

BETTER LABS FOR BETTER HEALTH

STRENGTHENING LABORATORY SYSTEMS IN THE WHO EUROPEAN REGION

Report of the 3rd Partners Meeting with a focus on
Antimicrobial Resistance



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Abbreviations

BLBH	Better Labs for Better Health
CAESAR	Central Asian and Eastern European Surveillance of Antimicrobial Resistance
CDC	Centers for Disease Controls and Prevention
CDC CAR	Centers for Disease Controls and Prevention – Central Asia Regional Office
ELI	European Laboratory Initiative for TB?
EQA	External quality assurance
EU	European Union
EU CBRN	European Union Chemical Biological Radiological and Nuclear Risk Mitigation
CoE	Centres of Excellence Initiative of the EU CBRN?
EUCAST	European Committee on Antimicrobial Susceptibility Testing
EVD-LabNet	Emerging Viral Diseases – Expert Laboratory Network
FAO	Food and Agriculture Organization
FIND	Foundation for Innovative Diagnostics
GOARN	Global Outbreak Alert and Response Network
HIV/AIDS	Human immunodeficiency virus/Acquired immune deficiency syndrome
HTP	High threat pathogens
IHR	International Health Regulations (2005)
ISO	International Organization for Standardization
LIMS	Laboratory information management system
LIS	Laboratory information system
LQMS	Laboratory quality management system
LQSI	WHO tool for the stepwise implementation of LQMS
MDR-TB	Multidrug-resistant tuberculosis
MoH	Ministry of Health
NLWG	National laboratory working group
NRL	National reference laboratory
OIE	World Organization for Animal Health
PHE	Public Health England
PVS	Performance of Veterinary Services
QMS	Quality management system
QSE	Quality system essential
RIVM	National Institute for Public Health and the Environment of the Netherlands
SL-LPA	Second-line line probe assays
TB	Tuberculosis
WHE	World Health Emergency Programme
WHO	World Health Organization
WHO CC	WHO collaborating centre

Executive summary

Better Labs for Better Health (Better Labs) was conceived in 2012 as an intersectoral approach to support Member States in eastern Europe and central Asia to improve the quality and timeliness of their public health laboratory services. Better Labs focuses on four main areas: development of national laboratory policies and strategic plans (**Area 1**), improve national training programmes and implement laboratory quality management systems (**Area 2**), establish laboratory networks for emergency preparedness and response (**Area 3**), and advocacy, partnership and leadership (**Area 4**).

Since 2012, National Laboratory Working Groups (NLWGs) were appointed in five countries that committed to Better Labs: Kyrgyzstan, the Republic of Moldova, Tajikistan, Turkmenistan and Uzbekistan. With Better Labs support these NLWGs have developed their national laboratory policies and strategic plans. Three countries (Kyrgyzstan, Tajikistan and Turkmenistan) have now endorsed their laboratory policies and developed their action plans (**Area 1**).

Participants from 75 laboratories in eastern and south-eastern European and central Asian countries have been trained in quality management, and national trainers are now starting to train laboratory staff in their own countries. Since 2015, 12 international laboratory mentors have been mentoring 15 laboratories in nine countries. In 2017, 10 nationally-trained mentors from Kyrgyzstan started mentoring 10 regional maternity and child hospital laboratories; this mentoring has been supported by a grant of USD 1 million from the World Bank for a project proposed by the NLWG with the support of Better Labs (**Area 2**).

In November 2017, a workshop was organized for south-eastern European countries to discuss their laboratory preparedness for high-threat pathogens (HTPs). Participants acknowledged significant gaps and needs for improvement in preparedness regarding HTPs and recognized that no country alone can handle the increasing demands on diagnostics of endemic and emerging HTPs (**Area 3**).

To advocate for the Better Labs initiative and enhance collaboration with countries and partners, Better Labs organized two partners' meetings in 2014 and 2016 and has published two activity reports, two guidance documents and two peer-reviewed papers (**Area 4**). In 2018, preceding the 3rd partners meeting, the Better Labs' activity report for 2016–2017 was published¹.

This report describes the outcomes of the 3rd WHO Regional Office for Europe Better Labs Partners' Meeting that was held in Almaty, Kazakhstan in October 2018 jointly with the WHO Regional Office for Europe's Antimicrobial Resistance (AMR) Programme. The meeting was attended by 25 representatives from national public health organizations in 11 Member States, including the now six Member States formally committed to Better Labs (Kyrgyzstan, the Republic of Moldova, Tajikistan, Turkmenistan, Ukraine and Uzbekistan), as well as 33 representatives from 20 national and international organizations, including WHO (see

¹ Better Labs' activity report for 2016–2017: <http://www.euro.who.int/en/health-topics/Health-systems/laboratory-services/publications>

Annex 1: Participating organizations), thus enhancing inter-organizational coordination and collaboration.

The focal areas for the meeting were to:

- discuss how Better Labs for Better Health builds national capacities to enhance countries' involvement and ownership (Areas 1 and 4); and
- share experiences, noteworthy achievements and complimentary activities between the key partners attending the meeting (Area 4);
- discuss how to improve laboratory quality management for AMR surveillance (Area 2);
- identify and discuss further needs for and approaches to strengthening national and international laboratory capacities for responding to high threat pathogens (Area 3).

Presentations provided by country representatives and the discussions facilitated by partners identified a number of needs – the main ones being the need for international and national external quality assurance (EQA); finding solutions specifically for the referral and transportation of samples for testing; and the need for continued support in the area of quality and safety management.

Consensus at the meeting also recognized that countries that have endorsed their national laboratory policies and strategies have made significant steps towards starting to reform their laboratory systems; a top priority is to improve the regulatory framework for laboratories, and a number of countries are currently addressing this area; the national laboratory working groups (NLWGs) have shown themselves to be key drivers for in-country laboratory system reform; and the national laboratory working groups are a key resource for collaboration with international partners.

Countries and partners that attended the meeting expressed their interest in joining the Better Labs initiative, and Armenia and Kazakhstan have officially requested support from the WHO Regional Office for Europe; this support will start in the coming months.



Figure 1: Session 1 – Implementing laboratory system reforms

Background to the 3rd Better Labs for Better Health partners meeting

Well-functioning, sustainable laboratory services operating according to international principles of quality and safety are an essential part of strong health systems and are crucial to improving public

health. Recognizing this, the WHO Regional Office for Europe launched the Better Labs for Better Health initiative in 2012 to fundamentally improve laboratory services in Member States in eastern Europe and central Asia.

Since then, three biennial partners' meetings have been held to monitor progress to date and to ensure that future activities are correctly prioritized. A session held jointly with another WHO programme and partner that focuses on a health topic of particular relevance to the participants is integrated into the agenda to increase the impact of these meetings.

The 1st Partners' Meeting on the Better Labs for Better Health initiative was held in Copenhagen, Denmark in June 2014 jointly with the Centres for Disease Control and Prevention (CDC) and the Regional Office's human immunodeficiency virus infection and acquired immune deficiency syndrome (HIV/AIDS) team. It was agreed that advocacy efforts are required not only to reach technical staff, but also to obtain political commitment for quality management systems to be implemented in laboratories. WHO, Member States, donors and partners were encouraged to continue improving their coordination.

The 2nd Partners' Meeting was held in Tbilisi, Georgia in December 2016 jointly with the Regional Office's European Laboratory Initiative (ELI). The main conclusion of this meeting was the need in a number of countries to improve regulatory frameworks pertaining to laboratory licensing and accreditation, and to develop guidance on public health laboratory systems to support those Member States implementing reforms.

This 3rd Partners Meeting was held in Almaty, Kazakhstan in October 2018 jointly with the Regional Office's Antimicrobial Resistance Programme to address common concerns regarding laboratory quality and biosafety management, implementing reforms and strengthening national capacities. Representatives from 11 Member States, including the six countries participating in Better Labs; along with partners such as the World Organization for Animal Health (OIE), the US Centers for Disease Control and Prevention (CDC), and Public Health England (PHE); together with representatives from laboratory networks and professional associations took part in the meeting to discuss these concerns and identify ways to address them.

Objectives

The main objectives of the 3rd Partners' Meeting were to:

- disseminate to a wide audience the progress of the Better Labs for Better Health initiative from 2016 to the present and to inform on current activities;
- show the progress made in national reforms of laboratory systems and in national capacity building in the area of laboratory quality and safety, and to discuss priorities for the establishment of laboratory networks for preparedness and response;
- discuss the role of laboratory quality management systems in AMR surveillance; and
- provide a forum for countries to work together to strengthen their laboratory services by sharing expertise, experience and lessons learned, including an open discussion on how to enhance countries' involvement and ownership of laboratory reforms.

Reflecting this, the meeting's agenda was built up around the following sessions:

- Introductory session
- Session 1: Implementing laboratory system reforms (Area 1)
- Session 2: Improving laboratory surveillance for antimicrobial resistance (AMR) (Area 2)
- Session 3: Improving the quality of laboratories through mentoring (Area 2)
- Session 4: Advocacy, leadership and partnerships (Area 4)
- Session 5: External quality assessments for laboratory preparedness and response (Area 3)

The full agenda is included in Annex 3: Agenda.



Figure 2: Session 2 - WHO Antimicrobial Resistance (AMR) Session

Introductory session: partners' activities

During the introductory session, the participating international organizations gave presentations on their relevant activities performed at country and regional levels. These activities are briefly summarized in the following sections.

WHO headquarters

The Country Health Emergency Preparedness and IHR Department presented its laboratory strengthening activities focused on the following areas: policies, strategies and plans, quality systems, biosafety and biosecurity, in-country diagnostic capability, laboratory networks, workforce development, EQA and simulation exercises, and global coordination and leadership. WHO headquarters plays a global role in laboratory strengthening by improving governance and quality of laboratory services. Better Labs works together with WHO headquarters, providing input to global guidance and tools as well as implementing joint projects.

WHO Regional Office for the Eastern Mediterranean (EMRO)

The Public Health Laboratories Unit in the WHO Regional Office for the Eastern Mediterranean's Department of Communicable Diseases Prevention and Control presented their strategic framework:

- strengthening leadership and governance of the national laboratory systems;
- strengthening the organization and quality management of national laboratory systems;
- establishing sustainable, sufficient and competent human resources for laboratory service delivery;
- ensuring safe and secure laboratory environments;
- promoting effective laboratory referral networking (in-country and among countries) and enhancing coordination; and
- promoting rational and evidence-based use of laboratory services.

Areas of common interest with Better Labs, such as the status of national regulatory frameworks, biosafety and biosecurity, workforce development, EQA and simulation exercises were presented and discussed.



Figure 3: Frank Konings, WHO EMRO laboratory programme

World Organization for Animal Health (OIE)

The three OIE PVS tools were presented: the OIE PVS (Performance of Veterinary Services) tool, the OIE PVS Gap Analysis Tool and the PVS Sustainable Laboratory Tool that help users to assess laboratory financial sustainability, the optimization and configuration of the national laboratory network, and the supply and demand for laboratory analysis in order to support strategic planning of veterinary services and decision-making. Although the activities presented focused on veterinary services, all three tools are relevant to general laboratory services.

Centers for Disease Control and Prevention office in Uzbekistan (CDC/Uzbekistan)

Better Labs has collaborated with the US CDC since the start of the Better Labs initiative in 2012. The LQMS training tool kit and LQSI tool, used in the Better Labs initiative, were developed with our CDC partners; and the first Better Labs partners' meeting in 2014 was organized jointly with a session dedicated to laboratory diagnosis of HIV/AIDS. At the country level, Better labs supported the development of a national laboratory policy and strategic plan in Uzbekistan, with the participation of the CDC office in Uzbekistan as a contributing partner.

CDC/Uzbekistan works with the Ministry of Health to improve Uzbekistan's capacity to perform sound health policy analysis and to identify updated control measures for important infectious diseases. Their activities include improvement of HIV laboratory services, the related legislative framework, and HIV surveillance.

Public Health England, Porton Down

Public Health England presented on the European Union Chemical Biological Radiological and Nuclear Risk Mitigation Centres of Excellence Initiative (or EU CBRN CoE) Project 53, which aims to strengthen the national legal framework and provision of specialized training on biosafety and biosecurity in central Asian countries.

74 individuals were trained as trainers in biosafety and biosecurity in the six participating countries (Afghanistan, Kazakhstan, Kyrgyzstan, Mongolia, Tajikistan and Uzbekistan). Support is being provided for these trainers to further perform training in their respective countries.

Emerging Viral Diseases-Expert Laboratory Network

The Emerging Viral Diseases – Expert Laboratory Network (EVD-LabNet) presented its work involving support to patient diagnostics, surveillance and outbreak response. The network focuses on virus families and genera that are rare, imported and (re)emerging in European Union/European Economic Area countries.

European Laboratory Initiative

The WHO Regional Office for Europe's European Laboratory Initiative (ELI)² initiative presented an update on its tuberculosis (TB), HIV and hepatitis activities. Recent activities include a TB laboratory maintenance plan, training for engineers and technicians on biosafety cabinet maintenance, and training on second-line line probe assays (SL-LPA) using the ELI training toolkit.

WHO Global Outbreak Alert and Response Network (GOARN)

WHO Regional Office for Europe's Technical Officer for Emergency Operations, the officer responsible for the partnership with the Global Outbreak Alert and Response Network, presented the development of a Mobile Laboratory Team and a Rapid Risk Assessment and Response Team to strengthen its rapid response capacities.

² European Laboratory Initiative (ELI): <http://www.euro.who.int/en/health-topics/communicable-diseases/tuberculosis/areas-of-work/laboratory-diagnosis/about-the-european-laboratory-initiative-eli>

During the GOARN meeting held in Serbia in June 2017, the GOARN Rapid Response Capacities team identified mobile laboratories as a mode for rapid deployment in response to outbreaks. Standardized technical and operational procedures for mobile laboratories would be beneficial. The upcoming WHO Regional Office for Europe's meeting in Saratov, Russian Federation, in November 2018, was presented: this meeting was to map the public health rapid response capacities and the presence of mobile laboratories in the WHO European Region, and to discuss needs and possibilities to establish mobile laboratory teams.

Session 1: Implementing laboratory system reforms

The WHO Regional Office for Europe's Health Emergencies Programme's Better Labs initiative provides support to countries in reviewing the organization of their public health laboratory services, revising their laboratory regulatory framework, and analysing laboratory cost-effectiveness. Recent key achievements in this area include the endorsement of national laboratory policies and strategies in Kyrgyzstan, Tajikistan, and Turkmenistan. The Republic of Moldova and Uzbekistan are currently finalizing their national policies and strategic plans.

Country representatives shared their experiences in developing these policies and strategic plans. Representatives from Kyrgyzstan and Tajikistan also shared their experiences in drafting proposals for improved organization of their public health laboratory systems, revising their national laboratory regulatory framework, and developing a national guideline on transportation of specimens and biological materials. Quality management system training courses for specialists from public health laboratories and infectious substance shipment training were highlighted. Next steps include the development of training packages for all staff involved in sample transportation, including training in the use of a coming sample referral tracking tool. Collaboration between different partners and disease-specific programmes that already have transport systems in place is needed to agree on common sample referral routes at national levels to improve cost-effectiveness.

Discussions covered accreditation, licensing and certification of laboratory services that are currently insufficiently regulated in Kyrgyzstan and Tajikistan. While these countries have existing licensing systems, these are restricted to private laboratories and there are no requirements for laboratories to comply with any national or international quality standards. Furthermore, local definitions of "accreditation", "licensing" and "certification" do not fully comply with international practice. Information technology and laboratory information management systems (LIMS) for the laboratories were discussed, and it was noted that many laboratories are not computerized.

Moreover, assessments of laboratories in Kyrgyzstan and Tajikistan have shown that there are many under-performing public health laboratories and that these countries' laboratory systems require significant reform. For this reason, Better Labs is working on public health laboratory optimization, which entails defining the required number of laboratories, their functions, the need for tiered systems based on the specific needs of the country (burden of disease, geography and hard-to-reach areas, etc) and the analysis of the cost-effectiveness of such systems. Together with ECDC, CDC and the Defense Threat Reduction Agency, the WHO Regional Office for Europe's Health Emergencies Programme's Better Labs initiative is also providing support for the optimization of the public health laboratory system in Ukraine as part of a wider reform of the public health system.

Session 2: Improving laboratory surveillance for antimicrobial resistance (AMR)

The joint session at the 3rd Partners' Meetings was arranged by WHO Regional Office for Europe's Antimicrobial Programme, which presented on the important role that laboratory surveillance plays in the global problem of antimicrobial resistance.

Controlling and preventing antibiotic resistance requires a comprehensive and coordinated national approach involving many different sectors, including national and regional laboratories.

Surveillance provides a basis for taking action to control antimicrobial resistance (AMR). It is a core pillar in both the Global Action Plan on Antimicrobial Resistance³ and the European Strategic Action Plan on Antibiotic Resistance⁴. To strengthen the evidence-base through enhanced and standardized global surveillance and research (strategic objective 2 of the Global Action Plan), in 2015 WHO developed the Global Antimicrobial Resistance Surveillance System (GLASS)⁵. GLASS supports the collection and reporting of data on AMR rates aggregated at the national level. The system enables comparable and validated data on AMR to be collected, analysed and shared with countries and partners to inform decision-making; to drive local, national and regional action; and to provide the evidence for interventions and advocacy. GLASS also supports the collection of data on the implementation status of national surveillance systems.

In the European Region, the main surveillance mechanisms gathering and presenting combined data from countries are the European Antimicrobial Resistance Surveillance Network (EARS-Net) and the Central Asian and Eastern European Surveillance of Antimicrobial Resistance (CAESAR) network. EARS-Net collects data from 30 European Union/European Economic Area (EU/EEA) countries, while CAESAR is setting up or strengthening AMR surveillance in 19 countries, primarily in eastern Europe, the Caucasus and central Asia. In combination, these two networks currently provide surveillance data for 40 of the 53 Member States in the European Region.

The demand for technical support and specialized expertise to strengthen AMR surveillance is increasing rapidly. As a result, the WHO Regional Office for Europe is working closely with collaborating centres (WHO CCs) across the Region. These provide crucial support to Member States in strengthening their AMR surveillance and developing new training modules, coordinated by the Regional Office.

In parts of the European Region, implementation of a national AMR surveillance system based on routine antibiotic susceptibility testing is limited by the under-utilization of microbiological diagnostics in routine clinical practice. To improve this, a proof-of-principle study, set up as a joint collaboration between the WHO Regional Office for Europe and the National Institute for Public

³ Global AMR Action Plan (2015), available at <http://www.who.int/antimicrobial-resistance/global-action-plan/en/>

⁴ European strategic action plan on antibiotic resistance, available at http://www.euro.who.int/_data/assets/pdf_file/0008/147734/wd14E_AntibioticResistance_111380.pdf?ua=1

⁵ Global Antimicrobial Resistance Surveillance System (GLASS) - <http://www.who.int/glass/en/>

Health and the Environment (RIVM) in the Netherlands, was carried out in several countries in the Region.

A presentation on the Regional AMR Action Plan and the use of AMR laboratory data for surveillance, as well as the role of national reference laboratories (NRLs) in AMR, was complemented by a presentation from the Country Representative from Armenia, who updated on the process of setting up AMR surveillance when routine sampling is limited in the country. This was followed by a panel discussion on the current status of AMR surveillance in the Region and how to proceed from there.

Questions regarding the possibilities of integrating the area of food safety into the CAESAR programme were raised. This issue is currently being addressed as more activities are being implemented together with the Food and Agriculture Organization (FAO) and OIE; however, integration is a long process. It was stressed that NRLs are provided with training and a standardized methodology for reference testing. The European Committee on Antimicrobial Susceptibility Testing (EUCAST) methodology is progressively being introduced.

At the global level, CAESAR started with the inclusion of blood and cerebrospinal fluid (CSF) sampling similar to the sampling done in the EU/EEA; however, it is now evolving to include other specimens such as feces and urine.

During an exchange of experiences from setting up a proof-of-principle study, concerns were expressed regarding problems with companies producing antibiotic discs of low quality, and regarding how to avoid this situation when those producers have been selected by tender. While this is difficult to manage, quality should remain a priority in procurement and detailed specifications for the reagents should be developed.

A study of nine international manufacturers conducted by EUCAST was referred to. This study showed a wide variation in the quality of antimicrobial disks, and it was pointed out that this means that the choice of disk supplier is important. The results of the evaluation are publicly available on the EUCAST website.

Better Labs' role in supporting the national AMR reference laboratories of Armenia and Uzbekistan in implementing their quality management systems through mentoring activities was discussed. These mentoring activities will be extended to other AMR reference and regional laboratories in the other countries that have committed to the Better Labs initiative. A meeting between experts providing support to laboratories for AMR diagnostics in the Region and the Better Labs quality management mentors is being organized to ensure the support provided is complementary.

Session 3: Improving the quality of laboratories through mentoring

The two main objectives of the Better Labs mentoring program were presented. These are the effective and efficient strengthening of laboratories through the implementation of a quality management system (QMS) based on the international quality standard ISO 15189:2012 or ISO 17025:2017; and the creation of a network of quality experts throughout the region. Since August 2014, 135 laboratory managers from 23 countries have been trained in laboratory quality management systems (LQMS)/laboratory quality stepwise implementation (LQSI). Currently there

are 12 international experts providing mentoring support for 15 national laboratories in nine countries and 10 national mentors covering 10 regional laboratories in Kyrgyzstan.

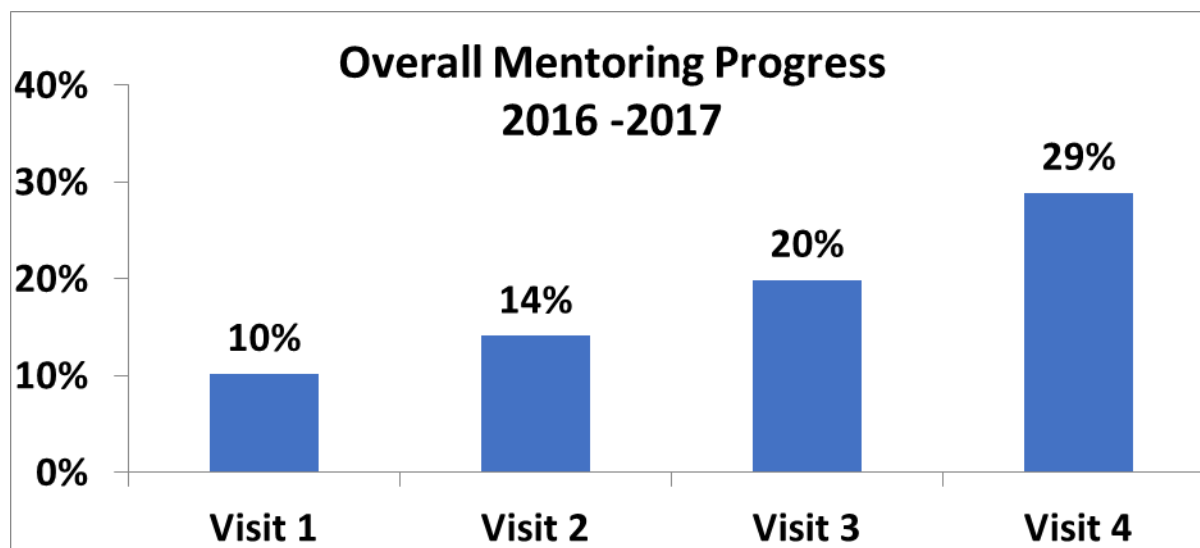


Figure 4: Results from mentoring visits

The progress of the mentoring programme was presented, including figures on the laboratories' scores measured against 12 quality system essentials (QSEs). As illustrated in Figure 4, the average of results from the first mentoring visit gave an overall baseline score measured against the QSEs of 10%. One can see a general improvement in the scores through the subsequent mentoring visits and faster progress after the two first visits – the average score rose to 14% after the second mentoring visit, 20% after the third visit and 29% after the fourth visit.

A presentation from the head of the State Institution National Reference Laboratory (NRL) in Tajikistan, which has received three visits from an international mentor, described how the mentoring programme had led to improvements to the quality of the services provided and that it motivated the staff and the laboratory director. Progress had been made in a number of areas including the implementation of a document control system, stock management and personnel files. Now the mentoring is focussing on the remaining areas that need to be implemented such as internal audits, quality indicators and management reviews. A second presentation provided the perspective from the point of view of an international quality expert in providing mentoring support for laboratories in Kyrgyzstan and Turkmenistan. The mentor described how all mentoring visits follow the same procedure and use the same tools, thus enabling progress to be monitored. This was complemented by a presentation on building national capacities for laboratory quality through training national mentors in charge of mentoring 10 regional Maternal and Child Health hospital laboratories in Kyrgyzstan. The upgrade of these laboratories as well as the cost of mentoring is supported by a World Bank grant to the Ministry of Health in collaboration with WHO, under the auspices of the Den Sooluk National Health Strategy 2012–2018.

Subsequent discussion recognized that training national experts to become mentors is an effective way to build national capacity within the area of laboratory quality management and has the following advantages: the training is built up gradually to be better tailored to the knowledge of the

laboratory specialists and this knowledge is then disseminated to laboratories throughout the country.

Currently, no laboratory has fully completed the quality management continuous improvement cycle process, because this usually takes between three and four years. However, three to four laboratories are expected to complete this cycle through the next mentoring visits in 2019.

In spite of the success of the mentoring programme, concerns were raised on the high staff turnover that is a chronic problem throughout the health sector in a number of eastern and south eastern Europe countries and that leads to repetition of training, regardless of whether it is supported by the government or partners, which is an ineffective use of resources. Better Labs is working with the NLWGs to seek ways to motivate and retain staff.

Participants identified a need to strengthen not only the mentoring capacities within countries, but also the capacities of the national accreditation bodies in the ISO 15189 accreditation process.



Figure 5: Session 4 - Advocacy, Leadership and Partnerships

Session 4: Advocacy, Leadership and Partnerships

Following presentations by Kyrgyzstan and Ukraine Kyrgyzstan, leaders in public health laboratory reform from these countries and Republic of Moldova discussed the details of their proposed public health laboratory services under the Ministry of Health.

Ukraine is currently reforming its public health system supported by WHO, the EU and other partners. The Sanitary and Epidemiological Services (SESS) was abolished in 2012 and some of its functions were relocated within the Food Safety and Consumer Protection Agency, which will now provide some sanitary functions as well as food safety testing. Outbreak response is managed jointly by the new public health centre, which replaced the SESS and the State Service of Ukraine on Food Safety and Consumer Protection. Currently in Ukraine there are six national reference laboratories in Kyiv, 25 regional (oblast) level laboratories, three laboratories for the railway, airways, and sea

transport services; 700 public health laboratories at district level; 100 HIV/AIDS laboratories; 25 regional TB laboratories; 811 clinical laboratories; over 1000 clinical laboratories at medical facilities; and 25 blood safety laboratories. The public health centre reported that it is now in the process of defining the roles and responsibilities within the tiered public health laboratory network, and reducing the number of laboratories.

In Kyrgyzstan, the NLWG highlighted duplications of many laboratory investigations by public health and clinical laboratories. Currently, three models for laboratory optimization in the Chui region (one laboratory instead of eight; two laboratories instead of eight; and four laboratories instead of eight) are being prepared by the national laboratory working group (NLWG) using the Laboratory Test Costing Tool developed by Better Labs.

The representative from the Republic of Moldova discussed the country's experience that results do not always match reform goals, because the actual implementation may give different results than expected and not all consequences of the reforms were foreseen. For example, 36 public health laboratories were reduced to 10 and the remaining laboratories became sample collection points. However, the reform was unpopular among staff, because it required staff to travel longer distances to work than in the previous setting. Likewise, in the second phase of the reform, 39 organizations were united into one legal entity, and the National Agency for Public Health (NAPH) is now burdened with secretariat coordination responsibilities in addition to its regular duties. In terms of quality assurance, the accreditation body for the health sector, which was under the Ministry of Health (MoH), has now been moved under the NAPH. This means that the accreditation of laboratories that fall under the NAPH would constitute a conflict of interest.

Session 5: EQAs for laboratory preparedness and response



Figure 6: Session - EQA for laboratory preparedness and response

External quality assessment (EQA) is an important component of quality systems for laboratory services. WHO and EVD-LabNet made presentations on guidelines and programmes on EQAs for health laboratories.

Usually, EQA providers are non-profit organizations that are independent of the participating laboratories.

Concerns were raised about difficulties in shipping specimens. For example, regulations in France covering shipments of high-risk agents/toxins that have been determined to have potential for use as bioweapons create restrictions. The concern is that this list also includes genetic material that is non-infectious material (French Order of April 30, 2012)⁶. In Germany, adherence to EU rules about the shipment of biological agents outside the EU will be stricter, making participation in international EQAs for countries outside the EU difficult.

The national reference laboratories participating in international EQAs explained that they encounter difficulties in importing panels and must often prepare the whole process several months in advance. Concerns were also raised regarding customs clearance and financial capacities for countries particularly in eastern Europe to participate in EQAs.

The complexity of national regulations for the importation and exportation of laboratory samples and the high cost of international EQAs means that national EQAs need to be encouraged for the majority of laboratories within a country.

WHO headquarters reminded the audience of the work being done on the biosafety/biosecurity regulatory framework, including a recent meeting organized by WHO headquarters earlier in October 2018, where 20 experts discussed a draft guidance document on this subject and the Nagoya protocol was discussed.

Kyrgyzstan mentioned that they have developed a national HIV EQA and the centre providing this EQA is seeking ISO 17043 accreditation with support from CDC.

The “WHO manual for organizing a national external quality assessment programme for health laboratories and other testing sites” was mentioned and links provided to the English⁷ and Russian⁸ versions.

⁶ **Biosafety and Biosecurity in European Containment Level 3 Laboratories: Focus on French Recent Progress and Essential Requirements**, Boris Pastorino, Xavier de Lamballerie and Rémi Charre, *Frontiers in Public Health* May 2017, Vol 6, Article 121.

⁷ English: <https://www.who.int/hiv/pub/toolkits/manual-external-quality-assessment-testing/en/>

⁸ Russian: <http://www.euro.who.int/ru/health-topics/communicable-diseases/influenza/publications/2017/who-manual-for-organizing-a-national-external-quality-assessment-programme-for-health-laboratories-and-other-testing-sites-2016>

Main conclusions

The meeting concluded that:

- Better Labs for Better Health continues to provide a valuable platform for laboratory strengthening and for continued coordination and collaboration between international partners and projects. This was evidenced by the fact that presentations by partners described complimentary work, creating a common strength and advocacy for laboratory improvement.
- Countries that have endorsed their national laboratory policies and strategies have made substantial progress towards reforming their laboratory systems; the national laboratory working groups (NLWGs) have shown themselves to be key drivers for in-country laboratory system reform, as well as a key resource for collaboration with international partners. In this respect, it is encouraging that countries and partners that attended the meeting expressed their interest in joining the Better Labs for Better Health initiative in some capacity, and Armenia, Belarus and Kazakhstan expressed their interest in officially joining the initiative.
- The mentoring programme for the implementation of laboratory quality management systems has proven effective in achieving tangible improvements to the quality of laboratory services and should be continued.
- Training national experts to become mentors is an effective way to build national capacity within the area of laboratory quality management; it enables training to be better tailored to the knowledge of local laboratory specialists and for this knowledge to be disseminated nationally.
- Participants identified a need to strengthen not only the mentoring capacities within countries, but also the capacities of the national accreditation bodies in the ISO 15189 accreditation process.
- Participants recognized that EQA is one of the best methods to evaluate and ensure correct performance of laboratories for the tests concerned. However, many laboratories within the countries cannot afford to participate in international EQAs and few national EQAs are available. National and international partners should coordinate and collaborate to expand the range of EQAs available, addressing issues of cost and barriers to shipment of panels. The participants agreed that the needs and concerns regarding EQAs should be discussed at a separate meeting.

Annex 1: Participating organizations

Centers for Disease Controls and Prevention – Central Asia Regional Office (CDC CAR)
Centers for Disease Controls and Prevention – Office in Uzbekistan
Emerging Viral Diseases-Expert Laboratory Network (EVD-LabNet)
Foundation for Innovative Diagnostics (FIND)
Global Outbreak Alert and Response Network (GOARN)
Kazakhstan Association of Legal Entities (ALME)
Kazakhstan Association of Medical Laboratories
Kazakhstan Association of Medical Laboratory Diagnostics (KAMLD)
Kyrgyzstan Ministry of Health – Endocrinological Center
Kyrgyzstan Ministry of Health – National Reference Laboratory
National Institute for Public Health and the Environment (RIVM)
Public Health England (PHE), Porton Down
Republic of Moldova National Agency for Public Health
WHO headquarters
WHO Regional Office for Europe’s Antimicrobial Resistance Programme
WHO Regional Office for Europe’s Better Labs for Better Health initiative
WHO Regional Office for Europe’s European Tuberculosis Laboratory Initiative (ELI)
WHO Regional Office for the Eastern Mediterranean’s Public Health Laboratories Unit
World Organization for Animal Health (OIE)

Annex 2: List of participants

Armenia	
Karine Teymurazyan	Standardization and Certification
Nune Kotsinyan	State Reference Laboratory Center
Azerbaijan	
Sanubar Salimova	Bacteriological Laboratory of the Republican Center for Hygiene and Epidemiology
Yegana Ahmadova	Bacteriological Laboratory of the Republican Center for Hygiene and Epidemiology
Belarus	
Halina Pyshnik	Department of Pharmaceutical Inspection and Organization of Medicines Supply, Ministry of Health
Sergey Beliaev	Anti-Doping Laboratory, Ministry of Health
Georgia	
Marine Ramishvili	Department of Biosafety and Especially Dangerous Pathogens, R. Lugar Center for Public Health Research of the LEPL National Center for Disease Control and Public Health
Medeia Eloshvili	Department of Biosafety and Especially Dangerous Pathogens, R. Lugar Center for Public Health Research of the LEPL National Center for Disease Control and Public Health
Kazakhstan	
Alena Magaj	National Public Health Centre
Gaukhar Nussupbaeva	National Public Health Centre
Sandugash Mukazhanova	Committee of Consumer's Rights Protection
Zabira Aushakhmetova	National Center of Expertise
Zhanar Suleimenova	Clinical-Diagnostic Laboratories Unit, Presidential Clinic
Kyrgyzstan	
Elmira Turkmenova	Ministry of Health
Indira Dzhumabaeva	Ministry of Health
Sveta Ibraeva	Department of Disease Prevention and State Sanitary and Epidemiological Surveillance
Tatiana Kuchuk	Republican Quality Center , Ministry of Health
Republic of Moldova	
Ala Halacu	National Center for Public Health
Tatiana Priputnevich	Federal Research Centre on Perinatology, Obstetrics and Gynecology "Kulakov"
Tajikistan	
Bunavsha Kholova	Tajik Research Institute of Preventive Medicine, Ministry of Health and Social Protection of the Population
Dilshod Davlyatov	Ministry of Health and Social Protection of the Population

Turkmenistan	
Gulbahar Hanmedova	Scientific and Clinical Center of Oncology
Nurnabat Aymuhammedova	Center of Prevention of Highly Dangerous Diseases
Ukraine	
Roman Rodyna	Center for Diseases Control and Monitoring, Ministry of Health
Tetiana Glushkevych	Public Health Center, Ministry of Health
Representatives of other organizations	
Alla Kim Dmitrieva	Kazakhstan Association of Medical Laboratories
Aybek Khodiev	Centers for Disease Control and Prevention (CDC)/Office in Uzbekistan
Dilyara Nabirova	Centers for Disease Control and Prevention (CDC)/Central Asia Regional Office
Gulzhan Muratbayeva	Centers for Disease Control and Prevention (CDC)/Central Asia Regional Office
Kekeletso Kao	FIND
Raikhan Mamyrova	Kazakhstan Association of Legal Entities "ALME"
Rysuly Mustafa	Kazakhstan Association of Medical Laboratory Diagnostics (KAMLD)
Shakhinya Karamatova	Centers for Disease Control and Prevention (CDC)/Office in Uzbekistan
Valentyana Sharandak	World Organization for Animal Health (OIE)/Kazakhstan
Temporary Advisers	
Chantal Reusken	Centre for Infectious Disease Control, RIVM
Christopher Logue	Novel and Dangerous Pathogens Training, Public Health England
Observers	
Kyal Ormokoeva	Endocrinological Center, Ministry of Health, Kyrgyzstan
Madina Andreyeva	Kazakhstan
World Health Organization	
Abdulakhad Safarov	WHO Regional Office for Europe, National Professional Officer, Tajikistan
Alexandr Gordon	WHO Regional Office for Europe, Driver, Kazakhstan
Ayjerem Myratdurdyeva	WHO Regional Office for Europe, National Professional Officer, Turkmenistan
Danilo Lo Fo Wong	WHO Regional Office for Europe, Programme Manager
Franciscus Konings	WHO Eastern Mediterranean Regional Office, Regional Advisor
Joanna Zwetyenga	WHO Regional Office for Europe, Technical Office, Better Labs for Better Health initiative
Kaliya Kasymbekova	WHO Regional Office for Europe, National Professional Officer, Kyrgyzstan
Krystyna Hagebro	WHO Regional Office for Europe, Programme Assistant
Maritha Osekre-Amey	WHO headquarters, Team Assistant, Office of the Assistant to DG
Mark Perkins	WHO headquarters, Network Leader
Nune Dolyan	WHO Regional Office for Europe, National Professional Officer, Armenia

Oleg Storozhenko	WHO Regional Office for Europe Health Emergencies Programme, Technical Officer
Saltanat Yegeubayeva	WHO Regional Office for Europe, National Professional Officer, Kazakhstan
Sebastian Cognat	WHO headquarters, Team Leader
Vusala Allahverdiyeva Jalal	WHO Regional Office for Europe, Technical Officer, Ukraine
Consultants	
Gulmira I. Kalmambetova	National Reference Laboratory, Ministry of Health, Kyrgyzstan
Makhalaia Akhalaia	
Maria Amante	WHO Regional Office for Europe, Better Labs for Better Health initiative
Natalia Costic	National Centre of Public Health, Republic of Moldova
Sergejs Nikisins	WHO Regional Office for Europe, Better Labs for Better Health initiative
Interpreters	
Anna Nikolskaya	Freelance interpreter/translator
Olga Aleksinskaya	Freelance interpreter/translator

Annex 3: Agenda

Tuesday, 9 October 2018

9:00 – 9:30	Official opening of the meeting <i>Alexay Tsoy, Vice Minister, Ministry of Health, Kazakhstan;</i> <i>Saltanat Yegeubayva, WHO Country Office Kazakhstan</i>
9:30 – 9:45	Introduction to the meeting agenda <i>Joanna Zwetyenga, WHO Regional Office for Europe</i>
9:45 – 10:00	Better Labs for Better Health update, 2016–2018 <i>Joanna Zwetyenga, WHO Regional Office for Europe</i>
10:00 – 10:15	WHO Headquarters Laboratory and Surveillance Strengthening team <i>Sebastien Cognat, WHO Headquarters Lyon Office</i>
10:15 – 10:30	WHO Regional Office for the Eastern Mediterranean laboratory program <i>Frank Konings, WHO Regional Office for the Eastern Mediterranean</i>
10:30 – 11:00	<i>Coffee break</i>
11:00 – 1:15	Improving Veterinary Services' compliance with OIE international standards <i>Valentyna Sharandak, World Organization for Animal Health</i>
11:15 – 11:30	CDC strengthening laboratory capacity for better laboratory service in Uzbekistan <i>Aybek Khodiev, U.S. Centers for Disease Control and Prevention, Office in Uzbekistan</i>
Session 1: Implementing laboratory system reforms	
11:30 – 11:45	Better Labs for Better Health: Guidance for public health laboratory system reform <i>Joanna Zwetyenga, WHO Regional Office for Europe</i>
11:45 – 12:05	Tajikistan: Laboratory system optimization proposal <i>Kholova Bunafsha, State Institution "Tajik Research Institute of Preventive Medicine" Ministry of Health and Social Protection of the Population</i>
12:05 – 12:25	Kyrgyzstan: Revision of the national laboratory regulatory framework <i>Indira Dzhumabaeva, Legal Sector, Ministry of Health</i>
12:25 – 12:45	Turkmenistan: Development of national policy and strategic plan <i>Nurnabat Aymukhamedova, Center for Prevention of Highly Dangerous Diseases, Ashgabat</i>
12:45 – 13:45	Lunch

Session 2: WHO antimicrobial resistance (AMR) session

- 13:45 – 14:15 Regional AMR Action Plan and use of AMR laboratory data for surveillance
Danilo Lo Fo Wong, WHO Regional Office for Europe
- 14:15 – 14:45 Discussion: What is the current status of surveillance and how do we proceed from here?
Facilitator: Danilo Lo Fo Wong, WHO Regional Office for Europe
- 14:45 – 15:00 Role of National Reference Laboratories in AMR
Danilo Lo Fo Wong, WHO Regional Office for Europe
- 15:00 – 15:30 *Coffee break and Group Photo*
- 15:30 – 15:50 Setting up AMR surveillance when routine sampling is limited: Armenia
Nune Kotsinyan, State Reference Laboratory Center National Center for Disease Control and Prevention
- 15:50 – 16:30 Discussion: Experiences from setting up a proof-of-principle study and main issues related to procurement of laboratory consumables for antimicrobial susceptibility testing?
Facilitator: Danilo Lo Fo Wong, WHO Regional Office for Europe
- 18:00 *Official dinner*

Wednesday, 10 October 2018

- 9:00 – 9:15 Recap of day 1
Joanna Zwetyenga, WHO Regional Office for Europe
- Session 3: Improving the quality of laboratories through mentoring**
- 9:15 – 9:30 Results of the Better Labs for Better Health Mentoring Program
Joanna Zwetyenga, WHO Regional Office for Europe
- 9:30 – 9:45 Mentoring from the perspective of a clinical laboratory in Tajikistan
Dilshod Aslamkhonovich Davlatov, State Institution “National Reference Laboratory” Ministry of Health and Social Protection of the Population
- 9:45 – 10:00 Mentoring from the perspective of the mentor
Natalia Costic, WHO Consultant
- 10:00 – 10:15 Building national capacities for laboratory quality through national mentoring: Kyrgyzstan
Gulmira Kalmambetova, WHO Consultant
- 10:15 – 10:45 Panel Discussion on Mentoring:
Expansion, maintenance and building national capacities
Facilitator: Joanna Zwetyenga, WHO Regional Office for Europe
- 10:45 – 11:15 *Coffee Break*

Session 4: Advocacy, leadership and partnerships (part 1)

- 11:15 – 11:30 Public health laboratory reform in Ukraine: Current state and prospective
Roman Rodyna, Public Health Center of the Ministry of Health of Ukraine
- 11:30 – 11:45 Drivers of Laboratory System Reform in Kyrgyzstan
Sveta Ibraeva, Coordination Laboratory Council, Department of Disease Prevention and State Sanitary and Epidemiological Surveillance, Ministry of Health
- 11:45 – 12:05 EU CBRN CoE Project 53: Strengthening biosafety and biosecurity through the national legal framework and provision of specialized training in central Asian countries
Christopher H. Logue, Public Health England
- 12:05 – 12:30 Panel Discussion: Implementing laboratory systems reform
Facilitator: Sebastien Cognat, WHO Headquarters Lyon Office
- 12:30 – 13:30 Lunch

Session 4: Advocacy, leadership and partnerships (part 2)

- 13:30 – 13:40 Why quality management matters in health laboratories video
Joanna Zwetyenga, WHO Regional Office for Europe
- 13:40 – 13:55 Update from the European Laboratory Initiative (ELI) on TB, HIV and Hepatitis
Webex presentation
Soudeh Ehsani, WHO Regional Office for Europe
- 13:55 – 14:10 Laboratory activities in Global Outbreak Alert and Response Network (GOARN)
Oleg Storozhenko, WHO Regional Office for Europe
- 14:10 – 14:35 Panel Discussion: Use of mobile laboratories in countries
Facilitator: Oleg Storozhenko, WHO Regional Office for Europe
- 14:35 – 14:45 Laboratory Test Costing Tool Video Guide
Joanna Zwetyenga, WHO Regional Office for Europe
- 14:45 – 15:15 Coffee break

Session 5: External quality assessments for laboratory preparedness and response

- 15:15 – 15:30 EQAs for health laboratories: guidelines and programs
Sebastien Cognat, WHO Headquarters Lyon Office
- 15:30 – 15:45 Emerging Viral Diseases (EVD) LabNet
Chantal Reusken, EVD LabNet Coordinator
- 15:45 – 16:00 Discussion: External Quality Assessment Needs
Facilitator: Mark Perkins, WHO Headquarters
- 16:00 – 16:15 Close of Meeting
Joanna Zwetyenga, WHO Regional Office for Europe

The WHO Regional Office for Europe

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