

BETTER LABS FOR BETTER HEALTH

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STRENGTHENING LABORATORY SYSTEMS IN THE WHO EUROPEAN REGION



Progress Report 2016–2017



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Maps

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Abbreviations

NAB	National accreditation body
AMR	Antimicrobial resistance
CCHF	Crimean-Congo haemorrhagic fever
CDC	Centers for Disease Control and Prevention, United States of America
ECDC	European Centre for Disease Prevention and Control
EEA	European Economic Area
EU	European Union
GF	The Global Fund to Fight AIDS, Tuberculosis and Malaria
GPW13	Thirteenth general programme of work of WHO 2019–2023
HIV	Human immunodeficiency virus
HTP	High threat pathogen
IHM	Infectious Hazards Management
IHR	International Health Regulations (2005)
ISST	Infectious Substances Shipping Training
LQMS	Laboratory Quality Management System
LQSI	Laboratory Quality Stepwise Implementation tool
LRF	Laboratory regulatory framework
MERS-CoV	Middle East respiratory syndrome coronavirus
MoH	Ministry of Health
MPH	Masters of Public Health
MS	Member States
NIS	Newly independent states of the former Soviet Union
NLWG	National laboratory working group

PEPFAR	US President's Emergency Program for AIDS Relief
PHL	Public health laboratory
QMS	Quality Management System
QSE	Quality system essential
SDG	Sustainable Development Goal
SECID	Southeast European Center for Surveillance and Control of Infectious Diseases
TB	Tuberculosis
ToT	Training of trainers
WHO	World Health Organization



Executive summary

Recognizing that laboratory services are an underlying necessity both for strengthening the health care system as a whole and for protecting the health of a country's population as part of the International Health Regulations (2005) (IHR)¹ core capacity implementation, WHO prioritizes laboratory system strengthening according to:

- the Maputo Declaration on Strengthening of Laboratory Systems, 2008²;
- the World Health Assembly resolution WHA58.29 on the Enhancement of Laboratory Biosafety, 2005³; and
- the Report on the Joint WHO-Centers for Disease Control and Prevention (CDC) Conference on Health Laboratory Quality Systems, 2008⁴.

With this background, Better Labs for Better Health 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. Through several decades, with the exception of disease-specific programs such as poliomyelitis, tuberculosis (TB) and human immunodeficiency virus (HIV), laboratory services in these countries had become fragmented, had lacked scrutiny and investment, and had sunken to poor levels of quality and safety. Furthermore, laboratories displayed overcapacity in both the number of facilities and staff compared to actual workloads, much duplication of functions, and insufficient access to international laboratory networks for emergency preparedness and response.

To help countries achieve much-needed reforms to their public health laboratory services, Better Labs for Better Health's collaborative activities with Member States and partners focus on four areas:

- Area 1: Development of national laboratory policies and strategic plans.
- Area 2: Improve national training programmes and implement laboratory quality management systems.
- Area 3: Establish networks for emergency preparedness and response.
- Area 4: Advocacy, partnership and leadership.

This report describes 2016–2017 and gives a brief overview of the priorities for 2018–2019.

During 2016–2017, the key results and achievements of the Better Labs for Better Health initiative in these four areas were as follows: two countries (Kyrgyzstan and Tajikistan) started implementing their action plan to improve national lab services based on national laboratory policies and strategic plans; quality was improved in 65 laboratories in eight countries through training and mentoring; and the establishment of networks for preparedness and response was initiated. In the area of advocacy, leadership and partnership,

¹ Alert, response, and capacity building under the International Health Regulations (IHR) – <http://www.who.int/ihr/lyon/hls/en/>

² Maputo Declaration on Strengthening of Laboratory Systems, 2008 – http://www.who.int/diagnostics_laboratory/Maputo-Declaration_2008.pdf

³ World Health Assembly resolution WHA58.29 on the Enhancement of Laboratory Biosafety – <http://apps.who.int/iris/handle/10665/20379>

⁴ Report on the Joint WHO-CDC Conference on Health Laboratory Quality Systems, 9-11 April 2008, Lyon, France – http://www.who.int/ihr/publications/WHO_HSE_IHR_LYO_2008.3/en/

the second biennial partners' meeting was held, two guidance or advocacy documents were disseminated and two peer-reviewed papers were published.

Purpose and target audience of this document

This document's target audience is Better Labs for Better Health's participants and partners, including Member States of the WHO European Region, laboratory experts and international partners. It is an update on the first activity report for the period 2013–2015⁵ and the report on the second partners' meeting held in Tbilisi, Georgia 1–2 December 2016⁶.

Introduction

Vision and goals

Laboratory services⁷ play a major role in all the key processes of detection, assessment, response, notification, and monitoring of acute public health events. Moreover, approximately 60–70% of medical decisions are based on laboratory results⁸. Reliable and timely laboratory services are thus crucial to a nation's health economy, and the optimization of national laboratory systems is therefore of benefit to both public health and public finances.

In recognition of this, the WHO Regional Office for Europe launched the Better Labs for Better Health initiative in 2012 to support the improvement of laboratory services in Member States in eastern Europe and central Asia and, in particular, to build the capacities to prevent, detect and respond to outbreaks as required under the International Health Regulations (2005) (IHR).

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 recognized principles of quality and safety, are essential for strong health systems and crucial for improving public health.

Better Labs for Better Health's overarching goal and focal areas are illustrated in Fig. 1.

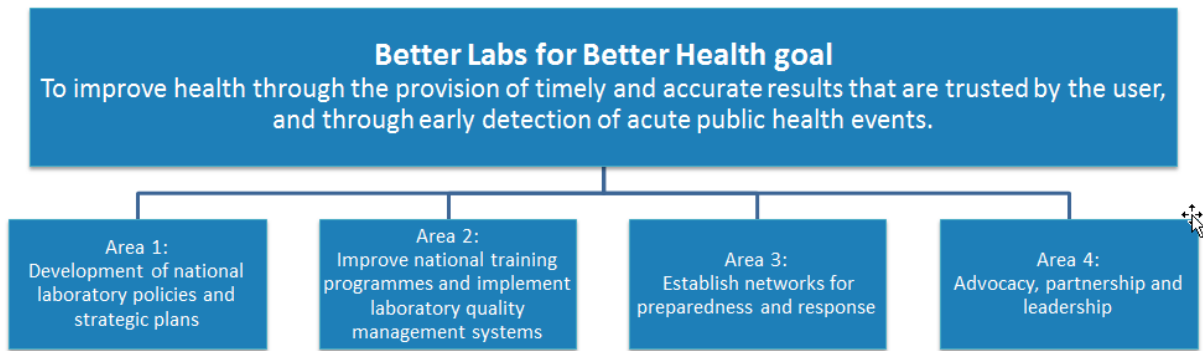
⁵ The Better Labs for Better Health initiative to strengthen laboratory systems in the WHO European Region. Activity Report January 2013–December 2015 http://www.euro.who.int/__data/assets/pdf_file/0020/318260/Better-Labs-Better-Health-initiative-activity-report.pdf

⁶ Partners' meeting report: Better Labs for Better Health – Second Partner's Meeting, December 2016 Report. http://www.euro.who.int/__data/assets/pdf_file/0005/337901/20170407_BLBH-Partners-meeting-report_en.pdf

⁷ Laboratory services are taken as: Communicable disease surveillance prevention and control; outbreak and emergency response to communicable diseases; environmental health and food safety; reference, specialized and diagnostic testing; biosafety and Containment Level 3 programs; integrated communicable disease data management; public health policy development and evaluation; laboratory improvement and regulation; training and education of health care and public health works; and public health related research. See http://www.bccdc.ca/resource-gallery/Documents/Guidelines%20and%20Forms/Guidelines%20and%20Manuals/Labs/PHMRL_Report_Corefunctions.pdf

⁸ Neglected Diseases, Delinquent Diagnostics, Kessel M, Science Translational Medicine, 05 Mar 2014: Vol. 6, Issue 226, pp. 226ed6; DOI: 10.1126/scitranslmed.3008194

Fig. 1. Better Labs for Better Health goal and areas of work



Way of working

Better Labs for Better Health is a cross-cutting initiative that works alongside disease-specific programs, and with veterinary and environmental laboratories alongside public health laboratories whenever possible. This acknowledges the fact that many managerial issues, such as quality and biosafety, are common to all laboratories, and that laboratories' services are often complementary, making it useful for network members to know where they can find specific laboratory services when needed. Better Labs for Better Health also aims to address a wide audience that includes partners, laboratory staff at all levels, and public health administrators.

Perhaps the best example of this is the national laboratory working group (NLWG) approach to developing national laboratory policies and strategies followed by action plans for reform, which is inclusive in terms of local actor involvement, and which seeks to create country ownership as well as build local expertise and capacity. Within WHO, Better Labs for Better Health is part of the WHO Health Emergencies Programme where it develops all-hazard and disease-specific laboratory strengthening measures by working with the Country Offices and with WHO headquarters as well as with the following WHO programmes for Vaccine-preventable Diseases and Immunization; Joint Tuberculosis, HIV/AIDS and Hepatitis; Antimicrobial Resistance and Food Safety. In the same way, Better Labs for Better Health works with the different partners, such as the Royal Tropical Institute, Amsterdam (KIT) utilizing their skills to improve national laboratory curricula, and collaborating with the European Centre for Disease Prevention and Control (ECDC) and CDC, together with professional organizations, whenever possible, such as the South East European Center of Infectious Disease Surveillance and Control (SECID), who supported Better Labs for Better Health in the identification of gaps and needs to improve preparedness and capacities for high threat pathogens outbreaks in their region.

Country focus

Five Member States – Kyrgyzstan, the Republic of Moldova, Tajikistan, Turkmenistan and Uzbekistan – formally committed to the Better Labs for Better Health initiative by 2015. Through the initiative's initial policy and strategy work in these countries, a clear need for reform was identified. Generally, laboratory services in these countries have been fragmented, have lacked oversight and investment, and quality and safety have been poor. There has also been overcapacity in both the number of facilities and staff compared to actual workloads, much duplication of functions, and insufficient access to international laboratory networks for emergency preparedness and response.

These factors implied a need to develop national health strategies and plans based on in-depth situational analyses in order to describe in detail the required structure, functions and financing of the public health laboratory (PHL) systems of the five committed Member States, with a view to the rationalization of their laboratory services. This top-down approach has been coupled with ongoing bottom-up support and assistance to improve the quality and safety of laboratory services through training staff at all levels, and through the mentoring of laboratory managers in the implementation of laboratory quality management systems (QMS).

Better Labs for Better Health’s work is largely conducted through support and assistance to the formally designated multi-sectoral NLWGs in participating countries, and extends also to supporting laboratory networks for emergency preparedness and response at both national and international levels, and to advocacy and leadership in getting governmental and donor commitment to improvements in laboratory services.

In addition to the five countries above, in 2017, as part of the health sector reform in Ukraine⁹, Better Labs for Better Health has led WHO’s support to the reform of the public health laboratory services in collaboration with the EU and the US CDC.

Results driven

Better Labs for Better Health is an indicator-driven initiative and Table 1 highlights the major indicators for the first two periods and the targets for 2018–2019 for these four areas.

Table 1. Better Labs for Better Health KPIs* and targets for 2018–2019

Better Labs for Better Health	KPI	Result		Target
		2012–2015	2016–2017	2018–2019
Area 1: Development of national laboratory policies and strategic plans	Number of Member States implementing their action plan to improve national lab services	0	2	4
Area 2: Improve national training programmes and implement laboratory QMS	Number of public health laboratories with trained laboratory managers in Member States where laboratories are mentored	34 labs in 8 MS	65 labs in 9 MS	100 labs in 10 MS
Area 3: Establish networks for preparedness and response	Number of national laboratory focal points in south eastern European and central Asian Member States	0	0	15
	Number of Member States having completed situational analysis of HTP diagnostics	0	0	15

⁹ http://healthsag.org.ua/wp-content/uploads/2015/03/Strategiya_Engl_for_inet.pdf

Area 4: Advocacy, partnership and leadership	Number of partners' meetings held	1	2	3
	Number of guidance or advocacy documents disseminated	0	2	5
	Number of peer-reviewed papers published	0	2	5

* BLBH's committed member states are Kyrgyzstan, the Republic of Moldova, Tajikistan, Turkmenistan and Uzbekistan

Moving forward, Better Labs for Better Health will be fully aligned with WHO's thirteenth General Programme of Work (GPW13) for 2019–2023¹⁰.

Achievements until 2015

By the end of 2015, five Member States – Kyrgyzstan, the Republic of Moldova, Tajikistan, Turkmenistan and Uzbekistan – had formally committed to the Better Labs for Better Health initiative, and all five had government-appointed NLWGs functioning as expert resources for laboratory issues at a national level.

With Better Labs for Better Health support, NLWGs in these countries developed national laboratory policies and strategic plans. These documents form the foundation for identifying the key priorities for reform; namely the regulations governing laboratories, finance, human resource development, specimen referral systems biosafety, equipment procurement and maintenance, laboratory information systems and quality management systems¹¹. Based on the identified priorities, the NLWGs developed a national laboratory action plan that takes available resources into account and ensuring laboratory reforms are harmonized with the country's other health-sector development plans.

As of December 2015, the Republic of Moldova and Tajikistan had completed policies awaiting government endorsement, Kyrgyzstan and Uzbekistan were actively developing their policies, and Turkmenistan had started the process of laboratory policy development.

To support improvements to national teaching curricula for laboratory staff, interactive curriculum review workshops were held in the Republic of Moldova, Kyrgyzstan, Tajikistan and Uzbekistan with both laboratory managers and representatives from laboratory education institutes. These workshops provided 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 had been capacitated to work according to modern methodologies.

Also in this period, Better Labs for Better Health actively assisted countries in using WHO's Laboratory Quality Stepwise Implementation tool¹² (LQSI tool). During 2014 and 2015, five five-day courses in laboratory quality and the use of LQSI were held for laboratory quality officers and their managers with 110 participants from 75 laboratories in eastern and south-eastern European, as well as central Asian countries.

¹⁰ WHO 13th WHO General Programme of Work – <http://www.who.int/about/what-we-do/gpw-thirteen-consultation/en/>

¹¹ Zwetyenga, J et al. (2015). Better Labs for Better Health: intersectoral challenges and solutions for laboratory systems strengthening. Public Health Panorama. 2015; 1 (2)

¹² Laboratory Quality Stepwise Implementation tool – http://www.who.int/ihr/lyon/hls_lqsi/en/

The Better Labs for Better Health initiative followed up on this training with mentoring in selected laboratories that supported these laboratories towards accreditation, and 10 laboratory experts were trained as mentors for this.

Other results in the 2012–2015 period included:

- A laboratory assessment and quality tool for antimicrobial resistance (AMR).
- A guidance on developing a national laboratory policy¹³ and a guidance on developing a national laboratory strategic plan¹⁴ – both based on experiences gained through the Better Labs for Better Health initiative.
- Articles on intersectoral challenges and solutions for laboratory systems strengthening and on policy formulation methodology.
- Translation into Russian of the WHO manual on organizing a national external quality assessment programme for health laboratories and other testing sites¹⁵.
- Training of laboratory experts throughout the region in biorisk management and shipment of infectious substances and training of laboratory managers in the Republic of Moldova.
- Launch of the Better Labs for Better Health website.
- The first partners' meeting¹⁶.

Achievements during 2016–2017

Area 1: Development of national laboratory policies and strategic plans

Endorsement of the national laboratory policy and strategy was achieved in Kyrgyzstan in March 2016 and in Tajikistan in March 2017¹⁷; and by the end of 2017 the Republic of Moldova, Turkmenistan, and Uzbekistan had finalized development of their national laboratory policies and strategic plans.

As the NLWGs have worked with their local ministry of health (MoH) to develop national laboratory policies and strategies, and to advocate for governmental endorsement, they have increased their countries' self-sufficiency in the area of laboratory reform and become platforms for change, driving the implementation of action plans. By the end of 2017, the NLWGs in Kyrgyzstan, Tajikistan, and Turkmenistan had developed action plans to address the following priority areas for reform:

- governance/regulatory policy;
- specimen referral systems;
- accessibility of services;
- leadership, commitment and coordination;
- laboratory information systems;
- a framework for training, retraining and career development of laboratory workers;

¹³ http://www.euro.who.int/__data/assets/pdf_file/0003/333471/Development-NLP.pdf

¹⁴ http://www.euro.who.int/__data/assets/pdf_file/0020/333470/Development-NLSP.pdf

¹⁵ <http://www.who.int/hiv/pub/toolkits/manual-external-quality-assessment-testing/en/>

¹⁶ 8 Member States were represented at the meeting: Armenia, Georgia, Kazakhstan, Kyrgyzstan, Republic of Moldova, Russian Federation, Tajikistan and Ukraine. Major donors and partners present included WHO, UNDP and GF, PEPFAR, U.S. CDC, U.S. DTRA, KIT, PHE, RKI, WHO – Supranational Reference Laboratory of Tuberculosis, Gauting (Germany), and Fondation Mérieux (France).

¹⁷ Turkmenistan endorsed its national laboratory policy and strategy in March 2018. Endorsement pending in the Republic of Moldova and Uzbekistan.

- finance;
- infrastructure development;
- biosafety and waste management;
- supply-chain management of laboratory supplies;
- maintenance of laboratory equipment;
- quality management systems; and
- ethics.

Addressing these priority areas goes hand-in-hand with the introduction of modern laboratory tests adapted to the local epidemiological context that are both cost effective and based on recognized international standards and norms for quality. Better Labs for Better Health is therefore also helping the NLWGs to identify which pathogens should be tested for at which level of their country's system, by means of which tests, and based on which standards. Proposals for laboratory system optimization determining the list of tests to be performed for priority pathogens at each level of the system, and evaluating the required number of tests, equipment and personnel, are being drafted by the NLWGs in Kyrgyzstan, Tajikistan and Ukraine. Kyrgyzstan and Tajikistan have also prepared proposals for the establishment of regulations pertaining to the licensing and accreditation of laboratories.

A noteworthy achievement in 2017 was the grant of USD 1 million by the World Bank for a project in Kyrgyzstan for quality improvement at 10 regional maternity and child hospital laboratories, under the Den Sooluk project¹⁸. This project is based on a proposal prepared by the NLWG with the support of Better Labs for Better Health, and will be mentored by 12 Kyrgyz mentors trained under the Better Labs for Better Health initiative.

During 2017, Better Labs for Better Health support in Area 1 was extended to Ukraine. A joint statement to summarize the conclusions and recommendations of assessments conducted by partners and a concept note was developed together with EU, ECDC, CDC and DTRA concerning the reforms needed. This document was added to the national strategy for epidemiology surveillance of infectious diseases.

Table 2 provides further details of Better Labs for Better Health's activities in Area 1 during 2016–2017.

¹⁸ <http://projects.worldbank.org/P126278/kyrgyz-second-health-social-protection-project?lang=en&tab=details>

Table 2. Activities – Area 1: Development of national laboratory policies and strategic plans

Country	Activity
Kyrgyzstan	Presentation of the consolidated national laboratory policy and strategic plan to stakeholders at a policy consultation convened by the Ministry of Health, led by the Coordination Laboratory Council of Kyrgyzstan.
	Approval by the Ministry of Health of the National Laboratory Policy and Strategic Plan under Order No. 347.
	Development of a roadmap for the implementation of the National Laboratory Policy and Strategic Plan (2017-2025).
	Revision of the laboratory regulatory framework, sample referral situation analysis and laboratory system optimization based on essential diagnostics.
	Terms of reference for reference laboratories.
Tajikistan	Endorsement of the policy and strategic plan.
	Development of the action plan for laboratory improvement, based on the national policy and strategic plan.
	Revision of the laboratory regulatory framework, sample referral situation analysis and laboratory system optimization based on essential diagnostics.
Turkmenistan	NLWG formally convened by Ministry of Health, with 29 permanent members.
	Development of national laboratory policy and strategic plan.
	Development of the national action plan.
Ukraine	Assessment of 7 public health laboratories.
	Development of a joint statement and a concept note to summarize the conclusions and recommendations of assessments conducted by partners (EU, ECDC, US CDC and DTRA).
	Laboratory system optimization based on essential diagnostics.
Uzbekistan	5 th and 6 th workshops for laboratory policy and strategy development.
Intercountry	Joint Kyrgyzstan-Tajikistan workshop on sample referral to draft national guidance for transport of samples.
	Roundtable discussions in Kyrgyzstan and Tajikistan to identify gaps and needs their laboratory regulatory frameworks; participants included the NLWG, lawyers from the MoH, and staff from the national medical accreditation units and licensing units.
	Organizational analyses of the laboratory system structures within the MoH of Kyrgyzstan and Tajikistan.

Area 2: Improve national training programmes and implement laboratory quality management systems (QMS)

Better Labs for Better Health provides training and mentoring to support Member States' implement QMS, apply the principles of biorisk management in the laboratory, and ensure the safe transport of specimens.

WHO has long worked with public health laboratories to implement QMS and, since its inception, Better Labs for Better Health has been providing training and support in this area for laboratory personnel at all

levels. Because QMS implementation is a long process and in order to enhance the effectiveness of training in QMS provided by WHO, Better Labs for Better Health established a mentoring programme in 2015 to support public health laboratories in QMS implementation. Better Labs for Better Health mentors are laboratory experts from across the European Region, selected based on both their theoretical knowledge and practical experience (including with ISO 15189) and further trained for their mentoring role (see *Mentoring*).

In addition, to training laboratories in implementing or improving their quality management, using the Laboratory Quality Stepwise Implementation (LQSI) tool¹⁹, which provides roadmaps with day to day guidance on implementing a quality management system that complies with ISO 15189, an online training course has been developed²⁰, to reduce travel and location costs, with the support of WHO Headquarters, Lyon.

Infectious substance shipping training²¹ (ISST) is also provided based on 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.

Better Labs for Better Health also holds biorisk management training²², to introduce the new concept of biorisk management, which combines risk assessment, risk mitigation, and performance systems. Participants are then capable to advise on sustainable biorisk management that will ultimately reduce the threat of infectious disease in local laboratory environments.

Altogether during 2016–2017, Better Labs for Better Health held 19 training courses and trained 382 people in Armenia, Kyrgyzstan, Lithuania, Malta, the Republic of Moldova, Russian Federation, Tajikistan, Ukraine and Uzbekistan – see *Improving national curricula for laboratory staff* .

- 88 people were trained in management and implementation of laboratory quality;
- 130 people were trained as trainers in the use of WHO’s Laboratory Quality Stepwise Implementation (LQSI) tool;
- 115 people were trained in infectious substance shipping; and
- 18 people were trained in biorisk management.

Training and mentoring in laboratory quality implementation

Because QMS implementation is a long process and to enhance the effectiveness of training in QMS provided by WHO, Better Labs for Better Health established a mentoring programme in 2015 to support public health laboratories in QMS implementation.

¹⁹ Laboratory Quality Stepwise Implementation (LQSI) tool – <https://extranet.who.int/lqsi/>

²⁰ <https://extranet.who.int/hslp/training/course/index.php?categoryid=34>

²¹ http://www.who.int/ihr/i_s_shipping_training/en/

²² http://www.who.int/ihr/training/biorisk_management/en/

Better Labs for Better Health’s on-going training and mentoring of laboratory managers in quality management and biorisk management is showing a steady increase in the number of trained personnel in key positions in public health laboratories, as illustrated in Table 3.

Table 3. Improving laboratory personnel qualifications – 2012–2017

	2012–2015	2016–2017
Mentors	10	12
Labs with trained lab managers	34	65
Labs with officially appointed quality manager	0	7

Mentoring

WHO has long worked with public health laboratories to implement QMS. QMS implementation needs ongoing engagement of all staff as it often requires a mind-set change, which explains why it is a long process.

Mentorship programs have proven successful in tackling this issue and a mentoring programme was therefore set up in 2015 under the Better Labs for Better Health initiative to help public health laboratories in the Region to implement QMS.

Mentors were selected and trained specifically for their new role (see *Training of mentors*).

The mentor works with the laboratory staff in the facility on all laboratory activities, whether managerial or technical, for periods of five days. Together, the mentors and staff use the LQSI activity check list and tool to develop a common understanding of the individual laboratory’s gaps and needs and a corresponding activity plan. The checklist is set up to cover the 12 quality system essentials (QSEs) defined in the Clinical and Laboratory Standards Institute model²³.

The number of international mentors rose from 10 at the end of 2015 to 12 by the end of 2017. In addition, 10 local mentors were trained in Kyrgyzstan in 2017. Mentors made 47 mentoring visits to 15 laboratories in eight countries during 2016–2017, see Table 4.

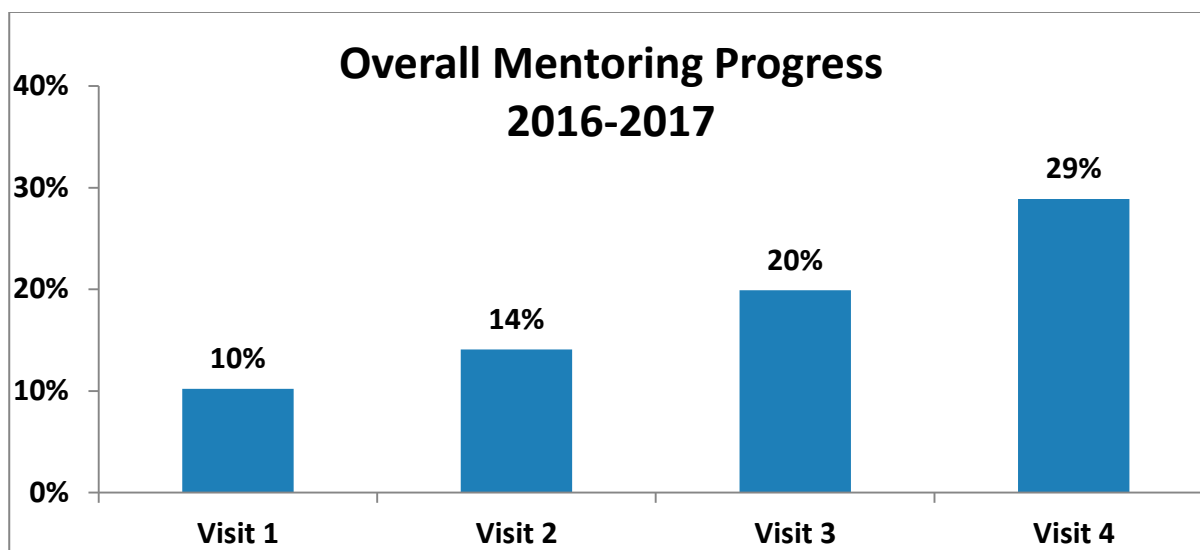
Fig. 2 shows the average score for 12 quality system essentials (QSE)²⁴ after each mentoring visit at eight laboratories currently being mentored in five countries²⁵.

²³ Continuous Quality Improvement: Integrating Five Key Quality System Components; Approved Guideline—Second Edition GP22-A2 Vol. 24 No. 35; http://www.zxyjhjy.com/upload/attached/file/20170406/20170406162017_3998.pdf

²⁴ Continuous Quality Improvement: Integrating Five Key Quality System Components; Approved Guideline—Second Edition GP22-A2 Vol. 24 No. 35; http://www.zxyjhjy.com/upload/attached/file/20170406/20170406162017_3998.pdf

²⁵ Bacteriology lab, Center of quarantine and especially dangerous infections (CQEDI), Kyrgyzstan; Clinical - Diagnostic laboratory of Republican Diagnostic center, Kyrgyzstan; Pathology laboratories of Mater Dei Hospital, Malta; Research Institute of Influenza, Russian Federation; State Research Center of Virology and Biotechnology "Vector", Russian Federation; National Reference Laboratory – Karabola, Tajikistan; Virology Laboratory of the Tajik Research Institute of Preventive Medicine, Tajikistan; Virology Reference Laboratory, Centre of Public Health and Nutrition, Turkmenistan.

Fig. 2. Progress from mentoring measured against the 12 Quality System Essentials



QSEs: Documents and records, equipment, information management, process improvement, organization, purchasing and inventory, occurrence management, service and satisfaction, personnel, process control, assessment, facilities and safety.

The average of results from the first visit gives the laboratories' overall baseline score measured against the 12 QSEs – 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.

Training of mentors

Mentors have been selected from among experienced laboratory staff from 10 countries across the WHO European Region²⁶ based on both their theoretical knowledge and practical experience, including with ISO 15189, and have been trained in a common mentoring approach using the LQSI tool.

The original mentor training was given at a workshop in 2015, during which the mentor candidates were briefed on the desired mentoring style and approach, using LQSI to implement a quality management system, risk assessment, how to listen and communicate, how to perform audits and provide feedback, and how to prioritize and establish a plan of action.

The mentors were then evaluated and selected based on their quality knowledge, communication aptitudes and quality of their homework presented throughout the workshop.

Annual refresher sessions have been held for the mentors, during which specific topics are taught on request by the mentors.

New mentors are selected based on their similar experience and knowledge, and they are briefed during the refresher sessions.

²⁶ Estonia, France, Georgia, Kazakhstan, Kyrgyzstan, Latvia, Netherlands, Republic of Moldova, Serbia, United Kingdom.

Better Labs for Better Health – strengthening laboratory systems in the WHO European Region

Improving national curricula for laboratory staff

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.

Better Labs for Better Health has been working with the Republic of Moldova on improving the national curricula for staff training in modern laboratory techniques, laboratory quality, biosafety and management, which the Republic of Moldova highlighted as one of the country's initial goals at the time of the country's commitment to the Better Labs for Better Health initiative in 2012.

During 2016–2017, Better Labs for Better Health's focus in the Republic of Moldova has mainly been on this goal and activities have been:

- A joint KIT and WHO visit in June 2016 to work with the School of Public Health to review its Masters of Public Health (MPH) curriculum and identify where competencies for laboratory managers and for laboratory management for public health and hospital managers could be integrated into the curriculum. After the development of a draft five-day MPH training module it was agreed to adapt WHO materials to the Republic of Moldova's context for use in laboratory leadership education in the MPH programme, and for use in a laboratory management module to educate all public health managers in the importance of laboratory management.
- A follow-up visit to the School in May 2017 to support the preparation of curriculum material. Three core topics were agreed on and developed: 1) the importance of the laboratory; 2) biosafety and biosecurity; and 3) quality and accreditation. Three support topics (planning, communication and emergencies) will be developed later, as the generic content for these topics is already taught within the School's MPH modules.

Area 2 overview

Table 4 lists the overall activities in Area 2 during 2016–2017.

Table 4. Activities – Area 2: Improve national training programmes and implement laboratory quality management systems

Country	Activity
Armenia	Two visits to assess the National AMR Reference Laboratory at the National Centre for Disease Control and Prevention using the WHO Laboratory Assessment Tool and 1 mentor visit.
Kyrgyzstan	Training of experts from the NLWG (Coordination Laboratory Council: CLC) to use WHO’s Laboratory Assessment Tool – 13 trainees and assessment of 10 regional maternity and child hospital laboratories and development of a project proposal to improve laboratory activities within these laboratories for the World Bank in 2017, under the Den Sooluk project – USD 1 million granted by World Bank for project to be coordinated by WHO with the NLWG..
	Development of national health laboratory standards.
	Mentoring at Clinical-diagnostic laboratory of the Republican Diagnostic Centre and Centre of Quarantine and Especially Dangerous Pathogens, SESS; 6 visits each.
	Training of trainers in LQSI – 21 trainees.
	National mentors training – 12 trainees.
	ISST training – 17 trainees.
Lithuania	Mentoring at National Public Health Surveillance Laboratory clinical testing department; 3 visits.
Malta	Mentoring at National Influenza Centre in Mater Dei Hospital; pre-mission assessment and 3 mentor visits.
Republic of Moldova	2 missions to work with School of Public Health on adapting WHO materials on laboratory leadership to the Republic of Moldova's context for use in the MPH programme: three core topics were agreed on and developed: 1) the importance of the laboratory; 2) biosafety and biosecurity; and 3) quality and accreditation..
	ISST training – 26 trainees.
	Training on national transport of samples – 26 trainees.
	Training of trainers in LQSI – 22 trainees.
Russian Federation	Mentoring at State Research Center of Virology and Biotechnology “vector” and at Research Institute of Influenza; 6 visits each.

Tajikistan	Mentoring at National Public Health Laboratory; 4 visits, at Tajik Research Institute of Preventive Medicine; 3 visits and at Kara Bola Reference Hospital; 2 visits.
	Training of trainers in LQSI – 19 trainees.
	ISST training – 20 trainees.
Ukraine	3 laboratories assessed in Donetsk, Lugansk and Mariupol in Governmental Controlled Areas.
Uzbekistan	LQSI training – 16 trainees.
	Mentoring at National Antimicrobial Resistance Centre at the Research Institute of Epidemiology, Microbiology and Infectious Diseases and Mentoring at Reference Laboratory Institute of Virology; 1 visit each.
Intercountry	Training of consultants working with AMR laboratories in implementing QMS into their visits and in provision of remote support between visits – 9 trainees; in collaboration with the Royal Tropical Institute (KIT), The Netherlands.
	Workshop on curriculum development for laboratory medical doctors – 18 participants; Turkey.
	Training of trainers in laboratory quality management and LQSI – 25 trainees; in collaboration with Rospotrebnadzor, the Federal Service for Supervision of Consumer Rights Protection and Human Welfare, Russian Federation.
	Workshop on laboratory system improvement in eastern Europe and central Asia – 25 participants; Denmark.
	Advanced mentors training course – 10 mentors; Denmark.
	Biorisk management training for Baltic countries – 18 trainees; Latvia.
	Development of an online LQSI curriculum in order to reduce location and travel costs of training.



An example from Kyrgyzstan illustrates Better Labs for Better Health’s development of local self-sufficiency.

In May 2017, Better Labs for Better Health trained 13 local experts from the Coordination Laboratory Council (CLC) to use WHO’s Laboratory Assessment Tool. These experts then proceeded to assess 10 regional maternity and child hospital laboratories and the results of the assessment, together with a proposal and action plan to improve quality in these 10 laboratories using Better Labs for Better Health support, were presented to the World Bank. Based on this, the World Bank granted USD 1 million for a project to improve quality at the 10 laboratories.

In October 2017, Better Labs for Better Health trained 21 laboratory experts as trainers using WHO’s LQSI tool. The 12 participants who achieved the highest score in the post-test of the LQSI training were subsequently trained as mentors in November 2017.

These 12 local mentors will support the quality improvement project at the 10 regional maternity and child hospital laboratories.

An international mentor provided by Better Labs for Better Health will coach the local mentors through their first visits to the laboratories from 2018 on.



Area 3: Establish networks for emergency preparedness and response

Laboratory networks are an important platform for emergency preparedness and response, for sharing information and expertise, and as a system for sharing clinical specimens and other biological material for testing. Effective networking is particularly important for laboratories in developing countries with limited resources. In addition, effective links between laboratories and surveillance and response systems are vital for the timely transfer of accurate and consistent information needed for appropriate public health responses. Furthermore, linkages between the academic, research, public health, veterinary, food safety

and environment laboratory sectors play an important role in the timely detection of outbreaks and emerging pathogens.

Under the WHO Health Emergencies Program, WHO supports networks, including the EDPLN, the Global Influenza Surveillance and Response System (GISRS)²⁷, the European Regional influenza network²⁸, the Global Outbreak Alert and Response Network (GOARN)²⁹, and the WHO collaborating centres³⁰. In the WHO European Region, there are also EU-supported networks, namely EVD-LabNet³¹, EMERGE³² and MediLabsecure³³, that include EU and European Economic Area (EEA) countries, as well as some EU enlargement countries.

However, there is a need to ensure laboratory networks exist for other high threat pathogens such as Ebola, Crimean-Congo haemorrhagic fever (CCHF), Middle East respiratory syndrome coronavirus (MERS-CoV) and plague, and that these include all countries of the WHO European Region³⁴.

Better Labs for Better Health is therefore working with Member States in collaboration with existing networks to identify gaps and the needs to improve these countries' preparedness and capacity for the laboratory response to HTP outbreaks. This work might lead to the expansion of existing or establishment of new national and international laboratory networks.

Additional efforts are also required to expand the international sharing and shipping of specimens.

In collaboration with SECID, Better Labs for Better Health organized a workshop in November 2017 for south-eastern European countries to discuss their laboratory preparedness for high-threat pathogens (HTPs), and to identify gaps and actions that could be taken to improve the situation³⁵.

Participants acknowledged significant gaps and needs for improvement in preparedness regarding HTPs in the south-eastern European region, and recognized that no country alone can handle the increasing demands on diagnostics of endemic and emerging HTPs. Consequently, it was agreed that closer collaboration between the countries' diagnostic laboratories is needed, and participants expressed their willingness to establish cooperation between their laboratories and laboratory networks, and with WHO Regional Office for Europe, ECDC and other partners.

²⁷ Global Influenza Surveillance and Response System – http://www.who.int/influenza/gisrs_laboratory/en/

²⁸ Regional and global influenza laboratory networks – <http://www.euro.who.int/en/health-topics/communicable-diseases/influenza/surveillance-and-lab-network/regional-and-global-influenza-laboratory-networks>

²⁹ Global Outbreak Alert and Response Network – http://www.who.int/ihr/alert_and_response/outbreak-network/en/

³⁰ WHO collaborating centres – <http://www.who.int/collaboratingcentres/en/>

³¹ EVD-LabNet (European expert laboratory network for emerging viral diseases focuses on virus families and genera that are rare, imported and (re)emerging in EU/EEA countries)

³² EMERGE (Efficient response to highly dangerous and emerging pathogens at EU level – comprised of some 40 diagnostic laboratories in EU countries focused on risk group 3 bacteria and risk group 4 viruses)

³³ MediLabsecure (One Health Network for the Prevention of Vector-Borne Diseases around the Mediterranean and Black Sea Regions – aims to increase the health security in the Mediterranean Area and South-East Europe Black Sea Region through capacity building, strengthening preparedness through the creation of a network of laboratories, and strengthening existing cooperation)

³⁴ See 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

³⁵ Report on the Status of Laboratory Networks for High Threat Pathogens in south-eastern European Countries, Sofia, Bulgaria, 23–24 November 2017 – http://www.euro.who.int/_data/assets/pdf_file/0003/364116/report-htp-see-eng.pdf

As a follow-up activity to the workshop, partners and participants agreed to complete a pathogen-based questionnaire (developed by Better Labs for Better Health based on the priority HTPs identified at the workshop) that would give an in-depth analysis of their expertise specifically regarding HTPs diagnostic capabilities, quality assurance, laboratory network involvement, as well as identifying their gaps and needs. The information collected will ultimately form the basis for the development of action plans corresponding to the country-specific needs.

Area 4: Advocacy, partnership and leadership

The work conducted under Better Labs for Better Health is made visible to its stakeholders through the Laboratory Services website and by publications in peer-reviewed journals. Sharing of information and experience is facilitated through intercountry meetings and the EZcollab online platform for laboratory managers and mentors. For example, national laboratory policies and strategic plans are shared between countries for inspiration and as a means to advocate change, to inform donors, and to enhance collaboration and the sharing of resources among national partners.

To maintain and further develop partnerships, a biennial partners’ meeting is held (see *2016 partners’ meeting*).

Table 5. Activities – Area 4: Advocacy, partnership and leadership

Country	Activity
Kyrgyzstan	National laboratory policy and strategy published by the MoH for public consultation
Tajikistan	Production of a video on Better Labs on Better Health initiative in Tajikistan, ongoing.
Ukraine	Joint statement developed with EU and US partners on the results of laboratory assessments conducted by partner organizations.
Intercountry and publications	RC66: Regional Committee technical briefing on strengthening national laboratory capacity in the Region; Denmark.
	Second Better Labs for Better Health partners’ meeting – 64 participants; in collaboration with the WHO European Tuberculosis Laboratory Initiative (ELI), Georgia.
	Better Labs for Better Health website translated to Russian.
	Seven publications – see Table 6. Better Labs for Better Health publications 2016–2017.

Work with partners

In addition to working with public health authorities in the European Region, the NLWGs, WHO Country Offices and a number of WHO programmes, Better Labs for Better Health has also collaborated with:

- The EU, ECDC, CDC and DTRA to support the reform of public health laboratory services in Ukraine.

- ECDC in a multi-country workshop in 2017 for EU enlargement countries on microbiology laboratory systems supporting public health, where work performed on public health laboratory systems was presented.
- The Royal Tropical Institute, Amsterdam (KIT), to set up and perform LQSI and mentors trainings and curriculum review.
- SECID in a workshop in 2017 for south-eastern European countries to discuss their laboratory preparedness for HTPs and to identify gaps and needs.

2016 partners' meeting

To enhance coordination among countries, donors and partners, Better Labs for Better Health held its second partners' meeting in December 2016 jointly with the WHO European Tuberculosis Laboratory Initiative (ELI). Similarly, the first partners' meeting in 2014 was conducted jointly with the WHO Regional Office for Europe HIV program and the US CDC's President's Emergency Program for AIDS Relief (PEPFAR) program. In the same spirit, the upcoming 2018 meeting will include the theme of antimicrobial resistance (AMR).

The 2nd partners' meeting was held in Georgia. 64 participants from 10 countries in which Better Labs for Better Health is active and from a range of national and international organizations – including CDC, Institut Pasteur, Public Health England and the Research Institute of Influenza (Russian Federation) – attended the meeting and reviewed Better Labs for Better Health's progress since the 1st partners' meeting in June 2014.

The mentoring project for implementation of laboratory quality management systems was presented, and various models of public health laboratory systems were presented and discussed.

The meeting also included a joint session with ELI to present that initiative and its TB laboratory maintenance plan.

In addition, the meeting aimed to widen the Better Labs for Better Health's audience, identify best practice models, and provide a forum for countries working to strengthen their laboratory services.

Key conclusions from the meeting were:

- Countries that have developed national laboratory policies and strategies have made significant steps towards improving their laboratory systems.
- A top priority is to improve the regulatory framework pertaining to the licensing and accreditation of laboratories, and a number of countries have made important progress.
- The NLWGs in Kyrgyzstan, the Republic of Moldova, Tajikistan, Turkmenistan and Uzbekistan are a key resource for providing expertise and advice regarding laboratory system strengthening to governments, partners and donors.
- There is a need to develop case studies and guidance on public health laboratory systems for countries in the process of reform.
- The laboratory quality mentoring project was proving its worth and should be continued.

The meeting report is available in English and Russian³⁶.

³⁶ Better Labs for Better Health - Second Partners' Meeting, December 2016 Report – <http://www.euro.who.int/en/health-topics/Health-systems/laboratory-services/publications/better-labs-for-better-health-second-partners-meeting,-december-2016-report>

Dissemination of information

During 2016–2017, the Better Labs for Better Health initiative released five publications on its website, submitted a sixth as a peer-reviewed article and had a seventh under preparation, see Table 6.

In addition, all major laboratory-related activities have been posted on the WHO Regional Office for Europe website as events and/or news items, so that partners and stakeholders can keep abreast of activities and developments within the Region.

The laboratory services website was translated to Russian in 2017.

Table 6. Better Labs for Better Health publications 2016–2017

Publications
The Better Labs for Better Health initiative to strengthen laboratory systems in the WHO European Region. Activity report 2013–2015 (English and Russian); 2016.
Better Labs for Better Health – Second Partners’ Meeting Report, (English and Russian); 2016.
Development of a national laboratory strategic plan – Best practices document and facilitators’ guide (English and Russian); 2017.
Development of national laboratory policies – Best practices document and facilitators’ guide (English and Russian); 2017.
WHO manual for organizing a national external quality assessment programme for health laboratories and other testing sites; translation to Russian; 2017.
Laboratory core capacities to be improved in two countries of Central Asia through addressing national sample referral mechanisms, submitted 2017; published 2018.
Guidance for the regulation of health laboratories; started 2017, development ongoing.

Guidance documents

Licensing of health laboratories

A document describing requirements for health laboratories’ licensing is being developed. It aims to:

- provide countries with a framework for laboratory licensing measures and accreditation according to national and international standards;
- explain the role of national accreditation bodies in the accreditation of laboratories according to international standards; and
- explain the role of the MoH as a regulator of laboratories according to national accreditation.

National sample transport guidance

NLWGs of Tajikistan and Kyrgyzstan have developed national guidelines for national transport of samples to better disseminate information on how to proceed to safe sample transport in their respective countries, in order to protect the environment, staff and the sample.

Laboratory system optimization

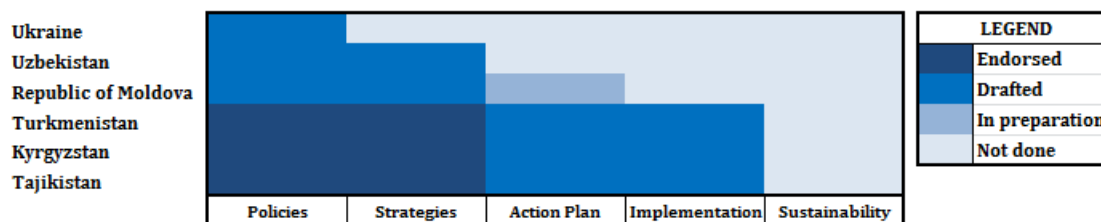
NLWGs of Tajikistan, Kyrgyzstan and Ukraine are working on proposals to develop laboratory testing capacities for Public health needs by defining national testing algorithms and tests to be performed per level for at least 20 pathogens. Based on their experience a guidance document is being developed.

Priorities in 2018–2019

Area 1: Development of national laboratory policies and strategic plans

Fig. 3 illustrates the status of the Area 1 milestones in early 2018, showing the different progress of the countries supported by Better Labs for Better Health. Kyrgyzstan, Tajikistan and Turkmenistan have endorsed their national laboratory policy and strategic plan, developed their action plans and are therefore in the beginning of the implementation phase.

Fig. 3. Better Labs for Better Health 2018 – Area 1 overview



Area 1 priorities for 2018–2019 are:

- Ongoing support for implementation of agreed reforms – proposals for required legislative changes and proposals for the structure of the public health laboratory system organization are being developed by the NLWGs in Kyrgyzstan and Tajikistan and will be submitted to their respective governments.
- Support for the Republic Moldova and Uzbekistan in finalization of their national action plans.
- Support for Ukraine’s reform of its public health laboratory system.

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

Area 2 priorities for 2018–2019 are:

- Mentoring visits to the currently mentored laboratories will continue and mentoring will be expanded to four additional laboratories in Kyrgyzstan and Tajikistan, and three laboratories in Ukraine.
- Implementation of national mentoring through mentoring training courses in Ukraine and for Russian-speaking AMR experts.
- Development and roll-out in countries of laboratory costing tools for improved sustainability of QMS.

Area 3: Establish networks for preparedness and response

The Area 3 priority for 2018–2019 is to establish networks for HTP diagnostics in south eastern European and central Asian countries with a view to increasing the national accessibility to corresponding diagnostics through training and improved coordination among relevant sectors.

Area 4: Advocacy, partnership and leadership

Area 4 priorities for 2018–2019 are:

- Preparation of best practice documents for laboratory licensing and laboratory system optimization based on the experiences gathered in Kyrgyzstan and Tajikistan.
- The 3rd partners' meeting in Kazakhstan, 9-10 October 2018.
- Development of video guides and training courses for sample transport.
- Increase dissemination of Better Labs for Better Health technical products eg. through engaging with professional organizations.

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- the European Union (European Commission's Directorate-General for International Cooperation and Development) as part of the project on strengthening health laboratories to minimize potential biological risks (contract IFS/2013/332312);
- the US Centers for Disease Control and Prevention under a Cooperative Agreement: Five-year strategy for reducing morbidity and mortality caused by influenza;
- the Partnership Agreement between the Netherlands and WHO; and
- the Pandemic Influenza Preparedness Framework Partnership Contribution.

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The WHO Regional Office for Europe

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