TECHNICAL REPORT

EU Laboratory Capability Monitoring System (EULabCap)

Report on 2014 survey of EU/EEA country capabilities and capacities

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Suggested citation: European Centre for Disease Prevention and Control. EU Laboratory Capability Monitoring System (EULabCap) – Report on 2014 survey of EU/EEA country capabilities and capacities. Stockholm: ECDC; 2016.

Stockholm, August 2016

ISBN 978-92-9193-985-5

doi 10.2900/993419

Catalogue number TQ-02-16-877-EN-N

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Abbreviations

AF	Advisory Forum
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 Laboratories 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	inter-quartile range
MDR TB	multidrug-resistant tuberculosis
MERS-CoV	Middle East respiratory syndrome coronavirus
MLST	Multi Locus Sequence Typing
NMFP	National Microbiology Focal Points
NAC	National Antimicrobial Susceptibility Committee
NRL	National Reference Laboratories
OECD	The Organisation for Economic Cooperation and Development
PCR	Polymerase Chain Reaction
Q1	first quartile
Q3	third quartile
SMAP	Strategic Multi-Annual Plan
VTEC/STEC	verotoxin- or Shiga toxin-producing *Escherichia coli*
TESSy	The European Surveillance System
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	Nominated representatives for public health microbiology in the EU/EEA Member States as part of the Competent Body Structure [3].
National Reference Laboratories	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 contribution to detection and diagnosis of infectious microorganisms, and the characterisation and surveillance of microorganisms with the potential to affect populations [4,5].

Executive summary

Background

The ECDC public health microbiology strategy (2012–2016) and ECDC strategic multi-annual programme (2014–2020) aim to strengthen the capability and capacity of the EU public health microbiology system to provide the timely and reliable information that underpins infectious threat detection, assessment and surveillance at Member State and EU level for effective prevention and control of infectious diseases [1,2]. To ascertain how well this is delivered, ECDC, in close collaboration with the National Microbiology Focal Points (NMFP) and the Advisory Forum (AF), has developed and piloted a system (EULabCap) for monitoring key public health microbiology capabilities and capacity for EU surveillance and epidemic preparedness on an annual basis. This assessment aims to help policymakers identify possible areas for action and to evaluate the impact of capacity strengthening activities and health system reforms. The first report on the pilot 2013 survey of EU/EEA (European Economic Area) country capabilities and capacities was published in February 2016 [8]. This second report presents the indicator results achieved in 2014 and a tentative comparison with the baseline data of 2013 for 30 EU and EEA countries.

Methods

The EULabCap monitoring tool combines 60 technical 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 divided into 38 indicators of laboratory capability and 22 of service capacity. About 3/4 of the indicators are based on EU policy targets or international technical standards, while the remainder assess EU surveillance and alert system contributions.

The indicators are grouped into 12 targets 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. Each indicator can be scored at three levels: low, intermediate and high capability or capacity. Aggregated indices are calculated for each target and dimension as the average of component indicator scores, adjusting all index values on a scale of 0–10.

A mixed method was used for data collection and scoring. To minimise the data reporting burden for the Member States, information for 20 indicators was retrieved by ECDC from data sets accessible in The European Surveillance System (TESSy) and EU disease network reports. For the remaining 40 indicators the NMFPs used a questionnaire to collect information from their country.

The data collected for 2014 were validated by the NMFPs and the preliminary results were summarised and reported to the NMFP before being reviewed in joint consultation by the NMFPs and the AF in May 2016. Results were reviewed for validity assessment and survey improvements and the information was used to develop actions at the national and/or EU level. At the request of the NMFPs, another round of data validation was performed to enable minor corrections of data both for 2013 and 2014.

Results

The country response to the survey was 100% (30/30 EU/EEA countries). Data from 2014 were provided for 95% of the indicators[1] (range per country, 78–100%). The average EULabCap aggregated index for the EU/EEA was 7.3 on a scale of 1–10, as compared to the final revised EU score of 6.9 in 2013.

As in 2013, substantial inter-country variation was found with overall EULabCap indices per country ranging from 5.0 to 9.5 (in 2014) compared to 4.7 to 9.2 (in 2013). There was also diversity of scores among targets, with common challenging areas for which many countries lacked critical capabilities and/or showed low capacity. In 2014, the main areas of strong capability, with high scores largely meeting policy targets and standards, were the same as in 2013. These included 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. As in 2013, the main challenges were found to be in the areas of provision and regulation of clinical microbiology services; diagnostic testing guidelines and utilisation, and national reference laboratory services relating to molecular typing for surveillance and national outbreak response support.

[1] For the survey on 2014 data, one indicator was excluded from the analysis as it was not applicable.

In 2014, notable improvements, unlikely to be explained by indicator modifications, were found against the 2013 baseline data in the following technical areas:

- Primary diagnostics: medical test reimbursement, medical laboratory licensing, biosafety for tuberculosis diagnostics, *Clostridium difficile* testing guidance and utilisation, and EUCAST breakpoint use.
- NRL services: NRL core function delivery, access to biosafety level 3 facilities, diagnostic confirmation capabilities for EU notifiable diseases and application of whole genome sequencing to national surveillance.
- Surveillance and outbreak support: laboratory-based outbreak detection, *Chlamydia trachomatis* surveillance, NRL contribution to outbreak investigations and diagnostic capability for emerging pathogens.

Conclusions and next steps

The high response rate of the EU/EEA countries in the EULabCap surveys highlights the EU/EEA countries' commitment to this new health system component monitoring and benchmarking process, thanks to the engagement of the NMFPs. The results of this second EULabCap annual survey confirmed that the EU/EEA as a whole, with an aggregated index score of 7.3 out of 10 for 2014, as compared with 6.9 in the 2013 pilot, can rely on a public health microbiology system with strong overall capability and substantial capacity to fulfil communicable disease surveillance and response requirements.

The main EU system strengths and weaknesses were consistent between the surveys, with specific areas of score increase suggesting that some of its public health microbiology capabilities improved. There remains substantial inter-country variation in the EULabCap index in 2014, but with preliminary evidence of a narrowing gap. These apparent trends will be assessed further in the surveys to come.

The EULabCap monitoring aims to provide information for national competent bodies and policy makers at the national and EU level. In May 2016, the results of the EULabCap 2014 report, and use of the first EULabCap reports in the Member States, were reviewed in consultation with the AF and NMFPs. The first EULabCap reports were found useful and had been widely disseminated to national stakeholders in the majority of countries and, in over half of them, findings had been addressed for targeted capacity building action.

The validity of the survey methodology and results was broadly supported by the AF and NMFPs during discussions at the May 2016 meeting. Clarifications for a few indicators and modifications in the survey process were agreed upon to improve efficiency of data collection, quality of data and timely reporting. Evaluation of the use of the EULabCap reports for policy action by the Member States will be integrated into the monitoring system reporting cycle.

Areas where further support for laboratory capacity could be provided at the EU level were also discussed. ECDC will develop these suggestions in accordance with its Country Support Strategy [9], in close collaboration with the European Commission health programme initiatives on reference laboratory coordination and global laboratory capacity strengthening under the International Health Regulations.

Introduction

The detection and characterisation by diagnostic and reference microbiology laboratories of infectious agents causing human disease provides pivotal information for clinical management, public health surveillance and outbreak alert and response. As the epidemic of Ebola virus disease in West Africa has dramatically shown, any gap in laboratory capacity at local and national levels may prove disastrous due to delayed outbreak recognition and response. Provision of sufficient national laboratory capacity for infectious health threat detection and control is required to fulfil the obligations set forth in EU [3] and international legislation [4]. This capacity hinges on close collaboration with the national surveillance institutes and adequate funding, infrastructure, and human resources within the national healthcare system.

Public health microbiology systems comprise three intertwined components. First, clinical laboratories performing primary diagnostics, antimicrobial drug susceptibility testing and screening focused on patient management and preventive services. Second, public health laboratories serving as reference functions at a national or subnational level, such as specialist diagnostics and biological agent characterisation. Third, laboratory networks performing harmonisation of methods, quality assessment and contribution to public health surveillance and alert systems, nationally and internationally.

National health systems in Europe are undergoing continuous administrative and organisational reforms to face up to the challenge of maintaining universal access to essential and high-quality care with reduced resources [5]. Following the financial crisis in 2008, health expenditure has either stopped growing or even decreased in various degrees across the EU Member States [5]. Public health budget cuts have affected resources available to and investment in 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 characterization of infectious agents which may threaten public health' [6]. 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 decade-long legacy of collaboration between infectious disease experts, microbiologists and epidemiologists 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 [6] and the European Commission [7], have revealed a wide diversity 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 devolution of specialist technical capacity at supranational level [6,7].

The ECDC public health microbiology strategy (2012–2016) and laboratory support within its strategic multi-annual programme (2014–2020) aim to strengthen the capability and capacity of the EU public health microbiology system to provide the timely and reliable information that underpins infectious threat detection, assessment and surveillance at Member State and EU level, as needed for effective prevention and control of infectious diseases [1,2]. To ascertain how well this is delivered, ECDC, in close collaboration with the National Microbiology Focal Points (NMFP) and the Advisory Forum (AF), 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 in 2012–14, the results of the first survey, launched in 2014, collecting information on 2013 system outputs for 30 EU/EEA countries, were published in February 2016 after extensive consultation [8].

The NMFP are the main contributors to the data collection and verification. They are responsible for disseminating the EULabCap country profile report within their Competent Bodies, in accordance with their terms of reference [2]. At the national level information can be used to provide decision-makers with options to strengthen the system where relevant (e.g. by adopting good practice or initiating bilateral laboratory cooperation). ECDC will also use the results of EULabCap to plan its laboratory work under the ECDC Country Support Strategy in the coming years [9].

This report presents the second EULabCap survey results which are based on 2014 data in the 30 EU/EEA countries.

Materials and methods

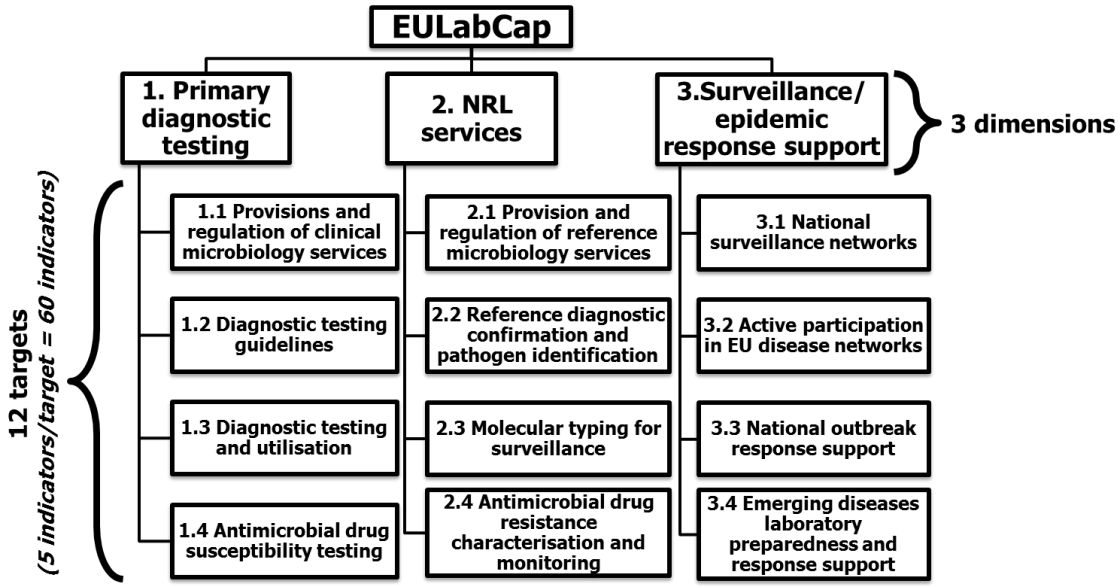
Survey population

The EULabCap second data call was launched in October 2015 to collect the information on the 2014 capabilities and capacities of the 28 EU Member States and two EEA countries. Liechtenstein is not included in the survey due to the outsourcing arrangements they have in place with laboratories in Switzerland to meet their public health microbiology needs.

Survey tool

An Excel-based data collection tool was developed and pilot tested for feasibility and clarity 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 the EULabCap indicators as grouped by dimension and target



The EULabCap indicators (Annex 1) are of a composite nature in terms of what element of the system they measure (structure or process) and how they measure it (functional capability or capacity). They comprise 24 structure and 36 process indicators. They are divided into 38 indicators for laboratory capability and 22 for 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 2 and 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 has three possible scores (0,1,2) and a 'not available' or 'not applicable' option. Each score was assigned to either a low, intermediate or high level of laboratory capability/capacity, based on the WHO laboratory assessment tool (Table 2) [10].

Table 2. Interpretation of score levels for laboratory capability and capacity

Score	Interpretation	Level
0	No or limited capability/capacity	Low
1	Partial capability/capacity (e.g. below the EU target, or partial compliance)	Intermediate
2	Complete capability/capacity (e.g. EU target reached, or high compliance)	High
NA	Capability/capacity not known or indicator not applicable to country	Not scored

Indicator modifications between the first and the second survey

For the second survey on 2014 data, the same indicators were used as in the first survey, with the following modifications in 2014:

A. Indicator 3.23 on participation in the European Invasive Bacterial Disease Laboratory Network (IBD-LabNet) was not applicable in 2014, due to interruption of part of the scored activities of this network.

B. The scoring method was modified by asking the NMFPs to provide absolute numerator and denominator data for 2014 and the score calculation was performed by ECDC, instead of self-scoring by the NMFP, as in 2013, for the following three capacity indicators:

- Indicator 1.33 'Total number of *Clostridium difficile* diagnostic tests performed/1 000 hospital inpatient days, based on national estimates'.
- Indicator 2.13 'The majority of NRLs delivered the following functions: reference diagnostics, reference material resources, scientific advice and diagnostic guidance, collaboration and research development, and monitoring, alert and response'.
- Indicator 2.35 'Total number of HIV isolates genotyped by ARV target sequences analysis divided by the total number of new HIV cases reported'

C. The score wording or calculation method was slightly modified for the following four indicators:

- Indicator 2.24 'Total number of O-serogrouped Shiga toxin-producing/verotoxin-producing *Escherichia coli* (STEC/VTEC) isolates, divided by the total number of TESSy-notified STEC/VTEC cases in accordance with EU case definition/ECDC FWD network guidance', where the change relates to the fact that non-typeable strains were included in the numerator in 2014.
- Indicator 2.34 'Total number of invasive *Neisseria meningitidis* isolates typed by serogroup: MLST:*porA*:*fetA* method reported to TESSy divided by the total of number of invasive cases reported to TESSy', where partial typing results obtained by either MLST or *porA*:*fetA* sequence analysis were included in the numerator in 2014.
- Indicator 2.44 'Human influenza virus susceptibility monitoring to neuraminidase (NA) inhibitors by phenotypic/genotypic methods was performed (by national services or a service agreement with another country) for human viral samples in accordance with ERLI-Net guidance', where the core options were further clarified.
- Indicator 3.34 'Ratio of the total number of *Listeria* isolates genotyped by pulsed-field gel electrophoresis (PFGE), or by whole genome sequencing (WGS), by the total number of notified cases (in percentage)', where the change includes a higher resolution typing method (WGS) as some countries are only using this method.

Data collection and validation process

Data collection and validation were performed between October 2015 and May 2016. A mixed method was used for data collection with: (a) information for 20 indicators retrieved by ECDC from data sets accessible in The European Surveillance System (TESSy) and EU disease network reports and (b) collection by the NMFP of information for the remaining 40 indicators using a questionnaire (Annex 1). Two rounds of validation were performed with the NMFP to ensure data accuracy and correct score calculation.

The 2014 data were validated by the NMFPs in March–April 2016. ECDC provided the preliminary report on these analysed results by means of individual country profiles and EU draft reports. These draft reports were discussed in joint consultation with the NMFPs and the AF in May 2016 and critically reviewed for validity assessment, public health relevance and possible survey improvements. At the request of the NMFPs, an additional round of data

validation was performed in May–June 2016, allowing minor corrections of data submitted in both the 2014 and 2013 surveys.

Data analysis and interpretation

Data completeness was calculated as a percentage of missing data for each indicator across the EU/EEA and overall for each country. Aggregated performance indices were calculated for each target and dimension as the average of component indicator scores per country, adjusting values on a scale of 0–10. Descriptive data analysis, including measures of central tendency (mean and median) and dispersion (standard deviation and inter-quartile range) of indicator scores and aggregated indices across the EU/EEA were calculated using Excel 2010. Overall EULabCap index scores per country were graded qualitatively at three performance levels: low (0 to 5.9), intermediate (6.0 to 7.9) and high (8.0 to 10). The data for 2014 were compared with the final data for 2013 by indicator, target and dimension as well as by country.

Interpretation of the 2014 findings in terms of level of performance by system component (indicator, target and dimension), by country and at EU level, as drafted in preliminary reports by the ECDC team, was validated and revised based on comments received during written bilateral consultation with each NMFP on their draft country report, and following the review of the draft EU report in a joint meeting with the NMFP and AF.

Data reporting

EU/EEA report

This report displays aggregated data on the EULabCap scores for all 30 participating EU/EEA countries, using histograms, radar and bar graphs, and maps to visualise the distribution of performance scores in 2014 for the system overall, by target and by dimension, in comparison with the tentative baseline 2013 data.

Individual country benchmark reports

An individual EULabCap country report was prepared for each participating EU/EEA country, including detailed information on the country score benchmark, and shared confidentially with the respective NMFP, for dissemination within and use by the Coordinating Competent Body. The EULabCap country 2014 indices were graded qualitatively into three capability and capacity levels of their public health microbiology system: 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 for country categorisation in the EU maps in this report.

Each country report provided a one-page executive summary as a customised policy brief for the country's decision-makers, presenting the overall benchmark scores within the EU, indicating the areas of good national system capacity/capability and the weaker areas in need of attention. As an annex to this summary, the survey methods were reviewed and the country results described and benchmarked using a) a radar graph comparing the country's median 2014 and 2013 EULabCap index scores for the 12 targets against the EU inter-quartile score range (IQR) for 2014; b) the score distribution among EU/EEA countries compared to the country's scores for each indicator, and c) the country's mean scores per target and indicator in 2013 and 2014.

Feedback on use of previous annual report

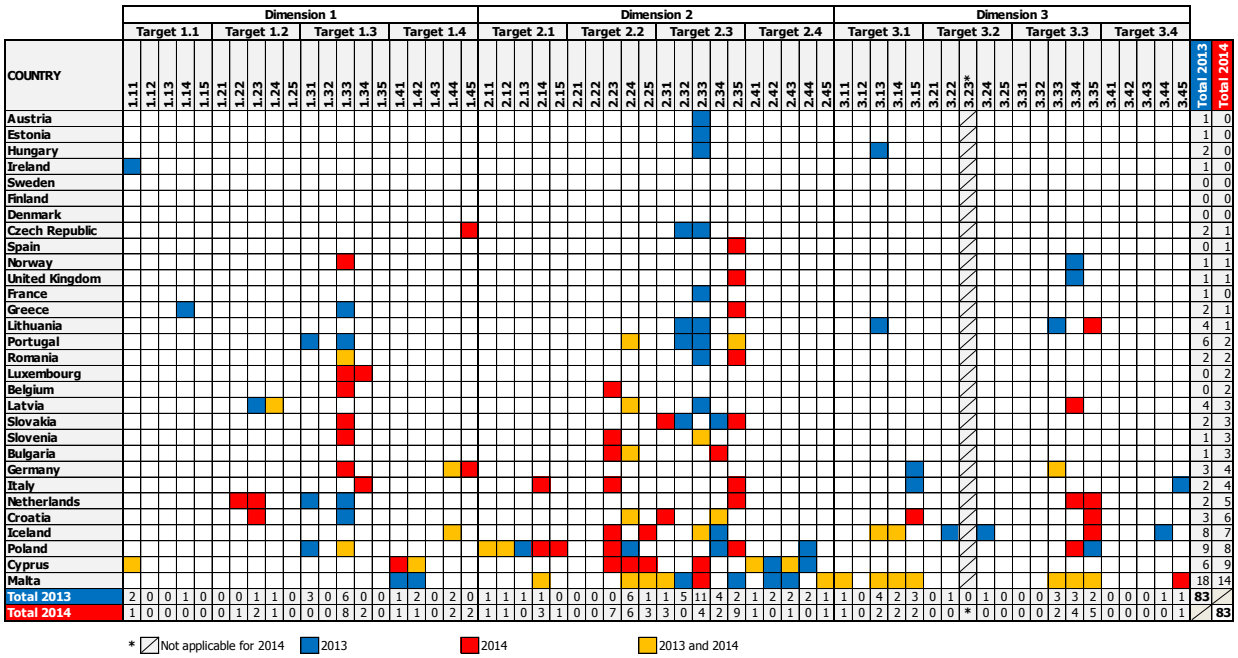
To obtain feedback on the usefulness of the previous EU and country EULabCap 2013 reports, an NMFP follow-up survey was performed in April 2016 on dissemination of these first reports and the use of findings for initiating corrective action at the national level, as well as on proposed areas for ECDC laboratory support activities [11]. This feedback was discussed at the joint NMFP-Advisory Forum meeting in May 2016 for developing new ECDC actions to be elaborated as part of its Country Support Strategy [9].

Results

Response rate and data completeness

The country response to the survey was 100% (30/30 countries), with 2014 data provided for 95% of the indicators (1 687 out of 1 770 data points), ranging from 78–100% data completeness by country and from 76–100% by indicator (Figure 2). Note that the denominator for the completeness calculation in the 2014 survey was 59 indicators, as one indicator (3.23) was not applicable.

Figure 2. Indicator completeness and distribution of missing data by country (sorted by descending order of completeness in 2014)



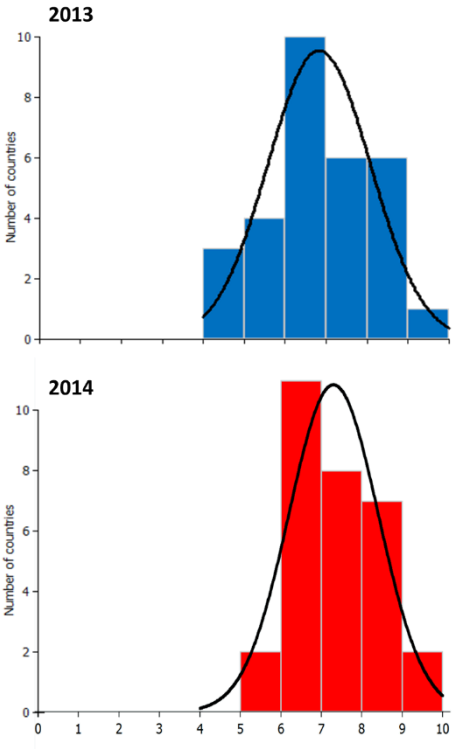
Note: Blue cells correspond to missing data (NA answers) in 2013 only, red cells in 2014 only and orange cells in both years. Indicator 3.23 (shaded cells) was not included in the 2014 data.

Overall, there was no improvement in data completeness, with 83 data points missing both in the 2014 survey and the 2013 survey. No major change was observed in the reporting by country. Seven indicators had missing data from more than three countries in 2014 (Figure 3). Those indicators were, in order of increasing completeness, 2.35, 1.33, 2.23, 2.24, 3.35, 2.33 and 3.34. Between the surveys, the data reporting improved for a few indicators (2.32 and 2.33) and worsened for others (2.23, 2.35 and 3.35). This may have been partly related to the new requirement to submit raw 2014 data for centralised scoring of indicators 1.33 and 2.35.

Laboratory capabilities and capacities at EU/EEA level

The overall EULabCap aggregated index score in 2014 was 7.3 on a scale of 1–10 (compared to 6.9 in 2013). As in 2013, the distribution of EULabCap index country scores in 2014 showed a substantial inter-country variation with unimodal distribution of scores ranging from 5.0 to 9.5. (Figure 3). Compared to 2013, the index distribution by countries narrowed somewhat in 2014, indicating less overall heterogeneity of capabilities across countries.

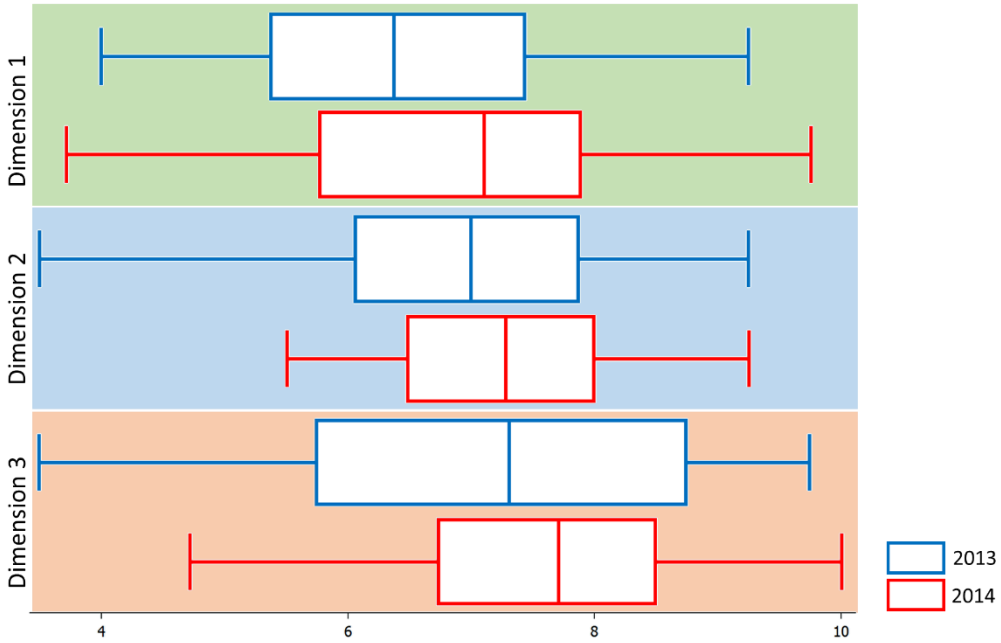
Figure 3. Distribution of overall EULabCap index country scores (N=30 EU/EEA countries), 2013 and 2014



In 2014, the index scores showed different distributions across dimensions, with a median index of 7.0 (IQR 6.0-7.8) for primary diagnostic testing, 7.3 (IQR, 6.5–8.0) for NRL services and 7.6 (IQR, 6.7–8.4) for laboratory-based surveillance and epidemic response support (Figure 4).

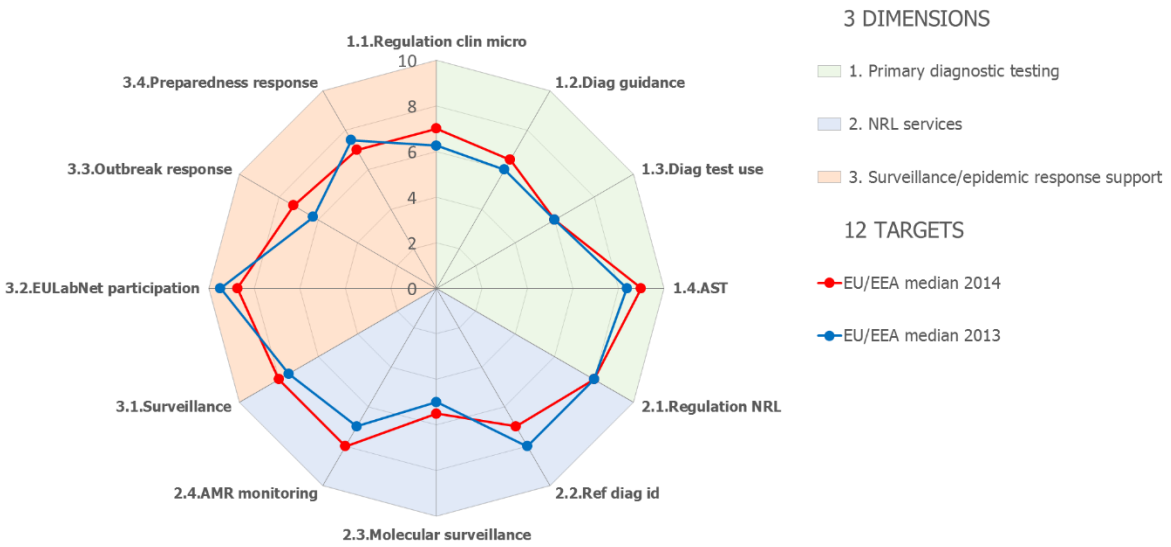
In comparison to 2013, the EU/EEA median index scores per dimension increased in all three dimensions, with the biggest increase noted in the dimension of primary diagnostic testing (Figure 4). The IQR narrowed in the indices for national reference laboratory services and laboratory-based surveillance and epidemic response support in 2014 compared with the 2013 baseline, indicating less heterogeneity across country for these system dimensions.

Figure 4. Boxplot of the EULabCap index scores by dimension (N=30 countries), 2013 compared with 2014



The comparison of the EU/EEA median for EULabCap index scores by target and dimension of the public health microbiology system for 2013 and 2014 is shown in Figure 5.

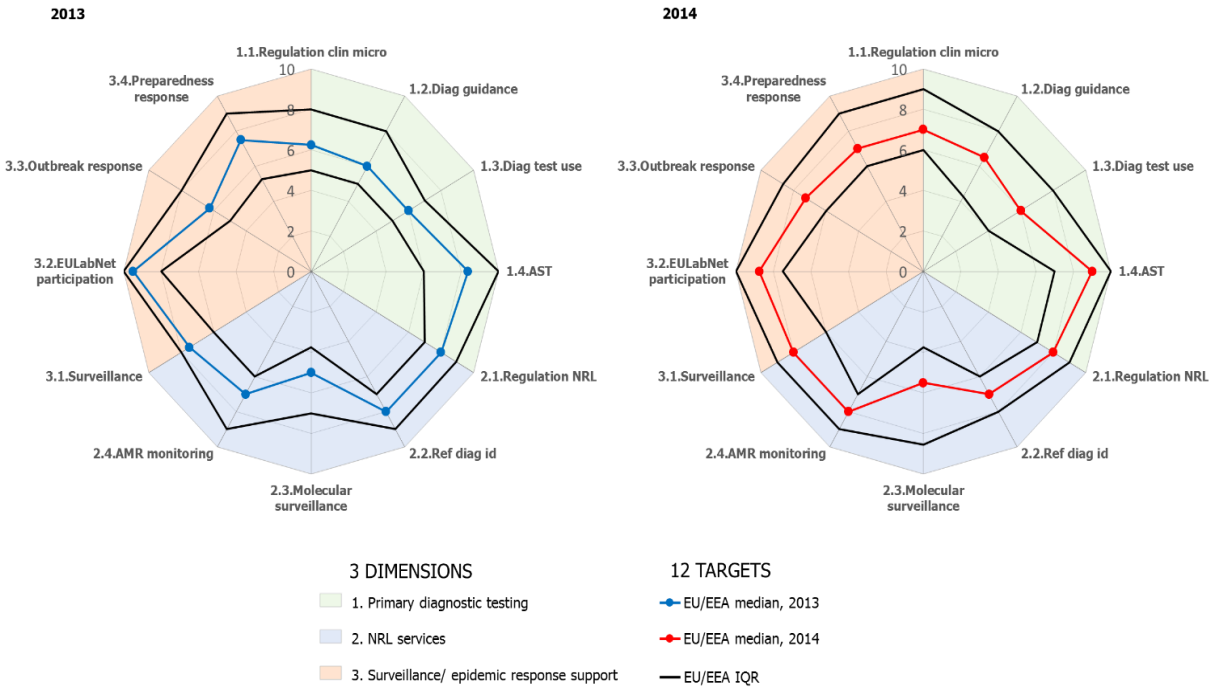
Figure 5. Distribution of median EULabCap index scores by target (N=30 EU/EEA countries), 2013 and 2014



Results in 2014 were largely consistent with the 2013 data (Figure 5). There were just a few differences between the two surveys in the median index score per target. An increase was observed in 2014 for eight targets dispersed across dimensions, with larger increases noted in Target 1.1 'Regulation of clinical microbiology services' and 3.3 'Laboratory support to outbreak response'. The median score decreased for three targets: Target 2.2 'Reference diagnostic confirmation and pathogen identification', Target 3.2 'Active participation in EU/EEA disease networks' and Target 3.4 '(Re)-emerging diseases laboratory preparedness and response support'.

The distribution of the EU median and interquartile range for EULabCap index scores by target and dimension of the public health microbiology system in 2013 and in 2014 is shown in Figure 6.

Figure 6. Distribution (median and inter-quartile range) of country EULabCap index scores by target (N=30 EU/EEA countries), comparison 2013 and 2014

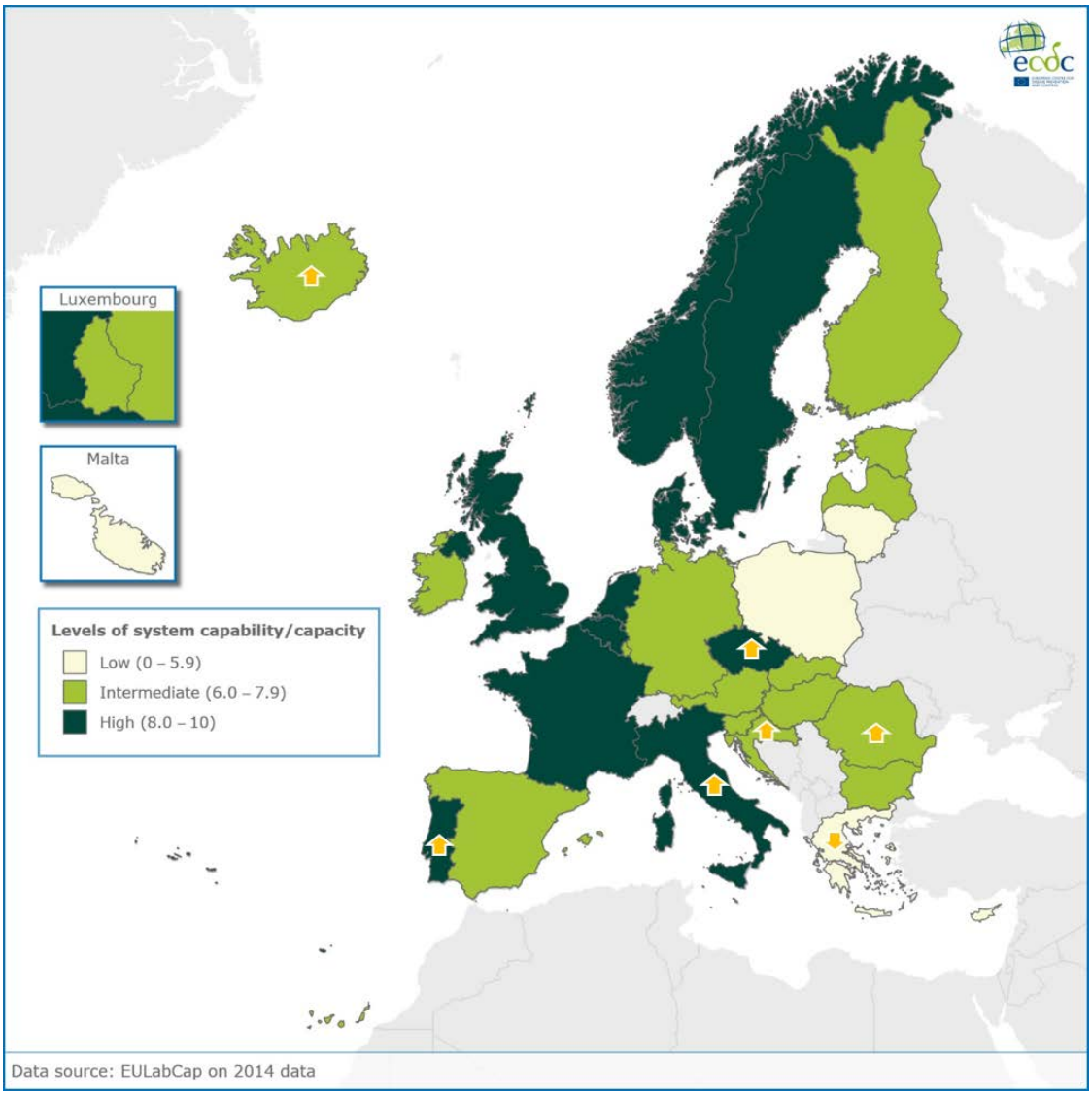


When the summary distributions (IQR) of the country indices per target across the EU/EEA were compared for 2013 and 2014, a widening IQR in 2014 was observed the following four Targets 1.2, 1.3, 2.3, 3.1, suggesting an increasing heterogeneity between countries for these capability targets.

Laboratory capabilities and capacities at country level

The EULabCap index showed substantial inter-county variation in 2014, with country scores ranging from 5.0 to 9.5. The map in Figure 7 shows the geographical distribution by country based on three capability and capacity performance levels (low, intermediate and high) and highlights countries displaying a level upgrade from 2013 to 2014 with an arrow. The geographical distribution of each target performance by country is shown in additional maps in Annex 4.

Figure 7. Level of public health microbiology system capabilities and capacities by country (N=30 EU/EEA countries, EULabCap Index 2014)

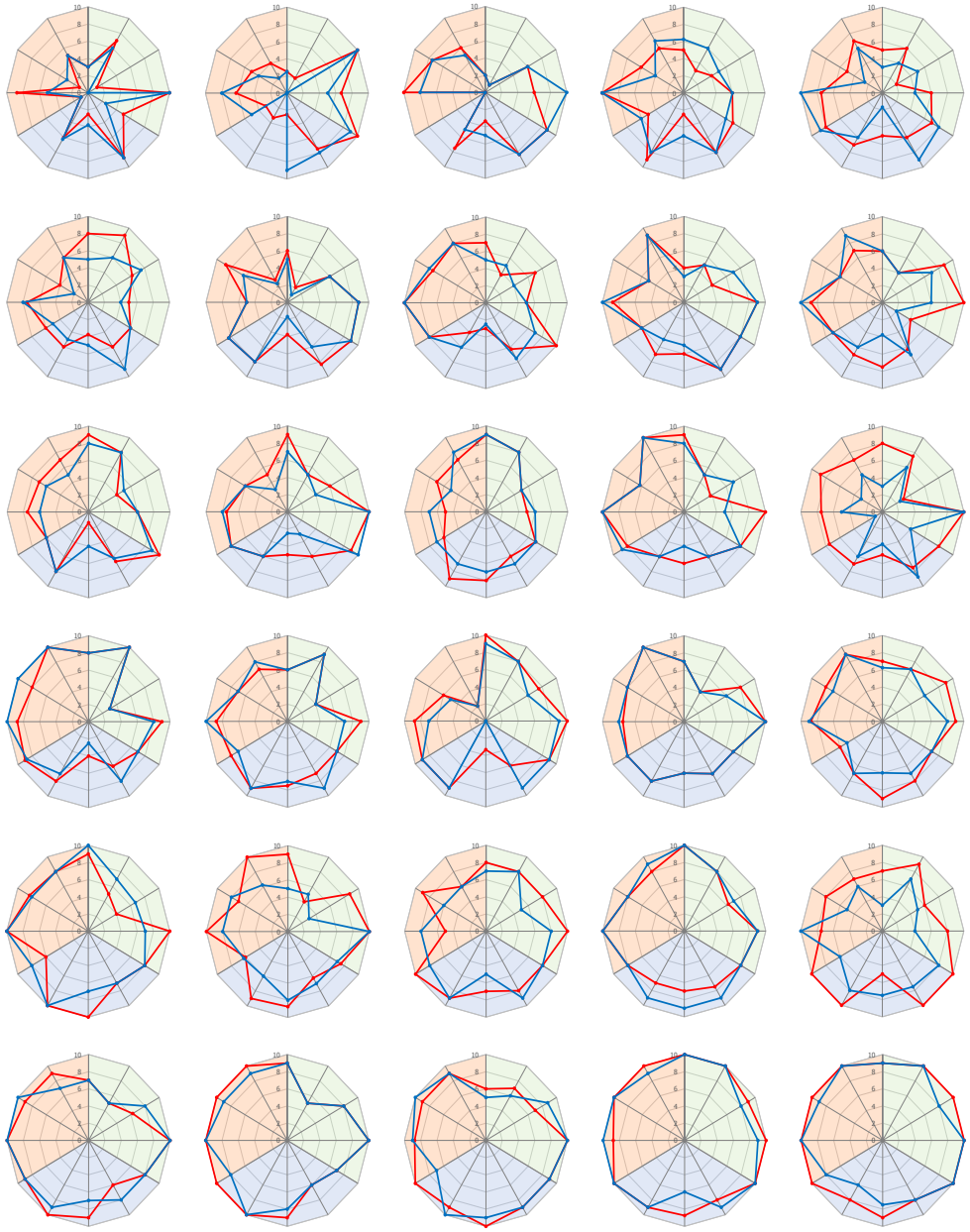


Note: Arrows indicate a transition to a higher or lower level in 2014 than in 2013.

It is interesting to note that a total of six countries (Croatia, Czech Republic, Iceland, Italy, Portugal and Romania) shifted to a higher level of system capability and capacity between surveys, while one country (Greece) shifted from intermediate to low level (Figure 7).

In addition to the variation in the EULabCap overall country scores, there was substantial variation within each country in the target index scores distribution as shown in the individual radar graphs (Figure 8), displaying the shape linking target index scores (capacity perimeter) for each EU/EEA country, by comparing 2013 and 2014. There is a noticeable imbalance in the performance scores achieved across targets in a number of countries. In addition, there were major changes in the radar shape for some countries.

Figure 8. Radar graphs of EULabCap target index scores for each country, ranked in ascending order of total index country score 2014 from top left to bottom right, showing 2014 indices (red line), compared with 2013 (blue line), N=30 EU/EEA countries



As in 2013, there is a noticeable imbalance in the performance scores achieved across targets in a number of countries in 2014. A comparison of the results by year shows very consistent geometry of the capacity perimeter in the majority of countries, with some notable exceptions. In a few countries, there are major changes in the radar shape, displaying either a multi-target expansion of capacities (three countries in the intermediate/high level) or a marked fluctuation over time in their strong/weak targets (two countries in the lower level).

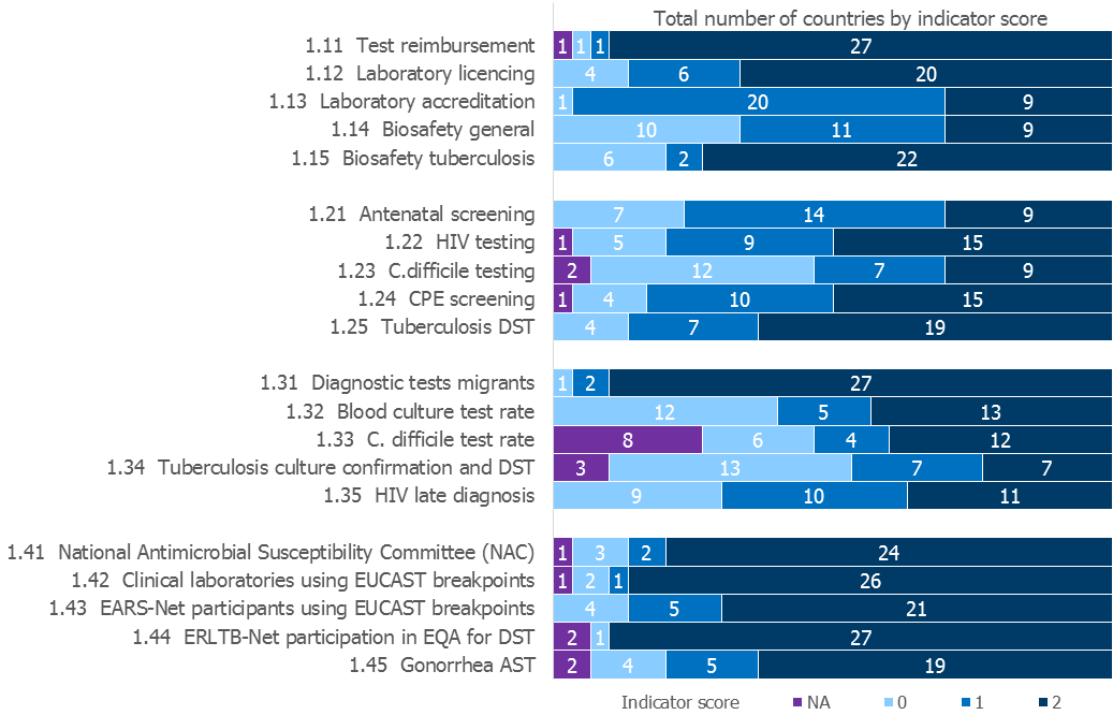
Indicator score distribution by dimension, target and country, 2013-14

A more detailed analysis of the 2014 country distribution of scores per indicator, broken down by system dimension – primary diagnostic testing, NRL services, and surveillance/epidemic response support – is presented in Figures 9 – 11). Results indicate the specific technical areas of EU/EEA strengths and weaknesses. Moreover, for each dimension the 2014 results are compared to the previous EULabCap report (2013 data) to explore possible early trends.

Primary diagnostic testing - 2014

In 2014, primary diagnostics indicators with generally low capability/capacity scores across the EU/EEA were the same as in 2013 and concerned quality accreditation of laboratories, biosafety regulation, and guidance on and usage of diagnostic testing.

Figure 9. EU distribution of scoring results by country for the 20 EULabCap indicators on primary diagnostic testing, 2014



Similarly, areas in which there is a high level of capability/capacity in the majority of EU/EEA countries in 2014 included antimicrobial susceptibility testing and diagnostic testing accessibility. It is interesting to note that in 2014 90% of countries publicly funded or reimbursed clinical microbiology tests and offered testing for HIV infection and tuberculosis to undocumented migrants.

Primary diagnostic testing – comparison to 2013

The comparison of the EU mean scores for 2013 and 2014 within the dimension of primary diagnostic testing by target and indicator is shown in Table 3.

Table 3. Comparison of EU mean scores for 2013 and 2014 by primary diagnostic testing target and indicator

Dimension 1	EU mean 2013	EU mean 2014
Target 1.1 Provision and regulation of clinical microbiology services	**6.3**	**7.2**
1.11 Test reimbursement	9.1	9.5
1.12 Laboratory licencing	5.7	7.7
1.13 Laboratory accreditation	6.0	6.3
1.14 Biosafety general	4.5	4.8
1.15 Biosafety tuberculosis	6.2	7.7
Target 1.2 Diagnostic testing guidelines	**6.0**	**6.2**
1.21 Antenatal screening	5.5	5.3
1.22 HIV testing	6.7	6.7
1.23 *C. difficile* testing	3.8	4.5
1.24 CPE screening	6.4	6.9
1.25 Tuberculosis DST	7.5	7.5
Target 1.3 Diagnostic testing utilisation	**5.9**	**6.0**
1.31 Diagnostic tests migrants	9.6	9.3
1.32 Blood culture test rate	6.2	5.2
1.33 *C. difficile* test rate	4.6	6.4
1.34 Tuberculosis culture confirmation and DST	3.7	3.9
1.35 HIV late diagnosis	5.3	5.3
Target 1.4 Antimicrobial drug susceptibility testing	**7.8**	**8.6**
1.41 National Antimicrobial Susceptibility Committee (NAC)	8.1	8.6
1.42 Clinical laboratories using EUCAST breakpoints	7.7	9.1
1.43 EARS-Net participants using EUCAST breakpoints	6.0	7.8
1.44 ERLTB-Net participation in EQA for DST	9.6	9.6
1.45 Gonorrhoea AST	7.7	7.7

The mean EU index increased between 2013 and 2014 for several primary diagnostic indicators (Table 3), including those on medical laboratory licensing, biosafety for tuberculosis diagnostics, *Clostridium difficile* testing guidance and utilisation, and EUCAST breakpoint use.

More detailed analysis of these changes showed that the number of countries requiring clinical microbiology laboratories to obtain a licencing authorisation/registration from health authorities increased from 14 countries in 2013 to 20 countries in 2014.

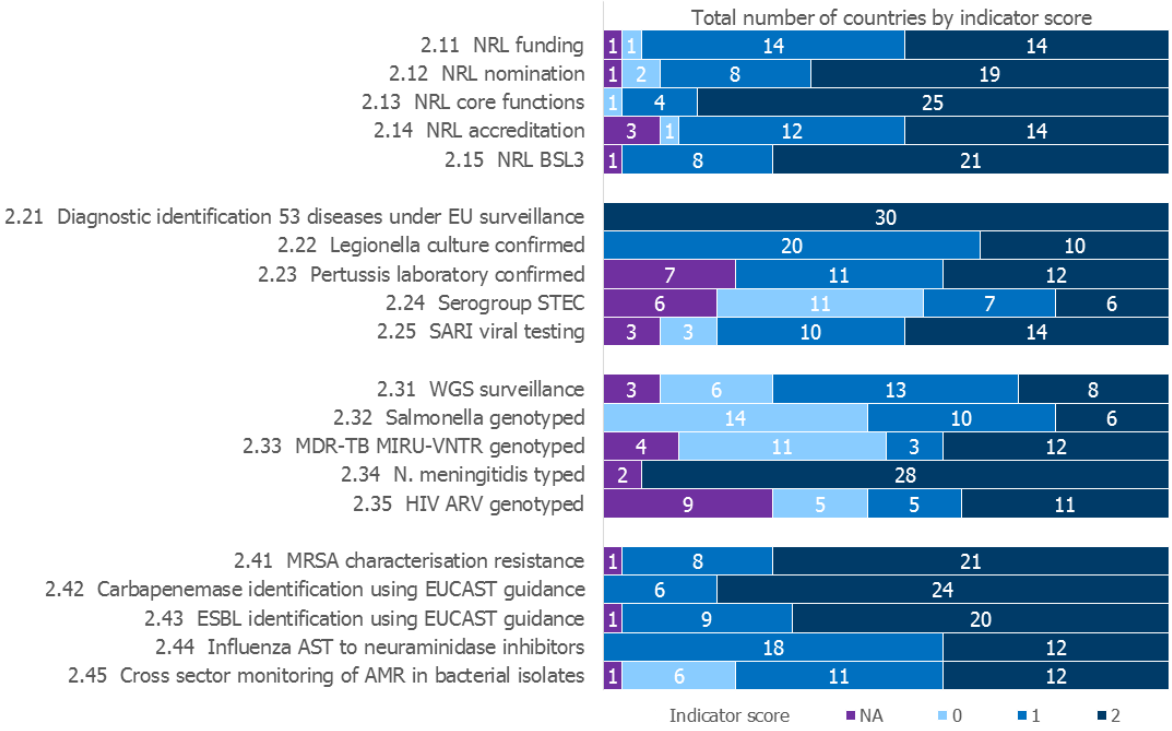
The EU average utilisation rate of *C. difficile* diagnostic testing in hospital care increased from 4.6 to 6.2 tests/1 000 patient-days between 2013 and 2014.

Two more countries demonstrated progress with standardisation of antibiotic susceptibility testing, having established a National Antimicrobial Susceptibility Committee (NAC) in 2014, and there was an increase in the number of clinical laboratories using EUCAST breakpoints, from 19 countries in 2013 to 26 in 2014.

National Reference Laboratory services - 2014

Figure 10 displays the distribution of countries' scores for the 20 National Reference Laboratory services indicators.

Figure 10. EU distribution of scoring results by country for the 20 EULabCap indicators on National Reference Laboratory services, 2014



Indicators regarding the national reference microbiology services for diagnostic confirmation, pathogen identification and antimicrobial drug resistance monitoring (Targets 2.1, 2.2 and 2.4) obtained intermediate or high scores, whereas indicators of molecular typing use for national or EU level surveillance (Target 2.3) in general scored lower.

All 30 EU/EEA countries reported in-country capability for case confirmation and pathogen identification for more than 35 of the 53 EU-notifiable communicable diseases according to the EU case definitions (Indicator 2.21) [12]. Confirmation capability was reported by all EU/EEA countries for 28 high-priority and/or epidemic-prone diseases (e.g. influenza, tuberculosis and listeriosis) (Table 4). For rare diseases or agents which require specialised testing facilities, materials, and know-how (e.g. rabies, yellow fever, or smallpox) domestic identification capability was available in only some countries. Countries lacking national capabilities for such diseases all reported that they had a technical cooperation agreement with other countries to outsource testing.

Table 4. Number of EU/EEA countries reporting diagnostic confirmation and pathogen identification testing available within the country for the 53 diseases/health issues listed in Decision 2119/98/EC, in accordance with the EU surveillance case definitions of the Community Network [12], 2014

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 cholera*)	
GIARDIASIS (*Giardia lamblia*)	
HAEMOPHILUS INFLUENZAE INVASIVE DISEASE (*Haemophilus influenza*)	
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 pneumonia)*	
RUBELLA (Rubivirus)	
SALMONELLOSIS (*Salmonella* spp. other than *Salmonella* Typhi and *Salmonella* Paratyphi	
SHIGELLOSIS (*Shigella* spp.)	
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, Yersinia pseudotuberculosis)*	
BRUCELLOSIS (*Brucella* spp.)	29
CHLAMYDIAL INFECTION (*Chlamydia trachomatis*) INCLUDING LYMPHOGRANULOMA VENEREUM (LGV)	
CRYPTOSPORIDIOSIS (*Cryptosporidium* spp.)	
DIPHTHERIA (*Corynebacterium diphtheria*, *C. ulcerans* and *C. pseudotuberculosis*)	
MUMPS (Mumps virus)	
RUBELLA, CONGENITAL (including Congenital Rubella Syndrome)	
Shiga toxin/verotoxin-producing *Escherichia coli* INFECTION (STEC/VTEC)	
ANTHRAX (*Bacillus anthracis)*	28
ECHINOCOCCOSIS (*Echinococcus* spp.)	
LEPTOSPIROSIS (*Leptospira* spp.)	
TULARAEMIA (*Francisella tularensis*)	
PLAGUE (*Yersinia pestis*)	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.)	
BOTULISM (*Clostridium botulinum*)	26
POLIOMYELITIS (Polio virus)	
VIRAL HAEMORRHAGIC FEVERS (VHF)	
WEST NILE FEVER (West Nile virus infection, WNV)	
RABIES (Lyssavirus)	24
YELLOW FEVER (Yellow fever virus)	22
CREUTZFELDT-JAKOB DISEASE, VARIANT (vCJD)	21
SMALLPOX (Variola virus)	17

The use of molecular typing characterisation of pathogens for surveillance (Target 2.3) indicated a low level of capability/capacity in many EU/EEA countries, as measured by the selected indicators. However, many of these indicators were based on TESSy reported data and therefore did not measure the national typing capacity but the capacity shared at EU surveillance level.

National Reference Laboratory (NRL) services – comparison to 2013

The comparison of the EU mean scores for 2013 and 2014 within the dimension of national reference laboratory services by target and indicator is shown in Table 5.

Table 5. Comparison of EU mean scores for 2013 and 2014 by NRL services target and indicator

Dimension 2	EU mean 2013	EU mean 2014
Target 2.1 Provision and regulation of NRL microbiology services	**7.6**	**8.1**
2.11 NRL funding	6.9	7.2
2.12 NRL nomination	7.9	7.9
2.13 NRL core functions	8.6	9.0
2.14 NRL accreditation	6.4	7.4
2.15 NRL BSL3	8.0	8.6
Target 2.2 Reference diagnostic confirmation and pathogen identification	**7.7**	**7.2**
2.21 Diagnostic identification 53 diseases under EU surveillance	9.0	10.0
2.22 *Legionella* culture confirmed	6.8	6.7
2.23 Pertussis laboratory confirmed	9.7	7.6
2.24 Serogroup STEC	5.4	4.0
2.25 SARI viral testing	7.1	7.0
Target 2.3 Molecular typing for surveillance	**5.6**	**6.1**
2.31 WGS surveillance	3.3	5.4
2.32 *Salmonella* genotyped	5.2	3.7
2.33 MDR-TB MIRU-VNTR genotyped	8.9	5.2
2.34 *N. meningitidis* typed	3.8	10.0
2.35 HIV ART genotyped	7.5	6.4
Target 2.4 Antimicrobial drug resistance characterisation and monitoring	**7.4**	**7.8**
2.41 MRSA characterisation resistance	8.1	8.6
2.42 Carbapenemase identification using EUCAST guidance	9.1	9.0
2.43 ESBL identification using EUCAST guidance	8.0	8.4
2.44 Influenza AST to neuraminidase inhibitors	6.4	7.0
2.45 Cross-sector monitoring of AMR in human and animal bacterial isolates	5.3	6.0

Between 2013 and 2014, the EU mean index increased for several NRL service indicators including those on provision and regulation of services, diagnostic confirmation capabilities for EU notifiable diseases and application of whole genome sequencing to national surveillance (Table 5).

The number of countries with NRLs fulfilling all core public health functions defined by the NMFPs increased from 21 in 2013 to 25 in 2014. Full NRL access to biosafety level 3 facilities increased from 18 countries in 2013 to 21 in 2014 (Figure 10). More countries also required quality accreditation for all their NRLs in 2014.

Diagnostic confirmation capabilities for more than 35 of the 53 EU notifiable diseases increased from 27 to 30 countries between 2013 and 2014. A decrease was noted in the indicator for capacity to confirm pertussis cases by culture or PCR (Table 5). The number of countries that reported more than ten percent of their cases being confirmed by culture or PCR decreased from 28 (in 2013) to 12 (in 2014). This drop was mostly due to fewer countries reporting the case confirmation method used in 2014 TESSy notified cases.

In the challenging area of molecular typing for surveillance, some indicator scores increased while others decreased between years (Table 5). The most remarkable change is that eight EU/EEA countries reported that they had introduced and used whole genome sequencing-based typing for the routine surveillance of at least one human pathogen in 2014, compared to none in 2013. In 2014, an additional 13 countries had plans to progress with the use of whole genome sequencing-based typing for surveillance. In contrast, decreasing scores were noted for indicators on use of conventional typing methods. For instance, the number of countries that reported *Salmonella* isolates genotyping data (by PFGE or MLVA) method to TESSy decreased from 19 (in 2013) to 16 (in 2014). Similarly, even though more countries reported genotyping data (by MIRU VNTR method) to TESSy in 2014 than in 2013, the percentage of multidrug-resistant *Mycobacterium tuberculosis* isolates genotyped by country decreased, leading to a lower EU average score for Indicator 2.33 in 2014.

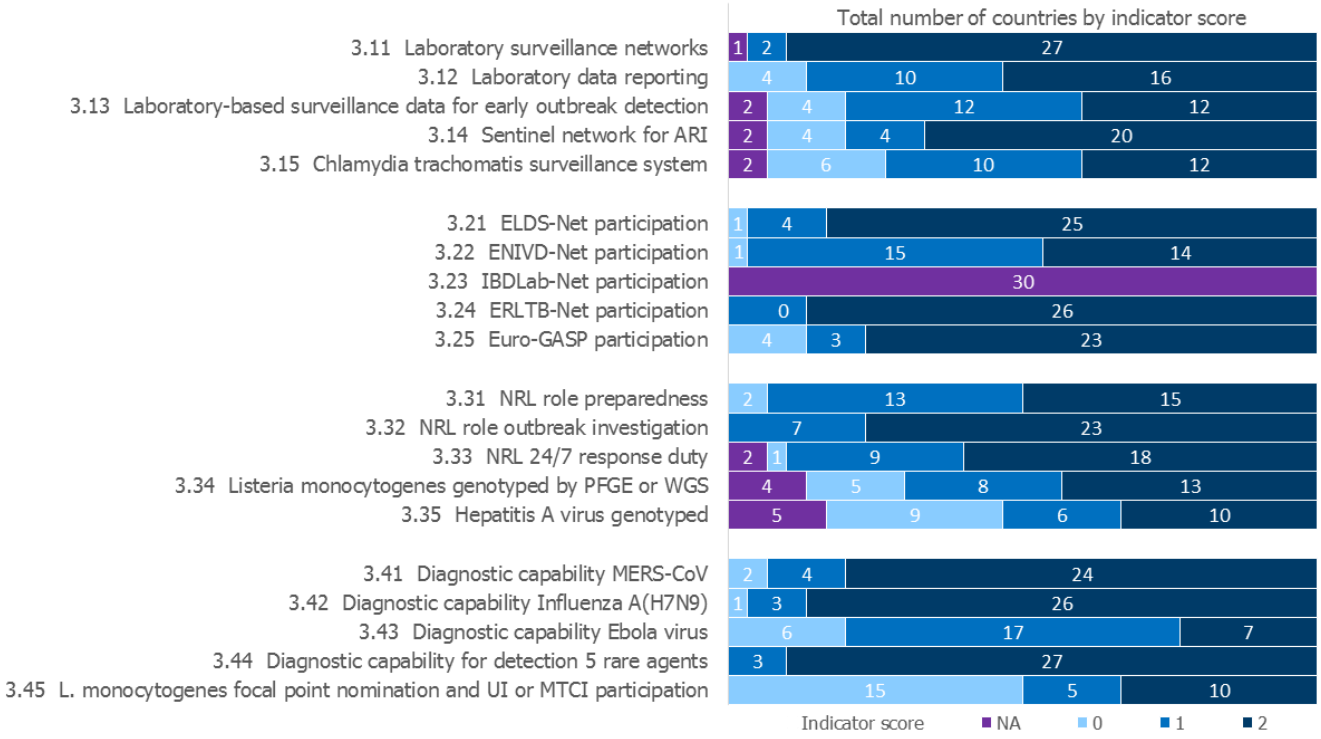
Several typing indicator score changes are likely to be artefacts related to modification of the data collection method or score calculation rule between surveys. For instance, Indicator 2.35 on proportion of new HIV case samples genotyped in 2014 is based on the absolute test numbers provided by the countries but was self-reported in 2013. The observed decrease in the EU score may be due to the fact that 30% of the countries were unable to provide raw data in 2014 (Table 5). Conversely, Indicator 2.34 on fraction of *Neisseria meningitidis* isolates genotyped was revised in 2014 to include partial genotype reporting (i.e. reporting only *fetA* and *porA* sequence type, or MLST type, instead of both) as

equivalent to reporting the full scheme type, required in 2013. With this less stringent scoring rule, the EU average indicator score drastically increased from 3.8 to 10 (Table 5).

Laboratory-based surveillance and epidemic response support – 2014

Figure 11 indicates the distribution of countries' scores and the EU/EEA mean score for the 20 surveillance/ epidemic response support dimension indicators.

Figure 11. EU distribution of scoring results by country for the 20 EULabCap indicators on surveillance/epidemic response support, 2014



Note: Indicator 3.23 (IBDLab-Net participation) was not applicable (NA) due to interruption of activities in 2014.

Overall, indicators of laboratory support to national surveillance networks, national outbreak response support, and preparedness and response for (re-)emerging diseases showed an intermediate-to-high level of capability/capacity performance in 2014, as was also reported for 2013. Target 3.2 'Active participation in EU disease networks' showed a high performance overall with an EU/EEA mean score of 8.4. Strong performance scores were reported by the majority of countries for the operation of national sentinel surveillance networks. It is interesting to note that 90% of EU/EEA countries had collaboration in place between reference laboratories and national networks of clinical laboratories for more than five rare diseases under surveillance. However, 16 countries reported low scores for automation of microbiology data reporting to national surveillance databases. Laboratory expert support to national outbreak response was limited in some countries and laboratory data were used in only 12 countries for early warning and outbreak detection. Capacity indicators for cluster detection based on molecular typing for listeriosis and hepatitis A scored low in many countries. Only 18 countries had a 24/7 NRL response support duty in place, and 15 countries reported that NRLs had defined roles and responsibilities in national preparedness plans for health threats that had been tested in simulation exercises. Laboratory-based surveillance and epidemic response support – comparison to 2013.

The comparison of the EU mean scores for 2013 and 2014 within the dimension of laboratory-based surveillance and epidemic response support by target and indicator is shown in Table 6.

Table 6. Comparison of EU mean scores for 2013 and 2014 by surveillance and response support target and indicator

Dimension 3	EU mean 2013	EU mean 2014
Target 3.1 Support to national surveillance networks	**6.9**	**7.4**
3.11 Laboratory surveillance networks	9.3	9.7
3.12 Laboratory data reporting	6.8	7.0
3.13 Laboratory-based surveillance data for early outbreak detection	5.4	6.4
3.14 Sentinel network for ARI	7.5	7.9
3.15 *Chlamydia trachomatis* surveillance system	5.0	6.1
Target 3.2 Active participation in EU/EEA disease networks	**8.7**	**8.4**
3.21 ELDS-Net participation	9.7	9.0
3.22 ENIVD-Net participation	8.8	7.2
3.23 IBDLab-Net participation	8.0	0.0
3.24 ERLTB-Net participation	10.0	9.3
3.25 Euro-GASP participation	7.0	8.2
Target 3.3 National outbreak response support	**6.4**	**7.2**
3.31 NRL role preparedness	6.3	7.2
3.32 NRL role outbreak investigation	7.7	8.8
3.33 NRL 24/7 response duty	8.1	8.0
3.34 *Listeria monocytogenes* genotyped by PFGE or WGS	5.0	6.5
3.35 Hepatitis A virus genotyped	5.0	5.2
Target 3.4 (Re)-emerging diseases laboratory preparedness and response support	**7.0**	**7.3**
3.41 Diagnostic capability MERS-CoV	8.0	8.7
3.42 Diagnostic capability influenza A(H7N9)	9.0	9.2
3.43 Diagnostic capability Ebola virus	5.0	5.2
3.44 Diagnostic capability for detection of five rare agents	8.6	9.5
3.45 *Listeria monocytogenes* focal point nomination and UI or MTCI participation	4.3	4.2

A substantial increase in the mean EU index was observed between 2013 and 2014, with several important surveillance and response support indicators, including those on laboratory-based outbreak detection, chlamydia surveillance, NRL contribution to outbreak investigations and diagnostic capability for emerging pathogens (Table 6).

Improvements were noticeable in the timely analysis of laboratory data for early warning and outbreak detection, as reported by 12 countries in 2014, compared to seven in 2013. NRL contribution to outbreak investigations and testing of preparedness plans increased from 17 countries in 2013 to 23 in 2014 (Figure 11).

Although in 2014 indicators showed strong NRL participation in EU disease laboratory networks, country participation in the tuberculosis network (ERLTB-Net), the *Legionella* network (ELDS-Net), and in the network for imported and emerging viral diseases (ENIVD-Net) decreased slightly compared to 2013. Due to temporary interruption of some intended activities by the Invasive Bacterial Disease Network (IBD-LabNet) in 2014, participation could not be assessed and therefore this indicator was 'not applicable' for all countries.

Discussion

The EULabCap is the first initiative to measure and monitor over time the broad spectrum of microbiology laboratory capabilities and capacities required at EU- and country-level to underpin effective communicable disease surveillance and epidemic preparedness. The consensus development and use of a new indicator framework applying a common terminology and taxonomy of public health microbiology services are pivotal to its success. The remarkable 100% country response and 95% complete reporting of 2014 indicators data illustrate the continuing commitment of the NMFPs to this monitoring process.

The results of this second survey add to the evidence that, with an average EULabCap index score of 7.3 on a scale of 0–10 in 2014, compared with 6.9 in the first survey of 2013 system outputs, the EU/EEA as a whole has a strong public health microbiology system, with substantial capacity to collectively fulfil communicable disease surveillance and response requirements. Strengths and weaknesses of the EU/EEA system were consistent between surveys. The areas of strong capacity and capability, with high levels of performance across the EU/EEA in both years, included primary antimicrobial drug susceptibility testing and resistance monitoring, technical capabilities of the national reference laboratory services and laboratory collaboration within national and EU surveillance networks. Those targets which appeared to be most challenging, where many countries showed limited provision of critical capabilities and/or low capacity in both surveys, concerned guidance and utilisation of primary diagnostic services as well as use of molecular typing for national and EU surveillance.

The EULabCap survey methodology and data have several limitations. Firstly, the country relevance of some indicators is limited, such as those that measure information sharing within a national reference laboratory network and apply mainly to larger countries. Similarly, capacity indicators for laboratory-confirmed cases do not apply in small countries due to low disease incidence. Secondly, about two-thirds of the indicators are of a self-reporting nature and thus liable to subjective interpretation. External validation, for example by means of EQA and simulation exercise, would be helpful to address this limitation [13-16]. Thirdly, data access was not universal and some NMFPs were not able to provide data for all indicators. Explanations for the missing data included: no active data collection instrument in place, lack of designated NRLs, outsourcing of reference services to other countries, and NMFP time constraints. As 'not available/not applicable' data were not included in the score calculation by target, this ascertainment bias may have led to an under- or over-estimation of country system performance. Finally, the availability of only two annual datasets; the classification bias due to minor modifications of indicators/scoring criteria, and the fact that the respondents have had to familiarise themselves with questionnaire administration as they have gone along, have limited the possibility to infer temporal trends. Future surveys should provide more robust information for trend analysis.

The two-fold variation in EULabCap index results by country in 2013 and 2014 indicates some degree of inequality in the public health microbiology system capacity across the EU/EEA. While a possible reduction in this disparity is suggested by the six countries that upgraded their performance level in 2014 from the previous year, it is too early to draw any conclusions on secular trends in EU microbiology capacity with only two annual data sets.

The EU median EULabCap index by dimension indicated that the lowest scores in 2013 were in the primary testing dimension, reflecting gaps in clinical laboratory service provision and regulation within national healthcare systems. It is thus encouraging to note that this parameter substantially increased in 2014. Specific improvements in primary testing included licencing of clinical microbiology laboratories, test reimbursement, biosafety for tuberculosis diagnostics, *Clostridium difficile* testing, and use of EUCAST breakpoints for antibiotic susceptibility testing.

The EU median index for the dimension of laboratory-based surveillance and epidemic response support also increased in 2014. Specific improvements were noted with laboratory-based data analysis for early outbreak detection, *Chlamydia trachomatis* surveillance, NRL contribution to outbreak investigations and diagnostic capability for emerging pathogens. Regarding molecular typing, low scores were expected for indicators on typing capacity in 2013 and 2014 as they reflect the early steps towards integration of molecular typing data into EU surveillance, as piloted by voluntary reporting during this period. Moreover, despite minor adjustments to the classification criteria in the second survey, indicators of typing coverage remain challenging to measure as technology is in rapid flux. Looking to new developments, it is noteworthy that in eight of the 19 EU/EEA countries that were planning to use whole genome sequencing (WGS) in 2013, the technology was already being applied to disease surveillance in 2014. This spectacular technology shift will require careful capacity monitoring and close collaboration with Member States to foster a smooth transition and comparability of surveillance data along the ECDC strategy on public health applications of WGS [17].

The improved capacity in antimicrobial drug susceptibility testing reflects wider implementation of the harmonised susceptibility breakpoints established by the European Committee on Antimicrobial Susceptibility Testing (EUCAST) in collaboration with National Antimicrobial Susceptibility Committees (NACs). There was significant further progress in 2014, with the vast majority of EU/EEA countries using EUCAST clinical breakpoints. This standard practice permits a better comparison of antimicrobial resistance data collected across the EU/EEA, in accordance with EU case definition. These achievements are in line with the EU- and global-policy focus on combating antimicrobial resistance and harmonising clinical practice across Europe through professional leadership [18,19].

The EULabCap index for the NRL services dimension showed good overall capacity, with the lowest inter-country variance of all system dimensions further decreasing over the two survey years. Future surveys will be able to confirm whether this indicates convergence of national public health practices after decades of collaboration across the EU. Areas of potential improvement include sustainability and quality assurance, with only half of the EU/EEA countries reporting accreditation and public funding of all their NRL services in 2014. Indicators scored better in 2014 for NRL delivery of core public health functions, access to biosafety level 3 facilities, service accreditation, range of confirmation capabilities for EU notifiable diseases and, as mentioned above, application of WGS to national surveillance.

In 2014, all countries declared having access to the range of specific agent diagnostic capabilities required to meet EU surveillance reporting obligations. 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 declared having a strong capacity for diagnosis and characterisation of emerging agents, such as avian influenza virus H7N9, MERS-CoV, Ebola virus and rare and/or imported viruses. This observation is consistent with the results of dedicated activities in the field of preparedness and response in Europe. Since diagnostic capability for other (re-)emerging infectious diseases (e.g. Zika virus, Lyme disease, new strains of multidrug-resistant bacteria) is not captured by the EULabCap, if a public health event is caused by a new agent, ad hoc surveys should be undertaken within EU networks to rapidly appraise the detection capacity in EU/EEA countries to underpin surveillance [15].

Strong scores were reported by a majority of countries in both years for indicators of national sentinel laboratory-based surveillance networks and EU laboratory network participation. However, many countries reported low or medium scores for indicators of rapid microbiology data analysis, reporting and cluster detection capability. This finding indicates that by 2014 there were still untapped opportunities for IT solutions to facilitate laboratory-based surveillance and alert systems within and across EU/EEA countries. The high level of NRL participation in ECDC disease-specific laboratory networks builds on a legacy of longstanding EU support for collaboration between laboratory scientists and public health specialists in Europe. It will be important to further assess the public health added-value of these networks and address the issue of sustainable long-term operational support.

Regarding the impact of EULabCap on the policy agenda in the Member States, the questionnaire survey on use of EULabCap 2013 reports in 2015-16 was completed by 25/30 NMFPs. Of these, 23 had found the reports useful and actively disseminated them to national stakeholders; 17 used the findings to initiate follow-up actions covering 14 technical areas, with the top five actions addressing quality and biosafety regulation of microbiology laboratories, service accreditation, NRL regulation and NRL resources allocation [11].

Conclusions

The results of the second EULabCap annual survey confirmed that the EU/EEA as a whole, with an aggregated index score of 7.3 out of 10 for 2014, as compared with 6.9 in 2013, can rely on a public health microbiology system with strong overall capability and substantial capacity to fulfil surveillance and response requirements.

Substantial inter-country variation in system capability and capacity index remains present across the EU/EEA in 2014. Even though preliminary evidence suggests a certain degree of convergence and improving country capability and capacity indices over time, future surveys will provide more robust information for trend analysis. With only two annual data sets available for comparison, together with minor modifications of a few indicators that limit comparability, it is too early to draw any firm conclusion on secular trends regarding overall EU microbiology capacity.

The main EU system strengths and weaknesses were broadly consistent between the surveys, with preliminary evidence of several specific improvements over the comparison period. The areas of best practice with consistently high levels of performance across the EU/EEA in both years, included primary antimicrobial drug susceptibility testing and antimicrobial resistance monitoring, technical capabilities of the national reference laboratory services and active laboratory collaboration within national and EU surveillance networks. The main challenge areas, with limited capabilities and/or low capacity, concerned guidance and utilisation of primary diagnostic services, use of molecular typing for national and EU surveillance, and laboratory support for national outbreak preparedness and response.

Preliminary evidence of improvement in 2014 over 2013 baseline data that cannot be explained by methodological modifications and requires confirmation in future surveys, was observed in the following areas:

- Primary diagnostics: medical test reimbursement, medical laboratory licensing, biosafety for tuberculosis diagnostics, *Clostridium difficile* testing guidance and utilisation, and EUCAST breakpoint use.
- NRL services: NRL core functions delivery, access to biosafety level 3 facilities, diagnostic confirmation capabilities for EU notifiable diseases and application of whole genome sequencing to national surveillance.
- Surveillance and outbreak support: laboratory-based outbreak detection, *Chlamydia trachomatis* surveillance, NRL contribution to outbreak investigations and diagnostic capability for emerging pathogens.

Next steps

The EULabCap annual monitoring aims to inform national competent bodies and policy-makers at the national and EU level. The feedback from the NMFPs showed that the first EULabCap reports were found to be useful and had been appropriately disseminated to national stakeholders in the majority of countries. Moreover, in over half of the countries a number of focus areas had been taken up for targeted capacity building actions.

The consultation held in May 2016 with the NMFPs and AF showed no major concern regarding the validity of the methods or the representativeness of the results. Suggestions to improve the timeliness and quality of EULabCap data by adjusting the collection, validation, analysis and reporting process and timelines were adopted for the upcoming 2015 data survey. Further fine tuning and updating of indicators will be minimised as necessary for reliable data retrieval and in agreement with new standards of practice. The EULabCap monitoring system will be made more operational by systematically collecting NMFP feedback on the use of the previous reports for action at national level, to analyse linkage between resource input and performance outputs in the EULabCap reports.

It was agreed that an action plan must now be developed and implemented to address findings of particular importance with regard to EU capacity to identify, monitor, assess and respond to infectious diseases, particularly those posing a significant cross-border threat. ECDC will prioritise its support activities to focus on challenging areas within its mandate, in collaboration with the EU/EEA countries, the European Commission and other European agencies and partners. The perspectives collected on new activities addressing generic laboratory capacity issues will be elaborated in 2016, in keeping with the ECDC Country Support Strategy [9]. Future surveys from 2017 onwards should help to evaluate the impact of national policies and EU support activities on system performance.

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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 = not available, 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 = not available, 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 = not available, 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 = not available, 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 = not available, 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 = not available, 0 = guidelines 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 testing and implementation is monitored within the country.	NMFP NA = not available, 0 = guidelines 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 = not available, 0 = guidelines 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 to screen hospitalised patients for carbapenem-non-susceptible/carbapenemase-producing *Enterobacteriaceae* and implementation is monitored within the country.	NMFP NA = not available, 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 = not available, 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 = not applicable, 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 inpatient days reported by EARS-Net participating hospitals from your country.	ECDC 0 = information not reported to EARS-Net, 1 = low blood culture test utilisation rate/1 000 patient days (first quartile), 2 = fair to high blood culture utilisation rate/1 000 patient days (upper three quartiles).
Indicator 1.33 *C. difficile* test rate Total number of *Clostridium difficile* diagnostic tests* performed/1000 hospital-inpatient 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.** NA = not available, 0 = not measured in the country, 1 = low diagnostic test utilisation rate/1000 patient days (first quartile); 2 = fair to high diagnostic test utilisation rate/1 000 patient days (upper three 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 NA = not available, 0 = <80% culture confirmed AND no DST, 1 = ≥80% culture confirmed BUT not 100% DST, 2 = ≥80% culture confirmed AND 100% DST.

Targets/Indicators	Source (NMFP/ECDC) and scoring options
Indicator 1.35 HIV late diagnosis Percentage of new HIV cases older than 14 years with initial CD4 counts (CD4<350 cells/µl - late diagnosis) reported.	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 TESSy, 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 is member of EUCAST General Committee.	ECDC NA = not available/not applicable, 0 = not established, 1 = NAC formation in process, 2 = NAC established.
Indicator 1.42 Clinical laboratories using EUCAST breakpoints Percentage of clinical laboratories that used EUCAST 2013 clinical breakpoints for interpretive reporting of antibacterial drug susceptibility testing results to clinicians. (Data as of August 2014).	ECDC NA = not available/not applicable, 0 = <10% clinical laboratories, 1 = 10-50% clinical laboratories, 2 = >50% clinical laboratories.
Indicator 1.43 EARS-Net participants using EUCAST breakpoints Percentage of clinical laboratories participating in EARS-Net that have used EUCAST 2013 clinical breakpoints for interpretive reporting of antibacterial drug susceptibility testing results to clinicians. (Data as of August 2014).	ECDC NA = not available/not applicable, 0 = <25% clinical laboratories, 1 = 25-75% clinical laboratories, 2 = >75% 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 2014 achieved 80% performance level for culture and susceptibility testing for first- and second-line drugs.	NMFP NA = not available/not applicable, 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 notified gonorrhoea cases.	NMFP NA = not available/not applicable, 0 = no surveillance of AMR at national level, 1 = <10% of notified cases, 2 = ≥10% of notified cases.

Note: Shorthand annotation for result presentation appears in red

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 = not available, 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 = not available/not applicable, 0 = no, 1 = some NRLs, 2 = all NRLs.
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 NA = not available/not applicable, 0 = no, 1 = yes. **NOTE: ECDC will use the scores provided for each function to calculate the overall score.** NA = not available/not applicable, 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 = not available/not applicable, 0 = no NRL accredited their tests, 1 = some NRLs, 2 = all NRLS.
Indicator 2.15 NRL BSL3 NRLs have access to biocontainment facilities with biosafety authorisation for performing Biosafety Level 3 operations.	NMFP NA = not available/not applicable, 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 and health issues. *according to the laboratory criteria described in the Case definitions of the Community Network (Decision 2119/98/EC).	NMFP NA = not available/not applicable, 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 notified cases in accordance with EU case definition/ELDS-Net guidance.	ECDC NA = not available/not applicable, 0 = not reported, 1 = <10%, 2 = ≥10%.
Indicator 2.23 Pertussis laboratory confirmed Laboratory confirmation of *Bordetella pertussis* (by culture or PCR) was performed for notified cases in accordance with EU case definition/EUPertLabNet guidance.	ECDC NA = not available/not applicable, 0 = no cases reported, 1 = <10%, 2 = ≥10%.
Indicator 2.24 Serogroup STEC Total number of O-serogrouped Shiga toxin-producing/verotoxin-producing *Escherichia coli* (STEC/VTEC) isolates, divided by the total number of TESSy notified STEC/VTEC cases in accordance with EU case definition/ECDC FWD network guidance.	ECDC NA = not available/not applicable, 0 = <80%, 1 = 80-99%, 2 = 100%.
Indicator 2.25 SARI viral testing National guidelines and reference virological diagnostic testing were available for investigation of Severe Acute Respiratory Infection 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 = not available, 0 = no national plan in place, 1 = a plan in place/in progress for at least 1 human pathogen, 2 = WGS-based typing is used routinely for national surveillance - of at least 1 human pathogen.
Indicator 2.32 *Salmonella* genotyped Percentage of *Salmonella enterica* isolates genotyped by pulsed-field gel electrophoresis (PFGE), Multilocus VNTR Analysis (MLVA) or WGS method, reported to TESSy.	ECDC NA = not available, 0 = not reported to TESSy, 1 = <20%, 2 = ≥20%.
Indicator 2.33 MDR-TB MIRU-VNTR genotyped Percentage of multidrug-resistant (MDR)-*Mycobacterium tuberculosis* isolates genotyped by MIRU-VNTR method reported to TESSy.	ECDC NA = not available/not applicable, 0 = <20%, 1 = 20-50%, 2= > 50%.
Indicator 2.34 *N. meningitidis* typed Percentage of typed invasive *Neisseria meningitidis* isolates by serogroup, MLST, or *porA* and *fetA* according to the fine-typing scheme recommended by European Meningococcal Disease Society (EMGM) reported to TESSy out of the total EU notified cases.	ECDC NA = not available/not applicable, 0 = not reported to TESSy, 1 = <20%, 2 = ≥20%.
Indicator 2.35 HIV ARV genotyped Total number of HIV isolates genotyped by ARV target sequence analysis divided by the total number of new HIV cases reported.	NMFP ***Number of initial HIV isolates genotyped=*** ***Number of new HIV cases reported in 2014=*** **NOTE: ECDC will use the numbers provided to calculate the percentage and score accordingly.** NA = not available/not applicable, 0 = <20%, 1 = 20-50%, 2 = >50%.

Targets/Indicators	Source (NMFP/ECDC) and scoring options
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 = not available/not applicable, 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 carbapenamase was performed for carbapenemase producing Gram-negative bacilli isolates in accordance with EUCAST 2013 guidance.	NMFP NA = not available/not applicable, 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 2013 guidance.	NMFP NA = not available/not applicable, 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 reported to TESSy.	ECDC NA = not available/not applicable, 0 = neuraminidase AST not monitored, 1 = selected viruses sent for central testing to WHO CC but not reported to TESSy, 2 = monitoring established and regular reporting TESSy.
Indicator 2.45 Cross sector monitoring of AMR in human and animal bacterial isolates Cross-sector monitoring of antimicrobial resistance (AMR) in human and animal bacterial isolates of public health relevance, was performed and reported annually based on antimicrobial susceptibility testing methodology calibrated to ISO and/or EUCAST methods.	NMFP NA = not available/not applicable, 0 = not established, 1 = occasional joint surveys, 2 = integrated annual reporting.

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 = not available/not applicable, 0 = no national networks, 1 = networks for 1-5 diseases/AMR issues, 2 = networks 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. *LIMS = laboratory information and management system	NMFP NA = not available/not applicable, 0 = no 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 LIMS.
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 = not available/not applicable, 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 sentinel network of virology laboratories was operating for surveillance of acute respiratory viral infections (ARI)/ Influenza-like illness (ILI).	NMFP NA = not available/not applicable, 0 = no ARI OR ILI sentinel laboratory network operational, 1 = only influenza, 2 = influenza AND other respiratory viruses.
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 = not available/not applicable, 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 = not available/not applicable, 0 = no, 1 = EQA OR annual meeting, 2 = EQA AND annual meeting
Indicator 3.22 ENIVD-Net participation Country was an active participant in the European Network for diagnostics of imported viral diseases (ENIVD-Net) - participated in annual meeting - updating laboratory capacity information	ECDC NA = not available/not applicable, 0 = no, 1 = annual meeting OR updated capabilities, 2 = annual meeting AND updated capabilities.
Indicator 3.23 IBDLab-Net participation Country was actively participating in the Invasive bacterial diseases in the EU Laboratory Network (IBDLab-Net) - participated in annual meeting - participated in workshops	ECDC NA = not available/not applicable, 0 = no, 1 = annual meeting OR workshops, 2 = annual meetings AND workshops.
Indicator 3.24 ERLTB-Net participation Country was an active participant in European Reference Laboratory Network for TB (ERLTB-Net) - participated in annual meeting - filled in list of capabilities in reference service table	ECDC NA = not available/not applicable, 0 = no, 1 = annual meeting OR updated capabilities, 2 = annual meeting AND updated capabilities.
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 = not available/not applicable, 0 = no, 1 = EQA AND/OR laboratory training, 2 = susceptibility testing.
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 = not available/not applicable, 0 = no, 1 = yes but without simulation exercises, 2 = yes with simulation exercises.
Indicator 3.32 NRL role outbreak investigation Proportion of outbreaks investigated at the national level for which NRL personnel participated as a member of outbreak investigation team.	NMFP NA = not available/not applicable, 0 = no, 1 = <25% of outbreaks, 2 = ≥25% of outbreaks.
Indicator 3.33 NRL 24/7 response duty NRLs for epidemic prone/high consequence pathogens have a mandate and trained personnel available for assistance in outbreak teams at national level.	NMFP NA = not available/not applicable, 0 = no, 1 = working hours, 2 = 24/7 duty roster.
Indicator 3.34 *Listeria monocytogenes* genotyped by PFGE or WGS Percentage of the total number of *Listeria* isolates genotyped by pulsed-field gel electrophoresis (PFGE), or by whole genome sequencing (WGS), out of the total number of notified cases.	NMFP NA = not available/not applicable, 0 = not done, 1 =<80%, 2 = 80-100%.

Targets/Indicators	Source (NMFP/ECDC) and scoring options
Indicator 3.35 Hepatitis A virus genotyped Percentage of hepatitis A virus clinical samples genotyped by sequence analysis out of all hepatitis A cases.	NMFP NA = not available/not applicable, 0 = not done, 1 = <20%, 2 = ≥20%.
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 in accordance with WHO surveillance guidance.	NMFP NA = not available/not applicable, 0 = no, 1 = screening test only, 2 = screening AND confirmation/identification.
Indicator 3.42 Diagnostic capability Influenza A(H7N9) Diagnostic capability for avian influenza A (H7N9) virus in accordance with ECDC/WHO surveillance guidance.	NMFP NA = not available/not applicable, 0 = no, 1 = screening test only, 2 = screening AND confirmation/identification (H AND N antigens).
Indicator 3.43 Diagnostic capability Ebola virus Diagnostic capability (within country AND/OR through formal international agreement with other laboratories) for Ebola virus infection.	NMFP NA = not available/not applicable, 0 = no national capacity but agreement, 1 = molecular detection at BSL3 level, 2 = further characterisation at BSL4 level.
Indicator 3.44 Diagnostic capability for detection 5 rare agents One or more reference virology laboratories in your country have detection capability for the following 5 rare AND/OR imported viruses: Chikungunya/Dengue/Hantavirus/Tick borne encephalitis/West Nile.	ECDC NA = not available/not applicable, 0 = none, 1 = for at least 2 out of 5, 2 = for all five.
Indicator 3.45 *Listeria monocytogenes* operational contact point nomination and UI or MTCI participation An operational contact point for molecular typing (MT-OCP) of *Listeria monocytogenes* is nominated for supporting molecular surveillance development and collaboration through the Epidemic Intelligence System – Food and Waterborne Diseases (EPIS-FWD) platform and has participated in Urgent Inquiries (UI).	ECDC NA = not available/not applicable, 0 = neither microbiology OCP for *Listeria monocytogenes* nominated nor MTCI/UI participation, 1 = Microbiology OCP for *Listeria monocytogenes* nominated OR MTCI/UI participation, 2 = Microbiology OCP for *Listeria monocytogenes* participated in UIs and/or MTCIs.

Annex 2. Policy rationale for the EULabCap targets of 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. References to EU/WHO policy documents or international standards applied for design and performance scoring of EULabCap indicators

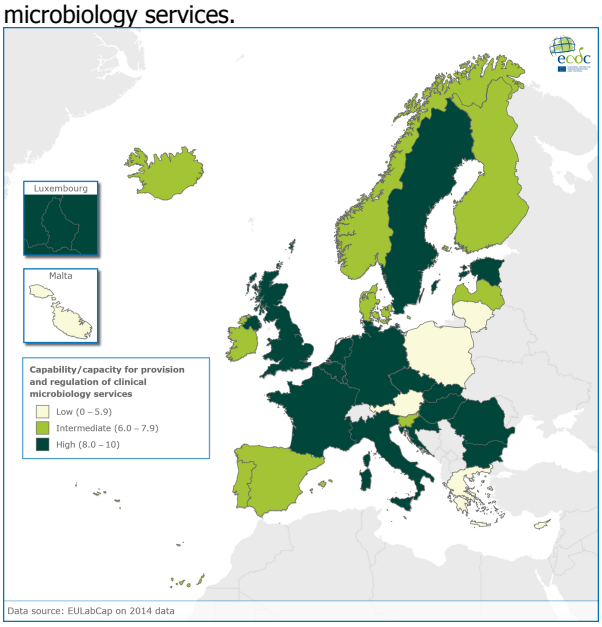
Indicator	Reference document(s)	Hyperlink
1.15	WHO Tuberculosis laboratory biosafety manual	http://www.who.int/tb/publications/2012/tb_biosafety/en/
	European Union Standards for Tuberculosis Care	http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3393116/pdf/erj-39-04-807.pdf
	Framework Action Plan to fight tuberculosis in the European Union	http://ecdc.europa.eu/en/publications/publications/0803_spr_tb_action_plan.pdf
1.22	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
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
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
1.35	Global update on HIV treatment 2013: Results, impact and opportunities; WHO in partnership with UNICEF and UNAIDS	http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2013/20130630_treatment_report_en.pdf
	Dublin declaration on Partnership to fight HIV/AIDS in Europe and Central Asia	http://www.unicef.org/ceecis/The_Dublin_Declaration.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
1.42	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
1.43	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
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
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, 2011	http://www.ecdc.europa.eu/en/publications/publications/gonococcal-antimicrobial-susceptibility-surveillance-27-mar-2013.pdf
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

Indicator	Reference document(s)	Hyperlink
2.15	WHO laboratory biosafety manual	http://www.who.int/csr/resources/publications/biosafety/Biosafety7.pdf?ua=1
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)	http://ecdc.europa.eu/en/publications/publications/1202-ted-eldsnet-operating-procedures.pdf
2.23	Guidance and protocol for the use of realtime PCR in laboratory diagnosis of human infection with *Bordetella pertussis* or *Bordetella parapertussis*	http://ecdc.europa.eu/en/publications/publications/guidance-protocol-pcr-laboratory-diagnosis-bordatella-pertussis-parapertussis.pdf
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?ua=1
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
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	http://ecdc.europa.eu/en/activities/surveillance/eldsnet/pages/index.aspx
3.22	ENIVD-CLRN	http://www.ecdc.europa.eu/en/activities/diseaseprogrammes/emerging_and_vector_borne_diseases/pages/enivd.aspx
3.23	IBDLab-Net	http://www.ecdc.europa.eu/en/activities/surveillance/EU_IBD/Pages/index.aspx
3.24	ERLTB-Net	http://www.ecdc.europa.eu/en/press/news/Documents/100125_ERLN_TB_information_flyer.pdf
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?ua=1
	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
3.45	EPIS	http://www.ecdc.europa.eu/en/activities/epidemicintelligence/pages/epidemicintelligence_tools.aspx

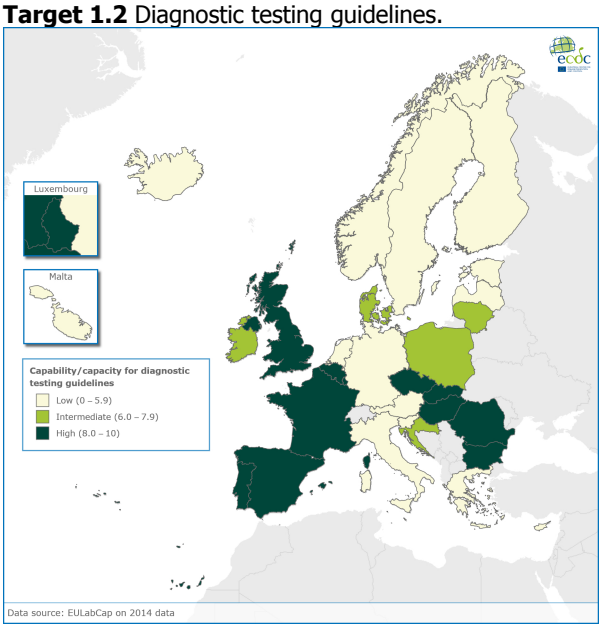
Annex 4. Maps showing geographical distribution of each target performance level by country

Targets (1.1–1.4), dimension 1 – 'Primary diagnostic testing' 2014

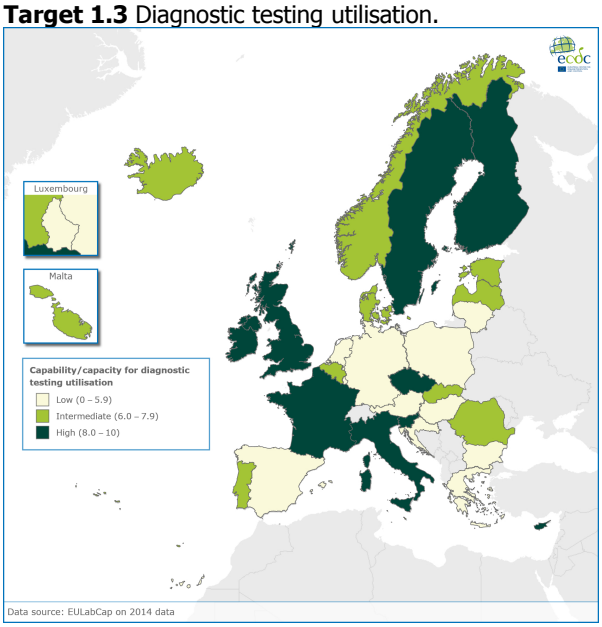
Target 1.1 Provision and regulation of clinical microbiology services.



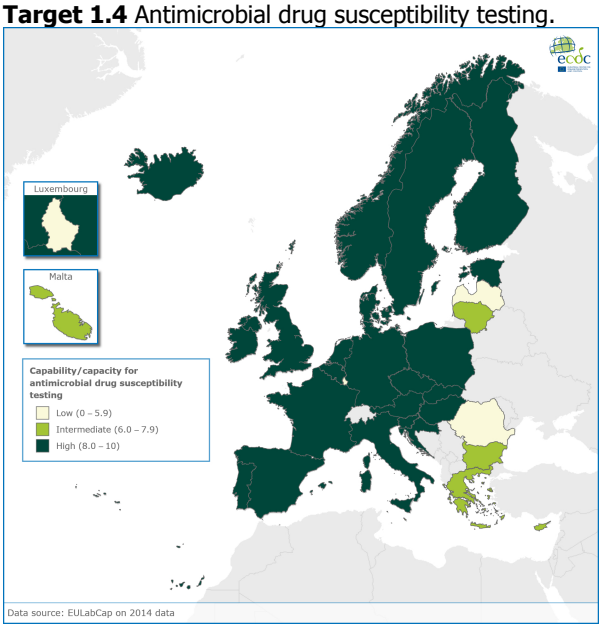
Target 1.2 Diagnostic testing guidelines.



Target 1.3 Diagnostic testing utilisation.

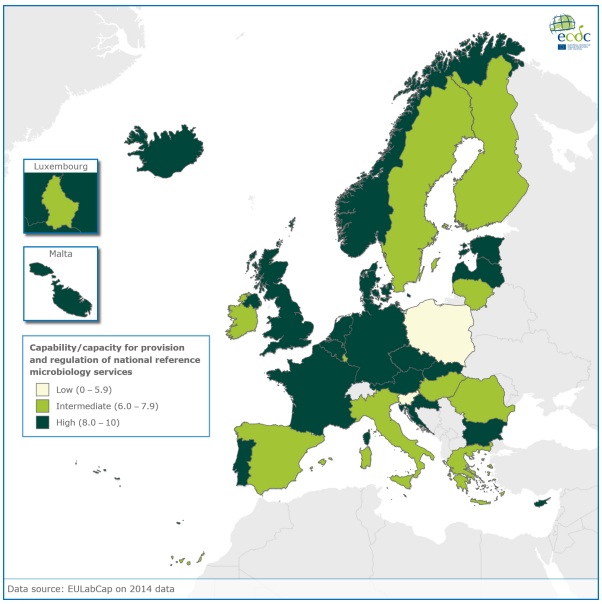


Target 1.4 Antimicrobial drug susceptibility testing.

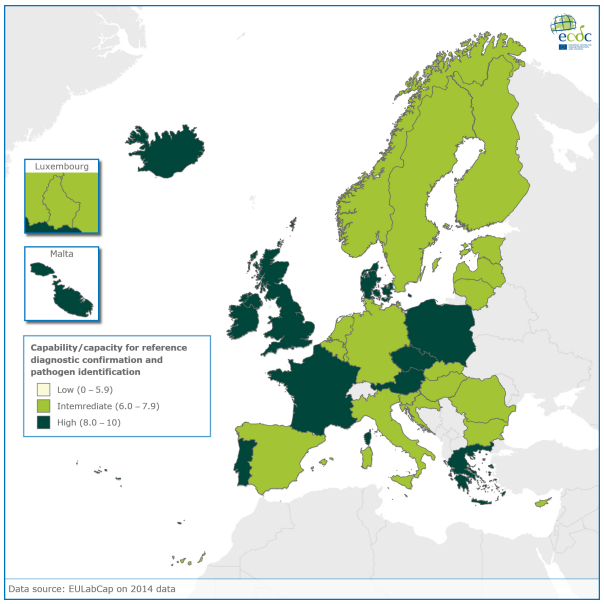


Targets (2.1–2.4), dimension 2 – 'National reference laboratory services (NRL)' 2014

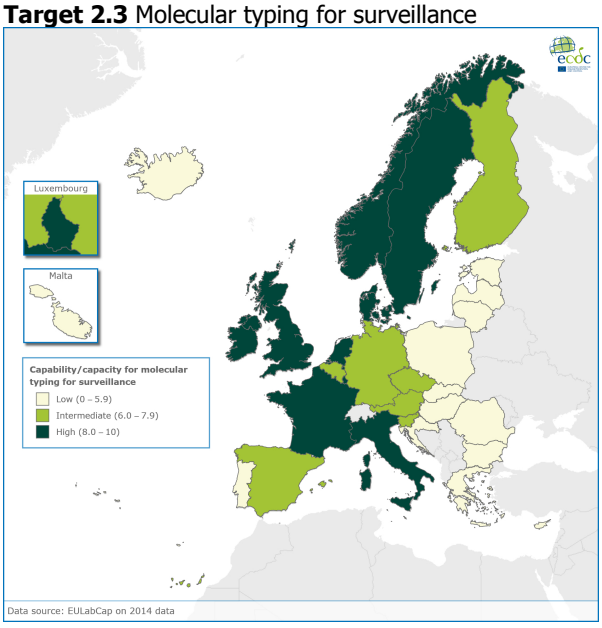
Target 2.1 Provision and regulation of national reference microbiology services



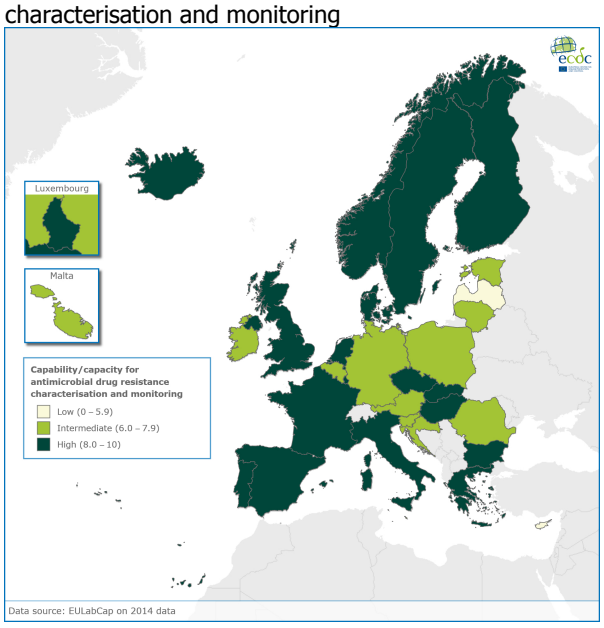
Target 2.2 Reference diagnostic confirmation and pathogen identification



Target 2.3 Molecular typing for surveillance

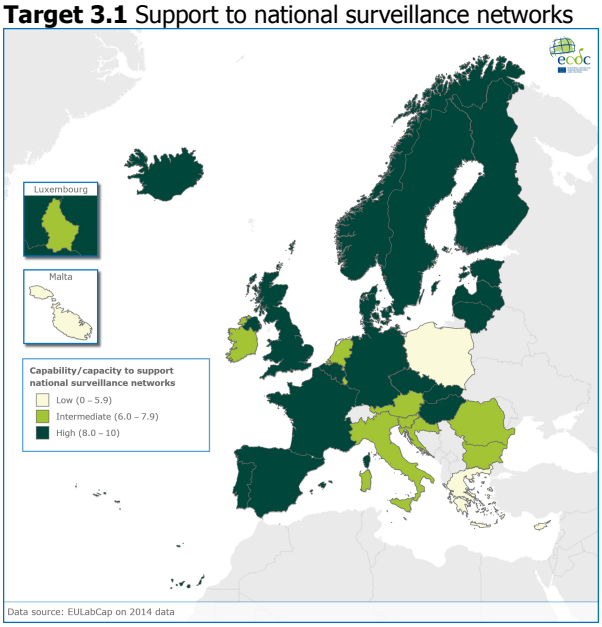


Target 2.4 Antimicrobial drug resistance characterisation and monitoring

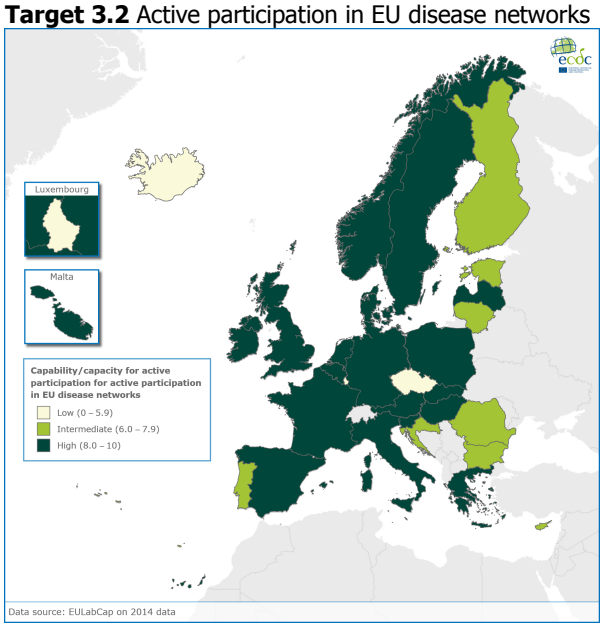


Targets (3.1–3.4), dimension 3 – 'Laboratory-based surveillance and epidemic response support' 2014

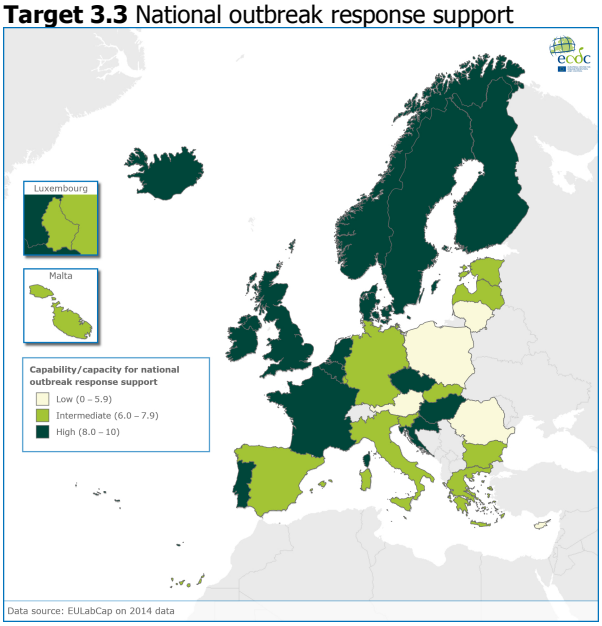
Target 3.1 Support to national surveillance networks



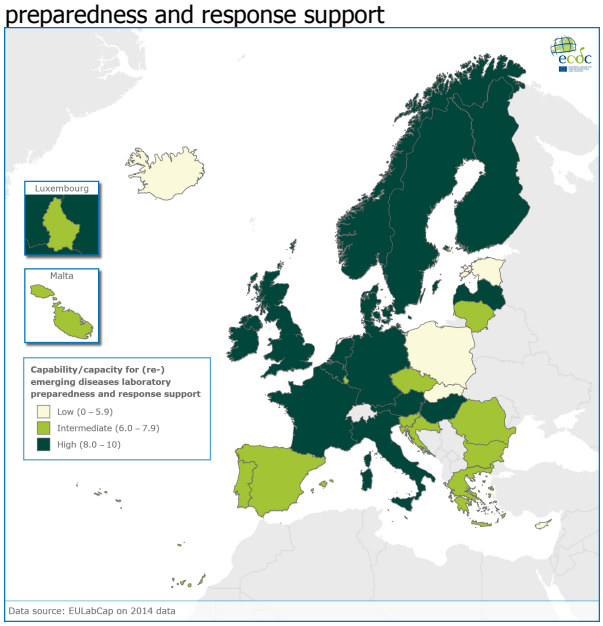
Target 3.2 Active participation in EU disease networks



Target 3.3 National outbreak response support



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



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