Better Labs for Better Health

activity report
2020–2021
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ABBREVIATIONS

- Ag-RDT – antigen rapid diagnostic testing
- AMR – antimicrobial resistance
- BSC – biosafety cabinet
- CDC – Centers for Disease Control and Prevention, United States of America
- CO – (WHO) country office
- COVID-19 – coronavirus disease 2019
- ELISA – enzyme-linked immunosorbent assay
- EMO – Emergency Operations (Programme)
- EQA – external quality assessment
- HIV – human immunodeficiency virus
- HTP – high threat pathogen
- GLLP – Global Laboratory Leadership Programme
- IMST – incident management support team
- ISO – International Organization for Standardization
- LET – Laboratory Expenditure Tool
- LQMS – laboratory quality management system
- LQSI – Laboratory Quality Stepwise Implementation tool
- LTCT – Laboratory Test Costing Tool
- MoH – Ministry of Health
- NLWG – national laboratory working group
- NRL – national reference laboratory
- PCR – polymerase chain reaction
- RT-PCR – real time polymerase chain reaction
- SARS-Cov-2 – severe acute respiratory syndrome coronavirus 2
- ToT – Training of Teachers
- QMS – quality management system
- QSE – quality system essential
- VOC – variants of concern
- WHE – WHO Health Emergencies Programme
- WHO – World Health Organization
- WHO CC – WHO collaborating centre
“The well established Better Labs for Better Health strategy proved itself to be extremely effective during the COVID-19 response. It enabled rapid mobilization of working groups and we were able to tailor training packages not only to countries themselves but to specific laboratories and also rapidly deploy mentors for further on-site support.”

Joanna Zwetyenga, Laboratory Team Lead for Incident Management Support Team (IMST) for COVID-19, WHO Regional Office for Europe and Better Labs for Better Health
INTRODUCTION

Well prepared laboratories are the first line of defence against the novel coronavirus in the WHO European Region

During routine disease surveillance as well as in the event of acute outbreaks, laboratories work largely unseen. They provide the vital link in the chain of activities required to keep populations safe from disease. The COVID-19 pandemic has highlighted the need for reliable laboratory evidence both from everyday health care and right through to emergency preparedness and response.

The mission is for laboratories to deliver timely and accurate results. It is essential to have a well established laboratory network in order to improve communication and collaboration between laboratories and ensure a proper response across regions and countries.

Better Labs has continued to perform its usual work throughout the pandemic, adjusting in the best way possible to respond to it.

The pandemic requires a comprehensive response and must be addressed using a variety of different approaches that complement each other. These include different levels – laboratory staff and their systems, policy and strategy, all of which need to be continually adapted and strengthened.

The fundamental pillars on which Better Labs is built remain the same, but these are now being applied to the current emergency scenario. Better Lab’s four activity areas are classically suited to preparedness and response to an infectious disease epidemic: Area 1 being laboratory/national level, Area 2 workforce level, Area 3 international networks and Area 4 advocacy. These four pillars are distinctly different yet tied together as elements of one very strong strategy.

Following the identification of the novel virus in January 2020, Better Labs moved quickly to identify laboratory needs and capacities in the European Region. This included strengthening capacities to test and care for patients to prevent and control infections.

The WHO Regional Office for Europe was facilitating the shipment of testing kits within a month of the virus first being isolated. Better Labs has been working closely with a network of designated laboratories to ensure every Member State has the capacity and resources required to quickly test, report and respond to any suspected case of COVID-19.
Supporting national laboratory system reforms
– National lab working groups, policy and strategic plan –

Improve national training programmes and quality management systems
– Training, mentoring, curriculum review –
Better Labs for Better Health’s goal is to improve health through the provision of timely and accurate results that are trusted by the user, and through early detection of acute public health events.

Establishing laboratory networks for emergency preparedness and response
- Networking, lab task force for high-threat pathogens

Advocacy, partnership and leadership
- Guidance, advocacy, publications
AREA 1:

Supporting national laboratory system reforms
Scaling up national laboratory capacity

During the first COVID-19 lockdowns, Better Labs embarked on a country-specific webinar series to help Member States rapidly prepare to significantly increase laboratory capacity. Around 20 sessions in total were dedicated to training laboratory staff on biosafety and the verification and validation of assays in the context of massively increased load due to the pandemic. The four-hour webinars explained how to scale up laboratory capacity, planning for needs and human resource priorities.

Developing a national plan for surge capacity and a strategy for scaling up involves identifying funding at the outset, ensuring sufficient reagents and consumables as well as availability of properly trained staff.

It is also necessary to establish the responsible laboratory for given regions while at the same time identifying additional laboratories that can be called upon if necessary.

A strategy must be developed for prioritizing those in the population who need testing first while identifying other activities that can be scaled back or ceased altogether. This was delivered to all WHO priority Member States.

WHO priority Member States
Albania | Armenia | Azerbaijan | Bosnia and Herzegovina | Georgia | Kazakhstan | Kyrgyzstan | North Macedonia | Republic of Moldova | Serbia | Tajikistan | Türkiye | Ukraine | Uzbekistan (I)

Country ownership through national laboratory working groups
The national laboratory working groups (NLWGs) have developed national laboratory policies and strategic plans setting out the framework for current and future laboratory activities, and to signal political commitment and country ownership. They are the drivers for in-country reform.

In 2020, these working groups were mobilized to discuss and set national action plans in response to COVID-19 and to agree on the testing strategies to be applied.

The NLWGs work hand-in-hand with relevant ministries such as ministries of health (MoH) and WHO to develop and implement national COVID-19 response testing strategies.
**Testing Strategies**

National testing strategies for COVID-19 are now in place and being applied in Kazakhstan, Kyrgyzstan, Tajikistan, Ukraine and Uzbekistan. Working alongside the NLWGs and MoH, Better Labs endeavours to increase preparedness to identify, manage and deal with new cases of COVID-19 with laboratory testing being an integral part of these strategies.

Each country had to assess its own risk and rapidly implement the necessary measures at the appropriate scale and prepare for a testing and clinical care surge to reduce both COVID-19 transmission and economic, public health and social impacts.

**Testing strategy goals**

- **Diagnosing COVID-19** – to help with treatment and care of patients
- **Controlling and preventing transmission of the virus by supporting contact-tracing**
- **Protecting health-care services** – to prevent, protect and deliver testing to support the safety of staff, patients and clients
- **Protecting vulnerable groups and managing increased transmission rates** – to safeguard and control infection in groups, communities or settings where there are greater risks
- **Enabling population health surveillance** – to allow business continuity, enabling people to return to work or education safely

This work is particularly challenging, as testing strategies need to be, not only country-specific but also flexible enough to evolve each time a new variant arrives upon the scene.

**Rapid pandemic response through strengthened laboratory capacity—Tajikistan**

After the first 15 cases of COVID-19 were announced at the end of April 2020, the number of daily cases in Tajikistan rose to 200 within just one month. COVID-19 transmission continued to rise rapidly during the course of 2020, but during this period, WHO intervened with provision of laboratory support.

Pandemic response activities were immediately set in motion by the incident management support team (IMST) of the WHO Regional Office for Europe in early May 2020, at the request of the Tajikistan Government.

Since 2016, a NLWG had developed a national laboratory policy and strategic plan, which was endorsed in 2017. Three major laboratories in Tajikistan had been trained and mentored for quality management system (QMS) implementation, based on International Organization for Standardization (ISO) standards and the use of the WHO Laboratory Quality Stepwise Implementation (LQSI) tool.

The most significant and transformative intervention was the rapid scaling-up and strengthening of national laboratory capacity for COVID-19 testing in Tajikistan.

The commitment of the Government of Tajikistan to the Better Labs programme meant that the country was able to rapidly agree to a national action plan for the laboratory response to COVID-19 and deploy much-needed expertise to improve laboratory capacities. All partners coordinated to ensure smooth implementation of the plan and a national testing strategy was set up.

Regional-level laboratories were identified, upgraded and activated to conduct COVID-19 testing. These were the sanitary epidemiological service (SES) laboratories in Bokhtar, Kulob, Dangara and...
Qubodiyon (Khatlon region), the SES laboratories in Tursunzoda (DRS), the City SES laboratory in Dushanbe, the SES laboratory in Khorog, Gorno-Badakhshan Autonomous Region (GBAO) and the SES laboratories in Khujand, Panjakent, Isfara and Istarafshan (Sughd Region).

This was in addition to major upgrades to the national-level laboratories (National Public Health Laboratory, Virology Laboratory at the National SES, National Reference Laboratory and Tajik Research Institute of Preventive Medicine) that were already conducting COVID-19 testing.

Nationwide capacity-building for all front-line workers on pandemic response took place, including COVID-19 testing protocols and procedures. The capacity-building training drew from the country’s pool of domestic expert trainers, whose skills had been previously strengthened through the Better Labs initiative.

Following an initial training-of-trainers (ToT) supported by WHO, national experts also carried out cascade trainings and provided supportive supervision to laboratory workers at national and regional levels. Training modules were developed covering laboratory quality management, guidance on COVID-19 protocols and procedures, establishing critical standard operating procedures, and staff technical competency assessments. Risk assessment training was also provided for national laboratory biosafety experts to support regional-level laboratories in identifying and mitigating risks.

From a national testing capacity estimated at 1612 tests per day during the situation analysis, testing capacity was increased to 3472 tests per day within three months. The increased testing capacity contributed significantly in the COVID-19 response in Tajikistan.

“The Tajikistan Government’s commitment to Better Labs meant we were able to rapidly respond to COVID-19 by deploying well-needed expertise to improve laboratory capacity”

Abdulakhad Safarov—National Professional Officer, Tajikistan Country Office (CO)
Republic of Moldova
February 2021–The WHO Regional Office for Europe supported the Ministry of Health of the Republic of Moldova with a mission to expand public health laboratory capacities and improve the overall COVID-19 response.

During the mission, trainings were held on SARS-CoV-2 antigen rapid diagnostic testing (Ag-RDT) for healthcare and laboratory workers who were collecting samples.

In addition, national laboratory experts were trained on cost evaluation using the WHO Regional Office for Europe costing tools. These tools were to help in analysing the costs of polymerase chain reaction (PCR) and Ag-RDT tests in the context of COVID-19.

The trainings also helped provide support to the Republic of Moldova in costing and establishing a monitoring framework for implementation of Ag-RDT.

Laboratory system strengthening in Uzbekistan
Following two targeted training sessions on using the WHO Laboratory Assessment Tool tailored to COVID-19, assessments of COVID-19 testing laboratories and their sample referral systems at central and regional levels were performed in 2020, during the pandemic, in Uzbekistan.

These revealed several gaps which were addressed urgently to further strengthen laboratory capacity and ease the response to COVID-19. QMS training sessions were also held for regional laboratory staff as well as two trainings and two advanced trainings for national mentors and two biosafety and biosecurity trainings in 2020.

Training was given for trainers about laboratory quality management system implementation based on the international ISO 15189:2012 standard. National mentors were coached by an international mentor to start the mentoring of three regional laboratories involved in COVID-19 testing. Further support to the SES was provided through the development of a national testing strategy for COVID-19 and by reviewing its needs regarding equipment for the national public health laboratory system.

In October 2021, the first workshop was held to engage laboratory stakeholders on topics such as laboratory quality through licensing mechanisms and the designation of national reference laboratories. The workshop included presentations on different mechanisms for regulating laboratories as well as a study of the designation and evaluation of national reference laboratories (NRLs) in 25 countries.

A round-table discussion was held on how the quality of laboratories can be improved. During the workshop, the National Accreditation Centre explored these issues, together with the licensing departments of the MoH and Service of Sanitary and Epidemiological Welfare and Public Health. It highlighted the importance of proper implementation of quality measures, including the need for biosafety cabinet (BSC) maintenance and for national external quality assessment providers, among other topics.

The workshop resulted in the Uzbekistan Government committing to revise the legislation on licensing. This was a first important step in ensuring sustainability of all laboratory strengthening conducted under COVID-19.

A workshop was also conducted to support laboratory staff from national and regional laboratories in developing a training package for new staff along with documentation to record of these training sessions.

Better Labs continues to provide mentoring support for the implementation of quality management systems in the main laboratories involved in COVID-19 testing.

Pre-service workshop in Uzbekistan
In October 2020 a three-day national workshop was organized in Tashkent, Uzbekistan to address the preparation of training material for the induction of new laboratory employees.

The workshop was attended by representatives of national public health laboratories, medical academics and WHO experts. A package of presentations was produced to include topics such as bioethics and confidentiality, organizational structure and introduction to laboratory quality, biosafety and biosecurity rules, and waste management for incoming employees and was distributed to participants for further implementation in their laboratories.
AREA 2:

Improve national training programmes and quality management systems
Trainings 2020–2021 – Better Labs is committed to delivering comprehensive and interactive trainings across all Member States and to supporting the implementation of quality management systems through mentoring.
**BETTER LABS ACTIVITY AREA 2**  
**IMPROVE NATIONAL TRAINING PROGRAMMES AND QUALITY MANAGEMENT SYSTEMS**

**Training**

**Rolling out biosafety and biosecurity training**  
Biosafety and biosecurity training is key to safe laboratory practices, particularly in the context of a pandemic and high demand for safe COVID-19 testing capacity.

The biosafety and biosecurity training package was developed by the IMST laboratory team at the WHO Regional Office for Europe as part of their action plan for the COVID-19 response and has been rolled out to Member States with a special focus on priority countries.

The interactive training is based on the newly published *Laboratory Biosafety Manual*, 4th edition (LBM4). This edition of the manual builds on the risk assessment framework, which allows safety measures to be balanced with the actual risk of working with biological agents on a case-by-case basis. The manual focuses on training and applying an evidence-based approach to biosafety and biosecurity. It covers good microbiological practices and procedures, risk assessment and control measures, engineering controls, personal protective equipment and biosafety programme management. The training also includes the most up-to-date WHO COVID-19 biosafety guidance with a focus on strengthening quality assurance and biosafety during SARS-CoV-2 sample collection and transport.

Guidance is also given for laboratories on improving their physical infrastructure based on biosafety and proper workflow requirements. At the same time, another biosafety and biosecurity training package is being introduced, specifically tailored for national mentors to acquire the necessary knowledge to provide adjusted recommendations during their mentoring visits.
**Mentoring**

The Better Labs mentoring programme
The Better Labs mentoring programme was set up to help laboratories of eastern Europe and central Asia to implement QMS.

The scheme began with the appointment of a selected number of international specialists travelling from one Member State to another throughout the region to mentor NRLs on all aspects of quality and to monitor each laboratory’s progress between each visit. This international approach to mentoring was very successful from the outset with progress increasing from 11.9% after the initial mentoring visit to 44.5% following the fifth visit - basic score of the quality management implementation based on the LQSI activity checklist. The approach allows and encourages mentored laboratory staff to take part in decision-making processes and to implement the activities personally with the guidance of the mentor. It makes for a more sustainable quality management implementation.

When COVID-19 broke out, international travel became very difficult and also the demand for quality testing increased sharply. It was therefore recognized that identifying and training in-country national experts as mentors themselves was essential in order to improve the efficacy and sustainability of the quality implementation.

National mentors are selected and trained with a common approach as for international mentoring, which implies using the LQSI tool. This activity checklist, based on the LQSI tool, covers the 12 quality system essentials (QSE), according to the Clinical and Laboratory Standards Institute model. On 11 March 2020, WHO declared the COVID-19 virus outbreak a global pandemic. As a result, many countries and regions imposed quarantine and travel restrictions. National capacity needed to be scaled up rapidly and national mentors were seen as the best option to strengthen the national laboratory capacities needed for COVID-19 response.

Better Labs not only mobilized the available existing trained mentors to deploy further QMS implementation across Kyrgyzstan and Tajikistan but also went to Kazakhstan and Uzbekistan to train national mentors to continue this support. National mentoring in Kazakhstan began in October 2020 covering 34 public health and clinical laboratories involved in COVID-19 testing. In total, 15 mentors performed 68 visits across laboratories in Kazakhstan and an average 9.1% increase in progress can be seen between the first two visits.

National mentors became essential actors in QMS implementation at regional level for COVID-19 testing labs. Quality testing is important as it guides diagnosis and treatment, surveillance and data-driven, evidence-based interventions and health policy.

Training national laboratory mentors is cultivating a precious resource and empowers the region through the development of and investment in local, national expertise. They are an integral component of country response against COVID-19. They not only help increase national laboratory capacity but are also the driving force of sustainable improvement towards laboratory quality in their countries.

Out of 102 laboratories enrolled: 31 laboratories are mentored by international mentors and 71 laboratories are mentored by national mentors.
Mentoring

Mentoring strengthens health laboratories through the implementation of a QMS based on the international quality standard ISO 15189:2012.

“Our current work during the pandemic is not just about setting up laboratories to test for COVID-19. These laboratories must be of quality. Data-driven interventions are totally reliant on surveillance based on consistent, quality testing”

Alexandr Jaguparov, Laboratory Consultant, Kazakhstan CO
**INTERNATIONAL MENTORING PROGRESS**

16 laboratories in eight Member States with five visits demonstrates steady progress from 11.9% from first visit to 44.5% from fifth visit.

- **32.6%** laboratories mentored
- **341** mentoring visits conducted
- **12** international mentors
- **34** national mentors
- **11** Member States participating in the programme:
  - Albania, Armenia, Kazakhstan, Kyrgyzstan, Lithuania, Malta, Russian Federation, Tajikistan, Turkmenistan, Ukraine, Uzbekistan.
International mentors’ meeting

International mentors from the Better Labs for Better Health initiative met in Istanbul, Türkiye, in December 2021. Representatives of the national mentors’ teams from Kazakhstan, Kyrgyzstan, Tajikistan and Uzbekistan attended to present the significant progress made to date and to give individual team perspectives on a wide range of topics.

A key purpose of the meeting was to improve the monitoring checklist based on the LQSI tool and to strengthen the implementation of phases 3 and 4. It was the first time in two years that mentors were able to meet face-to-face to exchange knowledge gained from the extensive work carried out in their respective countries.

A comprehensive checklist of items is used to monitor QMS implementation. This checklist must be followed chronologically to move through each stage of the process. The phases are relatively complex and involve laboratories fundamentally adopting a philosophy of good management, leadership, continuous improvement, and preparation for accreditation. Progress is monitored throughout by mentors during each visit and activity.

During the meeting, mentors worked in teams to identify additional checklist elements required to further refine each phase of QMS implementation and to help ensure that laboratories commit to and follow a process of continuous improvement. This in-depth exchange of ideas culminated in a significant revision of the QMS procedures to improve and streamline the process moving forwards.
National mentoring programme for QMS implementation in Kyrgyzstan laboratories

The Better Labs national mentoring programme was first introduced in 2017 in Kyrgyzstan. The aim was to provide continuous training, on-the-job mentoring and capacity-building to national laboratory experts through a sustainable approach of QMS implementation.

QMS implementation has been ongoing and evaluated in Kyrgyzstan since 2018. Two antimicrobial resistance (AMR) laboratories are enrolled in the programme. Over the course of three years (2018–2021), mentors carried out five visits and fed back the following results.

Table 1 (above) demonstrates a steady progress from 2.9% documented on Visit 1 in 2018 to 29.0% on Visit 5 in two AMR labs, bringing 26.1% increase over the period 2018–2021. Mentoring was also started in 2017 in 10 maternity and childhood hospital labs in Kyrgyzstan by nine national mentors. To date eight visits have been completed during the period 2018–2021 (Table 2, above).

Due to the pandemic, many facilities that were already in the mentoring programme were called upon both for COVID-19 testing due to a surge in demand. Better laboratory services could be provided thanks to all previous support and progress made through this mentoring initiative.

During the pandemic, Better Labs has continued to scale up the in-country programmes. As a result, many countries were able to rely on their national laboratory experts to implement QMS in COVID-19 laboratories.

Following the establishment of the national mentors’ scheme in Kyrgyzstan in 2017, other countries in the region have introduced the programme including Kazakhstan, Uzbekistan and Tajikistan – for all types of public health, AMR and clinical diagnostic laboratories.

Within the programme, annual mentors’ meetings were organized to help the pool of experts exchange their experience and knowledge. These meetings involved national and international mentors working together to develop new plans and procedures to be implemented in mentored labs.

An intercountry national mentors’ meeting was held in Kyrgyzstan in August 2021, including national mentors from Kazakhstan, Kyrgyzstan, Tajikistan, Turkmenistan and Uzbekistan.

During this meeting, it was decided that a series of standard operating procedures (SOPs) were needed specifically for COVID-19 laboratories and working groups were set up to work on these SOPs. To finalize this process, a workshop was organized in Istanbul, Türkiye on 20–21 December 2021 to elaborate and establish an COVID-19 SOP handbook that is readily available to be used and contextualized for any laboratory doing COVID-19 diagnostics.

The workshop brought together 28 laboratory experts from Kazakhstan, Kyrgyzstan, Tajikistan, Ukraine and Uzbekistan.
Laboratory accreditation

Many laboratories enrolled in the Better Labs QMS mentoring process are on the road to accreditation which is a lengthy and ongoing process, taking on average 4-6 years.

Certification and accreditation aim to ensure the safety and the quality of tests, while promoting a culture of continual quality improvement within the individual laboratory.

Certification can be a useful tool to give a laboratory credibility by demonstrating that its services comply with recognized levels of quality. Accreditation is the most advanced level of public control in the conformity assessment system.

In the certification process, a laboratory is visited by representatives of a conformity assessment body or authoritative body. It is not compulsory for the inspecting organization to be accredited.

In the ISO international accreditation process, a laboratory is visited by representatives from an accreditation body that has itself been accredited under ISO 17011:2017.

Principles of international accreditation

ISO 9001:2015 “Quality management systems – Requirements” is used by organizations to demonstrate their ability to consistently provide products and services that meet customer and management requirements and to demonstrate continuous improvement, while ISO 15189 and ISO 17025 focus in addition on technical requirements (being competent in providing reliable results).
Internationally-recognized standards (ISO norms for health laboratories):

- ISO 15189:2012 “Medical laboratories - Requirements for quality and competence”
- ISO/IEC 17025:2017 “General requirements for the competence of testing and calibration laboratories”

Accreditation and certification should be integrated in the licensing process
The technical regulation authorities in charge of the development of the licensing requirements and corresponding legislation should collaborate with the health authorities to ensure that laboratory quality requirements are implemented using national and/or international laboratory standards.

There are two options for integrating laboratory standards into the licensing process:
include references to the applicable laboratory standards in the licensing legislation; or set out the laboratory standards in the licensing legislation and include them as licensing requirements.

Uzbekistan accreditation success – AMR Centre, Tashkent
The AMR Centre in Tashkent achieved great success with their accreditation:

March 2020 – accreditation against O‘z DST ISO 15189:2019 (2)

Kyrgyzstan accreditation success – Republican Centre of Quarantine and Especially Dangerous Infections
The Republican Centre of Quarantine and Especially Dangerous Infections achieved great success by being accredited twice:

January 2021 – accredited for brucellosis | March 2021 – accredited for SARS-CoV-2 PCR

“For us to be accredited twice during the pandemic was a real challenge. We are very proud as it is so important to us. The real difference we are seeing is the increase in the trust coming from our patients, our customers, the general public.”

Aigul Djaparova, Quality Manager, Republican Centre of Quarantine and Especially Dangerous Infections, Kyrgyzstan
In addition to training and mentoring, it is also essential to review the basic curriculums for different levels of laboratory worker and identify where those curriculums can be strengthened and brought up to date with current technologies and best practices.

Support was provided to an NLWG on developing the curriculum for both the initial specialization and continuous education of microbiological and sanitary-hygienic laboratory staff in public health laboratory services of Kyrgyzstan’s Ministry of Health and Social Development.

The programme/curriculum was developed by the NLWG itself, alongside the Kyrgyz State Medical Institute of Continuous Education.

A best practices and facilitator’s guidance document was subsequently published to allow review and revision of laboratory curriculums that will provide a model for other countries.

Laboratory accreditation

“The implementation of QMS in our laboratory via the Better Labs mentoring process as well as our accreditation means delivery of true quality services to the public”

Dilshoda Akhmedova, National Mentor and Quality Manager, National AMR Centre, Uzbekistan

Curriculum review

In addition to training and mentoring, it is also essential to review the basic curriculums for different levels of laboratory worker and identify where those curriculums can be strengthened and brought up to date with current technologies and best practices.

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AREA 3: Establishing laboratory networks for emergency preparedness and response
International networks

Lab Task Force
International networks for laboratory surveillance, preparedness and response are an important tool for laboratory strengthening, because they can serve both as a platform for sharing information and expertise, and as a system for the referral of diagnostic specimens for primary and confirmatory testing.

Among the European Region priority Member States of the WHO Health Emergencies Programme (WHE), several do not participate in international laboratory preparedness and response networks for high-threat pathogens (HTPs). In order to address this gap, the WHO Regional Office for Europe established the European Regional Laboratory Task Force for High Threat Pathogens (Lab Task Force).

The Lab Task Force was launched following a preparatory meeting held in Istanbul, Türkiye, in January 2019 where the terms of reference for the Lab Task Force were agreed upon and a laboratory tool to assess national laboratory diagnostic capacities for HTPs was reviewed.

First meeting of the European Regional Laboratory Task Force for High Threat Pathogens, February 2020:
This was the first official meeting of the Lab Task Force’s members and partners and the opportunity to provide information on the the SARS-Cov-2 virus globally and in the Region, including laboratory readiness. The progress of the Lab Task force in its first year and the results of the first assessments with national laboratory capacities for HTPs were presented. Furthermore, activities of existing international laboratory networks and WHO collaborating centres (WHO CCs) in HTPs were discussed to enable liaison with these networks for the Lab Task Force to achieve its goals.

Participants at the meeting included 22 experts in HTP diagnostics from 16 WHE priority countries and three other countries in the European Region. In addition, representatives of five WHO CC and five international laboratory networks were present.

The ongoing COVID-19 outbreak was a test for existing networks and a strong affirmation for the need for HTP capacities and capabilities in the Region. A second Lab Task Force meeting is planned for June 2022 in Türkiye.

Study on transport of infectious substances
As a result of the first Lab Task Force meeting, a study was conducted on the legislation for infectious substances and their transport in 35 countries and there is now a study being carried out on the licensing mechanisms of the same. This was identified as a priority requirement during the meeting.

Many other priority Member States expressed having similar challenges to the shipping of infectious substances including:

- difficulty maintaining the cold-chain
- lack of access to timely courier services or airlines
- limited access to training or packaging materials
- confusing regulations.

Global health is often hampered by the fact that not enough specimens get to testing sites in a timely manner.
WHO Collaborating Centre for Laboratory Preparedness, Response for HTPs and Biorisk

In early 2020, the Centre for Infectious Diseases Research (RIVM, Netherlands) was designated as a WHO CC for Laboratory Preparedness and Response for High Threat Pathogens and Biorisk.

A key role of the new WHO CC is to support WHO in finalizing assessments of national capacity and capability for laboratory diagnostics of HTPs across the WHO European Region.

A first meeting was held with the Bilthoven-based centre in November 2021, at the WHO Regional Office for Europe in Copenhagen, with WHO headquarters to plan activities and to discuss support to be provided in 2021 and 2022.

The new WHO CC will assist WHO in the strengthening of accurate, safe and secure laboratory preparedness and response systems, through hosting a series of coaching and technical training events.

This is the first WHO CC which is a biosafety level 3 laboratory and will combine laboratory preparedness and response and biorisk to HTPs.

It will be assisting WHO in building national capacities and ensuring biosafety and biosecurity in biomedical laboratories, through the development of online training for basic and advanced biosafety and biosecurity.

WHO supports maintenance of biosafety cabinets in Uzbekistan

Protecting personnel, samples and the environment from exposure to biohazards and cross-contamination during routine procedures is extremely important, especially during a pandemic.

In 2020, during COVID-19 lab response missions, Better Labs carried out assessments of capacity and capability of central and regional public health laboratories to test for SARS-CoV-2.

In all of the laboratories visited in Uzbekistan, including virology laboratories that were testing for COVID-19, it was noted that none of the installed BSCs were being checked by a certified engineer. This is purely due to the fact that no local company in Uzbekistan is qualified to do this.

The Agency for Sanitary-Epidemiological Health and Well-Being requested support from the WHO Regional Office for Europe. Funds were quickly obtained from the WHO Essential Medicines Operations (EMO) programme. This made it possible to identify, source and contract a company in Kazakhstan with a valid licence and the experience to carry out the BSC servicing work needed in Uzbekistan.

As a result, it was possible to carry out certified maintenance on 207 BSCs throughout the whole of Uzbekistan during December–January 2020.

Similar programmes for BSC maintenance were also set up in Kyrgyzstan and Tajikistan.
AREA 4:
Advocacy, partnership and leadership
Further such events are being organized throughout the Region. Better Labs is advocating for different countries to engage in a dialogue that they have never had the opportunity to have previously and to properly identify their laboratory requirements, taking the discussion onto a government, policy and legislative level.

**Advocacy videos**
A picture can tell a thousand words. If produced and executed correctly, a video can tell a million words. Following on from the huge success of the “We are Lab Workers” video in 2019, Better Labs is committed to producing a range of short films showcasing the work being done in various Member States. A film called “Better Labs - Making a Difference in Uzbekistan” has just been released and others will follow shortly.

**COVID-19 SOP handbook**
Better Labs identified the need to provide a clear list of COVID-19 SOPs.

A COVID-19 handbook outlining SOPs has been developed with a global network of laboratory experts. The handbook is designed for all COVID laboratories and is available in a Russian language version only.

**National guideline on sample collection for laboratory testing in Uzbekistan**
Sample type, adequate timing and method of collection, sample storage and transportation are critical points in a diagnostic process as interpretation and accuracy of test results depend heavily on the quality of samples.

Given this importance, a national sampling guideline for microbiology testing was developed in Uzbekistan in 2020 by national laboratory specialists. This document specifies key requirements of the preanalytical phase of bacteriological diagnostics to ensure the quality of preanalytical and initial analytical procedures of microbiological testing, including SOPs for each step of the process.

The guideline was approved by the MoH and disseminated in both Russian and Uzbek. Training in all regions of Uzbekistan was organized to introduce the guideline for clinicians, nurses, and laboratory staff of health-care facilities.

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**Advocacy and partnership**

Further such events are being organized throughout the Region. Better Labs is advocating for different countries to engage in a dialogue that they have never had the opportunity to have previously and to properly identify their laboratory requirements, taking the discussion onto a government, policy and legislative level.

**Advocacy videos**
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**Designation of national reference laboratories**

A key gap identified when developing laboratory policies and strategic plans was the need to revise the governance and regulatory policies pertaining to health laboratories. Better Labs reviewed and analysed the licensing legislation covering health laboratories in more than 17 countries.

The review of health laboratory licensing legislation demonstrates that there is no standard/universal solution and different countries apply different approaches to license their health laboratories. Some countries regulate the standards and requirements in their health laboratory licensing legislation, whilst other countries refer to the applicable laws.

When terms of reference define clear roles and responsibilities of NRLs, their important role in the management of diseases is strengthened not only at national level but also globally. Therefore, ensuring and then maintaining the quality of laboratories, in particular NRLs, is crucial to diagnose and respond to health threats and challenges effectively.

Both of these studies have been used to formulate a series of workshops entitled Licensing and Designation of National Reference Laboratories to examine and discuss the regulation of quality in laboratories.

The first workshop was held in Uzbekistan and included participants from both the national licensing and accreditation authorities and heads of laboratories.
Global Laboratory Leadership Programme (GLLP)

To lead efforts in the development and direction of capable laboratory systems, laboratory leaders require meaningful education and training in leadership and management skills.

The GLLP programme follows the principles of the One Health approach that combines Human, animal and environmental sectors communicating and working together to achieve better public health outcomes.

Six leading organizations partnered to develop the GLLP and the Regional Office decided to contribute to its implementation in order to identify and nurture potential future laboratory leaders and managers for Kazakhstan.

When the GLLP was first initiated in Kazakhstan in May 2021, it had already been implemented in some other countries. However, this represented a significant first for central Asia, as was the choice of the modules that were to be piloted for the first time. Phase 1 of GLLP implementation in Kazakhstan consisted of two modules: QMS and biosafety and biosecurity, which are particularly needed to contribute to the response to the COVID-19 outbreak. This first phase was co-funded by the European Union, Chemical, Biological, Radiological and Nuclear Risk Mitigation Centres of Excellence initiative.

In April 2021, five Kazakhstan national experts were selected as facilitators to train and mentor 15 potential laboratory managers who were chosen in May 2021 from the veterinary, public health, and clinical sectors.

Working alongside and supported by the WHO, facilitators had prime responsibility for preparing materials in order to train those 15 participants with specific modules on QMS and biosafety and biosecurity.

“For me, GLLP is a powerful tool that every laboratory specialist needs and the knowledge I received at GLLP is helping me better understand QMS. Each GLLP laboratory leader improves their knowledge and will use it to develop and strengthen their laboratory”

Aknur Mutalieva, GLLP Participant, Kazakhstan
In total, participants received 240 hours of tutoring in these subjects. The participants were also given six months to research and prepare individual theses on their chosen, relevant topics. These they then presented and defended at a meeting on 25-26 November in Almaty – to a judging panel made up of facilitators, WHO and CDC experts.

Phase 2 of GLLP implementation in Kazakhstan is planned for 2022. The GLLP will create a new, sustainable generation of laboratory leaders and managers not only in Kazakhstan but also in other countries where strong interest in the programme is being expressed.

First national dialogue for SARS-CoV-2 laboratory professionals in Kyrgyzstan

While responding to the COVID-19 outbreak, laboratory professionals acquired a great deal of experience while facing many challenging scenarios.

Nearly one-and-half years since the pandemic started, the WHO Regional Office for Europe hosted a first national dialogue in central Asia in Kyrgyzstan from 26 to 27 August 2021. SARS-CoV-2 laboratory professionals and representatives from several international organizations active in laboratory services, attended to enhance coordination, share experience and perform gap analysis.

A list of findings and recommendations was developed and shared with national officials.
Costing – Laboratory Expenditure Tool

Costing has been shown to be particularly important during the COVID-19 pandemic when reliance on laboratory surge capacity is needed and costs are difficult to predict.

The Laboratory Expenditure Tool (LET) helps to estimate the total financial expenditure for running a laboratory for one whole year.

It includes the cost and comparative efficiency of laboratory services, effectiveness of use of laboratory personnel labour time and the feasibility of expanding existing or adding new types of services to a laboratory.

The LET is designed for laboratory directors, coordinators, quality managers, MoH representatives, policy-makers, health economists and administrators.

Laboratory Test Costing Tool roll out

Better Labs for Better Health has developed the Laboratory Test Costing Tool (LTCT) (3) to help laboratories evaluate the cost of a specific laboratory test, justify this cost and produce price lists for laboratory tests.

It helps to evaluate costs and compare cost-effectiveness and is having a real impact in terms of the way in which laboratories run their day-to-day operations both generally but also, importantly, in these pandemic emergency times. It takes into account all elements that could contribute to the cost of a test. Very often, the cost of a test is calculated as simply the reagents plus consumables plus personnel time. The tool challenges the way labs think about the costs they incur when doing one test.

With the current pressure in laboratory testing the LTCT can help laboratories strategize their operations and justify their costs to match changing demands.

The LTCT is now being rolled out in earnest and trainings have been conducted eight Member States. Further LTCT training will be taking place in other Member States.
Costing: lessons learned

Moving forwards – collaboration and consideration Throughout the period of the pandemic, a number of lessons have been learned and must be taken into account for fine-tuning costing models during the forthcoming period.

Without a standardized tool, laboratory testing costs can be inaccurately calculated. This goes for all areas of costing including maintenance, equipment, personnel costs and indeed time itself which must be accounted for when calculating the actual price of one laboratory test. It has been observed that health insurance companies have a tendency to compare the price of testing with private laboratories and this could have the effect of forcing public health laboratories to lower their prices in order to compete.

Certain laboratory equipment items, such as biosafety cabinets for instance, are often donated rather than purchased. It is essential to take into account the quite significant maintenance costs incurred for this equipment later down the line.

Above all, Member States need to think about their sustainability and develop laboratory systems where roles and responsibilities of each laboratory are clearly defined to avoid duplication and wasted resources.

“The Lab Test Costing Tool enables laboratory experts and laboratory financial experts to communicate using the same vocabulary. It is a standardized tool which enables both types of expert to be advocates for the laboratory when justifying prices”

Maria Valerie Amante, Public Health Consultant, Better Labs for Better Health, WHO Regional Office for Europe
Moving forward 2022–2023

Priorities 2022–2023

• Continue work on national sample transport and its respective in-country legislations

• Laboratory Expenditure Tool is to be published in 2022

• Finalize and distribute COVID-19 SOP handbook

• Finalize training package on setting national EQAs

• Expand and continue mentoring programme

• Expand and continue GLLP in central Asia

• Encourage countries to review their national laboratory systems and cost-effectiveness to address sustainability
REFERENCES

1. **Action plan to improve public health preparedness and response in the WHO European Region 2018–2023**


3. **Laboratory test costing tool: user manual/training manual**

ADDITIONAL RESOURCES

- **Laboratory licensing: an essential part of the national laboratory regulatory framework**

- **Report of the first meeting of the European Region Laboratory Task Force for High-Threat Pathogens**

- **Development of a national laboratory strategic plan: best practices document and facilitators’ guide, December 2016**
  Copenhagen: WHO Regional Office for Europe; 2017 (https://apps.who.int/iris/handle/10665/353746).

- **Development of national laboratory policies – Best practices document and facilitators’ guide**

- **European Regional Laboratory Task Force for High Threat Pathogens. Terms of reference (2019)**

- **Outbreak preparedness and resilience.**
The WHO Regional Office for Europe

The World Health Organization (WHO) is a specialized agency of the United Nations created in 1948 with the primary responsibility for international health matters and public health. The WHO Regional Office for Europe is one of six regional offices throughout the world, each with its own programme geared to the particular health conditions of the countries it serves.

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