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RefLabCap

Overview report of strengths, weaknesses, and further needs for improving capacity for detection and characterisation of antimicrobial-resistant priority pathogens in national networks of clinical laboratories

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European Health and Digital Executive Agency

Third EU Health Programme

Overview report on capacity in national networks of clinical laboratories

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Kosovo

'This designation is without prejudice to positions on status, and is in line with United Nations Security Council resolution 1244/99 and the International Court of Justice Opinion on the Kosovo declaration of independence.'

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1. EXECUTIVE SUMMARY

The EURGen-RefLabCap coordinators in 37 countries were invited to conduct a mapping survey of the capacity for detection and characterisation carbapenem- and/or colistin-resistant Enterobacterales, *Pseudomonas aeruginosa* and *Acinetobacter baumannii*, hereafter referred to as 'priority pathogens', within their national networks of clinical laboratories (CLs). The contractors (SSI and DTU) introduced the exercise and provided a questionnaire template including 22 questions, data and reporting templates to the EURGen-RefLabCap coordinators, who conducted the mapping survey, data analysis and evaluation of results in their respective countries. The questionnaire template allowed for addition of up to 10 bespoke questions of relevance to each country and translation into another preferred language.

The survey addressed the following 10 areas:
1) information about the national networks,
2) criteria for submission of clinical samples to the CLs,
3) diagnostic testing,
4) quality of laboratory services,
5) reporting/management of test results from the CLs,
6) participation in national/international surveillance,
7) referral of samples to the national reference laboratories (NRLs),
8) membership of laboratory network,
9) staffing situation,
10) finally, the support in demand by the CLs from the NRLs.

A total of 25 (out of 37) countries in EURGen-RefLabCap conducted surveys in their respective networks of CLs. Among those, 21 countries completed a narrative report in English on the key findings in their national surveys that was submitted to the EURGen-RefLabCap project team by February 2023. Four countries submitted raw data extractions from EUSurvey only.

The aim of this consolidated report was to provide an overview of the key findings highlighted by the coordinators in their individual survey reports. Moreover, we highlight suggestions for improvements received from the EURGen-RefLabCap coordinators. Based on the key findings and suggestions from the coordinators, we propose options for actions at national level and needs at European level.

The target audience of this report includes the country coordinators of EURGen-RefLabCap, HaDEA, DG SANTE and ECDC.

1.1 Key findings, strengths and weaknesses in the 10 areas of the survey

Key findings within the 10 areas of the survey are summarised here, using relative terms to indicate the proportion of the countries (and CLs) where the strengths/weaknesses/needs were observed including:

- most/majority indicates a proportion of > 60%,
- common/frequent/moderate indicates a proportion of 40-60%, and
- some/few indicates a proportion of < 40%.

1. National networks

A network of CLs was in place in most countries conducting the mapping survey (see section 5.1). The networks had been in place for more than 5 years (at the time of the survey) in most countries. The median percentage of invited CLs replying to the mapping survey within the respective national networks was 72% (ranging from 11% to 100% of invited CLs in the respective networks replying to the survey) (see section 5.1). Furthermore, involvement of private laboratories in network activities was inconsistent within countries and between countries.

2. Criteria for submission of clinical samples to the CLs

In most countries, CLs issued guidance on submission of clinical samples and/or provided advice upon request to their users (see section 5.2). However, guidance on sampling practices and/or admission screening for hospitalised patients was not harmonised between CLs and implementation was not consistent between hospitals within each country. Moreover, carbapenem- and/or colistin-resistant *Acinetobacter baumannii* complex and *Pseudomonas aeruginosa* were often not included in admission screening guidance.

3. Diagnostic testing

The capacity to conduct phenotypic antimicrobial susceptibility testing (AST) following European Committee on Antimicrobial Susceptibility Testing (EUCAST) guidance seemed to be well developed in most CLs participating in the survey (see section 5.3). In most countries, molecular testing for the priority pathogens was conducted by few CLs only.

4. Quality of laboratory services

The majority of CLs used control material for species identification and AST and participated in external quality assessment (EQA) on phenotypic AST (see section 5.4). In most countries, accreditation of methods was not prioritised due to insufficient personnel and financial resources.

5. Reporting/management of test results from the CLs

Most CLs in most countries had access to an electronic laboratory information management system (LIMS) for collection, tracking, storage and reporting of diagnostic test results (see section 5.5). However, continuous reporting of data into a national integrated digital system was unavailable in most countries.

6. Participation in national/international surveillance

In the majority of countries, more than 60% of the participating CLs reported results on all priority pathogens to at least one national surveillance system (voluntary, mandatory or sentinel systems) (see section 5.6). In a few countries, participation in national surveillance for the priority pathogens was lacking, resulting in poor coverage of AST-data at national level.

7. Referral of samples to the national reference laboratories (NRLs)

Systematic referral to the NRLs of most newly detected strains of the priority pathogens had been implemented in the majority of countries (see section 5.7).

In some countries the proportions of CLs referring carbapenem- and/or colistin-resistant Enterobacterales were higher than the proportions of CLs referring *P. aeruginosa* and *A. baumannii* isolates to the NRL.

8. Membership of laboratory network

In most countries, either the majority or frequently, laboratories were members of one or more national networks of CLs (see section 5.8). Fewer CLs reported that they were

members of regional or international laboratory networks and groups aimed at capacity building or research, but this may be an underestimate.

9. Staffing situation

In the majority of countries, the staffing situation varied within each country with a distribution of scores frequently being 'somewhat adequate'(score=3), 'adequate' (score=4) or 'fully adequate' (score=5)' (see section 5.9). Only few coordinators reported overall staffing situations as 'not adequate' or 'not adequate at all'. Training of staff, quality assurance management, participation in EQAs and implementation of new methods and other areas were affected negatively by the inadequate staffing.

10. Support in demand by the CLs from the NRLs

The CLs of the national networks ranked supporting activities that could be provided by the NRL/national expert laboratory (NEL) to them (see section 5.10). The highest ranking was given to receiving training by the NRLs in the CLs, receiving control materials, receiving support for outbreak detection and management, access to EQAs for phenotypic AST, participation in laboratory networks and receiving support for accreditation practices.

2. OPTIONS FOR ACTIONS AT NATIONAL LEVEL AND NEEDS AT EU LEVEL

Options for actions related to most of the areas of the survey are listed below. The suggestions are aimed at national level (N). Moreover, needs at European level (E) are listed for selected areas. The numbering refers to the 10 areas of the survey listed above.

2.1. Options for actions at national level (N)

1: NRLs/NELs networks of CLs should cover each country entirely or, at least, as far as possible. It would be beneficial if private laboratories participated in surveillance activities either on a voluntary or mandatory basis, depending on the country situation. In some countries, networks may need to be organised at multiple levels (e.g. by administrative region or other sub-divisions of health services), for example if the number of CLs is very large and unmanageable for the NRL to handle.

2: Guidance on sampling practices and/or admission screening should be available for all priority pathogens at least as 'Guidance on the principles' for the local epidemiological situation. Guidance should be issued at national level and, if needed, adapted to local level and/or epidemiological situations. NRLs/NELs should develop communication strategies to ensure that all CLs obtain information on available guidance on sampling practices and/or admission screening for the priority pathogens.

3: All CLs should be capable of detecting phenotypes of carbapenemases. Furthermore, colistin susceptibility testing should be performed by using broth micro-dilution method recommended by EUCAST only. Countries should develop a plan to implement molecular testing in the CLs or to streamline the NRL support provided to the CLs that are not equipped for molecular testing.

The diagnostic testing capability of CLs and, in particular, the capability to detect phenotypes mediated by carbapenemases and by colistin resistance determinants should be regularly monitored by EQAs

4: Participation in EQA should be further promoted to ensure that all CLs produce reliable results that in turn promotes confidence in their output nationally and internationally. Importantly, NRLs/NELs should follow-up on the results of each EQA.

5: All CLs should have access to a LIMS or software for collection, tracking, storage and reporting of diagnostic test results. A national integrated digital system with an interface that allows *ad hoc* comparisons of data in real-time for infection control and public health purposes, should be set up in all countries, and the LIMS of CLs should be set-up to be able to transfer data to such national system automatically or semi-automatically.

The purposes for routine extraction and communication of data should be extended to consistently include early warning and quality improvement purposes.

6: All CLs should report AST-data on defined cases of the priority pathogens to at least one national surveillance system. This could be supported through national mandates for surveillance and proactive communication by the NRL with the CLs. Establishment of electronic reporting of AST-results to a national digital system is key to the implementation of national surveillance and early antimicrobial resistance (AMR) warning systems.

7: NRLs should encourage the CLs in their networks to refer strains of carbapenem- and/or colistin-resistant *P. aeruginosa* and *A. baumannii* to the NRL (in addition to the already well-established referral of carbapenem and/or colistin-resistant Enterobacterales (CCRE)). Referrals should also be promoted via national guidance, protocols and/or laboratory user manuals.

8: Countries/NRLs should be encouraged to support the formation and operation of national networks of CLs, aimed at issuing national harmonised guidance on diagnostic methods, laboratory quality management systems, interpretation of results (according to EUCAST) and reporting to national surveillance systems, capacity building in the member laboratories and research.

9: The coordinators suggested a large number of supporting activities that the NRLs should carry out to support the CLs, including support on accreditation, provision of surge capacity, national surveillance (tasks), evaluation of new diagnostic test, deliver training on AMR priority pathogens, reporting on data, training on methodologies including whole genome sequencing (WGS), offer observerships for graduates, recruiting strategies, and influencing funding bodies.

10: The NRLs should review the outcomes of their national mapping surveys to identify, plan and conduct supporting activities to help the CLs to provide high quality diagnostic testing services, including adequate data output on detection of AMR priority pathogens.

2.2. Needs at EU level (E)

5: Support to the countries that need to implement national integrated digital systems may be provided in form of guidance on the minimum set of information that should be communicated by laboratories within and between countries, to allow interoperability across borders.

6: Participation in international surveillance should be encouraged.

3. BACKGROUND

National reference laboratories (NRLs)/national expert laboratories (NELs) in the 37 countries participating in the EURGen-RefLabCap project were invited to conduct the survey of capacity for detection and characterisation of priority pathogens (see methods section) within their national networks of clinical laboratories (CLs). The aim of the survey was to identify strengths and weaknesses, gaps and further needs as a basis for further

national capacity building within each country. The findings of the 'strengths and weaknesses' analyses are intended to support the NRLs/NELs to work with networks of CLs in their own countries to build capacity for detection and characterisation of priority pathogens. This report contains a summary of key findings in the individual country reports and a comparison of similarities and differences between the countries.

4. METHODS

The contractors (SSI and DTU) introduced the exercise and provided a questionnaire template including 22 questions, data and reporting templates to the EURGen-RefLabCap coordinators, who conducted the mapping survey, data analysis and evaluation of results in their respective countries. The questionnaire template allowed for addition of up to 10 bespoke questions of relevance to each country and translation into another preferred language.

The methodology and content of the draft questionnaire was discussed with the country coordinators at the EURGen-RefLabCap workshop at SSI, Copenhagen on 29 June 2022.

The aim of this consolidated report was to provide an overview of the key findings highlighted by the coordinators in their individual survey reports. Moreover, we highlight suggestions for improvements received from the EURGen-RefLabCap coordinators. Based on the key findings and suggestions from the coordinators, we propose options for actions at national level and needs at European level.

The target audience of this report includes the country coordinators of EURGen-RefLabCap, HaDEA, DG SANTE and ECDC.

The twenty-two questions (in English) were provided via EUSurvey allowing for addition of further questions to address specific country-associated issues. Countries were allowed to translate the questionnaire into their local languages. Results of the respective national surveys and narratives of the evaluations, were provided in English in pre-made reporting templates (Microsoft Excel and Word). The survey included 10 areas (dimensions) of laboratory capacity (see Table 1).

Table 1. Areas of the EURGen-RefLabCap survey of clinical laboratory capacity for detection and characterisation of priority pathogens in the national networks.

	Survey areas
1	Information about the participating clinical laboratories in the network
2	Criteria for submitting samples to the clinical laboratory
3	Diagnostic testing
4	Quality of laboratory services provided
5	Reporting and management of test results
6	Participation in national and international surveillance
7	Referral of samples to NRL/NEL
8	Membership of laboratory networks
9	Staffing
10	Support from the NRL/NEL to the CLs

A total of 25 countries conducted the survey in their respective countries, of which 21 countries completed the narrative report in English, while 4 countries submitted data extractions from EUSurvey only.

The summaries of strengths, weaknesses and needs presented in this overview report were based on the countries' own conclusions and/or reported survey data on different aspects as outlined in the 'Reporting template' and 'Data reporting template' provided for the individual country reports. For convenience, the questions of the survey are listed at the beginning of each survey area, even though this report does not provide an analysis of the detailed answers to each question. The authors of this report have limited knowledge of internal structures and setups in each country, and it was clear from the national reports that the raw data provided by the CLs required a degree of interpretation based on internal knowledge. Thus, this report provides a qualitative and semi-quantitative overview of the findings in the national reports, highlights suggestions for improvements received from the EURGen-RefLabCap coordinators, and proposes recommendations for improvement at national and European levels.

In this overview report, relative terms were used to indicate the proportion of the countries (and CLs) where the strengths/weaknesses/needs were observed including:

- **most/majority** indicates a proportion of > 60%,
- **common/frequent/moderate** indicates a proportion of 40-60%, and
- **some/few** indicates a proportion of < 40%.

In the overview report, the following terms were used:

- **NRL/NEL or coordinators**, to indicate the authors of the national reports.

- **Clinical laboratory networks/clinical laboratories (CLs)**, to indicate the local clinical (microbiology) laboratories that are part of the laboratory network for the priority pathogens in the countries.
- **Priority pathogens** included:
  - carbapenem- and/or colistin-resistant *Escherichia coli*
  - carbapenem- and/or colistin-resistant *Klebsiella pneumoniae*
  - carbapenem- and/or colistin-resistant *Acinetobacter baumannii*
  - carbapenem- and/or colistin-resistant *Pseudomonas aeruginosa*.

Recommendations are provided at national level (**'N'**) and European level (**'E'**), respectively, in each of the categories of the mapping survey.

5. RESULTS

5.1. Area 1: Information about the participating clinical laboratories in the network

NRLs/NELs in 37 countries were invited to conduct the mapping survey on capacity for detection and characterisation of priority pathogens within their national networks of CLs. At the time of writing this report, the mapping survey was completed in 25 countries, of which 21 countries completed the narrative report in English using the provided reporting template. Among those that completed the mapping survey report, ten had the status as 'priority countries' and two as 'additional countries' in the EURGen-RefLabCap project (see Table 2). The NRLs in 4 countries only collected the raw data without completing the narrative report. Among the participating countries, 21 countries were part of EU/EEA and 4 countries are part of the WHO European Region (see Table 2). Some NRLs needed extensions of their timelines to complete their surveys and their results are thus not part of this report.

The number of CLs answering the survey in each country ranged from 1 to 91. In total, 513 CLs participated in the national surveys. The percentage of the invited CLs participating in the survey varied between countries, and ranged from 11% to 100% of CLs out of the total number of CLs in the national networks, invited by the NRLs/NELs, with a median of 72%. Information on the participation of private laboratories in the national networks was insufficient for analysis.

The estimated population coverage suffers from limitations, since it is based on best estimates provided by the respondents. Furthermore, CL catchment populations are notoriously difficult to assess due to variation in the organization of healthcare sectors and methods used to generate the catchment populations. As a result, comparative data on national population coverage are not included in this report.

Table 2. Countries that conducted the mapping survey of the capacity in national networks of CLs (please note this table has been truncated due to confidentiality)

	Country	Region	EURGen-RefLabCap status	Network surveyed (laboratories participating in designated networks or groups)
1	Austria	EU/EEA	Non-PC	EARS-Net
2	Bosnia-Herzegovina	WHO	PC	CAESAR
3	Croatia	EU/EEA	PC	National AMR Surv. Network
4	Cyprus	EU/EEA	PC	Newly established
5	Czechia	EU/EEA	PC	National AMR Surv. Network
6	Denmark	EU/EEA	Non-PC	All national CLs
7	Estonia	EU/EEA	PC	Estonian EUCAST and Clinical Microbiology Working Group
8	Finland	EU/EEA	Non-PC	U
9	France	EU/EEA	Non-PC	University hospital network (AZAY) and public & private CLs that refer samples to Natl. Ref. Center (NRC) network
10	Germany	EU/EEA	Non-PC	NRC network
11	Greece	EU/EEA	PC	All national public hospitals
12	Hungary	EU/EEA	Non-PC	EARS-Net and other
13	Iceland	EU/EEA	Non-PC	NA
14	Kosovo	WHO	Non-PC	AMR Ref. Lab.
15	Lithuania	EU/EEA	PC	All national CLs
16	Luxembourg	EU/EEA	Non-PC	All national bacteriology laboratories
17	Malta	EU/EEA	Non-PC	NA
18	Moldova	WHO	AC	National AMR Surv. Network
19	Norway	EU/EEA	Non-PC	All national CLs
20	Poland	EU/EEA	AC	NRL network
21	Romania	EU/EEA	PC	EUSCAPE/EURGen-Net
22	Serbia	WHO	PC	National AMR Network
23	Slovenia	EU/EEA	PC	National laboratory and Medical Faculty
24	Spain	EU/EEA	AC	National AMR Network, Level 2 laboratories
25	Sweden	EU/EEA	Non-PC	All national CLs

AC, Additional Country; CL, Clinical Laboratory; NA, not applicable; PC, Priority Country; U, unknown.

Strengths

A network of CLs was in place in most countries (n=22) involved in the EURGen-RefLabCap project (except for 3 countries that only had one laboratory in each country). Such networks have been in place for more than 5 years (at the time of the survey) in **most** countries (n=22).

Weaknesses

The most common reasons for CLs not taking part in the survey were their prioritisation of other online surveys that are mandatory, and the complexity of the current survey. Furthermore, in some countries, collaborations between the NRL/NEL and the CLs were not well established, and not all national networks of CLs were officially nominated, which also impacted on the responsiveness. Finally, involvement of private laboratories in network activities was inconsistent both within countries and between countries.

The national population covered by the CLs answering the mapping survey was not clearly defined in **most** countries, and there are uncertainties associated with the data reported.

Assessments

It is positive that NRLs/NELs in the majority of the countries in EURGen-RefLabCap, including countries that did not have an economic incentive to conduct the mapping survey, produced a report. From individual feedback provided by some priority countries, it appeared that the mapping survey was useful mainly to signal that the NRL/NEL is actively engaging with the national network of CLs, as some of the information collected via the survey was already known to the NRLs/NELs. The main limitation of this mapping survey exercise was the high variation (between countries) in the proportions (percentages) of the CLs within each national network that participated in the survey. This limitation should be kept in mind, when reading this report.

Area 1. Optional actions and needs

N: NRLs/NELs networks of CLs should cover each country entirely or, at least, as far as possible. It would be beneficial if private laboratories participated in surveillance activities either on a voluntary or mandatory basis, depending on the country situation. In some countries, networks may need to be organised at multiple levels (e.g. by administrative region or other sub-divisions of the health services), for example if the number of CLs is very large and unmanageable for the NRL to handle.

5.2. Area 2: Criteria for submitting samples to the clinical laboratory

Q1. Does your laboratory (or other authorities) issue guidance on submission of clinical samples (including types and quality of samples, types of containers and documentation required) to their users? (Manual/handbook/SOP; Upon request (e.g. by phone); None)

Q2. Does your laboratory (or other authorities) issue guidance on sampling practices and/or admission screening for hospitalised patients for any of the following priority pathogens? (Carbapenem- and/or colistin-resistant Escherichia coli; Carbapenem- and/or colistin-resistant Klebsiella pneumoniae; Carbapenem- and/or colistin-resistant Acinetobacter baumannii complex; Carbapenem- and/or colistin-resistant Pseudomonas aeruginosa)

- *Sub-question: Does the guidance on sampling practices and/or admission screening provide instructions on any of the following? (Sample type; Sample procedure; Sample container; Sample transport; Patient information; Criteria for screening at admission; Number of admission screening sample accepted per patient; No answer)*

Strengths

In **most** countries, the CLs issued guidance (and/or provided advice upon request) to their users on submission of clinical samples.

Weaknesses

In **most** countries, guidance on sampling practices and/or admission screening for hospitalised patients was not harmonised between CLs and, also, implementation of existing guidance on sampling practices and/or admission screening was not consistent between hospitals.

In **most** countries, guidance on sampling practices and/or admission screening was available for a subset of priority pathogens only (being carbapenem- and/or colistin-resistant *Acinetobacter baumannii* complex and *Pseudomonas aeruginosa* often not included in such guidance).

In **some** countries, it seems that not all CLs were aware of existing guidance on sampling practices and/or admission screening issued by the NRL/NEL.

Assessments

Based on the individual country reports submitted, it appears that guidance issued by the NRL on sample submission was available to most CLs. On the contrary, availability of NRL guidance on sampling practices and/or admission screening for hospitalised patients was highly variable, which hampers effective surveillance. The fact that NRLs/NELs reported that some CLs were not aware of guidance documents published on the NRL/NEL websites is surprising but should be relatively straightforward to address.

Area 2. Optional actions and needs

N: Guidance on sampling practices and/or admission screening should be available for all priority pathogens at least as 'Guidance on the principles' for the local epidemiological situation. Guidance should be issued at national level and, if needed, adapted to local level and/or epidemiological situations. NRLs/NELs should develop communication strategies to ensure that all CLs obtain information on available guidance on sampling practices and/or admission screening for the priority pathogens.

5.3. Area 3: Diagnostic testing

Q3. Does your laboratory perform species identification for any of the following pathogens? (Escherichia coli; Klebsiella pneumoniae; Acinetobacter baumannii complex; Pseudomonas aeruginosa; No, none of these pathogens)

- *Sub-question: Which method(s) do you use for species identification? (MALDI-TOF; Selective plating; Antigen testing; Biochemical testing; WGS; Other)*

Q4. Does your laboratory perform antimicrobial susceptibility testing for any of the below pathogens? (Escherichia coli; Klebsiella pneumoniae; Acinetobacter baumannii complex; Pseudomonas aeruginosa; No, none of these pathogens)

- *Sub-question: Which method(s) do you use for antimicrobial susceptibility testing? (Agar dilution; Automated system; Commercial broth microdilution; Disc Diffusion; Gradient test; In-house broth microdilution; Other)*
- *Sub-question: Which antimicrobial susceptibility testing guidance (for methodology and breakpoints) do you use in your laboratory? (EUCAST; CLSI; Other guidance)*

Q5. Does your laboratory perform susceptibility testing for colistin? (Yes; No)

- *Sub-question: Which method(s) do you use for colistin susceptibility testing? (Agar dilution; Automated system; Commercial broth microdilution; Disc Diffusion; Gradient test; In-house broth microdilution; Other)*

*Q6. Does your laboratory use any **rapid test** to **detect carbapenemases**? (Chromogenic biochemical assay, Immunochromatographic assay, Direct chromogenetic tests; Rapid PCR; Other commercial assays)*

*Q7. Does your laboratory perform **molecular testing** for any of the following priority pathogens? (Yes; No)*

- *Sub-question: For which purpose(s) do you use molecular testing of CRE/CCRE? (Detection of organism; Detection of AMR genes; Determination of genotype; Epidemiological investigation)*
- *Sub-question: Which methods do you use for molecular testing? (In-house PCR; Commercial PCR; Microarray; LAMP-based assay; WGS; Other)*

Strengths

Most CLs in **all** countries had the capacity to perform species identification (mainly by MALDI-TOF, biochemical tests and/or selective plating) and phenotypic AST for the priority pathogens. **Most** CLs had the capacity to conduct AST by using more than one method (disk diffusion, gradient tests, automated systems and/or broth microdilution).

Most CLs in **most** countries used EUCAST guidance for AST, and it appears that the **few** CLs using CLSI guidance were gradually shifting towards using EUCAST guidance.

Most CLs in **most** countries used rapid tests to detect carbapenemases.

Weaknesses

Implementation of rapid tests to detect carbapenemases was not as widespread as the NRLs/NELs wished. Given the importance of rapid confirmation of carbapenemase-production for therapeutic decisions and infection prevention and control purposes, more widespread implementation of rapid tests is desirable.

In **most** countries, there were **few** CLs that performed colistin susceptibility testing by using methods not recommended by EUCAST.

In **most** countries, molecular testing for the priority pathogens was conducted by **few** CLs only.

Assessments

The capacity for phenotypic AST seems to be well developed in most CLs participating in the survey, and it was positive to observe that the use of EUCAST guidance was harmonised across **most** CLs and countries. Further efforts to build capacity in all CLs to perform detection and characterisation of carbapenemases and of colistin resistance are needed.

Area 3. Optional actions and needs

N: All CLs should be capable of detecting phenotypes of carbapenemase (either directly in the CLs or by fast-track referral to the NRL). Furthermore, colistin susceptibility testing should be performed by using methods recommended by EUCAST only. Countries should develop a plan to implement molecular testing in the CLs or to streamline the NRL support provided to the CLs that are not equipped for molecular testing.

N: The diagnostic testing capability of CLs and, in particular, the capability to detect phenotypes mediated by carbapenemases and by colistin resistance determinants should be regularly monitored by EQAs.

5.4. Area 4: Quality of laboratory services provided

Q8. Does your laboratory provide individual reports on test results for any of the above priority pathogens to hospitals/other healthcare facilities? (Yes, individual reports on test results are issued to clinicians to inform antibiotic treatment; Yes, individual reports on test results are issued to infection prevention and control teams to inform infection prevention and control measures; No, individual reports on test results are not issued to hospitals/healthcare facilities)

Q9. Does the laboratory use control material (specimens, DNA etc.) from a reliable source for quality control testing of the following methods? (Antimicrobial susceptibility testing; Species identification; Molecular testing (PCR); Whole genome sequencing (WGS); No, the laboratory does not have access to controls from a reliable source)

Q10. Has the laboratory participated in any external quality assurance (EQA) exercise for antimicrobial susceptibility testing for any of the carbapenem- and/or colistin-resistant priority pathogens within the last 3 years? (Yes; No; Do not know)

Q11. Does the laboratory hold accreditation or certification for some or all laboratory services provided? (Yes; No)

Strengths

In **all** countries, **most** CLs provided individual reports on test results to clinicians to inform antimicrobial treatment and **commonly** also to inform infection prevention and control teams to inform infection prevention and control measures.

In **most** countries, the vast majority of CLs used control materials for species identification and AST and participated in EQA on AST.

Weaknesses

In **some** countries, **some** (>1) CLs performed testing (species identification, AST and/or PCR) without using appropriate control materials.

In **most** countries, accreditation of methods was not prioritised due to insufficient personnel and financial resources.

Assessments

Most CLs reported to be using quality controls and participating in EQAs, thereby providing reliable results to clinicians. Nonetheless, improvements should be made to ensure that all CLs perform testing at the level of minimum quality requirements (e.g. by using

appropriate control materials) in order to promote confidence in their work both nationally and internationally.

Area 4. Optional actions and needs

N: Participation in EQA should be further promoted to ensure that all CLs produce reliable results that in turn promotes confidence in their output nationally and internationally. Importantly, NRLs/NELs should follow-up on the results of each EQA.

5.5. Area 5: Reporting and management of test results

Q12. Does the laboratory have access to an electronic laboratory information management system (LIMS) or software application (e.g. WHONET) for collection, tracking, storage and reporting of diagnostic test results? (Yes; No)

Q13. Does the laboratory use 'selective reporting' of antimicrobial susceptibility testing results as a tool to guide clinicians towards prudent antimicrobial usage? (Yes; No)

Q14. Are test results on priority pathogens from your laboratory continuously transferred to a national (or regional or international) integrated digital system with an interface that allows ad hoc comparisons of data in real-time for infection control and public health purposes? (Yes; No)

Q15. Does the laboratory (or other department) routinely extract and communicate pre-defined data sets on species ID and antimicrobial test results for any of the following purposes? (Infection prevention and control purposes; Local surveillance purposes (e.g. surveillance within the hospital, institution or area); Early warning purposes (e.g. accumulation of cases, new variants of concern); Quality improvement purposes (e.g. by reporting cases to hospital management); No, none of the above)

Strengths

Most CLs in **most** countries had access to an electronic laboratory information management system (LIMS) or software application (e.g. WHONET) for collection, tracking, storage and reporting of diagnostic test results, and routinely extracted and communicated pre-defined data sets on species identification and AST-results for infection prevention and control purposes and local surveillance purposes.

Most CLs in **most** countries performed 'selective reporting' of AST-results to guide clinicians towards prudent antimicrobial usage.

Weaknesses

In **most** countries, CLs used different LIMS with limited interoperability, which hampers automated data extraction and transfer to a national integrated digital system. In fact, in **most** countries, there is no possibility to continuously report data to a national integrated digital system.

In **most** countries, routine extraction and communication of pre-defined data sets on species identification and AST-results for early warning purposes and quality improvement purposes were performed by **some** CLs only.

Assessments

Data reporting and management suffered from lack of standardisation and, as a consequence, continuous reporting of data into a national integrated digital system is

currently unavailable in most countries. The area of 'data reporting and management' seems to be in urgent need of harmonisation and modernisation.

Area 5. Optional actions and needs

N: All CLs should have access to a LIMS or software for collection, tracking, storage and reporting of diagnostic test results. A national integrated digital system with an interface that allows *ad hoc* comparisons of data in real-time for infection control and public health purposes should be set up in all countries, and LIMS of CLs should be set up to be able to transfer data to such national systems automatically or semi-automatically.

N: The purposes for routine extraction and communication of data should be extended to consistently include early warning and quality improvement purposes.

E: Support to the countries that need to implement national integrated digital systems may be provided in form of guidance on the minimum set of information that should be communicated by laboratories within and between countries, to allow interoperability across borders.

5.6. Area 6: Participation in national and international surveillance

Q16. Does the laboratory participate in any type of national surveillance for the priority pathogens?

Q17. Does the laboratory submit pre-defined data sets on antimicrobial-resistant pathogens to any of the following international surveillance networks?

Strengths

In the majority of countries, more than 60% of the CLs reported laboratory data on all priority pathogens to one or more types of national surveillance system (either voluntary, mandatory and/or sentinel surveillance). In the majority of countries (21 countries) most CLs submitted data to national surveillance systems for carbapenem- and colistin-resistant *E. coli* and/or *K. pneumoniae*; and in 20 countries most CLs submitted data to national surveillance systems for carbapenem- and colistin-resistant *A. baumannii* and/or *P. aeruginosa*.

In most countries, a subset of the enrolled CLs were members of international surveillance networks, including the ECDC European Antimicrobial Resistance Surveillance Network (EARS-Net), WHO Central Asian and European Surveillance of Antimicrobial Resistance (CAESAR) and Global Antimicrobial Resistance and Use Surveillance System (GLASS).The enrolled CLs submitted standardised AST-results on invasive isolates of Enterobacterales, *A. baumannii* and *P. aeruginosa* to one or more international surveillance systems. Data on Enterobacterales in urine were also reported to CAESAR (and in some countries to GLASS).

In countries participating in any of the WHO surveillance networks (CAESAR, GLASS) there was a high reporting coverage (83-100%) of the enrolled CLs. In countries that submitted data to ECDC EARS-Net, high coverage of the enrolled CLs (64-100%) was observed in most countries, but variation in coverage of the enrolled CLs was higher than seen among countries in WHO surveillance. However, the countries reporting to WHO surveillance systems were generally smaller and had smaller national networks of CLs.

Countries frequently indicated that the AST-data were confirmed by the NRL or national public health institute before the data were submitted to the international surveillance systems.

Weaknesses

In few countries, participation in national surveillance for the priority pathogens was lacking coverage in few CLs for one or more priority pathogens. These countries had few (or no) CLs reporting data on any priority pathogens to national surveillance systems, while 40-60% of CLs in few countries reported carbapenem- and colistin-resistant *E. coli*, C/CRAb and/or C/CRPa to national surveillance. This resulted in poor coverage of AST-data at national level with some geographical and/or healthcare sectors of these countries not being sufficiently covered. Reasons for the lack of participation in national surveillance programmes included issues with national governance, lack of a formal mandate of the national surveillance systems for some or all priority pathogens, and lack of providing information, and engaging with the CLs by the NRL/public health institute. National surveillance networks were often operated on a voluntary basis and did not include all CLs, hospitals nor healthcare sectors. Moreover, a fatigue among staff for collecting and reporting health data in general was indicated as a barrier to participation in national surveillance.

In few countries that submitted surveillance data to EARS-Net, the coverage was lacking with only 40-60% of CLs reporting, or < 40% of CLs.

The lack of state-of-the-art IT-systems (including LIMS and national digital systems) allowing automated electronic reporting was also indicated as a barrier to participating in national surveillance. Paper-based and semi-automated data reporting procedures were still used in some countries.

Finally, the quality of the output of the surveillance systems and the lack of early AMR (and high-risk clone) warning systems, and timely analysis of data to detect outbreaks were also mentioned as weaknesses.

Assessments

Designated "contact persons" in each country ensure consistent and continuous reporting to the international surveillance systems that in turn allows for comparisons between countries over time. Participation in either one of these international surveillance networks has led to standardisation of collection, analysis and reporting procedures and training of laboratory personnel. The streamlining and standardisation of AMR surveillance procedures has allowed the publication of comparable data on AMR to be made available at European and global levels.

Area 6. Optional actions and needs

N: All CLs should report AST-data on defined cases to at least one national surveillance system. This could be supported through national mandates for surveillance and proactive communication by the NRL with the CLs. Establishment of electronic reporting of AST-results to a national digital system is key to the implementation of national surveillance and early AMR warning systems.

E: Participation in international surveillance should be encouraged.

5.7. Area 7: Referral of samples to NRL/NEL

Q18. Does your laboratory refer (send) newly detected isolates of the following priority pathogens to the national reference (or expert laboratory) laboratory for further testing? (Carbapenem- and/or colistin-resistant Escherichia coli, carbapenem- and/or colistin-resistant Klebsiella pneumoniae; carbapenem- and/or colistin-resistant Acinetobacter baumannii complex; carbapenem- and/or colistin-resistant Pseudomonas aeruginosa)

Q19. If your laboratory refers newly detected isolates to the national reference laboratory (or expert laboratory), which of the following situations or selection criteria apply? (All isolates resistant to carbapenem and/or colistin; a subset of carbapenem- and/or colistin-resistant isolates for the purpose of sentinel surveillance; only carbapenem- and/or colistin-resistant isolates consistent with a national case definition (for example indicated in national protocol or laboratory manual); other criteria)

Strengths

Systematic referral of newly detected strains/isolates of the priority pathogens to the NRLs had been implemented in **the majority of** countries. Typically, a national protocol (or guidance) defined referral criteria for submission of carbapenem- and/or colistin-resistant Enterobacterales, *P. aeruginosa* and *A. baumannii* to the NRL. Referral criteria used in the CLs **frequently** included 'all newly detected isolates of priority pathogens' or 'all isolates complying with a national case definition (e.g. aligned with EUCAST guidance). **Some** countries had implemented sentinel surveillance that included referral of a predefined 'subset of all isolates' of the priority pathogens. Combinations of two or all three options were also observed.

Weaknesses

Only **few** NRLs/NELs had problems with receiving too few referrals of isolates of the priority pathogens. In some countries the proportions of CLs referring carbapenem- and/or colistin-resistant Enterobacterales were higher than the proportions of CLs referring *P. aeruginosa* and *A. baumannii* isolates. Isolates from urine, sputum and other types of samples were less frequently referred to NRLs/NELs than isolates from blood and cerebrospinal fluid, and antimicrobial susceptible isolates were also rare among referrals.

The lack of referrals of priority pathogens in **some** countries were explained by the lack of national guidance, protocols or laboratory manuals (including national criteria for selection of isolates for referral) and insufficient communication between the NRLs/NELs and the CLs, some of which could be explained by insufficient staffing of the NRLs. Organisation of the healthcare sectors also impacted on the referral patterns of isolates (e.g. private hospitals did not refer isolates to the NRL in **some** countries).

In **some** countries capability for detecting the priority pathogens and further molecular testing was lacking in CLs, which resulted in insufficient detection of the priority pathogens.

Some NRLs were not ready to collect and store the referred isolates. On the other hand, the annual numbers of referrals to NRLs/NELs had decreased in **some** countries, as many CLs had improved their capability and capacity to detect the priority pathogens themselves. In some countries, isolates were only sent to the NRL/NEL, if they had unusual phenotypes or were difficult to characterise. In **some** countries, public health and/or patient or citizen data legislation was either unclear or obstructive to the sharing of NRL/NEL test results (data) with the CLs, hospitals and other healthcare sectors and to setting up national surveillance. The lack of adequate national IT-systems exacerbated this in some countries.

Assessments

The infrequent referral of some pathogens and/or sample types to the NRLs/NELs may hinder surveillance efforts in some countries. It appears that the implementation of national surveillance programmes and/or national networks of CLs has promoted systematic referral of isolates to the NRLs/NELs. Improved capability and capacity for molecular diagnostics and rapid testing (e.g. for carbapenemases) had also been developed in many CLs in recent years, which can provide rapid preliminary test result to clinicians and aid the selection of relevant isolates to be referred to the NRLs/NELs for further investigations.

Area 7. Optional actions and needs

In order to increase the numbers of isolates referred to the NRLs, the coordinators proposed the following actions:

- development of national guidance and sampling strategy issued as user manual (or protocol) for the users of the NRLs,
- obtaining government support and mandate for surveillance,
- obtaining sufficient funding (for transport of isolates),
- proactive and more frequent communication between the NRLs/NELs and the CLs,
- establishing networks of CLs,
- conducting national education and training workshops for the staff in the CLs, and
- obtaining sufficient funding for NRL/NEL staff to a streamlined process of referrals from the CLs to the NRLs.

N: NRLs/NELs should encourage the CLs in their networks to refer strains of carbapenem- and/or colistin-resistant *P. aeruginosa* and *A. baumannii* to the NRL. Referrals should also be promoted via national guidance, protocols and/or laboratory user manuals.

5.8. Area 8: Membership of laboratory networks

Q20. Is your laboratory a member of any of the following types of networks? (national network of clinical laboratories; regional network of clinical laboratories; national group of laboratories involved in capacity building activities in diagnostics and/or research; international group of laboratories involved in capacity building activities in diagnostics and/or research; no, none of the above).

Strengths

In **most** countries, it was either the **majority** (> 60%) or **frequent** (40-60%) that CLs were members of one or more national network, but the CLs were less frequently members of regional and/or international networks of laboratories. However, the frequency of membership (among CLs) of international and regional networks/groups may have been underestimated, as some coordinators indicated that the question had been misunderstood by some CLs, and because many of CLs that provided surveillance data to EARS-Net and CAESAR (see Q17) did not report that they were members of international groups of laboratories.

The NRLs/NELs were either the organiser or lead or a member of the national network of CLs. Exceptions were identified in a **few** countries, where organisations of hospitals (or private laboratories), or a central private laboratory, were in charge of small national networks that included CLs.

Activities and roles of the networks of CLs included:

- issuing national guidance on diagnostic methods,
- harmonisation of sampling and transport (referral) of isolates
- harmonisation of quality control and accreditation
- standardisation of interpretation of results (e.g. suppressed reporting of AST-results)
- expert function and provision of advice to authorities and others
- building diagnostic capacity in the CLs
- participation in international research groups
- coordination of the reporting of diagnostic test results to national surveillance programmes
- coordination of submission of data to EARS-Net or WHO surveillance programmes

Weaknesses

Only **few** countries (typically in countries with only few CLs) did not have established networks of CLs. Participation in the national networks of CLs appeared to be voluntary in **most** countries. In **some** countries this resulted in relative low participation frequencies with a potential impact on efforts to standardise diagnostic methodology, referral of samples and development of diagnostic capacity in the CLs.

Memberships of regional and international laboratory networks or groups of laboratories, aimed at capacity building or research, were **frequently** reported by the countries, but with higher variation among the CLs than seen for their memberships of national networks.

Assessments

If not all, or the majority of CLs, are members of the national network in their country, implementation of standardised methodology and/or referrals to the NRLs may be challenging.

Area 8. Optional actions and needs

In order to increase the membership and strengthen the national networks of CLs, the coordinators suggested:

- improving NRLs communication with the CLs to disseminate information about pre-existing national networks and encourage the CLs to join the networks
- improving cooperation and exchange of information between all CLs of the network (including an AMR-alert function)
- improving the cooperation between the NRL, CLs and public health institutions to strengthen the national surveillance
- issue guidance on reporting of CL testing results
- digitalisation of data reporting in countries where reporting is done by paper or standalone software
- establish reporting of AST-data for the priority pathogens, and include as many CLs as possible in national surveillance
- obtain government (public) funding for operating a national network of CLs, especially in countries with many laboratories
- hosting annual meetings in the network of the CLs (and obtaining funding for this).

N: Countries/NRLs should be encouraged to support the formation and operation of national networks of CLs aimed at issuing national harmonised guidance on diagnostic methods, laboratory quality management systems, interpretation of results (according to EUCAST) and reporting to national surveillance systems, capacity building in the member laboratories and research.

5.9. Area 9: Staffing in clinical laboratories

Q21. On a scale from 1 to 5, how would you rate your staffing situation in relation to the workload resulting from the four priority pathogens (with 1 being not adequate at all and 5 being fully adequate)? (If your staffing situation is not fully adequate (score 1-4), please describe which areas are most affected (e.g. diagnostic testing, quality assurance, participating in EQA, paperwork, training and continuous education of staff etc.)

Strengths

In the **majority** of countries, the staffing situation of the CLs varied within each country with a distribution of scores being 3 ('somewhat adequate'), 4 ('adequate') or 5 ('fully adequate').

Across all participating CLs, a score of 1 was reported in 1.6%, score of 2 in 10.2%, score of 3 in 22.7%, score of 4 in 27.5% and score of 5 in 38% of CLs. The median score provided by all respondent CLs (n=502) was (4) 'adequate staffing'. Median scores of either 4 (10 countries) or 5 (10 countries) was reported **frequently** among countries.

In the **majority** of the countries 'fully adequate staffing' (score=5) was reported **frequently** by the CLs in combination with the lower scores of 'adequate staffing' (score=4) in **few** CLs, and/or 'somewhat adequate staffing' (score=3) in **few** CLs.

One coordinator pointed out that it was not all staff groups that were lacking in the clinical laboratories, but only IT-staff and specialised molecular biologists.

Weaknesses

Few national coordinators reported having few CLs with a staffing situation 'not adequate at all' (score=1) in few CLs.

However, it was frequent that national coordinators reported staffing situation deemed as 'not adequate' (score=2) in some CLs, or 'somewhat adequate' (score=3) in few CLs. Overall, median scores of 2 or 3 were reported in few countries.

Areas that were most effected by inadequate staffing level included;

- teaching and training members of staff and continuous education to maintain skills and proficiency
- completing paperwork (including mandatory documentation)
- quality assurance management
- performing admission and routine screening of hospitalised patients
- participation in external quality assessments
- implementation of new methodologies and services
- participation in professional networks

- accreditation of methodologies
- diagnostic testing (although this was prioritised over other functions)
- processing increased numbers of clinical samples referred to the CLs

The reasons for inadequate staffing varied from insufficient organisational resources or funding for the laboratory services to structural issues, such as competition with the private sector when recruiting, frequent retirements and lack of succession in the posts, lack of specialised laboratory personnel and medical doctors, and in some countries emigration of qualified staff to higher income countries.

The increasing pressures to perform quality controlled laboratory testing and holding accreditation are expected to exacerbate the situation, as the quality control and accreditation procedures require additional documentation, training, documentation etc. In addition to employing more staff, more laboratory automation would be helpful to free up the specialised (scientific) laboratory staff.

Area 9. Optional actions and needs

The NRL coordinators suggested a number of actions aimed at reducing the negative impact of inadequate staffing in CLs in their countries, including:

- the NRLs should support the accreditation procedures in the CLs (or networks of these), including training, provision of control material and organise EQAs for priority pathogens
- collaboration between the NRL and CLs should be enhanced, and surge capacity should be provided by the NRLs in extraordinarily busy periods
- the NRL should contribute to national surveillance
- the NRL should perform evaluations on newly commercial diagnostic tests
- the NRL should conduct training on how to perform diagnostic tests (e.g. by using on-line protocols or videos)
- the NRL should offer support to the NRLs on administrative issues
- the NRLs should share efficient bioinformatic tools with the CLs
- the NRL should provide training sessions and continuous education on antimicrobial resistance for priority pathogens for the CLs
- the NRL should provide training on electronic data reporting
- the NRL should provide training for newly hired laboratory staff (including a requirement for training on WGS and bioinformatics)
- the NRL should provide possibilities for training and education of laboratory staff through observerships and courses

Some coordinators also suggested some strategic and organisational actions, including:

- The NRL should apply for additional funding (if possible) or argue to the relevant national organisations and funding bodies that increased funding is key to provision of adequate microbiology services that in turn underpin preparedness in the countries
- Recruiting strategies should be improved in order to hire qualified personnel and stabilise an adequate staffing situation

N: The coordinators suggested a large number of supporting activities that the NRLs should carry out to support the CLs, including support on accreditation, provision of surge capacity, national surveillance (tasks), evaluation of new diagnostic test, deliver training

on AMR priority pathogens, reporting on data, training on methodologies including WGS, offer observer ships for graduates, recruiting strategies, and influencing funding bodies.

5.10. Area 10: Support from the NRL/NEL to the clinical laboratories

Based on the coordinators' assessments of the overall needs for support in their respective networks of CLs, activities were ranked with the most frequently requested activity being highest (i.e. no. 1):

Training/workshops for laboratory staff, NRL support visit to your laboratory

Training activities and workshops provided by the NRL for laboratory staff in the CLs were prioritised as an important (or most important) activity in all countries. More frequent and continuous training sessions (online and onsite) would be beneficial. In some countries, NRL visits to the CLs were requested in order to build laboratory capacity. Moreover, in some countries the CLs were not aware of existing NRL training activities; and more effective communication by the NRL was needed.

Examples of topics for the desired training included:

- diagnostics
- AST
- resistance in Gram-negative bacteria to carbapenems and/or colistin
- molecular biology techniques for detection of resistance mechanisms (PCR)
- comprehensive training in bioinformatics
- continuous training of specialised laboratory staff
- bespoke training based on the survey outcome of the training needs of the CLs

In conclusion, there was a need for supporting the CLs in building capacity and expertise in the core areas of the laboratories' services. Training activities and workshops would be beneficial for most CLs as well as participation in EQAs, having access to control material and receiving targeted supported when implementing new methodologies.

1. ***Receiving control materials***

Receiving control materials (isolates, DNA etc.) was also emphasised as one of the most import support functions that NRL should provide in the countries. The CLs also requested guidance on control materials from trusted sources (including national and international collections). It was also highlighted by several coordinators that receiving control materials in association with an EQA, and/or in association with training sessions, would be beneficial to the CLs. It was also suggested that control materials should be provided to entire networks of CLs to ensure easy and continued access to the control materials. Source funding for acquiring the control materials was needed in some countries.

2. ***Support for outbreak detection and management (including guidance)***

Support for outbreak detection and management was also requested in many countries. CLs expressed the need for protocols or guidance on outbreak detection and management, and also direct support provided by the NRL to the CLs during outbreaks, including advice and molecular typing and WGS analysis of isolates from putative outbreak cases. One coordinator suggested that the guidance provided on outbreak detection and management should be based on EU-level criteria.

The request (ordering) of outbreak support and typing/WGS from the NRLs should be formalised and made easy for the CLs. The NRL should inform the networks of CLs about

the outbreak services they provided (including details of typing and WGS services and storage of isolates). In addition to the support and guidance, the CLs also needed to build capacity for outbreak detection within their own laboratory or organisation. Coordinated efforts and cooperation between NRLs, public health organisations and the CLs were also suggested.

3. *External quality assessment (EQA) exercises for phenotypic antimicrobial susceptibility testing*

The CLs in most countries valued or requested that the NRLs frequently (e.g. yearly) organise EQAs especially for phenotypic AST. As mentioned above, the EQAs should be followed up by making control materials available to the CLs (isolates, DNA) and associated with training sessions.

The NRLs were asked to communicate/announce the EQA schemes, including those that cover the EURGen-RefLabCap priority pathogens.

4. *Participation in laboratory network*

The CLs in most countries considered the networks of laboratories helpful in building capacity and addressing their common needs for support, including all of the areas and issues described in this report, e.g.:

- EQA-exercises for phenotypic AST (and other methodologies)
- support for outbreak detection and management
- training for laboratory staff
- support for accreditation practices
- access to control materials

It was further suggested by one coordinator, that the NRL (or public health organisation in the country) should organise and coordinate the network in order to achieve a 'formal status' which would encourage more CLs to routinely send isolates to the NRL, and to communicate any novel needs or weaknesses. It was also pointed out that funding for running the network should be made available in each country (if not already covered).

5. *Accreditation practices*

Most coordinators mentioned that there was a need for the NRL to provide training and support to CLs that work on accrediting diagnostic methodologies. Support on practices and procedures of implementing and maintaining the accreditation (to the standards of CLs according to ISO 15189) was needed. As mentioned above, in the section on staffing, the support for accreditation practices was caused by inadequate staffing levels in some CLs.

6. *Funding for transportation of samples*

Most countries also mentioned the need for funding for transportation of samples from the CLs to the NRL, as this was not sufficiently covered in the budgets of the CLs. However, this needs to be solved at national level in each of these countries as outside the scope of this project.

7. *Long-term storage of isolates*

Few countries also mentioned the need for long-term storage of isolates. This is mostly relevant for isolates that are submitted by the CLs to the NRLs and subjected to WGS. However, this also needs to be solved at national level in each of these countries as outside the scope of European capacity building.

Area 10. Optional actions and needs

N: The NRLs should review the outcomes of their national mapping surveys to identify, plan and conduct supporting activities that would help the CLs to provide high quality diagnostic testing services including adequate data output on detection of priority pathogens.

6. LIMITATIONS

Some coordinators believed that some questions had been misunderstood by some of their respondents likely due to the reason that translations were not used frequently although available through translation services provided by EUSurvey.

Qualitative assessments in this report were primarily based on the comments and conclusions of the individual national surveys provided by the NRL coordinators. When narratives were not submitted, the national survey results (provided in Data reporting template) were used if possible. However, the authors of this report have limited knowledge of internal structures and setups etc. in each country.

The representativeness of the CLs in each country varied, as not all CLs were enrolled in their respective national networks (e.g. private laboratories are often not participating in NRL/NEL network activities). Moreover, the population coverage within the countries is a 'rough estimate', and should not be compared between countries. Standardization of population sizes reported in this survey was not possible, as the populations covered in each country were based on best estimates provided by respondents. The sizes and national coverage of the networks depended on multiple factors, including current setup and commissioning of CLs in the participating countries. Moreover, the coordinators in some countries may not have had knowledge about CLs outside their own sector or organisation. The variation in the national coverage by the respective national networks potentially introduced reporting bias in the semi-quantitative assessments of results of the survey. The different sizes of networks of CLs in the reporting countries should also be considered: small countries with few laboratories (1-3 or so) tend to report very high proportions of performing each activity or complying with requirements/guidance in contrast to large countries with many laboratories. Also, the laboratory functions of CLs in the small countries are maybe inherently more prone to cover national aspects than CLs in large countries with large numbers of CLs. As a result of these inconsistencies, comparisons between the participating countries should be done with caution.

7. CONCLUSIONS

The mapping survey of capacity for detection and characterisation of antimicrobial-resistant priority pathogens (carbapenem- and/or colistin-resistant Enterobacterales, *Pseudomonas aeruginosa* and *Acinetobacter baumannii*) was conducted by the national EURGen-RefLabCap coordinators among their networks of clinical laboratories in 25 European countries. The survey was aimed at identifying strengths and weaknesses in the national setups with a view to further develop or fill the gaps in the capacity for detection and characterisation of the priority pathogens within the participating countries.

This report provides a qualitative and semi-quantitative overview of the findings in the national reports, highlight suggestions for improvements received from the EURGen-RefLabCap coordinators, and propose options for actions at national levels and needs at European levels (see also: Executive summary).

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