCC meetings.

Danilo LO FO WONG enquired whether data on new antibiotics and new sample types might be shared with the WHO Global Antimicrobial Resistance and Use Surveillance System (GLASS). ECDC clarified that data sharing with GLASS would take place, under the data sharing agreement with WHO/Europe.

Arjana TAMBIĆ (ArTa) advised against the inclusion of other types of samples as data quality would likely be poor and this could affect data representativeness and as a result data comparability. One of the reasons for the poor data quality could

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be limited IT support in countries. If the data burden increases due to the increase in the number of samples, this would require more IT support as the countries would need to rely on downloading data from their laboratory information systems. The issue might be resolved by helping countries develop laboratory information systems and transfer these data to the national level. ECDC replied that efforts in e-Health are ongoing.

### **ECDC** action

• Consider including the EURL topic for further discussion in upcoming EARS-Net DNCC meetings.

### EARS-Net update

### Attachment 3: C - EARS-Net update.pdf

Hanna MERK (HaMe) gave a presentation on the current **EARS-Net DNCC** and an upcoming change to the DNCC Members, with Jos MONEN (JoMo) stepping down after 25 May 2024. ECDC and the DNCC thanked JoMo for all his work with EARS-Net. There will not be an *ad hoc* election to replace JoMo. The current DNCC mandate ends on 19 February 2025 and a new DNCC election is foreseen for November-December 2024.

The **main achievements** of EARS-Net in 2023 and so far in 2024 were presented, as well as **planned work for 2024**. The latter included:

- Reports and products *(in chronological order):* 
  - Technical report on blood culture set definition work Q2 2024.
  - EQA report 2023 data October 2024.
  - 2023 data in ECDC Surveillance Atlas ahead of EAAD 2024.
  - AER 2023 data EAAD 2024.
  - 2023 data joint ECDC-WHO/Europe summary EAAD 2024.
  - EQA multi-annual report (2021-2024) Q4 2024.
  - 2024 EARS-Net data call Spring/Summer 2024.
- 2024 EARS-Net EQA Summer 2024.
- Survey of EARS-Net laboratories on new antibiotics 2024/2025.
- Manuscript work that was ongoing:
- EARS-Net estimated incidence rates methodology and results improving surveillance.
- Manuscript work under consideration:
  - Descriptive summary of the European Antimicrobial Resistance Surveillance System (EARSS) and EARS-Net activity.
  - EARS-Net 2023 data findings.
  - Surveillance results before, during and after non-pharmaceutical interventions against COVID-19.
  - EARS-Net EQA 2021-2024 data.
- Meetings:
  - DNCC meeting 17 April 2024 virtual ongoing.
  - Network meeting 11-12 June 2024 in person.
  - *Resources permitting* Other meetings to be determined.
  - Country visits in accordance with the <u>Regulation on serious cross-border threats to health, article 8 'Assessment</u> of prevention, preparedness and response planning'
    - Belgium, Finland, Estonia, Spain, Sweden, Malta, and Luxembourg.
- Activities related to the <u>EU Council recommendation on stepping up EU actions to combat antimicrobial resistance</u> in a One Health approach (2023/C 220/01)
  - Work on EpiPulse Cases for the next annual EARS-Net data collection:
    - migration of historical AMR surveillance data.
    - preparation and release of EpiPulse Cases.
- Together with the designated EURL for AMR in bacteria, prepare for EARS-Net EQAs after 2024.
- Under consideration resources permitting:
  - Criteria for adding new antibiotics under surveillance.
  - Digital EQA (DEQA).

For the **upcoming data call**, the WHONET and ECDC data management team are available for support. ECDC will strictly enforce the EARS-Net data call deadlines:

1 July: The EARS-Net data call closes. *All data must be reported and approved in EpiPulse by this date.* 

1 July-15 August: Validation of submitted data. *The second half of August is no longer available for validation.* 

16 August: Database frozen for analysis. *All data corrections must be completed before this date. Data available in EpiPulse at this date will be included in the ECDC analyses.* 

In 2024, EAAD (18 November) is ion a Monday and ECDC EAAD activities will take place on Monday 18 November 2024.

The DNCC members and observers were informed that the current **planned DNCC input requests** for 2024 include feedback on: the 2024 EQA panel consensus results; the 2023 EQA report; the Joint Summary 2023 data - EU/EEA section; the 2023 AER report; the next EQA panel, process & material; the reporting protocol and analysis changes; the blood culture set definition technical report; the EQA multi-annual report; and the estimated incidence uncertainty criteria. Moreover, resources permitting, this would also include work on inclusion criteria and analysis of new antibiotics in EARS-Net; a survey of EARS-Net laboratories on new antibiotics; and a digital EQA (DEQA) exercise.

The **JIACRA** IV report was published in February 2024. ECDC, the European Food Safety Authority (EFSA) and the European Medicines Agency (EMA), are awaiting the EC request for a fifth JIACRA report. The work will be led by EFSA, is expected to include data for 2022-2025, and to be published by the end of 2026. Work is ongoing towards agreeing on a more limited scope, shorter report, and increased harmonisation of the data sources.

As in 2023, ECDC intends to produce a **joint ECDC WHO/Europe AMR summary** in 2024. There will be no joint comprehensive AMR report in 2024 with WHO/Europe. ECDC is the lead publishing agency for the summary in 2024, and a 2024 production timeline has been agreed. The plan is that ECDC and WHO/Europe publish the joint summary on 18 November 2024. Work on an overall co-publishing agreement between ECDC and WHO/Europe is ongoing. Moreover, data will be shared with WHO/Europe for GLASS purposes – within the data sharing agreement and established routine.

ECDC also provided an update about the ongoing **e-Health projects**. (a) the pilot project as part of the in the European Health Data Space (EHDS) that ECDC contributes to is progressing with colleagues from Belgium, Croatia, and Finland. This pilot project includes data transfer agreements; agreeing on and setting up secure processing environments; preparing for analysis of data by country; and preparing for analysis of aggregated data from multiple countries. While the next steps are to run the analyses in Q2 2024, and evaluate and report on the outcome in Q4 2024. (b) ECDC's SURveillance from Electronic Health Data (SUREHD) project is ongoing with 19 participating countries and seven observer countries. In 2024, the project focuses on surveillance of healthcare-associated blood stream infections (HA-BSI incidence), including AMR patterns. In the following 12 months, work on this project will include a protocol, multiple meetings, country and EU/EEA reports and a scientific manuscript.

The results from the **blood culture set definition** work done by ECDC in 2023 was presented by Pete KINROSS (PeKi). A short discussion with the DNCC followed about the proposed update, which the work indicated would be feasible for 14 out of 17 countries:

"Total number of blood culture requests: One request consists of any number of blood culture bottles that are taken for diagnostic purposes from one patient on a single occasion in a hospital served by laboratory(s) that report to EARS-Net. The data on the number of requests should be from the hospitals for which the aggregated denominator (NumPatDaysForRateCov) is provided.

If these data are unavailable, please estimate the number, by dividing the total number of blood culture bottles taken by the estimated total number of bottles per blood culture request."

A short update was also provided by PeKi about the **EURGen-Net CRAb survey**. A microbiological Expert Group was established using the ECDC Expert Directory with eleven experts, including DNCC member Dorota ŻABICKA (DoZa) and DNCC observers Thierry NAAS (ThNa; ESGARS) and Christian GISKE (EUCAST), and a first meeting was held on 26 March 2024. Most of the meeting agenda was dedicated to the laboratory manual that accompanies the survey protocol, such as data collection on phenotypic AMR, patient-level antimicrobial use, and criteria to identify eligible species within *Acinetobacter* spp..

#### **DNCC feedback**

Regarding the blood culture set definition, the DNCC Chair indicated that a focus on 'request' rather than the current 'sets' might not be technically feasible. ArTa said that the definition was unclear and might therefore not generate an improvement in data quality. ArTa favoured 'bottles' over 'sets' or 'request'. MCPI said that, as clinical guidelines indicate larger number of bottles, 'request' may be the better option. However, both MCPI and Helena ŽEMLIČKOVÁ (HeZe) agreed with the DNCC Chair that data on 'requests' could be difficult to extract from the laboratory information systems.

### ECDC action

 Consider whether to present the current blood culture set definition results and proposed definition update at the upcoming EARS-Net network meeting before or after having produced a technical report on the results that will be shared with the DNCC for feedback.

### **Resistance to new antibiotics - surveillance plans**

### Attachment 4: D - Resistance to new antibiotics – surveillance plans.pdf

PeKi presented an overview on recent updates to the list of **antimicrobials included in ECDC ARHAI surveillance networks**. The overview showed that while updates had been made to HAI-Net ICU and EARS-Net, neither ESAC-Net, nor HAI-Net PPS nor HAI-Net HALT (HAI and antimicrobial use in long-term care facilities) had changed their included antimicrobials. EURGen-Net, however, could include new antibiotics. So far, HAI-Net ICU plans the inclusion of ceftazidime-

avibactam, meropenem-vaborbactam, imipenem-relebactam, ceftolozane-tazobactam, cefiderocol, temocillin, plazomicin, and eravacycline.

HaMe summarised that **EARS-Net had included new antibiotics**, which allowed their reporting in TESSy/EpiPulse, for the data collection in 2024 based on three main considerations: (a) focus on a current major challenge in the EU/EEA, i.e. carbapenem-resistant Gram-negative bacteria; (b) 'Reserve' antibiotics within the <u>WHO Access, Watch, Reserve (AWaRe)</u> classification system from 2023 used to treat carbapenem-resistant Gram-negative bacteria; and (c) to provide situational awareness on the resistance percentage, at country and EU/EEA level. For *Escherichia coli, Klebsiella pneumoniae, Pseudomonas aeruginosa*, and *Acinetobacter* spp., the included antibiotics were cefiderocol (FDC), ceftolozane-tazobactam (CZT), imipenem-relebactam (IMR), meropenem-vaborbactam (MEV), and ceftazidime-avibactam (CZA).

For the **EARS-Net data analysis** for outputs in Q4 2024, the likely focus will be on carbapenem-resistant isolates and show the percentage of resistance to each of the above-mentioned new antibiotics/combinations and highlight the absence of data. Expected limitations to the analysis include: limited data availability in 2024, the number of years with data, that the combinations may not always be relevant – and could require an update of metadata for 2025, and there would likely be challenges with representativeness and selection bias as it has so far been unclear how/where/why/how often antimicrobial susceptibility testing (AST) was done by the various laboratories that contribute to EARS-Net.

Adding new antibiotics highlighted that there were no **criteria for inclusion of new antibiotics** in EARS-Net surveillance. Based on the work so far, ECDC presented draft considerations that could be used as criteria for the inclusion of new antibiotics in the future:

- 1. The aim would be to acquire information to support interpretation by ECDC EARS-Net of phenotypic AST data that is generated by local/regional/national clinical laboratories in the EU/EEA.
- 2. EARS-Net AMR surveillance data is the relevant surveillance network for the ECDC data collection.
- 3. TESSy/EpiPulse surveillance indicator-based surveillance is the relevant tool for standardised data collection and reporting.
- 4. Invasive isolates are sufficiently suitable for surveillance of resistance to the new antibiotic/s.
- 5. Potential criteria to define antibiotic group:
  - a) included in the WHO AWaRe classification of antibiotics,
  - b) used to treat a specific large, identified threat,
  - c) no matter whether EMA approved or not,
  - d) no matter whether there are European Committee on Antimicrobial Susceptibility Testing (EUCAST) breakpoints or not,
  - e) used to treat one or more EARS-Net pathogens.

ECDC was planning to conduct a **survey of the EARS-Net laboratories** to collect more background information. The survey would be carried out by the EQA contractor in 2024-2025. Currently the thinking was to focus the survey on three potential areas: (a) description of the participating laboratory, (b) whether the new antibiotics were tested for and if so why and how, and (c) how many of the tests were carried out.

### **DNCC feedback**

The DNCC Chair advised that, in the laboratories that contribute to EARS-Net, AST is likely be carried out for only a limited selection of isolates. However, Carlo Gagliotti (CaGa) indicated that, although this may be the case in some countries, other countries are facing the need to test for new antibiotics more frequently.

The DNCC Chair said that there may be issues with the reliability of the AST for several of the new antibiotics. Tim ECKMANNS (TiEc) also indicated that AST for cefiderocol could be challenging and the results unreliable. ThNa agreed with TiEc's assessment. DoZa also raised that for cefiderocol only disk diffusion breakpoints were available from EUCAST.

ArTa added that focussing surveillance and analysis on carbapenem-resistant isolates would be good.

DoZa indicated that there are EUCAST breakpoints for the new antibiotics for Enterobacterales, but not for *Acinetobacter* spp.. Also, inclusion of these new antibiotics in the EARS-Net EQA exercise may be challenging.

Moreover, DoZa said that new antibiotics may not be tested as they may not be available in some countries. TiEc agreed with this concern and highlighted that countries may be using other new antibiotics.

JoMo and the DNCC Chair both argued that EARS-Net indicator-based surveillance was not a good tool for an overview of resistance to new antibiotics. Instead, studies within countries, or event-based reporting, or reporting of specific isolates would be preferable.

The DNCC Chair agreed that the laboratory survey that was planned was a good idea to assess feasibility but suggested a simple laboratory survey and not to ask for information about the laboratory catchment area.

If a new antibiotic were to be included in EARS-Net, it was argued by ArTa and MCPI that existing EUCAST breakpoints would need to be a requirement. This would hopefully resolve the issues raised about technical challenges with AST for new antibiotics.

### **ECDC** action

DoMo summarised that the way forward to be considered by ECDC could be:

- event-based rather than indicator-based surveillance of resistance to new antibiotics with EUCAST breakpoints at this time. Moreover, the isolates could potentially be collected and analysed centrally.
- inclusion of EUCAST breakpoints as a criterion for adding a new antibiotic to EARS-Net surveillance and as a result for its analysis.
- ECDC will consider how to proceed with the laboratory survey based on the feedback received from the DNCC, and at the upcoming EARS-Net Network Meeting.

### **EARS-Net reporting protocol**

### Attachment 5: E - EARS-Net reporting protocol.pdf

HaMe presented changes made to the **EARS-Net reporting protocol for 2024**, including: the regular annual updates, inclusion of new antibiotics, formatting and editing by ECDC editors, an update of the section on 'Reporting to TESSy' as TESSy has moved under EpiPulse, changes due to metadata changes to AMRTEST (the coded value list for 'Serotype' was updated to also contain Type 15B/C, and the new antibiotics were added), and adjustments to reflect analysis changes (norfloxacin/*E. coli* and norfloxacin/*K. pneumoniae* are no longer included under microorganism and antimicrobial agent combinations under surveillance by EARS-Net, and a description of the methodology to calculate the estimated incidence was added).

**Changes for 2025** could include: (a) adjustments to the 'Reporting to TESSy' section as full migration of TESSy to EpiPulse was foreseen in 2024-2025; (b) regular annual updates; (c) analysis text changes for example of the analysis of new antibiotics and limitations to the estimated incidence; (d) metadata changes, for example, the blood culture set definition, and changes as a result of EUCAST breakpoint changes.

### **DNCC feedback**

ArTa would look into EUCAST breakpoint changes and get back to ECDC via email with changes for consideration by ECDC.

### **ECDC** action

• Consider adjusting the reporting protocol to include recent changes of the EUCAST breakpoints.

### Estimated incidence of bloodstream infections with resistant bacteria - plans

# Attachment 6 and 7: F - Estimated incidence of bloodstream infections with resistant bacteria - plans\_adjusted.pdf and F G - Carlo DNCC\_240417.pdf

HaMe indicated that in the **AER produced in 2023 (data for 2022)**, the estimated incidence was calculated for the three key recommended targets. In the **AER being produced in 2024 (2023 data)**, the estimated incidence will be calculated for all bacterial species-antimicrobial group/agent combinations under regular EARS-Net surveillance and routinely presented in the AER. This applies to a table for the EU and also a table in the country summary. Moreover, CaGa presented a suggestion for **criteria on how to indicate when the estimated incidence should be interpreted with caution** and provided examples of their application. In summary, the suggestion was to indicate that incidence estimates should be interpreted with caution if:

- 1. Bacterial species-antimicrobial group/agent combinations with resistance data availability < 75%, for the year. OR\*:
  - 2. Bacterial species-antimicrobial group/agent combinations with:
    - population coverage < 50%  $AND \ge 1$  representativeness indicator 'Low' or 'Medium' or missing, for the year. OR
    - population coverage (≥ 50% and < 75%) AND ≥ 2 representativeness indicators 'Low' or 'Medium' or missing, for the year.

### **DNCC feedback**

Regarding the first criterion about data availability, there was mixed feedback. It was advised to leave it at '< 75%' by TiEc, but the DNCC Chair suggested increasing it to higher than '<75%', for example '<90%'.

For the second criterion, the DNCC Chair and JoMo advised against including population coverage.

CaGa agreed with the input from the DNCC Chair and JoMo.

TiEc and JoMo also raised that the criteria do not include the element of ICU sampling bias and that this was a limitation with the suggested criteria.

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In summary, the DNCC advised that the estimated incidence results should be tagged as associated with limitations if data availability was an issue for fewer isolates, for example by increasing the criterion to `<90%'. Thus, requiring more data than suggested by ECDC. It should also be tagged as associated with limitations if 1 or more representativeness indicators were not `High'. Moreover, population coverage should not be included as part of the limitation criteria.

### **ECDC** action

 Consider the feedback provided by the DNCC on the criteria for tagging estimated incidence as associated with limitations.

\*Note after the meeting: In line with the discussions during the presentation, slide 5 in 'F - Estimated incidence of bloodstream infections with resistant bacteria - plans\_adjusted.pdf' was corrected after the meeting, by replacing the text "1. AND 2." with "1. OR 2.".

### **Cerebrospinal fluid specimens in EARS-Net**

### Attachment 7 and 8: F G - Carlo DNCC\_240417.pdf and G - Cerebrospinal fluid specimens in EARS-Net.pdf

PeKi presented an overview of the **surveillance of** *Streptococcus pneumoniae* by the ECDC Vaccine Preventable Diseases & Immunisation (VPI) section, known as invasive pneumococcal disease (IPD) surveillance. The similarities and differences with ECDC ARHAI/EARS-Net surveillance for *S. pneumoniae* were highlighted. The similarities include annual data collection and collection of phenotypic AMR data. The differences include the focus on cases, the inclusion of all types of samples, and collection of data on clinical presentation and infection outcome. This overlap led to *S. pneumoniae* being reported twice in the ECDC Surveillance Atlas of Infectious Diseases and in AERs. The latest data from IPD surveillance showed a similar pattern to the time series observed in the latest EARS-Net data, i.e. a large increase in the number of reported cases of *S. pneumoniae* BSIs towards the end of 2022 compared to 2018-2021.

CaGa then presented data on **cerebrospinal fluid (CSF) isolates included in the EARS-Net** analysis by species and year in 2018-2022. At EU/EEA level, CSF isolates represented  $\leq 1\%$  of all isolates reported to EARS-Net with the exception of *Acinetobacter* spp. (1.2%-2.8% CSF isolates) and *S. pneumoniae* (5.3%-6.4% CSF isolates). Looking at the proportion of penicillin non-wild-type *S. pneumoniae*, the results for all isolates (including CSF isolates) and for only blood isolates were very close to that of CSF isolates only. For *Acinetobacter* spp., carbapenem resistance percentages in CSF isolates were close to that of all isolates and of only blood isolates.

It was suggested that, for the pathogens with  $\leq$ 1% CSF isolates, the exclusion of CSF isolates would not have any impact on the EU/EEA AMR percentages in EARS-Net outputs. For *S. pneumoniae*, the exclusion of CSF isolates would not have an important impact on the AMR percentages for all isolates reported in EARS-Net outputs. One possible approach could be to perform a separate analysis for CSF isolates, but this would be based on a few isolates and would not be feasible at national level. For *Acinetobacter* spp., the exclusion of CSF isolates does not appear to have a significant impact on the carbapenem resistance percentage.

ECDC followed up by asking the DNCC for advice on whether to keep including CSF isolates in EARS-Net, and related to this also on the ECDC surveillance of *S. pneumoniae*.

### **DNCC feedback**

JoMo advised that keeping CSF isolates in the data collection did not make much difference. Moreover, the current development of specific breakpoints for meningitis led to challenges in how to report and interpret data from CSF isolates. In addition, excluding CSF isolates should allow for a simpler communication of EARS-Net results. This advice was also supported by Stephen Murchan (StMu) and MCPI. The DNCC Chair agreed with this view, but also added that if CSF isolates are kept in EARS-Net, then reporting it separately would be the way to proceed to avoid that data on CSF isolates are misinterpreted due to differences in breakpoints for meningitis.

But other DNCC members advised differently: TiEc suggested to keep collecting CSF isolates in EARS-Net for only *S. pneumoniae*. This was also supported by HeZe. Whereas ArTa suggested keeping CSF isolates in EARS-Net for all included microorganisms, as it was difficult to collect data already as it was and dropping CSF would mean a loss of data.

ArTa also indicated that *S. pneumoniae* allowed EARS-Net to get a better overview of community-acquired infections in addition to the overview provided by other EARS-Net pathogens that are often healthcare-associated. The latter was also supported by HeZe and StMu. Moreover, the DNCC Chair and MCPI both supported keeping *S. pneumoniae* in both EARS-Net and IPD surveillance. However, TiEc indicated that including *S. pneumoniae* twice in the ECDC Atlas could be confusing.

#### **ECDC** action

• Consider the feedback provided by the DNCC.

### **EARS-Net EQA EURL and reports**

### Attachment 9: H - EARS-Net EQA-related.pdf

PeKi presented updates related to the EARS-Net EQA. They included:

- 1. The establishment of an EURL for AMR in bacteria, and that a consortium led by Statens Serum Institut (SSI, Denmark) and also composed of Danmarks Tekniske Universitet (DTU, Denmark) and the Clinical Microbiology Region Kronoberg (Sweden) has been designated to that end. Currently a call for proposal for EURL grants is ongoing, and the first EURLs are expected to start working at the end of Q4 2024. Of particular interest for EARS-Net were the mandatory tasks for the EURL for AMR to conduct EQA exercises specifically for phenotypic AMR for local clinical laboratories, but also the biennial laboratory network meetings. Among the potential additional activities for the EURL were *ad hoc* surveys, and the development and implementation of a DEQA exercise for phenotypic AMR data and organisation of additional meetings. The EURL for AMR is also expected to do work related to EURGen-Net.
- 2. **EARS-Net 2023 EQA results**. All EU/EEA countries participating and collected EQA data from 871 laboratories. Most results were correctly reported but there were also errors, mainly related to *E. coli, K. pneumoniae* and *A. baumannii*.
- 3. The **EARS-Net 2024 EQA** panel was still awaiting final AST results on the selected strains from a reference laboratory. Once these are available (May 2024), the resulting consensus results proposal will be shared with the DNCC for feedback. The EARS-Net 2024 EQA exercise is planned to take place in June-July 2024 with the EQA report being published, after having been reviewed by the DNCC, in Q3-Q4 2025.
- 4. A **multi-annual EQA report** covering 2021-2024 is planned for publication in Q3-Q4 2025. The aim is to publish a short report that would (a) describe participation in the EQA exercises over time and its association with participation in EARS-Net surveillance, (b) comment on AST results by year and over time, and (c) reflect on the scoring system as well as the usefulness and impact of the EARS-Net EQAs. There is also a plan to potentially write and submit a manuscript on the findings.

### **DNCC feedback**

Three DNCC members (the DNCC Chair, MCPI, StMu) indicated that having the EQA exercise during the summer is not ideal, as it is a challenge for not only the participating laboratories but also for national coordination.

Regarding the multi-annual report and the upcoming annual epidemiological report (AER), it was suggested that they also highlight how many of the EARS-Net laboratories participate in the EARS-Net EQA exercise.

For specifically Ireland, StMu indicated that there is no need for DTU to verify directly with the laboratories that are included on national lists for the EQA exercise whether they wish to participate in the EARS-Net EQA. In addition, it had been noted that the ECDC contractor generated updated contact details for the laboratories, which were therefore different than the contact list held by the national EQA coordinator, and that this was challenging.

### **ECDC** action

- Consider, for EQA exercises after 2024, that these are conducted at another time than during the summer.
- Contact DTU and StMu to explore potential solutions to the challenges raised by StMu.

### **EARS-Net network meeting**

### Attachment 10: I - EARS-Net NetworkMeeting.pdf

PeKi presented the tentative **agenda for the upcoming EARS-Net network meeting**, which is planned for 11-12 June 2024, and should include a dinner on 11 June to celebrate the 25<sup>th</sup> anniversary of EARSS/EARS-Net. The planned agenda topics are an update from/regarding ECDC and ARHAI, presentation of EARS-Net trends in recent surveillance data, recent work and achievements for example related to the estimated incidence of resistant pathogens, and future directions for ARHAI networks other than EARS-Net. In addition, the agenda should also cover, future directions for EARS-Net, including work on: new antibiotics, updates to EARS-Net and EpiPulse, and a potential survey of EARS-Net laboratories, reducing the number of bacterial species and antimicrobial agent/group combinations under EARS-Net surveillance, work on the blood culture set definition, inclusion of CSF isolates in EARS-Net, work on electronic surveillance such as EHDS, data completeness in EARS-Net surveillance within EARS-Net was also suggested. The aim would be to invite three countries with different experiences to give a presentation. Another possible topic would be the EARS-Net EQA for 2021-2024, but also 2025-2032. Time has also been set aside for meeting EARS-Net colleagues and administrative support with completion of reimbursement forms. It was also suggested that the DNCC present themselves and the work of the DNCC.

### **DNCC feedback**

The DNCC chair declined to present at the network meeting, suggesting that the discussion on the inclusion of new antibiotics in surveillance may instead need more discussion as part of the meeting.

Meeting of the EARS-Net Disease Network Coordination Comm	ittee
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### ECDC NORMAL

For the country presentations, the DNCC members from Norway and the Netherlands indicated that although they could be one of the countries presenting at the network meeting, they would be happy to have other countries present their experiences. On the other hand, the member from Germany offered to ask Ines NOLL about whether she would be happy to present as this would be her final EARS-Net network meeting. It was also suggested that a country that recently joined EARS-Net may also be a good candidate.

Celebrating the 25<sup>th</sup> anniversary of EARSS/EARS-Net as part of the planned dinner was supported by the DNCC.

### **ECDC** action

• Consider adjusting the agenda based on the provided advice.

### **Closing of meeting**

HaMe summarised some of the main points from the meeting including the advice for the blood culture set definition; to include EUCAST guidelines as part of the criteria for adding new antibiotics to EARS-Net surveillance; to simplify the criteria for tagging estimated incidences as needing cautious interpretation; and the feedback on the draft network meeting agenda. Moreover, ECDC was looking forward to receiving input regarding updates to EUCAST breakpoints relevant to EARS-Net. It was also mentioned that, as a next step, the DNCC should, in addition to the DNCC meeting minutes, expect to receive the consensus results for the upcoming EARS-Net EQA for feedback. All participants were then thanked for attending the meeting and for their active participation. Finally, JoMo was thanked for his invaluable contributions to EARSS and EARS-Net.

### Attachments

The following attachments are provided in the EARS-Net DNCC sftp server.

Attachment 1: A - EARS-Net\_DNCC\_meeting\_20240417.pdf

Attachment 2: B - EARS-Net DNCC\_2024\_Update on ECDC and ARHAI.pdf

Attachment 3: C - EARS-Net update.pdf

Attachment 4: D - Resistance to new antibiotics - surveillance plans.pdf

Attachment 5: E - EARS-Net reporting protocol.pdf

Attachment 6: F - Estimated incidence of bloodstream infections with resistant bacteria - plans\_adjusted.pdf

Attachment 7: F G - Carlo DNCC\_240417.pdf

Attachment 8: G - Cerebrospinal fluid specimens in EARS-Net.pdf

Attachment 9: H - EARS-Net EQA-related.pdf

Attachment 10: I - EARS-Net NetworkMeeting.pdf

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# **Annex 1. EARS-Net Disease Network Coordination Committee**

### Members (alphabetical order)

Name	Country	E-mail	Organisation	Role in EARS-Net
Tim ECKMANNS	Germany	EckmannsT@rki.de	Robert Koch Institut	NFP for AMR, OCP for Epidemiology (AMR)
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Stephen MURCHAN	Ireland	Stephen.Murchan@hpsc.ie	Health Protection Surveillance Centre	OCP for TESSy/IT data manager (AMR)
Marie-Cécile PLOY	France	marie-cecile.ploy@unilim.fr	University of Limoges	OCP for Microbiology (AMR)
Helena RIBIČ	Slovenia	helena.ribic@nlzoh.si	National Laboratory of Health, Environment and Food	NFP for AMR, OCP for Epidemiology (AMR)
Gunnar SKOV SIMONSEN (Chair)	Norway	gunnar.skov.simonsen@unn.no	University Hospital of North Norway	NFP for AMR, OCP for Epidemiology (AMR)
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Helena ŽEMLIČKOVÁ (Deputy Chair)	Czechia	helena.zemlickova@szu.cz	National Institute of Public Health	NFP for AMR, OCP for Epidemiology (AMR), OCP for Microbiology (AMR)

NFP, National Focal Point; OCP, Operational Contact Point; AMR, Diseases Caused by Antimicrobial-Resistant Microorganisms.

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### **Observers (alphabetical order)**

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