

# The “Better Labs for Better Health” initiative to strengthen laboratory systems in the WHO European Region. Activity report

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## Keywords

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## Maps

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## Abbreviations

AMR – Antimicrobial Resistance

APHL – Association of Public Health Laboratories

CDC – Centers for Disease Control and Prevention

DCH – Division of Communicable Disease and Health Security

DG-DEVCO – European Commission’s Directorate-General for International Cooperation and Development

DTRA – U.S. Defence Threat Reduction Agency

EQA – External Quality Assurance

GF – Global Fund

GIZ – Deutsche Gesellschaft für Internationale Zusammenarbeit GmbH

HIV – Human Immunodeficiency Virus

IHR – International Health Regulations (2005)

ISST – Infectious Substances Shipping Training

KIT – Royal Tropical Institute

LAT – Laboratory Assessment Tool

LQMS – Laboratory Quality Management System

LQSI – Laboratory Quality Stepwise Implementation

NIC – National Influenza Centre

NLWG – National laboratory working group

PEPFAR – U.S. President’s Emergency Plan for AIDS Relief

PEST – Political, Economic, Social and Technological

PHE – Public Health England

QMS – Quality Management System

RKI – The Robert Koch Institute

ROF – Rumour-Opinion-Fact

SWOT - Strengths, Weaknesses, Opportunities and Threats

TB – Tuberculosis

UNDP – United National Development Program

WHO – World Health Organization

## Foreword

Dr Zsuzsanna Jakab, WHO Regional Director for Europe

Each and every one of us at one time or other in our life is reliant on the services of a laboratory, whether related to a communicable or noncommunicable disease, food safety or the quality of drinking-water. The results laboratories provide must be timely and of high quality, to generate trust. High quality services are achieved through national coordination and overview, and a multisectoral approach to laboratory strengthening. I am therefore delighted to see this initiative gaining momentum, with five countries formally committed to implement laboratory strengthening as an integrated component of their health reforms, Health 2020 and IHR.



## Executive summary

**The Better Labs for Better Health initiative is part of the WHO Regional Office for Europe's efforts to assist Member States to meet their commitment under the International Health Regulations (IHR) to report certain disease outbreaks and public health events to WHO. It is an intersectoral program focusing on laboratory strengthening, as part of IHR core capacity implementation.**

A proposal for the Better Labs for Better Health initiative was developed in 2012 based on a situational analysis in priority eastern (Newly Independent States) and south-eastern European countries<sup>1</sup> and with input from the Divisions of Communicable Diseases, Health Security and Environment and Health Systems at the Regional Office and WHO headquarters. Countries were invited to formally commit to the initiative and, by the end of 2015, the Republic of Moldova, Kyrgyzstan, Tajikistan, Turkmenistan and Uzbekistan had provided such commitment.

### Intersectoral collaborative approach

The Better Labs for Better Health initiative's intersectoral approach involves collaborative activities with Member States and sharing of best practices in order to:

- develop national laboratory policies and strategic plans;

- improve national training programs and implement quality management systems;
- upgrade critical infrastructure such as teaching laboratories and external quality assessment programs.

Since 2012, the WHO Regional Office for Europe has worked with Member States to establish intersectoral national laboratory working groups (NLWG), with the involvement of partners, in order to develop national laboratory policies and strategies. International partners were also the target audience of the first Better Labs for Better Health partners meeting in 2014, as were eight Member States, nongovernmental organizations (NGO), foundations, and donors, to achieve consensus on the Better Labs for Better Health initiative's direction.

Among other collaborative activities since implemented as routine, NLWGs hold regular meetings to take forward the Better Labs for Better Health objectives, discuss laboratory-related activities, provide advice at a national level, and identify synergies with other lab-related initiatives.

In addition, analysis of national training requirements has identified training on Laboratory Quality Management Systems (LQMS) as a priority, with focus on Laboratory Quality Stepwise Implementation (LQSI) and mentoring.

The Better Labs for Better Health initiative operates within the WHO framework, applying WHO methodologies and tools, and working with other WHO initiatives wherever appropriate. Examples of this are collaboration with the Control of Antimicrobial Resistance (AMR) programme and training on use of the LQMS manual. The initiative also works with the following WHO programmes: International Health Regulations; Influenza and Other Respiratory Pathogens; Vaccine-preventable Diseases and Immunization; Joint Tuberculosis, HIV/AIDS and hepatitis; Alert and Response Operations; and Food Safety.

<sup>1</sup> Albania, Armenia, Azerbaijan, Belarus, Bosnia and Herzegovina, Bulgaria, Croatia, Georgia, Kazakhstan, Kyrgyzstan, Kosovo (in accordance with Security Council resolution 1244 (1999)), the Republic of Moldova, the former Yugoslav Republic of Macedonia, Montenegro, Romania, the Russian Federation, Serbia, Slovenia, Tajikistan, Turkey, Turkmenistan, United Kingdom of Great Britain and Northern Ireland, and Uzbekistan

## Results to date

The Better Labs for Better Health initiative has been active in a wide area, with involvement across south-eastern and eastern Europe and central Asia. Four countries have made significant progress in developing a national laboratory policy – as of December 2015, the Republic of Moldova and Tajikistan had completed policies awaiting government endorsement, and Kyrgyzstan and Uzbekistan were actively developing their policies. A fifth country, Turkmenistan, started the process on laboratory policy development in late 2015. All five countries have government-appointed NLWGs that function as expert resources for laboratory issues at a national level.

To help countries improve their national training programs, five-day interactive curriculum review workshops have been held in the Republic of Moldova, Kyrgyzstan, Tajikistan and Uzbekistan with both laboratory managers and representatives from laboratory education institutes, resulting in recommendations covering strengthening collaboration between the institutes and the laboratories, improving examination methods, developing managerial training, and curricula reviews

to ensure that newly-qualified laboratory scientists have been capacitated to work according to modern methodologies.

To help countries implement LQMS, Better Labs for Better Health is assisting countries to use WHO's tool for the stepwise implementation of LQMS, the LQSI tool. A five-day course in laboratory quality and use of the LQSI tool is provided to laboratory quality officers and their managers. Five courses were held in 2014 and 2015 for 110 participants from 75 laboratories in eastern and south-eastern European, as well as central Asian countries. The Better Labs for Better Health initiative follows up on this training in selected laboratories with mentoring that supports these laboratories towards accreditation and 10 laboratory experts have been trained as mentors for this. The aim is to increase from one laboratory mentored in 2015 to eight in 2016 and 12 in 2017. Laboratories that complete all phases of the LQSI stand in good stead to achieve international-level standardization, e.g. ISO 15189 for medical laboratories.

In addition, three laboratory assessment and quality tools have been developed (for influenza, HIV and microbiology – AMR - laboratories); and laboratory experts throughout the region have been trained in biorisk management and shipment of infectious substances.

Implementing a quality management system also implies management challenges, and the Better Labs for Better Health initiative therefore also provided training for laboratory managers in the Republic of Moldova. The above initiatives are now supported by an online forum that supports best laboratory practice through group discussions and the exchange of documents.

The Better Lab for Better Health initiative has two major priorities for 2016–2017: to assist Member States in the implementation of their national laboratory strategic and operational plans, and to increase the number of laboratories being mentored under LQMS towards ISO 15189 accreditation.

## Purpose and target audience of this document

**This document provides a description of the first three years of implementation of the Better Labs for Better Health initiative. It includes the key achievements and a forward look. The target audience is participants and partners of Better Labs for Better Health. It is the first update since the partners meeting held at the WHO Regional Office for Europe in June 2014<sup>2</sup>.**

## Introduction

### What is Better Labs for Better Health?

Better Labs for Better Health is a new intersectoral approach to provide sustainable improvements to the quality of all laboratories that deal with health.

Better Labs for Better Health is based upon WHO's global vision of laboratory strengthening (the Maputo Declaration on Strengthening of Laboratory Systems, 2008), namely that well-functioning, sustainable laboratory services, operating according to international principles of quality and safety, are essential for strong health systems and crucial for improving public health. Within this context, the Better Labs for Better Health initiative reflects that the laboratory sector is one of the core capacities that countries must develop for the implementation of the International Health Regulations [2005], because laboratory services play a major role in all the key processes of detection, assessment, response, notification, and monitoring of events.

<sup>2</sup> Partners meeting report: The WHO Regional Office for Europe (2014). Report of the WHO Regional Meeting on strengthening laboratory capacities to support national programmes in eastern Europe and central Asia. [http://www.euro.who.int/\\_\\_data/assets/pdf\\_file/0018/262611/Report-of-the-WHO-Regional-meeting-on-strengthening-laboratory-capacities-to-support-national-programmes-in-eastern-Europe-and-central-Asia-Eng.pdf?ua=1](http://www.euro.who.int/__data/assets/pdf_file/0018/262611/Report-of-the-WHO-Regional-meeting-on-strengthening-laboratory-capacities-to-support-national-programmes-in-eastern-Europe-and-central-Asia-Eng.pdf?ua=1)

Likewise, improving the quality of laboratory services in health care systems is an essential step towards protecting the health of the country's population and strengthening the health care system as a whole. Laboratory services are thus a key component/target to achieving Sustainable Development Goal 3: Ensure healthy lives and promote well-being for all at all ages.

Better Labs for Better Health also follows the One Health approach, which is “the collaborative effort of multiple disciplines—working locally, nationally and globally—to attain optimal health for people, animals and the environment”.

The Better Labs for Better Health initiative has been subject to a WHO-wide review, including reviews by the Division of Health Systems and Public Health, and the various programmes within the Division of Communicable Diseases and Health Security (DCH).

The Better Labs for Better Health initiative works completely in line with WHO headquarters, using global tools that are adapted when required. For example, global tools in frequent use are the Laboratory Quality Management Systems training toolkit, handbook and quality manual and the

Laboratory Quality Stepwise Implementation tool, along with training modules in Biorisk Management and Infectious Substance Shipping.



**Fig. 1: Mentor training course, Copenhagen**

Activities are coordinated with other laboratory-strengthening activities in the Region and conducted in line with Health 2020, the European policy for health and well-being, as well as ongoing health system and public health reforms at country level. This provides a platform for coordination with external partners and donors in laboratory strengthening to ensure best use of scarce resources.



The Better Labs for Better Health initiative is integrated with existing Regional Office laboratory strengthening work through the Division of Communicable Diseases and Health Security Laboratory Coordination Group. During monthly meetings, laboratory-related activities being undertaken by the various member programmes are discussed, advice provided and synergies made where appropriate.

An example of such a synergy is the adaptation of the National Influenza Centre Laboratory Assessment Tool (LAT), developed for use by the Influenza and other Respiratory Pathogens programme, for use in AMR laboratories and by the Joint Tuberculosis and HIV programme in laboratories performing HIV testing.

Better Labs for Better Health was launched in 2012. It was developed in partnership with the WHO Collaborating Centre for Laboratory Strengthening at the Royal Tropical Institute (KIT), the Netherlands.

#### **Why is Better Labs for Better Health needed?**

In several countries in the region, laboratory services lack national coordination, oversight and standards. As a result, services are often fragmented, functions are duplicated, and there can be a lack of sustained

investment by government and donors alike, many laboratories operate under insufficient quality and safety levels and staff are often trained using outdated curricula. Better Labs for Better Health is needed because no other initiatives in the WHO European Region are aimed at improvement of national laboratory systems as a whole. Better Labs for Better Health builds on the successes of disease-specific programmes such as polio, measles and rubella, TB and HIV, to ensure best use of existing resources. The ultimate aim of Better Labs for Better Health is to ensure that all laboratories are quality assured so that there is trust among users and full implementation of the International Health Regulations.

### **Goal**

**The overarching goal of Better Labs for Better Health is to improve health by providing timely and accurate laboratory results from quality-assured laboratories that are trusted by the user.**



**Fig. 2: National laboratory working group, Tajikistan**

## Objectives

The main objectives of Better Labs for Better Health are to:

- Fundamentally improve laboratory services in target countries, thereby improving health systems and public health overall.
- Enhance national laboratory information and communication systems in order to ensure detection of important public health events, including Public Health Emergencies of International Concern declared under the International Health Regulations.
- Create a model for laboratory services strengthening that can be applied in countries throughout the Region and beyond.
- These objectives are achieved through an interlinked three-pronged approach that leads to:
  - Development of national laboratory policies and strategic plans (Area 1);
  - Improvements to national training programmes and the implementation of laboratory quality management systems based on international standards (Area 2);
  - Upgraded critical infrastructure such as teaching laboratories, national EQA programmes, and maintenance and metrology units (Area 3).

This report describes progress in Areas 1 and 2.



Fig. 3: Laboratory training, St. Petersburg

## Results

### Area 1: Development of national laboratory policies and strategic plans

#### National laboratory working groups

For each of the five countries working with the Regional Office, the first step towards Better Labs for Better Health is the development of a national laboratory policy by a formally recognized intersectoral expert group (laboratory coordination unit) or national laboratory working group (NLWG) – Fig. 4. These policies are based on broad consensus and inform the development of national strategic plans. Through these national policies and strategic plans, Better Labs for Better Health uses an intersectoral approach to strengthen the core elements of laboratory systems identified by the NLWGs.

NLWGs include national experts who know the national system well and can determine what is needed. These experts represent facilities and services including public health laboratories; clinical diagnostics, chemical, radionuclear, food safety, toxicology, and veterinary services; metrology service, teaching universities and colleges; and laboratory accreditation agencies, as well as the ministries of health and other relevant ministries (e.g. ministries of education, ministries of agriculture and ministries of the environment), and private laboratories.



Fig. 4: National laboratory working group meeting, Uzbekistan

**“Establishment and functioning of the NLWG doesn’t only result in the development of the national laboratory policy and strategic and operational plans. During this work one can see the development of the professional community of specialists from often neglected fields of health care. By setting quality standards, providing training, developing curricula, performing assessments and managing flagship laboratories, this community becomes a crucial element of sustainable national laboratory services.”**

**Dr Elmira Turkmenova, Chief Laboratory Doctor of Kyrgyz Ministry of Health.**



Fig. 5: Mentors training course, Copenhagen

# Laboratory policy development

## Rationale and process

A national laboratory policy is a deliberate system of principles that guides future activities, signals political commitment and puts the country in the driving seat. Such a policy is essential for developing sustainable laboratory services; providing criteria for accepting or refusing activities, and ensuring optimal use of scarce resources. The policy should be consistent with other national policies in related fields, aligned to ongoing country laboratory initiatives and wider health system reforms, and based on broad consensus<sup>3</sup>.

Policy and strategy development in the Better Labs for Better Health model covers all laboratories dealing with health, including laboratories for:

- prevention and management of acute and chronic diseases
- control of outbreaks
- antimicrobial resistance
- adverse events associated with pharmaceutical or vaccine use

- food, water and biological product safety
- control of animal health
- environmental monitoring.

The national laboratory policy and strategic plan are developed by the NLWG that has high level technical expertise and is supported by the Ministry of Health, other relevant ministries and international partners.

The national laboratory policy is developed over a period of up to one year (Fig. 6) through a facilitated, country-tailored, step by step approach under the umbrella of the formally established NLWG, facilitated by the Better Labs for Better Health team. The methodology is based on examples from other countries and WHO regions, and uses a range of analytical approaches such as: a structured systems analysis (Fig. 7); the strengths, weaknesses, opportunities and threats framework; the political, economic, social and technological (PEST) framework; root-cause analysis; and rumour-opinion-fact (ROF) analysis to collect and evaluate the evidence. The NLWG members are trained in the use of these techniques during the policy development workshops.

There are nine steps in the national laboratory policy development, involving three steps for each of three phases covering preparatory activities in phase 1 (establish NLWG, conduct situational analysis using the WHO laboratory system assessment tool), policy development in phase 2 and policy endorsement in phase 3 (Fig. 6 & 7). The methodology for the development of a national laboratory policy has been published in the first edition of the Regional Office's journal Public Health Panorama.

<sup>3</sup> WHO workshop on laboratory policy development in Uzbekistan <http://www.euro.who.int/en/health-topics/Health-systems/laboratory-services/news/news/2013/12/who-workshop-on-laboratory-policy-development-in-uzbekistan>

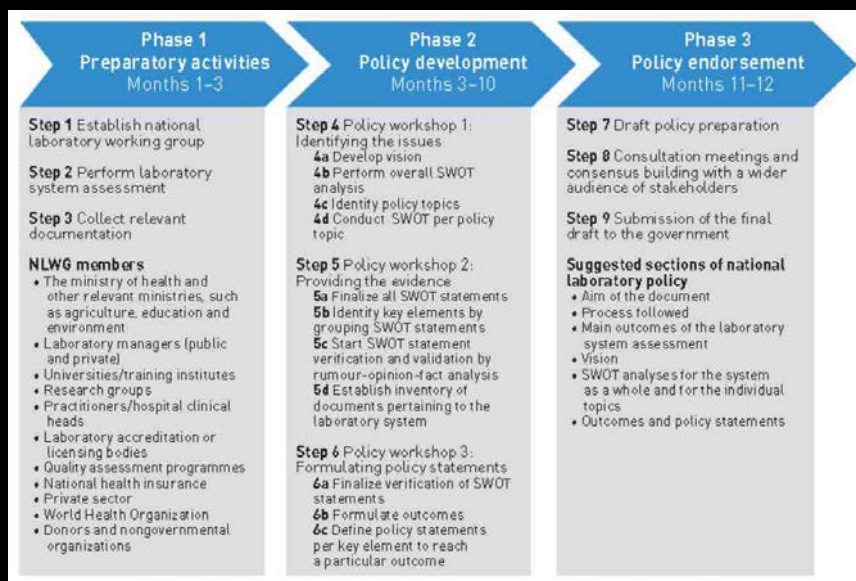


Fig. 6: Phases in the development of a national laboratory policy<sup>4</sup>

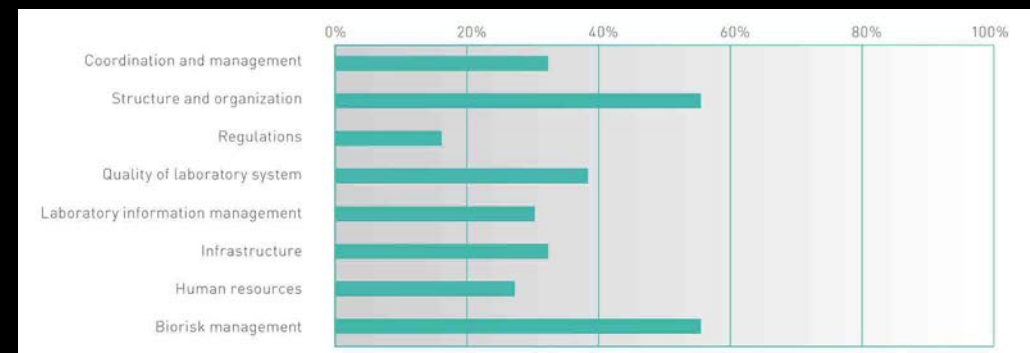


Fig. 7: Example of indicator results from a laboratory assessment performed using the WHO Systems Laboratory Assessment Tool, used as part of the analysis for policy development<sup>5</sup>

4 Brown et al, 2015. New policy-formulation methodology paves the way for sustainable laboratory systems in Europe. Public Health Panorama. 2015;1(1)

5 Brown et al, 2015. New policy-formulation methodology paves the way for sustainable laboratory systems in Europe. Public Health Panorama. 2015;1(1)

## Case study: Kyrgyzstan

The Ministry of Health of Kyrgyzstan committed to working with the Better Labs for Better Health initiative and, following the establishment of the NLWG, four laboratory policy workshops were held and a draft national laboratory policy was developed (Fig. 8). The work on policy development in Kyrgyzstan has built on an assessment conducted in 2014 by the Ministry of Health in collaboration with the Central Asia Republic (CAR) office of the United States Centers for Disease Control and Prevention (CDC).

The NLWG included laboratory directors from the two major branches of Ministry of Health laboratory services: public health and clinical/diagnostic laboratories, from both central and regional levels. Private laboratories were also represented.

In spite of the NLWG members being busy professionals with multiple responsibilities, they have appreciated the support received from WHO and use the processes described and the meeting opportunities for all kinds of networking and information exchange.

**“For the NLWG, the most valuable aspect of the process has been the formation of a community. Thanks to WHO support, they produce results and policies and, because they see the results of their efforts and appreciation for these results, they are better motivated to develop the country’s laboratories further.”**

**Olga Slobodskaya, WHO laboratory quality consultant:**



Fig. 8 National laboratory policy consultation, Kyrgyzstan

## Strategic plan development

### Rationale and process

The national laboratory strategic plan is the first step to translating the laboratory policy into action. Based on the policy statements, the NLWG develops strategic objectives. Strategic planning is underpinned by information gathered during the process of policy and strategy development, namely documents pertaining to the legal base and organization of the laboratory system, including laws and regulations, organizational structures and financing mechanisms. The strategic objectives form the starting point for operational plans: each operational plan may be based on one or more strategic objectives. The national laboratory strategic plan covers a time span of three to five years while operational plans usually cover a time span of one year. The operational plans should be developed based on a prioritization of the strategic objectives by the NLWG and according to the resources available in the country. In this way, implementation of the national laboratory strategic plan is harmonized with other planning mechanisms in the country<sup>6</sup>.

<sup>6</sup> Public health laboratories' regionalization strategy in the Republic of Moldova  
<http://www.euro.who.int/en/health-topics/Health-systems/laboratory-services/news/news/2012/10/public-health-laboratories-regionalization-strategy-in-the-republic-of-moldova>



**Fig. 9: Progress on laboratory policy and strategy development per country**



## Case study: Tajikistan

In Tajikistan, the Better Labs for Better Health activities promoted an integrated, intersectoral and laboratory sector-wide approach towards sustainable modernization and improvement of the laboratory services. The Ministry of Health established an intersectoral, high-level, Laboratory Coordination Committee and an NLWG, including representatives from the human and veterinary health laboratories, the educational system and the accreditation body, that was tasked with developing the national laboratory policy and strategic plan. Strategic planning objectives were subsequently prioritized to provide the basis for an operational plan.

Two of the strategic priorities identified for 2016 include the development and approval of a resolution by the Government of Tajikistan on the reform of laboratory services, based on the evidence collected during the strategic plan development process, and secondly, harmonization of current legislation with international policies and regulations, including the International Health Regulations (2005). The Laboratory Coordination Committee and NLWG will work towards these and other objectives in 2016, at government level and with international partners.

The strategic plan with associated operational plans can be presented at national health cluster donor coordination meetings, chaired by WHO, and form the basis for donor and partner support.

**“The Tajikistan National Laboratory Working Group is a group of enthusiastic and knowledgeable lab professionals all of whom are dedicated to improving the laboratory services. The Better Labs for Better Health approach empowered them to take the lead in the improvement process, form a think tank for the lab services in Tajikistan and also provided them with the opportunity to learn from experiences in other countries through international advisors.”**  
**Linda Oskam, Head of the WHO Collaborating Centre for Laboratory Strengthening based at KIT.**

Fig. 10: St. Petersburg laboratory training



## Area 2: Improve national training programmes and implement laboratory quality management systems

### National training curriculum evaluation and development

#### Rationale and process

Better Labs for Better Health works with universities, training colleges and other institutions, as well as with public and private laboratory managers, to revise laboratory worker curricula so that they are aligned with actual needs. Quality and biosafety management and the use of modern equipment and new techniques should be integrated in the basic training curricula, which should also cover ethics as well as collaboration and communication with different stakeholders. Partnership with the Ministry of Education and the national quality assurance agency is required to ensure accreditation of the revised curricula. Countries also need a comprehensive human resources plan to address the number and types of laboratory workers to be trained, performance management, motivation, career pathways, retention strategies and continuing education policies.

Better Labs for Better Health has reviewed training curricula to identify gaps, develop competencies and propose recommendations for training improvements in close collaboration with national stakeholders. An assessment of the training curriculum is performed through interviews with educational institutions, national laboratories and students, as well as the Ministry of Health. The findings of this curriculum assessment form the basis for the evaluation of the current training curricula, which is performed in a five-day interactive workshop with representatives of the laboratory education institutes and laboratory managers, the end users. The workshop helps to identify the competencies desired for the laboratory service doctors and scientists (Fig. 11). Next, to identify the gaps, the desired competencies are compared with the curriculum and the learning objectives of the current training curriculum of the concerned staff.

The process has so far been conducted in four countries: the Republic of Moldova, Kyrgyzstan, Tajikistan, and Uzbekistan. Recommendations to date have included improved practical training of students by strengthening collaboration between educational institutions and public and private laboratories; improved methods of examination of practical skills; development of training for laboratory managers; and review of curricula based on the competencies developed<sup>7</sup>.

<sup>7</sup> Strengthening laboratory policies and training in the Republic of Moldova  
<http://www.euro.who.int/en/health-topics/Health-systems/laboratory-services/news/news/2014/07/strengthening-laboratory-policies-and-training-in-the-republic-of-moldova>

## Case study: Kyrgyzstan

At the request of the national laboratory working group, also known as the Laboratory Coordination Council, representatives of the Ministry of Health, various Kyrgyzstan universities, medical colleges, as well as heads of medical laboratories and the head of a private laboratory came together to review the curricula for laboratory medical doctors, laboratory technicians and laboratory managers.

Participants reviewed the curricula together to identify gaps and discuss actions to improve the respective curricula. An example of collaboration during the first workshop was a private laboratory offering places for practical training, which will alleviate the shortage of practice places within the public health system.

**“Some participants had never met each other before. The workshop helped them realize that they could collaborate to ensure the improvement of curricula and training of laboratory workers, as well as who should be equipped with updated competencies, skills and knowledge in order to respond to the needs of the population through modern laboratory services.”**

**Prisca Zwanikken, head of KIT's Health Education department and consultant to WHO**



Fig. 11/12: Curriculum development workshop, Istanbul

## Training and mentoring in laboratory quality

### Rationale and objectives

Until recently, laboratory services were amongst the weakest components of disease treatment and control efforts in high-burden, resource-limited countries. Strengthening laboratory services and systems is essential for universal access to high quality laboratory diagnostic services. One of the best methods of laboratory strengthening is to implement a quality management system that complies with the requirements of international quality standards; in particular ISO 15189 for any laboratories dealing with clinical samples; ISO 17025 for veterinarian, food safety and environmental testing laboratories; or (national) standards with similar requirements.

The LQMS Training Toolkit is used to train laboratory managers, senior biologists and technologists in quality management systems as a step towards obtaining national or international recognition, such as ISO 15189.



**Fig. 13: Training in LQMS implementation using the LQSI tool, Copenhagen**

It provides comprehensive materials for the design and organization of training workshops for all stakeholders in health laboratory processes, from management to administration to bench-work laboratory scientists. The materials can be selected and customized to fit local needs. The LQMS training toolkit is complemented by the WHO LQSI tool, which is a stepwise plan, developed by WHO and the Royal Tropical Institute (KIT) in the Netherlands to guide medical laboratories towards implementing a quality management system in compliance with ISO 15189. Laboratories that complete all four phases can apply for ISO 15189 accreditation. Implementation of an LQMS in a laboratory requires institutional commitment and significant human and financial resources. To support laboratories of eastern and south-eastern Europe to implement an LQMS in their laboratories, Better Labs for Better Health developed a training and mentoring programme focused on the use of the LQSI tool.

The unique 5-day training module in laboratory quality implementation trains senior laboratory managers and quality officers in laboratory quality and in the utilization of the complementary LQSI tool. KIT also regularly provides training on use of the tool twice a year. At the end of the course, participants develop action plans to improve the quality of their laboratories, the implementation of which can be subsequently supported and mentored by the Better Labs for Better Health initiative. Laboratories may choose to implement all stages or only relevant parts according to their national laboratory standards. To enhance the further roll-out of these tools, the complete LQMS toolkit has been translated into Russian, French Turkish, and the LQSI tool has been translated into Russian and French, with Turkish, Spanish and Arabic to follow in 2016.

Five courses were conducted in 2014 and 2015 (Fig. 13 & 14), involving 110 participants from 75 laboratories from 23 eastern and south-eastern European countries (Fig. 15).



**Fig. 14: Process analysis exercise, LQSI training, Copenhagen**

Following the LQSI training, mentoring is being established in targeted laboratories to assist them towards the implementation of a quality management system.

#### **On-site mentoring: training & mentor selection**

Although the use of the LQSI tool minimizes the need for external assistance in the process of implementing an LQMS, regular mentoring remains crucial, and on-site mentoring can provide targeted support to help laboratories move towards accreditation in a systematic and efficient manner<sup>8</sup>. During these mentoring visits the mentors can meet with management to describe the process and request and provide support, answer questions, help to develop action plans to overcome obstacles, perform external audits and provide training. Better Labs for Better Health has therefore established a pool of mentors in laboratory quality. 7 mentors from across the European Region with theoretical and practical knowledge of the ISO15189 standard, as well as at least five years' experience of working in a laboratory, were selected during a mentor workshop in September 2015 (Fig. 2).

<sup>8</sup> The Regional Office provides mentoring towards ISO 15189 accreditation <http://www.euro.who.int/en/health-topics/Health-systems/laboratory-services/quality-tools-and-training/who-europe-provides-mentoring-towards-iso-15189-accreditation>

## Training and mentoring in laboratory quality



Fig. 15: Number of people trained in LQSI per country

During the workshop, they were briefed on the desired mentoring style and approach, and tested on their quality knowledge and communication aptitudes. They were also introduced to the structure of the LQSI tool and briefed on how to use it in practice<sup>9</sup>.

The Better Labs for Better Health initiative aims to increase mentoring capacity from one laboratory in 2015 to eight in 2016 and 12 in 2017.

<sup>9</sup> The Regional Office identifies 7 mentors to help eastern and south-eastern European countries improve the quality of their laboratories  
<http://www.euro.who.int/en/health-topics/Health-systems/laboratory-services/news/news/2015/10/who-europe-identifies-7-mentors-to-help-eastern-and-south-eastern-european-countries-improve-the-quality-of-their-laboratories>

## Case study: St. Petersburg National Influenza Centre

The WHO Regional Office for Europe has a long-standing collaboration with the National Influenza Centre (NIC) at the Research Institute of Influenza in St. Petersburg, and the Institute's staff have attended LQSI courses organized through Better Labs for Better Health. On-site mentoring support was offered to the Institute, which readily accepted the opportunity to receive refresher quality management systems training and to develop a plan for ISO 15189 accreditation.

Better Labs for Better Health partnered the Institute with two experienced mentors with complementary skills and experience: one has worked for more than 20 years on guiding laboratories towards accreditation in the United Kingdom of Great Britain and Northern Ireland and neighbouring countries; the other works at a national accreditation centre in Estonia.

The first mentor visit took place in November 2015 (Fig. 16). The mentoring team found receptive and eager staff which enthusiastically collaborated with the team. The team and staff went through the LQSI checklists to determine the achievements and gaps in quality management systems implementation, which allowed a draft action plan to be developed. The action plan included development of a process map for all key activities, and the appointment of a quality manager.

Since the visit, communication has been maintained with the NIC and the action plan continues to be developed.

Three mentoring visits are planned for 2016.

Our mentors said: "We were very excited, and a little nervous, to be making our first visit to the Russian Research Institute of Influenza as part of the Better Labs for Better Health mentor programme. Excited because we were looking forward to meeting and working with the Institute's staff, yet nervous because this was a new venture and we found it difficult to prepare a plan for the week. However, we needn't have worried. We were made very welcome and the staff's enthusiasm for the project was clear from the start.

**"The Institute has a highly skilled workforce and we saw many examples of good practice, so our work with key staff enabled us to develop the action plan during just a week. It was an excellent start to a long journey."**



Fig. 16: Mentoring on data management, St. Petersburg



### **Distance-mentoring: national influenza centres in south-eastern Europe**

In collaboration with the Better Labs for Better Health initiative, the CDC, together with the Association of Public Health Laboratories (APHL), began a laboratory twinning project in south-eastern Europe in 2015, providing mentoring to NICs in Albania, Bosnia and Herzegovina, Kosovo (in accordance with Security Council resolution 1244 (1999), the former Yugoslav Republic of Macedonia, the Republic of Moldova, and Montenegro, that had previously been trained by WHO in laboratory quality and the LQSI tool. NICs in Bulgaria, Croatia, Romania, Serbia and Slovenia received distance mentoring from KIT, to assist the laboratory representatives to develop and implement long-term plans for improving their LQMS using the LQSI tool.

Good progress was made, in spite of constraints such as staff not having sufficient authority to facilitate LQMS implementation in their institute, along with a high workload. Key lessons learned were that some on-site visits were required to make best use of the support provided and that sensitization of laboratory management was required for efficient QMS

implementation. These lessons were taken on board to develop the Better Labs for Better Health on-site mentoring project.

### **Mentoring program for antimicrobial resistance laboratories**

Close collaboration exists with the AMR programme, with the development of a laboratory assessment tool (LAT) for use in microbiology laboratories, and participation in laboratory training and assessment missions for AMR surveillance<sup>10</sup>. A mentor training course will take place for AMR specialists in February 2016 so that laboratory quality management implementation can be included in technical missions to supported laboratories in the Region.

### **Training in laboratory quality for food safety laboratories**

The Better Labs for Better Health initiative was presented during the subregional Food Safety meeting on foodborne infections and related antimicrobial resistance in Tashkent, Uzbekistan in November

<sup>10</sup> Training course on antimicrobial resistance surveillance and stewardship in Istanbul, Turkey  
<http://www.euro.who.int/en/health-topics/Health-systems/laboratory-services/news/news/2015/12/training-course-on-antimicrobial-resistance-surveillance-and-stewardship-in-istanbul,-turkey>

2015. Basic LQSI training was performed for the microbiologist participants on this course (Fig. 17)<sup>11</sup>.



**Fig.17: LQSI training for food safety scientists, Uzbekistan**

<sup>11</sup> Subregional intersectoral training for the central Asian republics on antimicrobial resistance from a food safety perspective  
<http://www.euro.who.int/en/health-topics/Health-systems/laboratory-services/news/news/2015/12/subregional-intersectoral-training-for-the-central-asian-republics-on-antimicrobial-resistance-from-a-food-safety-perspective>

## Management and leadership course

### Rationale and objectives

Training is the Achilles heel of the laboratory system: without properly trained and confident staff it is extremely difficult to provide quality services. The management and Leadership course therefore provides basic knowledge of laboratory quality management principles, and an understanding both of how a quality management system is integrated into routine laboratory processes, and of how a laboratory's work is affected by the system's implementation.

The quality management system affects all routine laboratory processes – staff responsibilities, tasks and authorizations must be adapted, procedures must be revised, and all staff members must accept and implement the necessary changes. As with any process of change, initial resistance from laboratory employees is likely and the laboratory manager therefore needs good management skills. Consequently, a substantial part of the course focuses on leadership, communication, and delegation, and the course provides a conceptual framework (Plan-Do-Check-Act) to build the required management skills.



**Fig. 18: Mentor training course, Copenhagen**

Participants learn how to analyse all aspects of laboratory activities and processes, how to implement quality control and quality assurance mechanisms in routine laboratory processes, and how a quality management system is integrated into the primary process of the laboratory. They also learn how to prevent, detect and solve problems, and how to effectively manage and lead their staff.

All in all, the course provides the knowledge and skills the laboratory director/manager requires to run a laboratory successfully, and to effectively direct and guide the implementation of a quality management system.

### Case study: National Institute of Public Health, the Republic of Moldova

The Better Labs for Better Health project undertook a workshop in curriculum evaluation in June 2014 for heads of laboratories in the Republic of Moldova. Following this on-site training, a working group of national training experts developed a curriculum evaluation for laboratory scientist education, to ensure the needs of the country's laboratories were being met by the theoretical and practical education on offer. This group continued its work during an intercountry curriculum development workshop in March 2016 (Fig. 11 & 12). Two further in-country WHO missions are planned in 2016 to adapt the Masters of Public Health curriculum to include modules on leadership and management, and to pilot these new modules during routine teaching.

## Training courses and tools for laboratory systems strengthening

At the global level and as part of the Better Labs for Better Health initiative, several tools and training courses have been developed, to assess and strengthen national laboratory systems and individual laboratories.

- Laboratory Quality Management System (LQMS) Training Toolkit: Developed through collaboration between the WHO Lyon Office for National Epidemic Preparedness and Response, the CDC - Division of Laboratory Systems and the Clinical Laboratory Standards Institute, its purpose is to train laboratory managers, senior biologists and technologists in quality management systems as a step towards obtaining international accreditation, such as ISO 15189 for laboratories handling clinical specimens. It provides comprehensive materials for the design and organization of training workshops for all stakeholders in health laboratory processes, from management and administration to bench-work laboratory scientists.
- Laboratory Quality Stepwise Implementation (LQSI) tool: Developed by WHO and KIT in the Netherlands, its purpose is to guide medical laboratories towards implementing a quality management system in compliance with ISO 15189. It trains seniors laboratory managers and quality officers leading to the development of action plans to improve the quality of their laboratories. Better Labs for Better Health subsequently developed a 5 day training on lab quality and implementation using the LQSI tool. As of December 2015, a total of 110 people from 75 laboratories have been trained in use of the tool. A Training of Trainers course in LQSI has also been developed, to allow for expanded roll-out of LQSI training in countries.
- Mentor Training: Developed by Better Labs for Better Health, the purpose of this activity is to provide reference laboratories with mentoring towards laboratory quality improvement and accreditation according to the ISO 15189 standard. The WHO Regional Office for Europe is working with mentors who have theoretical and practical knowledge of ISO 15189 and/or ISO 17025.
- Laboratory Assessment Tool (LAT): Developed by WHO, its goal is to offer guidance to assess laboratories and national laboratory systems. Its target audience is any stakeholder performing laboratory assessments: national health authorities, multilateral agencies, NGOs, laboratory managers, etc.
- Training of Trainers courses in Laboratory Quality Management and Laboratory Management and Leadership developed by Better Labs for Better Health: These modules have been designed for easy incorporation into training curricula for laboratory scientists, to ensure that scientists are trained in the key areas of quality, management and leadership.

- Biorisk Management: The goal of this course is to assist countries and facilities to understand, adopt, and implement biorisk management strategies, and thus strengthen countries' capacities to effectively reduce biorisk in laboratory environments. WHO has developed several tools and training courses to supplement the courses: WHO biosafety manual, training of trainers' course in Biorisk Management, Infectious Substances Shipment Training (ISST) and films demonstrating safe practices in different laboratory settings.
- Infectious Substance Shipment Trainings (ISST): Developed under the United Nations Model Regulations for the transport of infectious substances. This training is the basis for international and national regulations addressing transport by air, road, rail, and sea. Training contributes to improving compliance with applicable regulations ensuring protection of staff, the public and the environment.

**Working with external partners**  
**External partners are essential to the progress of Better Labs for Better Health activities, due to the opportunities for synergy that they provide (e.g. participation in policy and strategy development and collaboration on mentoring activities), and to ensure Better Labs for Better Health builds on work done by others, leading to links at the national and regional level.**

The first Better Labs for Better Health partners' meeting took place in Copenhagen in 2014. Eight Member States were represented at the meeting: Armenia, Georgia, Kazakhstan, Kyrgyzstan, the Republic of Moldova, the Russian Federation, Tajikistan, and Ukraine.

Several donors and partners were also present including United National Development Program (UNDP), Global Fund to fight AIDS, Tuberculosis and Malaria (GF), the President's Emergency Plan for AIDS Relief (PEPFAR), U.S. Defence Threat Reduction Agency (DTRA), U.S. Centers for Disease Control and Prevention (CDC), Royal Tropical Institute (KIT), Public Health England (PHE), the Robert Koch Institute (RKI), the WHO – Supranational Reference Laboratory of Tuberculosis, Gauting (Germany), and Fondation Mérieux (France).

This meeting ensured that the Better Labs for Better Health initiative was well-received in the Member States, and was perceived as a continuation of efforts in the region and a platform for open dialogue on key policies and best laboratory practices. Participants agreed that activities to strengthen laboratory capacities should result in the integration of services, such as public health and clinical diagnostic laboratories, as well as appropriately trained and motivated laboratory staff.

## Dissemination of information



**Fig. 19: Mentor training course, Copenhagen**

The first three years of Better Labs for Better Health activities focused on establishing methodologies for the standardized development of national laboratory policies and strategies, following the formation of national laboratory working groups, and for curriculum evaluation and development. These methodologies have been documented and shared throughout the Region and through the Better Labs for Better Health website, and through a dedicated online forum (EZCollab) facilitated by WHO to allow discussion and exchange of documents. Information was also shared through the 2014 partners meeting,<sup>12</sup>

through publication of peer-reviewed articles<sup>13</sup> and presentation at international meetings.

### **Laboratory services website**

All laboratory-related activities are posted on the WHO Regional Office for Europe website as events and/or news items (Fig. 20). In this way, internal and external partners can be kept abreast of activities and developments within the Region. This also provides a convenient method for describing proposed or upcoming activities to Member States and potential partners<sup>14</sup>.

Recent top stories have included a report on antimicrobial resistance training for Member States in Turkey, and the publication of an article by the Better Labs for Better Health team on an analysis of four national laboratory policies developed through the Better Labs for Better Health initiative.

<sup>12</sup> The WHO Regional Office for Europe (2014). Report of the WHO Regional Meeting on strengthening laboratory capacities to support national programmes in eastern Europe and central Asia.

[http://www.euro.who.int/\\_\\_data/assets/pdf\\_file/0018/262611/Report-of-the-WHO-Regional-meeting-on-strengthening-laboratory-capacities-to-support-national-programmes-in-eastern-Europe-and-central-Asia-Eng.pdf?ua=1](http://www.euro.who.int/__data/assets/pdf_file/0018/262611/Report-of-the-WHO-Regional-meeting-on-strengthening-laboratory-capacities-to-support-national-programmes-in-eastern-Europe-and-central-Asia-Eng.pdf?ua=1)

<sup>13</sup> Brown, C et al. New policy formulation methodology paves the way for sustainable laboratory systems in Europe. *Public Health Panorama*. 2015;1(1); Zwetyenga, J et al. Better Labs for Better Health: intersectoral challenges and solutions for laboratory systems strengthening. *Public Health Panorama*. 2015;1(2).

<sup>14</sup> Building capacity for laboratory services  
<http://www.euro.who.int/en/health-topics/Health-systems/laboratory-services/news/news/2015/07/building-capacity-for-laboratory-services>

### Laboratory services

- [News](#)
- [Events](#)
- [Better Labs for Better Health](#)
- [Networks and outbreak response](#)
- [Biorisk management](#)
- [Quality tools and training](#)
- [Country work](#)
- [Contact us](#)



### Laboratory services

Well-managed, high-functioning laboratory services play a crucial role in public health. WHO/Europe coordinates laboratory networks and works with WHO collaborating centres to support the surveillance and control of targeted diseases such as polio, measles, rubella, influenza and multidrug-resistant tuberculosis

[Read more about laboratory services](#)

### Top story



#### National laboratory policy and strategic plan of Kyrgyzstan published for comments

10-03-2016

On 1 March 2016, led by the Ministry of Health of Kyrgyzstan, a broad range of stakeholders met to consult on a proposal for a national laboratory policy and strategic plan for Kyrgyzstan.

[Read more](#)

### Biorisk management



### News

#### WHO/Europe trains laboratory and education experts on curriculum development for laboratory doctors

03-04-2016

#### WHO collaborating centre strengthens laboratory capabilities in national influenza centres

01-04-2016

#### Training course on mentoring skills for consultants in antimicrobial resistance

11-03-2016

[More news](#)

### Call for expressions of interest for mentors in laboratory quality

WHO/Europe is seeking expressions of interest from experts with a background in laboratory quality to support the implementation of quality management systems in

### Better Labs for Better Health



Through the Better Labs for Better Health (BLBH) initiative and in line with WHO's global vision, WHO/Europe assists countries to improve the overall quality of their laboratory services.

[Read more about the Better Labs for Better Health initiative](#)

### Laboratory networks and outbreak response



Fig. 20: The WHO Regional Office for Europe website

## Better Labs for Better Health focus in 2016-2017

**Three main priorities have been identified for the 2016-2017 biennium: assist Member States in the implementation of their national laboratory strategic plans, increase the number of laboratories being mentored for LQMS implementation towards ISO 15189 accreditation and introduce indicators to measure progress made.**

### Strategic priorities for implementation during the next 3-5 years

- National laboratory licensing revision/creation: During the development of national policies and strategies, it became clear that countries need to develop or revise legislation concerning laboratory practices. This legislation can also reinforce the integration of quality and biorisk management systems. The activity involves creation or optimization of a certification body, the establishment or amendment of a laboratory licensing framework, and inventories of existing laboratories. It includes the establishment or optimization of an external quality assurance system with follow-up of unsatisfactory results.
- National public health laboratory network revision: A national public health laboratory network is composed of laboratories that serve each level of the health system (health centre, district, regional/provincial, national) and that can provide correct diagnosis of infectious diseases for public health decision-making, directed at effective control and prevention of priority diseases in the country and potential public health emergencies

of international concern, as required by the International Health Regulations. This activity involves using gap analysis to determine the required structure and minimum needs for the country, and then restructuring the system to facilitate the requirements identified.

### Progress indicators

The Better Labs for Better Health initiative has started to use indicators to monitor the progress and impact of its activities. The indicators are in the process of being finalized and will include:

- Number of policies approved/number of countries implementing Better Labs for Better Health.
- Number of strategic plans approved/number of countries implementing Better Labs for Better Health.
- Number of inventories of key documents/laws/regulations performed/number of countries undergoing policy development.
- Number of operational plans developed from strategic plans/number of strategic plans approved.

- Number of operational plans being implemented/number of operational plans developed from strategic plans.
- Number of revised curricula approved/number of curricula assessed.
- Number of laboratories being mentored for implementation of a quality management system/number of laboratories trained on the LQSI tool.
- Number of mentor visits performed/total number of mentor visits planned.

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**Fig. 21: Curriculum development training, Istanbul.**



## References and resources

The WHO Regional Office for Europe Laboratory Services website (<http://www.euro.who.int/en/health-topics/Health-systems/laboratory-services>)

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Alert, response, and capacity building under the International Health Regulations (IHR) (<http://www.who.int/ihr/lyon/hls/en/>)

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