ECDC Meeting Report

International Relations Section / Director's Office

ECDC Multi-country workshop for EU enlargement countries on microbiology laboratory systems supporting public health

20-21 June 2017, Ohrid, the former Yugoslav Republic of Macedonia

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Executive summary

This report summarises the discussions and outcomes of ***ECDC Multi-Country Workshop for EU Enlargement Countries on Microbiology Laboratory Systems Supporting Public Health*** that took place on 20-21 June, 2017 in Ohrid. Nineteen representatives from Western Balkan countries and Turkey attended the meeting together with seven speakers and working group facilitators from the EU Member States (Austria, Belgium, Finland, Germany, Latvia, and Romania), two observers from Croatia and Bulgaria, one official from the European Commission, Directorate-General Health and Food Safety (DG SANTE), one representative from WHO Regional Office for Europe, and three officials from ECDC International Relations and Microbiology Coordination Sections.

National leaders in public health microbiology and epidemiology and National ECDC Correspondents reflected the work done by countries in reviewing and re-organising their national laboratory networks. They discussed the gaps at the national level including the reference laboratory functions, and shared their views on available expertise, to identify those laboratories that could potentially serve as reference laboratories for other countries in the region.

The meeting acknowledged that there high level political attention and recognition at decision-making level is needed for the commitment towards major upgrading of laboratory system to enhance patient management, patient safety, and public health. To reach these objectives a comprehensive strategy for the national microbiology laboratory system is needed, linked also to public health control programs. Learning from the best practices or models in the EU MS could facilitate strategic direction in the countries.

To address the sustainability of financial resources for microbiology laboratory services supporting public health there is an opportunity for innovative approaches such as de-directing resources through structural re-organisation, sharing of services between sectors, and cross-border collaboration.

Western Balkan countries and Turkey acknowledged that the EULabCap tool customised by ECDC for the use of EU enlargement countries (ENLabCap) (including individualised country reports with benchmarking against EU standards) could help them to promote necessary changes in national public health microbiology systems and initiate their implementation, as well as to advocate for sustainable financing mechanisms to ensure the delivery of reforms.

To guarantee that primary care physicians effectively use microbiological diagnostic tests, countries need to address key issues of availability of diagnostic and screening tests and raise physicians' awareness and understanding on the benefits of testing to the patient and to the public health. In addition, key areas/programs (including enteric disease/diarrhoea diagnostics, AMR testing for patient management and antibiotic policy guidance) require high quality support both from clinical and reference laboratories.

There is a need to clarify and better define licensing-accreditation processes and ensure that quality of laboratory services not only requires good coverage of EQAs, but also needs to be supported by infrastructure and trained personnel.

To increase capabilities for microbiology laboratory services and to develop them further, EU enlargement countries should ensure that formal agreements for collaboration are in place with relevant institutions within and outside the countries. They should also consider application of new and emerging microbiology laboratory methods and techniques.

Transportation of specimens and handling of samples of highly contagious agents is a common issue in the majority of EU Enlargement countries. To remedy this a regulatory framework for sample transfers is needed (within and outside the country), including e.g. the organisation of the transportation process, handling of specimens, and intergovernmental collaboration.

To implement the policies/strategies on microbiology laboratory systems including the necessary technical advancements it is essential to build partnerships and seek functional partners while ensuring the national commitment for sustainability.

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1 Background

EU enlargement countries (Albania, Bosnia and Herzegovina, Kosovo[1], Montenegro, Serbia, the former Yugoslav Republic of Macedonia, and Turkey) are the focus of ECDC technical assistance for non-EU/EEA countries since 2008. In the framework of the European Commission's Instrument of Pre-accession Assistance (IPA), experts from Western Balkan countries and Turkey have been regularly participating, together with EU/EEA Member State experts, in ECDC technical discussions on various topics related to communicable disease prevention and control, including public health microbiology systems.

In addition, upon request from the Commission, ECDC has assessed country capacities in the area of communicable disease prevention and control in Montenegro, Serbia, Turkey, and the former Yugoslav Republic of Macedonia. The countries' compliance and implementation of EU legislation, and availability of human resources for this were assessed to draw recommendations on reforms needed to meet essential public health system requirements as part of the accession process. In this regard, one of the six areas of assessment was national system of public health microbiology laboratories.

Problem overview

In 2013, during the ***ECDC Regional meeting on the participation of EU enlargement countries in the ECDC-coordinated European surveillance networks***, the senior surveillance leaders discussed challenges, perspectives, and needs for effective participation in the European indicator- and event-based surveillance networks. Among the key strategic issues for the development of communicable disease reporting and surveillance systems, the majority of countries acknowledged the importance and the challenge of:

1) **integrating microbiology services for public health with epidemiology services**, as well as laboratories in other sectors (e.g. environmental sector for FWD surveillance system), and to link and streamline laboratory reporting with the surveillance system;
2) **improving capabilities of public health reference laboratories** in terms of reporting system, diagnostic tests, and services; and
3) the **development and strengthening of national laboratory networks** to enhance public health systems.

The ***National ECDC Correspondents of the EU enlargement countries agreed in 2014*** that observer function in the National Microbiology Focal Points (NMFP) forum is a strong tool to strengthen public health microbiology in their respective countries and to raise awareness on its importance among national counterparts and decision makers. In addition, in response to the expressed interest from counterparts and in line with ECDC International Relations Policy 2014-2020, as of beginning of 2015 ECDC has been supporting the progressive integration of the EU enlargement countries into ECDC EPIS thematic platforms (starting with EPIS ELDSNet and EPIS FWD) and reporting surveillance data to TESSy in selected diseases/health issues in the context of ECDC technical pre-accession cooperation activities. Countries were also invited to submit indicator data of 2015 to the EU Laboratory Capability Monitoring System (EULabCap). The initial monitoring of countries' participation in ECDC systems revealed rather low level of activity in EPIS-FWD and EPIS-ELDSNet arguably due to, *inter alia*, **insufficient laboratory capability/capacity** (including for molecular typing methods) and lack of comparable data, including data necessary to reply to urgent inquiries or report laboratory data to ECDC.

The assessments of communicable diseases surveillance and control systems in four EU enlargement countries (Montenegro, Serbia, Turkey, the former Yugoslav Republic of Macedonia) suggests a common need to define and further strengthen public health microbiology laboratory system to attain adequate level of capability to provide timely and reliable information on pathogen detection and characterisation for effective infectious disease treatment, prevention, alert, and control. This means that the

[1] This designation is without prejudice to positions on status, and is in line with UNSCR 1244/1999 and the ICJ Opinion on the Kosovo declaration of independence

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roles of clinical microbiology laboratories serving mainly clinical decision making as well as public health laboratories are reviewed and redefined as necessary. One of the common areas for improvement was the need (i) to **review the primary clinical microbiology laboratory systems** to address gaps and limitations in capabilities and access to them; (ii) to **develop laboratories as an integrated system**, including defined programmes and logistics for referral of specimens from sub-national clinical microbiology laboratories, and to develop national guidance on good clinical and microbiology practice, and (iii) to **critically review reference laboratory (NRL) systems and functions**. Another generic system challenge evident across most of the assessed countries is the development and implementation of national surveillance case definitions able to be efficiently mapped according to EU reporting requirements. The surveillance systems sensitivity is not optimal and could be improved by developing clinical guidelines and laboratory testing algorithms for aetiological diagnosis of common infections. Developments were also generally needed in the range of the tests offered by primary clinical microbiology laboratories, including public health laboratories, and in the access to them, for both doctors and patients. The sustainability of the epidemiological and microbiological workforce is also a recurrent issue.

To address the sensitivity of surveillance systems and effective integration and use of EU case definitions, the use of surveillance information for public health purposes, and recognition, investigation, and management of outbreaks, key national stakeholders gathered in the ***ECDC Regional Seminar on Communicable Diseases Surveillance and Strategic Meeting of National ECDC Correspondents of EU enlargement countries*** in Budva, Montenegro, **in 2016**. Among other items, the representatives from the countries reiterated needs to:

- Improve the integration of **laboratory services in the surveillance system** (verification of the laboratory services by external quality schemes and decision to reallocate underused laboratory resources are necessary steps in majority of countries; EQA schemes for regional laboratories would be highly valuable)
- Develop or improve **national laboratory networks** (similarly to AMR). Countries should consider having at least one reference laboratory in each country with centralised capacity for advanced analyses (as the expertise may exist in the countries but is not known by adjoining countries, a regional workshop could be beneficial to identify the strengths of different reference laboratories and agree on shared expertise across countries)

As a follow up on the above mentioned regional discussions, National ECDC Correspondents, observer NMFPs, senior leaders of national epidemiology service and management called for a multi-country workshop on reference laboratories for the region to reflect on the current state-of-play, identify the strengths of different reference laboratories and agree on shared expertise across countries. This could imply that some laboratories would serve all countries in the region on a specific area of expertise.

Scope and purpose of the meeting

In light of the above, the overall aim of the ECDC regional multi-country workshop was to **reflect the work** done by countries **in reviewing and re-organising their national laboratory networks**; to **identify gaps** at the national level **related to the reference laboratory functions**, and to **agree on shared expertise** across countries, so that some laboratories could serve as reference laboratories for other countries in the region. It was also anticipated that the discussions during the Multi-country workshop will pave the way for further actions at country level and/or in collaboration with neighbouring national institutions in the long-term perspective to arrive at arrangements of multi-country reference laboratories serving the region.

Objectives

Specific objectives of the multi-country workshop were:

- to map the current state-of-play of the review and possible restructuring of the national public health laboratory networks in the countries (both clinical microbiology and public health laboratories, private and public);

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- to discuss the gaps identified and ways to address those gaps;
- to facilitate dialogue for identification of national and regional needs for specialist reference laboratory services and availability of shared expertise in the region; and
- to learn from good practices from the EU/EEA Member States and exchange experiences about solutions to similar public health microbiology challenges.

The agenda of the "*ECDC Multi-Country Workshop for EU Enlargement Countries on Microbiology Laboratory Systems Supporting Public Health"* is annexed to this report in Annex 1.

Participants

The target audience of this meeting was:

- National ECDC Correspondent
- Observer to the ECDC National Microbiology Focal Points forum
- Senior expert having leadership of the national communicable disease surveillance system – epidemiological management, design and development, preferably senior management of national public health institute or similar, if National Correspondent is not director of national public health institute (NPHI)

Nineteen representatives from Western Balkan countries and Turkey, seven speakers and working group facilitators from EU Member States (Austria, Belgium, Finland, Germany, Latvia, and Romania), two observers from Croatia and Bulgaria, one official from the European Commission, Directorate-General Health and Food Safety (DG SANTE), one representative from WHO Regional Office for Europe, and three officials from ECDC International Relations and Microbiology Coordination Sections gathered together in this regional ECDC event (List of participants, including reference to participation in the working group discussions, is available in Annex 2).

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2 Discussion

2.1 Update from the European Commission

Under the EU enlargement policy framework, the European Commission (DG SANTE) under Chapter 28 on Consumer and Health Protection is performing regular reviews of candidate countries' progress to meet EU accession requirements:

- Transposition of EU health acquis
- Implementation and enforcement of the EU health acquis
- Adequate administrative and institutional capacity

The Lisbon Treaty– in its Article 168 – introduced powers for the EU to take action to combat serious cross-border health threats, complementing national policies. The EU has adopted a Decision to improve preparedness planning for serious cross-border health threats across the EU and strengthen the capacity to coordinate response to health emergencies. To assist the EU by identifying and assessing the risk of current and emerging threats to human health posed by infectious diseases ECDC was set up through 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. There is a body of EU legislation on communicable diseases including soft acquis, such as resolutions, guidelines, Council decisions, best practices in EU Member States (*http://ec.europa.eu/health/index_en.htm*).

To assess existing administrative/institutional capacity, verify sustainability of the systems (financial and human resources), assess implementation of EU best practices, identify system strengths and weaknesses, as well as areas for further development and reforms, EC and ECDC performs assessments in the light of the EU enlargement policy framework. The overall aim of the EU enlargement countries' assessment and its follow-up activities is to support countries' progress towards meeting the closing benchmarks and be fully operational in the field of communicable diseases prevention and control. As an important follow-up step countries are invited to develop post-assessment Action Plans based on recommendations and generic challenges that are stated in the Technical Assessment Report (TAR).

When developing the Action Plan, a country is invited to select top priorities of the recommendations as they are considered an important precondition for the fulfilment of requirements to meet a closing benchmark in the field of public health. To meet a closing benchmark however, the wider set of recommendations needs to be adequately fulfilled or implementation of plans for fulfilment have started.

Crucial elements of the Action Plan for implementation of *EU acquis* and recommendations:

- Does the country have the **infrastructure** in place to implement the EU acquis and related recommendations?
- Does the country have the **administrative capacities**, including human resources, technical equipment and sustainable financing to implement the EU acquis and related recommendations?

EU standards requirements to be considered in the national Action Plan:

- **Surveillance of communicable diseases** as regards epidemiologic data on all diseases under the EU surveillance, their case definitions and reporting protocols,
- **Preparedness and response system** in epidemic intelligence and preparedness,
- **Institutional capacity** to timely provide comparable data and to participate in coordinated actions organized by ECDC and the EU.

The post-assessment country Action Plan shall include purpose, clear and measurable objectives, deadlines, responsible bodies for implementation of actions, financial resource allocation, outcome indicators, and monitoring and evaluation framework.

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EU financial instrument to support implementation of the national Action Plans is the Instrument of Pre-accession Assistance (IPA), however strong national government demand should be expressed as at the moment health is not among priority policy areas for financial assistance during the 2014-2020 financial perspective. Thus, Technical Assistance and Information Exchange instrument of the European Commission (TAIEX) could be used to address ad hoc need for legislative alignment with *EU acquis*, implementation of *EU acquis*, and sharing EU best practices (e.g. multi-country workshops, study visits and/or expert missions).

Progress in Closing Benchmark EU Common Position includes legislative and regulative framework, as well as wider set of TAR recommendations fulfilled or implementation planned/started.

Antimicrobial Resistance (AMR) is a priority for the Commission and a new EU Action Plan on AMR will be adopted on 29 June 2017. This follows the expressed commitment at the World Health Assembly (WHA) 2015 to develop strategy against AMR ensuring inter-sectoral cooperation: public health, animal health, food safety, environmental health. The Action Plan is underpinned by a One Health approach that addresses resistance in both humans and animals**.** In parallel, the Commission also adopted the first deliverable of the plan: EU Guidelines on the prudent use of antimicrobials in human health targeted to all actors including doctors, nurses, pharmacists, and hospital administrators.

2.2 Update from the WHO/Europe on public health laboratory system reforms in Eastern Europe and Asia

WHO Regional Office for Europe through its inter-sectoral initiative „Better Labs for Better Health“seeks to support national laboratory systems and improve laboratory management, thereby strengthening health systems and improving public health in the European region.

The initiative reflects the fact that the laboratory sector is one of the core capacities that countries must develop for the implementation of the IHR (2005), because laboratory services play a major role in all the key processes of detection, assessment, response, notification, and monitoring of events. It involves collaborative activities with Member States to:

- develop national laboratory policies and strategic plans;
- improve national training programmes and implement quality management systems;
- upgrade critical infrastructure such as teaching laboratories and external quality assessment programmes

Ukraine, Moldova, Uzbekistan, Turkmenistan, Kyrgyzstan, and Tajikistan currently participate in this initiative.

There is a large diversity of existing public health laboratory systems as countries differ in terms of factors defining delivery of public health functions by a network of public health laboratories. The design of the public health laboratory system is influenced by the capacity of the clinical and academic laboratories for public health events, the state organization (federal vs centralized), coordination mechanisms (central public health sector's interactions with regional and sub-regional (oblast) levels, with environmental labs, food safety sector), private sector involvement, financing and external funding (potential donors, recovering costs). Many countries are willing to reform their national public health laboratory systems looking at other countries' models and lessons learned.

It is suggested for redesigning of the laboratory network to take into account the list of priority diseases and defining the importance of each laboratory by the following evaluation criteria:

- ✓ Workload: the number of performed tests per working day per staff
- ✓ Geographical position of the lab: road access, population density surrounding, quantity of labs surrounding, proximity to health care, specific disease burden
- ✓ State and space of the lab facility: old facilities, and/or insufficient space require investments – to be considered

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- ✓ Equipment availability: if modern equipment, consider the investment

Representative from WHO/Europe invited experts from EU enlargement countries to express their interest to provide information for case studies on this initiative to demonstrate examples of efficient and well-functioning public health laboratory systems to participating countries from Eastern Europe and Central Asia.

The WHO Laboratory Assessment Tool offers guidance to assess laboratories and national laboratory systems and describes a general process for assessing laboratories and provides tools to help assess national laboratory systems and individual laboratories.

2.3 ECDC overview of core functions of microbiology reference laboratories for communicable diseases and monitoring laboratory capabilities and capacities at EU level

As agreed by consensus of opinion of the ECDC National Microbiology Focal Points (NMFP) forum, **public health microbiology** is a cross-cutting area of human, animal, food, water, and environmental microbiology, with focus on human health and disease. The EU public health microbiology system includes:

- National and EU networks for data sharing and method harmonisation and quality;
- National Reference Laboratories for specialised diagnostics and pathogen characterisation; and
- Clinical laboratories for diagnostics and drug susceptibility, as well as typing.

In its Technical Report on Core functions of microbiology reference laboratories for communicable diseases (June 2010), ECDC has defined **5 core functions** that include:

1. Reference diagnostics
2. Reference material resource
3. Scientific advice
4. Collaboration and research
5. Monitoring, alert, and response

Moreover, Study on cost-benefit analysis of reference laboratories for human pathogens (commissioned by the European Commission, 2016) suggests **additional functions of the EU reference laboratory networks**:

6. External quality assessment (to organise proficiency tests and inter-laboratory comparison for laboratories in the network)
7. Training (to undertake training activities for laboratories in the network and to provide scientific advice to sub-level laboratories)
8. Governance of the network (to administer and coordinate the network, as well as to ensure provision of IT tools where relevant)

To monitor key public health microbiology capabilities and capacity for EU surveillance and epidemic preparedness on an annual basis and to help policymakers of EU/EEA countries identify possible areas for action and evaluate the impact of capacity strengthening activities and health system reforms, ECDC together with its NMFP network developed the **EULabCap survey methodology**. Based on this tool ECDC annually collects data on 60 technical indicators to assess the capability and capacity of microbiology laboratories to provide essential public health functions that are grouped in 12 targets. The latest EU level of microbiology capabilities is reported in ECDC Technical Report on EU Laboratory Capability Monitoring System (EULabCap) with 2015 data. The tool with EU-level targets on national reference laboratory services (dimension 2) is used, *inter alia*, to monitor progress of EU/EEA countries towards ECDC strategy on whole genome sequencing for public health surveillance by 2020, which strives that:

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- within five years ECDC will have contributed to the establishment of standards and systems enabling the EU-wide use of WGS as the method of choice for typing of microbial pathogens, replacing other methods;
- this will improve the accuracy and effectiveness of disease surveillance, outbreak investigation and evaluation of prevention policies by enhanced assessment of disease and drug resistance transmission dynamics.

EULabCap data based on NMFP survey of 2016 suggests that number of countries the routinely apply WGS-based typing for national surveillance is annually increasing.

Observers to NMFP from EU enlargement countries were invited to **pilot collection of national 2015 data using the EULabCap monitoring tool**. In response to this invitation two countries participated: Serbia and the former Yugoslav Republic of Macedonia. As a result, ECDC:

- provided individual EULabCap country profile reports with comparison of their national capabilities to the EU/EEA countries;
- observed certain limitations of using EULabCap tool by EU enlargement countries (non-EU/EEA):
    - several indicators of the EULabCap monitoring system are established for the EU/EEA Member States and they are not currently applicable for the EU enlargement countries (e.g. indicators based on data reporting to TESSy or on participation in activities of EU disease networks),
    - the results of the pilot survey are solely based on self-scorings of the participating EU enlargement countries thus country profile reports shall be interpreted with caution and in close linkage to the outcomes of other relevant EC/ECDC assessments/evaluations,
- would be willing to know the level of interest from countries to use the EULabCap tool that is customized for EU enlargement countries (ENLabCap);
- could share the standardised indicator tool with other non-EU/EEA countries, if there is an interest to further adapt it for in-country needs or regional monitoring;
- could support EULabCap tool customisation (into ENLabCap) and data analysis, subject to availability of resources and strong interest from countries.

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2.4 Experiences and lessons learned from EU Member States

Microbiology support for public health programmes in Finland

Currently, there is a strong **interface between the Disease control programmes[2] and microbiology component of surveillance** in the National Institute for Health and Welfare of Finland (THL). However, it was a long process to arrive at this point redefining objectives and structures in the field of public health.

Development of microbiology in the 'National Institute' initially started some hundred years ago with small-scale diagnostics and vaccine production and gradually developed towards increased laboratory testing, public health research, and epidemiology with a public health objective. After key structural changes more than forty years ago, several regional laboratories were closed and others were converted into centres of reference with little or no routine laboratory services. This was to ensure that microbiology laboratories at 'Public Health Institute' only perform tests with a clear public health 'added value', and no routine clinical microbiology for patient management purposes are carried out. This resulted into significant increase in the number of original research articles in international journals, thus suggesting high scientific impact of such structural changes. Further on, there was a clear need to intensify coordination among small microbiology units and develop coordination mechanism between microbiology and epidemiology. As a result, this increased joint outbreak investigations, integration of IT systems, setting joint disease specific objectives for testing, as well as principles on how to use microbiological and epidemiological data in reporting and research. To support the integration of epidemiology and microbiology, organisational changes enabled experts in epidemiology and microbiology to work together in the same department as well as reduced resources for reference microbiology functions in the country.

Development of the clinical microbiology laboratories in health care services included mergers of publicly funded laboratories into larger units, dissociation of many of the hospital laboratories from the hospital organisation, and participation of larger laboratories in national and UK NEQAS EQA rounds.

National licensure system and EQA for clinical microbiology is based on the Communicable Disease Law, with the following key principles:

- patient safety
- quality of clinical microbiology tests results support communicable disease surveillance for public health
- accreditation alone does not ensure high quality

Application procedure for license is clearly described, license is usually valid for three years, and THL keeps the register of licensed laboratories. Licensure system has free access to all EQA results of all laboratories, which may trigger on-site inspections. These are also carried out annually either with a random sample of licensed laboratories or by a comprehensive regional inspection of all laboratories.

Development of the role of the microbiology laboratories in surveillance enabled and mandated all microbiologically confirmed cases to be registered according to EU case definitions in the National Infections Disease Register (NIDR). Both physician and laboratory notify 32 diseases and their causative microbes (physician notification complements the laboratory notification); 40 named microbes or microbe groups are laboratory notifiable only; and laboratory 'gives the specificity' for the case. Paper-based notification will be completely phased out in the near future and all data are currently stored in the NIDR. Since 2004 laboratories are obliged to send specified microbial isolates (in some diseases specimens) to NIDR. Reference laboratories are adapting new typing methods, including Whole Genome Sequencing (WGS), majority of their services are free of charge, and the submission of isolates/samples is high. Laboratory Information and Specimen Management Systems is a key for efficient reference function and surveillance system integration.

[2] AMR, HAI, Vaccination programme, FWD, Influenza and other respiratory infections, HIV/STD and blood-borne infection, TB, and Emerging and vector-borne infections

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Current challenges:

- Physician notification to be fully integrated in health care patient record IT systems
- National patient record holding archive/repository
- Clinical microbiology samples, e.g. blood cultures, sent across borders
- Rapid methodological developments in reference microbiology
- A major structural health care reform in the next 2-3 years
- Strategic planning needs to look 5-10 years ahead for opportunities provided by the changing health care IT and other infrastructure

Restructuring laboratory systems supporting public health in Austria

The activities of the Division of Public Health of the Austrian Agency for Health and Food Safety (AGES) are defined by the Austrian Health and Food Safety Act (GESG) including examinations, diagnoses and assessments for the control of communicable diseases in accordance with the relevant legal provisions, as well as the monitoring and investigation of non-communicable diseases. AGES also provides the services for both Federal Office for Food Safety and for Safety in Health Care with the means required to carry out their tasks.

The Institute for Medical Microbiology and Hygiene, Graz (*Centre for Foodborne Infectious Diseases),* the Institute for Medical Microbiology and Hygiene, Vienna (*Centre for Anthropogenic Infections),* and the Institute for Hydroanalytik, Linz are the three authorities performing public health tasks in Austria.

Activities of the Department for Surveillance and Infectious Disease Epidemiology of AGES include:

- Outbreak-investigation in cooperation with the competent authorities
- Training of the health authority staff in the field of intervention epidemiology
- Surveillance
- Database operation (mandatorily reportable diseases)
- Drafting reports on mandatorily reportable diseases (on behalf of the Federal Ministry of Health)
- External contacts with institutions and persons affected by an epidemic

AGES cooperates with both food and veterinary laboratories for reference activities. The community and national reference laboratories contribute to a high quality and uniformity of analytical results by carrying out activities such as the application of validated analytical methods, ensuring that reference materials are available, the organisation of comparative testing and the training of staff from laboratories.

The federal legal basis (Health and Food Safety Act) enabled AGES to apply the EU food legislation[3] principles for enforcement of implementation of EU communicable disease legislation, namely the Decision No 2119/98/EC[4].

AGES participates in the EU funded project **EMERGE: Efficient response to highly dangerous and emerging pathogens at EU level** which aims to enable an efficient response to serious emergent and re-emergent cross-border events by reinforcing the existing EU network of BSL 3 and BSL 4 laboratories active in the field of identification of dangerous bacterial and viral human pathogens.

Organisation of national reference laboratory system supporting public health in Latvia

National laboratory system consists of 85 medical laboratories, more than 45 labs deal with the diagnostics of infectious diseases, including 19 bacteriology labs. There are two national reference laboratories: National Reference Laboratory for human pathogens (human microbes, parasites and viruses) and Institute of Food

[3] Regulation (EC) No 178/2002 on general principles and requirements of food law, establishing the European Food Safety Authority and procedures for food safety and Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules

[4] Decision No 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community

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Safety, Animal Health and Environment (for animal field). 32 (38%) of national medical laboratories are accredited according to LVS ES ISO 15189 standard, and both reference laboratories are accredited according to LVS ES ISO 15189 and LVS ES ISO/ IEC 17025 standards.

The **core functions of the National Reference Laboratory**:

- Reference diagnostic or conformation tests, using diagnostic algorithms, clarification of unclear cases, testing of uncommon samples
- Operation of a biological safety laboratory which can perform specific tests in situation of increased risk
- Provision of 24/7 preparedness and diagnostic for dangerous infectious diseases, outbreaks, epidemics and bioterrorism
- Monitoring, alert and response
- Identification of imported, rare, emerging and re-emerging biological agents and maintenance of the capacity to diagnose them
- Identification of infectious diseases pathogens in accordance with case definitions as determined by legal acts of Latvia and the EU
- Participation in working groups and infectious diseases networks of the WHO, the ECDC and other international organizations in the field of public health microbiology
- Methodological work
- Purchase of diagnostic reagents for HIV and TB for the distribution to laboratories involved in the epidemiological surveillance; monitoring the usage of those reagents

Workflow and organisation of NRL:

- Ministry of Health grants status to the NRL, may suspend the work of NRL or may withdraw the status of the NRL;
- List of laboratory tests to be performed by the NRL is determined by the regulations;
- NRL annually draws up a laboratory testing programme for the next year and it is coordinated with the Centre for Disease Prevention and Control and the National Health Service;
- NRL annually reports to the MoH regarding the performed tasks and usage of the State funds;
- Annually the National Health Service concludes a contract with the NRL about the implementation of the planned laboratory testing programme and funding allocated for it.

It is important in the legislation to have clear definitions of reference laboratory tests and clear NRL functions, list certain requirements, rights and obligations of the NRL, set up financing based on NRL activities and clarify supervision of NRL and the use of funds.

Remaining challenges in Latvia:

- Full implementation of the new NRL regulation
- There is no experience in preparation of laboratory testing programme reports and coordination of them
- Ensure cost effectiveness and at the same time necessary funding for NRL
- Transportation of samples to the NRL (laboratory capacity)
- NRL activities in the field of antimicrobial resistance

Next steps involve:

- Development of new arrangement for the financing the NRL
- Determine the necessary funding for the NRL
- development and approval of the NRL testing programme, including the reference functions in the AMR field
- Concluding agreements on the NRL functions

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Roadmap for the implementation of a national reference laboratory network in Belgium

Objectives of the national reference laboratories (NRL) are defined in the **Action plan for the implementation of the NRL**. The tasks include confirmation of diagnostic results, follow-up and evaluation of new diagnostic and typing assays, development and maintaining reference materials, sharing technical/clinical information and expertise with stakeholders (e.g. PHI, peripheral labs, MoH), research on specific topic and collaborating with regional and international research units, and participation to the surveillance of infectious disease and outbreak investigation. In terms of organisation, there are different possibilities: (i) one centralised laboratory collecting all samples and epidemiological information, (ii) consortia of a few labs with different expertise, or (iii) one centralised lab supervising a network of peripheral laboratories.

Decision on **which pathogens** shall be covered is based on the list of (national) notifiable infectious diseases, availability of expertise within key laboratories, data reporting to international bodies, and necessity of confirmation analysis, surveillance, and outbreak investigation. In addition, definition of which pathogens shall be included in the list could be organised by individual pathogens or pathogens grouped by symptomatic diseases (e.g. Respiratory infectious diseases, sexually transmitted diseases, bacterial meningitis, viral meningitis, hepatitis, bacterial antimicrobial susceptibility, nosocomial infections, congenital infectious diseases) or according to lists available for laboratory capacity monitoring by ECDC, WHO, bioterrorism lists of U.S. CDC, etc.

Requirements of the NRL include:

- In terms of public health – participation to available national public health programs, provide expertise in outbreak investigation and surveillance of infectious diseases, participate to international workgroups on infectious diseases;
- In terms of quality – accreditation certification of e.g. ISO15189, ISO17025, auditing system including qualification of auditors, participation to proficiency testing, complaints recording system;
- Other requirements, such as collection of a set of reference materials, availability of up-to date reference methods in operation, availability of the correct infrastructure (BSL2, BSL3, animal housing), access to new diagnostic technologies, availability to adapt the testing capacity in function of epidemiological situation, collaborations with food and veterinary laboratories, possibilities to form network or consortia.

Selection procedure of laboratories is based on well-defined criteria (requirements) and is implemented by scientific advisory board for the period of 3-5 years with possibility of renewal. The NRL is required to provide activity report (financial reimbursement), international data reporting, and scientific reporting (surveillance reports).

Different options are available for **financial compensation** of microbiology laboratory reference services: all activities are funded, no financial compensation, or partial compensation is available. It should be noted that it is important to define different **stakeholders**; they might include funding institution, public health institute/epidemiology for surveillance and data reporting, clinical laboratories for providing sample/strains for confirmation testing, hospital settings for nosocomial investigation, food and veterinary institutes for outbreak investigation, international organization for data reporting.

There are key phases of **planning the NRL**:

- Preparation:
  - Selection list of pathogens
  - Select scientific advisory board
  - Describe 'Terms of References' (ToR)
  - Consider finalisation of any legal aspects, if relevant
  - Determine possible stakeholders (MoH, WHO, sponsor)
  - Website construction
- Application

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- Invite all possible lab candidates for application
- Apply by completing application form

- Evaluation
  - Send application forms to 3 reviewers
  - Review and complete evaluation grid in function of criteria
  - Collection of evaluation forms
  - Review and summarize evaluations
- Selection
  - Final selection by the scientific advisory board
  - Agree on a contract between the MoH and the selected NRL
  - Communication of corresponding address of NRL to all clinical laboratories
  - Publish the testing criteria in centralised website (confirmation testing, surveillance collection, outbreak investigation)
  - Foresee centralised data reporting and scientific reporting

Having agreed key performance indicators at the start of planning process would help to undertake the final evaluation of national reference laboratory functions at the end of the performance cycle.

Microbiology laboratory role in MDR-TB outbreak investigation in Romania

Before the outbreak, TB laboratories in Romania used diagnostic algorithm recommended by NTP, used SOPs recommended by NRL-NTP/MoH, participated in QA program for performed tests, collaborated with next level lab in the network. NRLs collaborate with SRL Stockholm and was an ERL-TB network member. An outbreak alert was identified when Romanian NPHI was notified about clusters of MDR-TB isolates in two EU countries linked to Romanian patients, and another one when XDR-TB cases were diagnosed among students from a university in Romania. Investigation of the outbreaks began with the establishment of the investigative team composed of national competent bodies from countries involved, national contact points for WHO, ECDC, NRLs, local PH authorities, clinicians, epidemiologists. Collaboration between national and international laboratories increased for referral of strains from local labs to NRL and then to SRL, and exchange of information regarding resistance pattern of isolates from patients in the area of outbreaks.

Outbreak investigation included cases without restriction on when isolates were collected in the countries, but with the same 24-loci MIRU VNTR pattern. In addition, strains from counties where index cases had residence in Romania were also included.

Lessons learned from TB laboratory role in outbreak investigation:

- Key strengths of the system
  - existence of TB labs network, NRLs
  - strain collection available in NRLs
  - standardized laboratory methods and SOPs
  - laboratory TB diagnostic manuals
  - QA system in place for microscopy (re-checking)-NTP
  - QA for M, C, DST
  - 32 accredited labs according to ISO 15189
  - international collaboration
- Remaining challenges and needs
  - reorganization of the network
  - use of molecular methods for genotyping (24-loci MIRU VNTR) to investigate outbreaks
  - continue international collaboration

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2.5 Review of laboratory networks in EU enlargement countries

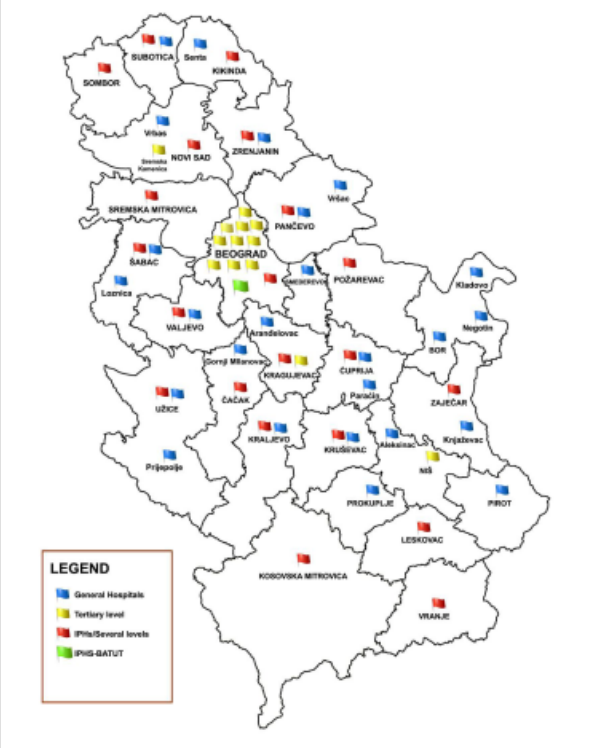
Serbia

Following EC/ECDC assessments of country capacities in the field of communicable disease prevention and control and subsequent development of post-assessment Action Plan to address key recommendations, Serbia is in the process to review and map public health microbiology laboratory system.

Primary diagnostic testing service is performed by 61 microbiology laboratories distributed across a range of health care and public health institutions, upon request from general practitioners and hospital medical practitioners. The health care system is organised at three levels: primary health care centres (PHCC, N=157), secondary level general hospitals (n=40) and tertiary care hospitals (n=31) including clinical centres, medical institutes and Military Medical Academy. The public health system is organised at three levels: the local PHCCs (n=157), the regional/district institutes of public health (RIPH n=23) and the IPHS. Diagnostic microbiology laboratories are located at general hospitals (n=25), RIPH (n=23) and tertiary care centres and institutes (n=13).

At the PHCC level there is no microbiology laboratory activity, except as a clinical collection point. In the case of an identified outbreak or when microbiological screening tests are taken to implement activities based on 'Rule book on mandatory medical examinations of certain categories of employees, other persons and germ-carriers', staff from the Regional Institute of Public Health (RIPH) come to the PHCC to take microbiological samples to be brought to the IPH. In all other cases, when microbiological test is needed, the patient is referred to the general hospital or RIPH laboratory for sampling, frequently to considerable distance in rural areas. Usually, the patient has to pick up the laboratory test result from the laboratory to bring it to the PHCC, again frequently over considerable distance.

In addition, private laboratories exist in major urban centres. There is no precise information on their number or clinical microbiological services offered. However, the private practitioners would sometimes refer to public general practitioner or public hospital patients with suspected communicable disease which they consider needing microbiological testing, as this testing is provided for free of charge to the patient only in the public sector.



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In case there is a RIPH adjacent to a general hospital, the laboratory at RIPH performs all of microbiology testing needed in the hospital, and all microbiology testing needed in the PHCC of the area. The general hospitals without an IPH in the same geographic location have their own microbiological laboratory staffed with microbiologist(s). In case of a tertiary care (university) clinical centre, the IPH in the same location covers a large proportion of the clinical microbiology testing for the hospital patients.

National Reference Laboratories (NRL) have been officially nominated by the Ministry of Health in 2008 following an EU-supported assessment of laboratories seeking NRL status in an open tender in 2007. The applicant laboratories were assessed by a multidisciplinary team, which also made site visits. The nomination was made for an undefined period of time. The recommendations in the EU-supported report 'Reference Laboratories Selection report 03/05/07' included a shortlist of laboratories in 15 different organisations. In the recommendation, some NRL functions were recommended to be 'sub-NRLs' to a laboratory in another organisation, however, the MoH nominated only full NRLs.

National Reference Laboratories in Serbia with four core functions (reference diagnostics, reference material resources, scientific advice, and collaboration and research).

The funding of NRL comes from various sources that differ according to the hosting institution. Two out of eight of the National Reference Laboratories situated in the IPH system, for which information was available, receive funding from the MoH budget in the 'Microbiology Program of Public Health in the activities of public interest of 2006'. Other Reference Laboratories in IPHs do not have defined budget for RL activities.

The NRLs located outside of the IPH system do not receive any funding from the MoH. Four NRLs in the Faculty of Medicine, University of Belgrade and five NRLs that are united with Clinical Centre Serbia, receive the majority of their funding from the Health Insurance Fund (HIF), and the rest of the sources includes market services/payment from a third party, Ministry of Science (research projects), WHO/MoH projects (TB), sponsors and donations (pharmaceutical industry), or the laboratories use income from other clinical microbiology activities to cover the public health NRL laboratory function.

The NRLs in Research Institutes cover the reference laboratory function by income from market services or payment from a third party, Ministry of Education and Science research project funding, and other sources.

There is **limited coordination between national public health reference microbiology laboratories and laboratories in other sectors**. There is no cross-disease coordination activity with environmental or with food microbiology laboratories. Examples where collaboration/coordination has functioned include haemorrhagic fever (Institute of Veterinary Medicine), identification of *mycobacteria* on species level for veterinary laboratories, and trichinosis with the veterinary specialist institutes and Faculty of Veterinary Medicine, University of Belgrade.

There are **various international collaboration activities** in the areas of enteric bacteria, tuberculosis, trichinellosis, *Neisseria meningitidis*, *Haemophilus influenzae*, influenza, measles and rubella, hepatitis A, haemorrhagic fever, poliomyelitis, and toxoplasmosis. The major collaborations form part of WHO laboratory networks for vaccine preventable diseases and for tuberculosis. In addition, NRL for Antimicrobial Resistance participated in the ECDC surveillance project EUSCAPE (European Survey on Carbapenemase-Producing Enterobacteriaceae in clinical specimens).

There is a number of **professional societies** active in the field of communicable disease and healthcare associated infections, including medical specialty sections of the Serbian Medical Association organising continuing education for physicians in the areas of infection diagnosis and disease control. The continuing medical education activities are accredited as CME credits by the Serbian Health Council.

In terms of **laboratory involvement in alert and response systems**, there is a legal obligation of immediate reporting for a number of diseases, however the laboratory reporting system doesn't support the detection of clusters or increasing trends of particular serotypes, genotypes, virulence types or drug resistance profiles of human pathogens. NRLs are very rarely (if at all) involved in outbreak investigations. Exceptions

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are the occasional participation of RL for *Salmonella*, *Shigella*, *V. cholerae* and *Y. enterocolitica* in investigation of some recent outbreaks.

National **quality assurance and accreditation** is limited in Serbia. There is no general national accreditation of district or national level laboratory services, even though some NRLs have obtained accreditation of some of their services according to ISO standards such as ISO 9001:2008, ISO 17025 or ISO 15189. In general, although accreditation of a specific process ensures its appropriate documentation and reproducibility, the provisions or requirements of specific ISO standards may be interpreted differently both on the national and the implementing level. It is common in microbiological laboratories to accredit one or part of their microbiological test functions, but this does not ensure that the rest of the laboratory's functions are of the same standard. Furthermore, accreditation does not automatically incorporate the participation and satisfactory performance in externally organised quality assurance programs (EQA), which are the 'gold standard' in ensuring the quality of microbiological laboratory functions on all levels of activity. Several NRLs participate in international external quality assessment schemes, that are organised by WHO and ECDC (TB, influenza, *Salmonella*, *Campylobacter*, measles, rubella and poliomyelitis) and EU zoonotic surveillance projects (trichinellosis, toxoplasmosis). AMR network (consists of 22 clinical lab) participates in EQA organised by CAESAR (WHO) network.

There is **no national biosafety legislation**, no designated biosafety officers to ensure compliance with good laboratory biorisk management practices. There are no BSL-3 facilities available in Serbia. The TB reference laboratory, as well the NRL for influenza and for haemorrhagic fevers have a well maintained BSL-2 facility, however external verification service of performance of level-2 biosafety cabinet is unavailable in Serbia.

Further to invitation from ECDC, in 2013, Ministry of Health of Serbia has officially nominated Observer and Alternate Observer to the ECDC NMFP with a key role to:

- ✓ transmit information about ECDC activities to relevant national stakeholders;
- ✓ report to ECDC on national developments and trends;
- ✓ identify and communicate public health microbiology priorities and needs in the preparation of Serbia for participation in ECDC work.

ECDC and **Observer NMFP** Country Action Plan (2013 with update in 2014) proposed the following actions:

- Exchange of information, best practice and training for use of EUCAST clinical breakpoints;
- Support for harmonized AMR monitoring for selected pathogens;
- Exchange of best practice on national strategy and action plan to combat AMR;
- Increase awareness of national authorities and decision-makers of the importance of public health microbiology;
- Assistance to conclude collaborative agreements for laboratory diagnostic support for diseases/pathogens under EU surveillance, for which no national diagnostic capabilities exist.

Proposed Country Action Plan has been shared with National ECDC Correspondent and other partners under the MoH and following that the MoH has recently nominated Subcommittee on Microbiology of the National Committee for Communicable Diseases and Action Plan has been presented to the members of the Subcommittee. One of the decisions taken was that all information and updates from ECDC (NMFP newsletter, documents) will be shared with all members of the Subcommittee and members of Section for Microbiology of the Serbian Physicians Society. The Subcommittee on Microbiology of the National Committee for Communicable Diseases prepared and submitted to MoH the detailed initiative and proposal to establish the Intersectorial Committee on Antimicrobial Resistance. As a result, national plan for implementation of EUCAST breakpoints instead of CLSI breakpoints was launched (National Committee for Antimicrobial susceptibility testing was established and Serbian data presented on EUCAST website). The data on antimicrobial consumption are being collected by national Agency for Medicines and Medical Devices of Serbia.

Sharing of best practice and experience with relevant EU experts helped participation of Serbia in CAESAR network and submitting AMR data to CAESAR and EARS-Net data manager. AMR results have been presented at the CAESAR Meeting during previous ECCMID and are included in CAESAR Annual Reports (2015, 2016).

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The **added value of the establishment of Observer role in ECDC NMFP in Serbia**:

- attendance to the ECDC NMFP forum Meetings is very useful;
- discussion with experts at NMFP meetings were helpful to explore ways how to address gaps in national diagnostic capability;
- reports from NMFP Meetings have been shared with National Correspondent and the MoH;
- ECDC NMFP Extranet was used for helpful information;
- The draft EU Protocol for harmonized monitoring of antimicrobial resistance in human *Salmonella* and *Campylobacter* isolates has been shared with NRLs for *Salmonella* and *Campylobacter* and with colleagues from veterinarian medicine;
- NRL for *Salmonella* and *Campylobacter* participate in ECDC supported EQA trials for *Salmonella*
- Serbia participated in ECDC project on European Survey on Carbapenemase-producing Enterobacteriaceae (EuSCAPE);
- Successful application on AMR Awareness Week campaign based on ECDC EAAD and sponsored by MoH have been organized since 2015;
- In 2016, Serbia participate in EULabCap project.

There are certain **challenges observed through the participation as Observer in ECDC NMFP**:

- ✓ Further raising awareness in Serbia of the importance of public health microbiology is needed;
- ✓ Inter-sectorial coordination, communication with veterinary and environmental sector remain areas to be improved;
- ✓ Assistance of ECDC is needed to conclude collaborative agreements for laboratory diagnostic support for pathogens under EU surveillance, for which no national diagnostic capabilities exist (no NRL for *Listeria*, *Legionella*, EHEC/STEC, etc.)

Continuation of NMFP Observer function in the future would:

- ✓ enable closer cooperation between ECDC and national public health microbiology system of Serbia;
- ✓ provide joint activities with ECDC and transfer of the information about ECDC activities to relevant stakeholders;
- ✓ help development of reference laboratory capabilities;
- ✓ help to identify and communicate to ECDC and relevant national stakeholders the public health microbiology priorities and needs in the preparation of Serbia for participation in ECDC work.

Montenegro

Organization of microbiology service in Montenegro partially is defined by legislation: **Law on Health Care**, **Law on Protection of Population against Communicable Diseases (Article 22)** and some bylaws. Article 50 of the Law on Health Care (003/16, 039/16 and 002/17) stipulates that the Institute of Public Health of Montenegro <…> *"performs microbiology and epidemiology at all levels of health care, coordinates and monitors professional work of health institutions, performing microbiological and epidemiological health care in the territory of Montenegro, conducts planning, supervision and evaluation of mandatory immunization".* This arguably establishes a legal basis for coordination and monitoring of microbiology laboratories, however enforcement of this clause is not defined by any implementing acts or bylaws.

Microbiology laboratory service network consists of 10+1 public (i.e. established by government) and 6 private microbiology laboratories. All of the public laboratories (including Clinical Centre of Montenegro (CMM) in the Institution of Public Health of Montenegro (IPH), as well as special hospital Brezovik) perform both public health and clinical laboratory functions. Each laboratory covers several municipalities (with exception of Herceg Novi, Budva, and Cetinje).

Following EC/ECDC assessments of country capacities in the field of communicable disease prevention and control and subsequent development of post-assessment Action Plan to address key recommendations, in 2017 Montenegro initiated assessment of microbiology laboratories in the country. With reference to bylaw on detailed conditions regarding standards, norms and ways of primary health care protection, the MoH delegated

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CMM in IPH to **perform the assessment of microbiology laboratory capacities in Montenegro**, taking into account facilities (space), staff, and equipment in laboratories (this excludes laboratory for diagnostics of TB in Brezovik).

The **overview of the assessment findings**:

- Staff

nr	1	2	3	4	5	6	7	8	9	10
LOCATION	Podgorica	Bar	Budva	Kotor	Herceg Novi	Cetinje	Nikšić	Berane	Bijelo Polje	Pljevlja
Date of visit	*	17.05.2017.	02.06.2017.	18.05.2017.	16.05.2017.	02.06.2017.	01.06.2017.	16.05.2017.	16.05.2017.	29.05.2017.
Name	IPH	PHCC	PHCC	PHCC	PHCC	PHCC	PHCC	PHCC	PHCC	PHCC
STAFF										
M.D. Spec. In Microbiology	✓10	✓1+1#+1*	1#+1*	1	1#+1*	1	✓3+2*	1#+2*	1#+1*	1
Biologist /molecular biologist	✓2	no	no	no	no	no	no	no	no	no
Lab. Engineer/ Technologist	✓4	1	no	no	no	no	no	no	no	no
Laboratory technician	✓40	✓6	✓3	✓3	✓3	✓3	✓12	✓6	✓6	✓4
Janitor/cleaning	✓3	no data	no data	no data	1	no data	1	no data	no data	no data
Legend: * On going specialization # temporary engagement ✓ appropriate number of staff										

- Field of expertise

nr	1	2	3	4	5	6	7	8	9	10
LOCATION	Podgorica	Bar	Budva	Kotor	Herceg Novi	Cetinje	Nikšić	Berane	Bijelo Polje	Pljevlja
Name	IPH	PHCC	PHCC	PHCC	PHCC	PHCC	PHCC	PHCC	PHCC	PHCC
Bacteriology	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Virology	✓	no	no	no	no	no	no	no	no	no
Serology	✓	no	no	no	no	✓ *	✓ *	✓*	no	no
Parasitology / Mycology	✓	✓ **	✓**	✓**	✓**	✓**	✓**	✓**	✓**	✓**
Molecular diagnostics	✓	no	no	no	no	no	no	no	no	no
Sanitary microbiology (food, water, air...)	✓	✓* **	no	no	no	no	no	no	no	no
Legend: * rapid tests ** partly *** water analysis										

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❖ Facilities and space

nr	1	2	3	4	5	6	7	8	9	10
location	**Podgorica**	**Bar**	**Budva**	**Kotor**	**Herceg Novi**	**Cetinje**	**Nikšić**	**Berane**	**Bijelo Polje**	**Pljevlja**
FACILITIES, GENERAL CONDITIONS	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Laboratory rooms space (m^2)	cca 1000	no data	24	32	34	61	56	196*	38	24
Number of laboratory rooms	11+12	2+4***	2	2	2	4	3	4	3	1
Light conditions	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Natural ventilation / Air condition climatization	✓ ✓	✓ no data	✓ no	✓ ✓	✓ ✓	✓ no	✓ no	✓ no	✓ no	✓ no
Invalid persons accsess	✓	✓	no	✓	✓	no	✓*	✓	✓	✓
Separate waiting room	✓	✓	✓	✓	✓	✓	✓	✓	✓	no
Separate sampling room	✓	✓	✓	✓	✓	✓	no	✓	✓	no
Separate labware washing room / dishwasher	✓ ✓	no no	N no	✓ no	✓ no	✓ no	no no	no data	no no	no
Separate laboratory kicthen	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Separate decontaminatiom room	✓	no	no	no	✓	✓	no	no data	no	no
Office(s), rest room(s)	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Separate toilets for patients	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Infective waste temporary storage	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Separated clean and dirty ways	✓	no	no	no	no	no	no	no data	no	no
Computers	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Internet accsess	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
LIMS	✓	no	no	no	no	no	no	no	no	no
Furniture / working surfaces	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

❖ Equipment

nr	1	2	3	4	5	6	7	8	9	10
location	**Podgorica**	**Bar**	**Budva**	**Kotor**	**Herceg Novi**	**Cetinje**	**Nikšić**	**Berane**	**Bijelo Polje**	**Pljevlja**
Microscop	6+3+2+1	2	2	1	1	2	2	2	1	1+1
Incubator	6+12	2+5*	1+2	1	2+1	2+1	1+2+1	3	3	1+1
CO2 incubator / Atmospheric jar	6 6	no 3	no 3	no 1	no no	no 3	no 3	1 3	no 2	no no
Dry steriliser	4	1+2	2	1	2	1+1	1+1	no data	1	1*
Refrigerator /freezer	20+ 10+	3+1* 2*	1+1+2 no data	3+1 no data	3+2 no data	3+2+1 no data	5+4 no data	2+1 no data	1+2 no data	2+1 no data
Autoclave	3+2	2	2	1+1	2+1	2+1	1+2	1	2	1+1
Water bath	6	1+3*	2	1	no	1+1	1	1+1	1	no
Technical balance	3	1	1	1	1	1	1	1	1	1
Centrifuge		1	1	1	no data	1	1+1	1	1	no
Ph meter	4	1	no	no	no	no	no	1	no	no
Densitometer	4	no	1	1	1	1	1	no	no	no
Vortex	20+	1+1*	1	1	1	1	1	no	no	no
BSC2	8+4	no	no	no	no	no	no	no	no	no
ELISA	4*+2	no	no	no	no	no	no	no	no	no
Automated haemoculture monitoring system	2	no	no	no	no	no	no	no	no	no
PCR	5*+1	no	no	no	no	no	no	no	no	no
MALDI -TOF	1*	no	no	no	no	no	no	no	no	no
Automated plates and tubes pouring system	1*	no	no	no	no	no	no	no	no	no

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In terms of **procedures**, all laboratories follow National guidelines of good clinical practise, however this is not a collection of SOPs, thus should be revised. There are no national guidelines for other fields in microbiology. CMM IPH provides standard strains of several bacteria for antimicrobial susceptibility testing for all laboratories in Montenegro and participates in several international EQAs (e.g. Influenza, WNV, food and waterborne pathogens). Biosafety SOPs are missing in all laboratories (with exception of CMM IPH) and majority of them do not follow biosafety rules.

In terms of **accreditation**, there are no accredited (e.g. ISO 15189) laboratories for clinical microbiology in Montenegro, and IPH (including laboratory part) is certified according ISO 9001 – 2015 standard. CMM laboratories for food and water testing in IPH are accredited according to ISO 17025 standard.

Supply chain with diagnostic kits, culture media, consumables etc. is regulated by 'Law on public procurements'. However, as specificities of supplies for the health care are not recognised in the law some obstacles in the procurement occur occasionally.

CMM in IPH is the largest laboratory in Montenegro and acts (de facto) as a reference laboratory. It consists of two parts:

- public health microbiology, as well as clinical microbiology, which covers all of three health care levels and
- food, water, and air testing.

In conclusion, **public health laboratories in Montenegro**:

- ✓ perform public health and clinical services;
- ✓ majority of laboratories perform bacteriology only;
- ✓ lack uniform procedures for the entire service;
- ✓ lack adequate system of coordination among the laboratories;
- ✓ lack adequate system for laboratory work monitoring (insufficient quality control);
- ✓ lack LIMS and informatics connection between laboratories;
- ✓ lack informatics connection between laboratories and other health care providers;
- ✓ lack diagnostic kits, culture media, consumables, etc. hamper diagnostic processes occasionally;
- ✓ Private laboratories are not included in "network".

Turkey

Turkey is subdivided into 81 provinces for administrative purposes, each province is divided into districts with a total of 923 districts in the country. Turkey is also subdivided into 7 regions and 21 sub-regions for geographic, demographic and economic purposes; this does not refer to an administrative division.

Turkey has a variety of medical laboratories that are owned and managed by investor-owned corporations, non-profit hospitals or various levels of government in the form of public health laboratories. **Four levels of laboratories form the public health laboratory (PHL) system** including private, local and hospital clinical laboratories; provincial public health laboratories; national reference laboratories (NRL) and international laboratory networks. The PHL is part of the public services with financial, human resources, payroll, purchasing and infrastructure support provided by Public Health Institution of Turkey (PHIT).

Laboratory testing for detection of priority diseases, specimen referral and transport system, effective modern point of care and laboratory-based diagnostics, and laboratory quality system are integral parts of national laboratory network. The complexity of diagnostic services and scientific expertise increases at higher levels in the system. The role of the different laboratory levels in surveillance and response to an epidemic is dynamic, varying with the disease or stage of an epidemic and with the state of development of diagnostics. For common diseases, diagnostics are usually available at the first contact laboratory while for rare diseases diagnostic testing may only be available at one laboratory.

There are 17 'level 1' **public health laboratories** at regional level and 66 'level 2' public health laboratories at provincial level: each province has one provincial public health laboratory with the exception of Istanbul.

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Some provincial laboratories have multiple sites within the province and those laboratories would typically have a few professional microbiologists. PHL perform clinical laboratory service and non-clinical functions and are linked to all sectors of the public health infrastructure (such as disease control and prevention, environmental health, epidemiology, occupational health and safety). PHL provides early detection of health risks associated with infectious agents and identifies causes of disease to support treatment and prevention.

Turkey has conducted multiple Strengths, Weaknesses, Opportunities, and Threats (SWOT) analysis for (i) PHLs, (ii) clinical/hospital microbiology laboratories; (iii) non-clinical laboratories looking into the key areas (e.g. organisation and legislation, surveillance, environmental monitoring, food and dairy safety, quality assurance, biosafety and biorisk management) and defining future strategies accordingly.

National reference laboratory functions include:

- Reference diagnostics
- Reference material resources (EQAS)
- Scientific advice
- Collaboration and research
- Monitoring, alert, and response
- National laboratory network

The primary laboratories are the National Microbiology Reference Laboratory in Ankara, and regional PHLs and University Labs. These laboratories serve multiple functions including front-line diagnostics, reference microbiology, and support to epidemiological surveillance, and conducting and coordinating laboratory surveillance. National surveillance systems for different infectious diseases have evolved independently of each other, and are largely stand-alone. For some infections (EHEC, VHF, WNF, *Coxiella*, Polio) all specimens are tested at the national level. For others such as influenza, *Salmonella/Shigella*, malaria, *Brucella,* and anthrax initial screening is performed at the provincial level and a sample is referred to the national microbiology reference laboratory for typing. It was concluded that efforts are being made regarding better coordination of NRL activities and while there is considerable laboratory input into infectious disease surveillance systems, closer links are needed to surveillance in general.

Through the multi-stakeholder health responsibility development programme, approaches to strengthen microbiology laboratories and national laboratory networks include:

- National policies, strategic and operational plans, guidelines, SOPs
- Establishment of quality-assured laboratories through training and mentoring in laboratory quality implementation
- Advocacy, partnership, and coordination

There is a solid **body of national microbiology standards** in Turkey, such as Communicable Disease Laboratory Diagnosis Guidelines, national biosafety guideline, National TB diagnosis Guideline, National Antimicrobial Resistance Surveillance system guideline, Laboratory Guideline for Physicians.

The **strategic priorities** include:

- ✓ Human resources planning, including promotion of growth and development of skilled workforce for PHLs;
- ✓ Formalize and sustain the national laboratory network role, including improvement of information exchange, strengthening lab-based surveillance, support to national emergency preparedness and response, and development of standards;
- ✓ Advocate for and develop better public health infrastructure, by enhancing capacity and capability, support to core functions of public health laboratories, promote benefits of efficient public health laboratory services, and enhancing focus on emerging issues and prevention;
- ✓ Support and foster high quality communicable disease reference services, including promotion of standard development practices and development of the national reference services program;

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- ✓ Facilitate and support research and training activities, including research funding, promotion of collaboration for better research, and improvement of training programs.

The **stepwise approach to enhance performance of public health laboratories** include:

1) Integrating front-line laboratories into the public health services. This is also supported by Multi-Stakeholder Health Responsibility Development Program.
2) Integrating of microbiology services for public health with epidemiology services, as well as laboratories in other sectors (e.g. environmental sector for FWD surveillance system), and to link and streamline laboratory reporting with the surveillance system. Here the start has already been made in the area of AMR and HAI and acute invasive bacterial infections.
3) Improving capabilities of public health reference laboratories in terms of reporting system, diagnostic tests, and services; and
4) developing and strengthening of national laboratory networks to enhance public health systems. This include improving capabilities of reference services for high containment labs and support to molecular surveillance; software (e-pulse, HSBYS); affiliation with universities and other institutions.

Organization and governance, coordination mechanisms, private sector involvement, multi-sectoral cooperation, and standardization are challenging areas that still need to be addressed in Turkey.

Labcap is used to review public health laboratory network capacities and capabilities to ensure that the public health laboratories have the appropriate capacity and protocols to respond effectively and collaboratively to the serious outbreak of infectious disease.

LabCap full review suggests to strengthen the role of laboratories in national infectious disease surveillance systems, create a more efficient, timely, and integrated platform for use of both public and private laboratories in surveillance and to expand the public health laboratory networks to integrate hospital and community-based laboratories.

In conclusion, current status of laboratory networks relies mainly on public health laboratories and does not sufficiently support EWRS, contribute little to sentinel systems, and does not sufficiently cover multidisciplinary coordination. Therefore, there is a need to ensure different microbiology disciplines in PHM, to describe how all microbiology labs collaborate in the public health network, regularly monitor capacities with LabCap analysis, and strengthen multidisciplinary teams. Legislation on how microbiology laboratories shall collaborate in the public health network will support the attainment of those future targets.

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3 Working group discussions

To discuss in depth the issues described in the overall workshop objectives and to share experiences from the EU MS, the participants were invited to share their views in two parallel working groups (see list of participants below in this document)

- ✓ **Working Group 1: Mapping the needs for restructuring and missing capacities of national laboratory systems supporting public health and system development**
- ✓ **Working Group 2: Opportunities for pooling microbiology reference laboratories capacities in EU enlargement countries**

To support effective discussions during the group work, EU enlargement countries were invited to reply to a **pre-workshop questionnaire** succinctly capturing the state-of-play of the ongoing revision of national systems and the currently available microbiology laboratory expertise (pre-workshop questionnaire is hereby attached to this report in Annex 3). Countries were expected to coordinate internally their replies with key national stakeholders and to map available capacities and expertise, and ongoing re-organisation initiatives, and reflect on feasibility to 'team up' of national reference laboratories for specific areas of expertise. All seven countries replied to pre-workshop questionnaire, thus response rate was 100%[5].

3.1 WG1. Mapping the needs for restructuring and missing capacities of national laboratory systems supporting public health and system development

WG1 objectives and expected outcomes

The objectives of the WG1 were:

- to map the state of play of restructuring public health microbiology services for effective, sufficient and sustainable structures to support communicable disease surveillance and control and gaps/missing capacities identified;
- to discuss what countries are doing to address those needs, as well as what are their current challenges;
- to develop possible tangible actions that shall address those gaps/identified challenges in the coming future, including reflection how EU MS or ECDC or other partners could play a role.

Baseline for working group discussions from analysis of pre-workshop questionnaire results

Referring to pre-workshop questionnaire (example of pre-workshop questionnaire is annexed to this document in Annex 3) countries indicated the following state-of-play regarding **necessary actions to restructure microbiology services and structures for communicable diseases surveillance**:

- ✓ Three countries have a **national database** of all available microbiology laboratories in public and private sectors (AL, ME, MK).
- ✓ Five countries **perform a national assessment of capacities, space, equipment, and staff**. Only Albania and Serbia do not.
- ✓ Turkey is the only country that indicated having established an efficient **electronic laboratory data reporting systems** from microbiology laboratories to the central level.

[5] *Note:* Responses from Bosnia and Herzegovina to ECDC Pre-workshop questionnaire to the following questions reflect situation in Federation of Bosnia and Herzegovina only: Q1 pathogens *Echninococcus spp.*, *Giardia lamblia*, *Streptococcus pneumoniae*, and Polio virus; Q2.1 and Q2.4. Organization and financing the health care in Bosnia and Herzegovina is under responsibility of the *Federation of Bosnia and Herzegovina*, the *Republic of Srpska* and the *Brčko District* of Bosnia and Herzegovina.

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- ✓ Five countries reported in the pre-workshop survey that they have established an **information exchange between the sectors**, including between laboratory and epidemiology services (but not the former Yugoslav Republic of Macedonia[6] and Turkey).
- ✓ Only Turkey has **external quality assurance systems** covering all the microbiology laboratories in the country
- ✓ Four countries have developed or have algorithms for **sample referral for cases of diarrhoea** (AL, BA, ME, TR)
- ✓ All countries except the former Yugoslav Republic of Macedonia have developed/have algorithms for **sample referral for meningitis**.
- ✓ All seven countries have the capacity to **identify methicillin-resistant *Staphylococcus aureus* (MRSA) isolates in accordance with EUCAST**/*Staphylococcus aureus* reference laboratory network guidance.

Overview of state-of play re microbiology laboratories for communicable disease surveillance systems and structures in countries:

Capacities currently available in countries, based on replies to pre-workshop survey	AL	BA	KS	ME	RS	MK	TR	Total number of countries
MRSA identification (as per EUCAST)	1	1	1	1	1	1	1	7
Algorithm referral in cases of meningitis	1	1	1	1	1	0	1	6
National assessment of lab capacities, space, equipment, staff, etc.	0	1	1	1	0	1	1	5
Efficient information exchange between sectors	1	1	1	1	1	0[6]	0	5
Algorithm referral in cases of diarrhoea	1	1	0	1	0	0	1	4
National database of all available PHM laboratories in private and public sectors	1	0	0	1	0	1	0	3
Efficient electronic laboratory data reporting systems	0	0	0	0	0	0	1	1
EQA systems covering all PHM laboratories	0	0	0	0	0	0	1	1

In terms of **capacity on national level to perform molecular typing**, four countries (BA, RS, MK, and TR) have the capacity for at least one of the following four pathogens (*Salmonella enterica, Listeria monocytogenes, Shiga-toxin producing E.coli*, Multidrug resistant *Mycobacterium tuberculosis*). Out of those four countries, Turkey had the most advanced capacity for molecular typing indicating capacity for all four pathogens surveyed.

[6] *Note:* After the Multi-country workshop Macedonia clarified that information exchange between epidemiology and laboratories is set out in the Law for protection of communicable diseases. Thus, microbiology laboratories must report microbiological result for 53 notifiable diseases, and Epidemiology department at Institute of Public Health publishes monthly report (bulletin) that is publicly available.

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Pathogen	Number of countries	Countries having capacity for molecular typing based on replies from pre-workshop questionnaire
Multidrug resistant *Mycobacterium tuberculosis*	4	Bosnia and Herzegovina, Serbia, the former Yugoslav Republic of Macedonia and Turkey
Salmonella enterica	2	Serbia and Turkey
Listeria monocytogenes	2	Serbia[7] and Turkey
Shiga-toxin producing *E.coli*	1	Turkey

Note: after the workshop Macedonia introduced clarification on typing capacity of *Salmonella enterica* and *Listeria monocytogenes* referring to existing capacity on collegial basis for human and food isolates at the laboratory of the Faculty of Veterinary medicine.

Four countries (AL, KS, MK, and TR) indicated having a **national policy for cross-sectoral and coordinated monitoring of antimicrobial resistance** in human and animal bacterial isolates of public health relevance.

All countries except Serbia had **laboratory specialists systematically involved in preparedness planning** and outbreak investigations at all levels.

When asking countries whether they recently **improved access** to and use of culture-based bacteriological laboratory testing services **at primary level**, Montenegro, the former Yugoslav Republic of Macedonia, and Turkey indicated improvement, and for the remaining four countries this was not improved.

Considering **key obstacles for effective use of microbiology diagnostic tests by physicians at primary level**, countries identified the following:

Key obstacles	Number of countries where this is an obstacle	Countries where this is NOT an obstacle
Diagnostic tests are not available	6	Turkey
Not enough trained laboratory personnel	4	Bosnia and Herzegovina, Serbia and Turkey
Insufficient technical laboratory equipment or reagents	6	Turkey
Doctors don't systematically test and/or refer patients for diagnostic testing	6	Bosnia and Herzegovina

[7] *Observation from ECDC*: Upon invitation from ECDC to nominate reference laboratory for participation in ECDC EQA of molecular typing of *Salmonella, STEC/VTEC* and *Listeria* in EU candidate and potential candidate countries 2017-2020, Serbia indicated that country does not have capacity for molecular typing of *Listeria monocytogenes.* In addition, in reply to the above-mentioned invitation re FWD EQA, Kosovo indicated interest by nominating reference laboratories for molecular typing of all three pathogens, i.e. *Salmonella spp.*, Shiga toxin/verocytotoxin -producing *Escherichia coli* (STEC/VTEC) and *Listeria monocytogenes*.

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Six countries (except Montenegro) shared their **good practices and lessons learned on achievements regarding structural changes** and provided the following 20 examples that might be grouped by areas:

Area	Achievement	Number of countries*
National reference laboratories	Nominated NRLs	2 (RS, MK)
	NRL deliver core functions	2 (RS, MK[8])
Antimicrobial resistance	AMR susceptibility testing, characterisation and monitoring	2 (RS, MK)
	Adherence to EUCAST	2 (RS, MK)
	Nomination of NAC	2 (RS, MK)
Structural changes	Merged laboratories	1 (BA)
	Established database of laboratories and assessment of laboratories	1 (AL)
Preparedness and response	Participation of laboratories in preparedness and response to outbreaks	2 (AL, MK)
	Increased capacity and capability of public health laboratories for surveillance and outbreak investigation	1 (TR)
Quality control	Established accreditation process	2 (BA, TR)
	Participate in EQA	2 (BA, MK)
	Establishment of EQA system	1 (TR)
	Establishment of quality management system	1 (TR)
	Developing Laboratory assessment tool	1 (TR)
	National tuberculosis network, legislation and performance monitoring system	1 (TR)
Networking and communication	Participation in international projects	2 (BA, MK)
	Improved intersectoral communication	3 (BA, KS, MK)
	Continuing public health microbiology network studies	1 (TR)

Key points discussed

There are certain issues in **organisational set up and structures of national laboratory systems** supporting public health that need to be addressed in the region:

- ✓ National regulations and nominations of reference laboratories are often missing or ambiguous; re-assessment of the situation for re-nomination is problematic in majority of countries;
- ✓ Opportunities for reallocation of resources exist and shall be used by focusing laboratory activity away from e.g. screening programs without scientific basis and tangible impact (and technical collaboration with other sectors);
- ✓ In some countries, there is no complete inventory and clear overview of all microbiology laboratories

Concerning **laboratory capacity for common diseases**, all countries (except Turkey) lack capacity for diagnostics of diseases/syndromes important for patient management and safety, and monitoring of public health programs, particularly on the regional and local level. In some countries, standard algorithms for performing laboratory testing of samples in common diseases/syndromes are not present or followed.

[8] Except EQA

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Moreover, in a number of countries, business continuity is a problem because of complex procurement processes or insufficient funding, and appropriately trained staff. It was discussed that key areas/programs that require much more and high quality support from clinical and reference laboratories include:

1) enteric disease/diarrhoea diagnostics: outbreak recognition is crucial for food safety programs;
2) AMR testing for patient management and antibiotic policy guidance.

These two areas were chosen as 'test' diseases for detailed discussion in the Working Group, but it is obvious that high quality laboratory support is missing in other areas that are important for patient safety and public health.

There is a major issue behind the fact that **physicians do not use laboratory testing** and the issues include both lack of understanding by the physicians of the benefits from testing to the patient and public health, and inappropriate use of clinical diagnostic and screening tests.

Even if many national reference laboratories and some clinical microbiology laboratories participate in **external quality assurance (EQA)**, in general the national implementation of EQA is either insufficient or completely missing in all countries (with the exception of Turkey).

In general, referral of samples is a problem in Western Balkan countries, partially related to **poor transportation logistics**, missing procedures, and some countries reported insufficient arrangements/resources for this function.

Conclusions from working group discussion on "*Mapping the needs for restructuring and missing capacities of national laboratory systems supporting public health and system development*"

- There is a **need for high level political attention and recognition for the commitment towards major upgrading of laboratory system** to address all – improvement of patient management, patient safety and public health.
- There needs to be a **comprehensive strategy on microbiology laboratory system** in the country, aiming at public health and linked to public health control programs. Learning from the best practices or models in the EU MS could facilitate strategic direction in the countries.
- To ensure that physicians at primary level **effectively use microbiology diagnostic tests**, countries need to address key issues of availability of diagnostic tests and raise understanding of physicians on the benefits from testing to the patient and to public health.
- Key areas/programs require much more and **high quality support from clinical and reference laboratories**, and those include at least the diseases/problems with focus in the Working Group:
    1) enteric disease/diarrhoea diagnostics: outbreak recognition is crucial for food safety programmes;
    2) AMR testing for patient management and antibiotic policy guidance
- There is a need to clarify and better define **licensing-accreditation processes** (management specific vs task specific) and ensure that quality of laboratory services not only requires good coverage of EQAs, but also needs to be supported by infrastructure and trained personnel.
- **Transportation of samples** and logistical arrangements for specimen referral need further improvement in majority of EU enlargement countries.

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3.2 WG2. Opportunities for pooling microbiology reference laboratories capacities in EU enlargement countries

WG2 objectives and expected outcomes

The objectives of the WG2 were:

- to map the capacities in the region to confirm cases by primary and/or reference laboratory for all mandatory notifiable communicable diseases as per EU acquis;
- to identify gaps in such capabilities and discuss how countries are addressing those gaps, as well as what are key challenges;
- identify national and regional needs for specialist reference laboratory services and availability of shared expertise in the Western Balkan countries and Turkey;
- to develop possible tangible actions that shall address those gaps in the coming future, including opportunities for pooling microbiology reference laboratory capacities in the region.

Baseline for working group discussions from analysis of pre-workshop questionnaire results

In terms of **countries' capacities to confirm cases by primary and/or reference laboratory for 53 notifiable communicable diseases as per EU acquis**[9], the capacity in EU enlargement countries ranged between 70% (37 out of 53 diseases for Kosovo) and 98% (52 out of 53 diseases for Turkey). No country reported having full diagnostic capacity for variant Creutzfeldt-Jacob disease, and only few countries for rare and emerging diseases like smallpox, SARS, and yellow fever. For botulism, plague, poliomyelitis, rabies, tetanus and yersiniosis the diagnostic capacity was limited. Overview of capacities in Western Balkan countries and Turkey by pathogen and by country is displayed below (where 0 corresponds to replies 'no capacity' and 1 – 'capacity exists'):

Disease / health issue under EU surveillance	AL	BA	KS	ME	RS	MK	TR	Total number of countries
ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS) AND HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION	1	1	1	1	1	1	1	**7**
ANTHRAX (*Bacillus anthracis*)	1	1	1	0	0	1	1	**5**
AVIAN INFLUENZA A/H5 OR A/H5N1 IN HUMANS	1	1	1	1	1	1	1	**7**
BOTULISM (*Clostridium botulinum*)	0	0	0	1	0	1	1	**3**
BRUCELLOSIS (*Brucella spp.)*	1	1	1	1	1	1	1	**7**
CAMPYLOBACTER (*Campylobacter spp.*)	1	1	1	1	1	1	1	**7**
CHLAMYDIAL INFECTION (*Chlamydia trachomatis*), INCLUDING LYMPHOGRANULOMA VENEREUM (LGV)	1	1	0	1	1	1	1	**6**
CHOLERA (*Vibrio cholerae*)	1	1	0	0	1	1	1	**5**
CREUTZFELDT-JAKOB DISEASE, VARIANT (vCJD)	0	0	0	0	0	1	0	**1**
CRYPTOSPORIDIOSIS (*Cryptosporidium spp.*)	0	1	0	1	1	1	1	**5**
DIPHTHERIA (*Corynebacterium diphtheriae , Corynebacterium ulcerans and Corynebacterium pseudotuberculosis*)	1	1	1	0	1	0	1	**5**
ECHINOCOCCOSIS (*Echinococcus spp.*)	1	1	1	1	1	1	1	**7**
GIARDIASIS (*Giardia lamblia*)	1	1	1	1	1	1	1	**7**
GONORRHOEA (*Neisseria gonorrhoeae*)	1	1	1	1	1	1	1	**7**
HAEMOPHILUS INFLUENZAE, INVASIVE DISEASE (*Haemophilus influenzae*)	1	1	1	1	1	1	1	**7**
HEPATITIS A (Hepatitis A virus)	1	1	1	1	1	1	1	**7**
HEPATITIS B (Hepatitis B virus)	1	1	1	1	1	1	1	**7**
HEPATITIS C (Hepatitis C virus)	1	1	1	1	1	1	1	**7**
INFLUENZA (Influenza virus)	1	1	1	1	1	1	1	**7**
INFLUENZA A(H1N1)	1	1	1	1	1	1	1	**7**
LEGIONNAIRES' DISEASE (*Legionella spp.*)	1	1	0	1	1	1	1	**6**

[9] According to laboratory criteria as per 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. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:262:0001:0057:EN:PDF.

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Disease / health issue under EU surveillance	AL	BA	KS	ME	RS	MK	TR	Total number of countries
LEPTOSPIROSIS (*Leptospira spp.*)	1	1	1	0	1	1	1	**6**
LISTERIOSIS (*Listeria monocytogenes*)	1	1	1	0	1	1	1	**6**
MALARIA (*Plasmodium spp.*)	1	1	1	1	1	1	1	**7**
MEASLES (Measles virus)	1	1	1	1	1	1	1	**7**
MENINGOCCOCAL DISEASE, INVASIVE (*Neisseria meningitidis*)	1	1	1	1	1	1	1	**7**
MUMPS (*Munps virus*)	1	1	1	1	1	1	1	**7**
PERTUSSIS (*Bordetella pertussis*)	1	1	1	1	1	1	1	**7**
PLAGUE (*Yersinis pestis*)	0	0	0	0	0	1	1	**2**
PNEUMOCOCCAL INVASIVE DISEASE(S) (*Streptococcus pneumoniae*)	1	1	1	1	1	1	1	**7**
POLIOMYELITIS (Polio virus)	1	0	0	0	1	0	1	**3**
Q FEVER (*Coxiella burnetii*)	1	1	1	1	1	1	1	**7**
RABIES (Lyssa virus)	0	0	0	0	1	1	1	**3**
RUBELLA (Rubella virus)	1	1	1	1	1	1	1	**7**
RUBELLA , CONGENITAL (including Congenital Rubella syndrome)	1	1	1	1	1	1	1	**7**
SALMONELLOSIS (*Salmonella spp.* other than *Salmonella Typhi* and *Salmonella Paratyphi*)	1	1	1	1	1	1	1	**7**
SEVERE ACUTE RESPIRATORY SYNDROME - SARS (SARS coronavirus, SARS-COV)	1	0	0	0	0	1	1	**3**
SHIGA TOXIN/VEROCYTO-TOXIN PRODUCING ESCHERICHIA COLI INFECTION (STEC/VTEC)	0	1	0	1	0	1	1	**4**
SHIGELLOSIS (*Shigella spp.*)	1	1	1	1	1	1	1	**7**
SMALLPOX (Variola virus)	0	0	0	0	0	0	1	**1**
SYPHILIS (*Treponema pallidum*)	1	1	1	1	1	1	1	**7**
SYPHILIS, CONGENITAL AND NEONATAL (*Treponema pallidum*)	1	1	1	1	1	1	1	**7**
TETANUS (*Clostridium tetani*)	1	1	0	0	0	1	1	**4**
TICK-BORNE ENCEPHALITIS (TBE virus)	1	1	0	1	1	1	1	**6**
TOXOPLASMOSIS, CONGENITAL (*Toxoplasma gondii*)	1	1	1	1	1	1	1	**7**
TRICHINELLOSIS (*Trichinella spp.*)	0	1	0	1	1	1	1	**5**
TUBERCULOSIS (*Mycobacterium tuberculosis complex*)	1	1	1	1	1	1	1	**7**
TULARAEMIA (*Francisella tularensis*)	0	1	1	0	0	1	1	**4**
TYPHOID/PARATYPHOID FEVER (*Salmonella Typhi/Paratyphi*)	1	1	1	1	1	1	1	**7**
VIRAL HAEMORRHAGIC FEVERS (VHF)	1	1	1	0	1	1	1	**6**
WEST NILE FEVER (West Nile virus infection, WNV)	1	1	1	1	1	1	1	**7**
YELLOW FEVER (Yellow fever virus)	1	0	0	0	0	0	1	**2**
YERSINIOSIS (*Yersinia enterocolitica* , *Yersinia pseudotuberculosis*)	1	1	1	1	1	1	1	**7**

Countries were asked to indicate whether they have any kind of **arrangements with other countries**, if capacity to confirm cases was not available in the country. The following was reported for seven diseases:

Disease	Number of countries having arrangements
AVIAN INFLUENZA A/H5 OR A/H5N1 IN HUMANS	2 (Montenegro, Macedonia[10]: with WHO CC, UK)
BOTULISM (*Clostridium botulinum*)	1 (Albania: with Bulgaria)
CREUTZFELDT-JAKOB DISEASE, VARIANT (vCJD)	1 (Turkey: with Germany)
INFLUENZA (Influenza virus)	2 (Montenegro, Macedonia[10]: with WHO CC, UK)
INFLUENZA A(H1N1)	2 (Montenegro, Macedonia[10]: with WHO CC, UK)
POLIOMYELITIS (Polio virus)	3 (Bosnia and Herzegovina: with Italy; the former Yugoslav Republic of Macedonia: with Bulgaria; Montenegro: with Serbia)
SHIGA TOXIN/VEROCYTO-TOXIN PRODUCING ESCHERICHIA COLI INFECTION (STEC/VTEC)	1 (Albania: with Italy)

For diphtheria, smallpox, viral haemorrhagic fevers and yellow fever, the former Yugoslav Republic of Macedonia indicated to inform the WHO Country Office and WHO/Europe. For variant Creutzfeldt-Jacob

[10] Note: Macedonia added to the list after Multi-country workshop clarification (i.e. added to results of pre-workshop questionnaire)

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Disease, rabies and tularaemia, Albania has indicated an arrangement with their Food Safety and Veterinary Institute. Serbia has not indicated any existing arrangement.

In terms of **compliance of current case definitions with EU case definitions** (noting that ICD10 coding is not considered as EU compliant), 83% of the case definitions used by the seven countries are compliant with EU case definitions (ranging from 74%-100%). Albania and Bosnia and Herzegovina show compliance with the EU case definitions for all the 53 diseases, and the former Yugoslav Republic of Macedonia reported compliance with EU acquis for all but Tick-Borne Encephalitis.

Country	AL	BA	KS	ME	RS	MK	TR
Number of case definitions EU compliant	53	53	39	48	43	52	43
Percentage of case definitions EU compliant	100%	100%	74%	91%	81%	98%	81%

Key points discussed

Capacities in the region to confirm cases by primary and/or reference laboratory for all mandatory notifiable communicable diseases as per EU acquis were broadly discussed revealing that 'Yes/No' grading does not reflect the real picture in the countries. This notably could be illustrated by example from Serbia which has capacity to confirm anthrax cases using veterinary laboratories, even if human medicine laboratories don't have such capacity. Majority of countries might have:

- a function of reference laboratory inside the country, even if reference laboratory is not formally nominated at national level
- capacity to confirm cases outside public health sector (e.g. veterinary or food safety side)
- agreements with other countries to send samples for confirmation
- some methods available in the country, which not fully/completely meet the requirements describe in EU case definitions.

Taking into account the above, the capacities in EU enlargement countries to confirm cases for mandatory EU notifiable communicable diseases shall be revised and changed including a category 'partial capacity' (mapping of capacities before the discussion is displayed on the left side and revised/changed into partial capacity on the right side, yellow colour reflects changes after in-depth discussions by the working group members):

Disease under EU surveillance	AL	BA	KS	ME	RS	MK	TR
ANTHRAX (Bacillus anthracis)	1	1	1	0	0	1	1
BOTULISM (Clostridium botulinum)	0	0	0	1	0	1	1
CHLAMYDIAL INFECTION (Chlamydia trachomatis), INCLUDING LYMPHOGRANULOMA VENEREUM (LGV)	1	1	0	1	1	1	1
CHOLERA (Vibrio cholerae)	1	1	0	0	1	1	1
CREUTZFELDT-JAKOB DISEASE, VARIANT (vCJD)	0	0	0	0	0	1	0
CRYPTOSPORIDIOSIS (Cryptosporidium spp.)	0	1	0	1	1	1	1
DIPHTHERIA (Corynebacterium diphtheriae, Corynebacterium ulcerans and Corynebacterium pseudotuberculosis)	1	1	1	0	1	0	1
LEGIONNAIRES' DISEASE (Legionella spp.)	1	1	0	1	1	1	1
LEPTOSPIROSIS (Leptospira spp.)	1	1	1	0	1	1	1
LISTERIOSIS (Listeria monocytogenes)	1	1	1	0	1	1	1
PLAGUE (Yersinia pestis)	0	0	0	0	0	1	1
POLIOMYELITIS (Polio virus)	1	0	0	0	1	0	1
RABIES (Lyssa virus)	0	0	0	0	1	1	1
SEVERE ACUTE RESPIRATORY SYNDROME — SARS (SARS-coronavirus, SARS-CoV)	1	0	0	0	0	1	1
SHIGA TOXIN/VEROCYTO-TOXIN PRODUCING ESCHERICHIA COLI INFECTION (STEC/VTEC)	0	1	0	1	0	1	1
SMALLPOX (Variola virus)	0	0	0	0	0	0	1
TETANUS (Clostridium tetani)	1	1	0	0	0	1	1
TICK-BORNE ENCEPHALITIS (TBE virus)	1	1	0	1	1	1	1
TRICHINELLOSIS (Trichinella spp.)	0	1	0	1	1	1	1
TULARAEMIA (Francisella tularensis)	0	1	1	0	0	1	1
VIRAL HAEMORRHAGIC FEVERS (VHF)	1	1	1	0	1	1	1
YELLOW FEVER (Yellow fever virus)	1	0	0	0	0	0	1

Disease under EU surveillance	AL	BA	KS	ME	RS	MK	TR
ANTHRAX (Bacillus anthracis)	1	1	1	0	0	1	1
BOTULISM (Clostridium botulinum)	0	0	2	1	2	2	1
CHLAMYDIAL INFECTION (Chlamydia trachomatis), INCLUDING LYMPHOGRANULOMA VENEREUM (LGV)	1	1	0	1	1	1	1
CHOLERA (Vibrio cholerae)	1	1	2	1	1	1	1
CREUTZFELDT-JAKOB DISEASE, VARIANT (vCJD)	2	0	2	0	0	2	0
CRYPTOSPORIDIOSIS (Cryptosporidium spp.)	1	1	2	1	1	1	1
DIPHTHERIA (Corynebacterium diphtheriae, Corynebacterium ulcerans and Corynebacterium pseudotuberculosis)	1	1	1	0	1	2	1
LEGIONNAIRES' DISEASE (Legionella spp.)	1	1	1	1	1	1	1
LEPTOSPIROSIS (Leptospira spp.)	1	1	1	0	1	1	1
LISTERIOSIS (Listeria monocytogenes)	1	1	1	1	1	1	1
PLAGUE (Yersinia pestis)	0	0	2	0	0	1	1
POLIOMYELITIS (Polio virus)	1	0	2	0	1	2	1
RABIES (Lyssa virus)	2	2	2	0	1	2	1
SEVERE ACUTE RESPIRATORY SYNDROME — SARS (SARS-coronavirus, SARS-CoV)	1	0	0	0	2	1	1
SHIGA TOXIN/VEROCYTO-TOXIN PRODUCING ESCHERICHIA COLI INFECTION (STEC/VTEC)	0	1	2	1	2	1	1
SMALLPOX (Variola virus)	0	0	2	0	0	2	1
TETANUS (Clostridium tetani)	1	1	2	0	2	2	1
TICK-BORNE ENCEPHALITIS (TBE virus)	1	1	0	1	1	1	1
TRICHINELLOSIS (Trichinella spp.)	0	1	0	1	1	1	1
TULARAEMIA (Francisella tularensis)	0	1	1	0	1	1	1
VIRAL HAEMORRHAGIC FEVERS (VHF)	1	1	1	1	1	1	1
YELLOW FEVER (Yellow fever virus)	1	0	2	0	0	2	1

Thus, following those discussions in the working group an overview of capacities by pathogen and by country was corrected by adding a category called "partial capacity" (the below table refers to the following: 0 – no capacity (highlighted in red); 1 – partial capacity (pink cells); 2 – full capacity):

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Table 1	AL	BA	KS	ME	RS	MK	TR	SUM of countries with full capacity	SUM of countries with "partial" capacity	SUM of countries with no capacity
ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS) AND HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION	2	2	2	2	2	2	2	7	0	0
ANTHRAX (Bacillus anthracis)	2	2	2	0	0	2	2	5	0	2
AVIAN INFLUENZA A/H5 OR A/H5N1 IN HUMANS	2	2	2	2	2	2	2	7	0	0
BOTULISM (Clostridium botulinum)	0	0	1	2	1	1	2	2	3	2
BRUCELLOSIS (Brucella spp.)	2	2	2	2	2	2	2	7	0	0
CAMPYLOBACTER (Campylobacter spp.)	2	2	2	2	2	2	2	7	0	0
CHLAMYDIAL INFECTION (Chlamydia trachomatis), INCLUDING LYMPHOGRANULOMA VENEREUM (LGV)	2	2	0	2	2	2	2	6	0	1
CHOLERA (Vibrio cholerae)	2	2	1	2	2	2	2	6	1	0
CREUTZFELDT-JAKOB DISEASE, VARIANT (vCJD)	1	0	1	0	0	1	0	0	3	4
CRYPTOSPORIDIOSIS (Cryptosporidium spp.)	2	2	1	2	2	2	2	6	1	0
DIPHTHERIA (Corynebacterium diphtheriae, Corynebacterium ulcerans and Corynebacterium pseudotuberculosis)	2	2	2	0	2	1	2	5	1	1
ECHINOCOCCOSIS (Echinococcus spp.)	2	2	2	2	2	2	2	7	0	0
GIARDIASIS (Giardia lamblia)	2	2	2	2	2	2	2	7	0	0
GONORRHOEA (Neisseria gonorrhoeae)	2	2	2	2	2	2	2	7	0	0
HAEMOPHILUS INFLUENZAE, INVASIVE DISEASE (Haemophilus influenzae)	2	2	2	2	2	2	2	7	0	0
HEPATITIS A (Hepatitis A virus)	2	2	2	2	2	2	2	7	0	0
HEPATITIS B (Hepatitis B virus)	2	2	2	2	2	2	2	7	0	0
HEPATITIS C (Hepatitis C virus)	2	2	2	2	2	2	2	7	0	0
INFLUENZA (Influenza virus)	2	2	2	2	2	2	2	7	0	0
INFLUENZA A(H1N1)	2	2	2	2	2	2	2	7	0	0
LEGIONNAIRES' DISEASE (Legionella spp.)	2	2	2	2	2	2	2	7	0	0
LEPTOSPIROSIS (Leptospira spp.)	2	2	2	0	2	2	2	6	0	1
LISTERIOSIS (Listeria monocytogenes)	2	2	2	2	2	2	2	7	0	0
MALARIA (Plasmodium spp.)	2	2	2	2	2	2	2	7	0	0
MEASLES (Measles virus)	2	2	2	2	2	2	2	7	0	0
MENINGOCCOCAL DISEASE, INVASIVE (Neisseria meningitidis)	2	2	2	2	2	2	2	7	0	0
MUMPS (Munps virus)	2	2	2	2	2	2	2	7	0	0
PERTUSSIS (Bordetella pertussis)	2	2	2	2	2	2	2	7	0	0
PLAGUE (Yersinis pestis)	0	0	1	0	0	2	2	2	1	4
PNEUMOCOCCAL INVASIVE DISEASE(S) (Streptococcus pneumoniae)	2	2	2	2	2	2	2	7	0	0
POLIOMYELITIS (Polio virus)	2	0	1	0	2	1	2	3	2	2
Q FEVER (Coxiella burnetii)	2	2	2	2	2	2	2	7	0	0
RABIES (Lyssa virus)	1	1	1	0	2	1	2	2	4	1
RUBELLA (Rubella virus)	2	2	2	2	2	2	2	7	0	0
RUBELLA , CONGENITAL (including Congenital Rubella syndrome)	2	2	2	2	2	2	2	7	0	0
SALMONELLOSIS (Salmonella spp. other than Salmonella Typhi and Salmonella Paratyphi)	2	2	2	2	2	2	2	7	0	0
SEVERE ACUTE RESPIRATORY SYNDROME - SARS (SARS coronavirus, SARS-COV)	2	0	0	0	1	2	2	3	1	3
SHIGA TOXIN/VEROCYTO-TOXIN PRODUCING ESCHERICHIA COLI INFECTION (STEC/VTEC)	0	2	1	2	1	2	2	4	2	1
SHIGELLOSIS (Shigella spp.)	2	2	2	2	2	2	2	7	0	0
SMALLPOX (Variola virus)	0	0	1	0	0	1	2	1	2	4
SYPHILIS (Treponema pallidum)	2	2	2	2	2	2	2	7	0	0
SYPHILIS, CONGENITAL AND NEONATAL (Treponema pallidum)	2	2	2	2	2	2	2	7	0	0
TETANUS (Clostridium tetani)	2	2	1	0	1	1	2	3	3	1
TICK-BORNE ENCEPHALITIS (TBE virus)	2	2	0	2	2	2	2	6	0	1
TOXOPLASMOSIS, CONGENITAL (Toxoplasma gondii)	2	2	2	2	2	2	2	7	0	0
TRICHINELLOSIS (Trichinella spp.)	0	2	0	2	2	2	2	5	0	2
TUBERCULOSIS (Mycobacterium tuberculosis complex)	2	2	2	2	2	2	2	7	0	0
TULARAEMIA (Francisella tularensis)	0	2	2	0	2	2	2	5	0	2
TYPHOID/PARATYPHOID FEVER (Salmonella Typhi/Paratyphi)	2	2	2	2	2	2	2	7	0	0
VIRAL HAEMORRHAGIC FEVERS (VHF)	2	2	2	2	2	2	2	7	0	0
WEST NILE FEVER (West Nile virus infection, WNV)	2	2	2	2	2	2	2	7	0	0
YELLOW FEVER (Yellow fever virus)	2	0	0	0	0	0	2	2	0	5
YERSINIOSIS (Yersinia enterocolitica, Yersinia pseudotuberculosis)	2	0	1	0	0	1	2	2	2	3

	AL	BA	KS	ME	RS	MK	TR
Number of diseases with full capacity	45	44	37	40	43	44	52
Percentage of diseases with full capacity	85%	83%	70%	75%	81%	83%	98%
Number of diseases with partial capacity	2	1	11	0	4	8	0
Number of diseases with full or partial capacity	89%	85%	91%	75%	89%	98%	98%

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For the majority of the diseases (n=33/53; 62%) all countries reported capacity in 2017.

Comparing country situation with the previous capacity (e.g. reported in Self-assessment questionnaire of ECDC assessments of countries capacities, SAQ, or from pilot participation in EULabCap), ECDC had data for four countries in total: from SAQ – Montenegro (2012), Turkey (2015), the former Yugoslav Republic of Macedonia (2016), and for Serbia that participated in the pilot EULabCap with 2015 data:

	ME	RS	MK	TR
Number of diseases for which country has national capacity according to case definitions reported in the SAQ or EULabCap	38	29	49	48
Percentage of diseases for which the country has national capacity according to case definitions reported in the SAQ or EULabCap	72%	55%	93%	91%

	ME	RS	MK	TR
Number of diseases for which country has **full national capacity** according to case definitions reported in 2017	40	43	44	52
In addition: Number of diseases for which country has **partial national capacity** according to case definitions reported in 2017	0	4	8	0
Number of diseases for which country has **full or partial national capacity** according to case definitions reported in 2017	40	47	52	52

Comparing findings from the Self-assessment questionnaires of ECDC assessments of countries capacities or from **pilot participation in EULabCap**, national capacity increased as follows:

- ✓ **Montenegro, Serbia and Turkey reported an increased number of diseases** for which their country has full national capacity in 2017 compared to the capacity reported in a previous SAQ or EULabCap;
- ✓ Serbia increased their capacity from 29 to 43 diseases and Turkey from 48 to 52 diseases and Montenegro from 38 to 40.

Technology transition to molecular surveillance and cluster detection was mentioned by majority of countries as a top priority area for which countries need immediate support

Priority area	Number of countries	Percentage of countries
Technology transition to molecular surveillance and cluster detection	**4**	**57 %**
Reporting and data exchange systems	3	43 %
Quality assurance	2	29 %
Training of laboratory staff	2	29 %
Testing guidance (including guidance for testing of sexually transmitted pathogens)	2	29 %
Antimicrobial resistance (*Acinetobacter, Pseudomonas, Klebsiella, M.tuberculosis*)	1	14 %
Biosecurity for highly infectious agents	1	14 %
Diagnostic support for pathogens that cannot be detected within the country (vCJD, plague, rabies...)	1	14 %

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Working group 2 discussion **identified gaps in capabilities for microbiology laboratory services in the EU enlargement countries** that include**:**

- The development of new and emerging microbiology laboratory methods and techniques (including next generation sequencing) and
- Formalising agreements with other institutions for collaboration (including those that are already identified but not officially appointed and those where capacity is not available)

Participants agreed that the following **needs at regional level shall be addressed** by exploiting availability of shared expertise with EU MS and EU added value**:**

- Transportation and handling of sampling of the specimens for highly contagious agents, including regulation on sample transferring, process of organisation, handling, and intergovernmental collaboration (this is in particular important for countries that e.g. are not subject to obligations to follow IATA rules).
- Smallpox topic: the need and interest to have a contact laboratory for exclusion of diagnosis. Smallpox topic could also be a perfect case study for feasibility / simulation exercise of transportation procedures (see preceding topic above).
- List of reference laboratories available in the broader region, including in EU MS (for some countries is publicly available) for possible conclusion of cooperative arrangements, upon request from the country in need.
- Training to raise awareness / familiarise with the feasibility to invest into technologies, methods and/or collaborative arrangements for next generation sequencing / whole genome sequencing, as well as learn how to interpret and understand NGS/WGS received results when samples are sent abroad.
- Access to samples for external quality assurance

It was importantly mentioned that **financial constraints** are a persistent challenge that – if not addressed – can ultimately lead to:

- ✓ lack of laboratory workforce (number);
- ✓ shortage of qualified laboratory workforce (training);
- ✓ insufficient laboratory materials/reagents/testing kits.

Conclusions from working group discussion on "*Opportunities for pooling microbiology reference laboratories capacities in EU enlargement countries* "

To address the needs mentioned during the discussion, the **following approaches for next steps were proposed**:

- Develop, harmonise and set procedures for transportation, logistics, and handling of specimens of highly pathogenic agents;
- Pre-arrange agreements needed for transportation of specimens in order to minimise non-productive security requirements where they are not essential;
- Identify contact laboratory/facility that is able to microbiologically exclude diagnosis of smallpox;
- Test the refined and harmonised specimens' transportation procedures using 'smallpox case study' as a regular feasibility/preparedness/simulation exercise activity to check if procedures work properly;
- Upon request from the country, make available the list of reference laboratories of specified pathogens (possible service with ECDC involvement);
- Provide training or study visits to EU MS to support decision making and feasibility to invest in next generation sequencing / whole genome sequencing technologies; in addition, provide training on how to interpret and understand received NGS/WGS results when samples are sent abroad;
- Ensure that training is cascaded further in the countries through training-of-trainers programmes, so that sustainability of trained workforce is better guaranteed;
- Embark on annual monitoring of laboratory capabilities based on standardised ECDC indicator tool customised for EU enlargement countries (ENLabCap) with overall aim to benchmark countries'

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capabilities in comparison with EU/EEA level and to help policymakers identify possible areas for action and support.

To implement the above, it is important to **build partnerships**/collaborators for future actions:

- Bilateral and multilateral cooperation in the region of all EU enlargement countries
- European Commission with external financial assistance, such as TAIEX, TWINNING or/and national IPA programming (such requests for external funding shall be in alignment with post-assessment national action plans)
- WHO Regional Office for Europe
- Between competent institutions from EU MS and Western Balkan countries and Turkey

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4 Meeting conclusions and follow-up

This regional multi-country workshop resulted in an improved common understanding of countries' efforts to review and reorganise national public health microbiology systems and related challenges, and supported countries in their efforts to identify the gaps at the national level related to the reference laboratory functions. The workshop also facilitated active interaction and open discussions and sharing experiences with all participants around common strategic issues of system development.

After the workshop, 19 national experts from Western Balkan countries and Turkey (i.e. National ECDC Correspondents, public health microbiology and epidemiology leaders of national communicable disease prevention and control systems):

- have a greater understanding of current state-of-play as well as existing gaps in terms of countries' efforts to map laboratory capacities and capabilities and restructure national laboratory systems supporting public health;
- have a deeper insight on gap analysis between the needs, standards and current situation on microbiology laboratory services for clinical and public health added value, and reflect on possible ways to address those gaps;
- have a better understanding on existing expertise for microbiology reference laboratory services for communicable diseases across countries;
- got impetus to initiate necessary structural changes in their national microbiology systems supporting public health and 'team-up' the national microbiology reference laboratory services in certain areas of expertise across national borders and across laboratory sectors.

Overall, the meeting was positively received for the openness of discussions, comprehensive presentations, and friendly atmosphere to share different views and experiences. Discussions in the working groups were seen as both useful and interesting, and participants also highly appreciated exchange of views among representatives with inspiring approaches towards addressing scarce funding issues for microbiology laboratory services supporting public health. Overview of meeting participants' feedback is attached to this report in Annex 4.

Multi-country workshop conclusions:

1. There is a **need for high level political attention and recognition at decision-making level for the commitment towards major upgrading of laboratory system** to address all – improvement of patient management, patient safety, and public health.

2. There needs to be a **comprehensive strategy on microbiology laboratory system** in the country, aiming at improved patient safety, public health and linked to public health control programs. Learning from the best practices or models in the EU MS could facilitate strategic direction in the countries.

3. There is an **opportunity for innovative approaches towards addressing the lack and sustainability of financing** of microbiology laboratory services for public health through savings of structural re-organisation, sharing of services between sectors, and cross-border collaboration.

4. Western Balkan countries and Turkey acknowledged that the **EULabCap tool customised by ECDC for the use of EU enlargement countries (ENLabCap)** (including individualised country reports with benchmarking against EU standards) could help them to promote necessary changes in national public health microbiology systems and start implementation of restructuring, as well as to advocate for sustainable financing mechanisms that ensure delivery of reforms.

5. To ensure that physicians at primary level **effectively use microbiology diagnostic tests**, countries need to address key issues of availability of diagnostic and screening tests and raise understanding of physicians on the benefits from testing to the patient and to public health.

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6. Key areas/programs require **high quality support from clinical and reference laboratories**, and those include particularly, but not only:
    a. enteric disease/diarrhoea diagnostics: outbreak recognition is crucial for food safety programmes;
    b. AMR testing for patient management and antibiotic policy guidance.

7. There is a need to clarify and better define **licensing-accreditation processes** (management specific vs task specific) and ensure that quality of laboratory services not only requires good coverage of EQAs, but also needs to be supported by infrastructure and trained personnel.

8. EU enlargement countries identified **needs to be addressed to increase capabilities for microbiology laboratory services and their further development**:
    a. Formalising agreements with other institutions for collaboration within and outside the countries (including those that are already identified but not officially appointed and those where capacity is not available) and
    b. New and emerging microbiology laboratory methods and techniques (including next generation sequencing, feasibility of its application, and training of laboratory personnel)

9. **Transportation of specimens and handling of samples** for highly contagious agents, including regulation on sample transferring, process of organisation, handling, and intergovernmental collaboration is a common issue in majority of EU enlargement countries.

10. **Building partnerships and collaborations** for future actions **while ensuring sustainability** is necessary to implement policy and technical commitments in the countries, and this shall include:
    a. Bilateral and multilateral cooperation in the region of all EU enlargement countries
    b. Dialogue with European Commission to mobilise external financial assistance from funding instruments available for EU enlargement countries, such as TAIEX, TWINNING or/and national IPA programming (such requests for external funding shall be in alignment with post-assessment national action plans)
    c. Cooperation with WHO Regional Office for Europe
    d. Utilising working arrangements between competent institutions from EU MS and Western Balkan countries and Turkey

Follow-up and next steps:

1. With the overall aim to help EU enlargement countries' stakeholders to promote necessary changes in national public health microbiology systems and to advocate for sustainable financing mechanisms that ensure delivery of reforms, **embark on annual monitoring of laboratory capabilities based on standardised ECDC indicator tool customised for EU enlargement countries (ENLabCap).** ENLabCap country profiles should include benchmarking of countries' capabilities in comparison with EU/EEA level and to help policymakers identify possible areas for action and support. In this regard, upon signature of ECDC-IPA5 project and availability of resources, ECDC could organise a regional **ENLabCap consultation meeting** to agree on the adjustments in the tool, on proposed process, and on individualised country profile report templates for the annual ENLabCap surveys.

2. Based on **completed reviews of national microbiology laboratory services (including private laboratories), countries should develop their comprehensive strategies** for public health microbiology laboratory systems with clear objectives and links to public health control programmes as the basis for possible reforms and reorganisation needed.

3. Provide training or study visits to EU MS to **support decision making of Western Balkan countries and feasibility to invest in next generation sequencing / whole genome sequencing technologies**. In addition, training of laboratory personnel on how to interpret and understand NGS/WGS results received from reference laboratories would be essential for optimising future choices to invest/utilise new microbiology technologies. Ensure that any training of laboratory experts/managers is cascaded further in the countries through training-of-trainers programmes, so that **sustainability of trained workforce** is guaranteed.

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4. Develop, harmonise, and set procedures for **transportation, logistics, and handling of biological specimens,** including highly pathogenic agents. **Test those transportation procedures using 'smallpox case study'** as a feasibility exercise activity to check if procedures work properly. This notably would imply identification of **contact laboratory/facility that is able to microbiologically exclude diagnosis of smallpox**, for the use of EU enlargement countries. In addition, pre-arranged agreements for transportation of specimens would be extremely helpful in order to minimise non-productive security requirements where they are not essential.
5. ECDC could facilitate / serve as a liaison for the **identification of list of reference laboratories for the specified pathogens**, when requested by the EU enlargement country. This would enable Western Balkan countries to address the missing capacities to confirm cases for the EU notifiable communicable diseases as per EU case definitions.

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Annex 1. Agenda

ECDC Multi-country workshop for EU enlargement countries on microbiology laboratory systems supporting public health

20-21 June 2017

(Hotel Belvedere Ohrid, St. Stephan Settlement B.B.)

DAY 1	**Tuesday, 20 June 2017** **Opening and plenary session 1 – Strategic issues of microbiology laboratory systems supporting public health for communicable disease prevention and control** *Chair: Maarit KOKKI, Head of International Relations Section, ECDC*
08:30 – 09:00	***Registration***
09:00 – 10:45	**Opening and welcome** Hosting country (Ass. Dr. Shaban MEMETI, Director of the Institute of Public Health) and ECDC ***Updates from the European Commission***, Dominique De Backer, DG SANTE, EC **Keynote address: *Microbiology support for public health programs – redefining objectives and structures over 40 years in Finland*,** Petri Ruutu, Finland ***Public health laboratory system reforms in Eastern Europe and Central Asia,*** Joanna Zwetyenga, Technical officer/Laboratory quality expert, Health Emergencies Programme, WHO Regional Office for Europe
10:45 – 11:15	***Coffee break***
11:15 – 12:30	**Microbiology laboratory systems supporting public health in EU enlargement countries**: common issues and challenges, Maarit Kokki, ECDC **Model of restructuring laboratory systems supporting public health** (*including role of microbiology laboratory services for effective communicable disease treatment, prevention and control, tbc*) – **Austria's example,** Franz Allerberger, Austria
12:30 – 13:30	**Group photo and lunch**
13:30 - 15:00	**Serbia's experience on national review of laboratory networks,** Ljiljana Pavlovic, Serbia **Latvia's experience in organization of national reference laboratory system supporting public health and overcoming the challenges,** Jana Feldmane, Latvia *Overview of pre-workshop questionnaire results and Introduction to Working group discussions (*Katrin Leitmeyer*, ECDC)*
15:00 – 15:30	***Coffee/tea break***

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DAY 1	**Working group session A (WG1 and WG2)**
15:30 – 18:00	**Working Group 1: Mapping the needs for restructuring and missing capacities of national laboratory systems supporting public health and system development** Moderator: Petri Ruutu (FI) Facilitators: Maarit Kokki (ECDC), Katrin Leitmeyer (ECDC), Andreas Reich (DE), Daniela Homorodean (RO) **Working Group 2: Opportunities for pooling microbiology reference laboratory capacities in EU enlargement countries** Moderator: Franz Allerberger (AT) Facilitators: Gaëtan Muyldermans (BE), Jana Feldmane (LV), Dominique De Backer (DG SANTE), Nadine Zeitlmann (DE)
Optional dinner outside meeting venue	

DAY 2	**Wednesday, 21 June 2017** **Plenary session 2 – Sharing practices on microbiology laboratory systems supporting public health for communicable disease prevention and control** *Chair: Maarit KOKKI, Head of International Relations Section, ECDC*
09:00 – 10:30	**Montenegro experience on national review of laboratory networks** **Strengthening microbiology laboratory systems supporting public health in Turkey,** Selçuk KILIÇ, Turkey **Roadmap for the implementation of a national reference laboratory network in Belgium,** Gaëtan Muyldermans, Belgium
10:30 – 11:00	***Coffee break***
11:00 – 12:00	**Microbiology laboratory role in MDR-TB outbreak investigation in Romania,** Daniela Homorodean, Romania **Core functions of microbiology reference laboratories for communicable diseases**: an EU perspective and an overview of reference level functions in the EU Member States, Katrin Leitmeyer, ECDC
DAY 2	**Working group session B (WG1 and WG2, continued)**
12:00 – 13:00	**WG 1: Mapping the needs for restructuring and missing capacities of national laboratory systems supporting public health and system development** Moderator: Petri Ruutu (FI) Facilitators: Maarit Kokki (ECDC), Katrin Leitmeyer (ECDC), Andreas Reich (DE), Daniela Homorodean (RO) **WG 2: Opportunities for pooling microbiology reference laboratory capacities in EU enlargement countries**

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	Moderator: Franz Allerberger (AT) Facilitators: Gaëtan Muyldermans (BE), Jana Feldmane (LV), Dominique De Backer (DG SANTE), Nadine Zeitlmann (DE)
13:00 – 14:00	***Lunch***
DAY 2	**Plenary session 3 – Debriefing from working groups, conclusions and next steps** *Chair: Maarit KOKKI, Head of International Relations Section, ECDC*
14:00 – 15:15	**Debriefing and key conclusions from WG1** (WG rapporteur and moderator) **Debriefing and key conclusions from WG2** (WG rapporteur and moderator) Plenary discussions
15:15 – 15:45	**Coffee/tea break**
15:45 – 16:30	Reflection on possibilities for revision and use of indicator tool for monitoring laboratory capabilities in the EU enlargement countries (ECDC) Concluding remarks (ECDC)

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Annex 2. List of participants

ECDC Multi-country workshop for EU enlargement countries on microbiology laboratory systems supporting public health

20-21 June 2017, Ohrid,
the former Yugoslav Republic of Macedonia

List of participants

Country	Name	Role and affiliation	Working Group
EU candidate and potential candidate countries			
ALBANIA	**Marjeta DERVISHI**	*Replacing National ECDC Correspondent* Epidemiologist, Institute of Public Health	*WG2*
	Andi KORAQI	*Observer NMFP* Microbiologist, Tirana University Hospital Centre	*WG1*
	Majlinda KOTA	*Senior expert having leadership of the national communicable disease surveillance system* Virologist, Institute of Public Health	*WG2*
BOSNIA AND HERZEGOVINA	**Pava DIMITRIJEVIĆ**	*Observer NMFP* Microbiologist, Head of the Department of Microbiology, Public Health Institute of the Republic of Srpska	*WG2*
	Amela DEDEIĆ-LJUBOVIĆ	*Senior expert having leadership of the national communicable disease surveillance system* Head of the Clinic for Microbiology Clinical Centre University of Sarajevo	*WG1*
KOSOVO*	**Lul RAKA**	*National ECDC Correspondent* Microbiologist, Professor assistant of Microbiology National Institute of Public Health	*WG1*
	Gjyle MULLIQI-OSMANI	*Observer NMFP* Professor of Microbiology National Institute of Public Health of Kosovo Department of Microbiology and University of Pristina	*WG2*
	Ariana KALAVESHI	*Senior expert having leadership of the national communicable disease surveillance system* Head of surveillance unit for communicable diseases Department of Epidemiology for Surveillance National Institute of Public Health	*WG2*
MONTENEGRO	**Boban MUGOSA**	*National ECDC Correspondent* Associate Professor Director of Institute of Public Health	*WG1*

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Country	Name	Role and affiliation	Working Group
	Zoran VRATNICA	*Observer NMFP* Director of the Centre for Medical Microbiology Institute of Public Health	*WG1*
	Božidarka RAKOČEVIC	*Senior expert having leadership of the national communicable disease surveillance system* Director of Department for Control and Prevention Communicable Diseases Institute of Public Health	*WG2*
SERBIA	**Goran STEVANOVIC**	*National ECDC Correspondent* Infectious diseases specialist Clinic for Infectious and Tropical Disease Clinical Centre of Serbia	*WG2*
	Ljiljana PAVLOVIC	*Alternate Observer NMFP* Head of Centre for Microbiology Institute of Public Health of Serbia	*WG2*
	Darija KISIC TEPAVCEVIC	*Senior expert having leadership of the national communicable disease surveillance system* Associate professor, Deputy Director National institute for public health in Serbia	*WG1*
THE FORMER YUGOSLAV REPUBLIC OF MACEDONIA	**Golubinka BOSEVSKA**	*Replacing National ECDC Correspondent (Alternate Observer NMFP)* Head of laboratory for virology and molecular diagnostics Institute of Public Health	*WG1*
	Milena PETROVSKA	*Observer NMFP* Prof., Institute of Microbiology and Parasitology Medical Faculty, University Ss Ciril and Methodius	*WG2*
	Kristina STAVRIDIS	*Senior expert having leadership of the national communicable disease surveillance system* Epidemiologist, Department for surveillance of communicable diseases Institute of Public Health	*WG1*
TURKEY	**Ahmet MIRAÇ SÖNMEZ**	*National ECDC Correspondent* EU Expert Ministry of Health of Turkey General Directorate of Affairs and European Union	*WG2*
	Selçuk KILIÇ	*Observer NMFP* Head of Microbiology Reference Laboratories Department Public Health Institution of Turkey	*WG1*

EU Member States representatives and speakers

AUSTRIA	**Franz ALLERBERGER**	Professor, Austrian Agency for Health and Food safety (AGES)	*WG2*
BELGIUM	**Gaëtan MUYLDERMANS**	Scientific collaborator, Epidemiology of Infectious Diseases, Public Health and Surveillance, Scientific Institute of Public Health	*WG2*
BULGARIA	**Svetla ANGELOVA**	Assistant Professor, National Centre of Infectious and Parasitic Diseases, National Laboratory "Influenza and ARD"	*WG1*

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CROATIA	**Blaženka HUNJAK**	Microbiologist, Medical Doctor, Croatian National Institute of Public Health	*WG1*
FINLAND	**Petri RUUTU**	Professor, National Institute for Health and Welfare	*WG1*
GERMANY	**Andreas REICH**	Epidemiologist, Surveillance Unit, Robert Koch Institute	*WG1*
GERMANY	**Nadine Cornelia ZEITLMANN**	Epidemiologist, Surveillance Unit, Robert Koch Institute	*WG2*
LATVIA	**Jana FELDMANE**	Head of the division of Environmental Health, Ministry of Health Republic of Latvia	*WG2*
ROMANIA	**Daniela HOMORODEAN**	Senior Microbiologist, Clinical Hospital of Pneumology	*WG1*
European Commission and WHO/Europe representatives			
DG SANTE	**Dominique DE BACKER**	Policy Officer, European Commission, DG Health and Food Safety (DG SANTE)	*WG2*
WHO/Europe	**Joanna ZWETYENGA**	Laboratory Quality Expert, WHO Regional Office for Europe	*WG1*
ECDC experts			
ECDC	**Maarit KOKKI**	Head of International Relations Section, Director's Office	*WG1*
	Katrin LEITMEYER	Senior Expert Virology, Office of the Chief Scientist	*WG1*
	Agnė BAJORINIENĖ	International Relations Officer, International Relations Section, Director's Office	*WG2*

* This designation is without prejudice to positions on status, and is in line with UNSCR 1244 and the ICJ Opinion on the Kosovo Declaration of Independence

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Annex 3. Example of pre-workshop questionnaire

ECDC Multi-country workshop for EU enlargement countries on microbiology laboratory systems supporting public health

20-21 June 2017, Ohrid, the former Yugoslav Republic of Macedonia

Pre-workshop questionnaire for Montenegro

Dear participants of the ECDC Multi-country workshop,

As mentioned in the description of the upcoming Multi-country workshop, to achieve the objectives of the ECDC meeting and to support effective discussions during the group work, we are kindly asking you to reply to the below questions.

With this questionnaire we aim to capture the state-of-play of ongoing mapping, review, and possible restructuring of microbiology laboratory systems supporting public health in your country and to map the available microbiology laboratory expertise in Montenegro. We are expecting you to send us coordinated replies from your country, and therefore the preparation of answers might entail in-country discussions with key national stakeholders and collection of available information together with other colleagues working in the field.

This questionnaire includes mainly Yes/No questions and we would very much appreciate if you could answer all seven questions with the information available at the moment. The time invested in replies will be very useful for ECDC to support your efforts to review and reorganise microbiology laboratory systems supporting public health, identify gaps at the national level related to the reference laboratory functions, and to provide you with an overview for possible shared expertise across EU enlargement countries.

Please rest assured that your responses will be analysed and used solely for the discussions in the working groups and any further use of country information will be discussed and agreed during the meeting.

If you have any questions about the Pre-workshop questionnaire, please email us at agne.bajoriniene@ecdc.europa.eu. We very much appreciate your input!

Thank you,

International Relations Section and Microbiology Coordination Section, ECDC

Explanatory note on terms used in this questionnaire:

'Public health microbiology' is a cross-cutting area that spans the fields of human, animal, food, water and environmental microbiology, with a focus on human health and disease. It requires laboratory scientists with the ability to work effectively across disciplines, particularly epidemiology and clinical medicine. Public health microbiology laboratories, or laboratories with these functions, play a central role in infectious disease detection, monitoring, outbreak response and providing scientific evidence to prevent and control disease.

Source:
http://ecdc.europa.eu/en/publications/Publications/1006_TER_Core_functions_of_reference_labs.pdf

1. Do you currently have the capacities to confirm cases by primary and/or reference laboratory for the following notifiable 53 communicable diseases as per EU acquis?

Please complete the below table. For your easier reference we have included answers from the Self-assessment questionnaire (SAQ) of EC/ECDC assessment of countries capacities or from EULabCap, where available.

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. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:262:0001:0057:EN:PDF. Please see laboratory criteria displayed in the comments of the last column of this table.

Disease under EU surveillance	National capacity according to case definitions in Montenegro reported in SAQ in 2012	Capacity in 2017 (Yes/No)	If no capacity, do you currently have arrangements with other countries? (Yes/No)	If you currently have arrangements with laboratories in other countries, please indicate the institution and country	Are Case definitions used in your country compliant with EU case definitions? (Yes/No) Please note that ICD10 coding is not considered as EU compliant	Links to EU case definitions Please see/click comment to display laboratory criteria as per EU case definitions for your easier reference
ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS) AND HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION	Yes					Laboratory Criteria (HIV)
ANTHRAX (*Bacillus anthracis*)	Yes					Laboratory Criteria (Anthrax)
AVIAN INFLUENZA A/H5 OR A/H5N1 IN HUMANS	Yes					Laboratory Criteria (Avian influenza A/H5 or A//H5N1 in humans)
BOTULISM (*Clostridium botulinum*)	Yes					Laboratory Criteria (Botulism)
BRUCELLOSIS (*Brucella spp.*)	Yes					Laboratory Criteria (Brucellosis)
CAMPYLOBACTERIOSIS (*Campylobacter spp.*)	Yes					Laboratory Criteria (Campylobacteriosis)
CHLAMYDIAL INFECTION (*Chlamydia trachomatis*), INCLUDING LYMPHOGRANULOMA VENEREUM (LGV)	Yes					Laboratory Criteria (Chlamydial infection)
CHOLERA (*Vibrio cholerae*)	Yes					Laboratory Criteria (Cholera)
CREUTZFELDT-JAKOB DISEASE, VARIANT (vCJD)	No					Laboratory Criteria (Creutzfelt-Jacob disease)
CRYPTOSPORIDIOSIS (*Cryptosporidium spp.*)	Yes					Laboratory Criteria (Cryptosporidiosis)
DIPHTHERIA (*Corynebacterium diphtheriae*, *Corynebacterium ulcerans* and *Corynebacterium pseudotuberculosis*)	No					Laboratory Criteria (Diphtheria)
ECHINOCOCCOSIS (*Echinococcus spp.*)	Yes					Laboratory Criteria (Echinococcosis)
GIARDIASIS (*Giardia lamblia*)	Yes					Laboratory Criteria (Giardiasis)
GONORRHOEA (*Neisseria gonorrhoeae*)	Yes					Laboratory Criteria (Gonorrhoea)
HAEMOPHILUS INFLUENZAE, INVASIVE DISEASE (*Haemophilus influenzae*)	Yes					Laboratory Criteria (Haemophilus influenzae)
HEPATITIS A (Hepatitis A virus)	Yes					Laboratory Criteria (Hepatitis A)
HEPATITIS B (Hepatitis B virus)	Yes					Laboratory Criteria (Hepatitis B)
HEPATITIS C (Hepatitis C virus)	Yes					Laboratory Criteria (Hepatitis C)
INFLUENZA (Influenza virus)	Yes					Laboratory Criteria (Influenza)
INFLUENZA A(H1N1)	Yes					Laboratory Criteria (Influenza A)
LEGIONNAIRES' DISEASE (*Legionella spp.*)	Yes					Laboratory Criteria (Legionnaire's disease)
LEPTOSPIROSIS (*Leptospira spp.*)	No					Laboratory Criteria (Leptospirosis)
LISTERIOSIS (*Listeria monocytogenes*)	Yes					Laboratory Criteria (Listeriosis)
MALARIA (*Plasmodium spp.*)	Yes					Laboratory Criteria (Malaria)
MEASLES (Measles virus)	Yes					Laboratory Criteria (Measles)
MENINGOCCOCAL DISEASE, INVASIVE (*Neisseria meningitidis*)	Yes					Laboratory Criteria (Meningococcal disease, invasive)
MUMPS (Mumps virus)	Yes					Laboratory Criteria (Mumps)
PERTUSSIS (*Bordetella pertussis*)	Yes					Laboratory Criteria (Pertussis)
PLAGUE (*Yersinia pestis*)	No					Laboratory Criteria (Plague)
PNEUMOCOCCAL INVASIVE DISEASE[S] (*Streptococcus pneumoniae*)	Yes					Laboratory Criteria (Pneumococcal invasive disease[s])
POLIOMYELITIS (Polio virus)	No					Laboratory Criteria (Poliomyelitis)
Q FEVER (*Coxiella burnetii*)	Yes					Laboratory Criteria (Q-fever)
RABIES (Lyssa virus)	Yes					Laboratory Criteria (Rabies)
RUBELLA (Rubella virus)	No					Laboratory Criteria (Rubella)
RUBELLA, CONGENITAL (including Congenital Rubella Syndrome)	Yes					Laboratory Criteria (Rubella, congenital)
SALMONELLOSIS (*Salmonella spp. other than Salmonella* Typhi and *Salmonella* Parstyphi)	Yes					Laboratory Criteria (Salmonellosis)
SEVERE ACUTE RESPIRATORY SYNDROME — SARS (SARS-coronavirus, SARS-CoV)	No					Laboratory Criteria (SARS)
SHIGA TOXIN/VEROCYTO-TOXIN PRODUCING ESCHERICHIA COLI INFECTION (STEC/VTEC)	No					Laboratory Criteria (STEC/VTEC)
SHIGELLOSIS (*Shigella spp.*)	Yes					Laboratory Criteria (Shigellosis)
SMALLPOX (Variola virus)	No					Laboratory Criteria (Smallpox)
SYPHILIS (*Treponema pallidum*)	Yes					Laboratory Criteria (Syphilis)
SYPHILIS, CONGENITAL AND NEONATAL (*Treponema pallidum*)	Yes					Laboratory Criteria (Syphilis, congenital and neonatal)
TETANUS (*Clostridium tetani*)	No					Laboratory Criteria (Tetanus)
TICK-BORNE ENCEPHALITIS (TBE virus)	No					Laboratory Criteria (Tick-borne encephalitis)
TOXOPLASMOSIS, CONGENITAL (*Toxoplasma gondii*)	Yes					Laboratory Criteria (Toxoplasmosis, congenital)
TRICHINELLOSIS (*Trichinella spp.*)	Yes					Laboratory Criteria (Trichinellosis)
TUBERCULOSIS (*Mycobacterium tuberculosis complex*)	Yes					Laboratory Criteria (Tuberculosis)
TULARAEMIA (*Francisella tularensis*)	No					Laboratory Criteria (Tularemia)
TYPHOID/PARATYPHOID FEVER (*Salmonella* Typhi/Parstyphi)	Yes					Laboratory Criteria (Typhoid)
VIRAL HAEMORRHAGIC FEVERS (VHF)	No					Laboratory Criteria (Viral hemorrhagic fevers)
WEST NILE FEVER (West Nile virus infection, WNV)	No					Laboratory Criteria (West Nile fever)
YELLOW FEVER (Yellow fever virus)	No					Laboratory Criteria (Yellow fever)
YERSINIOSIS (*Yersinia enterocolitica*, *Yersinia pseudotuberculosis*)	Yes					Laboratory Criteria (Yersiniosis)

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2. Considering necessary actions to restructure microbiology services in order to arrive at effective, efficient and sustainable structures of microbiology laboratories for communicable disease surveillance, do you currently have:	
2.1 a national database of all available microbiology laboratories in public and private sectors	
2.2 national assessment of laboratory capacities, space, equipment, staff	
2.3 efficient electronic laboratory data reporting systems from microbiology laboratories to the central level	
2.4 efficient information exchange between sectors, including between laboratory and epidemiology services in your country	
2.5 external quality assurance systems covering all the microbiology laboratories in your country	
2.6 algorithms for sample referral in cases of diarrhoea	
2.7 algorithms for sample referral in cases of meningitis	
2.8 capacity in the clinical microbiology laboratories to identify methicillin-resistant *Staphylococcus aureus* (MRSA) isolates in accordance with EUCAST/*Staphylococcus aureus* reference laboratory network guidance	
2.9 capacity on the national level to perform molecular typing for at least one of the following: *Salmonella enterica, Listeria monocytogenes,* Shiga-toxin producing *E.coli* , Multidrug resistant *Mycobacterium tuberculosis*	
If yes, please specify which ones	
Salmonella enterica	
Listeria monocytogenes	
Shiga-toxin producing E.coli	
Multidrug resistant Mycobacterium tuberculosis	
2.10 a national policy for cross-sector and coordinated monitoring of antimicrobial resistance in human and animal bacterial isolates of public health relevance	
2.11 laboratory specialists systematically involved in preparedness planning and outbreak investigations at all levels	

3. <u>At primary level</u>, have you recently improved access to and use of culture-based bacteriological laboratory testing services?	
Please indicate Yes or No	

4. <u>At primary level</u>, what do you consider as key obstacles in your country for effective use of microbiological diagnostic tests by physicians? (please check all options that are relevant)	
4.1 diagnostic tests are not available	
4.2 not enough trained laboratory personnel	
4.3 insufficient laboratory technical equipment or reagents	
4.4 doctors don't systematically test and/or refer patients for diagnostic testing	

5. In reference to the above questions 2, 3 and 4, what would you indicate as a successful achievement that you would be proud to share with other countries undergoing similar efforts in structural changes? Please name one or several examples

6. Could you identify <u>one priority area</u> in which your country needs immediate support (apart from financial support and staff), e.g. testing guidance, reporting and data exchange systems, quality assurance, technological transition to molecular surveillance, cluster detection, training of laboratory staff, etc.?	
Please indicate your priority support area and specify for which pathogens	

7. Would you be interested to use ECDC support for annual monitoring of laboratory capabilities based on the standardised ECDC indicator tool (EULabCap) after customising it for EU enlargement countries (possibly EnLabCap)?	
Please indicate Yes or No	

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Annex 4. Participant's satisfaction

At the end of the workshop, participants were invited to provide their feedback on usefulness of information received during the meeting and overall comment on general organisation. 24 evaluation forms were collected.

ECDC Multi-country workshop for EU enlargement countries on microbiology laboratory systems supporting public health

20-21 June 2017, Ohrid

Feedback / evaluation review

Note: For the analysis of evaluation responses, the scoring is introduced to calculate average rating score where 3 is associated with the best value, 2 – middle importance, 1 – not relevance and 0 reflects no answer. N=24

Number of responses from representatives from EU enlargement country (Western Balkan countries and Turkey)	**17**
Number of responses from speakers, working group moderators or facilitators (EU MS, SANTE, WHO/Europe, ECDC)	**5**
Other	**2**

	Very good	Somehow fine	To be improved	Average of satisfaction	Total number of replies
Overall meeting scope, importance, format and implementation	21	2	1	**2.83**	**24**

Liked most:
Very cosy familiar and open atmosphere, open discussions and exchanges of experience, and very good support from ECDC.
Exchange of experiences; open discussions x4
Open discussions, friendly atmosphere x2
Fruitful discussions between participants from all the countries which is not a matter of course
Comprehensive presentations and discussions
Discussion was so open, every participant could talk in an open way. Moderator was so helpful for information
Examples from different countries, possibility to discuss in working groups on different issues x4
Working groups because it was great opportunity to aware about different approaches

	Achieved	Partially achieved	Not achieved	Average of achievement extent	Total number of replies
Extent to which the following outcomes were achieved					
To have a greater understanding of current state-of-play as well as existing gaps in terms of countries' efforts to map laboratory capacities and capabilities and restructure national laboratory systems supporting public health;	23	1	0	**2.96**	**24**
To have a deeper insight on gap analysis between the needs, standards and current situation on microbiology laboratory services for clinical and public health added value, and reflect on possible ways to address those gaps;	21	3	0	**2.88**	**24**

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To have a better understanding on existing expertise for microbiology reference laboratory services for communicable diseases across countries;	18	6	0	**2.75**	**24**
To benefit from the opportunity to interact with EU MS experts and each other around common strategic issues facing countries in system development;	20	4	0	**2.83**	**24**
To get impetus to initiate necessary structural changes in their national microbiology systems supporting public health and 'team-up' the national microbiology reference laboratory services in certain areas of expertise across national borders and across laboratory sectors	17	7	0	**2.71**	**24**
	Very relevant and appropr.	**Somehow relevant and to some extent appropr.**	**Not really relevant**	**Average of relevance rating**	**Total number of replies**
Rating of agenda topic/presentation					
Update from European Commission (DG SANTE)	20	3	1	**2.79**	**24**
Keynote address on Finland experience from Petri Ruutu	21	3	0	**2.88**	**24**
WHO/Europe overview on public health laboratory system reforms	19	4	0	**2.71**	**23**
ECDC viewpoint on microbiology laboratory systems supporting public health in EU enlargement countries	21	2	0	**2.79**	**23**
Austria's mode of restructuring laboratory systems	24	0	0	**3.00**	**24**
Serbia's experience on national review of laboratory networks	19	5	0	**2.79**	**24**
Latvia's experience in organisation of national ref labs system	13	10	0	**2.46**	**23**
Montenegro experience on national review of lab networks	20	4	0	**2.83**	**24**
Turkey overview on microbiology laboratory systems	21	2	0	**2.79**	**23**
Belgium experience on national ref labs network implementation	20	3	0	**2.75**	**23**
ECDC overview on reference functions of microbiology labs for communicable diseases and EULabCap	20	3	0	**2.75**	**23**
Note from ECDC: apologies for accidentally not including into meeting evaluation form the Romania's experience on microbiology laboratory role in MDR-TB outbreak investigation					
	Very good / very satisfied	**Somehow fine**	**Unsatis-factory**	**Average of satisfaction**	**Total number of replies**
WG1. Mapping the needs for restructuring and missing capacities of national laboratory systems supporting public health and system development					
Preparations by collecting country information via Pre-workshop questionnaire with elements to be discussed in the working groups	11	0	0	**3.00**	**11**
Working group discussions and its results/follow-up actions	11	0	0	**3.00**	**11**

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WG2. Opportunities for pooling microbiology reference laboratory capacities in EU enlargement countries					
Preparations by collecting country information via Pre-workshop questionnaire with elements to be discussed in the working groups	13	0	0	**3.00**	**13**
Working group discussions and its results/follow-up actions	13	0	0	**3.00**	**13**
Overall meeting	**Very satisfied**	**Somehow fine**	**To be improved**	**Average of satisfaction**	**Total number of replies**
ECDC travel arrangements for ECDC funded participants, transfers, information with travel logistics	22	1	0	**2.96**	**23**
Venue of the meeting (including location, meeting rooms and other facilities)	17	6	1	**2.67**	**24**
Time in the agenda allocated for discussions and country reflections	23	1	0	**2.96**	**24**
Coffee breaks and lunches	17	7	0	**2.71**	**24**
Optional dinner on 20 June	14	2	0	**2.88**	**16**

Workshop discussion topics that were appreciated and perceived as most relevant and useful:

- Applying of EULabCap to policies maker
- Finding new idea about budget for microbiology
- Everything was perfect!
- Sharing experience with other countries x3
- Turkey's presentation
- The issues are almost the same everywhere; the problems will not be resolved by their own; there is no money for "nothing"; a lot of possible "resolutions" are in our hands (ministries and government are of the great importance, but...)
- Nomination of reference labs; transportation of biological materials
- All topics were relevant and useful for my work. Collaboration with other NRL of other countries for those diagnosis which are missing in my country
- All information was relevant
- Coordination of NRL
- Report about WHO Europe regional reform in public health laboratory network, because it was new information and most relevant for my work. Also working group was very informative and relevant for my work.
- Overview over EU enlargement countries' public health laboratory systems and challenges

Workshop topics that not have been addressed, but would be of interest

- Biorisk infections, biosafety, transport of specimens
- Nothing, I think that this training was completed my expectations
- Updates from the European Commission was relevant to the meeting content, but personally for my work it was less useful than other reports. But I found this information comprehensive and interesting
- Some contents could be tried to be brought across in a non-plenary way (I prefer a switch between plenary and group work, interactive methods)

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