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Abbreviations and acronyms

CDC	U.S. Centres for Disease Control and Prevention
DBS	Dried blood spot
DTRA	U.S. Defence Threat Reduction Agency
EIDSS	Electronic Integrated Disease Surveillance System
EU-DEVCO	European Commission's Directorate-General for Development and Cooperation
GF	The Global Fund to Fight AIDS, Tuberculosis and Malaria
GiZ	Deutsche Gesellschaft für Internationale Zusammenarbeit GmbH
IEC	International Electrotechnical Commission
IHR	International Health Regulations
ISO	International Organization for Standardization
KIT	Royal Tropical Institute, Netherlands (Dutch: Koninklijk Instituut voor de Tropen)
LAT	Laboratory assessment tool
LQMS	WHO's laboratory quality management system
LQSI	WHO's laboratory quality stepwise implementation
NCDC	National Centre for Disease Control and Prevention
NLWG	National laboratory working groups
PEPFAR	U.S. President's Emergency Plan for AIDS Relief
PHE	Public Health England
POCR	Point-of-Care Testing
RKI	Robert Koch Institute
SOP	Standard operating procedures
ToT	Training of Trainers
TWG	Technical Working Group
UNDP	United Nations Development Programme
WHO	World Health Organization

Executive summary

Some 60 participants met in Copenhagen at a two-day regional meeting to discuss strengthening laboratory capacities to support national programmes in eastern Europe and central Asia on 17 and 18 June 2014. The meeting was jointly organized around two initiatives of the WHO Regional Office for Europe, namely the *"Better Labs for Better Health"* initiative and a new initiative *"Strengthening laboratory capacities to support national programmes on HIV prevention treatment and care in eastern Europe and central Asia"*.

On the agenda was how the initiative can build sustainable laboratory capacities in the WHO European Region. During the meeting partners and donors presented their activities in laboratory capacity strengthening, Member States presented the reforms and progress made in the recent years, as well as the challenges that they are facing, and experts covered technical aspects such as laboratory quality management and health services integration.

This meeting established that the *"Better Labs for Better Health"* initiative is well-received in the Member States, and WHO will continue to implement this initiative in coordination with partners. It was agreed that WHO should advocate for, and continue to work with, Member States to improve the quality of laboratories by developing national laboratory policies and strategies, implementing laboratory quality management systems and upgrading national training programs for laboratory staff. In this context the new initiative *"Strengthening laboratory capacities to support national programmes on HIV prevention, treatment and care in eastern Europe and central Asia"* was perceived as a continuation of efforts in the region and a platform for open dialogue on key policies and best laboratory practices in a more specific area. The Regional meeting also concluded that all partners should continue to improve their coordination while conducting activities to strengthen laboratory infrastructure, procurement and supply management, and equipment maintenance (especially for biosafety cabinets). Activities to strengthen laboratory capacities should result in integration of services, such as public health and clinical diagnostic laboratories, appropriately trained and motivated laboratory staff. Efforts should take into account logistics as these are a key factor when defining laboratory networks and services.

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

Key summary points

- The "*Better Labs for Better Health"* initiative is gaining momentum, and the progress made since 2012 in Republic of Moldova, Tajikistan, and Uzbekistan shows the value of a rational approach to laboratory strengthening. It is a well-received initiative in the Member States, and WHO will continue to implement it in coordination with, and supported by, partners.

- The goals and objectives of the new initiative *"Strengthening laboratory capacities to support national programmes on HIV prevention, treatment and care in eastern Europe and central Asia"* were well-received while a closer work with Member States to identify the current status of HIV laboratories inventory and assess needs for capacity building is a critical immediate action to be taken. This initiative will seek inclusion and active involvement of all seven WHO priority Member States that are covered at this time, namely Kazakhstan, Kirgizstan, Tajikistan, Turkmenistan, the Russian Federation, Ukraine, Uzbekistan, and will continue leveraging interest of more Member States to engage as appropriate.

- WHO should take a leading role in advocating at the political level for the regulation of laboratory activities. In particular, laboratory quality management systems should be implemented according to national standards based on internationally recognized standards such as ISO 15189 for medical labs, and this should be defined appropriately in national laboratory policies, strategies and regulations. This was previously outlined in the joint statement that followed the WHO-CDC conference on laboratory quality systems that took place in Lyon, France, in April 2008.

- WHO, Member States, donors and partners should continue to improve their coordination in the area of laboratory strengthening and find ways to address acute needs such as improving procurement and maintenance of equipment.

- WHO, Member States and partners should ensure that their activities to strengthen laboratory capacities result in integration of services, such as public health and clinical diagnostic laboratories and appropriately trained and motivated laboratory staff. Logistics must be taken into account as these are a key factor when defining laboratory networks and services

- WHO should support research to measure the impact of the donors' activities, identify best practices, and make this information available for future action.

I. Background

Better Labs for Better Health

The *"Better Labs for Better Health"* initiative launched in 2012 by WHO Regional Office for Europe and its partner, the new WHO Collaborating Centre for Laboratory Strengthening at the Royal Tropical Institute, Amsterdam, builds on the premise that sustainable laboratory services in low and middle income Member States require a rational approach to laboratory system strengthening, as well as government and donor commitment.

The initiative aims to improve:

- laboratory services through the development of national laboratory policies and strategic plans;
- laboratory quality and biosafety
- national teaching curricula for laboratory staff resulting in well-trained laboratory experts and managers;
- health systems and overall public health

The initiative aims to become a model that can be applied in Member States throughout the region and beyond.

The activities are implemented through formal intersectoral NLWG which include international partners. Since 2012, NLWGs have been established in the following Member States: Republic of Moldova, Tajikistan, and Uzbekistan. A number of these activities are summarized in the following section of this report.

Strengthening Regional Laboratory Capacity to support national HIV/AIDS prevention and treatment programs in EECA

The WHO & CDC joint initiative "Strengthening Regional Laboratory Capacity to support national HIV/AIDS prevention and treatment programs in EECA", established a regional TWG in 2013. In January 2014 the TWG met for the first time in Moscow, Russian Federation, and requested a renewed, more substantial effort to improve existing laboratory capacity in a framework of an agreed Regional Laboratory Capacity Building Strategy for EECA Member States to support the development of integrated National Laboratories Strategic Plans. It was suggested that a coherent regional strategic approach could better support the development of integrated national laboratory strategic plans. To achieve this, it was further proposed to initiate a broader regional dialogue with selected Member States to address challenges, define priorities and assess the potential interest of Member States in engaging in a regional strategic initiative towards strengthening institutional and human capacities to support national programs in EECA. Consequently, the current regional meeting hosted by WHO in Copenhagen, Denmark incorporated key topics proposed by the TWG into the agenda and technical sessions. Representatives of TWG worked through the consultation and met separately to follow up on decisions to be taken and define next steps.

This initiative currently covers seven WHO priority Member States: Kazakhstan, Kirgizstan, Tajikistan, Turkmenistan, the Russian Federation, Ukraine, and Uzbekistan. WHO is leveraging interest and resources towards engaging more Member States where and as appropriate.

II. Overview of laboratory strengthening activities

The overview of activities being conducted by WHO, partners and donors' in collaboration with Member States, showed that there are a large number of programs being conducted in the Region. These programs often share similar approaches and methodologies (e.g.: focus on integration of services, tiered quality management systems…). WHO also has multiple strategies or work plans dedicated partially or fully to lab work in the areas of disease control, Surveillance, Alert and Response (SAR), and antimicrobial resistance.

Activities fit into 5 main categories:

1. *Advocacy and development of national laboratory policies and plans:* although the strengthening of laboratories can be done at the individual laboratory level, it is preferable for such efforts to be integrated in a national policy that is coherent vertically (national, regional and local level) as well as horizontally (across different types of laboratories and pathologies). There was consensus among the meeting's participants was that it is WHO's role to advocate for such policies. Once a Member State has shown political commitment on this issue, designing and implementing these policies remains a challenge. Donors can provide technical assistance, recommendations, and expertise, but it is important that the Member States and their specialists keep ownership of the process. WHO's Better Labs for Better Health initiative ensures this by working through formal intersectoral National Laboratory Working Groups comprising national senior experts. National Laboratory Working Groups develop policies and strategic plans that are integrated with existing health strategies, and will be a key factor in rationalizing and prioritizing subsequent donor' activities.

2. *Curriculum development and training:* the lack of qualified, experienced personnel has been put forward by many Member States as one of their main problems. This issue is sometimes attributable to inadequate initial training. As part of the Better Labs for Better Health initiative in Uzbekistan, the laboratory training curriculum for doctors and technicians was evaluated by the National Laboratory Working Group with an aim to improving in-country pre-service teaching curricula. Several improvements have been identified and are ready to be implemented in the relevant institutes, such as an increase in hands-on training. The problem of inadequate training is often compounded by a high staff turn-over (linked to low job satisfaction), which prevents the younger technicians and managers from benefitting from contact with more experienced staff. Staff turnover cannotbe addressed by progress in training, but its consequences can be mitigated by continuous education of technicians and managers. Many partners have included this component in their programmes, using different modalities: WHO for example often provides training courses through its collaborating centres. Other donors, such as DTRA in Uzbekistan, have focused on in-country ToT, a cost-effective method that has the advantage of being sustainable even after a donor has stopped its involvement in the country. PHE's virology projects in central Asia have been characterized by a focus on

institute-to-institute collaborations, and have therefore relied on the establishment of scientific links, with participation in fieldwork and laboratory twinning.

3. *Quality management systems implementation:* the implementation of a quality management system is one of the best ways to strengthen a laboratory. It is also a complex, extensive and resource-intensive process. Therefore, initiatives presented by the partners have focused on tiered, stepwise implementation of quality management systems, with tailor-made solutions taking into account the cultural, financial, environmental and political context of the Member States. For example, WHO Regional Office for Africa and CDC's SLIPTA approach benchmarks a laboratory's progress towards an accreditation which uses a 0-to-5 star scale. This process, less demanding than ISO15189, is based on a checklist covering twelve sections, and is particularly adapted to Member States that lack national regulations. Following the initial audit, workshops, mentoring and improvement activities are interspersed with regular laboratory visits. This program has allowed laboratories in Africa to obtain accreditation within 18-48 months of the initial audit. KIT has developed for WHO a Laboratory Quality Stepwise Implementation tool that allows laboratories to implement quality management improvements consistent with ISO15189 standards requirements, while giving a lot of freedom for the user to decide on the sequence or focus of these improvements. This tool is further referred to in the Quality Management section of this report.
4. *Infrastructure, procurement and equipment:* UNDP's and GF's activities in Tajikistan identified infrastructure, inadequate stocks, procurement and supply management issues, and equipment maintenance as some of the major challenges for the national laboratory networks. As a result significant resources have been devoted to addressing those challenges. For example, all UNDP GF Regional laboratories now have standard equipment of the same brands/manufacturer. Contracts with local maintenance companies have been signed, and preventative maintenance was included in the budget, coordinated and monitored.

5. *Research:* it is important to assess the actual effectiveness of the broad range of activities conducted to strengthen laboratories in the Region. Therefore, evidence-based evaluations, such as those conducted by KIT, are needed to measure the impact of the donors' activities, identify best practices, and make this information available for future actions.

From the presentations showed in this meeting, some factors were determined to be critical for an activity to achieve success:

- Securing political commitment at national level (referring to the example of CDC's work on laboratory accreditation in India)
- Conducting a thorough, standardized evaluation of the laboratory system (similar to WHO's work in Turkey, presented in this meeting and described in section IV)
- Involving national experts from all relevant sectors in laboratory strengthening (as with the Better Lab for Better Health initiative and its National Laboratory Working Groups)
- Empowering the local staff (referring to PHE's work in central Asia)

- Devising and implementing solutions that are tailor-made and sustainable (similar to DTRA's ToT activities in Uzbekistan and GF standardization of equipment, procurement, maintenance, etc)
- Optimizing testing strategies to reach key populations and approach services closer to those in need (relying on Innovative Strategies for Quality of HIV POCT presented by CDC, which suggest bringing the test conveniently and immediately to the patient)

III. Situation in the Member States

Member States presented the following topics:

Country	Presentation
Armenia	Laboratory strengthening as part of IHR (Sergey Karapetyan)
Georgia	Laboratory strengthening as part of IHR (Ekaterine Adeishvili)
Kazakhstan	Improved quality assurance at national level in Kazakhstan (Galiya Tajibayeva)
Kyrgyzstan	Overview of laboratory services (Kaliya Kasymbekova)
Republic of Moldova	Laboratory reforms (Natalia Costic)
Tajikistan	National laboratory policy development (Firuz Davlatov) Overview of HIV related laboratory services (Hanifa Ihtiarova)
Ukraine	Optimizing HIV testing strategies in key populations (Iryna Andrianova)
Uzbekistan	National policy development and quality of services (Caroline Brown, WHO/Europe)

Armenia

Reforms of the laboratory system in Armenia started in 2007, with the implementation of the IHR 2005. Following an assessment of the country's IHR core capacities, a national program was devised in 2009. After a first round of implementation, the IHR program was extended from 2012 to 2014. This extension was especially rich in developments in the field of laboratory services. It started with an evaluation of the laboratory system performed in cooperation with DTRA and CDC, which have since provided additional support, and using the WHO system LAT. The results prompted the development and adoption of a national strategic plan and the establishment of both a NLWG and the NCDC. The NCDC is now at the top of a tiered system, supported by 15 regional laboratories. Considerable efforts also led to the training of over 300 staff in biosafety, IT, LQMS and sampling methodology.

Georgia

Reforms of the laboratory system in Georgia were also initiated under the impetus of IHR, and led to the integration of the Medical Statistics Centre and Public Health Department into the NCDC in 2007. In 2013, the Lugar centre, a top-tiered institution, was also integrated into NCDC's laboratory network, and now serves as a reference laboratory for Georgia's public health system. The national laboratory network is organized around 64 district Public Health Centres, supported by 3 Zonal Diagnostic Laboratories and 7 Local Surveillance Stations attached to the Lugar Centre. Data on notifiable diseases and especially dangerous pathogens in both humans and animals is shared via the EIDSS. It is foreseen that EIDSS will interconnect with a nation-wide, unified, Health Management Information System called "e-Health". The work is being supported by DTRA and CDC.

Kazakhstan

The Republic of Kazakhstan has district level AIDS centres, city level centres and other urban city level centres. Overall it implies 17 labs (1 republican level laboratory, 2 city labs and 14 labs of district levels). Kazakhstan is now actively developing a national quality assurance system for laboratory services. Building capacities activities recently supported by CDC and a mentoring program has been initiated to assure compliance with international approaches in laboratory accreditation and quality assurance of laboratory practices. For the pilot project supported by CDC six laboratories have been chosen to go though an initial assessment and mentoring for laboratory accreditation process. There is a questionnaire developed to evaluate the work overall. Results of the initial assessment have shown strengths and weaknesses of the technical and process related situation. Currently the internal and external quality assurance is in place. Up to 2008 some external quality assurance activities through international programs have occurred. Adequate recording practices, appropriateness of procurement and supplies have been validated through evaluation visits on sites. Capacity building and continuing professional development is assured through national entities and occurs regularly. Among challenges the lack of comprehensive guidelines for quality assurance management in laboratories was clearly defined. The undertaken close assessment of inventory and practices in pilot laboratories detected strengths and weaknesses and also proposed solutions to existing problems and follow up actions.

- New staff units with the functions of managers for quality assurance in laboratories were proposed at district level and job descriptions developed and approved through local institutions and departments of health on pilot sites
- A comprehensive algorithm of testing and counselling tactics in cases of confirmed laboratory HIV cases has been developed, regulated and introduced on pilot sites.
- In one of assessed laboratories the space was increased to meet the needs of daily appropriate practices.
- There key documents have been developed and are now in place for the pilot laboratories: guidance on quality of lab practices, guidance on biosafety procedures and technical guide for laboratories

Additional assessments are planned as next step to detect problems on sites and propose actions towards improved quality of laboratory practices across the country. Based on good examples and validated results from pilot sites a scale up of effective interventions will be proposed for other laboratories in the country.

Republic of Moldova

Since 2009, the national public health system has been undergoing reforms to strengthen it and to harmonize it with EU standards. This reform has culminated with the development of a national public health strategy, which includes a review of the public health laboratory system, and an upgrade of its regional components, as designed in 2012 by the National Laboratory Working Group, with technical support from WHO/Europe and KIT and donor support from EU-DEVCO.

A key aspect of this laboratory development plan is to shift from a lab system composed of 36 territorial labs towards a more streamlined, upgraded system organized around 10 regional labs. Capacity building is currently underway, with significant equipment purchases being made for the regional labs. 2 pilot laboratories have been designated, and operational mechanisms will be defined in 2015. Staff training and equipment installation will also be completed next year.

WHO's assistance in these reforms has gone through the Better Lab for Better Health initiative, starting with an initial assessment mission in 2012, then with a series of workshops that led to a national laboratory policy paper, as well as with an assessment of the laboratory training curriculum. Finalization and government endorsement of the national laboratory policy is expected by the end of 2014.

Tajikistan

In October 2012, an inter-sectoral committee for coordination and management of laboratories, which includes international partners and donors, was established by order of the Ministry of Health. Members of this committee included representatives from health services, agriculture, Academy of science, Chemical Institute, Agency for radiation safety, Tajikstandard (Agency for Standardization, Metrology, Certification and Trade Inspection), and international partners (UNDP/GF, FIND, Project HOPE, CDC). This committee and its technical working group, supported by the Better Lab for Better Health initiative, developed the following objectives:

- perform a gap-analysis of the country's laboratory services;
- develop a national policy for laboratory strengthening, as well as sectoral plans;
- support the implementations of these plans with focus on resource allocation.

The technical working group has developed a vision and is currently in the process of developing a concept paper for national policy in the field of laboratory activities. It includes 14 topics divided into four areas (country system level, infrastructure, practice in laboratories, and standards). These were identified during a SWOT analysis of the country's laboratory system.

A more specific approach to the laboratory system for was also presented in a special technical session. A comprehensive overview of laboratory system that assures HIV diagnosis and treatment monitoring in Tajikistan was also presented in a separate technical session. HIV testing techniques include ELISA (the major diagnostic practice used in the country and WHO recommended kits are use for this), rapid tests (used by all laboratories of the AIDS Service, including those of anonymous examination rooms), immunoblotting test (available only at the National Reference Laboratory of the Republican AIDS Center). At the reference laboratory of the Republican AIDS Center and 4 diagnostic labs of the regional AIDS centers, flow cytometry equipment is in place (for CD4+, CD8+, CD3+ counts). The laboratories also assure sentinel surveillance that is nationally well regulated. SOPs in each laboratory participating in sentinel surveillance include comprehensive guidance for pre-analytical, analytical, post-analytical stages. Guidelines on detecting HIV, HVC and syphilis antibodies in DBS are currently in a process of approval at national level. ELISA on DBS is done only with DBS-adapted testing kits and procurement of DBS testing kits is centralized.

Since 2010, labs of the AIDS centers have been participating in the system of External Quality Assurance at the international level (5 labs) with the support of GF. The Reference Laboratory of the Republican AIDS Center has been developing its own standard serum panel for EQA at the national level (18 labs) since 2011. With the support of GF, ICAP, WHO, ASCP over 80 specialists were trained through a three-step training course on Quality Assurance and Quality Control of Laboratory HIV Diagnosis. On-site mentoring and consultations was conducted by professionals of the Republican AIDS Center's Reference Laboratory. In spite the good progress and regulations in pace along with good external support for capacity building the country representative express the need for further actions and defined the areas of work. To assuring further sustainability of the system the country would need to:

- Expand the range of DBS testing kits through developing proper testing techniques and registering the appropriate DBS testing kits in the country
- Develop National DBS reference panels for external laboratory quality control
- Assure EQA through international programs for all laboratories tied to the AIDS centers (currently only 5 laboratories have EQA).

Ukraine

The key population groups remain a challenge in assuring access to HIV prevention and care services. Ukraine has certain examples of increasing the access to HIV testing for key populations. National laboratories tied to HIV care specialised institutions are supportive and closely collaborating with the mobile teams, outreach services and penitentiaries. In addition, Ukraine has a well established family medicine system that implies increased intake into HIV testing and care of key populations through these additional primary care setting. However, challenges remain in assuring continuum of care across the HIV care cascade. There are also different approaches in regulated procedures within the HIV specialized services and medical services provided through penitentiary, e.i. different budget sources, different structures, which makes hard to monitor and evaluate the quality of testing and care in penitentiaries. Services integration is a key function in this context and may significantly increase access to HIV testing and monitoring of ART in key populations overall.

The basic patient management includes HIV testing, testing for STIs, CD4 counts, VL. POC approach is now a newly introduced practice in some areas in the country and is at the very beginning of its implementation. Multidisciplinary groups were established and well trained to assure HIV testing and counselling while a master curricula for multidisciplinary teams training is also in place in the country. Donors and pregnant women are the main groups covered the most through testing. Rapid tests are more and more used. Some 209211 people were tested for HIV in 2013 overall; these are mostly key populations. 10% from key population 32% confirmed key populations

Up to now Ukraine has 800 trusty rooms, 18 mobile teams, the numbers are growing. There are outreach groups and organized community centres to assure HIV testing in IDUs and other key populations. There is a need of closer cooperation, ambulatory mobile teams need to be regulated within the system and certainly the integration of services remains a key issue in this context. Many ambulatory (out patient testing and care) are not having access to external quality assurance

programs and there are concerns on assuring appropriate quality of testing through such entities in the country. Therefore, improving the quality of testing for HIV remains a priority especially at primary care level. The role of reference laboratories at interregional level decreased lately given good equipment and technologies provided to each district in the country and appropriate conditions have been assured for appropriate HIV testing and counselling services and ART monitoring. A significant support was provided by the Global Fund for additional equipment which certainly made needed services available for small cities and rural areas in the country. The country is committed to work now on establishing algorithms of testing and data reporting from mobile primary care testing, indicators of effectiveness of testing, training, validation remain next challenges. The nationally approved algorithm of diagnosis for HIV infection is in line with WHO recommendations, endorsed by the Ministry of Health and in place. The following laboratory methods are used: immuno-ferment analysis (IFA) (all population groups, including key populations and penitentiaries), ИХЛА (blood donors), rapid tests (all population groups, including key populations and penitentiaries), IFA – third generation (all population groups, except donors which are tested through IFA tests of fourth generation or ИХЛА). In future, the country aims to assure early HIV testing IFA of fourth generation should be in place.

Further plans would imply decentralization of laboratories, staff rotation to assure better coverage and timely interventions, investigating the possibility of expanding the use of new methods of diagnostics using the dry blood spot. Early HIIV testing may have tremendous benefits and the country will align with this in future.

The strategy of assuring the quality of testing at sites: the external quality assurance of testing for at national level is regulated and in place since 2012. The use of rapid tests and the dry blood techniques are still at a pilot level. EQA remains a challenge for regular CD4 counts and VL tests and the country commits to assure EQA while technical support might be required from international programs where appropriate. So far only national quality assurance programs are in place, mostly coordinated by the Ukrmetrteststandard (a national entity that regulates the accreditation and QA programmes overall in the country). 124 labs that are providing testing for HIV are officially included in the national QA programme. A regulation of quality of intralaboratory testing techniques is in process right now. Additional support from MoH, WHO and CDC would strengthen the efforts and move the agenda forward.

Uzbekistan

Better Labs for Better Health activities have been implemented in Uzbekistan with the support of GiZ since November 2013. Firstly an assessment was conducted using the WHO laboratory system laboratory assessment tool (WHO system LAT). Based on this assessment, two policy development workshops were organized to develop a vision, identify the stakeholders, and perform a SWOT analysis of the laboratory system. Once the statements from this SWOT analysis are verified, it is expected that a third workshop will lead to the development of a policy paper.

In parallel to this policy development, other activities have focused on assessing national training curricula of the laboratory staff, together with professors and future employers.

In addition to finalization of current activities, future activities in Uzbekistan are expected to include implementation of a LQMS and rationalization of the laboratory system. Currently, the

NLWG members are from the Sanitary Epidemiological System (SES; public health laboratory services) and discussions are underway to include members from clinical diagnostic laboratories, agriculture/veterinary laboratories, etc.

Kyrgyzstan

The laboratory network of the Kyrgyz Republic comprises 600 laboratories, including 65 working with class 2 microorganisms or above. Public Health laboratories have a National Accreditation System for compliance with the International Standard ISO/IEC 17025. The government is committed to improving the national laboratory system, therefore Better Labs for Better Health activities are scheduled to start there in the second half of 2014, with support from EU-DEVCO and CDC. The NLWG is currently being established, and WHO system LAT, curriculum assessment and first policy workshop will take place in September.

IV. Quality management

As illustrated in the previous chapters, a wide array of interventions can be applied to strengthen a Member State's laboratory capacity. These interventions can focus on several areas such as national policy, infrastructure, staff education, etc... Among these areas, quality management is perhaps the one that has received the most attention in partners' activities.

Intervening on laboratory quality management presents several desirable features:

- it is easily scalable and adaptable to the particular Member State, system or laboratory; implementation can be done in stages;
- initial costs are relatively low;
- benefits are immediate and sustainable at minimal cost;
- benefits are not limited to a specific test or pathogen;
- spill-over effects can include empowerment and higher job satisfaction of staff, reduced costs of testing, increased customer satisfaction.

The implementation of LQMS in Turkey was presented during this meeting. It was part of the third phase of an EU-funded project on Surveillance and Control of Communicable Diseases that started in 2004. This implementation phase relied heavily on the use of three tools available online: WHO's LAT, WHO's LQMS training toolkit, and WHO's LQSI tool. WHO's LAT was developed by the WHO Office in Lyon, France and allows laboratories to see their strengths and weakness in 10 areas based on ISO15189 standard. It can be used both for self-assessment and for external assessment. WHO's LQMS training toolkit aims to provide training for participants from technicians to high level specialists, imparting a good understanding of laboratory quality management concepts and practices. WHO's LQSI tool, developed by KIT, can be used to implement or improve quality management systems. It is used either by working through activities sequentially, or by working on one area of quality management at a time.

It is worth noting that these three tools draw heavily on the international ISO15189 standard. This guarantees coherence in the process, from gap analysis of the system to remedial measures in individual laboratories.

In the Turkish example, the first step in the implementation of LQMS was to assess the laboratories and their practices. This was done by local assessors using the WHO-LAT after an initial training, as well as by use of a web-based survey. 47 laboratories were visited in 2011, and another 530 took part in the survey. Based on these results, the next step was to train local staff in LQMS. To this end, 84 local trainers from hospital and universities were chosen to take part in a training of trainers on the use of the LQMS training toolkit. These trainers then proceeded to train 917 participants in LQMS over 10 training sessions. These participants, armed with the knowledge acquired in this training, will later be able to implement Quality Management in their home institutions by using the LQSI tool.

Laboratory quality management is largely an internal matter for individual laboratories. Audits, improvements and investigation of non-conformities are the responsibility of the laboratory's quality manager. Yet, external quality assessment remains a component of LQMS that receives a lot of attention, as inter-laboratory comparison is a requirement of many forms of accreditation and certification. Laboratories associated with WHO networks at a regional or global level can be offered several EQAs, for example for polio, measles and rubella, influenza, foodborne infections, HIV, hepatitis, tuberculosis, or dengue. Additionally, national and international EQAs are also available through a range of commercial or not-for-profit organizations. Two points were emphasized during this meeting:

- EQAs are strong networking, standardization and educational tools, but they are ineffective if not followed by remedial actions.
- EQAs are only a very small part of LQMS, and their importance should not be over-estimated.

During the meeting, Member States were asked to list the obstacles that implementation of LQMS has faced or will be facing in the future. The following problems were identified:

- lack of understanding/need for advocacy, both at political and management level;
- lack of resources, in particular for maintenance and to finance exclusive quality management positions;
- low interest for EQAs due to negative repercussions in case of subpar performance.

V. Policy and Programme Integration

A recurring theme during this meeting was the necessity for integration, both horizontally (across pathogens, across projects and donors) and vertically (from national policy level to service level). Laboratory networks as well as donors' programmes have had a tendency to be organized vertically (GISRS, polio eradication programme…), which is reflected by the large number of global or regional programmes conducted by WHO that include a laboratory component. Indeed, quality management and bio-risk management seem to be so far the only two areas that are operating horizontally.

The Health Services Delivery Programme at the WHO Regional Office for Europe presented 7 key areas where action is needed to work towards more coordinated/integrated delivery systems.

1. *Care:* designing comprehensive models, coordinating providers and continuous improving performance
2. *Communication*: promoting the continuous flow of information/data
3. *Competencies*: developing a skilled workforce; with adequate trainings; supervision programs; and career opportunities
4. *Policy*: creating a common national vision; strong implementation for laboratory regulations; structure responsibilities for monitoring
5. *Resources:* properly utilizing and making available
6. *People*: empowering them with the information/responsibility for managing their health
7. *Culture:* professionally/publically – ensuring a spirit of "working together" is internalized

Member States and donors were also invited to present examples of vertical or horizontal integration:

- The Russian Federation mentioned cooperation between AIDS centres and prison laboratories as a successful local programme. The funding of method training centres (for example for ELISA) by local reagent suppliers was also a good illustration of horizontal integration.

- Republic of Moldova indicated that their national public health centre is taking on the coordination of their new, streamlined laboratory network, including training and standardization of equipment and procedures.

- Ukraine presented the vertical integration of HIV testing with HIV treatment and services, obstetrics department, blood donor services

- PHE described the vertical organization of the United Kingdom's laboratory system, where local hospitals do point-of-care testing, while more complex tests are handled at regional/reference level, with PHE coordinating and developing SOPs.

- Kyrgyzstan is in the process of turning their centralized microbiology laboratory into a national reference lab, allowing for personnel to develop multiple skills and therefore working across diseases.

VI. Recommendations, next steps and concluding remarks

Presentations and discussions that took place during these meetings highlighted a lot of positive developments. Member States have welcomed the donors' initiatives and showed commitment both at a political and technical level. The adoption of IHR in particular has been a driving force for reforms in several Member States. The increased HIV treatment across the region suggested the need to strengthen the quality of laboratory practices. Donors show signs of building on their experience of previous activities: this meeting clearly showed a convergence in the donors' goals, and an agreement on key success factors, such as integration or customization of activities to fit the local context.

The Better Labs for Better Health initiative is gaining momentum, and the progress made since 2012 in Republic of Moldova, Tajikistan, and Uzbekistan show the value of a rational approach to laboratory strengthening. In particular, the NLWGs have been well received and have produced results in terms of strategic planning, and system evaluation. Lessons learned from these Member States will be applied to future activities in Armenia, Georgia, and Kyrgyzstan, which are scheduled to take place in 2014/2015. Policy workshops (Tajikistan and Kyrgyzstan), training of trainers on teaching modules (Republic of Moldova), and training in LQSI (all Member States) are among forthcoming activities planned for the end of 2014.

The new initiative *"Strengthening laboratory capacities to support national programmes on HIV prevention, treatment and care in eastern Europe and central Asia"* was well-received. There is an immediate and critical need to work more closely with Member States to identify the current status of HIV laboratories inventory and assess needs for capacity building. This initiative will seek inclusion and active involvement of all seven WHO priority Member States that are covered at this time, i.e. Kazakhstan, Kirgizstan, Tajikistan, Turkmenistan, the Russian Federation, Ukraine, Uzbekistan. the initiative will continue leveraging interest and resources towards the engagement of more Member States where and as appropriate. To gather the best possible advice from the ground, the WHO/CDC Technical Working Group established in October 2013 under this initiative will continue to operate. The group will facilitate a consensus on laboratory practices and overall approaches applied, specifying which approaches are likely to be most effective in different contexts around the region. The WHO/CDC initiative will develop further specific interventions seen as a priority for the region. These will consist of developing a regional framework leading to a regional strategy, conducting an inventory of HIV laboratory services in the region involving national entities and strengthening laboratory capacities in priority Member States.

Funding was brought up several times by participants. The significant contributions made by donors through the activities described in this report have resulted in a strengthening of the laboratory systems and increased capacity, but maintaining these gains also requires substantial funding (equipment maintenance and operation, reagents, salaries, logistics, etc…). It is therefore imperative for improvements to be implemented in a rational way, at an appropriate pace, and to be backed by a political commitment that will guarantee sustainable gains.

Often, as part of the broader discussion on funding during the meeting, the question of private sector involvement was raised. The German model, where almost all diagnostic laboratories are privatized, boasts some of the lowest costs per test in industrialized Member States, while offering

high quality and short processing times. This is thanks to a very high level of automation and elaborate logistics. On the other hand, participants have voiced some concerns regarding the need for clear regulations and standards for private laboratories.

During the meeting, a number of key points and requests for support were made. Three stand out:

- *Advocacy*: political commitment is essential to the success of laboratory strengthening activities. Partners must assume the role of advocates at the highest political level, with WHO in the front line. Technical experts sent by Member States asked WHO to take a leading role in advocating at the political level for the regulation of laboratory activities. In particular, laboratory quality management systems should be implemented according to national standards based on internationally recognized standards such as ISO 15189 for medical labs, and this should be defined appropriately in national laboratory policies, strategies and regulations. In addition, occasional opposition to specific reforms from the staff at a local level, as well as lack of familiarity with certain topics (like LQMS), require advocacy efforts to also target technical staff.

- *Coordination:* WHO, Member States, donors' and partners should continue to improve their coordination in the area of laboratory strengthening, with focus on infrastructure, stocks, procurement and supply management, and equipment maintenance.

- *Integration:* Special attention should be paid to integration, both horizontal (benefits in laboratory strengthening should occur across diseases and facilities) and vertical (Interventions at policy, system and service level should be mutually compatible and complement each other). Successful integration takes into account logistics, as they are a central aspect of laboratory networks. This also implies making services more accessible to those in need and in this context the point of care testing (POCT) tactics should be promoted.

The participants also agreed on the additional need to work closely to identify further needs for on-site technical support as well as expand training and institutional capacity building, tailored to the situation in country and evidence of efficacy. Regular interactions and meetings would help discussing and assuring harmonization of efforts and interventions.

As John Nkengasong from CDC mentioned in his closing remarks: "laboratory strengthening is a long-term effort which calls for a stepwise approach, with a focus on measurable attributes that can be more easily funded and advocated."

Annex 1: Resources

Partners' meeting announcement – Better Labs for Better Health: http://www.euro.who.int/en/media-centre/events/events/2014/06/partners-meeting-on-the-better-labs-for-better-health-initiative

Regional meeting on strengthening laboratory capacities to support national programmes in eastern Europe and central Asia (EECA): http://www.euro.who.int/en/media-centre/events/events/2014/06/regional-meeting-on-strengthening-laboratory-capacities-to-support-national-programmes-in-eastern-europe-and-central-asia-eeca

Influenza and Other Respiratory Pathogens Programme, at WHO Regional Office for Europe: http://www.euro.who.int/en/health-topics/communicable-diseases/influenza

WHO Collaborating Centre for Laboratory Strengthening, at the Royal Tropical Institute (KIT): http://www.kit.nl/kit/biomedical-research-About-KIT-Biomedical-Research

WHO LAT: http://www.who.int/ihr/publications/laboratory_tool/en/

WHO LQMS training toolkit: http://www.who.int/ihr/training/laboratory_quality/en/

WHO LQSI: https://extranet.who.int/lqsi/

European Action Plan for HIV/AIDS 2012–2015 http://www.euro.who.int/en/health-topics/communicable-diseases/hivaids/publications/2011/european-action-plan-for-hivaids-20122015

HIV/AIDS in the WHO European Region, at WHO Regional Office for Europe http://www.euro.who.int/en/health-topics/communicable-diseases/hivaids

WHO Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection. http://www.who.int/hiv/pub/guidelines/arv2013/download/en/

Innovative strategies for quality assured HIV Point-of-Care Testing (POCT). Right patient. Right testing. Right result. Report from CDC meeting on POCT, Atlanta, GA, USA, February 2014Technical and operational considerations for implementing HIV viral load testing. Interim technical update. http://www.who.int/hiv/pub/arv/viral-load-testing-technical-update/en/

Guidelines for Assuring the Accuracy and Reliability of HIV Rapid Testing: Applying a Quality System Approach. http://www.who.int/diagnostics_laboratory/publications/HIVRapidsGuide.pdf?ua=1

HIV drug resistance: WHO publications http://www.who.int/hiv/pub/drugresistance/en/

Annex 2: List of participants

National representatives

Armenia: Sergey Karapetyan

Georgia: Ekaterine Adeishvili

Kazakhstan: Rafail Kipshakbayev, Galya Tazhibayeva

Kyrgyzstan: Damira Ashyralieva, Kaliya Kasymbekova, Venera Maitieva, Kunduz Momusheva, Zhanat Nupbaeva

Republic of Moldova: Natalia Costic

Russian Federation: Mariia Pisareva, Dmitry Kuevda, Elena Tsyganova, Dinara Nabiulina

Tajikistan: Sukhrob Akramov, Shakhnoza Bobokalonova, Firuz Davlatov, Hanifa Ikhtiyarova**,** Dilorom Rakhimova

Ukraine: Iryna Andrianova, Volodymyr Kurpita, Natalia Nizova

Consultants

Marta Galinska

Representatives of other organizations

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Fondation Mérieux: Soudeh Ehsani

Royal Tropical Institute (KIT): Paul R. Klatser

Robert Koch Institute (RKI): Walter Biederbick

Public Health England (PHE): Jane Shallcross

Threat Reduction Program (TRPO): Jennifer Smith

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Dokuz Eylul University: Yusuf Hakan Abacioglu

UNDP: Ryan Jose Ruiz III

Institute of Microbiology and Laboratory Medicine Gauting: Harald Hoffmann

World Health Organization

Regional Office for Europe: Anne-Marie Andersen, Myriam Corinne Ben Mamou, Caroline Sarah Brown, Silviu Ciobanu, Andrei Dadu, Martin Christopher Donoghoe, Bente Drachmann, Irina Eramova, Evgeniy Gavrilin, Diane Gross, Krystyna Hagebro, Michala Hegermann-Lindencrone, Pernille Jørgensen, Zafar Khamidov, Hans Kluge, Dmitriy Pereyaslov, Bhim Narayan Pradhan, Annemarie Rinder Stengaard, Juan Tello, Elena Victorovna Vovc

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