TECHNICAL REPORT

EU Laboratory Capability Monitoring System (EULabCap)

Report on 2015 survey of EU/EEA country capabilities and capacities

www.ecdc.europa.eu

ECDC TECHNICAL REPORT

EU Laboratory Capability Monitoring System (EULabCap)

Report on 2015 survey of EU/EEA country capabilities and capacities

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

Acknowledgments

The following National Microbiology Focal Points (NMFP) contributed to the revision of the survey, the data collection and validation, the interpretation of the survey results, and provided advice on the survey design and reporting format: Franz Allerberger (Austria NMFP member), Petra Apfalter (Austria NMFP alternate), Steven Van Gucht (Belgium NMFP member), Katelijne Dierick (Belgium NMFP alternate), Iva Christova (Bulgaria NMFP member), Stefka Krumova (Bulgaria NMFP alternate), Vera Katalinić-Janković (Croatia NMFP member), Blazenka Hunjak (Croatia NMFP alternate), Despo Bagatzouni (Cyprus NMFP member), Sophia Kyradji (Cyprus NMFP alternate), Pavla Křížová (Czech Republic NMFP member), Martina Havlíčková (Czech Republic NMFP alternate), Thea Kølsen Fischer (Denmark NMFP member), Eva Møller Nielsen(Denmark NMFP alternate), Rita Peetso (Estonia NMFP member), Külli Rae (Estonia NMFP alternate), Saara Salmenlinna (Finland NMFP member), Carita Savolainen-Kopra (Finland NMFP alternate), Bruno Coignard (France NMFP member), , Guido Werner (Germany NMFP member), Annette Mankertz (Germany NMFP alternate), Alkiviadis Vatopoulos (Greece NMFP member), Kyriaki Tryfinopoulou (Greece NMFP alternate), Ákos Tóth (Hungary NMFP member), Ágnes Dánielisz (Hungary NMFP alternate), Karl Kristinsson (Iceland NMFP member), Hjördis Hardardóttir (Iceland, NMFP alternate), Eleanor McNamara (Ireland NMFP member), Robert Cunney (Ireland NMFP alternate), Annalisa Pantosi (Italy NMFP member), Paola Stefanelli (Italy NMFP alternate), Violeta Mavcutko (Latvia NMFP member), Olga Arta Balode (Latvia NMFP alternate), Joël Mossong (Luxembourg NMFP member), Matthias Opp (Luxembourg NMFP alternate), Christopher Barbara (Malta NMFP member), Paul Caruana (Malta NMFP alternate), Nico Meessen (Netherlands NMFP member), Ellen Stobberingh (Netherlands NMFP alternate), Ulf Dahle (Norway NMFP member), Dominique Caugant (Norway NMFP alternate), Anna Skoczyńska (Poland NMFP member), Rafał Gierczyński (Poland NMFP alternate), Jorge Machado (Portugal NMFP member), Gabriel Ionescu (Romania NMFP member), Olga Dorobat (Romania NMFP alternate), Cyril Klement (Slovak Republic NMFP member), Lucia Madarova (Slovak Republic NMFP alternate), Metka Paragi (Slovenia NMFP member), Katarina Prosenc (Slovenia NMFP alternate), Julio Moreno Vazquez (Spain NMFP member), José Miguel Rubio Muñoz (Spain NMFP alternate), Karin Tegmark-Wisell (Sweden NMFP member), Hans Gaines (Sweden NMFP alternate), Maria Zambon (United Kingdom NMFP member), and Nandini Shetty (United Kingdom NMFP alternate).

ECDC experts contributing to data collection/validation and interpretation of results: Julien Beauté, Eeva Broberg, Birgitta de Jong, Céline Gossner, Vahur Hollo, Liselotte Högberg, Csaba Ködmön, Taina Niskanen, Anastasia Pharris, Gianfranco Spiteri, Ivo Van Walle, Robert Whittaker, and Hervé Zeller.

Suggested citation: European Centre for Disease Prevention and Control. European Centre for Disease Prevention and Control. EU Laboratory Capability Monitoring System (EULabCap) – Report on 2015 survey of EU/EEA country capabilities and capacities. Stockholm: ECDC; 2017.

Stockholm, May 2017

ISBN 978-92-9498-058-8
doi: 10.2900/27007
Catalogue number TQ-01-17-411-EN-N

Contents

Figures

Tables

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 laboratory Network for Tuberculosis
ESBL	Extended spectrum beta-lactamase-producing *Enterobacteriaceae*
EUCAST	European Committee on Antimicrobial Susceptibility Testing
FWD	Food- and waterborne diseases
HIV	Human immunodeficiency virus
IQR	Interquartile range
MDR TB	Multidrug-resistant tuberculosis
MERS-CoV	Middle East respiratory syndrome coronavirus
MLST	Multilocus sequence typing
NMFP	National microbiology focal points
NAC	National Antimicrobial Susceptibility Committee
NRL	National reference laboratories
OECD	Organisation for Economic Cooperation and Development
PCR	Polymerase chain reaction
SMAP	ECDC's strategic multi-annual programme
VTEC/STEC	Verotoxin- or Shiga toxin-producing *Escherichia coli*
TESSy	The European Surveillance System
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	Public health microbiology laboratories with national responsibility and appropriate tools and skills to be able to support national surveillance and capacity to deal with emergency situations [4,5].
Public health microbiology	A cross-cutting area of microbiology that spans the fields of human, animal, food, water, and environmental microbiology, with a focus on human health and disease. It covers the laboratory 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 timely and reliable information for infectious threat detection, assessment and surveillance at the Member State and EU levels, thus ensuring effective prevention and control of infectious diseases [4,6]. To ascertain how well this is delivered, ECDC, in close collaboration with its national microbiology focal points and the Advisory Forum, developed the EULabCap survey methodology 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 of EU/EEA (European Union/ European Economic Area) countries identify possible areas for action and evaluate the impact of capacity strengthening activities and health system reforms. The reports on the 2013 and 2014 surveys were published in 2016 [7,8]. This third report presents the laboratory capabilities and capacities measured in 2015 in comparison with previous surveys.

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 three quarters 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 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; all index values are displayed 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 17 indicators was retrieved by ECDC from data sets accessible in The European Surveillance System (TESSy) and EU disease network reports. For the remaining 41 indicators, the national microbiology focal points (NMFPs) used a questionnaire to collect information from their country. Two indicators were excluded from the analysis because they were not applicable in 2015.

The data collected for 2015 were validated by the NMFPs, and the draft report was shared to review the validity of the data analysis and result presentation. A feedback survey was conducted on the use and the dissemination of the 2013 report to help develop actions at the national and EU levels.

Results

The country response rate to the 2015 survey was 97% (29 EU/EEA countries, with Lithuania not reporting). Data from 2015 were provided for 96% of the indicators[1] (range per country, 84–100% complete data available). The average EULabCap 2015 aggregated index for the EU/EEA was 7.5 on a scale of 0–10, as compared to 7.3 in 2014 and 6.9 in 2013.

As in previous surveys, substantial inter-country variation around this average persisted in 2015, with EULabCap indices per country ranging from 5.6 to 9.6 (2015) compared to 5.0 to 9.5 (2014) and 4.7 to 9.2 (2013). There was also diversity of scores among public health targets, with a number of areas for which many countries lacked critical capabilities and/or showed low capacity. In 2015, as in the previous years, the main areas of strong capability, with high scores largely meeting policy targets 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 previous years, challenges were found in the areas of diagnostic testing guidance and utilisation, national reference laboratory use of molecular typing for surveillance, and active contribution to preparedness/response to epidemics.

[1] For the survey on 2015 data, two indicators were excluded from the analysis as they were not applicable.

In 2015, notable improvements – unlikely to be explained by indicator modifications and/or the non-participation of one country – were found in the following technical areas:

- Primary diagnostic testing: medical laboratory licensing, biosafety regulation and safe tuberculosis diagnostic practice, *Clostridium difficile* testing guidance, accessible testing of migrants for HIV and tuberculosis, early HIV diagnosis, participation in external quality assessments (EQAs) for tuberculosis drug susceptibility testing, and gonococcal antimicrobial susceptibility testing.
- National reference laboratory (NRL) services: NRL delivery of core public health functions, severe acute respiratory infection (SARI) viral diagnostic testing guidance, HIV genotyping for antiretroviral dug resistance, influenza virus susceptibility monitoring to neuraminidase inhibitors, and application of whole genome sequencing to national surveillance.
- Laboratory-based surveillance and epidemic response support: automated laboratory data reporting to national surveillance system, laboratory-based outbreak detection, *Chlamydia trachomatis* surveillance, Euro-GASP participation, role of NRLs in epidemic preparedness, *Listeria monocytogenes* genotyping, participation in EU molecular surveillance/cluster detection, and NRL diagnostic capability for emerging pathogens.

Conclusions and next steps

The high response rate of the EU/EEA countries in the EULabCap surveys highlights the commitment to this new health system component monitoring and benchmarking process, thanks to the engagement of the NMFPs. It also gives robustness to the EU-wide assessment of collective capacity. The results of this third annual survey confirm that the EU/EEA on the whole, with an aggregated index score of 7.5 out of 10 for 2015 can rely on public health microbiology services that are characterised by strong and improving capability and capacity. Overall, public health microbiology services in the EU/EEA largely meet all key communicable disease surveillance and response requirements. It is remarkable that 19 countries reached 'sufficient microbiology capacity' (if defined as intermediate or high capacity for at least 10 of 12 EULabCap targets) already in 2015, a target formulated by ECDC's strategic multiannual programme 2014–2020.

The strengths and weaknesses within the EU microbiology system components were consistent between surveys. Increases in indicator scores over the past three years suggest that shortcomings in public health microbiology capabilities were addressed. There remains substantial variation in the EULabCap index between countries in 2015, but this disparity seems to be declining. These positive trends will hopefully be confirmed in the forthcoming surveys.

The EULabCap monitoring provides health system information for national competent bodies and policymakers at the national and EU levels, with individual country profile reports shared with each ECDC coordinating competent body. Surveys in the Member States indicated that EULabCap reports were found useful and were disseminated to national stakeholders in the majority of countries. The majority of the countries reported ongoing activities addressing the suggestions for targeted capacity building made in the reports. The use of the EULabCap results at the national levels will be evaluated in the next surveys.

Support for laboratory capacity directed towards the strengthening of protection against cross-border infectious threats to health will be reviewed and discussed with the competent bodies in the Member States in close collaboration with the European Commission and international partners in order to devise an action plan.

Introduction

The laboratory detection and characterisation 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 [9] and international legislation [10]. 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:

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

National health systems in Europe are undergoing continuous administrative and organisational reforms to face up to the challenge of maintaining universal access to essential and high-quality care with reduced resources [11]. Following the financial crisis in 2008, health expenditure has either stopped growing or even decreased in various degrees across the EU Member States [11]. Public health budget cuts have affected the available resources and investments for laboratory operations. The Founding Regulation of ECDC (EC No. 851/2004) states that 'by encouraging cooperation between expert and reference laboratories, the Centre shall foster the development of sufficient capacity within the Community for the diagnosis, detection, identification and characterization of infectious agents which may threaten public health' [12]. In this dynamic context, monitoring the collective laboratory capabilities in the EU/EEA is important in order to identify best practices and address potential vulnerabilities.

Europe benefits from a 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 [13] and the European Commission [14], 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 entrusting of specialist technical capacity at supranational level [13,14].

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 levels, as needed for effective prevention and control of infectious diseases [4,6]. To ascertain how well this is delivered, ECDC, in close collaboration with its national microbiology focal points (NMFPs) 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 2012–2014, the first survey was launched in 2014 (on 2013 system outputs) for 30 EU/EEA countries. After extensive consultation, the results were published in February 2016 [7].

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

This report presents the results of the third EULabCap survey, based on 2015 indicator data collected from 29 of the 30 EU/EEA countries invited (Lithuania did not participate).

Materials and methods

EULabCap survey

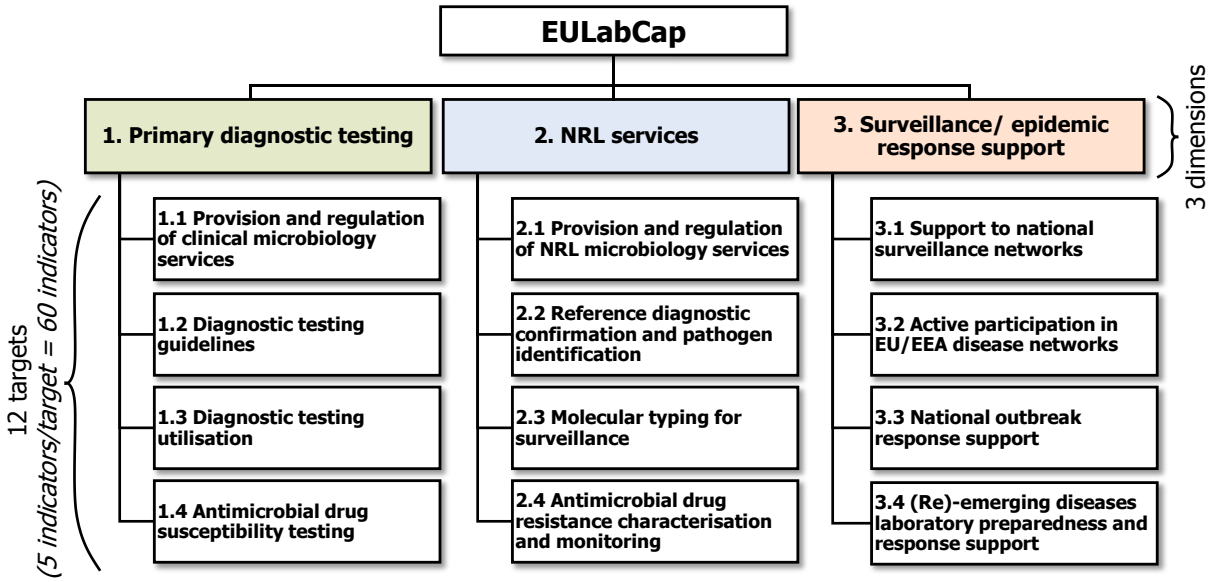
Survey population

The third data call for the EULabCap survey was launched in July 2016 to collect the information on the 2015 capabilities and capacities of 28 EU Member States and two EEA countries. Liechtenstein is not included in the surveys due to outsourcing arrangements with laboratories in Switzerland which meet their public health microbiology needs.

EULabCap survey tool

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

Figure 1. Structural overview of the EULabCap indicators as grouped by dimension and target



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

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

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

Scoring system

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

Indicator modifications

For an overview of all indicator modifications by dimension see footnotes for Figures 11–13.

For the third EULabCap survey (2015 data), the same indicators were used as in the second survey, with the following exceptions:

The following indicators were excluded from the analysis as they were not applicable in 2015.

- Indicator 3.22, 'Country was an active participant in the European Network for diagnostics of imported viral diseases (ENIVD)'; discontinued because network activities were stopped in 2015.
- Indicator 3.23 'Country was an active participant in the European Invasive Bacterial Disease Laboratory Network (IBD-LabNet)'; this was due to interruption of part of the scored activities of this network during 2015.

The score calculation was slightly modified for one indicator.

- Indicator 1.34, 'Percentage of new pulmonary tuberculosis cases confirmed by culture and tested for susceptibility to first-line drugs', was changed with the optimum score to include a lower threshold percentage of cultures tested for drug susceptibility to first-line drugs (changed to >95%, instead of 100% of cultures tested for drug susceptibility).

NMFPs provided absolute numerator and denominator data for 2015 for one indicator:

- 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'.

Data collection and validation process

Data collection and validation for the 2015 survey were performed between July and November 2016. As in the previous surveys, a mixed method was used for data collection. As two indicators were not applicable to the collection of 2015 data, information for 58 indicators was retrieved as follows: (a) 17 indicators measured by ECDC from datasets accessible in TESSy and EU disease network reports, and (b) 41 indicators reported by the NMFPs through the questionnaire (Annex 1). Two rounds of validation were performed between October and November 2016. The NMFPs were asked to review and verify the data and correct indicator score calculations.

Data analysis, performance measurement and interpretation

Data completeness was calculated as a percentage of 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 means of component indicator scores per country; all values were displayed on a scale of 0–10.

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

This report, for the first time, also measured the number of EU/EEA countries with 'sufficient capacity', as foreseen in the ECDC strategic multiannual programme 2014–2020 [6]. While taking a balanced provision of services across targets into account, sufficient country capacity was defined as an EULabCap index score at an intermediate or high performance level (score 6 or above) for at least 10 of 12 microbiology system targets.

Descriptive data analysis was performed, including measures of central tendency (mean and median) and dispersion (interquartile range) of indicator scores and aggregated indices across the EU/EEA. Means were used for comparing indicator scores over time and average levels of system capability and capacity by country/for the EU/EEA. Medians (and interquartile range) were used for comparing the inter-country distribution of index scores by targets and dimensions over time.

The ECDC Microbiology Coordination Section shared the individual country profiles/reports in December 2016. A draft report of this document, which provided more detail on the level of performance by system component

(indicator, target and dimension), at the EU level, was circulated in February 2017 and validated by the NMFPs after a number of revisions and a review of the individual country profiles.

Data reporting

EU/EEA report

This report presents aggregated results of the EULabCap scores for the 29 participating EU/EEA countries, using histograms, radar and bar graphs, and maps to visualise the distribution of performance scores in 2015 for the system overall, by indicator, target and dimension; 2015 data are also compared to the 2013 and 2014 survey data.

Individual country benchmark reports

An individual EULabCap country profile report (including detailed information on the country score benchmark) was prepared for each participating EU/EEA country and shared confidentially with the respective NMFP for dissemination to the Coordinating Competent Body. The EULabCap country 2015 indices were grouped into three capability and capacity levels: the index of a national public health microbiology system could be 'low level' (score 0 to 5.9), 'intermediate level' (score 6.0 to 7.9) and 'high level' (score 8.0 to 10). These three categories are also used in the maps produced for this report.

Each country report consisted of a customised one-page executive summary for the country's decision makers, presenting the overall benchmark scores in the EU, areas of good national system capacity/capability, and the weaker areas in need of attention. Survey methods were explained, and country results were illustrated with a) a radar graph comparing the country's median 2015 EULabCap index scores for the 12 targets against the 2015 EU/EEA interquartile score range; b) the score distribution among EU/EEA countries compared to the country's scores for each indicator in 2015, and c) the country's mean scores per target and indicator for 2013–2015.

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

To obtain feedback on the usefulness of the previous reports, NMFP follow-up surveys were performed in April and October 2016. The surveys focused on the dissemination of previous reports, on proposed areas for ECDC laboratory support activities, and on whether the findings were used to take corrective actions at the national level (Annex 4). Feedback was also discussed at two NMFP meetings in May and October 2016.

Results

EULabCap survey

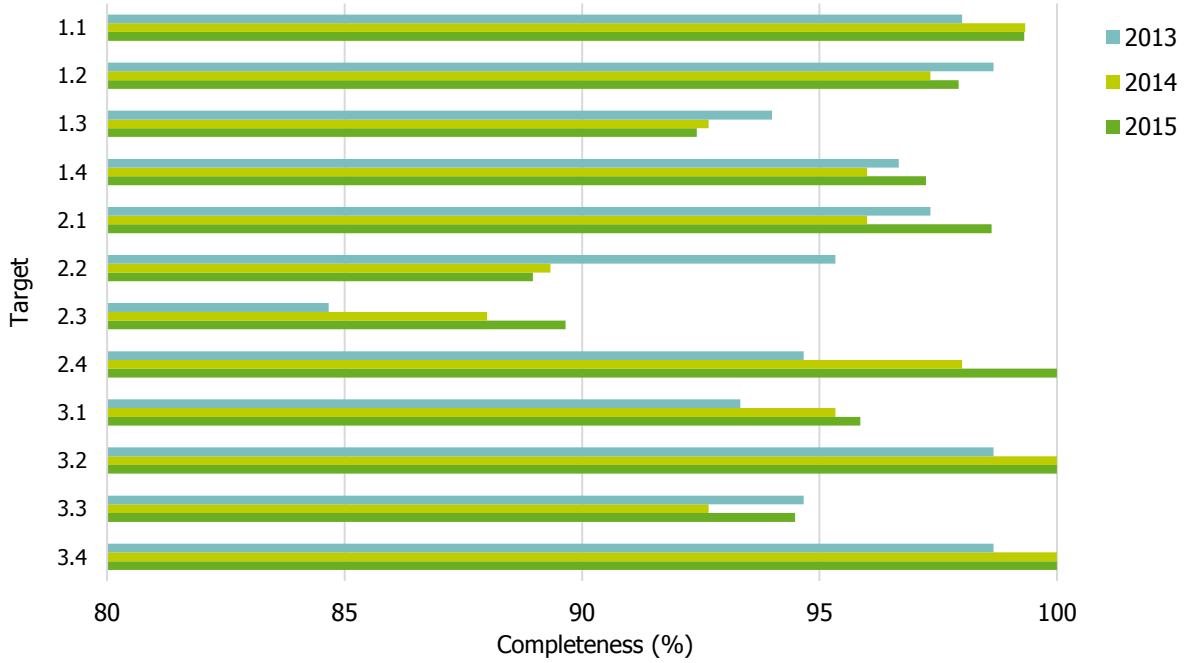
Response rate and data completeness

The country response to the 2015 survey was 97% (29 EU/EEA countries, Lithuania did not participate), with data provided for 96% of the indicators (1 616 out of 1 682 data points). Data completeness ranged from 78–100% by country and from 69–100% by indicator (Annex 5). Compared to previous surveys, data completeness increased slightly in 2015. However, denominators in the 2015 survey changed because two indicators were no longer applicable, and one country did not participate.

The completeness by target ranged from 89% to 100%, with four targets (sorted in order of increasing completeness: 2.2, 2.3, 1.3 and 3.3) being below 95% (Figure 2).

The completeness of responses to some indicators in Target 1.3 (diagnostic testing utilisation) and Target 2.2 (reference diagnostic confirmation and pathogen identification) continued to be low without any notable improvement while, the completeness of responses to Target 2.3 (molecular typing for surveillance) improved over the survey years.

Figure 2. Data completeness by target; 2013, 2014 (N=30 countries) and 2015 (N=29 countries)



Note: Completeness for Target 3.2 is calculated with a different number of indicators for 2014 (four indicators) and 2015 (three indicators)

No major change was observed in the reporting by country. Six indicators had missing data from more than three countries in 2015 (Annex 5). Those indicators were, in order of increasing completeness, 1.33, 2.35, 2.24, 2.23, 2.33, and 3.35. Between the surveys, the data reporting improved for 18 indicators and worsened for four.

Laboratory capabilities and capacities at EU/EEA level

The average EULabCap aggregated index score was 7.5 on a scale of 0–10 in 2015 for the 29 participating EU/EEA countries (compared to a 30-country average score of 7.3 in 2014 and 6.9 in 2013; the same upward trend remains if Lithuania's score is not counted). As in 2014, the distribution of EULabCap index country scores in 2015 showed a substantial inter-country variation, with unimodal distribution of scores ranging from 5.6 to 9.6 (Figures 3 and 4). Compared to 2014, the index distribution by countries narrowed somewhat in 2014, indicating less overall heterogeneity of capabilities across countries.

Figure 3. Distribution of overall EULabCap country index scores for 2013–2014 (N=30 countries) and 2015 (N=29 countries)

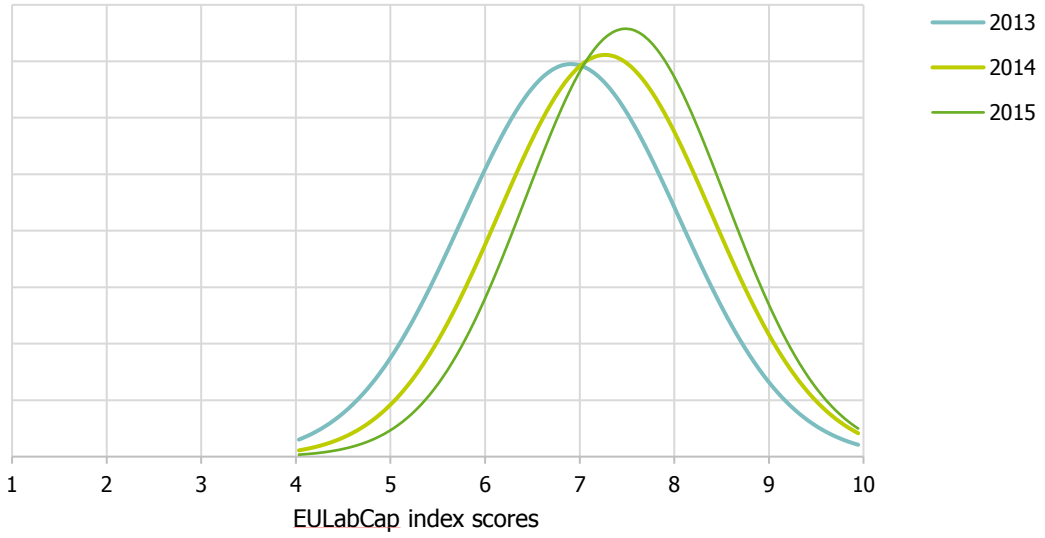
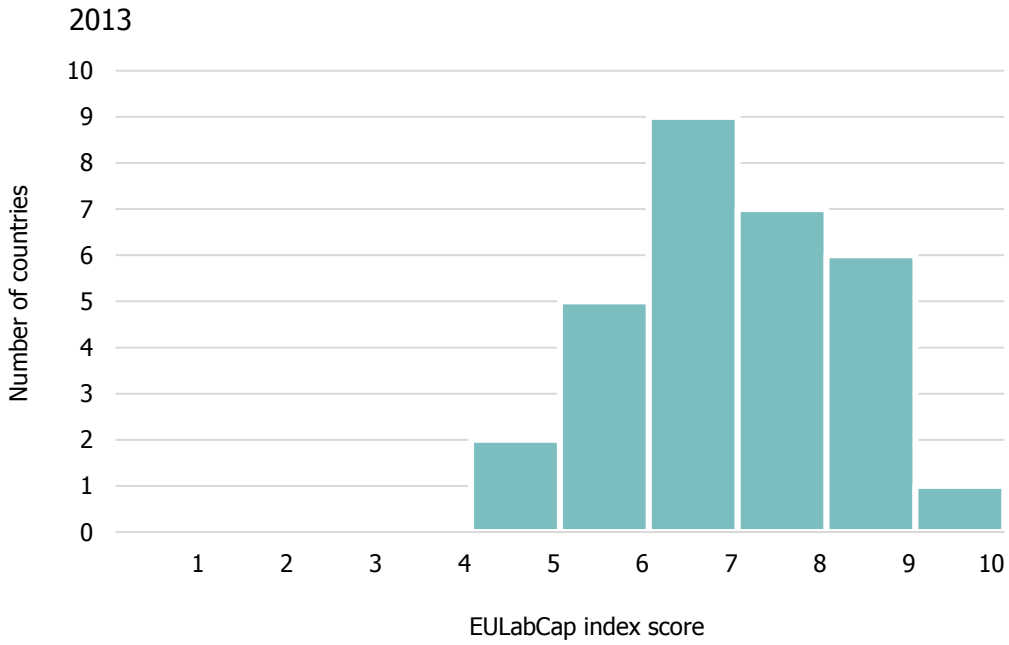
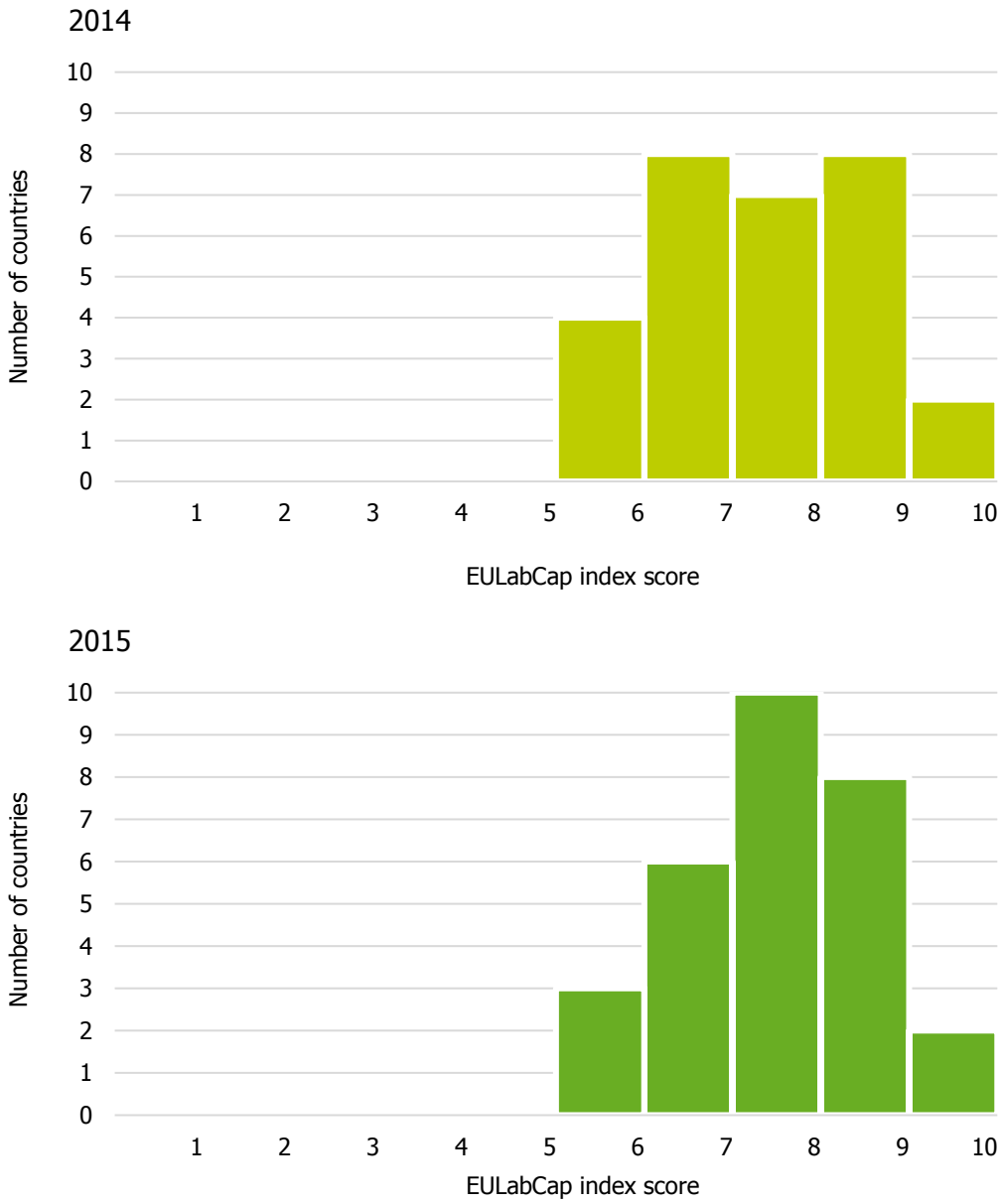


Figure 4. Distribution of overall EULabCap country index scores for 2013–2014 (N=30 countries) and 2015 (N=29 countries)

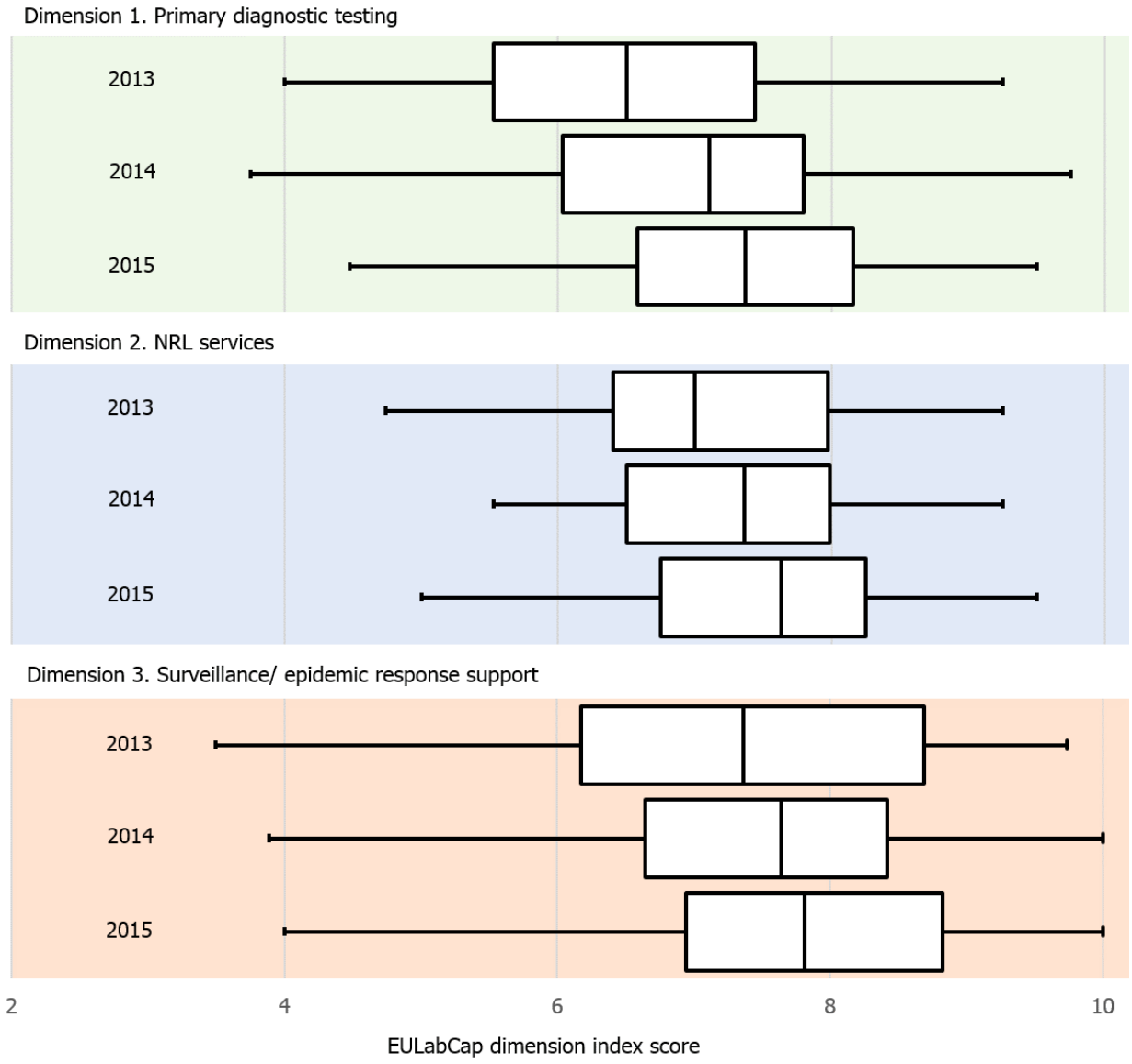




In 2015, the index scores showed a different distribution across dimensions, with a median index of 7.4 (IQR 6.6–8.2) for primary diagnostic testing, 7.6 (IQR, 6.8–8.3) for NRL services, and 7.8 (IQR, 6.9–8.8) for laboratory-based surveillance and epidemic response support (Figure 5).

In comparison to 2014, the EU/EEA median index scores per dimension increased in all three dimensions, with the biggest increase in primary diagnostic testing (narrowing IQR, see Figure 5). In 2015, compared with 2014, the range widened for the indices of NRL services, indicating more heterogeneity across countries for this system dimension.

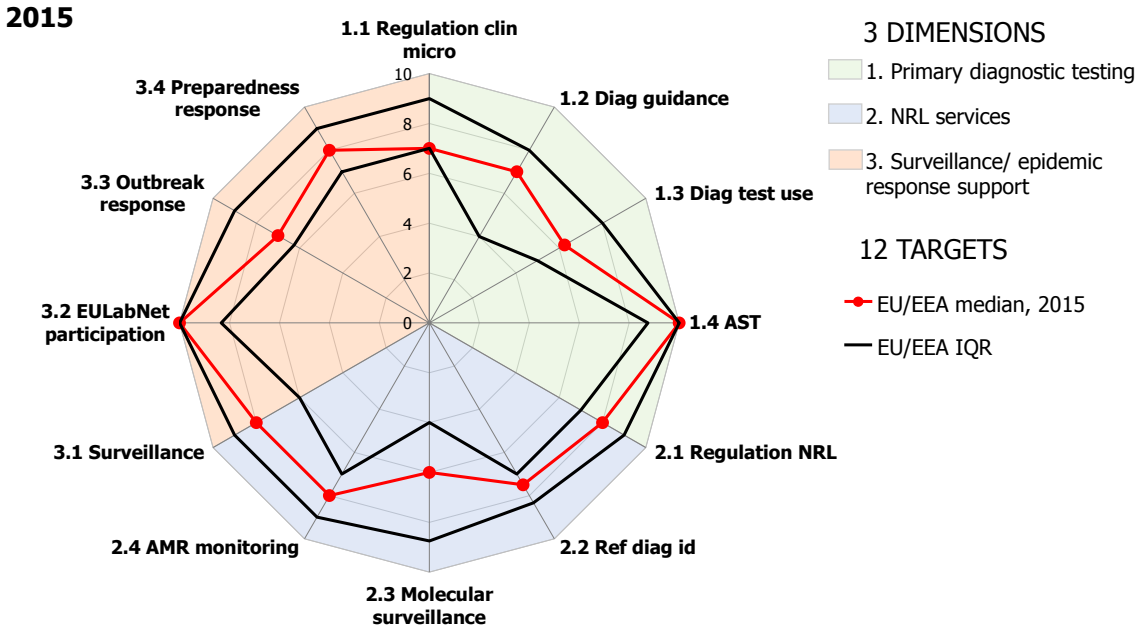
Figure 5. Boxplot (median, interquartile and minimum–maximum ranges) of the EULabCap index scores by dimension; 2013, 2014 (N=30 countries) and 2015 (N=29 countries)



Overall, 2015 indices were largely consistent with the previous years, with a gradual and parallel shift to higher median scores for all dimensions over the years (Figure 5).

The comparison of the EU/EEA median and interquartile range for EULabCap index scores by target and dimension of the public health microbiology system in 2015 is shown in Figure 6. High performance (median score 8 and above) was noted for Targets 1.4, 2.1, 2.4, 3.1, 3.2 and 3.4.

Figure 6. Distribution of country EULabCap index scores (EU/EEA median and interquartile range) by target (N=29 countries)



Temporal trends for EU performance by target, 2013–2015

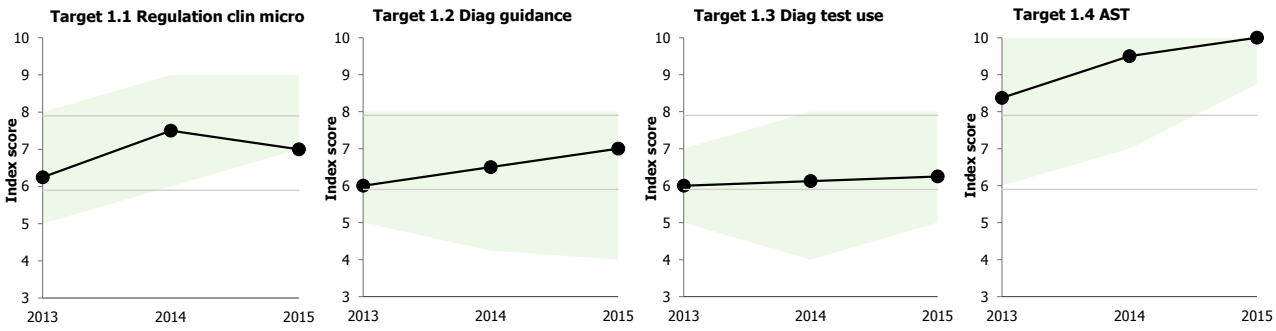
To show early trends in the evolution of average laboratory performance per target and explore the heterogeneity among the EU/EEA countries, Figures 7–9 present the yearly median (IQR) EULabCap scores per target and by system dimension (primary diagnostic testing, NRL services, laboratory-based surveillance and epidemic response support).

Between 2013 and 2015, the index showed an upward trend for targets in primary diagnostic testing, except for Target 1.1 (Figure 7). By contrast, no clear temporal trend was apparent in target scores for NRL services and laboratory-based surveillance and epidemic response support.

Primary diagnostic testing targets

EU/EEA median (IQR) scores (2013–2015) for targets in the dimension of primary diagnostic testing are shown in Figure 7.

Figure 7. EULabCap median score and interquartile range of targets in primary diagnostic testing, 2013–2014 (N=30 countries) and 2015 (N=29 countries)



Target 1.1. Provision and regulation of clinical microbiology services. This target showed fluctuation in the median score despite a narrowing range of performance over time. In 2015, more than 50% of the EU/EEA countries had a score of 7.0 (intermediate: 6.0 to 7.9) or more for this target.

Target 1.2. Diagnostic testing guidelines. Although a continuous positive trend in performance has been observed over time, the widening interquartile ranges still reflect disparity between many countries that also scored low with regard to the availability of national primary diagnostic testing and screening guidelines.

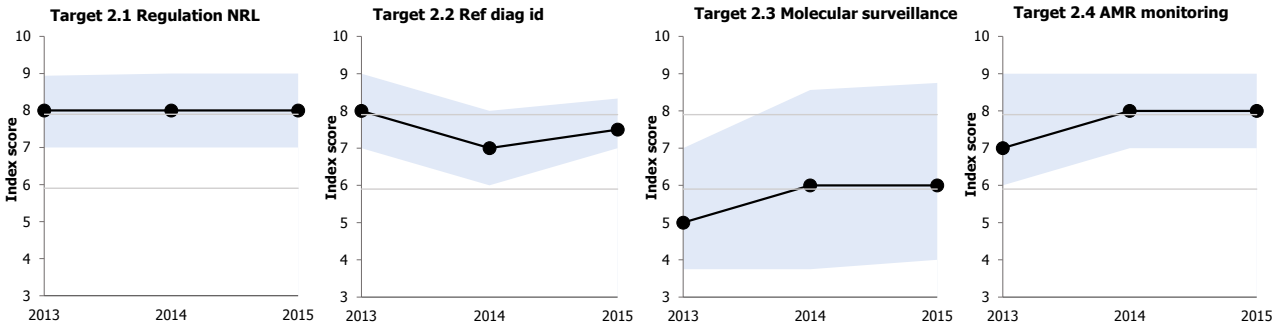
Target 1.3. Diagnostic testing utilisation. This is a weaker target within the primary diagnostic testing dimension. Almost half of the EU/EEA countries are characterised by low capacities in this area. A slight increase of the median score and a narrowing IQR would suggest a gradual improvement.

Target 1.4. Antimicrobial drug susceptibility testing. This target shows rapid improvement over time, with more than 75% of the EU/EEA countries ranking as 'high capacity/capability' for harmonised testing in 2015; differences in performance are also narrowing between countries.

National reference laboratory services

EU/EEA median (IQR) scores (2013–2015) for targets in the area of national reference laboratory services are shown in Figure 8.

Figure 8. EULabCap median score and interquartile range of targets in national reference laboratory services, 2013–2014 (N=30 countries) and 2015 (N=29 countries)



Target 2.1. Provision and regulation of NRL microbiology services. A strong target, for which the majority of the EU/EEA countries show a stable, intermediate to high level of capacity/capability of organisation, regulation, and funding of their NRL infrastructure and delivery core public health functions over the years.

Target 2.2. Reference diagnostic confirmation and pathogen identification. A fairly strong target, the level of reference testing capability/capacity remains intermediate in a majority of the EU/EEA countries with a narrowing inter-country range. The observed dip between 2013 and 2014 is likely due to changes in the indicator scoring method between those surveys.

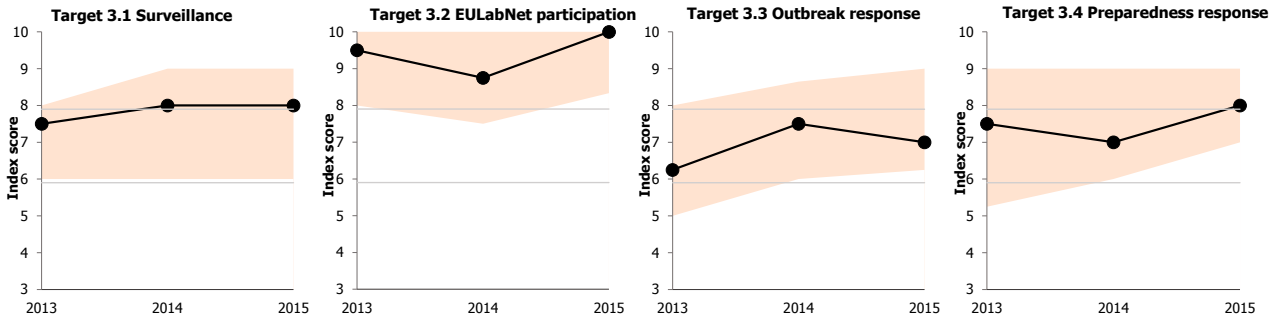
Target 2.3. Molecular typing for surveillance. A challenging target with low baseline level of capability/capacity in many EU/EEA countries for use of molecular typing for surveillance at national and EU levels, as measured by the selected indicators over the years. The median score increase observed in 2014 is related in part to relaxed criteria for scoring meningococcal typing as well as to true progress with the introduction of WGS methodology and wider participation in EU molecular surveillance for MDR TB. Great heterogeneity is observed between countries with a widening IQR.

Target 2.4. Antimicrobial drug resistance characterisation and monitoring. A strong target, the capacity/capability of the EU/EEA countries to accurately characterise and monitor antimicrobial resistance determinants for national/EU-wide surveillance increased on average from intermediate to high level from 2013 to 2014. In 2015 the performance levels remained stable with 75% of the countries scoring above 7.

Laboratory-based surveillance and epidemic response support

EU/EEA median (IQR) scores by target in the dimension of laboratory-based surveillance and epidemic response support from 2013 to 2015 are shown in Figure 9.

Figure 9. EULabCap median score and interquartile range of targets in laboratory-based surveillance and epidemic response support, 2013–2014 (N=30 countries) and 2015 (N=29 countries)



Target 3.1. Support to national surveillance networks. This score increased from intermediate to high from 2013 to 2014, when half of the EU/EEA countries showed high capacity/capability of their clinical/public health laboratories for reporting diagnostic information to surveillance databases. However, the lower performing half of the countries showed a wider scoring diversity.

Target 3.2. Active participation in EU/EEA disease networks. Target assessment suffered from business discontinuity in several ECDC-supported laboratory networks, resulting in one missing indicator in 2014 and two missing indicators in 2015. In 2015, more than 75% of the EU/EEA countries were actively participating in the EU/EEA networks.

Target 3.3. National outbreak response support. This NRL core function is a weaker target, with increasing scores over time as a group. In 2015, half of the EU/EEA countries had intermediate capacity/capability in preparedness and response to outbreaks, with a score of 7.0 or more. Interestingly, the median decreased from 2014–2015 (7.5–7.0), while the EU/EEA mean increased (6.4 in 2013, 7.2 in 2014, 7.4 in 2015).

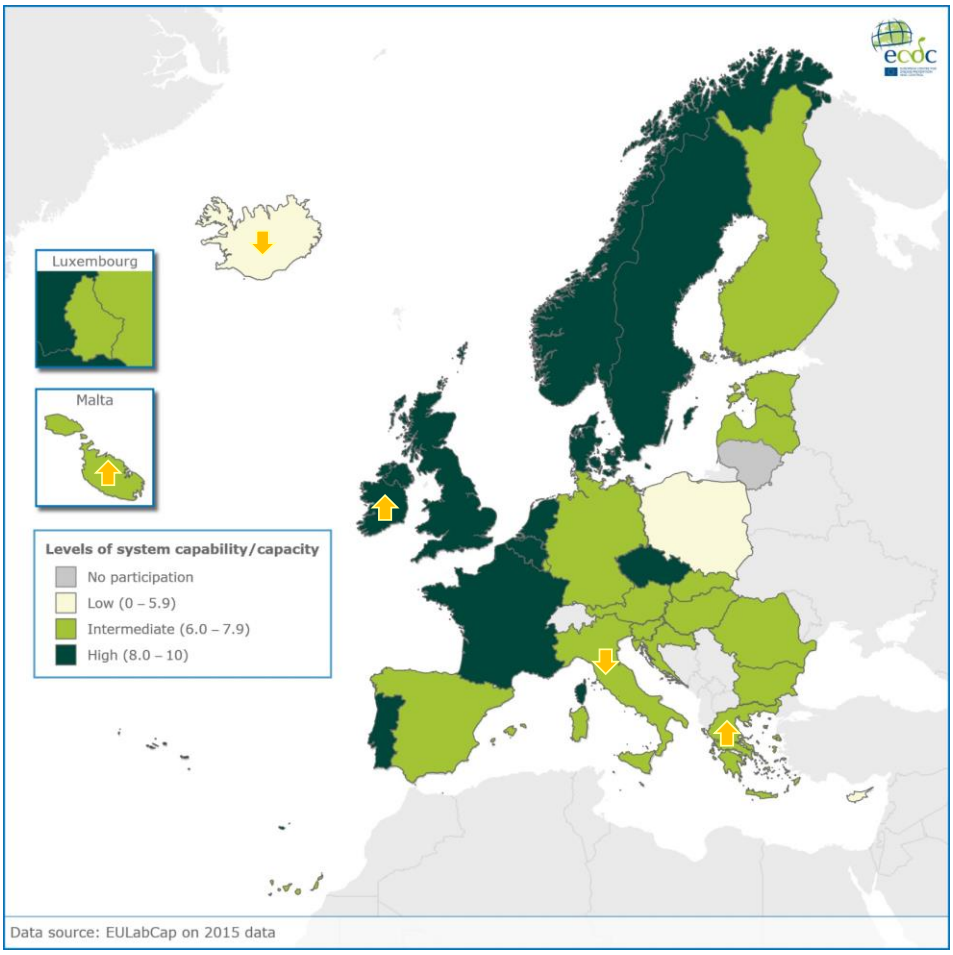
Target 3.4. (Re)-emerging disease laboratory preparedness and response support. Over the years, the up-to-date diagnostic capability for rare and (re)emerging diseases improved in the EU/EEA, with half of the countries reaching a high level of capability in 2015. The diversity between the countries decreased over time, as indicated by the narrowing IQR.

Laboratory capabilities and capacities at country level

As in previous years, the country EULabCap index showed substantial variation. In 2015, country scores ranged from 5.6 to 9.6 in 2015. This represents a narrowing interval compared with the 2014 country score range from 5.0 to 9.5 (Figure 3 and 4).

The map in Figure 10 shows the geographical distribution of overall system capability and capacity performance (low, intermediate and high) in EU/EEA countries (Lithuania did not report data for 2015).

Figure 10. Average level of public health microbiology system capabilities and capacities, EULabCap index 2015 (N=29 countries)



Note: Arrows indicate transition to higher/lower level in 2015 compared with 2014.

Between 2014 and 2015, three countries (Greece, Ireland and Malta) reached a higher level of system capability and capacity, whereas two countries (Iceland and Italy) scored lower (Figure 10). The EU/EEA country performance level for 12 targets is shown in Annex 6.

As with the overall country scores, there was also substantial variation within each of the countries in the target index scores distribution. The individual radar graphs for each EU/EEA country (Annex 7) display the geometric shape which links target index scores for each EU/EEA country (2014 and 2015). There is a noticeable imbalance in the performance scores across targets in a number of countries.

Most countries show a consistent pattern in their capacity profiles. The changes observed between 2014 and 2015 were less marked than the ones observed for some of the countries in 2013 and 2014. As in 2014, there is still a number of countries in 2015 with a noticeable imbalance in the performance scores across targets (Annex 7).

For the first time in this report, the number of countries with sufficient capacity, as outlined in the ECDC strategic multiannual programme 2014–2020, was measured. In 2015, 20/29 countries had reached a sufficient level of public health microbiology capacity, defined as reaching an EULabCap index score of at least 6 (i.e. 'intermediate') for at least 10 of 12 microbiology system targets. This result meets the target set for 2020 in the ECDC strategic multi-annual programme 2014–2020.

Indicator score distribution for 2015

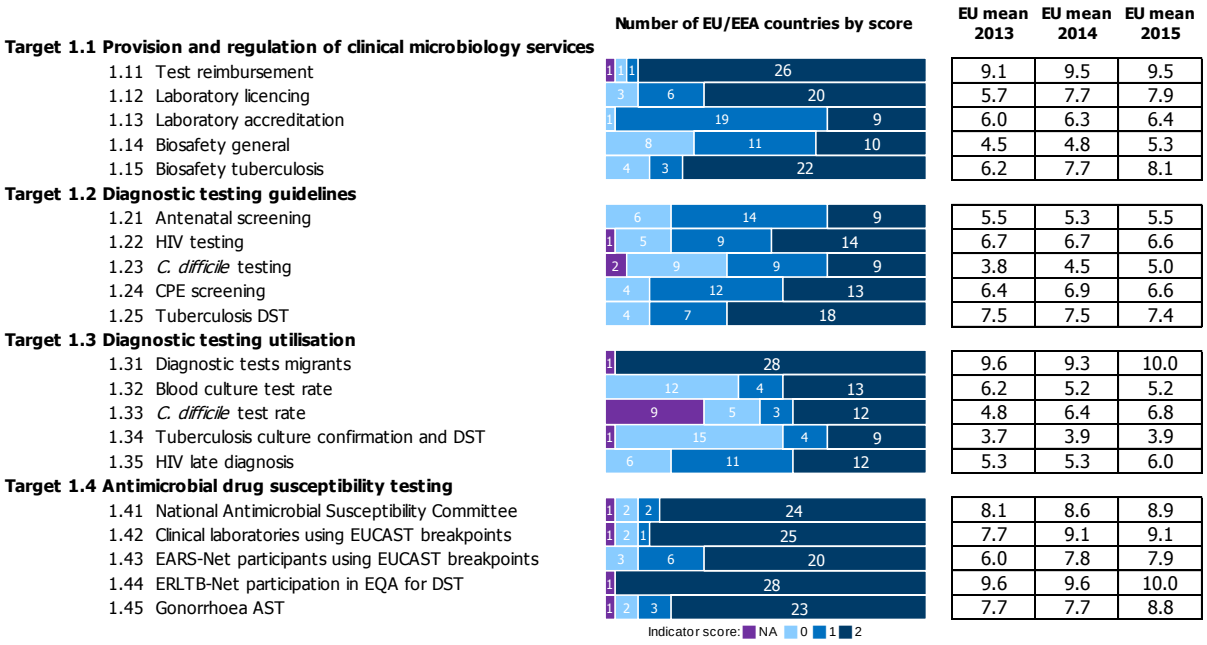
A detailed analysis of the 2015 distribution of national scores per indicator (primary diagnostic testing, NRL, and laboratory-based surveillance and epidemic response support) is presented in Figures 11, 12 and 13. Results indicate the strengths and weaknesses in specific technical areas. For each dimension the EU mean scores per indicator are compared for 2013–2015 to explore possible early trends.

Primary diagnostic testing

Figure 11 shows the distribution of country scores for the 20 indicators on primary diagnostic testing in 2015 and the EU/EEA mean scores per indicator for 2013–2015.

In 2015, primary diagnostics indicators (quality accreditation of laboratories; biosafety regulations; guidance for, and use of, diagnostic testing) scored low across the EU/EEA. The score for several indicators increased over time, e.g. for clinical laboratory licencing, biosafety, *C. difficile* testing guidelines and testing practice, HIV testing, and antibiotic susceptibility testing (Figure 11). Other indicators showed no notable progress, with stable score distribution and unchanged mean scores in 2013–2015 (Figure 11; see also Figure 7).

Figure 11. EU/EEA distribution of 2015 results by country for the 20 EULabCap indicators on primary diagnostic testing and mean scores, 2013–2015



Note: For 2014 and 2015, the score for Indicator 1.33 was calculated by ECDC based on raw data; the 2013 score was based on self-scoring.

In 2015, EU/EEA capacity was good in several primary diagnostic testing areas: more than 90% of the responding countries publicly funded or reimbursed clinical microbiology tests, and all countries offered testing for HIV infection and tuberculosis to undocumented migrants. Antimicrobial susceptibility testing reached a high level of capability/capacity in most EU/EEA countries. Standardisation of antibiotic susceptibility testing was well advanced, with more than 80% of the countries having established a National Antimicrobial Susceptibility Committee (NAC) and EUCAST breakpoints being used for interpretive reporting of antibacterial drug susceptibility testing results in the majority of the clinical laboratories. The proportion of EU/EEA countries providing susceptibility data on gonorrhoea cases increased to 80% of all countries in 2015, compared with 63% in 2014 (Figure 11).

Gaps remained for certain indicators on diagnostic testing and drug susceptibility accessibility. For instance, less than half of the EU/EEA countries reached a susceptibility testing rate of 80% for new culture-confirmed tuberculosis cases in 2015. Even though more countries reported the CD4 cell counts of newly diagnosed HIV cases to TESSy, less than half of the cases were diagnosed early across the EU/EEA in 2015 (Figure 11).

National reference laboratory services

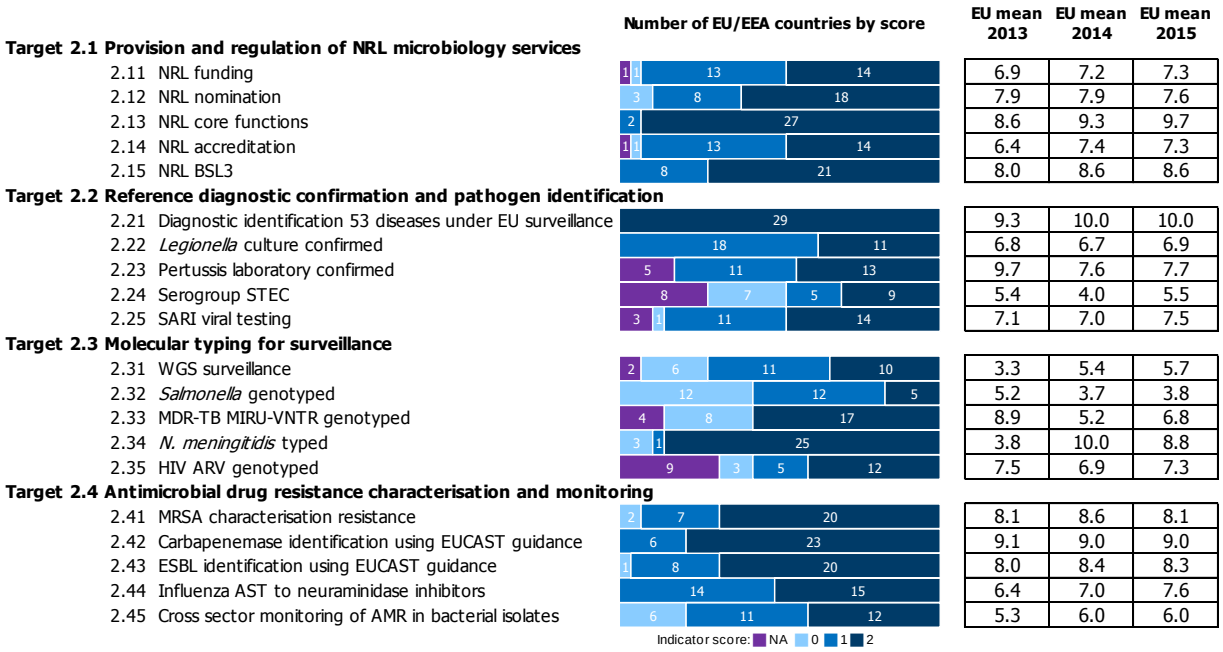
Figure 12 shows the national scores for the 20 indicators on national reference laboratory services in 2015 and the EU/EEA mean scores per indicator for 2013–2015.

In 2015, as in previous surveys, indicators regarding the provision and regulation of national reference services, indicators on capabilities for diagnostic confirmation, and indicators on capacity for antimicrobial drug resistance monitoring showed intermediate or high scores, whereas capacity indicators on difficult-to-detect pathogen confirmation and the use of molecular typing data for national or EU level surveillance in general scored lower (Figure 12, see also Figure 8).

Several mean scores for NRL indicators increased over time, e.g. on NRL funding, the delivery of core public health functions, test accreditation, diagnostic identification of EU-notifiable diseases, monitoring of influenza virus susceptibility to neuraminidase inhibitors, and use of WGS-based typing for national surveillance (Figure 12). Other

indicators showed no notable progress, with stable score distribution and mean scores in 2013–2015 (Figure 12; see also Figure 8).

Figure 12. EU/EEA distribution of 2015 scores by country for the 20 EULabCap indicators on national reference laboratory services and mean scores, 2013–2015



Notes:
Indicator 2.13: ECDC-calculated score, based on raw data (2014 and 2015); the 2013 score was based on self-scoring.
Indicator 2.24: Modified formula to include non-typeable STEC strains in the numerator (2014 and 2015); data were collected at the national level by NMFPs (2015) or retrieved as reported to ECDC (2013 and 2014).
Indicator 2.34: Modified formula to include partial typing results in the numerator (2014 and 2015).
Indicator 2.35: CDC-calculated score, based on raw data (2014 and 2015); the 2013 score was based on self-scoring.

The survey showed a disparity of capability/capacity levels between EU/EEA countries in the area of molecular typing of pathogens for surveillance, as measured by the indicators in the three surveys (Figure 12). Many indicators are based on data which were reported to TESSy and therefore do not measure the national typing capacity but the capacity shared at the EU surveillance level. In this fast moving area, some indicator scores increased while others decreased between the survey years. The most remarkable change in 2015 was the introduction of whole genome sequencing-based typing in routine surveillance (one human pathogen or more) by ten EU/EEA countries. In 2014, eight countries introduced WGS-based typing, while in 2013 no country had done so. In 2015, an additional 11 countries had plans to introduce WGS-based typing for national surveillance.

Other capacity indicators that showed increasing scores were noted for gene sequence-based typing of *Neisseria meningitidis* isolates (based on a partial/full European Meningococcal Society (EMGM) typing scheme) and of HIV for ARV resistance testing. The improving scores for the typing of *Neisseria meningitidis* isolates were in part due to relaxing the indicator criterion in 2014. By contrast, indicators on the EU reporting of 'fingerprinting' data showed low/decreasing scores for genotyping of *Salmonella enterica* isolates by PFGE or MLVA and intermediate capacity for typing of MDR-*Mycobacterium tuberculosis* by MIRU-VNTR. In fact, more countries reported MDR TB typing data to TESSy over the years (17 countries in 2015), even though the EU mean score fluctuated by a dilution effect as it measures the national sampling fraction of cases. The proportion of EU/EEA countries reporting data to TESSy on influenza virus drug susceptibility rose from 40% in 2014 to 52% in 2015.

In 2015, EU/EEA countries had a high capacity for case confirmation and pathogen identification (EU case definitions), covering more than 35 of the 53 EU-notifiable communicable diseases (Figure 12) [15]. In-house confirmation capability was reported by all EU/EEA countries for a total of 28 high-priority and/or epidemic-prone diseases (Table 2). For rare diseases or agents (e.g. rabies, yellow fever, or smallpox) which require specialised testing facilities, materials, and know-how, identification capability was available either domestically or by outsource testing agreements with other countries. In 2015, three countries, compared with four countries in 2014, were reporting no capability for diagnostic confirmation and pathogen identification for poliovirus and viral haemorrhagic fever viruses (Table 2).

Table 2. Number of EU/EEA countries in 2015 reporting diagnostic confirmation and pathogen identification testing available in the country for the 53 communicable diseases listed in Decision 2012/506/EU

Disease/health issue	Number of countries (N=29)
ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS) AND HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION	29
AVIAN INFLUENZA A/H5 OR A/H5N1 IN HUMANS	
CAMPYLOBACTERIOSIS (*Campylobacter* spp.)	
CHOLERA (*Vibrio cholerae*)	
GIARDIASIS (*Giardia lamblia*)	
GONORRHOEA (*Neisseria gonorrhoeae*)	
HAEMOPHILUS INFLUENZAE, INVASIVE DISEASE (*Haemophilus influenzae*)	
HEPATITIS A (Hepatitis A virus)	
HEPATITIS B (Hepatitis B virus)	
HEPATITIS C (Hepatitis C virus)	
INFLUENZA (Influenza virus)	
INFLUENZA A (H1N1)	
LEGIONNAIRES' DISEASE (*Legionella* spp.)	
LISTERIOSIS (*Listeria monocytogenes)*	
MALARIA *(Plasmodium* spp.*)*	
MEASLES (Measles virus)	
MENINGOCCOCAL DISEASE, INVASIVE (*Neisseria meningitidis*)	
PERTUSSIS (*Bordetella pertussis)*	
PNEUMOCOCCAL INVASIVE DISEASE(S) (*Streptococcus pneumoniae)*	
RUBELLA (Rubella virus)	
SALMONELLOSIS (*Salmonella enterica* other than *Salmonella* Typhi and *S.* Paratyphi)	
SHIGELLOSIS (*Shigella* spp.)	
SYPHILIS (*Treponema pallidum*)	
SYPHILIS, CONGENITAL AND NEONATAL (*Treponema pallidum)*	
TOXOPLASMOSIS, CONGENITAL (*Toxoplasma gondii)*	
TUBERCULOSIS (*Mycobacterium tuberculosis* complex)	
TYPHOID/PARATYPHOID FEVER (*Salmonella* Typhi/Paratyphi)	
YERSINOSIS (*Yersinia enterocolitica, Y. pseudotuberculosis*)	
BRUCELLOSIS (*Brucella* spp.)	28
CHLAMYDIAL INFECTION (*Chlamydia trachomatis*) INCLUDING LYMPHOGRANULOMA VENEREUM (LGV)	
CRYPTOSPORIDIOSIS (*Cryptosporidium* spp.)	
DIPHTHERIA (*Corynebacterium diphtheriae, C. ulcerans* and *C. pseudotuberculosis*)	
MUMPS (Mumps virus)	
RUBELLA, CONGENITAL (including Congenital Rubella Syndrome)	
STEC/VTEC INFECTION (Shiga toxin/verocytotoxin-producing *Escherichia co*li)	
ANTHRAX (*Bacillus anthracis)*	27
ECHINOCOCCOSIS (*Echinococcus* spp.)	
LEPTOSPIROSIS (*Leptospira* spp.)	
TULARAEMIA (*Francisella tularensis*)	
PLAGUE (*Yersinia pestis*)	26
POLIOMYELITIS (Polio virus)	
Q FEVER (*Coxiella burnetii*)	
SEVERE ACUTE RESPIRATORY SYNDROME — SARS (SARS-coronavirus, SARS-CoV)	
TETANUS (*Clostridium tetani*)	
TICK-BORNE ENCEPHALITIS (TBE virus)	
TRICHINELLOSIS (*Trichinella* spp.)	
VIRAL HAEMORRHAGIC FEVERS (VHF viruses)	
BOTULISM (*Clostridium botulinum*)	25
WEST NILE FEVER (West Nile virus)	
RABIES (Lyssa virus)	24
CREUTZFELDT-JAKOB DISEASE, VARIANT (vCJD)	22
YELLOW FEVER (Yellow fever virus)	21
SMALLPOX (Variola virus)	17

Among remaining gaps in NRL services noted in 2015, full NRL access to biosafety level-3 facilities was not available in eight countries, and quality accreditation of reference tests was required in only half of the EU/EEA countries.

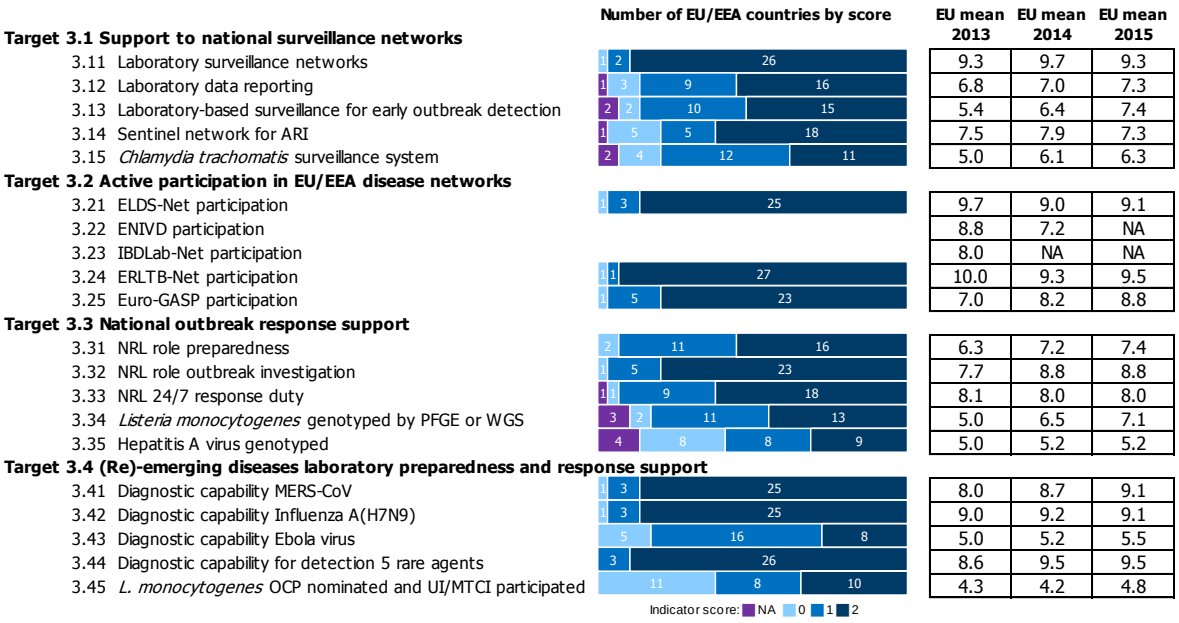
Laboratory-based surveillance and epidemic response support

Figure 13 shows the distribution of national scores for the 20 indicators on laboratory-based surveillance and epidemic response support in 2015 and the mean scores per indicator for 2013–2015.

Overall, indicators on laboratory contribution to national and EU surveillance networks, outbreak detection and response support, and preparedness and response for (re-)emerging diseases, showed intermediate to high levels of capability/capacity in 2015, as in the previous years (Figure 13; see also Figure 9).

The mean scores of several indicators increased over the last few years, for example in the areas of laboratory support to national surveillance and outbreak detection, the use of EU harmonised methods for *C. trachomatis* surveillance, participation in the Euro-GASP network, and detection capabilities for MERS-CoV and other emerging viral pathogens (Figure 13). All three indicators on active participation in EU disease networks received high marks in 2013–2015, but due to an interruption of activities in the IBD-LabNet and ENIVD networks, participation could not be assessed; in addition, some indicators were 'not applicable' in 2014–2015 (Figure 13).

Figure 13. EU/EEA distribution of 2015 results by country for the 20 EULabCap indicators on laboratory-based surveillance and epidemic response support and mean scores, 2013–2015



Notes
Indicator 3.22: Indicator was not applicable in 2015 due to service interruption.
Indicator 3.23: Indicator was not applicable in 2014 and 2015 due to partial service interruption.
Indicator 3.34: Modified in 2014 and 2015 to include improved typing (WGS).
Indicator 3.44: Due to service interruption, 2014 data were used as a proxy for the 2015 survey.

In 2015, as in previous surveys, most countries received strong performance scores for the operation of national sentinel surveillance networks, with 90% of all EU/EEA countries reporting collaboration between reference laboratories and national networks of clinical laboratories for more than five diseases or AMR pathogens under surveillance. However, despite improving capabilities over the years, 16 countries still reported low scores for the automation of microbiology data reporting to national surveillance databases in 2015.

In 2015, laboratory-based outbreak detection and response support was good to excellent. Regular analysis of microbiology data on rate exceedance or cluster detection was implemented for national outbreak detection in 25 countries. Analyses were performed on a weekly basis in 15 countries in 2015, compared with 12 in 2014, and only seven in 2013. While the number of countries genotyping *Listeria monocytogenes* at the national level increased from 21 to 24 between 2014 and 2015, only 10 were actively participating in *Listeria monocytogenes* typing data exchange for cross-border outbreak detection and response. Twenty-three countries involved NRL experts in over 25% of national outbreak investigation teams in 2015, but only 18 countries had a 24/7 NRL response support duty team in place for assisting the national outbreak teams. Likewise, 16 countries reported that

NRLs had defined roles and responsibilities in national preparedness plans that were tested in simulation exercises that year (Figure 13).

In 2015, some technical areas for the characterisation of epidemic-prone pathogens were rather weak, e.g. national capacities for hepatitis A cluster detection by molecular typing and characterisation of Ebola virus, which was only available in those eight countries that have biosafety level-4 virology facilities (Figure 13).

Country use of EULabCap reports and follow-up actions

Between August 2015 and April 2016, 25 countries replied to the feedback survey on the use of the EULabCap 2013 report. Twenty-three of 25 countries (92%) found the individual country reports that were produced as part of the 2013 EULabCap useful for advising their national authorities. In the majority of the countries, both the main report and the country reports were disseminated. Results were mainly discussed with microbiologists and epidemiologists but half of the countries communicated the reports to decision makers (Table 3).

Table 3. Summary results of the feedback survey on dissemination and use of the EULabCap 2013 reports (N=25 EU/EEA countries, May 2016)

Type of activity	Country profile report only	EU/EEA report only	Both reports	Total
Discussed with microbiologists involved in public health	4	1	13	**18**
Communicated to decision makers	1	2	12	**15**
Discussed with infectious disease epidemiologists	2	1	9	**12**
Shared/made available nationally	2	2	5	**9**
Other way(s) of dissemination	1	0	2	**3**
Translated into national language (partially or fully)	0	0	0	**0**
Did not disseminate the report(s)				**2**

Sixteen countries reported one or more follow-up actions in response to technical areas of attention that were pointed out in country-specific EULabCap reports (shared in August 2015) while six reported no follow-up activity until the full survey was launched in April 2016. The number of follow-up actions during the eight month follow-up period varied significantly between countries, ranging from one to six (Table 4).

Table 4. Follow-up actions taken between August 2015 and May 2016 on areas of attention in as indicated by the 2013 EULabCap country reports (N=22 countries)

Areas of attention which were followed up	Individual replies	Total
Regulation of NRL services (e.g. appointments and operations)		**6**
Resource allocation to NRL services (e.g. funding, staffing, equipment)		**6**
Clinical laboratory accreditation		**5**
Biosafety regulation and monitoring		**5**
NRL accreditation		**5**
Sharing molecular typing data via TESSy		**4**
Diagnostic testing guidance development		**4**
Regulation of clinical microbiology laboratories		**3**
Other follow-up actions		**2**
Automation of reporting laboratory data to public health surveillance databases		**2**
Diagnostic testing guidance compliance measurement		**2**
Diagnostic test use rate measurement (priority diseases)		**2**
Involvement of NRL experts in national outbreak investigations		**1**
No follow-up		**6**

Discussion

Monitoring process

The EULabCap is the first initiative to measure and monitor the microbiology laboratory capabilities and capacities that are required to ensure effective communicable disease surveillance and epidemic preparedness at the EU- and country levels. Developing and applying a new indicator framework with a common terminology and taxonomy of public health microbiology services was essential to the success of the EULabCap methodology. The remarkable 97% country response rate (with only one EU country not participating), and 96% data completeness in 2015 illustrate the commitment of the NMFPs to a robust monitoring process.

EU public health microbiology capacities

The average 2015 EULabCap index score of 7.5 (on a scale of 0–10) confirms that the EU/EEA on the whole has a strong public health microbiology system, with substantial capacity for communicable disease detection, surveillance, risk assessment, and response requirements. After a detailed analysis of trends at the indicator and target levels, we think that the observed increase in the EU/EEA average EULabCap index from 6.9 in 2013 to 7.3 in 2014 to 7.5 in 2015 likely represents progress of the technical and organisational capacities of the laboratory systems in the Member States. A small part of this score increase in the EU, however, is an artefact caused by minor changes in the scoring methodology after the first survey and the non-participation of one country in the third survey. The 2015 EULabCap index score would be slightly lower (7.4) if we used 2014 data from the non-participating country as a proxy for the missing 2015 missing data.

The two-fold variation in the EULabCap index by country found in all the surveys indicates substantial inequality in public health microbiology capacity across the EU/EEA. While a gradual reduction in this disparity is suggested by the fact that six countries improved their performance level in 2014 (and a further three in 2015), these early trends remain to be confirmed. In 2015, two countries reverted to a lower level of system capability/capacity, a change which was related to more complete reporting of indicators in one country and to decreased laboratory contributions to outbreak response in the other.

Although it is debatable what exactly constitutes 'sufficient' capacity, it is encouraging to note that 19 EU/EEA countries would have reached 'sufficient' public health microbiology capacity in 2015 if measured by reaching an intermediate or high capacity level for at least 10 of 12 EULabCap targets (Annex 8).

Strengths and vulnerabilities

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

In the first survey in 2013, the EU/EEA median EULabCap index was lowest scores in the primary diagnostic testing dimension, reflecting gaps in clinical laboratory service provision and regulation within national healthcare systems. It is encouraging to see that these scores substantially increased over subsequent surveys. Specific improvements in primary diagnostic testing included licencing of clinical microbiology laboratories, biosafety regulations, tuberculosis diagnostics, *Clostridium difficile* testing guidance, improved access to HIV and tuberculosis testing for migrants, external quality assessment for tuberculosis drug susceptibility testing, and gonococcal antimicrobial susceptibility testing. Several of these improvements were guided by updated European expert diagnostic testing guidance, adoption of EU harmonised laboratory-based surveillance protocols, and a variety of technology transfer and quality assurance activities carried out in EU laboratory networks supported by ECDC and the EU Health Programme [16-23].

The steadily improving capacity of the Member States for harmonised antimicrobial drug susceptibility testing reflects the efforts for a wider implementation of the susceptibility breakpoints established by the European Committee on Antimicrobial Susceptibility Testing (EUCAST) in collaboration with national antimicrobial susceptibility committees (NACs). In 2015, the vast majority of EU/EEA countries have established a NAC and enabled most clinical laboratories to use EUCAST breakpoints for the interpretation of susceptibility testing results. Joint efforts are underway to ensure that all EU/EEA countries will have access to the guidance of a NAC to fully implement EUCAST methods and standards. Harmonised practice permits a better comparison of antimicrobial resistance data collected across the EU/EEA, in accordance with the EU case definitions. These achievements are in

line with the EU and global-policy focus on combating antimicrobial resistance and a testimony to quality improvement of clinical laboratory practice across Europe through professional leadership [24,25]. However, laboratories face new challenges, for example detecting the rapid emergence (and monitoring the spread) of new multidrug- and pandrug-resistant human and zoonotic pathogens, which is particularly worrying with regard to gram-negative bacteria [26-28]. Therefore, improved laboratory detection and characterisation methods are needed for the timely and accurate surveillance of antimicrobial resistance [26-28]. In this context, the EULabCap results are extremely encouraging because they show that all EU/EEA countries have the capability to identify carbapenemase production in gram-negative bacteria and that 23 countries applied this capability to national monitoring surveys in 2015. This directly relates to the EuSCAPE study on Carbapenemase-producing bacteria in Europe [29], which should be repeated based on WGS technology. Progress can also be seen in the integrated ('one health') surveillance of antimicrobial resistance across health sectors: a majority of EU/EEA countries perform cross-sector monitoring of antimicrobial resistance in human and animal isolates, but only less than half of them published an annual integrated one health report in 2015.

The EULabCap index highlighted the good EU/EEA overall capacity for NRL services (lowest inter-country variance of all explored system dimensions) and showed the further convergence of country scores over the years. This supports the observation of convergence of national public health practices after decades of collaboration across the EU. Areas of potential improvement in 2015 include service sustainability and quality assurance, with less than half of the EU/EEA countries reporting public funding of their NRL services; also, national test accreditation in 2015 was only required by less than half of all countries. Nevertheless, core public health functions were covered by almost all NRLs in 2015. Since 2014, all EU/EEA countries declared having access to a range of diagnostics for specific agents, which is required to meet obligations for EU surveillance reporting. There were only a handful of rare diseases or high-consequence pathogens requiring specialised containment facilities for which countries relied on third party arrangements. Increasing capacity was observed for reference diagnostics and characterisation of viruses of public health importance, genotyping of HIV viruses for antiretroviral resistance, and the testing of influenza virus for resistance to neuraminidase inhibitors. More countries had guidelines and reference virological testing available for investigating severe acute respiratory infections (SARI) clusters. A majority of EU/EEA countries also declared having a strong capacity for diagnosis and characterisation of emerging agents, such as avian influenza virus A(H7N9), MERS-CoV, and rare and/or imported viruses. This observation is consistent with the results of dedicated activities in the field of laboratory preparedness and response in Europe, including those supported by ECDC and the EU Health Programme [30]. Since diagnostic capability for other (re-)emerging infectious diseases (e.g. Zika virus infection, Lyme disease, infections with new strains of multidrug-resistant bacteria or fungi) is not covered by EULabCap, ad hoc surveys should be undertaken within EU networks to rapidly appraise the detection capacity in Europe if a public health event is caused by a new agent [31].

In the area of molecular typing, scores for typing capacity were expected to be low because the integration of molecular typing data into EU surveillance is still in its early stages (voluntary reporting during the period 2012–13). Despite minor updates to the classification criteria, indicators of typing coverage were difficult to measure as technology is in rapid flux and indicators need to be reviewed as monitoring progresses. A key system innovation highlighted by the EULabCap results is the shift towards the use of whole genome sequencing for public health surveillance of communicable diseases and antimicrobial resistance. In 2015, ten EU/EEA countries reported the use of whole genome sequencing-based typing for the routine surveillance of at least one human pathogen, compared with eight countries in 2014 and none in 2013. An additional 11 countries were planning to introduce whole genome sequencing-based typing for surveillance purposes. This massive method shift across the EU/EEA over only three years is consistent with the transition plan proposed in an ECDC Expert Opinion on whole genome sequencing for public health surveillance published in 2016 [32]. This innovation requires meticulous capacity monitoring at the EU level and close collaboration with Member States to ensure a smooth transition as outlined by the ECDC roadmap on WGS for public health surveillance [32,33]. WGS-based typing was successfully used in 2016 by Member States and ECDC to investigate and resolve cross-border outbreaks of salmonellosis, STEC infection, MDR tuberculosis and surgical device-related *Mycobacterium chimaera* prosthesis infection [34-39].

Regarding laboratory-based surveillance and epidemic response support, the EU/EEA index increased in 2015. The majority of countries scored high on indicators of national sentinel laboratory-based surveillance. However, despite gradual improvement over the years, many countries still scored low or medium for indicators of rapid microbiology data reporting and cluster detection capability. This finding indicates untapped opportunities for applying IT solutions to automate data transfer and analysis for improving efficiency and timeliness of laboratory-based surveillance and alert systems in EU/EEA countries. Specific improvements were noted in laboratory data reporting and data analysis for early outbreak detection, *Chlamydia trachomatis* surveillance, participation in Euro-GASP, diagnostic capability for emerging pathogens, and the contribution of NRLs to preparedness and outbreak response. The latter two laboratory contributions, however, remain underutilised in a significant minority of countries where they deserve further interinstitutional integration efforts.

Finally, scoring EU networking activities also revealed both strengths and vulnerabilities. Whereas NRL participation in ECDC disease-specific laboratory networks was consistently at a high level due to a longstanding EU collaboration between laboratory scientists and public health specialists, several EULabCap indicators could not be

measured over time as a result of discontinuous ECDC support to key networks, which points at the issue of sustainable long-term operational support. A cost–benefit analysis of the EU reference laboratory networks concluded that the benefits of maintaining an overarching system of EU reference laboratory networks are likely to outweigh the costs, both from a Member State and from an EU perspective [40].

Impact of EULabCap in the Member States

To estimate the impact of EULabCap reports on the policy agenda in the Member States, a 2016 survey on the use of the 2013 EULabCap country reports showed that the majority of NMFPs found the reports useful, and more than half shared them with decision makers in the country. The majority also reported one or more follow-up actions within six months of the reports. National regulatory changes (e.g. funding, accreditation and regulation of clinical and/or reference laboratories) were the most frequently reported actions. ECDC will continue to monitor how NMFPs communicate the EULabCap results to national decision makers and if medium-term follow-up actions are taken.

Limitations

EULabCap survey methods have several limitations. Firstly, some indicators have variable country relevance, such as those on information sharing within a national network, which applies mainly to the larger countries. Similarly, some capacity indicators on laboratory-confirmed cases may not apply to smaller countries due to low disease incidence.

Secondly, about two-thirds of the indicators are of a self-reporting nature and thus liable to some degree of subjective interpretation by national experts collecting the information. External validation of capabilities, for example by means of external quality assessments (EQAs) and simulation exercises, would be helpful to address this limitation [31,32,41-43].

Thirdly, data access was not universal, and some NMFPs were unable to provide data for all indicators. This could be related to the lack of an active data collection instrument, a lack of designated NRLs for specific diseases, outsourcing of some 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 overestimation of country system performance. Furthermore, EULabCap country scores do not necessarily reflect the laboratory capacity throughout the country. The assessment of laboratory capacity may be correct for small countries or countries with centralised services but not for countries with decentralised services of heterogeneous capacity across subnational regions. Quantitative capacity indicators of primary diagnostic testing utilisation were particularly challenging and onerous to measure, leaving room for variation in data accuracy and representativeness between countries.

Finally, data comparability over time was slightly hampered by classification bias due to minor modifications of a limited number of indicators/scoring criteria, and the fact that respondents had to first familiarise themselves with questionnaire administration. The requirement since 2014 to provide absolute numerator and denominator data to enable capacity score calculation by ECDC, instead of self-scoring by the NMFP, reduced room for individual interpretation and improved transparency. The quality of the data improved and indicator scoring became more consistent over the years. Thus, the first analysis of secular trends as attempted in this report should be interpreted with caution considering that only three annual datasets were available and longitudinal comparability was imperfect.

Conclusions

The results of the third EULabCap annual survey confirmed that the EU/EEA on the whole, with an aggregated index score of 7.5 out of 10 for 2015, can rely on a public health microbiology system with strong overall capability and substantial capacity to fulfil EU surveillance and response requirements.

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

Substantial inter-country variation in system capability and capacity remains present across the EU/EEA in 2015. Available evidence suggests a certain degree of convergence between countries and overall improvement over time. In 2015, specific improvements that are unlikely to be explained by indicator modifications and/or the non-participation of one country, were found in the following technical areas:

- Primary diagnostic testing: medical laboratory licensing, biosafety regulation and safe tuberculosis diagnostic practice, *Clostridium difficile* testing guidance, accessible testing of migrants for HIV and tuberculosis, early HIV diagnosis, participation in EQAs for tuberculosis drug susceptibility testing, and gonococcal antimicrobial susceptibility testing.
- National reference laboratory (NRL) services: NRL delivery of core public health functions, severe acute respiratory infection (SARI) viral diagnostic testing guidance, HIV genotyping for antiretroviral dug resistance, influenza virus susceptibility monitoring to neuraminidase inhibitors, and application of whole genome sequencing to national surveillance.
- Laboratory-based surveillance and epidemic response support: automated laboratory data reporting to national surveillance system, laboratory-based outbreak detection, *Chlamydia trachomatis* surveillance, Euro-GASP participation, NRL role in epidemic preparedness, *Listeria monocytogenes* genotyping and participation in EU molecular surveillance/cluster detection, and NRL diagnostic capability for emerging pathogens.

EULabCap 2015 monitoring data will be disseminated for review by competent bodies and policymakers at the EU and national levels. ECDC will continue its monitoring of the European laboratory capacity as basis for future country support and capacity building activities, in collaboration with the EU/EEA countries, the European Commission and other EU agencies and partners. Feedback from the NMFPs showed that EULabCap reports are useful at the national level. Moreover, in half of the countries a number of focus areas was targeted for capacity building actions after EULabCap feedback. The usefulness of the EULabCap monitoring system will be further evaluated by systematically collecting NMFP feedback on the use of reports for action at national level.

An action plan is being developed to ensure full EU capacity with regard to the identification, monitoring, assessment and response to infectious diseases, particularly those posing a significant cross-border threat. ECDC will optimise its laboratory support activities, including EQAs, to assess and promote the quality of disease/antimicrobial resistance monitoring and responsiveness to infectious threats. Moreover, ECDC will continue to appraise technological developments in microbiology and facilitate appropriate innovation by sharing of best practices and supporting the integration of harmonised genomic data in Member States and ECDC surveillance systems.

References

1. Centers for Disease Control and Prevention. Public Health Preparedness Capabilities: National Standards for State and Local Planning. 2011. USA: CDC; [109-18]. Available from: https://www.cdc.gov/phpr/capabilities/dslr_capabilities_july.pdf.
2. Witt-Kushner J, Astles JR, Ridderhof JC, Martin RA, Wilcke B, Downes FP, et al. Core Functions and Capabilities of State Public Health Laboratories: A Report of the Association of Public Health Laboratories. Morbidity and Mortality Weekly Report (MMWR). 2002 September 20;51(RR14):1-8.
3. European Centre for Disease Prevention and Control. Coordination Competent Bodies: structures, interactions and terms of references. Stockholm ECDC; 2012. Available from: http://ecdc.europa.eu/en/aboutus/governance/competent-bodies/documents/coordinating-competent-bodies-structures-terms-of-reference-and-interactions-w-annexes.pdf.
4. European Centre for Disease Prevention and Control. Updated public Health Microbiology Strategy and Work Plan 2012-2016. Stockholm: ECDC; 2011. Available from: http://ecdc.europa.eu/en/healthtopics/microbiology/Documents/1203_updated-ECDC-public-health-microbiology-strategy-work-plan-2012-2016.pdf.
5. European Centre for Disease Prevention and Control. Core functions of microbiology reference laboratories for communicable diseases. Stockholm: ECDC; 2010. Available from: http://ecdc.europa.eu/en/publications/Publications/1006_TER_Core_functions_of_reference_labs.pdf.
6. European Centre for Disease Prevention and Control. ECDC strategic multi-annual programme 2014–2020: Stockholm; 2014. Available from: http://ecdc.europa.eu/en/aboutus/Key%20Documents/Strategic-multiannual-programme-2014-2020.pdf
7. European Centre for Disease Prevention and Control. EU Laboratory Capacity Monitoring System (EULabCap) - Report on 2013 survey of EU/EEA capabilities and capacities. Stockholm: ECDC; 2016. Available from: http://ecdc.europa.eu/en/publications/Publications/EU-laboratory-capability-monitoring-system-2013.pdf.
8. European Centre for Disease Prevention and Control. EU Laboratory Capacity Monitoring System (EULabCap) - Report on 2014 survey of EU/EEA capabilities and capacities. Stockholm: ECDC; 2016. Available from: http://ecdc.europa.eu/en/publications/Publications/laboratory-capability-monitoring-2014-eu-labcap.pdf.
9. Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC Text with EEA relevance (2013).
10. World Health Organization. International Health Regulations Second ed. Geneva: WHO; 2005.
11. The Organisation for Economic Co-operation and Development. Health at a Glance: Europe 2014. Paris: OECD Publishing; 2014. Available from: http://www.oecd.org/health/health-at-a-glance-europe-23056088.htm.
12. European Commission. Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European Centre for disease prevention and control. Official Journal L 1422004 p. 0001 - 11.
13. European Centre for Disease Prevention and Control. Fostering collaboration in public health microbiology in the European Union. Stockholm ECDC; 2010. Available from: http://ecdc.europa.eu/en/publications/Publications/1012_TER_Fostering_collaboration.pdf
14. European Commission. Call for tender no Chafea/2014/Health/06 concerning the study on cost-benefit analysis of reference laboratories for human pathogens Luxembourg: EC/CHAFEA; 2011. Available from: http://cordis.europa.eu/news/rcn/30157_en.html.
15. European Commission. Decision No 2012/506/EU of the Commission of 8 August 2012 amending Decision 2002/253/EC laying down case definitions for reporting communicable diseases to the Community network under Decision No 2119/98/EC of the European Parliament and of the Council (notified under document C(2012) 5538) 2012. Available from: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:262:0001:0057:EN:PDF.
16. European Centre for Disease Prevention and Control. ECDC supported laboratory network activities 2017. Available from: http://ecdc.europa.eu/en/healthtopics/microbiology/microbiology-activities/Pages/Networks.aspx

17. European Centre for Disease Prevention and Control. HIV testing: increasing uptake and effectiveness in the European Union. Available from: https://www.cdc.gov/phpr/capabilities/dslr_capabilities_july.pdf.

18. European Committee on antimicrobial suceptibility testing. EUCAST Guidance Documents in susceptibility testing 2016. Available from: http://www.eucast.org/ast_of_bacteria/guidance_documents/.

19. European Centre for Disease Prevention and Control. Molecular typing for surveillance of multidrug-resistant tuberculosis in the EU/EEA 2016. Available from: http://ecdc.europa.eu/en/publications/Publications/multidrug-resistant-tuberculosis-molecular-typing-surveillance.pdf.

20. Crobach MJ, Dekkers OM, Wilcox MH, Kuijper EJ. European Society of Clinical Microbiology and Infectious Diseases (ESCMID): data review and recommendations for diagnosing *Clostridium difficile*-infection (CDI). Clin Microbiol Infect. 2009 Dec;15(12):1053-66.

21. QUANDHIP project. Quality Assurance Exercises and Networking on the Detection of Highly Infectious Pathogens 2017. Available from: http://www.emerge.rki.eu/Emerge/EN/Content/Quandhip/quandhip_node.html.

22. European Centre for Disease Prevention and Control. ECDC roadmap for integration of molecular typing into European-level surveillance and epidemic preparedness 2013. Available from: http://ecdc.europa.eu/en/publications/Publications/molecular-typing-EU-surveillance-epidemic-preparedness-2013.pdf.

23. European Centre for Disease Prevention and Control. Response plan to control and manage the threat of multidrugresistant gonorrhoea in Europe 2012. Available from: http://ecdc.europa.eu/en/publications/publications/1206-ecdc-mdr-gonorrhoea-response-plan.pdf.

24. Kahlmeter G. Defining antibiotic resistance-towards international harmonization. Ups J Med Sci. 2014 May;119(2):78-86.

25. Brown D, Canton R, Dubreuil L, Gatermann S, Giske C, MacGowan A, et al. Widespread implementation of EUCAST breakpoints for antibacterial susceptibility testing in Europe. Euro Surveill. 2015;20(2).

26. European Centre for Disease Prevention and Control. Plasmid-mediated colistin resistance in *Enterobacteriaceae.* Stockholm: ECDC; 2016. Available from: http://ecdc.europa.eu/en/publications/Publications/enterobacteriaceae-risk-assessment-diseases-caused-by-antimicrobial-resistant-microorganisms-europe-june-2016.pdf.

27. European Centre for Disease Prevention and Control. Carbapenem-resistant *Acinetobacter baumannii* in healthcare settings. Stockholm: ECDC; 2016. Available from: http://ecdc.europa.eu/en/publications/Publications/8-Dec-2016-RRA-Acinetobacter%20baumannii-Europe.pdf.

28. Skov RL, Monnet DL. Plasmid-mediated colistin resistance (mcr-1 gene): three months later, the story unfolds. Euro Surveill. 2016;21(9).

29. Albiger B, Glasner C, Struelens MJ, Grundmann H, Monnet DL, European Survey of Carbapenemase-Producing *Enterobacteriaceae* working group. Carbapenemase-producing *Enterobacteriaceae* in Europe: assessment by national experts from 38 countries, May 2015. Euro Surveill. 2015;20(45).

30. Nisii C, Vincenti D, Fusco FM, Schmidt-Chanasit J, Carbonnelle C, Raoul H, et al. The contribution of the European high containment laboratories during the 2014-2015 Ebola Virus Disease emergency. Clin Microbiol Infect. 2017 Feb;23(2):58-60.

31. Pereyaslov D, Rosin P, Palm D, Zeller H, Gross D, Brown CS, et al. Laboratory capability and surveillance testing for Middle East respiratory syndrome coronavirus infection in the WHO European Region, June 2013. Euro Surveill. 2014;19(40):20923.

32. European Centre for Disease Prevention and Control. Expert Opinion on whole genome sequencing for public health surveillance. Stockholm, 2016. Available from: http://ecdc.europa.eu/en/publications/_layouts/forms/Publication_DispForm.aspx?List=4f55ad51-4aed-4d32-b960-af70113dbb90&ID=1555.

33. European Centre for Disease Prevention and Control. ECDC roadmap for integration of molecular and genomic typing into European-level surveillance and epidemic preparedness 2016. Available from: http://ecdc.europa.eu/en/publications/Publications/molecular-typing-EU-surveillance-epidemic-preparedness-2016-19-roadmap.pdf.

34. European Centre for Disease Prevention and Control. Multi-country outbreak of *Salmonella* Enteritidis PT8 infection, MLVA type 2-10-8-5-2, associated with handling of feeder mice. Stockholm: ECDC; 2016. Available from: http://ecdc.europa.eu/en/publications/_layouts/forms/Publication_DispForm.aspx?List=4f55ad51-4aed-4d32-b960-af70113dbb90&ID=1609.

35. European Centre for Disease Prevention and Control/ European Food Safety Authority. Multi-country outbreak of Shiga toxin-producing *Escherichia coli* infection associated with haemolytic uraemic syndrome, 5 April 2016 2016. Available from: http://ecdc.europa.eu/en/publications/Publications/RRA-Escherichia-coli-O26-Romania-Italy-April2016.pdf.

36. European Centre for Disease Prevention and Control. Re-emerging multi-country WGS-defined outbreak of *Salmonella* Enteritidis, MLVA type 2-12-7-3-2 and 2-14-7-3-2, 3 February 2017. Stockholm: ECDC; 2016. Available from: http://ecdc.europa.eu/en/publications/Publications/rapid-risk-assessment-WGS-defined-outbreak-Salmonella-Enteritidis-3-feb-2017.pdf.

37. European Centre for Disease Prevention and Control. Invasive cardiovascular infection by *Mycobacterium chimaera* associated with the 3T heater-cooler system used during open-heart surgery. Stockholm: ECDC; 2016. Available from: http://ecdc.europa.eu/en/publications/_layouts/forms/Publication_DispForm.aspx?List=4f55ad51-4aed-4d32-b960-af70113dbb90&ID=1605.

38. European Centre for Disease Prevention and Control. Extensively drug-resistant (XDR) tuberculosis – multi-country cluster, Romania. Update, 21 October 2016. Stockholm: ECDC; 2016. Available from: http://ecdc.europa.eu/en/publications/Publications/RRA-xdr-tuberculosis-romania-october-2016.pdf.

39. European Centre for Disease Prevention and Control. Extensively drug-resistant (XDR) tuberculosis – multi-country cluster, Romania. 19 October 2016. Stockholm: ECDC; 2016. Available from: http://ecdc.europa.eu/en/publications/Documents/RRA-xdr-tuberculosis-romania-19-october-2016.pdf.

40. European Commission. Study on cost-benefit analysis of reference laboratories for human pathogens 2016. Available from: http://ec.europa.eu/health/sites/health/files/preparedness_response/docs/2016_laboratorieshumanpathogens_frep_en.pdf.

41. European Centre for Disease Prevention and Control. Fourth External Quality Assessment Scheme for typing of verotoxin-producing *E. coli* (VTEC) Stockholm ECDC; 2014. Available from: http://ecdc.europa.eu/en/publications/Publications/4th-External-Quality-Assessment-typing-of-verocytotoxin-producing-E.-coli-VTEC-web.pdf.

42. European Centre for Disease Prevention and Control. External quality assurance scheme for diphtheria diagnostics. Stockholm: ECDC; 2013. Available from: http://ecdc.europa.eu/en/publications/Publications/diphtheria-external-quality-assessment-2012.pdf.

43. Both L, Neal S, De Zoysa A, Mann G, Czumbel I, Efstratiou A, et al. External quality assessments for microbiologic diagnosis of diphtheria in Europe. J Clin Microbiol. 2014 Dec;52(12):4381-4.

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 <95% DST of cultures, 2 = ≥80% culture confirmed AND ≥95% DST of cultures.

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 are used EUCAST 2013 clinical breakpoints for interpretive reporting of antibacterial drug susceptibility testing results to clinicians.	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	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 2015 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.

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. *according to the laboratory criteria described in the Case definitions of the Decision 2012/506/EU).	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%.

Targets/indicators	Source (NMFP/ECDC) and scoring options
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.	NMFP 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 in 2015=** **Number of new HIV cases reported in 2015=** **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%.
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.

Targets/indicators	Source (NMFP/ECDC) and scoring options
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%.
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 EULabCap targets: key capabilities/capacities

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

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

Indicator	Reference documents	Hyperlink
1.15	WHO Tuberculosis laboratory biosafety manual	http://www.who.int/tb/publications/2012/tb_biosafety/en/
	European Union Standards for Tuberculosis Care	http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3393116/pdf/erj-39-04-807.pdf
	Framework Action Plan to fight tuberculosis in the European Union	http://ecdc.europa.eu/en/publications/publications/0803_spr_tb_action_plan.pdf
1.22	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 2014: Results, impact and opportunities; WHO in partnership with UNICEF and UNAIDS	http://www.who.int/hiv/pub/global-update.pdf
	Global health sector strategy on HIV/AIDS 2011-2015 Dublin declaration on Partnership to fight HIV/AIDS in Europe and Central Asia	http://www.unicef.org/ceecis/The_Dublin_Declaration.pdf
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, 2013	http://ecdc.europa.eu/en/publications/_layouts/forms/Publication_DispForm.aspx?List=4f55ad51-4aed-4d32-b960-af70113dbb90&ID=1329
2.11	Core functions of microbiology reference laboratories for communicable diseases	http://www.ecdc.europa.eu/en/publications/Publications/1006_TER_Core_functions_of_reference_labs.pdf
2.12	Core functions of microbiology reference laboratories for communicable diseases	http://www.ecdc.europa.eu/en/publications/Publications/1006_TER_Core_functions_of_reference_labs.pdf
2.13	Core functions of microbiology reference laboratories for communicable diseases	http://www.ecdc.europa.eu/en/publications/Publications/1006_TER_Core_functions_of_reference_labs.pdf
2.14	Core functions of microbiology reference laboratories for communicable diseases	http://www.ecdc.europa.eu/en/publications/Publications/1006_TER_Core_functions_of_reference_labs.pdf
2.15	WHO laboratory biosafety manual	http://www.who.int/csr/resources/publications/biosafety/Biosafety7.pdf

Indicator	Reference documents	Hyperlink
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	External quality assurance scheme on PCR for *Bordetella pertussis*, 2012	http://www.ecdc.europa.eu/en/publications/Publications/20120906-TER-EQA-pertusis.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
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_gui_chlamydia_control_in_europe.pdf
3.21	ELDSNet	http://ecdc.europa.eu/en/activities/surveillance/eldsnet/pages/index.aspx
3.22	EVD-LabNet (former 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
	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. EU/EEA country survey on use of EULabCap reports and follow-up actions

The questionnaire on the feedback on dissemination and use of EULabCap reports on 2013 data was opened on 19 April until 27 May 2016 and included the following questions:

1. Country
2. How were the EULabCap reports (2013 data) disseminated in your country?

- Shared/made available nationally
- Translated into national language (partially or fully)
- Discussed with microbiologists involved in public health
- Discussed with infectious disease epidemiologists
- Communicated to decision makers
- Other way(s) of dissemination
- Did not disseminate the report(s)

3. Did you find the EULabCap individual country report (2013 data) useful?
4. Did you follow-up on any of the suggested areas of attention from the EULabCap individual country report (2013 data)?

- Clinical laboratory accreditation
- Sharing molecular typing data via TESSy
- NRL accreditation
- No follow-up action
- Regulation of clinical microbiology laboratories
- Biosafety regulation and monitoring
- Diagnostic testing guidance development
- Diagnostic test use rate measurement (priority diseases)
- Regulation of NRL services (e.g. appointments and operations)
- Involvement of NRL experts in national outbreak investigations
- Diagnostic testing guidance compliance measurement
- Resource allocation to NRL services (e.g. funding, staffing, equipment, etc.)
- Automation of reporting laboratory data to public health surveillance databases
- Other follow-up action(s)

5. In your opinion, which areas could ECDC develop new activities in addressing generic laboratory capacity/capability issues?
6. Any other questions or comments about the EULabCap reports (2013 data) dissemination/use or ECDC Country Support?

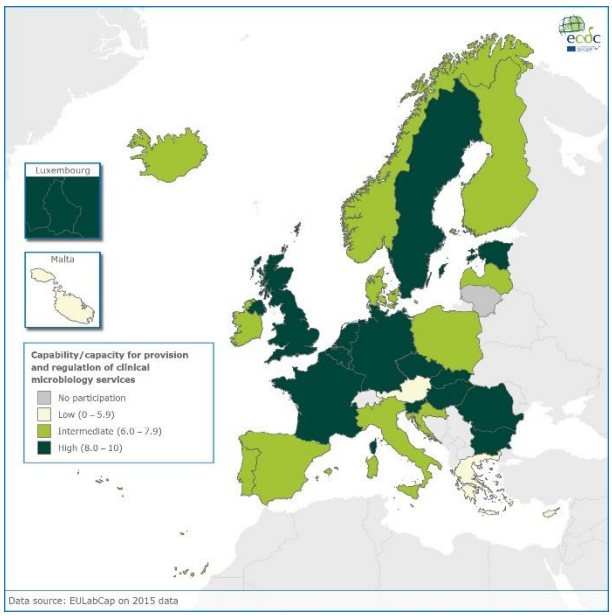
Annex 5. Data completeness, EULabCap surveys 2013–2015, by indicator

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

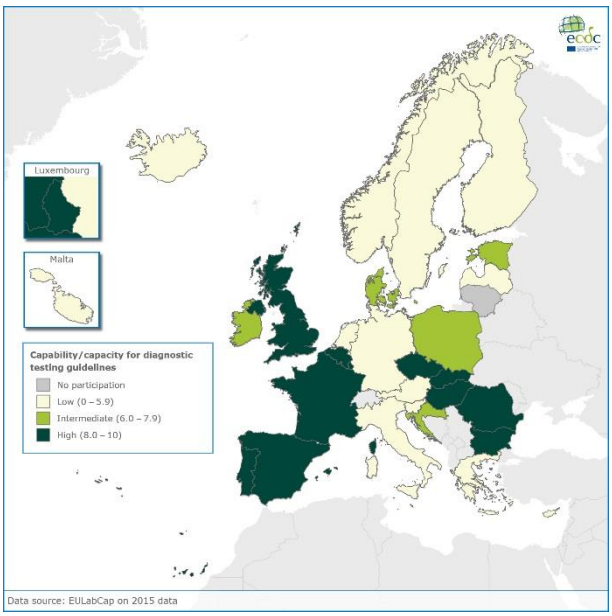
*Legend: AT (Austria), BE (Belgium), BG (Bulgaria), CY (Cyprus), DE (Germany), DK (Denmark), EE (Estonia), EL (Greece), ES (Spain), FI (Finland), FR (France), HR (Croatia), HU (Hungary), IE (Ireland), IS (Iceland), IT (Italy), LT (Lithuania), LV (Latvia), LU (Luxembourg), MT (Malta), NL (Netherlands),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

Annex 6. Maps of EULabCap target performance level by country

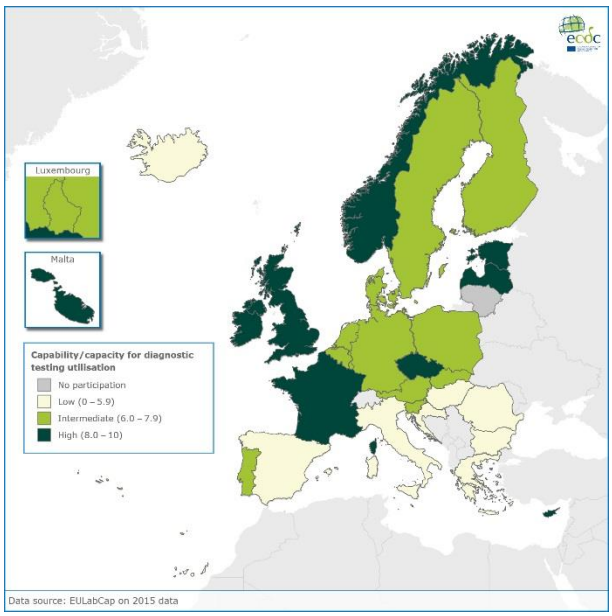
Target 1.1 Provision and regulation of clinical microbiology services



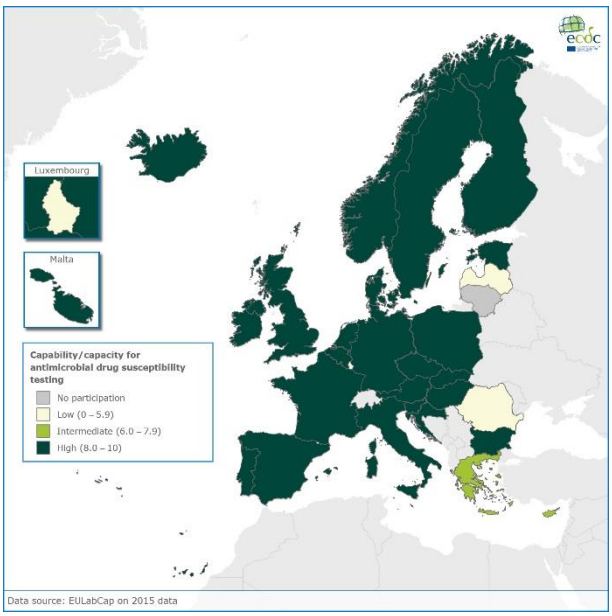
Target 1.2 Diagnostic testing guidelines



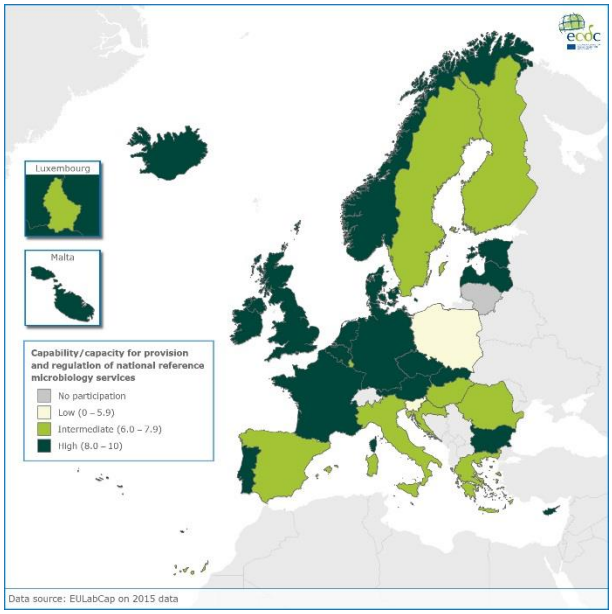
Target 1.3 Diagnostic testing utilisation



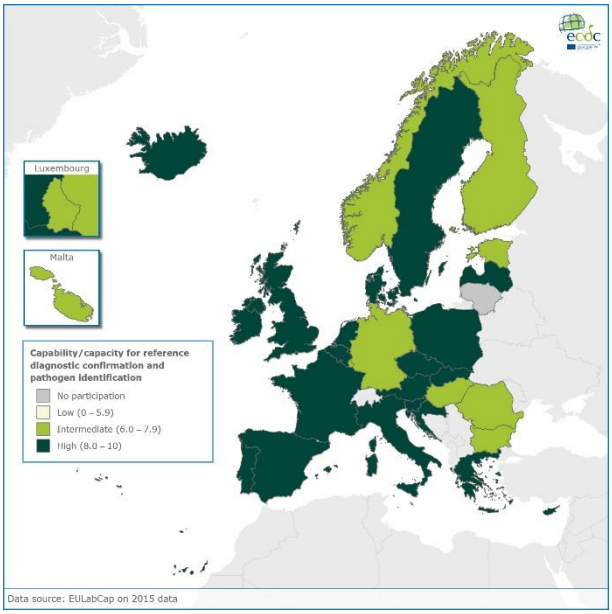
Target 1.4 Antimicrobial drug susceptibility testing



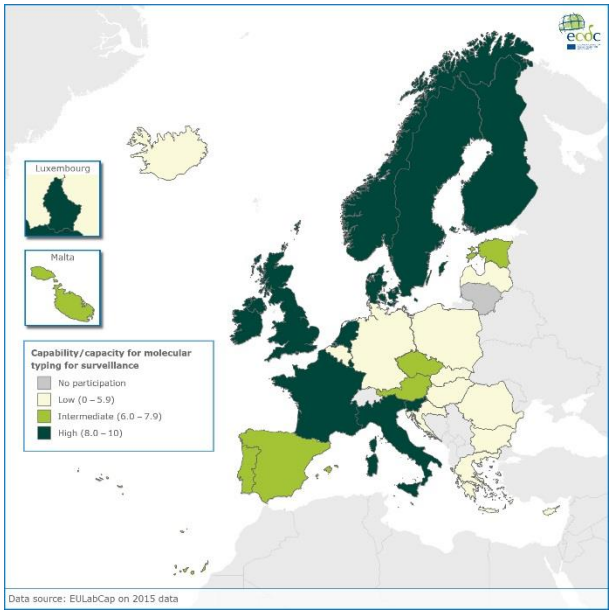
Target 2.1 Provision and regulation of national reference microbiology services



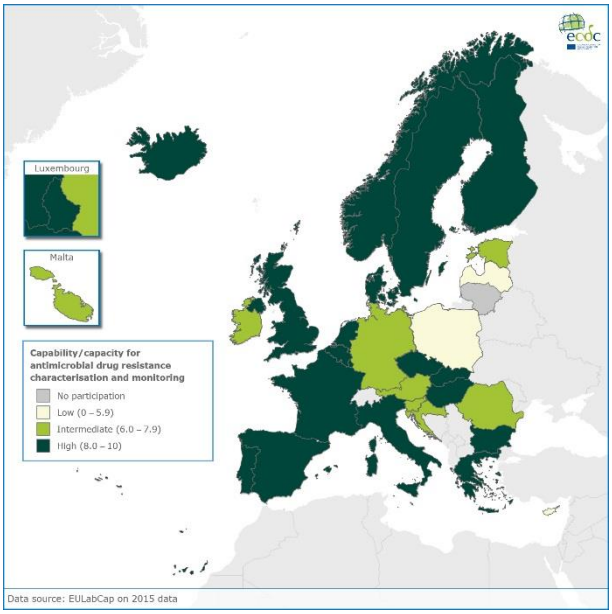
Target 2.2 Reference diagnostic confirmation and pathogen identification



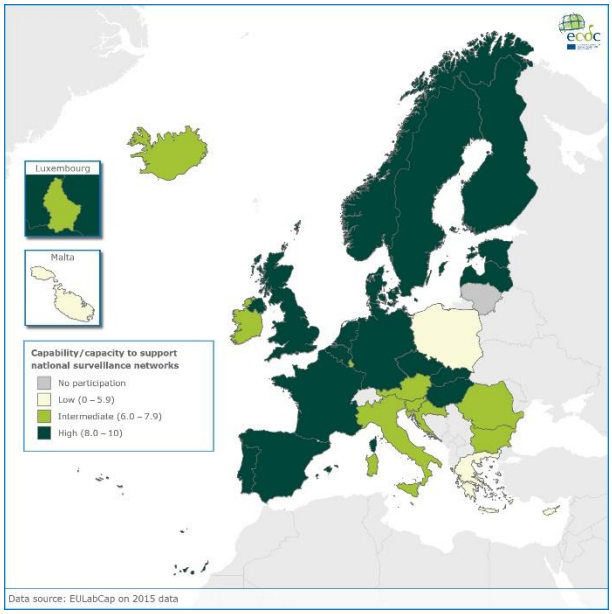
Target 2.3 Molecular typing for surveillance



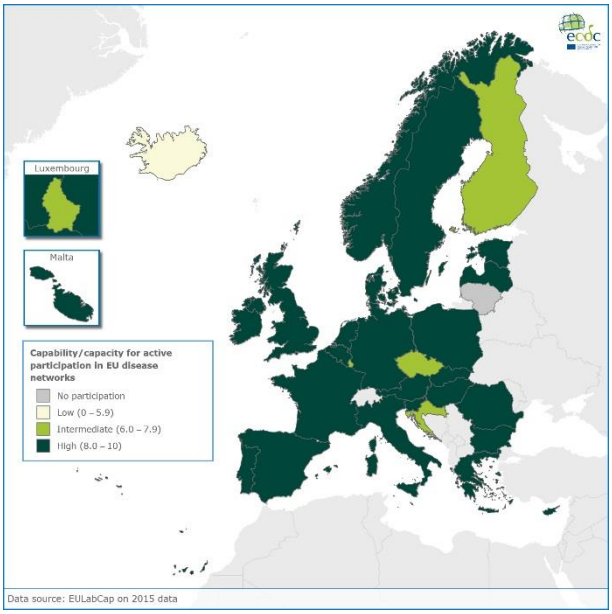
Target 2.4 Antimicrobial drug resistance characterisation and monitoring



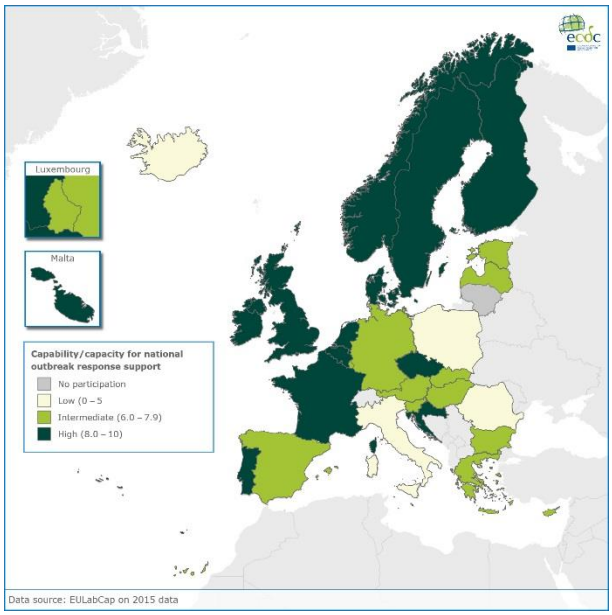
Target 3.1 Support to national surveillance networks



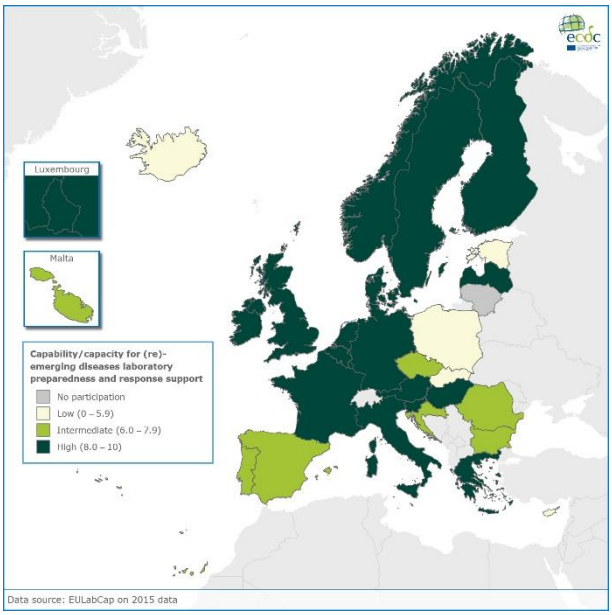
Target 3.2 Active participation in EU disease networks



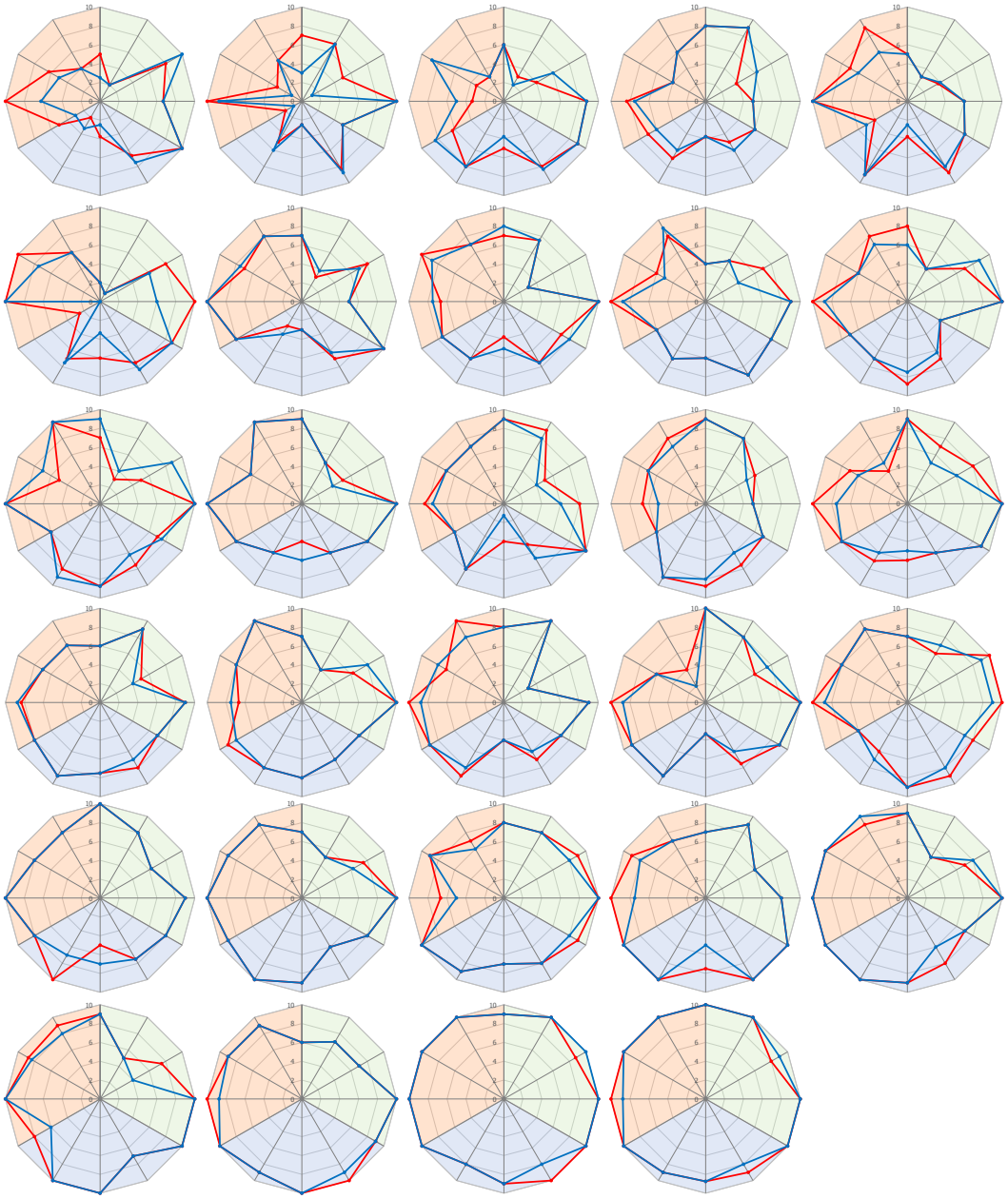
Target 3.3 National outbreak response support



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

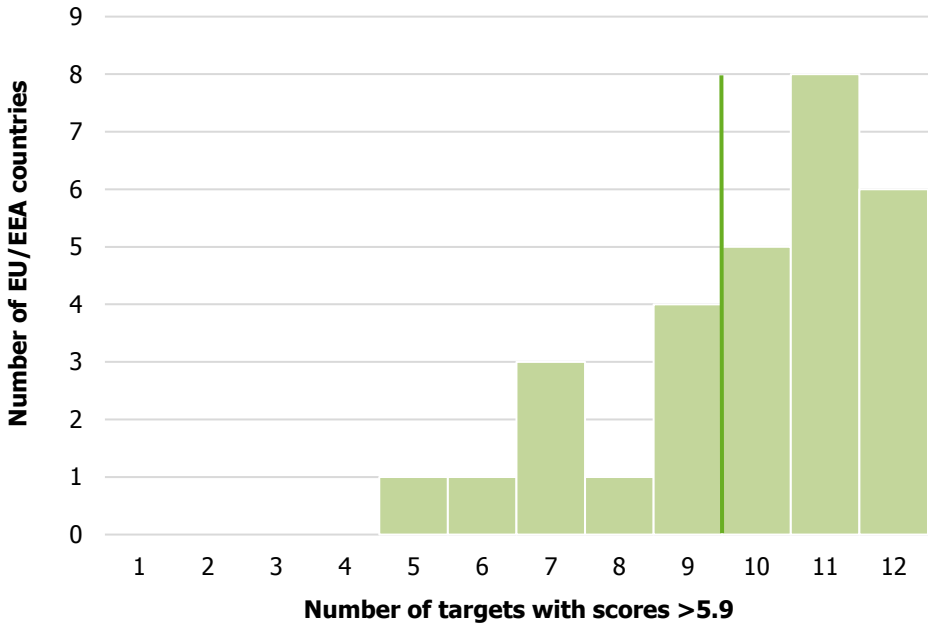


Annex 7. Radar graphs of EULabCap target index scores for each country, 2014 and 2015



Note: The radars are displaying the comparison of the EULabCap target index scores for each country between the 2015 indices (red line, N=29 EU/EEA countries), and the 2014 (blue line, N=30 EU/EEA countries) scores. The radars are ranked in ascending order of total index country score for 2015 from top left to bottom right.

Annex 8. Distribution of EU/EEA countries by number of targets with a score of 6 and above (intermediate level of capacity/capability)



European Centre for Disease Prevention and Control (ECDC)

Postal address:
Granits väg 8, SE-171 65 Solna, Sweden

Visiting address:
Tomtebodavägen 11A, SE-171 65 Solna, Sweden

Tel. +46 858601000
Fax +46 858601001
www.ecdc.europa.eu

An agency of the European Union
www.europa.eu

Subscribe to our monthly email
www.ecdc.europa.eu/en/publications

Contact us
publications@ecdc.europa.eu

Follow us on Twitter
@ECDC_EU

Like our Facebook page
www.facebook.com/ECDC.EU

ECDC is committed to ensuring the transparency and independence of its work

In accordance with the Staff Regulations for Officials and Conditions of Employment of Other Servants of the European Union and the ECDC Independence Policy, ECDC staff members shall not, in the performance of their duties, deal with a matter in which, directly or indirectly, they have any personal interest such as to impair their independence. Declarations of interest must be received from any prospective contractor(s) before any contract can be awarded.
www.ecdc.europa.eu/en/aboutus/transparency

HOW TO OBTAIN EU PUBLICATIONS

Free publications:

- one copy:
  via EU Bookshop (http://bookshop.europa.eu);
- more than one copy or posters/maps:
  from the European Union's representations (http://ec.europa.eu/represent_en.htm);
  from the delegations in non-EU countries (http://eeas.europa.eu/delegations/index_en.htm);
  by contacting the Europe Direct service (http://europa.eu/europedirect/index_en.htm) or
  calling 00 800 6 7 8 9 10 11 (freephone number from anywhere in the EU) (*).

  (*) The information given is free, as are most calls (though some operators, phone boxes or hotels may charge you).

Priced publications:

- via EU Bookshop (http://bookshop.europa.eu).

Publications Office