TECHNICAL REPORT

EU Laboratory Capability Monitoring System (EULabCap)

Report on 2016 survey of EU/EEA country capabilities and capacities

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This report of the European Centre for Disease Prevention and Control (ECDC) was prepared by Katrin Leitmeyer, Joana Revez and Marc Struelens (ECDC Microbiology Coordination Section).

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Abbreviations

AMR	Antimicrobial resistance
ARV	Antiretroviral
CPE	Carbapenemase-producing *Enterobacteriaceae*
EARS-Net	European Antimicrobial Resistance Surveillance Network
EQA	External quality assessment
EU/EEA	European Union/European Economic Area
EULabCap	EU Laboratory Capability Monitoring System
ERLTB-Net	European reference laboratory network for tuberculosis
ESBL	Extended spectrum beta-lactamase-producing *Enterobacteriaceae*
EUCAST	European Committee on Antimicrobial Susceptibility Testing
FWD	Food- and waterborne diseases
HIV	Human immunodeficiency virus
IQR	Interquartile range
MDR TB	Multidrug-resistant tuberculosis
MERS-CoV	Middle East respiratory syndrome coronavirus
MLST	Multilocus sequence typing
NMFP	National microbiology focal points
NAC	National antimicrobial susceptibility committee
NRL	National reference laboratories
OECD	Organisation for Economic Cooperation and Development
PCR	Polymerase chain reaction
SMAP	ECDC's strategic multi-annual programme
VTEC/STEC	Verotoxin- or Shiga toxin-producing *Escherichia coli*
TESSy	The European Surveillance System (ECDC)
TB	Tuberculosis
TB-DST	Tuberculosis drug susceptibility testing
VHF	Viral haemorrhagic fever
WGS	Whole genome sequencing
WHO	World Health Organization

Glossary of terms

Laboratory capability	The ability to perform the following functions: manage laboratory activities; perform sample management; conduct testing and analysis for routine and surge capacity; support public health investigations and report results [1].
Laboratory capacity	Consists of output services completed over a defined time period for each capability [2].
National microbiology focal points	Appointed representatives for public health microbiology in the EU/EEA Member States as part of the Competent Body Structure [3].
National reference laboratories	Public health microbiology laboratories with national responsibility and appropriate tools and skills to be able to support national surveillance and capacity to deal with emergency situations [4,5].
Public health microbiology	A cross-cutting area of microbiology that spans the fields of human, animal, food, water, and environmental microbiology, with a focus on human health and disease. It covers the laboratory's contribution to the detection and diagnosis of infectious microorganisms, and the characterisation and surveillance of microorganisms that have the potential to affect populations [4,5].

Executive summary

Background

ECDC aims to foster and reinforce the EU public health microbiology system to provide timely and reliable information for infectious threat detection, the assessment of such threats, and their surveillance at the Member State and EU levels, thus ensuring the effective prevention and early control of infectious diseases [4]. To ascertain how well this is delivered, ECDC developed, in close collaboration with national microbiology focal points from all European Union/European Economic Area (EU/EEA) countries and the ECDC Advisory Forum, the EULabCap survey methodology for monitoring. The EULabCap survey assesses, on an annual basis, key public health microbiology capabilities and capacities for EU surveillance and epidemic preparedness. The EULabCap results help policymakers at all levels identify possible areas for action and evaluate the impact of capacity strengthening activities and health system reform.

This fourth EULabCap report presents EU/EEA laboratory capabilities and capacities for 2016 and compares them with previous survey results [6-8].

Methods

The EULabCap monitoring tool combines 60 indicators to assess the capability and capacity of microbiology laboratories to provide essential public health functions, as defined in EU policies and action plans, international health regulations, and technical standards. The EULabCap indicators comprise 24 structure and 36 process indicators. They are grouped into 12 targets distributed across three dimensions: primary diagnostic testing, national microbiology reference laboratory services, and laboratory-based surveillance and epidemic response support. Each indicator can be scored at three levels: low, intermediate or high capability/capacity. Aggregated indices were calculated for each target and dimension as the average of component indicator scores; all index values are displayed on a scale of 0–10. In 2016, two indicators were not applicable, and two indicators were replaced by new ones to reflect new and updated EU standards.

A mixed method was used for data collection and scoring, which took place from October to December 2017. To minimise the data reporting burden for the Member States, ECDC retrieved information for 18 indicators from TESSy datasets (The European Surveillance System) and EU disease network reports. For the remaining 40 indicators, the national microbiology focal points (NMFP) used a questionnaire to collect information from their country. The data collected for 2016 were validated by the NMFP in December 2017. As soon as validated data became available, country profile reports and benchmarking results were shared with the NMFP so that they could inform the national stakeholders about key results and areas that required attention. Maps illustrating the country scores (EULabCap index levels) were published on the ECDC Web portal.

In January–March 2018, an NMFP feedback survey was conducted on the dissemination and use of the EULabCap reports for 2014 and 2015 to develop measures for capacity strengthening at the national level.

Results

The country response rate to the 2016 survey was 100%. Data were provided for 97% of the applicable indicators (range per country, 90–100% complete data available).

The average EULabCap 2016 index for all EU/EEA countries was 7.5 on a scale of 0–10, as compared to 7.5 in 2015, 7.3 in 2014, and 6.9 in 2013. In 2016, individual EULabCap indices per country ranged from 5.6 to 9.6 as compared to 4.7 to 9.2 in 2013, indicating that differences between national systems gradually decreased over the period 2013–2016. Ten countries improved their EULabCap index; five climbed from low to fair, and another five countries went from fair to high.

Average EULabCap scores varied among the EULabCap public health targets, with improvement found in many areas, but also consistently low scores in two areas:

- Strong overall EU/EEA capacities since 2013: antimicrobial drug susceptibility testing; antimicrobial drug resistance monitoring; laboratory collaboration within national and EU surveillance networks; provision and regulation of NRL microbiology services; and reference diagnostic confirmation for EU notifiable diseases;
- Improved capabilities across Europe in 2016: provision and regulation of clinical and reference microbiology services, diagnostic testing guidance, contribution of reference laboratories to detection and response to emerging diseases and multi-drug resistance threats;
- Persistent low capacity for many countries in 2016: utilisation of diagnostic testing and molecular typing data reporting for EU surveillance.

Not all EU/EEA Member States have reached sufficient levels of laboratory capability and capacity across all targets to conduct effective public health surveillance and provide an adequate level of disease threat response. In 2016, as in 2015, 19 countries fulfilled sufficient (fair to high) capacity levels for at least 10 of 12 EULabCap targets. Eight of these countries scored sufficient capacity levels for all targets.

The NMFP of 27 EU/EEA countries participated in a survey on national dissemination and use of EULabCap reports. The EU LabCap country reports based on 2013–16 data were disseminated by NMFP to stakeholders in all responding countries; they were considered useful in 23 countries as a tool for advising national authorities. Overall, the EULabCap country reports were mainly discussed with microbiologists and epidemiologists at the national level; in 17 countries the reports were communicated also to decision makers or senior management.

In 24 countries, follow-up actions were undertaken between August 2015 and March 2018 to address areas that required attention while three countries reported no follow-up activities. National capacity strengthening efforts focused on the following five areas: quality of reporting of microbiological surveillance data to ECDC, regulation of national reference laboratory services, transition to WGS for typing, involvement of reference laboratory in outbreak investigations, and development of national diagnostic testing guidance.

Conclusions

The high response rate to the EULabCap surveys highlights the continued commitment of EU/EEA countries to this health system benchmarking process. It also enables a robust assessment of collective EU/EEA and country-level laboratory system capacity. The results of this fourth annual survey confirm that the EU/EEA, with an aggregated index score of 7.5/10 for 2016, can rely on microbiology services that are already fairly strong and contribute substantially to public health capabilities that are continuously improving.

Overall, public health microbiology services in the EU/EEA meet most key requirements for communicable disease surveillance and response. However, not all EU/EEA Member States have yet reached sufficient levels of laboratory capability and capacity across all targets assessed by EULabCap in order to deliver effective public health surveillance and threat response. 'Sufficient microbiology capacity' (defined as intermediate or high capacity for at least 10 of 12 EULabCap targets) was achieved by 19 of the 30 EU/EEA Member States in 2015–16.

Steady increases in the average EULabCap indices of a substantial number of countries over the past four years suggest that public health microbiology shortcomings are being addressed. Narrowing variation in the EULabCap index between countries over the past years indicates technical convergence and progress toward a more equitable balance of laboratory capacities among Member States.

The survey results can assist countries in focussing their efforts to achieve a level of 'sufficient microbiology capacity'. EULabCap monitoring provides detailed EU/EEA benchmarking information for national competent bodies and policymakers at the national level. It is noteworthy that results from the 2018 feedback survey indicated that the annual EULabCap reports were disseminated to stakeholders in all countries. EULabCap reports were also considered useful for advising national authorities in the vast majority of the participant countries where relevant system capacity strengthening actions were carried out over the last years.

Gaps and inefficiencies still to be addressed in some countries include the development of wider clinical guidance for upgrading to genomic methods for the detection and characterisation of epidemic agents, guidance on the adequate utilisation of diagnostic tests, and enhanced digital connections between laboratory information and public health monitoring and early warning systems at national and EU levels. These gaps were reviewed by ECDC, the competent bodies in the Member States, the European Commission, and several international partners in 2017 to inform the ECDC microbiology priorities and support activities for 2018–22.

Introduction

The laboratory detection and characterisation of infectious agents causing human disease provides essential information for clinical management, public health surveillance, and outbreak alert and response. As the epidemic of Ebola virus disease in West Africa has shown, any gap in laboratory capacity may prove disastrous because of delayed outbreak recognition and response. Sufficient national laboratory capacity for infectious health threat detection and control is required to fulfil the obligations set forth in EU [9] and international legislation [10] and relies heavily on close collaboration with national surveillance systems, adequate funding, infrastructure, and human resources at national healthcare systems.

Public health microbiology systems comprise three intertwined components:

- Clinical laboratories performing primary diagnostic testing, antimicrobial drug susceptibility testing and screening, with a focus on patient management and preventive services.
- Public health laboratories serving as reference functions at a national or subnational level, providing specialist diagnostics and characterisation of biological agents.
- Laboratory networks performing harmonisation of methods, quality assessment, and contributing to public health surveillance and alert systems, nationally and internationally.

National health systems in Europe are undergoing continuous administrative and organisational reforms to respond to the challenge of maintaining universal access to essential and high-quality care with reduced resources [11]. Following the financial crisis in 2008, health expenditure has either stopped growing or even decreased by various degrees across EU Member States [11]. Public health budget cuts have affected the available resources and investments for laboratory operations.

The Founding Regulation of ECDC (EC No. 851/2004) states that 'by encouraging cooperation between expert and reference laboratories, the Centre shall foster the development of sufficient capacity within the Community for the diagnosis, detection, identification and characterisation of infectious agents which may threaten public health' [12]. In this dynamic context, monitoring the collective laboratory capabilities in the EU/EEA is important in order to identify best practices and address potential vulnerabilities.

Europe benefits from a legacy of collaboration between infectious disease experts spanning decades. Microbiologists and epidemiologists have for years participated in dedicated surveillance networks and other professional initiatives to harmonise laboratory methods, promote quality, and build capacity. Results from previous laboratory mapping exercises in the EU, conducted by ECDC [13] and the European Commission [14], have revealed significant differences in services, infrastructure, technical capacity, public health activities and human resources. Specific areas identified as being of potential EU added-value included the training of laboratory staff, method harmonisation, and the establishment of specialist technical capacity at the supranational level [13,14].

The 2012–2016 ECDC public health microbiology strategy aimed to strengthen the capability and capacity of the EU public health microbiology system to provide timely and reliable information that underpins infectious threat detection, assessment and surveillance at the EU level to ensure the effective prevention and control of infectious diseases [4]. ECDC, in close collaboration with its national microbiology focal points (NMFP) and the ECDC Advisory Forum, developed and piloted a system (EULabCap) for monitoring key public health microbiology capabilities and capacity for EU surveillance and epidemic preparedness. After piloting the data collection and indicator scoring instrument, the first survey was launched in 2014 (on 2013 system outputs) [7] and repeated, with minor adjustments, for the 2014 and 2015 data collection [6,8].

The NMFPs are the main contributors to data collection and verification. They are also responsible for disseminating the EULabCap country profile report to their competent bodies, in accordance with their terms of reference [3]. At the national level, detailed benchmarking information – provided as country profiles – can be used to provide decision makers with options to strengthen the system where relevant (e.g. by adopting good practices or initiating bilateral laboratory cooperation).

This report presents the results of the fourth EULabCap survey of laboratory capabilities and capacities in the EU/EEA; the 2016 results are compared with previous surveys [6-8] and the results of a country feedback survey on the national use of previous EULabCap reports.

Materials and methods

EULabCap survey

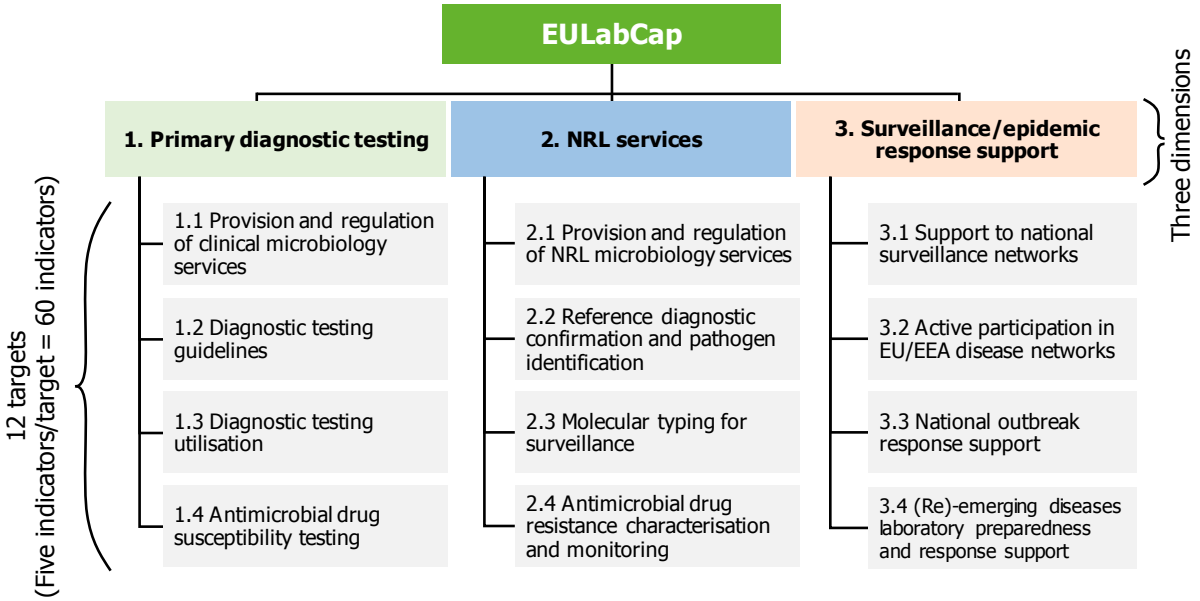
Survey population

The fourth data call for the 2016 EULabCap survey on the laboratory capabilities and capacities of 28 EU Member States and two EEA countries was launched in October 2017. Liechtenstein was not included in the survey due to outsourcing arrangements with laboratories in Switzerland.

EULabCap survey tool

An Excel-based data collection tool was developed and pilot tested in close collaboration with the NMFPs. The EULabCap monitoring tool is composed of 60 performance indicators, grouped into 12 targets (Annex 1) which are equally distributed across the following three public health microbiology system dimensions: primary diagnostic testing, national microbiology reference laboratory (NRL) services, and laboratory-based surveillance and epidemic response support (Figure 1).

Figure 1. Structural overview of EULabCap indicators, by dimension and target



The EULabCap indicators (Annex 1) are of a composite nature in terms of which system elements are measured (structure or process) and how they measure these elements (functional capability or capacity). They consist of 24 structure and 36 process indicators. They are divided into 38 indicators on laboratory capability and 22 on capacity (Table 1). The policy rationale for the design of indicators/targets and score levels was based on previously agreed EU policy targets or international technical standards for three quarters of the indicators, while the remainder assess EU surveillance and alert system contributions (Annexes 1 and 2). EU/WHO policy documents and international standards used to develop EULabCap indicators are provided in Annex 3.

Table 1. Distribution of EULabCap indicators by dimension, element and function measured

Dimension	Number of indicators by element		Number of indicators by function	
	Structure	Process	Capability	Capacity
Primary diagnostic testing	11	9	11	9
National reference laboratory services	5	15	14	6
Surveillance/epidemic response support	8	12	13	7
Total	24	36	38	22

Scoring system

Each indicator was scored at three levels: low (0, 'no or limited capability/capacity'), intermediate (1, 'partial capability/capacity', e.g. below the EU target, or partial compliance) or high (2, 'complete capability/capacity', e.g. EU target reached, or high compliance). Indicators for which data were not available or that were not applicable (NA) to the country were not scored [7].

Indicator modifications

EULabCap indicators and scoring criteria for the fourth survey were reviewed for clarity of wording and applicability by the NMFP and ECDC disease experts in 2017. The following indicators were modified to conform to current EU standard practice or address emerging issues:

Two obsolete indicators were replaced:

- New indicator 2.45, 'Antimicrobial susceptibility data were reported to ECDC in accordance with the EU protocol for harmonized monitoring of antimicrobial resistance in human *Salmonella* and *Campylobacter* isolates'.
- New indicator 3.45, 'National guidance was available for colistin susceptibility testing and detection of acquired colistin resistance in carbapenem-resistant *Enterobacteriaceae* and confirmation and identification of colistin resistance mechanism was provided by NRL to clinical laboratories'.

The scoring criteria for the following indicators were slightly modified:

- Indicator 2.32, '*Salmonella enterica* serotype Typhimurium and Enteritidis isolates were characterised with MLVA genotype and reported to ECDC'.
- Indicator 2.34, 'Percentage of typed invasive *Neisseria meningitidis* isolates by (serogroup and MLST) or (serogroup and *porA* and *fetA*) according to the fine-typing scheme recommended by the European Meningococcal Disease Society (EMGM)/IBD-LabNet, reported to ECDC out of the total of EU reported cases.
- Indicator 3.14, 'National Influenza Centres/influenza reference laboratories performed a systematic sentinel sampling of influenza and respiratory syncytial viruses (RSV)'.
- Indicators 3.22-3.25 revised to include participation in EQAs and/or surveillance data reporting.
- Indicator 3.42, 'Diagnostic and characterisation capability for avian influenza A(H7Nx) and A(H5Nx) viruses available at national level in accordance with ECDC/WHO surveillance guidance'.

The following indicators were not applicable in 2016, due to interruption of scored activities of networks:

- Indicator 3.21, 'Country was an active participant in the European Legionnaires' Disease Surveillance Network (ELDSNet)'.
- Indicator 3.23 'Country was an active participant in the European Invasive Bacterial Disease Laboratory Network (IBD-LabNet)'.

Data collection and validation

Data collection and validation were performed between October and December 2017. As in the previous surveys, a mixed method was used. As two indicators were not applicable to 2016 data, information was retrieved for 58 indicators as follows: a) 18 indicators measured by ECDC from datasets accessible in TESSy and EU disease network reports, and b) 40 indicators reported by the NMFPs through the questionnaire (Annex 1). Two rounds of validation were performed between November and December 2017. The NMFPs were asked to review and verify the data and correct indicator score calculations.

Data analysis, performance measurement and interpretation

Data completeness was calculated as a percentage of reported data for each indicator across the EU/EEA and for all indicators in each country. Aggregated performance indices were calculated for each target and dimension as the means of component indicator scores per country; all values were displayed on a scale of 0–10.

Overall EULabCap index scores per country were graded qualitatively (by three performance levels), indicating a country's average capability and capacity with regard to its public health microbiology system: low level (index value range: 0 to 5.9), intermediate level (6.0 to 7.9) and high level (8.0 to 10).

The number of EU/EEA countries with 'sufficient capacity' was measured by taking into account the balance of service provision and performance across EULabCap targets. 'Sufficient country capacity' was defined as reaching an EULabCap target index at an intermediate or high performance level (score 6 or above) for more than 10 of the 12 targets.

Descriptive data analysis was performed, including measures of central tendency (mean and median) and dispersion (minimum–maximum range, interquartile range) of indicator scores and indices across the EU/EEA countries. Means were used for comparing EU scores average levels by indicator. Medians (and interquartile range) were used for comparing the intercountry distribution of index scores by targets and dimensions over time.

Data reporting

Individual country reports

In December 2017, the ECDC Microbiology Coordination Section confidentially shared individual EULabCap country profile reports with the respective NMFP for dissemination to their national Coordinating Competent Body stakeholders. Each country report consisted of a customised one-page executive summary for the country's decision makers, presenting the benchmark scores in the country, the areas of good national system capacity/capability, and the weaker areas in need of attention. In an annex, survey methods were explained. All country results were illustrated with: a) a radar graph comparing the country's median 2016 EULabCap index scores for the 12 targets against the 2016 EU/EEA interquartile score range; b) the score distribution among EU/EEA countries compared with the country's scores for each indicator in 2016, and c) the country's mean scores per target and indicator for 2013–2016.

EULabCap maps

In December 2017, the EULabCap country capability/capacity levels 2016 were published as EU/EEA online maps. Maps illustrated the EULabCap index scores: 'low level' (score 0 to 5.9), 'intermediate level' (score 6.0 to 7.9) and 'high level' (score 8.0 to 10) as used in this report.

EULabCap report

This report presents and discusses results of the EULabCap 2016 survey from all EU/EEA countries, using histograms, radar graphs, line graphs and bar graphs. It also uses maps to visualise the distribution of EULabCap index scores among countries for the microbiology system overall, by indicator, target and dimension. Also presented are the 2013–2016 survey data for target and dimension indices.

Survey on the use of EULabCap reports and follow-up actions

To obtain feedback on the national dissemination of the previous EULabCap reports and their usefulness for policy advice and changes in laboratory practice, a NMFP follow-up survey was conducted between 19 December 2017 and 5 March 2018. The online questionnaire survey included four questions that focused on the usefulness of the reports for advising national authorities, the reports' dissemination, and on the usefulness of findings with regard to corrective actions at the national level between 2015 and 2017 (Annex 4).

Results

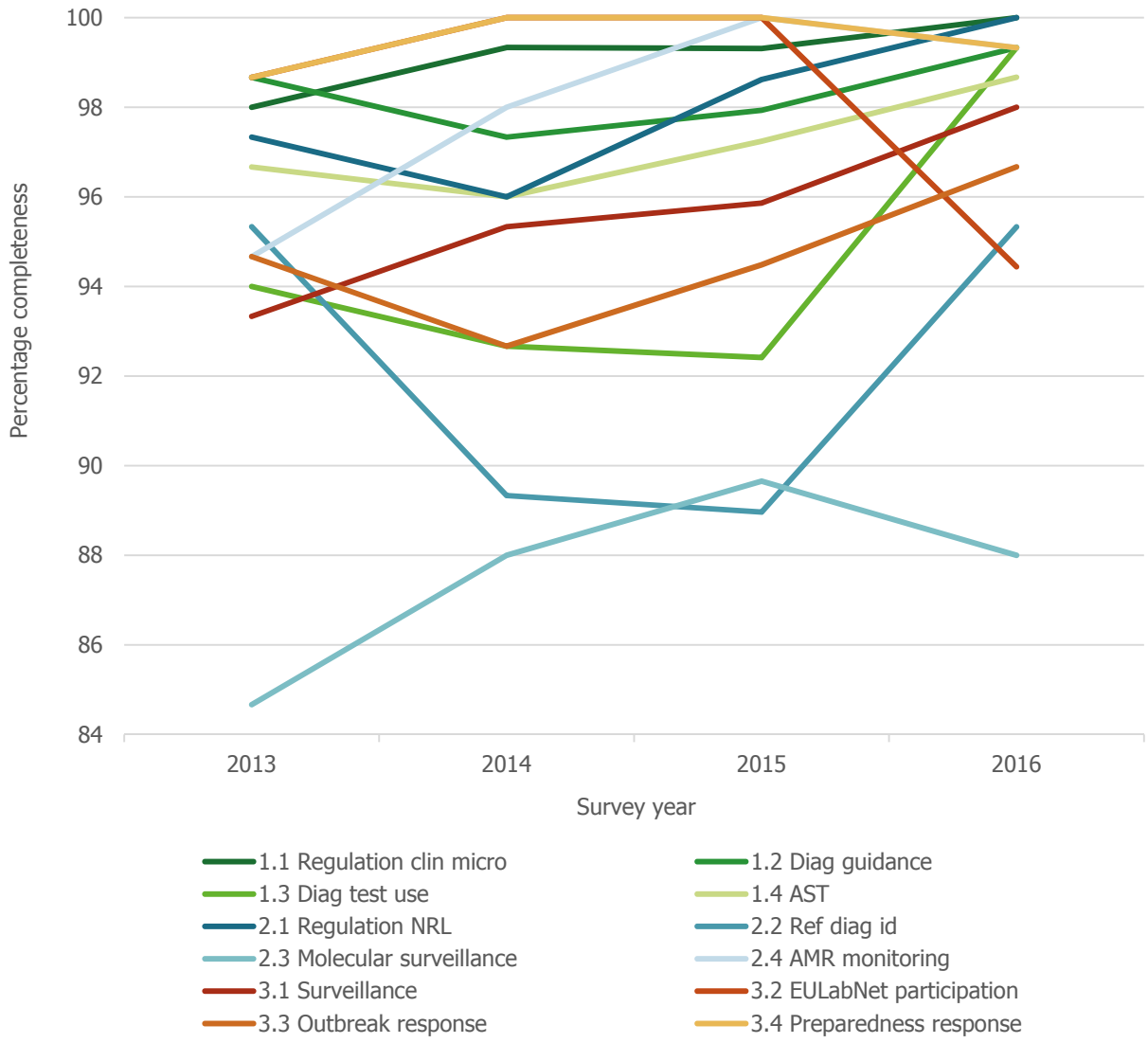
EULabCap survey

Response rate and data completeness

The country response to the 2016 survey was 100% (30 EU/EEA countries participating). Data were provided for 97% of the indicators (1 696 out of 1 740 data points). Data completeness ranged from 90–100% by country and from 69–100% by indicator (Annex 5). In 2016, the completeness by target ranged from 88% to 100%, with target 2.3 'Molecular surveillance' lagging behind (Figure 2). Only four indicators had missing data in excess of 10% (i.e. four or more countries failed to submit their 2016 data, compared with six indicators in 2015; Annex 5).

Compared with previous surveys, data completeness continued to increase slightly in 2016 (Figure 2). This was in part due to the revision of several indicators: unlike last year, when data that were not reported to the national surveillance system were marked as 'not available/missing information', unreported data for 2016 received a score of 0 ('low capacity').

Figure 2. EULabCap data completeness by target, 2013–2016 (N=30 countries, except N=29 countries in 2015)



Note: Completeness for Target 3.2 – EU networks used a different denominator for 2014 (four indicators) and 2015–2016 (three indicators)

Laboratory capabilities and capacities at the EU/EEA level

In 2016, the average EULabCap aggregated index score for the 30 participating EU/EEA countries was 7.5 on a scale of 0–10. The average score in 2015, calculated for 29 participating countries, was also 7.5. In 2014, the average score was 7.3; a year earlier, the score was 6.9.

As in previous surveys, the 2016 EULabCap index country scores showed unimodal distribution with broad intercountry variation, ranging from 5.6 to 9.6. The index distribution by country narrowed around the mean over survey years, indicating a continuous decrease of heterogeneity across countries (Figure 3 and Annex 6).

Figure 3. Normal distribution of EULabCap country index scores by survey year, 2013–2016 (N=30 countries, except N=29 countries in 2015)

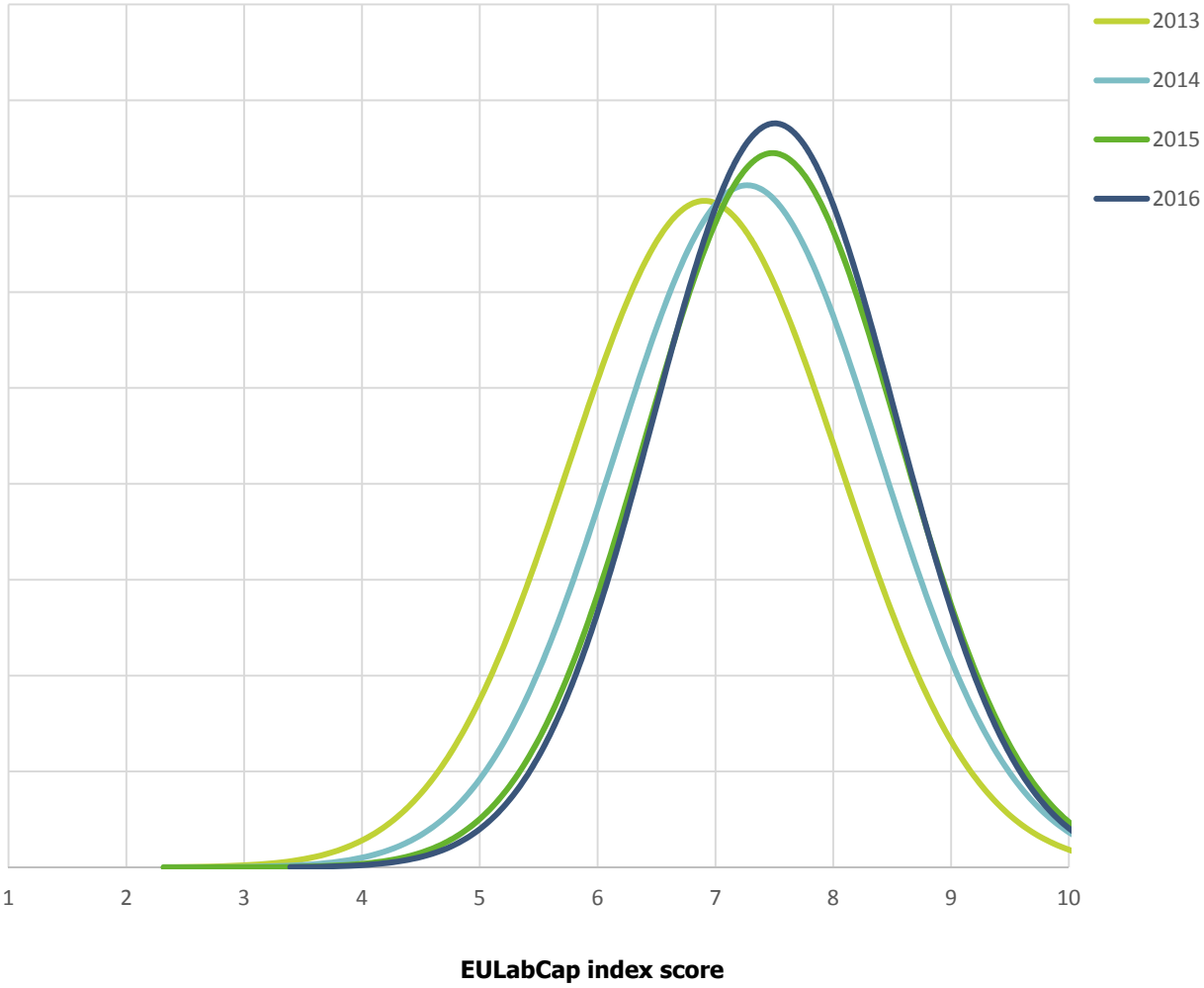
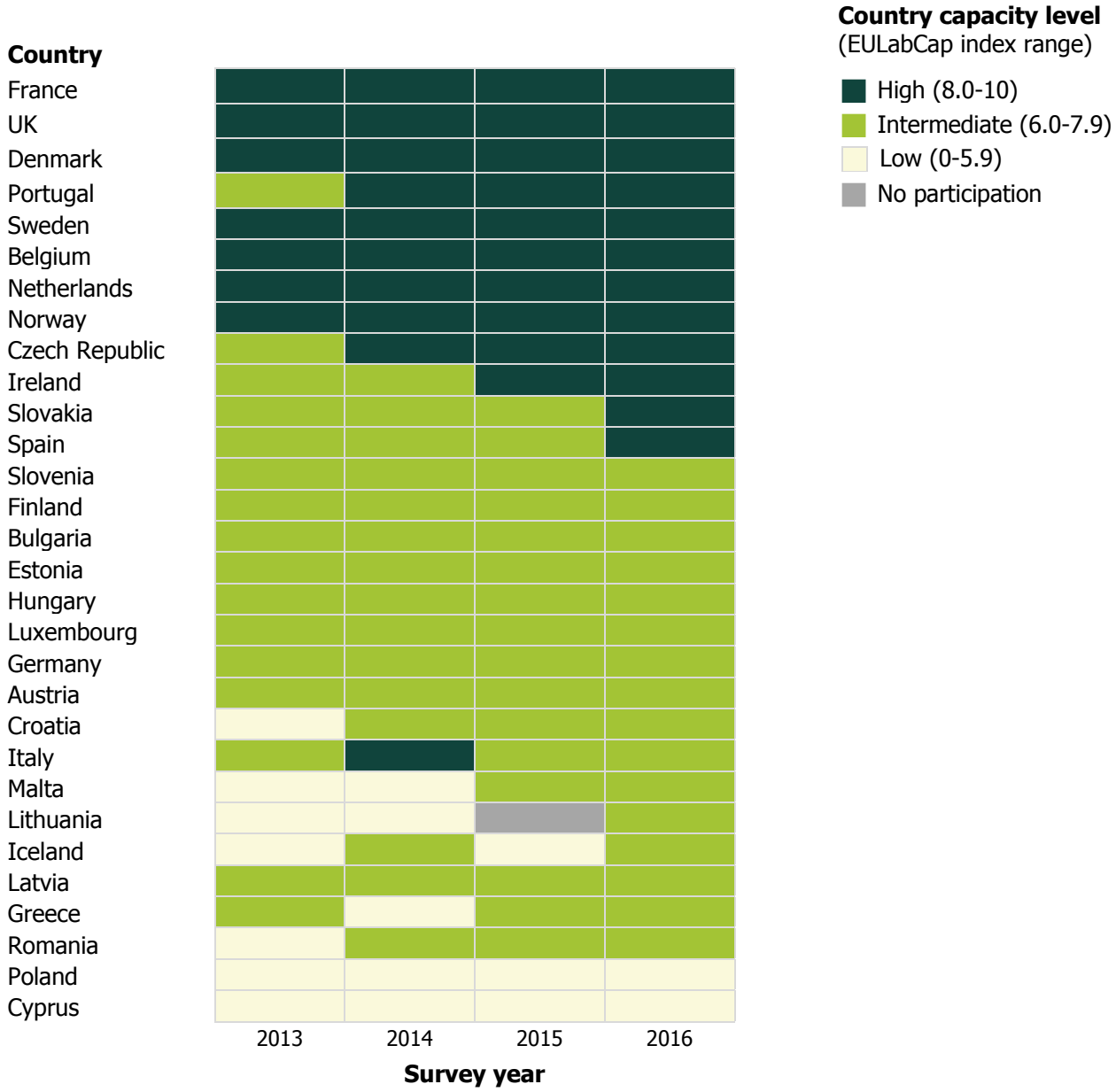


Figure 4. Change in annual distribution of EU/EEA countries by capacity level based on EULabCap index scores, 2013–2016 (N=30 countries, except N=29 countries in 2015)



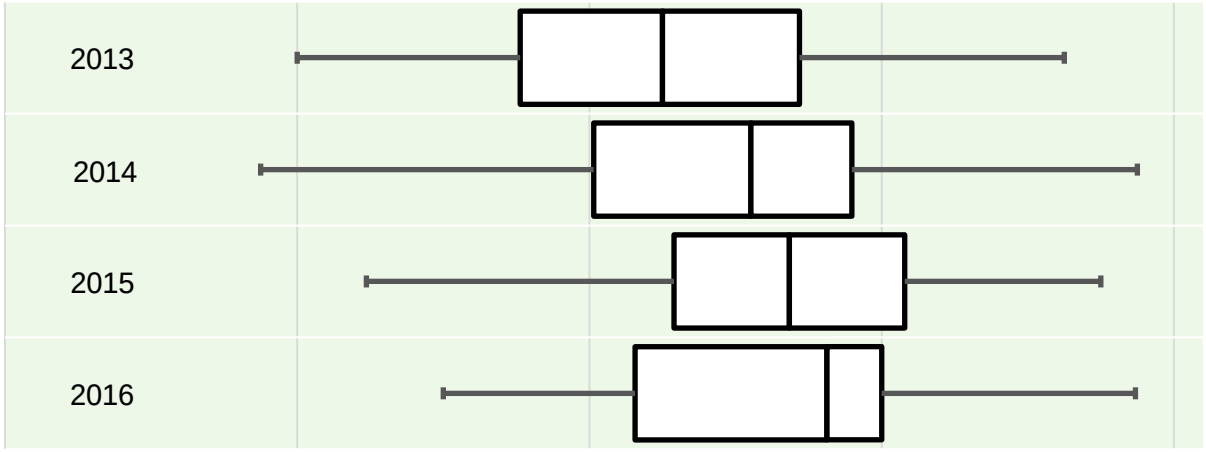
Between 2013 and 2016, inequalities between nationals systems gradually decreased, with ten countries upgrading their EULabCap index from low to fair (five countries) or fair to high (five countries) (Figure 4).

An analysis of performance scores by microbiology system dimension showed different distributions across dimensions in 2016, with a median index of 7.6 (IQR 6.3–8.0) for primary diagnostic testing, 7.6 (IQR, 6.8–8.3) for NRL services, and 7.8 (IQR, 6.9–8.8) for laboratory-based surveillance and epidemic response support (Figure 5).

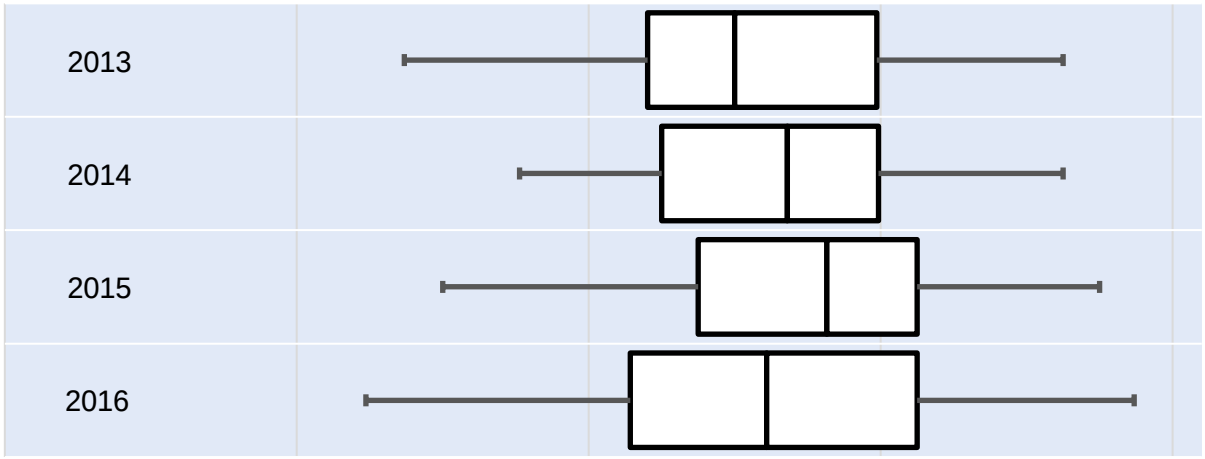
The EU/EEA median index scores per dimension steadily increased in all three dimensions between 2013 and 2016 (Figure 5). The largest increase was noted for laboratory-based surveillance and epidemic response support (median index increase from 7.4 to 8.2) and primary diagnostic testing. By contrast, the median index for NRL services decreased and the range widened in 2016 in comparison to 2015, indicating that heterogeneity between countries for this system dimension also grew.

Figure 5. Box plot (median, interquartile and minimum–maximum ranges) of EULabCap index scores by dimension and survey year, 2013–2016 (N=30 countries, except N=29 countries in 2015)

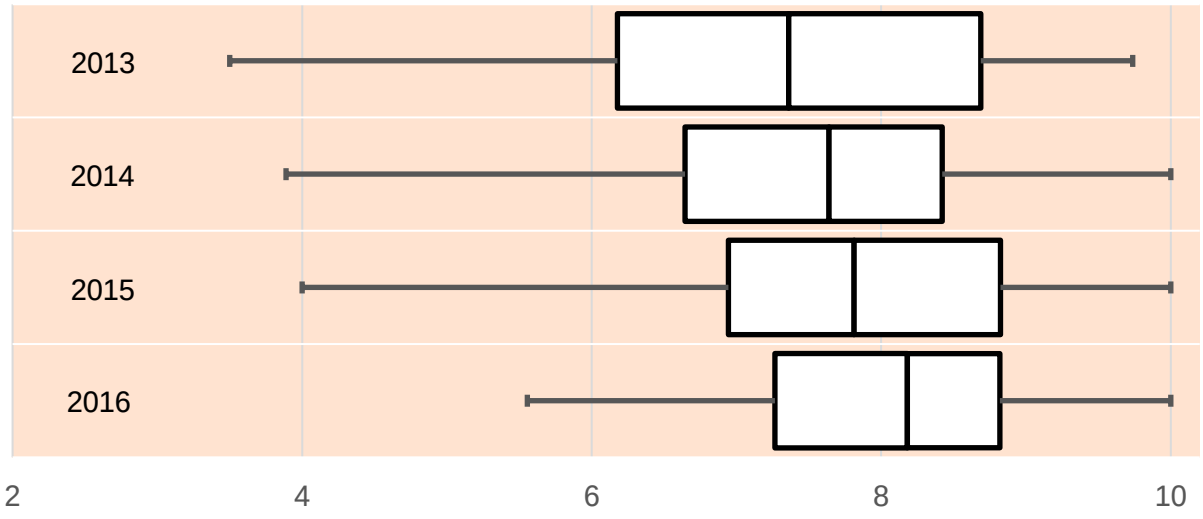
Dimension 1. Primary diagnostic testing



Dimension 2. NRL services



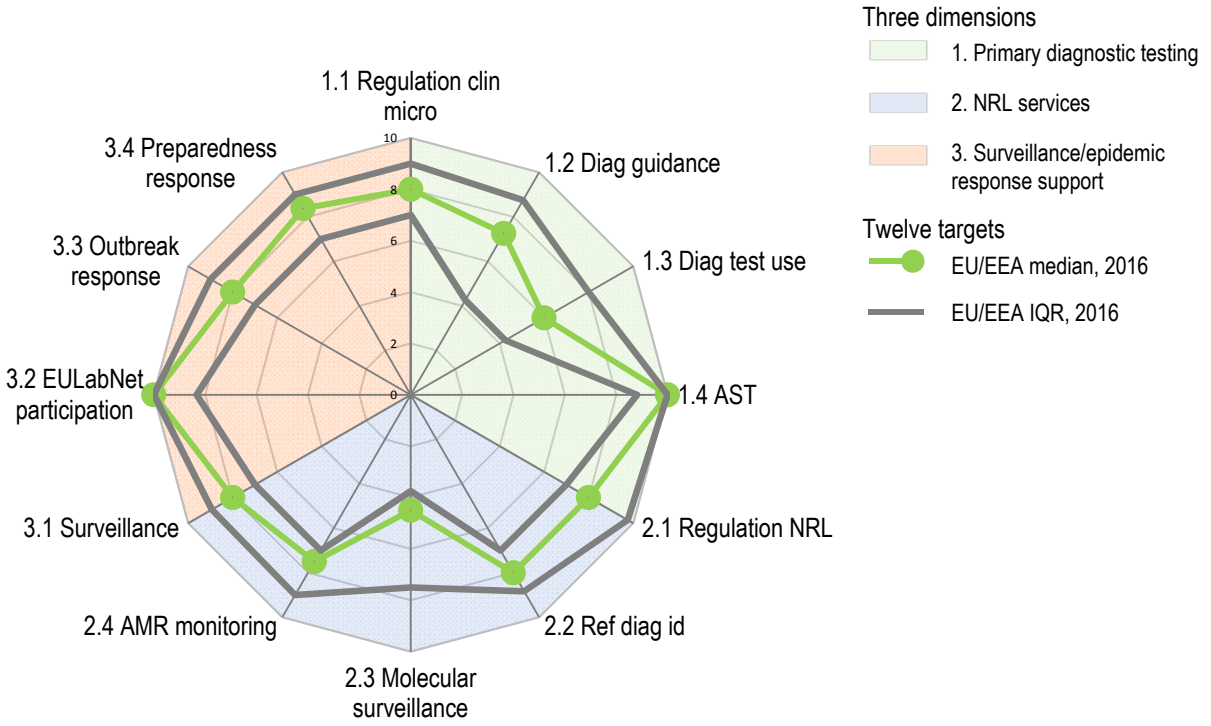
Dimension 3. Surveillance/ epidemic response support



EULabCap dimension index score

Analysis of performance scores by system target. An analysis of the 2016 EULabCap target index scores (median and interquartile range) showed a high average performance level (median score 8 and above) for the majority of targets, except for the use of diagnostic tests and guidance for diagnostic tests; AMR monitoring and molecular surveillance were also underperformers (Figure 6).

Figure 6. Distribution of EULabCap index scores (EU/EEA median and interquartile range) by target in 2016 (N=30 countries)



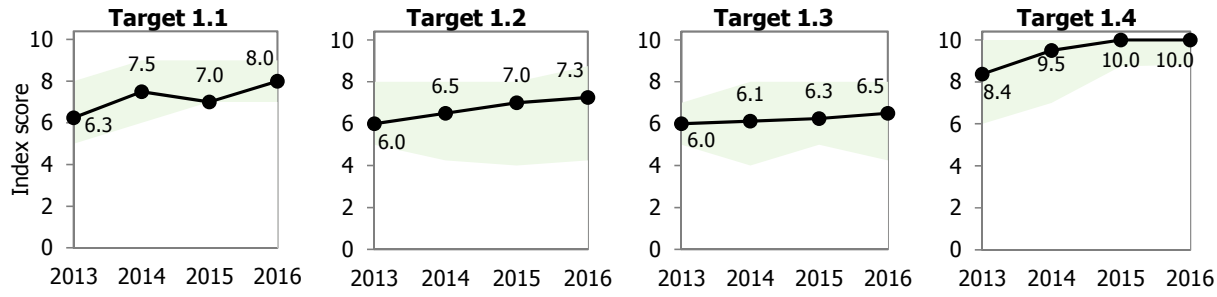
Temporal trends for EU performance by target, 2013–2016

To monitor the evolution of average EU laboratory performance per target and explore the heterogeneity between EU/EEA countries, Figures 7–9 present the yearly median (IQR) EULabCap scores per target and by system dimension over survey years.

Primary diagnostic testing targets

EU/EEA median (IQR) scores (2013–2016) for targets in the dimension of primary diagnostic testing are shown in Figure 7. Between 2013 and 2016, the index showed an upward trend or a stable performance level for all targets in primary diagnostic testing (Figure 7).

Figure 7. Median and interquartile range of yearly EULabCap target scores in primary diagnostic testing, 2013–2016 (N=30 countries, except N=29 countries in 2015)



Target 1.1. Provision and regulation of clinical microbiology services. This target showed fluctuation in the median score, but there was an overall improvement of performance over time. In 2016, 17 EU/EEA countries had a high level of capacity/capability (score of 8.0 or above) for this target.

Target 1.2. Diagnostic testing guidelines. Although a continuous positive trend in performance was observed over time, the widening interquartile ranges still reflect disparity between countries with regard to the availability of national diagnostic and screening guidelines. In 2016, 14 EU/EEA countries had a high level of capacity/capability (score of 8.0 or above) for this target.

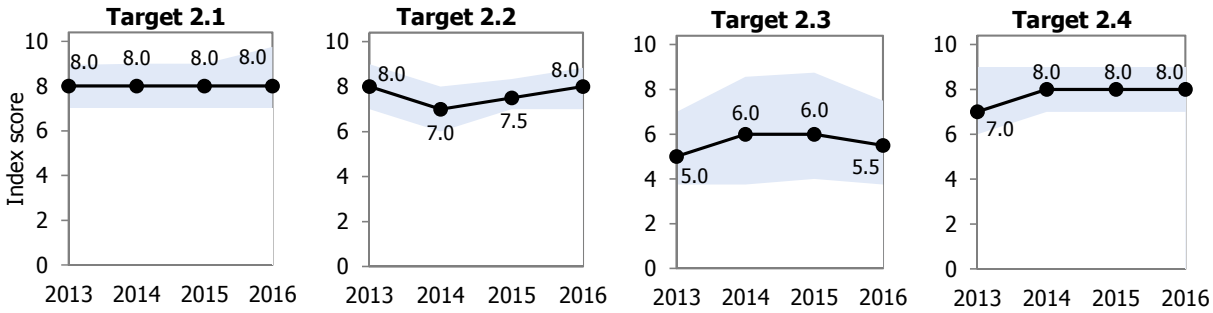
Target 1.3. Diagnostic testing utilisation. This is a weaker target within the primary diagnostic testing dimension. In 2016, only 10 EU/EEA countries had a high level of capacity/capability (score of 8.0 or above) for this target.

Target 1.4. Antimicrobial drug susceptibility testing. This target showed rapid and continuous improvement over the years, with 25 EU/EEA countries ranking as 'high capacity/capability' for harmonised testing in 2016.

National reference laboratory services

EU/EEA median (IQR) scores (2013–2016) for targets in the area of national reference laboratory services are shown in Figure 8.

Figure 8. Median and interquartile range of yearly EULabCap target scores for national reference laboratory services, 2013–2016 (N=30 countries, except N=29 countries in 2015)



Target 2.1. Provision and regulation of NRL microbiology services. High scores were found across all targets; 21 EU/EEA countries show a stable, high level of capacity/capability with regard to organisation, regulation, and funding of their NRL infrastructure; all core public health functions were delivered consistently over the years.

Target 2.2. Reference diagnostic confirmation and pathogen identification. Solid results across all countries, with testing capability/capacity remaining at an intermediate level in 11 EU/EEA countries in 2016; another 17 achieved a high level of performance. A dip observed between 2013 and 2014 is likely due to methodological changes.

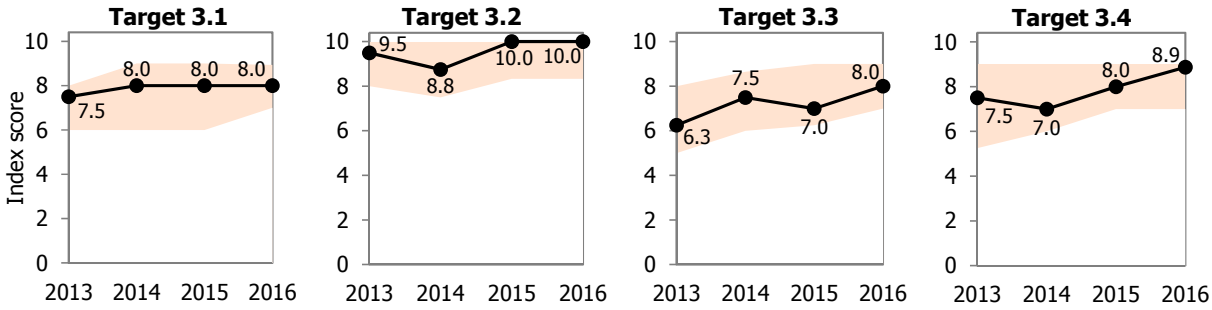
Target 2.3. Molecular typing for surveillance. A challenging target characterised by a low baseline level of capability/capacity for molecular typing for surveillance purposes in half of the countries. (Methodological note: indicators for this target were adapted several times over the years). There is persistent heterogeneity among EU/EEA Member States. The decrease in median scores observed in 2016 is related in part to a revision of indicators and a decrease in the percentage of MDR-TB isolates genotyped by classic methods. These context and technical changes mask progress achieved through the introduction of the WGS methodology for surveillance by 15 EU/EEA countries in 2016.

Target 2.4. Antimicrobial drug resistance characterisation and monitoring. Good results across the EU/EEA; 16 EU/EEA countries showed a stable, high level of capacity/capability over the last three years because they were able to accurately characterise and monitor antimicrobial resistance determinants for national/EU-wide surveillance. Four countries were rated as 'low capacity' in 2016.

Laboratory-based surveillance and epidemic response support

EU/EEA median (IQR) scores by target in the dimension of laboratory-based surveillance and epidemic response support from 2013 to 2016 are shown in Figure 9.

Figure 9. Median and interquartile range of yearly EULabCap target scores for laboratory-based surveillance and epidemic response support, 2013–2016 (N=30 countries, except N=29 countries in 2015)



Target 3.1. Support to national surveillance networks. This score increased from intermediate (2013) to high (2016), with 17 EU/EEA countries showing a high level of capacity/capability of laboratories reporting diagnostic data to surveillance systems. In 2016, the capability gaps between the countries became smaller.

Target 3.2. Active participation in EU/EEA disease networks. This target suffered from business discontinuity in several ECDC-supported laboratory networks, resulting in an indicator that could not be applied in 2014 and a further two that were not applicable in 2015 and again in 2016. In 2016, 24 EU/EEA countries were actively participating in the EU/EEA networks, with between 26 and 28 countries participating in the external quality assessments offered that year.

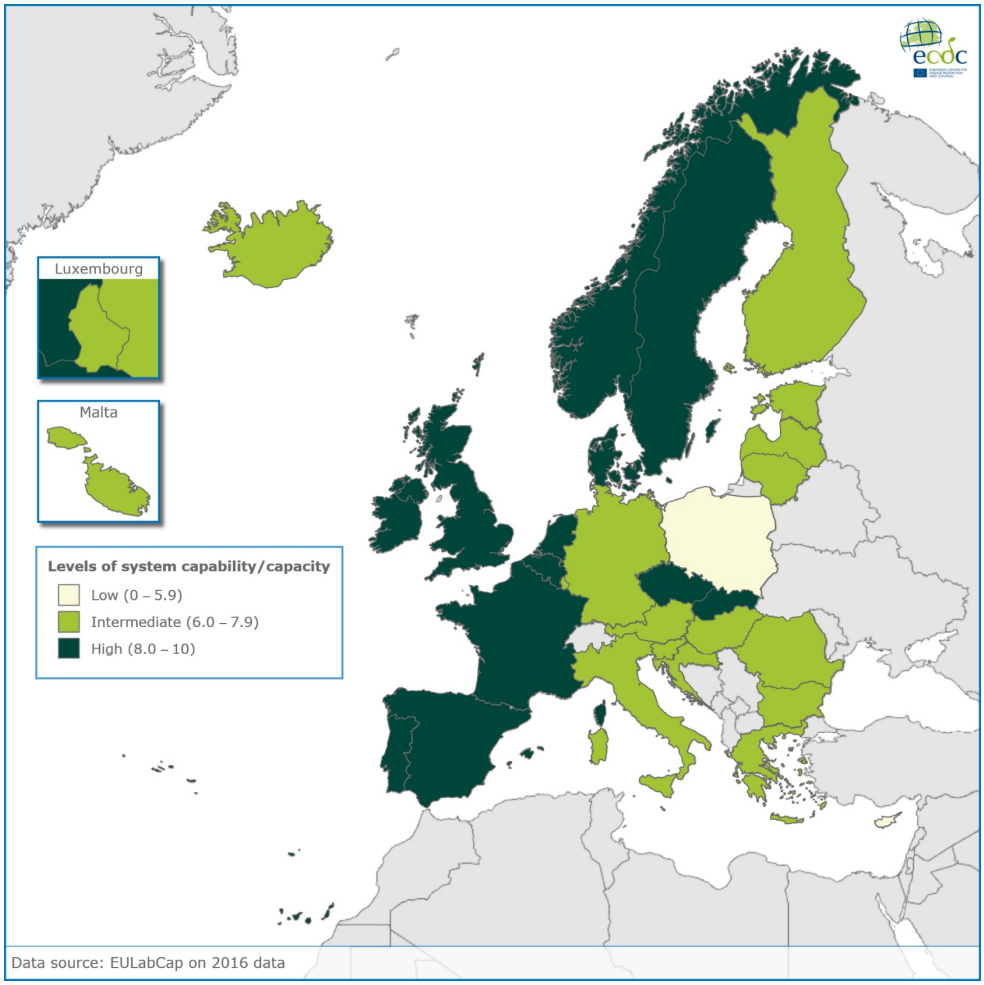
Target 3.3. National outbreak response support. This NRL core function showed substantial improvement in 2016, with 18 EU/EEA countries reaching a high level of capacity/capability in outbreak preparedness and response.

Target 3.4. (Re-)emerging disease laboratory preparedness and response support. Over the years, the up-to-date diagnostic capability for rare and (re-)emerging diseases improved in the EU/EEA, with 20 countries reaching a high level of capability in 2016. In 2016, variation was probably biased due to replaced, updated or extended disease scopes for several indicators.

Laboratory capabilities and capacities at country level

As in previous years, the country EULabCap index showed substantial variation between EU/EEA countries but at narrowing intervals (Figure 3). Figure 10 shows the system capability and capacity performance levels (low, intermediate or high) in the EU/EEA in 2016.

Figure 10. Level of public health microbiology system capability/capacity, by EULabCap index in 2016, EU/EEA (N=30 countries)

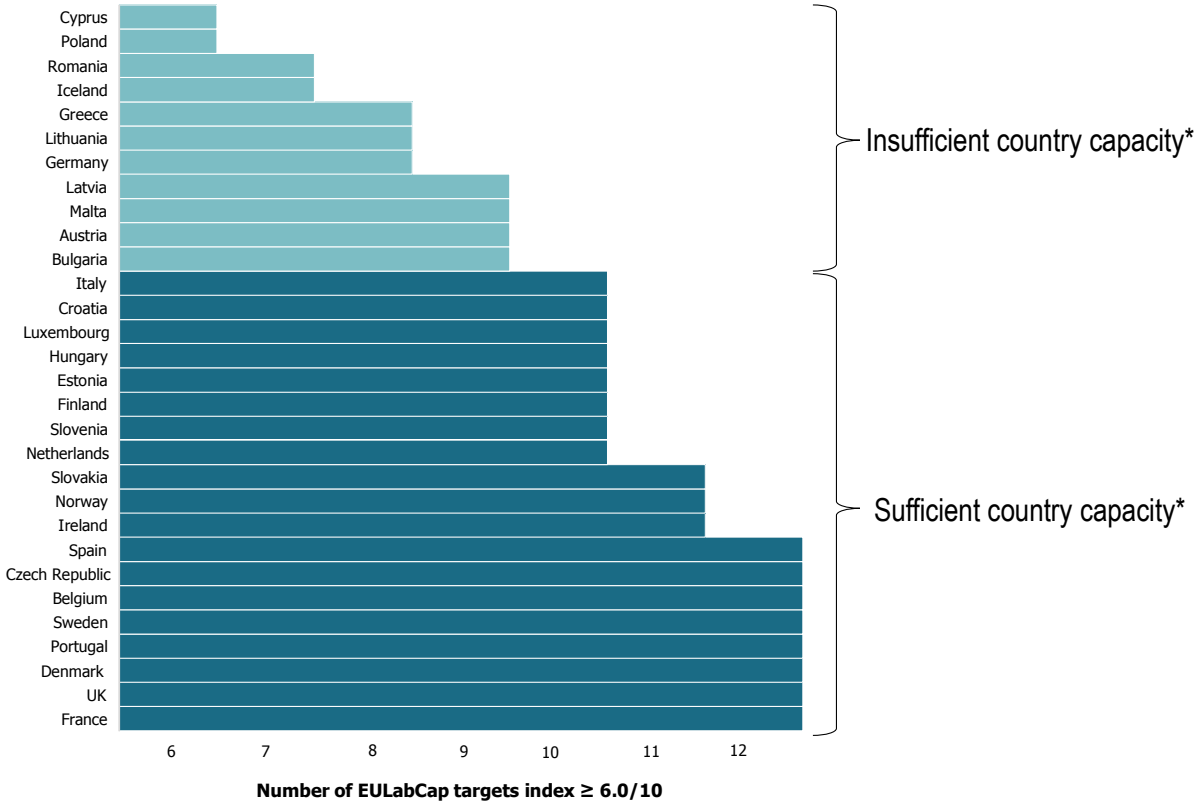


In 2016, three more countries (Iceland, Slovakia and Spain) reached a higher level of system capability and capacity than in 2015; all other countries remained at the same level (Figure 10).

Similar to the EULabCap country index scores, the distribution of target index scores varied substantially between countries. The EU/EEA country performance level for all 12 targets is available in a map format (Annex 7). Country-specific radar graphs (Annex 8) display the target index scores for each EU/EEA country (2015 and 2016). There is a noticeable imbalance in the performance scores across targets in a number of countries.

Eleven of the 30 participating countries had insufficient capacity levels (defined as an EULabCap index score of less than 6.0, i.e. 'low' capacity), which indicates an uneven or lopsided capacity across their systems (Figure 11). In 2016, 19 countries reached 'sufficient capacity' for at least than 10 out of 12 microbiology system targets, which indicates a fairly well-balanced array of capacities across system targets (Figure 11).

Figure 11. Distribution of EU/EEA countries ranked by the increasing number of EULabCap targets with target index ≥6.0/10, 2016 (n=30 countries)



** 'Sufficient country capacity' is defined as reaching an EULabCap target index at an intermediate or high performance level (score 6 or above) for at least 10 out of the 12 targets (■) while 'insufficient country capacity' is defined as an EULabCap index score of less than 6 for at least 9 targets (■).*

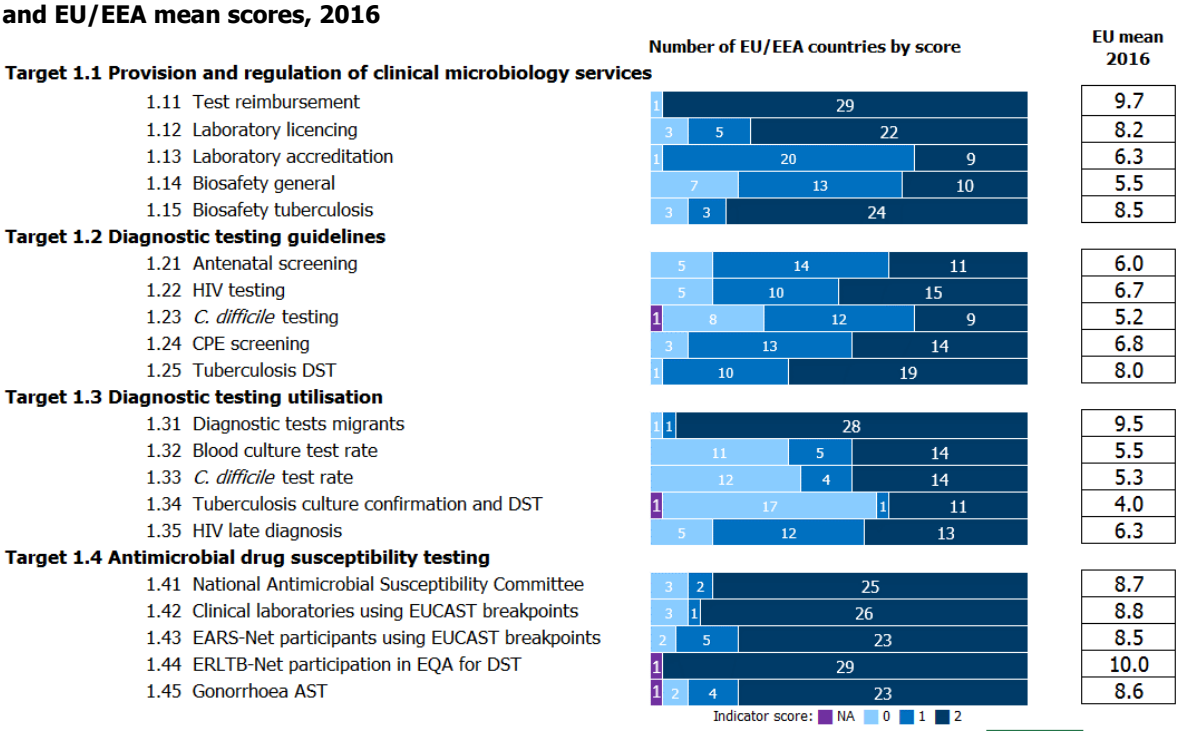
Indicator score distribution for 2016

Figures 11, 12 and 13 present a detailed analysis of the 2016 distribution of national scores by indicator and system dimension (primary diagnostic testing, NRL, and laboratory-based surveillance and epidemic response support). Results indicate the strengths and weaknesses in specific technical areas.

Primary diagnostic testing

Figure 12 shows the distribution of country scores for the 20 indicators on primary diagnostic testing and the EU/EEA mean scores per indicator for 2016. In 2016, some primary diagnostics indicators (quality accreditation of laboratories, biosafety regulations, test utilisation) scored low across the EU/EEA. The score for several indicators increased over time, e.g. for clinical laboratory licencing, safe tuberculosis diagnostic practice, antenatal screening, tuberculosis drug susceptibility testing guidelines, and HIV testing (Figure 7).

Figure 12. Distribution of scores for EULabCap indicators of primary diagnostic testing by country and EU/EEA mean scores, 2016



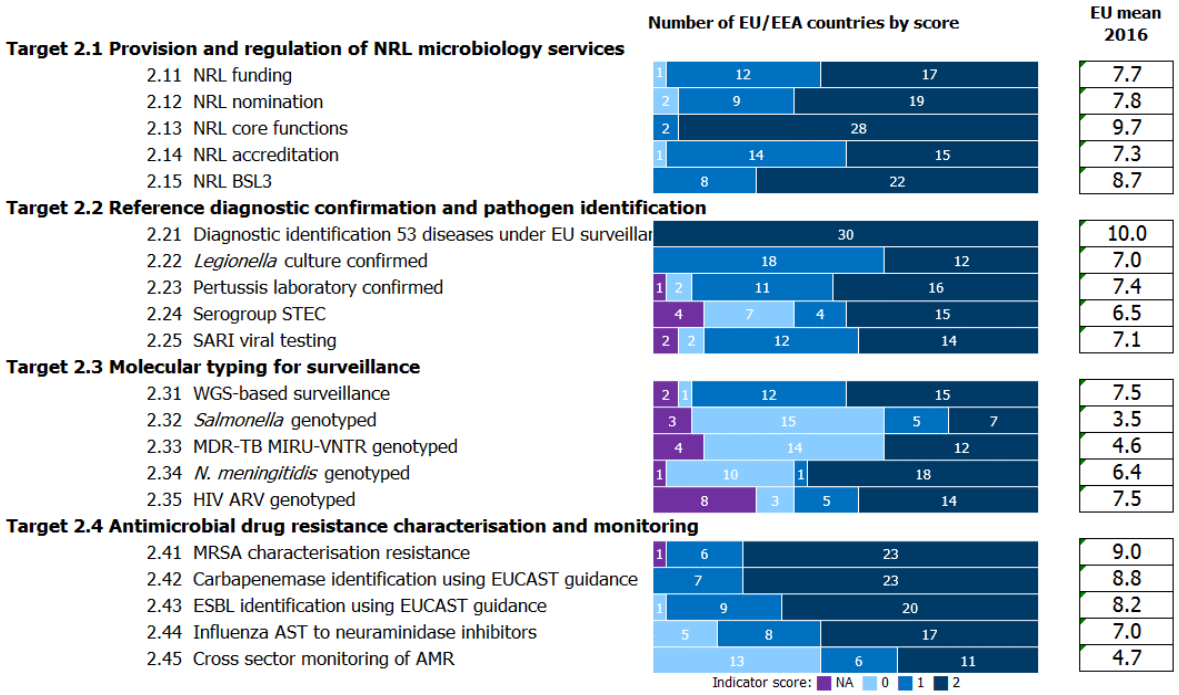
In 2016, EU/EEA capacity was good in several primary diagnostic testing areas (Figure 12): all but one country publicly funded or reimbursed clinical microbiology tests, and almost all countries offered testing for HIV infection and tuberculosis to undocumented migrants. Antimicrobial susceptibility testing maintained a high level of capability/capacity in most EU/EEA countries. Standardisation of antibiotic susceptibility testing was well advanced, with 25 countries having established a national antimicrobial susceptibility committee (NAC). EUCAST breakpoints were used for interpretive reporting of antibacterial drug susceptibility testing results in the majority of the clinical laboratories. The number of countries with clinical laboratories participating in EARS-Net that used EUCAST breakpoints increased to 23 countries in 2016.

Gaps remained for certain indicators on diagnostic and drug susceptibility testing access. For instance, fewer than half of the countries reached the target of 80% of culture-confirmed tuberculosis cases in 2016. The EU/EEA median percentage of new HIV cases older than 14 years with initial CD4 counts <350 (late diagnosis) is still around 50%.

National reference laboratory services

Figure 13 shows the national scores for the 20 indicators for measuring national reference laboratory services and the EU/EEA mean scores for these indicators in 2016. In 2016, as in previous surveys, indicators measuring the provision and regulation of national reference services, indicators gauging the capabilities for diagnostic confirmation, and indicators assessing the capacity for antimicrobial drug resistance yielded intermediate or high scores, whereas capacity indicators on the confirmation of difficult-to-detect pathogens and the use of molecular typing data for national or EU-level surveillance scored lower (Figure 13).

Figure 13. Distribution of scores for EULabCap indicators of national reference laboratory services and EU/EEA mean scores, 2016



In 2016, the majority of the NRLs in 28 EU/EEA Member States delivered all five core public health functions (reference diagnostics, reference material resources, scientific advice and diagnostic guidance, collaboration and research development as well as monitoring, alert ad response). However, eight countries still had no full-NRL access to biosafety level-3 facilities, and quality accreditation of reference tests was only required for laboratories in half of the countries.

EU mean scores increased in 2016 for several NRL indicators, e.g. NRL funding, *Bordetella pertussis* infections confirmed by culture or PCR, STEC/VTEC isolates characterisation by O-serogroup, identification of resistance mechanisms and/or genotyping of MRSA isolates, and use of whole genome sequence-based typing for surveillance.

The disparity of capability/capacity levels between EU/EEA countries in the area of molecular typing of pathogens for surveillance, as measured by the indicators, remains (Figure 13). Many of these indicators are based on data reported to ECDC's surveillance system and therefore do not measure national typing capacity but capacity shared at the EU level. In this fast-moving area, some scores increased while others decreased from survey to survey. Remarkably, the introduction of whole genome sequencing for typing in routine surveillance (one or more human pathogens) progressed in 15 EU/EEA countries in 2016 (2015: 11, 2014: 8, 2013: 0). In 2016, an additional 12 countries had plans to introduce WGS to their national surveillance schemes.

The decreasing scores for the typing of *Neisseria meningitidis* isolates are likely attributable to more stringent indicator scoring. The replacement of the qualitative indicator for cross-sector monitoring of antimicrobial resistance by a quantitative indicator for EU reported susceptibility data on *Salmonella enterica* and *Campylobacter jejuni/C. coli* in accordance to the EU protocol led to an artificial score decrease of this indicator.

In 2016, EU/EEA countries had extensive capabilities for case confirmation and pathogen identification (EU case definitions), with all countries covering at least 36 of the 53 EU-notifiable communicable diseases (Figure 13) [15]. In-house confirmation capability was reported by all EU/EEA countries for a total of 29 high-priority and/or epidemic-prone diseases (Table 2). For rare diseases or agents (e.g. rabies, yellow fever, or smallpox), which require specialised testing facilities, materials, and know-how, identification was available either domestically or by testing agreements with other countries. In 2016, four countries were still reporting no capability for diagnostic confirmation and pathogen identification for poliovirus and viral haemorrhagic fever viruses, and seven countries still lacked capability for yellow fever diagnostics (Table 2).

Table 2. Number of EU/EEA countries capable of diagnostic confirmation and testing for pathogens related to the 53 diseases/health issues listed in Decision 2012/506/EU, 2016

Disease/health issue	Number of countries (N=30)
ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS) AND HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION	30
AVIAN INFLUENZA A/H5 OR A/H5N1 IN HUMANS	
CAMPYLOBACTERIOSIS (*Campylobacter* spp.)	
CHOLERA (*Vibrio cholerae*)	
GIARDIASIS (*Giardia lamblia*)	
GONORRHOEA (*Neisseria gonorrhoeae*)	
HAEMOPHILUS INFLUENZAE, INVASIVE DISEASE (*Haemophilus influenzae*)	
HEPATITIS A (Hepatitis A virus)	
HEPATITIS B (Hepatitis B virus)	
HEPATITIS C (Hepatitis C virus)	
INFLUENZA (Influenza virus)	
INFLUENZA A (H1N1)	
LEGIONNAIRES' DISEASE (*Legionella* spp.)	
LISTERIOSIS (*Listeria monocytogenes)*	
MALARIA *(Plasmodium* spp.*)*	
MEASLES (Measles virus)	
MENINGOCCOCAL DISEASE, INVASIVE (*Neisseria meningitidis*)	
PERTUSSIS (*Bordetella pertussis)*	
PNEUMOCOCCAL INVASIVE DISEASE(S) (*Streptococcus pneumoniae)*	
RUBELLA (Rubella virus)	
SALMONELLOSIS (*Salmonella enterica* other than *Salmonella* Typhi and *S.* Paratyphi)	
SHIGELLOSIS (*Shigella* spp.)	
STEC/VTEC INFECTION (Shiga toxin/verocytotoxin-producing *Escherichia coli*)	
SYPHILIS (*Treponema pallidum*)	
SYPHILIS, CONGENITAL AND NEONATAL (*Treponema pallidum)*	
TOXOPLASMOSIS, CONGENITAL (*Toxoplasma gondii)*	
TUBERCULOSIS (*Mycobacterium tuberculosis* complex)	
TYPHOID/PARATYPHOID FEVER (*Salmonella* Typhi/Paratyphi)	
YERSINOSIS (*Yersinia enterocolitica, Y. pseudotuberculosis*)	
BRUCELLOSIS (*Brucella* spp.)	29
CHLAMYDIAL INFECTION (*Chlamydia trachomatis*) INCLUDING LYMPHOGRANULOMA VENEREUM (LGV)	
CRYPTOSPORIDIOSIS (*Cryptosporidium* spp.)	
MUMPS (Mumps virus)	
RUBELLA, CONGENITAL (including Congenital Rubella Syndrome)	
ANTHRAX (*Bacillus anthracis)*	28
DIPHTHERIA (*Corynebacterium diphtheriae, C. ulcerans* and *C. pseudotuberculosis*)	
ECHINOCOCCOSIS (*Echinococcus* spp.)	
LEPTOSPIROSIS (*Leptospira* spp.)	
TULARAEMIA (*Francisella tularensis*)	
POLIOMYELITIS (Polio virus)	27
Q FEVER (*Coxiella burnetii*)	
SEVERE ACUTE RESPIRATORY SYNDROME — SARS (SARS-coronavirus, SARS-CoV)	
TETANUS (*Clostridium tetani*)	
TICK-BORNE ENCEPHALITIS (TBE virus)	
TRICHINELLOSIS (*Trichinella* spp.)	
VIRAL HAEMORRHAGIC FEVERS (VHF viruses)	
BOTULISM (*Clostridium botulinum*)	26
PLAGUE *(Yersinia pestis)*	
WEST NILE FEVER (West Nile virus)	
RABIES (Lyssa virus)	25
YELLOW FEVER (Yellow fever virus)	23
CREUTZFELDT-JAKOB DISEASE, VARIANT (vCJD)	22
SMALLPOX (Variola virus)	18

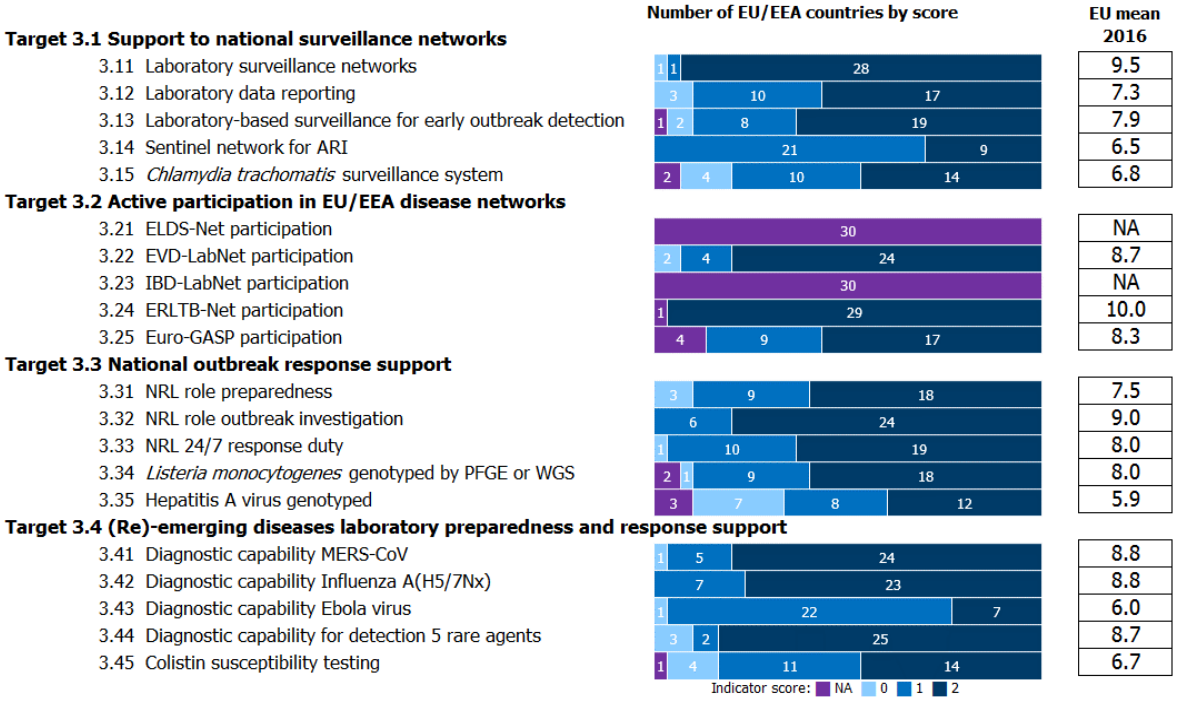
Laboratory-based surveillance and epidemic response support

Figure 14 shows the distribution of national scores for the 20 indicators on laboratory-based surveillance and epidemic response support and the mean scores per indicator. As in the previous years, these indicators showed intermediate to high levels of capability/capacity (Figure 9).

The mean scores of several indicators increased over the years, for instance in the areas of laboratory support to national surveillance and outbreak detection and the use of harmonised methods for *C. trachomatis* surveillance in the EU. Eighteen countries used genotyping for surveillance of *Listeria monocytogenes,* and 12 countries used genotyping for hepatitis A viruses.

All three indicators on active participation in EU disease networks received high marks in 2016, but due to an interruption of activities in the IBD-LabNet and ELDSNet networks, participation could not be assessed; in addition, some indicators were 'not applicable' in 2014–2016. Seventeen countries reported data to Euro-GASP, and 26 countries participated in the EQA for gonococcal susceptibility testing.

Figure 14. Distribution of scores for EULabCap indicators of laboratory-based surveillance and response support and EU/EEA mean scores, 2016



In the 2016 survey, as in previous surveys, most countries received strong performance scores for the operation of national sentinel surveillance networks. All EU/EEA countries – except for those that have only one reference laboratory – reported collaboration between reference laboratories and national clinical laboratory networks for six or more diseases or AMR pathogens. However, despite expanding capabilities over the years, 13 countries reported that they had no automated electronic system for reporting microbiology data to national surveillance databases in 2016.

In general, laboratory-based outbreak detection and response support was good to excellent in the majority of the countries. Regular analysis of microbiology data on rate exceedance or cluster detection was implemented for national outbreak detection in 27 countries in 2016. The number of countries performing such analyses on a weekly basis increased from seven in 2013 to 19 in 2016. The same trend was observed in the number of countries genotyping *Listeria monocytogenes* at the national level.

All countries involved NRL experts in outbreak investigations at the national level. In 24 countries, NRL experts contributed to the national outbreak investigation teams in more than 25% of the outbreaks in 2016. NRL response support duty teams for assisting the national outbreak teams are in place in 19 countries, and 18 countries reported that NRLs had clearly defined roles and responsibilities in national preparedness plans. These 18 countries also tested their national preparedness plans by conducting simulation exercises in 2016 (Figure 14).

Characterisation of epidemic-prone pathogens was more limited although improvements were noted, e.g. for hepatitis A cluster detection by molecular typing and for molecular detection of Ebola virus: 29 countries reported that they had access to such services in 2016 (Figure 14).

A number of changes in the 2016 scores were likely the result of indicator updates in the 2016 survey. The decreasing score for the sentinel network for acute respiratory infections (ARI) could be partially due to a revision of the scoring method, which is now based on data reported to ECDC and was extended to include respiratory syncytial virus. The replacement of the indicator on 'active participation in the *Listeria monocytogenes* typing data exchange for cross-border outbreak detection and response' with an new indicator measuring the 'availability of guidance for colistin susceptibility testing and the detection of acquired colistin resistance in carbapenem-resistant *Enterobacteriaceae'* led to an increase of the average score from low to intermediate.

Country use of EULabCap reports and follow-up actions

Between December 2017 and March 2018, the NMFP of 27 EU/EEA countries replied to the feedback survey on national dissemination and use of EULabCap reports. Twenty-three NMFP reported that the country reports based on the 2013–2016 surveys were considered useful for advising their national authorities. Three of the four countries that considered the country reports 'not useful for policy issues' still disseminated the reports to leaders, senior administrators and decision makers. Overall, the EULabCap country reports were mainly discussed with microbiologists and epidemiologists at the national level; in 17 countries, the reports were shared with decision makers, administrators and managers (Table 3).

Table 3. Summary results of the feedback survey on dissemination and use of the EULabCap reports (N=27 EU/EEA countries, March 2018)

Type of activity	Number of countries
Discussed with microbiologists involved in public health	21
Discussed with infectious disease epidemiologists	17
Communicated to policy and budget decision makers/administration	17
Did not disseminate the reports	0

From August 2015 until March 2018, NMFP from 24 countries reported that one or more follow-up actions were taken in response to the EULabCap reports. Only three countries reported no follow-up activity. The number of follow-up actions varied significantly between countries, ranging from 1 to 9 (Table 4). Efforts to strengthen national capacity focused on the following areas: transfer of microbiological surveillance data to ECDC), regulation of NRL services, transition to WGS for typing, involvement of NRL in outbreak investigations, and development of diagnostic testing guidance.

Table 4. Follow-up actions taken between August 2015 and March 2018 in response to EULabCap country reports for 2013–2016 (N=24 countries)

Areas for attention that were followed up	Individual replies	Total
Improving microbiological data reporting to TESSy	■■■■■■■■■■■	11
Regulation of public health national reference (NRL) services	■■■■■ ■■■■■	10
Transition to WGS-based typing at NRL level	■ ■■■■ ■■ ■■	9
Involvement of NRL experts in national outbreak investigations	■■■ ■ ■■■■ ■	9
Diagnostic testing guidance development	■■■ ■ ■ ■■	7
NRL quality accreditation	■ ■ ■■■ ■ ■	7
Other follow-up	■ ■■■■■	6
Biosafety regulation and monitoring of clinical and/or reference laboratories	■ ■■ ■ ■	5
Resource allocation to NRL services (e.g. funding, staffing, equipment, etc.)	■ ■ ■■ ■	5
Clinical laboratory quality accreditation	■■ ■ ■ ■	4
Regulation of clinical microbiology laboratories	■■ ■	3
Sharing molecular/WGS-based typing data via EPIS/TESSy	■ ■ ■	3
Automation of reporting laboratory data to PH databases	■ ■ ■	3
Measurement of diagnostic test use rates	■ ■	2
Sharing molecular/WGS-based typing data via EPIS/TESSy	■ ■	2
Measurement of compliance with diagnostic testing guidance	■■	2
Resource allocation to clinical microbiology laboratory services	■	1
No follow-up action	■■■	3

Discussion

Monitoring process

The EULabCap is the first EU-wide initiative to measure and monitor the capabilities and capacities of EU/EEA microbiology laboratories necessary to ensure effective communicable disease surveillance and epidemic preparedness. The indicator framework developed for this purpose, with its common terminology and taxonomy of public health microbiology services, was essential to its success. The sustained response rate of 100% and 97% completeness of data reporting in 2016 illustrate the continued commitment of the NMFP to a robust monitoring process.

EU public health microbiology capacities

The 2016 EULabCap index score of 7.5 (on a scale of 0–10) confirms that the EU/EEA on the whole has a strong public health microbiology system, with substantial capacity for communicable disease detection, disease surveillance, risk assessment, and outbreak response.

The observed increase in the average EULabCap index – from 6.9 in 2013 to 7.5 in 2016 – probably reflects genuine progress with respect to the technical and organisational capacities of the laboratory systems in the Member States over the last four years. Only a small part of the score increase is due to artefacts caused by minor changes in the indicators or scoring methodology.

The considerable variation in the EULabCap index by country that was detected by all surveys indicates substantial inequality in public health microbiology capacity across the EU/EEA. This inequality has been gradually declining over the years, as shown by a narrowing intercountry EULabCap index range.

Although it is debatable what exactly constitutes 'sufficient' capacity, 19 EU/EEA countries reached an intermediate or high capacity level for at least 10 of 12 EULabCap targets in 2016. This level of capacity was proposed to the NMFP as an indication of 'sufficient' public health microbiology capacity and eventually accepted.

Strengths and vulnerabilities

Strengths and weaknesses of the EU/EEA public health microbiology system were largely consistent across surveys. The areas showing high and improving levels of performance across the EU/EEA include use of harmonised methods for primary antimicrobial drug susceptibility testing, provision and regulation of NRL services, and laboratory collaboration within national and EU surveillance networks. By contrast, areas with limited capabilities and/or low capacity concerned the provision of national diagnostic guidance, utilisation rates of primary diagnostic services, and the use of molecular typing for surveillance.

In 2016, specific improvements that are unlikely to be explained by indicator modifications and/or the non-participation of a country, were found in the following technical areas:

- Primary diagnostic testing: medical laboratory licensing, safe tuberculosis diagnostic practice, diagnostic guidance for antenatal screening of congenital infection and tuberculosis drug susceptibility testing/interpretation, early HIV diagnosis, percentage of clinical laboratories participating in EARS-Net that have used EUCAST clinical breakpoints for reporting of drug susceptibility testing results to clinicians.
- National reference laboratory (NRL) services: NRL funding, percentage of *Bordetella pertussis* infections confirmed by culture or PCR and STEC/VTEC isolates by O-serogroup, identification of resistance mechanisms and/or genotyping of MRSA isolates, and application of whole genome sequencing to national surveillance.
- Laboratory based surveillance and epidemic response support: laboratory-based outbreak detection, *Chlamydia trachomatis* surveillance, *Listeria monocytogenes* and hepatitis A genotyping.

In the first EULabCap survey in 2013, the EU/EEA median index scored lowest in the primary diagnostic testing dimension, reflecting gaps in clinical laboratory service provision and a lack of regulations for national healthcare systems. It is encouraging to see that scores substantially increased over the last four years. Specific improvements in primary diagnostic testing included licencing of clinical microbiology laboratories, biosafety regulations, safe tuberculosis diagnostics, diagnostic guidance for antenatal screening of congenital infection, guidance for tuberculosis susceptibility testing/interpretation, early HIV diagnosis, and external quality assessment for gonococcal antimicrobial susceptibility testing. Several of these improvements were guided by updated guidance on diagnostic testing, adoption of harmonised EU protocols on laboratory-based surveillance, technology transfer, and quality assurance activities carried out by EU laboratory networks, with the support of ECDC and the EU Health Programme [16-23,43].

The steadily improving capacity of the Member States for harmonised antimicrobial drug susceptibility testing reflects the efforts of the European Committee on Antimicrobial Susceptibility Testing (EUCAST), in collaboration with national antimicrobial susceptibility committees (NACs), to establish EUCAST susceptibility breakpoints in all Member States. In 2016, NACs are established in the vast majority of EU/EEA countries and an increasing number of clinical laboratories use EUCAST breakpoints for the interpretation of susceptibility testing results, notably for EU surveillance reporting to EARS-Net. Joint efforts are underway to ensure that all EU/EEA countries have access to NAC guidance in order to fully implement EUCAST methods and standards. Harmonised practice permits a better comparison of antimicrobial resistance data collected across the EU/EEA, in accordance with the EU case definitions. These achievements are in line with the EU and global-policy focus on combating antimicrobial resistance and a testimony to quality improvement of clinical laboratory practice across Europe through professional leadership [24,25]. However, laboratories face new challenges, for example how to detect and monitor the rapid emergence of new multidrug- and pandrug-resistant human and zoonotic pathogens, which is particularly worrying with regard to gram-negative bacteria [26-28]. Therefore, improved laboratory detection and characterisation methods are needed for the timely and accurate surveillance of antimicrobial resistance [26-28]. In this context, the EULabCap results are encouraging because they show that in 2016 all EU/EEA countries had the capability to identify carbapenemase production in gram-negative bacteria, and that 23 countries used this capability in structured surveys for national monitoring purposes/surveys. This directly relates to the EuSCAPE study on carbapenemase-producing bacteria in Europe [29], which is now being repeated with WGS technology [30].

In 2016, an overall median decrease with a widening interquartile range was observed for NRL services. This was due to the scores for the target of molecular typing for surveillance, which were very diverse. In addition, several indicators were either revised or replaced. Within the fast moving target of molecular typing for surveillance, low scores were not unexpected because national molecular typing data are often not passed on to EU disease surveillance systems. Indicators of typing coverage were still difficult to measure as technology is still in flux, and indicators were reviewed and adjusted as monitoring progressed. One of the major factors in this context is the rapid expansion of WGS for typing in Europe, an essential element of public health capacity [31]. Despite the overall high level of capacity for antimicrobial drug resistance surveillance, the newly introduced indicator on compliance with the EU protocol for harmonised monitoring of antimicrobial resistance in human *Salmonella enterica* and *Campylobacter jejuni/C. coli* isolates [32] introduced a negative scoring artefact.

All but two EU/EEA Member States had NRLs that delivered the five core public health functions (reference diagnostics; reference material resources; scientific advice and diagnostic guidance; collaboration and research development; and monitoring, alert and response). Improvement are needed in the area of national test accreditation – only 50% of the countries require accreditation – and full-NRL access to biosafety level-3 facilities, which only 75% of the participating EU/EEA countries can offer.

Since 2014, all EU/EEA countries declared having access to a range of diagnostics for specific agents, which is required to meet obligations for EU surveillance reporting. There were only a handful of rare diseases or high-consequence pathogens requiring specialised containment facilities for which countries relied on third party arrangements. A majority of EU/EEA countries also reported extended capabilities for the diagnosis and characterisation of emerging agents, such as novel types of avian influenza viruses, and rare and/or imported viruses such as MERS-CoV and Ebola virus. This observation is consistent with the results of investigations in the field of laboratory preparedness and response in Europe, including those conducted with the support of ECDC and the EU Health Programme [33,34].

Since diagnostic capability for other (re-)emerging infectious diseases (e.g. Zika virus infection, Lyme disease, infections with new strains of multidrug-resistant bacteria or fungi) is not covered by EULabCap, ad hoc surveys of EU networks should be used to rapidly appraise detection capacities in Europe if a public health event is caused by a new agent [35].

A key system innovation highlighted by the annual EULabCap results is the rapid shift towards the use of whole genome sequencing for the public health surveillance of communicable diseases and antimicrobial resistance. In 2016, 15 EU/EEA countries reported the use of WGS for typing in the routine surveillance of at least one human pathogen [31]. This massive method shift is consistent with the transition plan proposed in an ECDC Expert Opinion on whole genome sequencing for public health surveillance [36]. This approach requires meticulous capacity monitoring at the EU level and close collaboration with Member States to ensure a smooth transition as outlined by the ECDC roadmap on WGS for public health surveillance [36-39].

Regarding laboratory-based surveillance and epidemic response support, the EU/EEA index increased in 2016, with a further convergence of scores among countries. The majority of countries scored high on indicators of national sentinel laboratory-based surveillance. Improvements were noted in data analysis for early outbreak detection, *Chlamydia trachomatis* surveillance, genotyping of *Listeria monocytogenes* and hepatitis A viruses, and in the area of NRL contributions to preparedness and outbreak response. However, despite gradual improvements over the years, many countries still received intermediate scores for their reporting of microbiology data. Cluster detection capability improved in several countries but not all countries perform a weekly analysis to ensure early warning

capabilities, and automated e-reporting of laboratory data is still not standard procedure in some of the countries. These countries should consider IT solutions which speed up data transfer and analysis to improve the efficiency and timeliness of laboratory-based surveillance and enhance their alert systems.

The EULabCap survey revealed both strengths and vulnerabilities of EU networking activities. Whereas NRL participation in ECDC disease-specific laboratory networks was consistently at a high level due to a longstanding EU collaboration between laboratory scientists and public health specialists, several EULabCap indicators could not be measured over time due to intermittent ECDC support to key networks, which points at the issue of sustainable long-term operational support. A cost–benefit analysis of the EU reference laboratory networks concluded that the benefits of maintaining an overarching system of EU reference laboratory networks are likely to outweigh the costs, both from a Member State and from an EU perspective [14].

Impact of EULabCap in the Member States

A survey on the use of the annual EULabCap country reports (distributed since 2015) showed the impact of EULabCap reports on policy and practice in the Member States: the vast majority of NMFP found the reports useful for advising their national authorities. The vast majority of respondents reported follow-up actions that were undertaken in their country after the receipt of the first EULabCap country reports. Improvements in data reporting to the European level (i.e. ECDC) and national regulatory changes were among the most frequently reported actions. At the national reference laboratory level, the transition toward WGS for typing and an increased involvement of NRL experts in national outbreak investigations were other follow-up improvements reported by the NMFP.

Limitations

EULabCap survey methods have several limitations. Firstly, some indicators vary with respect to country relevance. For example, the indicator 'information sharing within a national network' is less relevant in a small country. Similarly, some capacity indicators on laboratory-confirmed cases may not apply to smaller countries due to low disease incidence.

Secondly, about two-thirds of the indicators are based on self-reporting and thus prone to a certain degree of subjective interpretation by the national experts who collect the information. An external validation of capabilities, for example through external quality assessments and simulation exercises, would be helpful to address this limitation [35,36,40-42].

Thirdly, data access was not universal, and some NMFPs were unable to provide data for all indicators. This could be related to the lack of an active data collection instrument, a lack of designated NRLs for specific diseases, outsourcing of some of the reference services to other countries, and NMFP time constraints. As data which were 'not available/not applicable' could not be used to calculate scores for a given target, an ascertainment bias may have led to an under- or overestimation of country system performance. Furthermore, EULabCap country scores do not necessarily reflect the laboratory capacity throughout the country. The assessment of laboratory capacity is probably accurate for small countries or countries with centralised services but less so for countries with decentralised services. Quantitative capacity indicators of primary diagnostic testing utilisation were particularly challenging and onerous to measure, leaving room for variation in data accuracy and representativeness between countries.

Finally, data comparability over time was slightly limited by classification bias due to minor modifications of a number of indicators/scoring criteria. A requirement, introduced in 2014, to provide absolute numerator and denominator data to enable ECDC to calculate capacity scores (instead of self-scoring by the NMFP), reduced room for individual interpretation and improved transparency. Revisions in 2016 further reduced the ambiguity in indicator and/or score interpretation. These revisions have ensured that indicators/scoring criteria are in line with new standards of practice but have also hampered the year-to-year comparability of a few indicators.

Conclusions

The results of the fourth EULabCap annual survey confirmed that the EU/EEA, on the whole, can rely on a public health microbiology systems with strong overall capability and substantial capacity to fulfil EU surveillance and response requirements. The available data – and the index score of 7.6 out of 10 for 2015 – show that Europe is steadily building more robust defences against human health threats such as antimicrobial resistance and epidemics by improving laboratory diagnostics. Inequalities among EU Member States in laboratory capabilities are slowly getting smaller. This indicates progress toward a stronger and more cohesive Europe for disease detection, surveillance and control.

Strengths and weaknesses of the EU/EEA public health microbiology system were largely consistent across the different surveys. Areas showing high levels of performance across the EU/EEA include the use of harmonised methods for primary antimicrobial drug susceptibility testing, the provision and regulation of NRL services, and the collaboration between laboratories and surveillance networks, both at the Member State level and in the EU as a whole. The EULabCap survey also identified areas of low capacity and limited capability: the provision and audit of national diagnostic guidance, suboptimal utilisation of diagnostic services, and underutilisation of electronic data reporting and molecular typing for surveillance.

In 2017, ECDC, together with the competent bodies in the Member States, the European Commission and several international partners, reviewed these microbiology system gaps to inform the ECDC microbiology strategic priorities and planned activities for 2018–22 (publication scheduled for summer 2018).

ECDC, in collaboration with the EU/EEA countries, the European Commission and other EU agencies and partners, will continue its monitoring of the European laboratory capacity as a basis for future country support and capacity building activities. The usefulness of the EULabCap monitoring system will be further evaluated by systematically collecting NMFP feedback on the use of reports for action at the national level. ECDC will also continue to appraise technological advances in microbiology, foster innovation, support the integration of harmonised genomic data into European surveillance systems, and share best practices across the European microbiology community.

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Annex 1. EULabCap survey list of targets, indicators and scoring options

Dimension 1. Primary diagnostic testing

Targets/indicators	Source (NMFP/ECDC) and scoring options
Target 1.1 Regulation clin micro Provision and regulation of clinical microbiology services.	
Indicator 1.11 Test reimbursement Clinical microbiology laboratory tests were funded/reimbursed in total, or in part, either by a national insurance scheme or by a governmental budget.	NMFP NA = information not reported by the NMFP, 0 = no tests are reimbursed, 1 = for hospital in-patient testing, 2 = for in- and outpatient testing.
Indicator 1.12 Laboratory licencing Clinical microbiology laboratories obtained a licencing authorisation/registration from health authorities (or professional organisations) according to legal/regulatory requirements.	NMFP NA = information not reported by the NMFP, 0 = not required by law/regulation, 1 = required for some laboratories, 2 = required for all laboratories.
Indicator 1.13 Laboratory accreditation Clinical microbiology laboratories accredited their diagnostic tests according to either ISO 17025, ISO 15189, or equivalent national standards.	NMFP NA = information not reported by the NMFP, 0 = no laboratories, 1 = some laboratories, 2 = all laboratories.
Indicator 1.14 Biosafety general Clinical microbiology laboratories must receive a biosafety authorisation/permit for performing operations at Biosafety Level (BSL)2 and BSL3.	NMFP NA = information not reported by the NMFP, 0 = not required by law/regulation, 1 = for BSL3 facilities, 2 = for both BSL2 and BSL3 facilities.
Indicator 1.15 Biosafety tuberculosis Culture-based tuberculosis diagnostic and drug susceptibility tests were restricted to laboratories compliant with performing BSL3 operations in line with the WHO tuberculosis laboratory biosafety manual.	NMFP NA = information not reported by the NMFP, 0 = not required by law/regulation, 1 = for DSTs, 2 = for all TB culture tests and TB DSTs.
Target 1.2 Diag guidance Diagnostic testing guidelines	
Indicator 1.21 Antenatal screening National guidelines are available for antenatal screening of congenital infection and implementation is monitored within the country.	NMFP NA = information not reported by the NMFP, 0 = guidelines information not available at the national level, 1 = guidelines are available without compliance monitoring, 2 = guidelines are implemented with compliance monitoring.
Indicator 1.22 HIV testing National guidelines are available for HIV diagnostic testing and implementation is monitored within the country.	NMFP NA = information not reported by the NMFP, 0 = guidelines information not available at the national level, 1 = guidelines are available without compliance monitoring, 2 = guidelines are implemented with compliance monitoring.
Indicator 1.23 *C. difficile* testing National guidelines are available for *Clostridium difficile* diagnostic testing in healthcare associated diarrhoea and implementation is monitored within the country.	NMFP NA = information not reported by the NMFP, 0 = guidelines information not available at the national level, 1 = guidelines are available without compliance monitoring, 2 = guidelines are implemented with compliance monitoring.
Indicator 1.24 CPE screening National guidelines are available for screening of hospitalised patients for carbapenem-resistant/carbapenemase-producing *Enterobacteriaceae* and implementation is monitored within the country.	NMFP NA = information not reported by the NMFP, 0 = guidelines not available at the national level, 1 = guidelines are available without compliance monitoring, 2 = guidelines are implemented with compliance monitoring.
Indicator 1.25 Tuberculosis DST National guidelines are available for tuberculosis laboratory diagnostic and drug susceptibility testing and implementation is monitored within the country.	NMFP NA = information not reported by the NMFP, 0 = guidelines not available at the national level, 1 = guidelines are available without compliance monitoring, 2 = guidelines are implemented with compliance monitoring.
Target 1.3 Diag test use Diagnostic testing utilisation	
Indicator 1.31 Diagnostic tests migrants Accessible diagnostic testing for HIV infection and/or tuberculosis was available to undocumented migrants in your country.	NMFP NA = information not reported by the NMFP, 0 = testing is not available, 1 = testing available for HIV infection, 2 = testing available for HIV infection and tuberculosis.
Indicator 1.32 Blood culture test rate Number of blood culture sets tested/1 000 hospital bed-days by EARS-Net participating hospitals from your country.	ECDC 0 = information not reported to EARS-Net, or not reported in the country, 1 = low blood culture test utilisation rate/1 000 hospital bed-days (first EU quartile), 2 = fair to high blood culture utilisation rate/1000 hospital bed-days (upper three EU quartiles).

Targets/indicators	Source (NMFP/ECDC) and scoring options
Indicator 1.33 *C. difficile* test rate Total number of *Clostridium difficile* diagnostic tests* performed/1000 hospital-bed-days, based on national estimate**. * A test = a stool sample tested by one or more diagnostic *Clostridium difficile* assays including toxin immunoassay, toxin cytotoxic cell-culture assay, PCR, or culture ** Estimate can be determined using a (representative) sample of a survey	NMFP ***Number of tests performed=*** ***Number of hospital-inpatient days=*** **NOTE: ECDC use the numbers provided to calculate first the diagnostic test utilisation and subsequently the quartiles.** 0 = not measured in the country, 1 = low diagnostic test utilisation rate/1000 hospital bed-days (first EU quartile); 2 = fair to high diagnostic test utilisation rate/1 000 hospital bed-days (upper three EU quartiles).
Indicator 1.34 Tuberculosis culture confirmation and DST Percentage of new pulmonary tuberculosis cases confirmed by culture and tested for susceptibility to first-line drugs.	ECDC 0 = <80% culture confirmed, 1 = ≥80% culture confirmed BUT <95% DST of cultures, 2 = ≥80% culture confirmed AND ≥95% DST of cultures.
Indicator 1.35 HIV late diagnosis Percentage of new HIV cases older than 14 years reported with initial CD4 counts (<350 cells/µl - late diagnosis).	ECDC **NOTE: ECDC use the numbers provided to calculate the country specific score according to the EU median (value).** NA = not available/not applicable, 0 = CD4 cell count not reported to ECDC, 1 = >EU Median, 2 = ≤EU Median.
Target 1.4 AST Antimicrobial drug susceptibility testing	
Indicator 1.41 National Antimicrobial Susceptibility Committee (NAC) A National Antimicrobial Susceptibility Committee (NAC) is established and its representative attended of EUCAST General Committee meeting.	ECDC 0 = NAC not established or inactive in 2016, 1 = NAC formation in process in 2016, 2 = NAC established and active in 2016.
Indicator 1.42 Clinical laboratories using EUCAST breakpoints Percentage of clinical laboratories in the country that used EUCAST clinical breakpoints for interpretive reporting of antibacterial drug susceptibility testing results to clinicians.	ECDC 0 = <10% of clinical laboratories, 1 = 10-50% of clinical laboratories, 2 = >50% of clinical laboratories.
Indicator 1.43 EARS-Net participants using EUCAST breakpoints Percentage of clinical laboratories participating in EARS-Net that have used EUCAST clinical breakpoints for interpretive reporting of antibacterial drug susceptibility testing results to clinicians	ECDC NA = information not reported to ECDC, 0 = <25% of clinical laboratories, 1 = 25-75% of clinical laboratories, 2 = >75% of clinical laboratories.
Indicator 1.44 ERLTB-Net participation in EQA for DST Tuberculosis Reference Laboratories that participated in ECDC-funded ERLTB-Net external quality assessment scheme in 2015 achieved 80% performance level for culture and susceptibility testing for first- and second-line drugs.	NMFP NA = information not reported by the NMFP, 0 = no participation, 1 = participation with performance <80%, 2 = participation with performance ≥80%.
Indicator 1.45 Gonorrhoea AST National surveillance of gonococcal antimicrobial resistance is providing susceptibility data on 10% or more of reported gonorrhoea cases.	NMFP NA = information not reported by the NMFP, 0 = no surveillance of AMR at national level, 1 = susceptibility data were provided for <10% of reported cases, 2 = susceptibility data were provided for ≥10% of reported cases.

Dimension 2. National reference laboratory services (NRL)

Targets/indicators	Source (NMFP/ECDC) and scoring options
Target 2.1 Regulation NRL Provision and regulation of national reference microbiology services	
Indicator 2.11 NRL funding National reference laboratory (NRL) for public health microbiology services were financially supported at least in part by health authorities or other competent bodies.	NMFP NA = information not reported by the NMFP, 0 = no funding, 1 = funding to some NRLs, 2 = funding to all NRLs.
Indicator 2.12 NRL nomination NRLs were officially nominated by health authorities or other competent bodies.	NMFP NA = information not reported by the NMFP, 0 = no NRL was officially nominated, 1 = some NRLs were officially nominated, 2 = all NRLs were officially nominated.
Indicator 2.13 NRL core functions The majority of NRLs delivered the following functions: (ECDC will use the answers provided for each function (indicators 2.13a to 2.13e) to calculate the indicator score) 2.13(a) Reference diagnostics. 2.13(b) Reference material resources. 2.13(c) Scientific advice and diagnostic guidance. 2.13(d) Collaboration and research development. 2.13(e) Monitoring, alert and response.	NMFP For 2.13a-2.13e 0 = no, 1 = yes. **NOTE: ECDC will use the scores provided for each function to calculate the overall score.** NA = information not reported by the NMFP, 0 = 1-2 functions, 1 = 3-4 functions, 2 = all 5 functions.
Indicator 2.14 NRL accreditation NRLs accredited at least some of their diagnostic tests according to either ISO 17025, ISO 15189, or equivalent national standard.	NMFP NA = information not reported by the NMFP, 0 = no NRL accredited their tests, 1 = some NRLs accredited their tests, 2 = all NRLs accredited their tests.
Indicator 2.15 NRL BSL3 NRLs have access to biocontainment facilities with biosafety authorisation for performing Biosafety Level 3 operations.	NMFP NA = information not reported by the NMFP, 0 = no BSL3 facility available for NRLs, 1 = partial access for some BSL3 operations, 2 = full access for all BSL3 operations.

Target 2.2 Ref diag id Reference diagnostic confirmation and pathogen identification	
Indicator 2.21 Diagnostic identification 53 diseases under EU surveillance Case confirmation* with pathogen identification for EU surveillance was available within your country by primary and/or reference laboratory for the 53 communicable diseases. *according to the laboratory criteria described in the Case definitions of the Decision 2012/506/EU).	NMFP NA = information not reported by the NMFP, 0 = <20 pathogens/issues, 1 = 20-35 pathogens/issues, 2 = >35 pathogens/issues.
Indicator 2.22 *Legionella* culture confirmed Culture confirmation of Legionnaires' disease was performed for EU reported cases in accordance with EU case definition/ELDS-Net guidance.	ECDC 0 = not reported to ECDC, 1 = <10% of reported cases were culture confirmed, 2 = ≥10% of reported cases were culture confirmed.
Indicator 2.23 Pertussis laboratory confirmed Laboratory confirmation of *Bordetella pertussis* (by culture or PCR) was performed for EU reported cases in accordance with EU case definition/EUPertLabNet guidance.	ECDC NA = not applicable because of zero cases reported, 0 = no case-based reporting to ECDC, 1 = <10% of reported cases were culture or PCR confirmed, 2 = ≥10% of reported cases were culture or PCR confirmed.
Indicator 2.24 Serogroup STEC O-serogrouping was performed and reported to ECDC for cases of STEC/VTEC in accordance with EU case definition (percentage of isolates with serogroup reported out of total number of cases reported, excluding non-typeable isolates).	NMFP NA = information not reported by the NMFP, 0 = serogroup was reported for <80% of reported cases, 1 = serogroup was reported for 80-99% of reported cases, 2 = serogroup was reported for 100% of reported cases.
Indicator 2.25 SARI viral testing National guidelines and reference virological diagnostic testing were available for investigation of Severe Acute Respiratory Infection (SARI) cluster in accordance with WHO guidance.	NMFP NA = not available/not applicable, 0 = not available at the national level, 1 = implemented without monitoring, 2 = implemented with monitoring.
Target 2.3 Molecular surveillance Molecular typing for surveillance	
Indicator 2.31 WGS surveillance Whole genome sequencing (WGS) -based typing of human pathogens was used in national reference laboratories for routine surveillance of one or more disease/health issue.	NMFP NA = information not reported by the NMFP, 0 = no activity and no national plan in place, 1 = no activity but a plan in place/in progress for at least 1 human pathogen, 2 = WGS is used routinely for typing in national surveillance - of at least 1 human pathogen.
Indicator 2.32 *Salmonella* genotyped *Salmonella enterica* serotype Typhimurium and Enteritidis isolates were characterised with MLVA genotype and reported to ECDC (percentage of isolates with MLVA type reported out of total number of cases reported).	ECDC NA = other molecular methods (including WGS) were performed for genotyping of those serotypes, 0 = MLVA data were not reported to ECDC, 1 = 1-20% of *S.* Typhimurium plus Enteritidis cases had MLVA genotype reported to ECDC, 2 = >20% of *S.* Typhimurium plus Enteritidis cases had MLVA genotype reported to ECDC.
Indicator 2.33 MDR-TB MIRU-VNTR genotyped Percentage of multidrug-resistant (MDR)-*Mycobacterium tuberculosis* isolates genotyped by MIRU-VNTR method and reported to ECDC.	ECDC NA = not applicable because zero cases reported, 0 = type reported for <20% of reported cases, 1 = type reported for 20-50% of reported cases, 2= type reported for > 50% of reported cases.
Indicator 2.34 *N. meningitidis* typed Percentage of typed invasive *Neisseria meningitidis* isolates by (serogroup and MLST), OR (serogroup and *porA* and *feta)* according to the fine-typing scheme recommended by European Meningococcal Disease Society (EMGM)/IBD-LabNet, reported to ECDC out of the total EU reported cases.	ECDC NA = not applicable because zero cases reported, 0 = no case-based reporting to ECDC or information on type not reported, 1 = type reported for 1-20% of reported cases, 2 = type reported for ≥20% of reported cases.
Indicator 2.35 HIV ARV genotyped Total number of HIV isolates genotyped by antiretroviral target sequence analysis divided by the total number of new HIV cases with sufficient HIV viral load reported to national surveillance.	NMFP **Number of initial HIV isolates genotyped =** **Number of new HIV cases reported=** **NOTE: ECDC will use the numbers provided to calculate the percentage and score accordingly.** NA = information not reported by the NMFP, 0 = type reported for <20% of reported cases, 1 = type reported for 20-50% of reported cases, 2 = type reported for >50% of reported cases.
Target 2.4 AMR monitoring Antimicrobial drug resistance characterisation and monitoring	
Indicator 2.41 MRSA characterisation resistance Identification of antimicrobial resistance mechanisms and/or genotyping was performed for methicillin-resistant *Staphylococcus aureus* (MRSA) isolates in accordance with EUCAST/*Staphylococcus aureus* reference laboratory network guidance.	NMFP NA = information no reported by the NMFP, 0 = not established/in process of establishment, 1 = performed upon request from diagnostic laboratory, 2 = performed as part of structured surveys for monitoring purposes.
Indicator 2.42 Carbapenemase identification using EUCAST guidance Identification of type of carbapenemase was performed for carbapenemase producing Gram-negative bacilli isolates in accordance with EUCAST guidance.	NMFP NA = information no reported by the NMFP, 0 = not established/in process of establishment, 1 = performed upon request from diagnostic laboratory, 2 = performed as part of structured surveys for monitoring purposes.
Indicator 2.43 ESBL identification using EUCAST guidance Identification of type of extended spectrum beta-lactamase was performed for ESBL-producing Gram negative bacilli isolates in accordance with EUCAST guidance.	NMFP NA = information no reported by the NMFP, 0 = not established/in process of establishment, 1 = performed upon request from diagnostic laboratory, 2 = performed as part of structured surveys for monitoring purposes.

Indicator 2.44 Influenza AST to neuraminidase inhibitors Human influenza virus susceptibility monitoring to neuraminidase inhibitors by phenotypic/genotypic methods was performed and results were reported by National Influenza Centres/influenza reference laboratories to ECDC.	ECDC 0 = Neuraminidase inhibitors susceptibility not monitored, 1 = Neuraminidase inhibitors susceptibility monitoring was performed but results not reported to ECDC, 2 = Neuraminidase inhibitors susceptibility monitoring was performed and results were reported to ECDC.
Indicator 2.45 Cross sector monitoring of AMR in human and animal bacterial isolates Antimicrobial susceptibility data on *Salmonella* and *Campylobacter* were reported to ECDC in accordance with the EU protocol for harmonized monitoring of antimicrobial resistance in human *Salmonella* and *Campylobacter* isolates.	ECDC NA = not available/not applicable, 0 = not established, 1 = occasional joint surveys, 2 = integrated annual reporting. 0 = Annual *Salmonella* and *Campylobacter* AST data were not reported to ECDC OR data reported were not compliant with EU harmonised protocol (either not-base-based or not quantitative); 1 = *Salmonella* AST data obtained by a EUCAST recommended method were reported quantitatively to ECDC as per EU protocol at least for (cefotaxime OR ceftazidime) AND (ciprofloxacin OR pefloxacin) AND meropenem; 2 = Fulfilling score 1 AND *Campylobacter* AST data obtained by a EUCAST recommended method were reported quantitatively to ECDC as per EU protocol at least for: erythromycin AND ciprofloxacin.

Dimension 3. Laboratory-based surveillance and epidemic response support

Targets/indicators	Source (NMFP/ECDC) and scoring options
Target 3.1 Surveillance Support to national surveillance networks	
Indicator 3.11 Laboratory surveillance networks Reference laboratories and/or public health bodies were collaborating with national networks of clinical laboratories contributing data on surveillance of communicable diseases.	NMFP NA = information not reported by the NMFP, 0 = no national network of laboratories, 1 = national networks collaborating for 1-5 diseases/AMR issues, 2 = national networks collaborating for more than five diseases/AMR issues.
Indicator 3.12 Laboratory data reporting Surveillance networks of clinical laboratories reported microbiological data to a central national public health surveillance database.	NMFP NA = information not reported by the NMFP, 0 = no surveillance report OR only paper-based reporting, 1 = for at least one disease by online forms/email files, 2 = for at least one disease by machine to machine upload from a laboratory information management system.
Indicator 3.13 Laboratory-based surveillance data for early outbreak detection Microbiology data from laboratory-based national surveillance systems were centrally analysed and reported to stakeholders for incidence trends and early warning of excess rates/clusters of epidemic prone disease above baseline rates for diseases under EU surveillance.	NMFP NA = information not reported by the NMFP, 0 = not performed at national level, 1 = for at least one disease performed at least monthly, 2 = for at least one disease performed at least weekly.
Indicator 3.14 Sentinel network for ARI National Influenza Centres/influenza reference laboratories performed a systematic sentinel sampling of influenza and respiratory syncytial viruses.	ECDC 0 = systematic sentinel sampling by the National Influenza Centres/influenza reference laboratory, 1 = sentinel sampling only for influenza, 2 = sentinel sampling for influenza AND respiratory syncytial virus.
Indicator 3.15 *Chlamydia trachomatis* surveillance system National system for collecting and reporting surveillance data on *Chlamydia trachomatis* infection was in place AND reported laboratory-based information in accordance with the guidance for *Chlamydia* control in Europe.	NMFP NA = information not reported by the NMFP, 0 = no reporting at national level, 1 = partial system, 2 = full system.
Target 3.2 EULabNet participation Active participation in EU disease networks	
Indicator 3.21 ELDS-Net participation Country was an active participant in the European Legionnaires' Disease Surveillance Network (ELDS-Net) - participated in external quality assessments (EQA) reported to/coordinated by ECDC - participated in annual meeting	ECDC NA = information not available/not applicable (e.g. no network membership), 0 = no participation to either EQA or annual meeting, 1 = EQA participation OR participation in annual meeting, 2 = EQA participation AND participation in annual meeting.
Indicator 3.22 EVD-LabNet participation Country was an active participant in the European expert laboratory network for emerging viral diseases (EVD-LabNet) - participated in external quality assessments (EQA) reported to/coordinated by ECDC - participated in annual meeting	ECDC NA = information not available/not applicable (e. no network membership), 0 = no participation to either EQA or annual meeting, 1 = EQA participation OR participation in annual meeting, 2 = EQA participation AND participation in annual meeting.
Indicator 3.23 IBD- LabNet participation Country was actively participating in the Invasive bacterial diseases in the EU Laboratory Network (IBD-LabNet) - participated in external quality assessments (EQA) reported to/coordinated by ECDC - participated in annual meeting	ECDC NA = information not available/not applicable (e. no network membership), 0 = no participation to either EQA or annual meeting, 1 = EQA participation OR participation in annual meeting, 2 = EQA participation AND participation in annual meeting.

Targets/indicators	Source (NMFP/ECDC) and scoring options
Indicator 3.24 ERLTB-Net participation Country was an active participant in European reference laboratory Network for TB (ERLTB-Net) - participated in external quality assessments (EQA) reported to/coordinated by ECDC - participated in annual meeting	ECDC NA = information not available/not applicable (e. no network membership), 0 = no participation to either EQA or annual meeting, 1 = EQA participation OR participation in annual meeting, 2 = EQA participation AND participation in annual meeting.
Indicator 3.25 Euro-GASP participation Country was an active participant in the European Gonococcal Antimicrobial Surveillance Programme (Euro-GASP) - participated in EQA and/or laboratory training - participated in data collection for *Neisseria gonorrhoeae* antimicrobial susceptibility testing	ECDC NA = information not available/not applicable (e. no network membership), 0 = no participation to either EQA or training, 1 = EQA participation but no reporting of susceptibility testing data to Euro-GASP, 2 = EQA participation and reporting of susceptibility testing data to Euro-GASP.
Target 3.3 Outbreak response National outbreak response support	
Indicator 3.31 NRL role preparedness NRLs had defined roles and responsibilities described and tested in exercises as part of the national preparedness and response plan for health threats due to epidemic prone/high consequence pathogens.	NMFP NA = information not reported by the NMFP, 0 = no, 1 = yes but without simulation exercises, 2 = yes with simulation exercises.
Indicator 3.32 NRL role outbreak investigation Percentage of outbreaks investigated at the national level for which NRL personnel participated as a member of the outbreak investigation team.	NMFP NA = information not reported by the NMFP, 0 = no participation in outbreak investigation team, 1 = participate in <25% of outbreaks, 2 = participate in ≥25% of outbreaks.
Indicator 3.33 NRL 24/7 response duty NRLs for epidemic prone/high consequence pathogens have trained personnel available for assistance in outbreak teams at national level.	NMFP NA = information not reported by the NMFP, 0 = no personnel available, 1 = personnel available during working hours, 2 = personnel available in 24/7 duty roster.
Indicator 3.34 *Listeria monocytogenes* genotyped by PFGE or WGS Percentage of the total number of *Listeria monocytogenes* isolates genotyped by pulsed-field gel electrophoresis (PFGE), or by whole genome sequencing (WGS), out of the total number of reported listeriosis cases at national level.	NMFP NA = information not reported by the NMFP/not applicable (e.g. less than 10 cases per year), 0 = genotyping was not done, 1 = type reported for <80% of reported cases, 2 = type reported for 80-100% of reported cases.
Indicator 3.35 Hepatitis A virus genotyped Percentage of hepatitis A virus clinical samples genotyped by sequence analysis out of all hepatitis A cases reported at national level.	NMFP NA = information not reported by the NMFP, 0 = genotyping was not done, 1 = type reported for <20% of reported cases, 2 = type reported for ≥20% of reported cases.
Target 3.4 Preparedness response (Re)-emerging diseases laboratory preparedness and response support	
Indicator 3.41 Diagnostic capability MERS-CoV Diagnostic capability for Middle East Respiratory Syndrome Coronavirus (MERS-CoV) infection available at national level in accordance with WHO surveillance guidance.	NMFP NA = information not reported by the NMFP, 0 = no diagnostic capability, 1 = screening test only, 2 = screening AND confirmation/identification.
Indicator 3.42 Diagnostic capability Influenza A(H7Nx) and A(H5Nx) Diagnostic and characterisation capability for avian influenza A(H7Nx) and A(H5Nx) viruses available at national level in accordance with ECDC/WHO surveillance guidance.	NMFP NA = information not reported by the NMFP, 0 = no specific diagnostic capability, 1 = HA identification available, 2 = HA and NA identification available.
Indicator 3.43 Diagnostic capability Ebola virus Diagnostic and characterisation capability (within country AND/OR through formal agreement with laboratories in other countries) for Ebola virus infection.	NMFP NA = information not reported by the NMFP, 0 = no national capacity nor formal agreement with other laboratories, 1 = molecular detection at BSL3 level or formal agreement with BSL3 laboratory in another country, 2 = further characterisation at BSL4 level within the country.
Indicator 3.44 Diagnostic capability for detection of five rare agents One or more reference virology laboratories in your country have detection capability for human infection with the following five rare AND/OR imported viruses: Chikungunya/Dengue/Hantavirus/Tick borne encephalitis/West Nile (according to the EVD-LabNet directory)	ECDC 0 = for less than 2 viruses, 1 = for at least 2 out of 5 viruses, 2 = for all 5 viruses.
Indicator 3.45 Guidance for colistin susceptibility testing /confirmation and identification of resistance mechanism by NAC or NRL National guidance was available for colistin susceptibility testing and detection of acquired colistin resistance in carbapenem-resistant *Enterobacteriaceae* and confirmation and identification of colistin resistance mechanisms was provided by NRL to clinical laboratories	ECDC NA = information not reported by the NMFP, 0 = neither guidance nor reference confirmation were available at national level, 1 = technical guidance for colistin susceptibility testing has been issued by the National Antimicrobial Susceptibilty Committee (NAC) and/or National Reference Laboratory OR confirmation of acquired colistin resistance and identification of resistance mechanism in clinical isolates are provided by the National Reference Laboratory to clinical laboratories, 2 = Both of the above were provided to clinical laboratories.

Annex 2. Policy rationale for EULabCap targets: key capabilities/capacities

Target	Rationale for key capability/capacity
1.1. Provision and regulation of clinical microbiology services	Provision of reliable, quality-assured, safe and fully-accessible clinical diagnostic microbiology services is a prerequisite for adequate case ascertainment and surveillance/threat notification systems.
1.2 Diagnostic testing guidelines	Availability of national primary diagnostic and screening testing guidelines (e.g. who to test, how to test, and when to test) is a prerequisite to guarantee sufficient sensitivity for case ascertainment and surveillance/threat notification systems.
1.3 Diagnostic testing utilisation	Awareness of national testing practices provides a basis for monitoring sensitivity of case ascertainment and surveillance/notification systems.
1.4 Antimicrobial drug susceptibility testing	Implementation and monitoring of compliance with EU standards for antimicrobial drug susceptibility testing is a prerequisite for accurate and comparable EU surveillance of antimicrobial resistance, in accordance with EU strategy on AMR.
2.1 Provision and regulation of national reference microbiology services	Organisation, regulation, and funding of national reference laboratory infrastructure and core public health functions are key elements for informing surveillance and epidemic preparedness at national and EU levels, in accordance with NMFP consensus.
2.2 Reference diagnostic confirmation and pathogen identification	Availability of national reference laboratory testing capability and capacity and a robust sample referral and reporting system to the national authorities is a prerequisite for effective surveillance and epidemic preparedness at national and EU levels in accordance with NMFP consensus.
2.3 Molecular typing for surveillance	Development and implementation of harmonised methodologies to integrate molecular typing data into surveillance for priority diseases form a prerequisite for informing public health action based on EU-wide risk assessment of disease transmission.
2.4 Antimicrobial drug resistance characterisation and monitoring	Accurate characterisation and monitoring of antimicrobial resistance determinants across human and animal populations for national/EU-wide surveillance informs public health action to contain cross-border and cross-species transmission of multidrug-resistant pathogens.
3.1 Support to national surveillance networks	National surveillance networks connecting clinical/public health laboratories for reporting diagnostic information to surveillance databases and linking microbiological and epidemiological information are essential for efficient communicable disease and drug resistance surveillance and early infectious threat detection.
3.2 Active participation in EU disease networks	Active participation and collaboration between experts in EU disease networks promotes exchange of best practice and capacity building, which foster sufficient collective capacity in the EU for threat detection, investigation, disease surveillance and epidemic preparedness.
3.3 National outbreak response support	Preparation and involvement of the national reference laboratory capacities and staff in outbreak monitoring and response activities in collaboration with clinicians, epidemiologists, and microbiologists ensure the effective contribution of laboratory testing to support epidemic detection and control.
3.4 (Re)-emerging diseases laboratory preparedness and response support	Up-to-date diagnostic capability for rare and (re)-emerging diseases and effective channels for collaboration are critical for laboratory preparedness and the deployment of timely and reliable emergency response to national and cross-border events.

Annex 3. EU/WHO policy documents or international standards used to develop EULabCap indicators

Indicator	Reference documents	Hyperlink
1.15	WHO Tuberculosis laboratory biosafety manual	http://www.who.int/tb/publications/2012/tb_biosafety/en/
	European Union Standards for Tuberculosis Care	http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3393116/pdf/erj-39-04-807.pdf
	Framework Action Plan to fight tuberculosis in the European Union	http://ecdc.europa.eu/en/publications/publications/0803_spr_tb_action_plan.pdf
1.21	Antenatal screening for HIV, hepatitis B, syphilis and rubella susceptibility in the EU/EEA - A Member State Survey	http://ecdc.europa.eu/en/publications/Publications/antenatal-screening-HIV-hepatitis-B-syphilis-rubella-EU.pdf
1.22	United Nations General Assembly Special Sessions on HIV/AIDS - Guidelines on construction of core indicators	http://www.unaids.org/en/media/unaids/contentassets/dataimport/pub/manual/2009/jc1676_core_indicators_2009_en.pdf
	HIV testing: increasing uptake and effectiveness in the European Union	http://ecdc.europa.eu/en/publications/Publications/101129_GUI_HIV_testing.pdf
	Dublin Declaration on Partnership to fight HIV/AIDS in Europe and Central Asia	http://www.unicef.org/ceecis/The_Dublin_Declaration.pdf
1.24	Risk assessment on the spread of carbapenemase-producing *Enterobacteriaceae* (CPE)	http://staging.ecdcdmz.europa.eu/en/publications/Publications/110913_Risk_assessment_resistant_CPE.pdf
	Update on the spread of carbapenemase-producng *Enterobacteriaceae* in Europe	http://antibiotic.ecdc.europa.eu/en/eaad/antibiotics-news/Documents/antimicrobial-resistance-EuSCAPE-Evidence-Brief.pdf
1.25	Framework Action Plan to fight tuberculosis in the European Union	http://ecdc.europa.eu/en/publications/publications/0803_spr_tb_action_plan.pdf
	Progressing towards TB elimination	https://ecdc.europa.eu/sites/portal/files/media/en/publications/Publications/101111_SPR_Progressing_towards_TB_elimination.pdf
1.31	Migrant health: Access to HIV prevention, treatment and care for migrant populations in EU/EEA countries	http://ecdc.europa.eu/en/publications/publications/0907_ter_migrant_health_hiv_access_to_treatment.pdf
1.32	Antimicrobial resistance surveillance in Europe	http://ecdc.europa.eu/en/publications/publications/antimicrobial-resistance-europe-2014.pdf
1.33	Underdiagnosis of *Clostridium difficile* across Europe: the European, multicentre, prospective, biannual, point-prevalence study of *Clostridium difficile* infection in hospitalised patients with diarrhoea (EUCLID)	http://www.thelancet.com/journals/laninf/article/PIIS1473-3099(14)70991-0/abstract
	Clostridium difficile: Guidance on infection prevention and control	http://ecdc.europa.eu/en/healthtopics/Healthcare-associated_infections/guidance-infection-prevention-control/Pages/guidance-prevention-control-infections-CDI.aspx
1.34	Framework Action Plan to fight tuberculosis in the European Union	http://ecdc.europa.eu/en/publications/publications/0803_spr_tb_action_plan.pdf
	Tuberculosis surveillance and monitoring in Europe, 2017	https://ecdc.europa.eu/en/publications-data/tuberculosis-surveillance-and-monitoring-europe-2017
1.35	Global update on HIV treatment 2014: Results, impact and opportunities; WHO in partnership with UNICEF and UNAIDS	http://www.who.int/hiv/pub/global-update.pdf
	Global health sector strategy on HIV/AIDS 2011-2015 Dublin declaration on Partnership to fight HIV/AIDS in Europe and Central Asia	http://www.unicef.org/ceecis/The_Dublin_Declaration.pdf
	Annual HIV/AIDS surveillance in Europe 2017 - 2016 data	https://ecdc.europa.eu/sites/portal/files/documents/20171127-Annual_HIV_Report_Cover%2BInner.pdf
1.41	EUCAST - Interaction of EUCAST Steering Committee with the network of national antimicrobial susceptibility testing committees	http://www.eucast.org/fileadmin/src/media/PDFs/EUCAST_files/EUCAST_SOPs/EUCAST_SOP_5_0_Interaction_with_NACs_20130104.pdf

Indicator	Reference documents	Hyperlink
	EUCAST - Interaction of EUCAST Steering Committee with the network of national antimicrobial susceptibility testing committees	http://www.eucast.org/fileadmin/src/media/PDFs/EUCAST_files/Statistics/Maps_EUCAST_status_Europe_January_2018.pdf
1.42	EUCAST - Breakpoint tables for interpretation of MICs and zone diameters	http://www.eucast.org/clinical_breakpoints/
1.43	EUCAST - Breakpoint tables for interpretation of MICs and zone diameters	http://www.eucast.org/clinical_breakpoints/
1.44	Framework Action Plan to fight tuberculosis in the European Union	http://ecdc.europa.eu/en/publications/publications/0803_spr_tb_action_plan.pdf
	Progressing towards TB elimination	https://ecdc.europa.eu/sites/portal/files/media/en/publications/Publications/101111_SPR_Progressing_towards_TB_elimination.pdf
1.45	Strengthening antimicrobial surveillance - Expanding Euro-GASP	http://www.ecdc.europa.eu/en/healthtopics/gonorrhoea/response-plan/Pages/strengthening-antimicrobial-surveillance.aspx
	Response plan to control and manage the threat of multidrug-resistant gonorrhoea in Europe	http://www.ecdc.europa.eu/en/publications/Publications/1206-ECDC-MDR-gonorrhoea-response-plan.pdf
	Gonococcal antimicrobial susceptibility surveillance in Europe	https://ecdc.europa.eu/en/publications-data/gonococcal-antimicrobial-susceptibility-surveillance-europe-2015
2.11	Core functions of microbiology reference laboratories for communicable diseases	http://www.ecdc.europa.eu/en/publications/Publications/1006_TER_Core_functions_of_reference_labs.pdf
2.12	Core functions of microbiology reference laboratories for communicable diseases	http://www.ecdc.europa.eu/en/publications/Publications/1006_TER_Core_functions_of_reference_labs.pdf
2.13	Core functions of microbiology reference laboratories for communicable diseases	http://www.ecdc.europa.eu/en/publications/Publications/1006_TER_Core_functions_of_reference_labs.pdf
2.14	Core functions of microbiology reference laboratories for communicable diseases	http://www.ecdc.europa.eu/en/publications/Publications/1006_TER_Core_functions_of_reference_labs.pdf
2.15	WHO laboratory biosafety manual	http://www.who.int/csr/resources/publications/biosafety/Biosafety7.pdf
2.21	Case definitions for reporting communicable disease to the Community Network	http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:262:0001:0057:EN:PDF
2.22	European Legionnaires' Disease Surveillance Network (ELDSNet)	https://ecdc.europa.eu/sites/portal/files/media/en/publications/Publications/1202-TED-ELDSNet-operating-procedures.pdf
2.23	External quality assurance scheme on PCR for *Bordetella pertussis*, 2012	https://ecdc.europa.eu/en/publications-data/guidance-and-protocol-use-real-time-pcr-laboratory-diagnosis-human-infection
2.24	Diagnostic work-up of suspected STEC enteritis and HUS cases related to the ongoing outbreak of STEC O104:H4	http://ecdc.europa.eu/en/healthtopics/escherichia_coli/outbreaks/laboratory_resources/Pages/diagnostic_guidance.aspx
2.25	WHO SARS International Reference and Verification Laboratory Network: Policy and Procedures in the Inter-Epidemic Period	http://www.who.int/csr/resources/publications/en/SARSReferenceLab.pdf
2.32	Molecular surveillance pilot - Evaluation report, 2014, Meeting minutes 38th Advisory Forum	http://www.ecdc.europa.eu/en/aboutus/organisation/af/Pages/Meeting_minutes.aspx
2.34	Resolution of a Meningococcal Disease Outbreak from Whole-Genome Sequence Data with Rapid Web-Based Analysis Methods	http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3421817/pdf/zjm3046.pdf
2.35	WHO HIV Drug Resistance Surveillance Network	http://www.who.int/drugresistance/hivaids/en/HIVdrugnetwork.pdf
2.41	EUCAST guidelines for detection of resistance mechanisms and specific resistances of clinical and/or epidemiological importance	http://www.eucast.org/fileadmin/src/media/PDFs/EUCAST_files/Resistance_mechanisms/EUCAST_detection_of_resistance_mechanisms_v1.0_20131211.pdf
2.42	EUCAST guidelines for detection of resistance mechanisms and specific resistances of clinical and/or epidemiological importance	http://www.eucast.org/fileadmin/src/media/PDFs/EUCAST_files/Resistance_mechanisms/EUCAST_detection_of_resistance_mechanisms_v1.0_20131211.pdf
2.43	EUCAST guidelines for detection of resistance mechanisms and specific resistances of clinical and/or epidemiological importance	http://www.eucast.org/fileadmin/src/media/PDFs/EUCAST_files/Resistance_mechanisms/EUCAST_detection_of_resistance_mechanisms_v1.0_20131211.pdf
2.44	ERLI-Net: Key tasks of the network	http://ecdc.europa.eu/en/activities/surveillance/eisn/laboratory_network/pages/key_tasks.aspx
2.45	EUCAST - Breakpoint tables for interpretation of MICs and zone diameters	http://www.eucast.org/fileadmin/src/media/PDFs/EUCAST_files/Breakpoint_tables/Breakpoint_table_v_3.1.pdf

Indicator	Reference documents	Hyperlink
3.11	Core functions of microbiology reference laboratories for communicable diseases	http://www.ecdc.europa.eu/en/publications/Publications/1006_TER_Core_functions_of_reference_labs.pdf
3.13	Case definitions for reporting communicable disease to the Community Network	http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:262:0001:0057:EN:PDF
3.15	*Chlamydia* control in Europe	http://www.ecdc.europa.eu/en/publications/publications/0906_qui_chlamydia_control_in_europe.pdf
3.21	ELDSNet	https://ecdc.europa.eu/en/about-us/partnerships-and-networks/disease-and-laboratory-networks/eldsnet
3.22	EVD-LabNet	https://ecdc.europa.eu/en/about-us/partnerships-and-networks/disease-and-laboratory-networks/evd-labnet
3.23	IBDLab-Net	http://www.ecdc.europa.eu/en/activities/surveillance/EU_IBD/Pages/index.aspx
3.24	ERLTB-Net	https://ecdc.europa.eu/en/about-us/partnerships-and-networks/disease-and-laboratory-networks/erltb-net
3.25	Euro-GASP	http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=19995
3.31	Core functions of microbiology reference laboratories for communicable diseases	http://www.ecdc.europa.eu/en/publications/Publications/1006_TER_Core_functions_of_reference_labs.pdf
3.32	Core functions of microbiology reference laboratories for communicable diseases	http://www.ecdc.europa.eu/en/publications/Publications/1006_TER_Core_functions_of_reference_labs.pdf
3.33	Core functions of microbiology reference laboratories for communicable diseases	http://www.ecdc.europa.eu/en/publications/Publications/1006_TER_Core_functions_of_reference_labs.pdf
3.41	WHO guidelines for investigation of cases of human infection with Middle East Respiratory Syndrome Coronavirus (MERS-CoV), July 2013	http://www.who.int/csr/disease/coronavirus_infections/MERS_CoV_investigation_guideline_Jul13.pdf
	Severe respiratory disease associated with Middle East respiratory syndrome coronavirus (MERS-CoV)	http://www.ecdc.europa.eu/en/publications/Publications/Middle-East-respiratory-syndrome-coronavirus-Saudi%20Arabia-Qatar-Jordan-Germany-United-Kingdom.pdf
3.42	Laboratory preparedness in EU/EEA countries for detection of novel avian Influenza A (H7N9) virus, May 2013	http://www.eurosurveillance.org/images/dynamic/EE/V19N04/art20682.pdf
3.43	Algorithm for laboratory diagnosis of Ebola virus disease	http://ecdc.europa.eu/en/healthtopics/ebola_marburg_fevers/algorithm-evd-diagnosis/Pages/default.aspx

Annex 4. EU/EEA country survey on use of EULabCap reports and follow-up actions

The questionnaire on the feedback on dissemination and use of EULabCap reports was opened on 19 December 2017 until 19 February 2018 and included the following questions:

1. Which country do you represent?

2. Did you find any of the previous EULabCap country reports useful for advising your national authorities?

3. How did you use and disseminate any of the previous EULabCap reports?

- I discussed with microbiologists involved in public health
- I communicated to policy and budget decision makers
- I discussed with infectious disease epidemiologist colleagues
- I did not use or disseminate any of the reports

4. Since 2015 until today, did action take place in your country addressing any of the suggested areas of attention stated in your EULabCap reports?

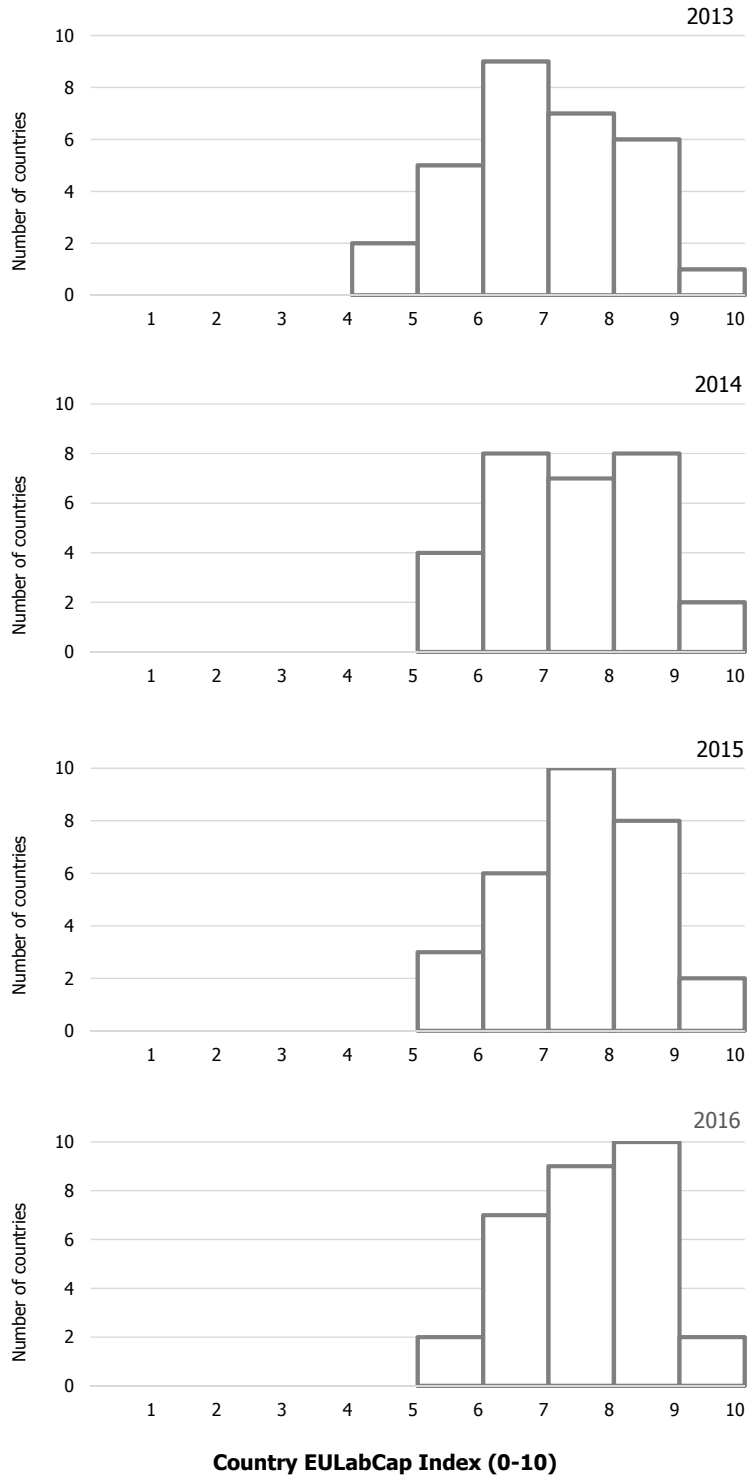
- No follow-up action
- Regulation of Public Health National Reference (NRL) services (e.g. nomination and functions)
- Resource allocation to NRL services (e.g. funding, staffing, equipment, etc.)
- NRL quality accreditation
- Involvement of NRL experts in national outbreak investigations
- Regulation of clinical microbiology laboratories
- Resource allocation to clinical microbiology laboratory services
- Clinical laboratory quality accreditation
- Biosafety regulation and monitoring of clinical and/or reference laboratories
- Diagnostic testing guidance development
- Measurement of compliance with diagnostic testing guidance
- Measurements of diagnostic test use rates#
- Automation of reporting laboratory data to public health surveillance databases
- Transition to WGS-based typing at NRL level
- Sharing molecular/WGS based typing data via EPIS/TESSy
- Improving microbiological data reporting to TESSy
- Other follow-up action(s)

Annex 5. Data completeness by indicator, EULabCap surveys 2013–2016

			2013		2014		2015		2016	
	Target	Indicator	Total number NA	Countries	Total number NA	Countries	Total number NA	Countries	Total number NA	Countries
Dimension 1	1.1	1.11	2	CY, IE	1	CY	1	CY	0	
		1.14	1	EL	0		0		0	
	1.2	1.22	0		1	NL	1	NL	0	
		1.23	1	LV	2	HR, NL	2	HR, NL	1	HR
		1.24	1	LV	1	LV	0		0	
	1.3	1.31	3	NL, PO, PT	0		1	NL	0	
		1.33	6	EL, HR, NL, PO, PT, RO	8	BE, DE, LU, NO, PO, RO, SI, SV	9	BE, DE, ES, FR, EL, IE, NO, PT, RO	0	
		1.34	0		3	FR, IT, LU	1	FR	1	FR
	1.4	1.41	1	MT	1	CY	1	CY	0	
		1.42	2	CY, MT	1	CY	1	CY	0	
		1.44	2	DE, IS	2	DE, IS	1	IS	1	IS
		1.45	0		2	CZ, DE	1	DE	1	DE
Dimension 2	2.1	2.11	1	PO	1	PO	1	PO	0	
		2.12	1	PO	1	PO	0		0	
		2.13	1	PO	0		0		0	
		2.14	1	MT	3	IT, MT, PO	1	MT	0	
		2.15	0		1	PO	0		0	
	2.2	2.23	0		7	BE, BG, CY, IS, IT, SI, PO	5	BE, BG, LU, MT, PO	1	MT
		2.24	6	BG, CY, HR, LV, MT, PT	6	BG, CY, HR, LV, MT, PT	8	CY, HR, EL, MT, PO, PT, RO, SV	4	CY, EL, HR, NL
		2.25	1	MT	3	CY, IS, MT	3	CY, IT, MT	2	CY, MT
	2.3	2.31	1	MT	3	HR, MT, SV	2	HR, SV	2	HR, MT
		2.32	5	CZ,LT, MT, PT, SV	0		0		3	DE, FR, PT
		2.33	11	CZ, EE, FR, HU, IS, LT, LV, PT, RO, SI, UK	4	CY, IS, MT, SI	4	CY, IS, LU, SI	4	HR, IS, MT,SI
		2.34	4	HR, IS, PO, SV	2	BG, HR	0		1	IS
		2.35	2	MT, PT	9	ES, EL, IT, NL, PO, PT, RO, SV, UK	9	ES, EL, IT, NL, PO, PT, RO, SV, UK	8	EL, ES, IT, NL, PL, RO, SV, UK
	2.4	2.41	1	CY	1	CY	0		1	CY
		2.42	2	CY, MT	0		0		0	
		2.43	2	CY, MT	1	CY	0		0	
		2.44	2	CY, PO	0		0		0	
		2.45	1	MT	1	MT	0		0	
Dimension 3	3.1	3.11	1	MT	1	MT	0		0	
		3.12	0		0		1	MT	0	
		3.13	4	HU, IS, LT, MT	2	IS, MT	2	CY, IS	1	CY
		3.14	2	IS, MT	2	IS, MT	1	MT	0	
		3.15	3	DE, IT, MT	2	HR, MT	2	HR, MT	2	HR, DE
	3.2	3.21	0		0		0		*	
		3.22	1	IS	0		*		0	
		3.23	0		*		*		*	
		3.24	1	IS	0		0		1	IS
		3.25	0		0		0		4	BG, FI, LT, RO
	3.3	3.33	3	DE, MT, LT	2	DE, MT	1	DE	0	
		3.34	3	MT, NO, UK	4	LV, MT, NL, PO	3	CY, IS, MT	2	LV, MT
		3.35	2	IS, MT	5	HR, IS, MT, LT, NL	4	HR, IS,MT, NL	3	HR, IS, MT
	3.4	3.44	1	IS	0		0		0	
		3.45	1	IT	0		0		1	LV

*Legend: AT (Austria), BE (Belgium), BG (Bulgaria), CY (Cyprus), CZ (Czech Republic), DE (Germany), DK (Denmark), EE (Estonia), EL (Greece), ES (Spain), FI (Finland), FR (France), HR (Croatia), HU (Hungary), IE (Ireland), IS (Iceland), IT (Italy), LT (Lithuania), LV (Latvia), LU (Luxembourg), MT (Malta), NL (Netherlands), NO (Norway), PL (Poland), PT (Portugal), RO (Romania), SE (Sweden), SI (Slovenia), SV (Slovakia), UK (United Kingdom). * Indicators were not applicable*

Annex 6. Distribution of overall EULabCap country index scores

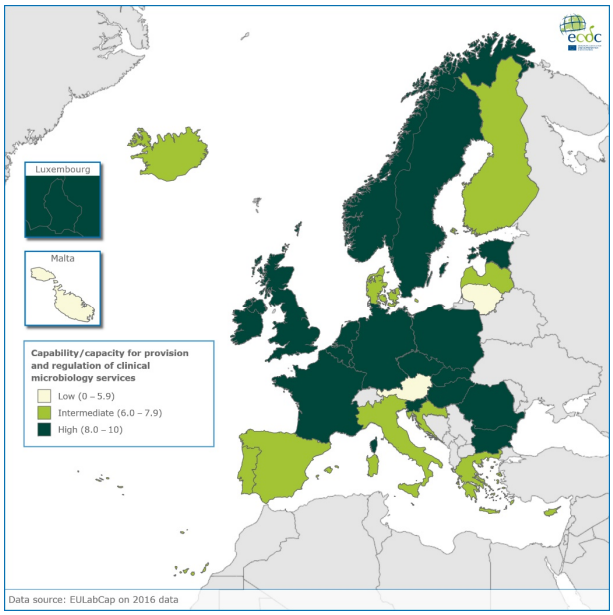


Note: Index scores for 2013–2014 (N=30 countries), 2015 (N=29 countries) and 2016 (N=30 countries).

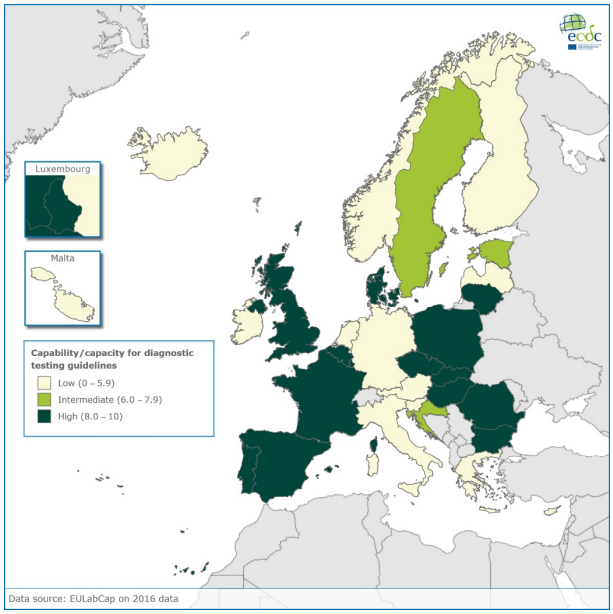
Annex 7. Maps of EULabCap target performance level by country

Dimension 1: primary diagnostic testing, targets 1.1–1.4, 2016

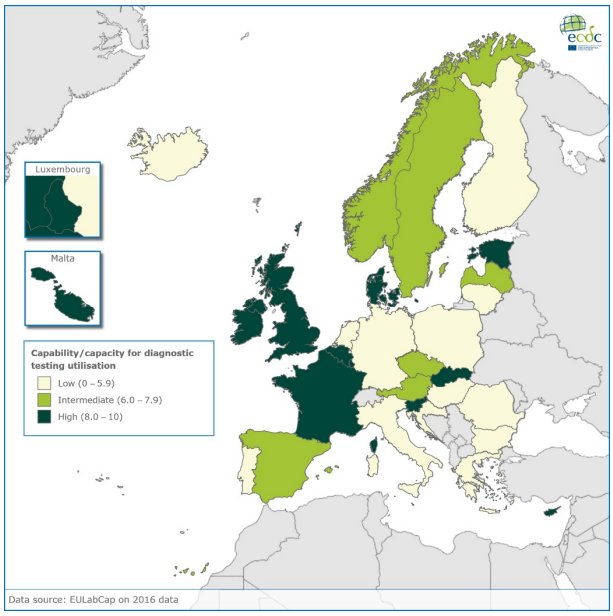
Target 1.1 Provision and regulation of clinical microbiology services.



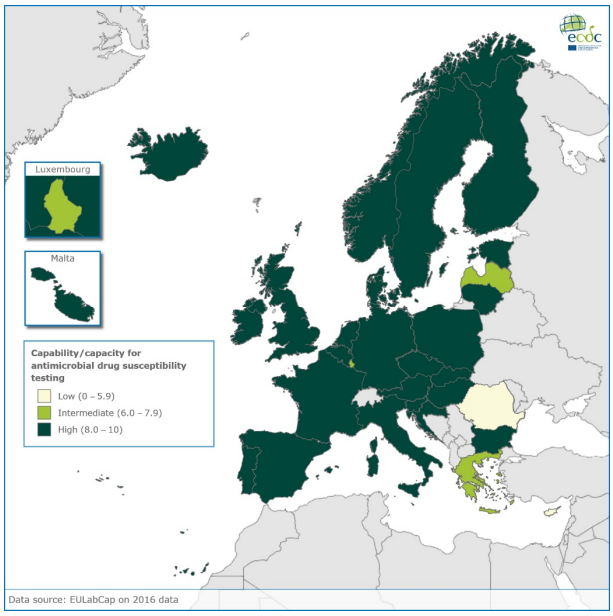
Target 1.2 Diagnostic testing guidelines.



Target 1.3 Diagnostic testing utilisation.

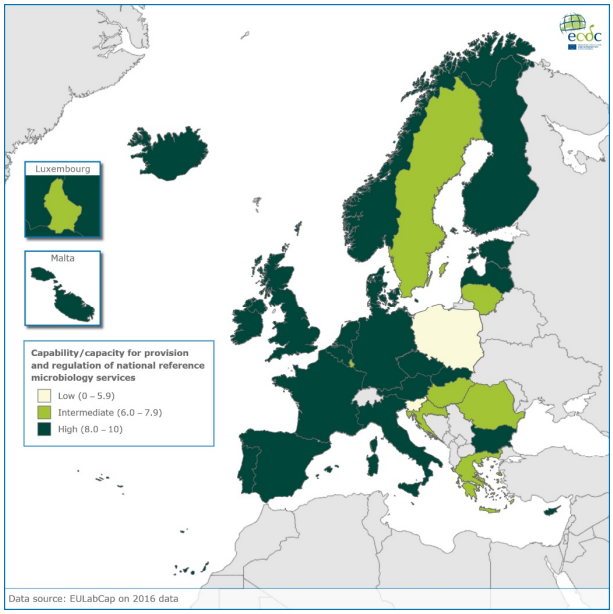


Target 1.4 Antimicrobial drug susceptibility testing.

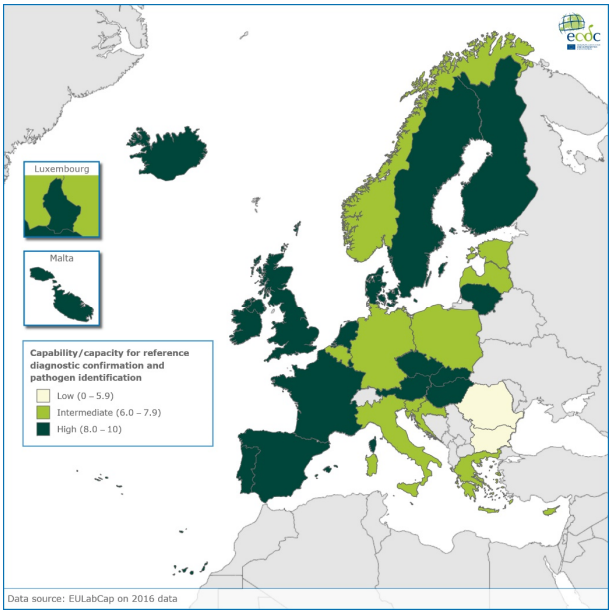


Dimension 2: national reference laboratory services, targets 2.1–2.4, 2016

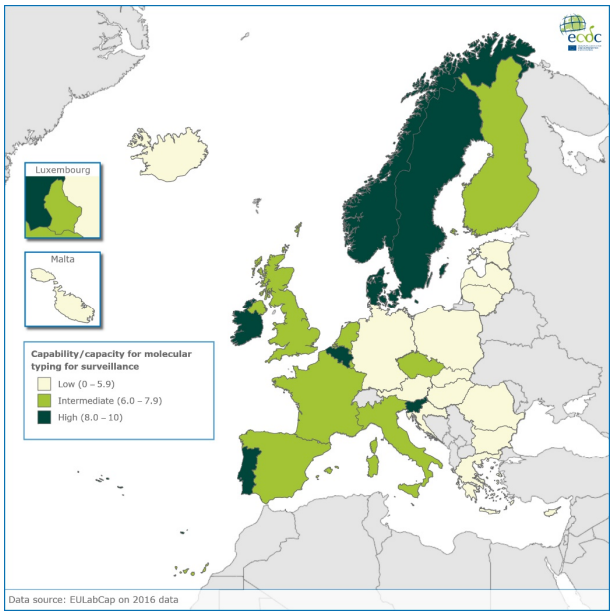
Target 2.1 Provision and regulation of national reference microbiology services.



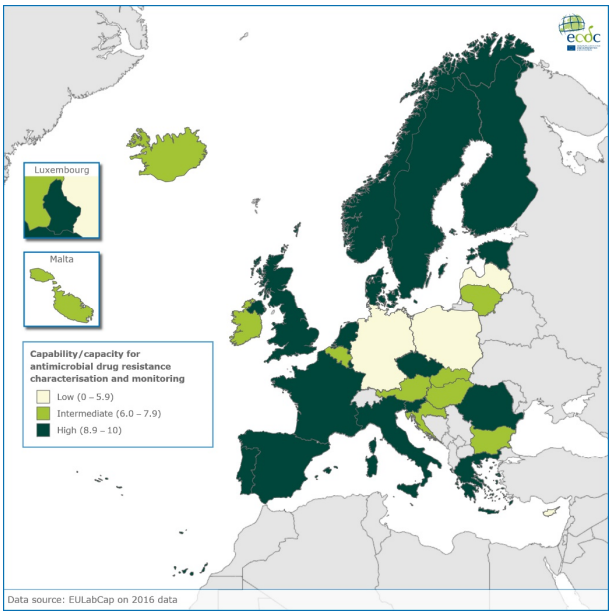
Target 2.2 Reference diagnostic confirmation and pathogen identification.



Target 2.3 Molecular typing for surveillance.

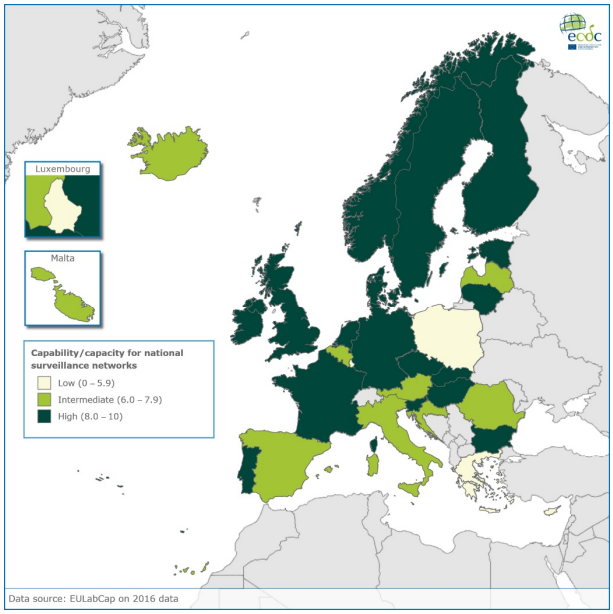


Target 2.4 Antimicrobial drug resistance characterisation and monitoring.

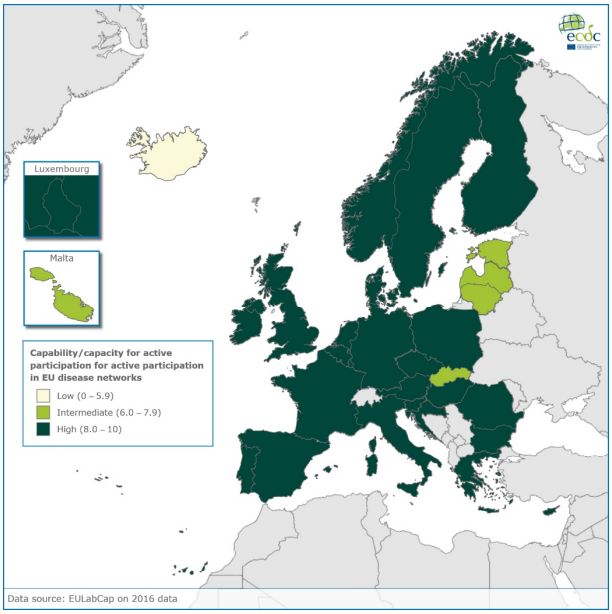


Dimension 3: laboratory-based surveillance and epidemic response support, targets 3.1–3.4, 2016

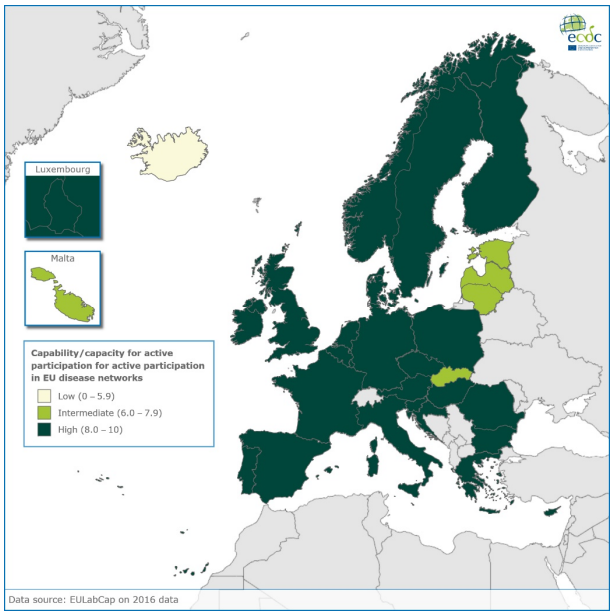
Target 3.1 Support to national surveillance networks.



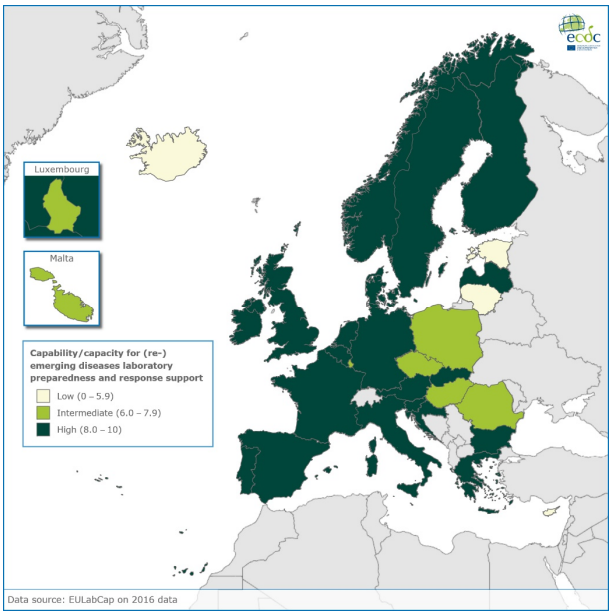
Target 3.2 Active participation in EU disease networks.



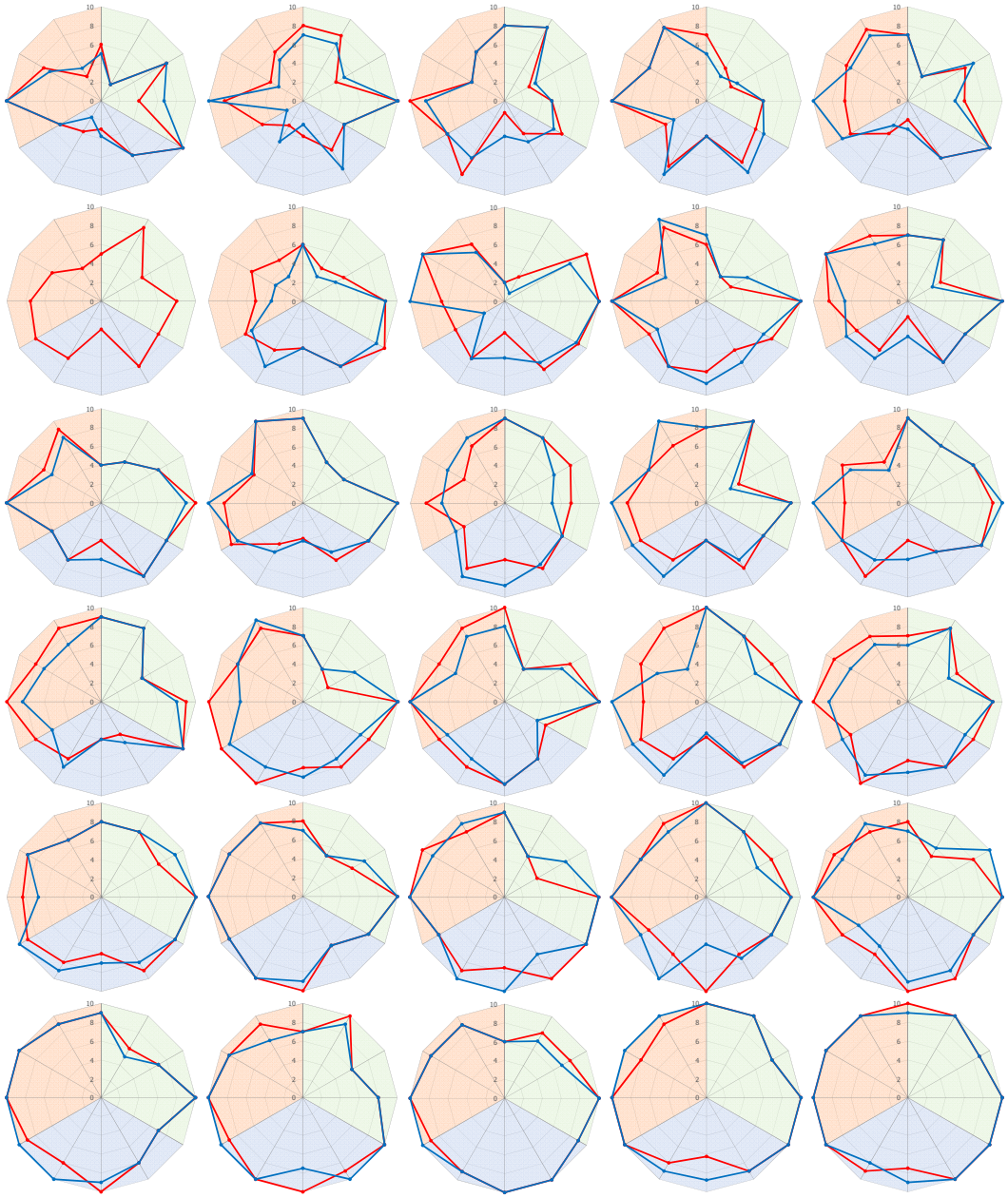
Target 3.3 National outbreak response support.



Target 3.4 (Re)-emerging diseases laboratory preparedness and response support.



Annex 8. Radar graphs of EULabCap target index scores for each country, 2015 and 2016



Note: The radar charts compare the EULabCap target index scores of 30 countries and two survey years: 2016 (red line, N=30 EU/EEA countries) and 2015 (blue line, N=29 EU/EEA countries) scores. The charts are displayed in ascending order of total index country score (2016) and arranged from top left to bottom right (lowest to highest score).

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