

REPORT ON THE STATUS OF LABORATORY NETWORKS FOR HIGH THREAT PATHOGENS IN SOUTH-EASTERN EUROPEAN COUNTRIES

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Executive summary

As part of the WHO health emergencies programmes' support to countries to prepare for and respond to emergencies involving high threat pathogens (HTPs), and implemented through the WHO Regional Office for Europe Better Labs for Better Health initiative, a meeting was held for countries of south eastern Europe to identify gaps in laboratory capacities and make proposals for solutions. Participants included 27 experts in viral and bacterial HTP diagnostics from 11 countries¹, including seven countries of the South-eastern European Health Network² (SEEHN) (http://www.euro.who.int/en/about-us/south-eastern-europe-health-network-seehn), together with representatives of international laboratory networks (EMERGE, EVD-LabNet and MediLabSecure) and CORDS (Connecting Organizations for Regional Disease Surveillance). The meeting was organized in collaboration with the Southeast European Center for Surveillance and Control of Infectious Diseases (SECID).

This first meeting of SEE countries on laboratory preparedness for HTP demonstrated many examples of collaboration among countries and with international laboratory networks, and confirmed that there was a strong willingness to continue and strengthen these collaborative efforts with the support of WHO.

Based on presentations provided by country representatives, as well as discussions during break-out sessions on their diagnostic capabilities, a number of gaps and needs were identified – the main ones being insufficient resources, insufficient training, lack of access to standardized assays and reference materials, and insufficient expedited shipment of samples to international reference laboratories.

Proposed solutions included advocacy to raise awareness among decision-makers, development of national and possibly regional strategies, revision of national regulations on shipments of infectious substances, provision of training and external quality assessment (EQA) programs, and the establishment of networks for laboratory response to HTPs that would include all the countries that participated in the meeting.

The meeting also identified the following HTP as the highest priority for the improvement of laboratory capacities: orthoanta virus, West Nile virus, Crimean Congo haemorrhagic fever virus, tick-borne encephalitis virus, Francisella tularensis, Brucella, Anthrax, Leptospira and Coxiella burnetti.

As a next step, countries will complete a questionnaire in order to collect detailed information that will form the basis for recommendations and for action plans tailored to country-specific needs.

¹ Albania, Bosnia and Herzegovina, Bulgaria, Croatia, Greece, Montenegro, Republic of Moldova, Serbia, Slovenia, the former Yugoslav Republic of Macedonia and Turkey.

² Countries in the South-eastern Europe Health Network (SEEHN) are Albania, Bosnia and Herzegovina, Bulgaria, Croatia, Israel, Montenegro, Republic of Moldova, Romania, Serbia and the former Yugoslav Republic of Macedonia.



Background

Under the new WHO Health Emergencies program (WHE), the area of Infectious Hazards Management (IHM) provides technical support to countries and communities to prevent and control outbreaks caused by high threat pathogens, including Ebola viruses, influenza A and B viruses, Crimean Congo haemorrhagic fever virus (CCHF), Zika virus, Rift Valley fever virus and cholera. This support includes strengthening national and international laboratory networks for HTPs, prepositioning reagents, deploying technical field assistance, helping strengthen national response capacity, and supporting preparedness plans

(http://apps.who.int/gb/ebwha/pdf files/WHA70/A70 7-en.pdf).

At the WHO Regional Office for Europe, this work is conducted as part of the Better Labs for Better Health initiative that focuses on strengthening country core laboratory capacities required under the International Health Regulations (2005) (IHR).

Both WHO and the European Union (EU) support laboratory networks for managing (HTPs) in the WHO European Region.

WHO-supported networks for emerging HTPs include:

- The Especially Dangerous Pathogens Laboratory Network (EDPLN)
- The WHO-coordinated networks for influenza the Global Influenza Surveillance and Response System (GISRS)
- The European Tuberculosis Laboratory Initiative (ELI)
- The European Measles and Rubella Laboratory Network
- The Polio Laboratory Network

See www.euro.who.int/labs.

EU-supported networks for emerging HTPs include:

- EVD-LabNet, a European expert laboratory network for emerging viral diseases(https://www.evd-labnet.eu/)
- EMERGE, a network for efficient response to highly dangerous and emerging pathogens at EU level https://www.emerge.rki.eu/
- MediLabSecure, a One Health Network for the Prevention of Vector-borne Diseases Around the Mediterranean and Black Sea Regions (http://www.medilabsecure.com/)

WHO-coordinated networks include all Member States of the WHO European Region, while EU-supported networks include some non-EU/EEA countries of south eastern and eastern Europe.

The Better labs for Better Health initiative has shown that public health laboratory networks in a number of these countries are functioning poorly

(http://www.euro.who.int/__data/assets/pdf_file/0020/318260/Better-Labs-Better-Health-initiative-activity-report.pdf), and lack of inclusion of these countries in international laboratory networks for HTP is therefore a key gap.

For these reasons, a workshop was organized in collaboration with SECID for countries of south eastern Europe to discuss the situation regarding capacities and capabilities for laboratory preparedness and response to HTPs, and to identify gaps and needs.

The list of participants and the agenda can be found in annexes 1 and 2 respectively.

Objectives of the meeting

- Discuss activities of existing international laboratory networks in the area of HTPs;
- Discuss priority HTPs relevant to the participating countries;
- Identify gaps and needs in laboratory capacities and capabilities to prepare for and respond to priority HTPs in countries of south eastern Europe;
- Identify actions that could be taken to improve the situation.

Activities of international laboratory networks

WHO-coordinated laboratory networks for HTPs include the WHO Regional Office for Europe's regional influenza laboratory network, which is part of the WHO GISRS and is comprised of national influenza centres (NICs) in 50 countries of the Region. 43 countries have NICs formally recognized by WHO. Among the participating countries, only in Bosnia and Herzegovina and the Former Yugoslav Republic of Macedonia are NICs yet to obtain WHO-recognition. In addition, WHO's EDPLN is a global network which contributes to preparedness and outbreak response as well as rapid development of diagnostic assays for emerging and infectious pathogens.

Three international networks for HTPs that are supported by the EU were represented at the meeting.

EMERGE is comprised of some 40 diagnostic laboratories in EU countries focused on risk group 3 bacteria and risk group 4 viruses (Ref. 4 and 5). EMERGE aims to provide a common, coordinated and effective response to infectious disease outbreaks at EU level and abroad. Member institutions were formally nominated by their countries and institutions from the following SEE countries are partners within the network: Croatia, Slovenia, Greece, Bulgaria, Hungary and Romania. The hub of this network is located at the Robert Koch Institut, Berlin, Germany for bacteria, and the Istituto Nazionale per le Malattie Infettive "Lazzaro Spallanzani", Rome, Italy for viruses (Ref. 6). The current project funding period ends in May 2018.

EVD-LabNet includes the following countries or areas of SEE: Albania, Bosnia and Herzegovina, Bulgaria, Croatia, Greece, Hungary, Serbia, Slovenia, the former Yugoslav Republic of Macedonia, Turkey (Ref. 7). Montenegro, Republic of Moldova and Kosovo (in accordance with United Nations Security Council Resolution 1244 [1999]) were not part of the network at the time of the meeting but have been members since December 2017. A prerequisite for identification, surveillance, assessment and communication of current and emerging infectious disease threats to Public Health, is the availability of reliable capability and sufficient capacity of diagnostic and reference laboratory services. To facilitate this, the European Centre for Disease Provention and Control (ECDC) has contracted the Erasmus Medical Centre to establish and operate an expert laboratory network for networking, external quality assessments and training of laboratory personnel involved in these activities. EVD-LabNet creates and maintains a (pro)active and flexible network of European expert laboratories that are involved in patient diagnostics, and that support public health activities in liaison with research activities of (re)emerging viral diseases. The network focuses on virus families and genera that are rare, imported and (re)emerging in EU/EEA countries. EVD-LabNet members agreed a Memorandum of Understanding (MOU) describing the conditions for EVD membership.

The **MediLabSecure** project aims to increase the health security in the Mediterranean Area and South-East Europe Black Sea Region through:

- Capacity building
- Enhancing and strengthening the preparedness to common health threats and bio-safety risks at national and regional levels by the creation of a network of laboratories
- Strengthening the cooperation already previously established by EpiSouth (R and 8).

The MediLabSecure network includes the following SEE countries or areas: Albania, Bosnia and Herzegovina, Montenegro, Republic of Moldova, the former Yugoslav Republic of Macedonia, Serbia, Turkey and Kosovo (in accordance with United Nations Security Council Resolution 1244 [1999]). It focuses on emerging vector borne viral diseases (arboviruses) and also covers medical entomology and public health issues. The hub of the network is located at the Pasteur Institute in Paris and is funded by the European Commission until summer 2018. Besides veterinary and human virology networks, MediLabSecure includes sub-networks for entomology and for public health reinforcement.

The different EU-supported networks include different countries of south eastern Europe and provide a number of benefits including information exchange, training workshops, participation in EQAs, etc. However, at the time of the workshop, none of them included all of the countries that participated in the workshop, as shown in Table 1.

Table 1: Participation in EU-supported laboratory networks by SEE countries represented at the meeting

Country or area	EVD- LabNet	EMERGE	MediLab -Secure
Albania	+		+
Bosnia and Herzegovina	+		+
Bulgaria	+	+	
Croatia			
Greece	+	+	
Hungary	+	+	
Montenegro	+*		+
Republic of Moldova	**		+
Romania	+	+	
Serbia	+		+
Slovenia	+	+	
The former Yugoslav Republic of Macedonia	+		+
Turkey	+		+
Kosovo (in accordance with United Nations Security Council Resolution 1244 [1999])	+*		+
	10/14	5/14	8/14

^{*}Member as of December 2017.

^{**} Pending as of February 2018.

High threat pathogens relevant to countries of south eastern Europe

In order to tailor its support to Member States in the area of preparedness and response to HTPs, the WHO's WHE programme focuses on those pathogens that pose a high public health risk because of their epidemic potential and because there are no, or insufficient, interventions. This includes the pathogens of global significance mentioned in Annex 2 of the IHR (2005)

(http://apps.who.int/iris/bitstream/10665/246107/1/9789241580496-eng.pdf), as well as pathogens prioritized by the WHO Research and Development Blueprint (Ref. 1). This list includes infectious pathogens such as Lassa Fever, Ebola, CCHF and MERS that pose a public health risk because of their epidemic potential and for which there are no, or insufficient, countermeasures and which are not covered in other WHO programs. There may be additional priority pathogens relevant to the WHO European Region, some of which are notifiable at the EU level (Ref. 2). These include vaccine preventable, sexually transmitted, food- and water-borne, air-borne and vector-borne diseases.

During the meeting, participants were asked to identify those HTPs for which they considered support was needed in the area of laboratory preparedness and response in their country.

Participants considered priority HTPs to be those that would pose the highest risk to the population (particularly highly transmissible pathogens that cause severe disease and death) and that these pathogens could be endemic, emerging or imported. Handling of patients and samples affected by such pathogens could require high levels of biosafety and biosecurity, as well as appropriate infection prevention and control practices by attending health personnel.

Participants considered the pathogens listed in Table 2 to have the highest priority regarding the need to improve laboratory capacities and capabilities.

Table 2: HTPs in SEE countries requiring improvements in laboratory capacities

Viruses:	Bacteria:
CCHF	Francisella tularensis
Hanta	Brucella
West Nile	Anthrax
Tick-borne Encephalitis	Leptospira
	Coxiella

Gaps identified and proposals for improvement

To obtain an overview of the current situation regarding diagnostic capacities for HTPs, the participating country representatives gave brief presentations on the current situation of HTP diagnostics, existing collaborations and the needs and gaps for improvement. Although not all countries provided a complete overview of their diagnostic situation, it was noticeable that there was some heterogeneity between the different countries: while some laboratories provide a wide spectrum of HTP diagnostics, others provide only very few PCR (detection) assays for some HTPs. This aligns with the previous findings in a multi-country workshop conducted by the European Centre for Disease Prevention and Control (ECDC) in June 2017 (Ref. 3).

Some of the SEE countries also presented weaknesses and gaps regarding laboratory preparedness for high threat pathogens, and all participants provided input to this discussion during break-out sessions. Table 3 provides an overview of both some of the common gaps and proposed solutions discussed during the workshop. Recommendations from the above-mentioned multi-country workshop conducted by ECDC are cross-referenced in the table.

Table 3: Gaps in laboratory diagnostics for HTPs and possible solutions.

Gap/issue	Proposed Solutions		Potential impact	Corresponding recommendation from ECDC workshop Ref. 3
	Country	SEE region		
HTPs that are rare and/or imported are not prioritized by the country resulting in insufficient resources for preparedness	Develop a strategic plan for HTPs that is endorsed by the government.	Collect and share strategic plans from SEE countries or beyond as examples of best practice. Develop advocacy materials and conduct fund-raising activities.	Government more likely to provide adequate resources.	1, 3
Countries lack a list of priority HTPs.	Each country should maintain an up-to-date list of priority HTPs.	Develop a risk classification for HTPs in the SEE region.	National public health authorities better informed of HTP risks for the population.	

In a ufficient a valence a of	Francis valariant inatitudiana	Consume time also mario mal	Enhanced moultinesternal	
Insufficient exchange of	Ensure relevant institutions	Ensure timely regional	Enhanced multisectoral	
information on HTPs within	in countries have access to	communication of IHR NFP	collaboration related to	
countries.	communication channels	and laboratory	HTPs.	
	to interact with the IHR national focal point (NFP).	representatives that can include all countries or a group of countries according to the event related to HTP and prepare rapid cross border preparedness and response plans to HTPs.	Rapid cross border preparedness and response plans and teams to priority HTPs are developed and identified.	
Insufficient exchange of information on HTPs among countries.	Ensure that IHR NFPs are using the WHO Event Information Site to exchange information and contact and exchange information with NFPs from other countries.	Continue to organize meetings to identify barriers and opportunities for IHR NFPs and laboratory experts to exchange information e.g. through SECID. Prepare a regional strategy on improving notification and risk communication within strengthening IHR capacities.	Enhanced intercountry collaboration on IHR issues.	3, 10

Outdated regulations for	Revision of national	Identify best-practice	Early detection of	9
international transport of	regulations for handling	examples from countries	outbreaks caused by HTPs.	
samples.	and shipment of samples	where regulations allow		
	containing HTPs, taking	rapid shipment and		
	into account national and	exchange of clinical		
	international biosafety	samples and reference		
	regulations.	strains.		
		Develop a regional		
		document with best		
		practice examples for rapid		
		shipment and exchange of		
		clinical samples and		
		reference strains.		
International institutional	Countries identify	Consider identifying	Early confirmation of	8, 9
agreements for cross-	international reference	laboratories in SEE	outbreaks caused by HTPs.	
border sharing of samples	laboratories for HTPs and	countries that would have		
that comply with existing	develop agreements as	a regional role and develop		
international frameworks	part of preparedness	terms of reference.		
(IHR, Nagoya protocol,	activities.			
Pandemic Influenza				
Preparedness Framework).				

Lack of staff trained in laboratory diagnostics for HTPs.	Provide training and workshops on diagnostic tests for HTP, including integrated training on biorisk management.	Conduct intercountry workshops where appropriate Preparation of a list of priority intercountry workshops.	Increased capacity of staff to detect HTPs under safe conditions.	8
Lack of reagents and consumables for HTPs.	Prepositioning of reagents and consumables at national level.	Establish a repository of diagnostic material and kits required for laboratory diagnostic of HTPs in one country of the SEE region according to the pathogen. Discuss joint procurement strategies for laboratory reagents, linking where possible to existing joint procurement strategies in the SEE region.	Reduce the time to detect HTPs in an outbreak situation.	
Lack of standardization of methods within and between countries.	Ensure every country with testing capacity has access to reference strains and materials as well as EQA for priority HTPs.	Collectively identify priority HTPs for which reference materials and EQA are not currently available.	Diagnostic assays for HTP performed by SEE countries validated according to international criteria.	8

Lack of laboratory	Allocate funds for	Identify qualified agencies	Equipment is more reliable	
maintenance and	equipment servicing and	that could provide	and regularly maintained.	
equipment servicing.	maintenance.	maintenance and		
		equipment servicing at a		
		reasonable price for the		
		region.		
Lack of Laboratory	Equip and train	Look for funding and make	Enhance the quality of	
Information Management	laboratories in the use of	a tender for an LIMS	information exchange	
System (LIMS).	LIMS.	provider for the region.	within and between	
		Identify best practices and	laboratories.	
		strategies for LIMS in		
		countries of the region.		

Conclusions and next steps

The first meeting of the SEE countries on laboratory preparedness for HTPs showed that there is a great willingness to collaborate among countries and together with international laboratory networks and other partners. Participants also agreed that there were significant gaps and needs for improvement in preparedness regarding HTPs in this region. Public health structures including laboratories do not always receive the resources necessary to be able provide appropriate, timely and efficient public health measures in case of an emergency. This is partly due to financial constraints and insufficient awareness among decision-makers. Consequently, raising awareness and development of national and possible regional strategies was mentioned as a priority. Careful planning, allocation of resources and training for laboratories will be crucial to improving the management of response activities and to guide the development of medical interventions. As no country alone can handle the increasing demand on diagnostics of endemic and emerging HTPs, closer collaboration between the diagnostic laboratories within and among countries in the SEE region is needed.

Participants were also in favour of establishing an SEE-regional laboratory network for HTPs adapted to their needs and targeting the regional gaps more precisely. To avoid duplication, such a network should build on and work with existing international networks for the management of public health events related to HTPs. The establishment of a network will require significant resources from countries, WHO and partners should be based on an in-depth analysis of the situation in countries specifically related to laboratory capacities for HTPs. It was therefore agreed that, after the workshop, countries would complete a pathogen-based fact sheet, the analysis of which would form the basis for recommendations and an action plan for their implementation.

Nearly all participants mentioned the need for further workshops, training and EQAs to improve preparedness and response for managing HTP events. Previous experience shows that it is advisable to couple training activities with both EQA and the provision of standard control materials in order to enable the laboratories to set up and establish the specific assays.

The gaps identified during this workshop are similar to those identified during the ECDC workshop for EU enlargement countries held in June 2017 (Ref. 3). The report from the ECDC workshop also identified the need for a comprehensive strategy for a microbiology laboratory system in Albania, Bosnia and Herzegovina, Montenegro, Serbia, The Former Yugoslav Republic of Macedonia, Turkey and Kosovo (in accordance with United Nations Security Council Resolution 1244 [1999]). The conclusions of both multi-country workshops include the need for high level political attention and recognition, building partnerships and collaborations, and improved specimen transportation. The need for training is also corroborated by the ECDC report "Training needs assessment for EU/EEA countries", which identified needs for training for disease surveillance, outbreak investigation and population-based research (Ref. 11).

The proposed next steps to be conducted by WHO Regional Office for Europe in collaboration with partners are to:

- 1. Distribute a questionnaire for HTP laboratory preparedness to the participating countries and collect and analyse the responses. The questionnaire will complement existing data collection mechanisms to avoid countries having to provide data that is already available.
- 2. Conduct a second workshop to discuss the results of the questionnaire and to develop both recommendations and an action plan.

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Annex 2: Agenda of the meeting

Programme

Thursday, 23 November 2017

08:30–09:00 09:00–9:30	Registration Opening – Overview of the tasks and objectives of the meeting Ministry of Health Head of Office: Dr. Skender Syla Joanna Zwetyenga, WHO EURO Silvia Bino, SECID
9:30–9:50	 Introductory presentations Context of the meeting: Joanna Zwetyenga Public Health considerations on the importance of high threat pathogens: Matthias Niedrig
9:50–10:30	Presentation of countries` representatives (participants) (Chair: Silvia Bino) Albania Bosnia and Herzegovina Bulgaria Croatia
10:30-11:00	Coffee break - Group Photo
11:00–12:00	Presentation of the countries` representatives (participants) (Chair: Silvia Bino) The former Yugoslav Republic of Macedonia Republic of Moldova Montenegro Serbia Greece Turkey Kosovo (in accordance with United Nations Security Council Resolution 1244 [1999])
12:00–13:00	Define priority list of high threat pathogens (group work) (Chair: Joanna Zwetyenga)
13:00 –14:00	Lunch Break

14:00 – 15:00	Identify gaps, needs and challenges for the diagnostic capacities and capabilities of HTPs and the quality assurance in the countries (group work) (Chair: Matthias Niedrig)
15:00 – 16:00	Identify actions that could be taken to improve the situation (group work) (Chair: Matthias Niedrig)
	Coffee break is served on the table
16:00 – 17:00	Define regulations for exchange of cross border information, materials and provide cross border support between laboratories (group work) (Chair: Joanna Zwetyenga
17:00 – 17:40	Presentation of the group work (Chair: Matthias Niedrig)
17:45	Closure of Day 1 meeting (Chair: Matthias Niedrig)
19:00	Dinner together
Friday, 24 November 2017	
9:00 – 9:30	Wrap – up of day 1 (Chair: Joanna Zwetyenga)
9:30 – 9:45	Mapping of the laboratory capacity in EU and beyond: EULapCap and pilot EnLabCap project – Katrin Leitmeyer (ECDC)
9:45 – 10:00	Introduction of different networks EVD LabNet MediLabSecure EMERGE CORDS
10:00 – 11:00	How different networks and initiatives can be supportive to SEE countries activities and initiatives (group work) (Chair: Matthias Niedrig)
11:00 – 11:30	Coffee break
11:30 – 12:30	Plan for future activities to fill the gaps and face the challenges (group work)

(Chair: Matthias Niedrig)

12:30 – 13:30	Lunch break
13:30 – 14:30	Plan for future meetings and trainings (group work) (Chair: Joanna Zwetyenga)
14:30 – 15:15	A regional plan for laboratory preparedness for high threats pathogens (Chair: Silvia Bino) Coffee break is served on the table
15:15 – 15:45	Wrap of the meeting and conclusions (Chair: Joanna Zwetyenga)
15:45 – 16:00	Miscellaneous
16:00	End of the meeting

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