World Health Organization

REGIONAL OFFICE FOR Europe

Meeting of the European Tuberculosis Laboratory Initiative (ELI) Core Group

Copenhagen, Denmark
25 February 2016

ABSTRACT

The European Tuberculosis Laboratory Initiative (ELI) aims to strengthen tuberculosis (TB) laboratory capacity in the WHO European Region, with a particular focus on the 18 countries of the Region in which addressing TB is a high priority. On 25 February 2016 the first meeting of the renewed ELI Core Group was held in Copenhagen, Denmark. The specific meeting objectives were: (a) to exchange information and know-how on TB laboratory development and to review and discuss relevant laboratory activities in the Region; (b) to review ELI priority areas; and (c) to reach consensus on at least three ELI priority actions. Meeting outcomes included strengthened group collaboration arising from the face-to-face discussions and from engagement in the working group process. Following working group and plenary discussions seven ELI priority actions were identified and agreed upon in the three key areas of: (a) developing regional laboratory diagnostic algorithms; (b) laboratory quality management systems; and (c) laboratory maintenance, sample transportation, biosafety and security.

Keywords

TUBERCULOSIS - diagnosis
TUBERCULOSIS, MULTIDRUG-RESISTANT- diagnosis
EXTENSIVELY DRUG-RESISTANT TUBERCULOSIS - diagnosis
CAPACITY BUILDING
CLINICAL LABORATORY TECHNIQUES
INTERNATIONAL COOPERATION

Address requests about publications of the WHO Regional Office for Europe to:
Publications
WHO Regional Office for Europe
UN City, Marmorvej 51
DK-2100 Copenhagen Ø, Denmark
Alternatively, complete an online request form for documentation, health information, or for permission to quote or translate, on the Regional Office website (http://www.euro.who.int/pubrequest).

CONTENTS

Executive summary

The European Tuberculosis Laboratory Initiative (ELI) aims to strengthen tuberculosis (TB) laboratory capacity in the WHO European Region, with a particular focus on the 18 countries of the Region in which addressing TB is a high priority. During its two previous meetings held in October 2012 and October 2014, the ELI provided a platform for participating countries to exchange experience and share knowledge. In addition, the challenges in scaling up the rapid detection of both MDR-TB and extensively drug-resistant TB (XDR-TB) were identified and potential solutions discussed and developed. Initial work has also been undertaken in developing a standard algorithm for the laboratory diagnosis of TB in the countries of the Region. Since 2012, the implementation of WHO-endorsed rapid molecular testing for the routine diagnosis of drug resistance has led to a significant increase in the number of laboratories with this capacity. In particular, the number of laboratories that routinely used the line probe assay for the routine diagnosis of drug-resistant TB has more than doubled from 95 in 2010 to 214 by the end of 2014. By the same point rapid molecular tests were available in 41 of 43 reporting countries, with 436 laboratories using them. Corresponding gains had also been recorded in reporting laboratories and countries in areas such as performing specimen culture and drug-susceptibility testing (DST). However, the increase in the number of laboratories performing DST has not been matched by a corresponding increase in the number of laboratories participating in, and successfully completing, an external quality assessment (EQA) programme.

In 2015 following a call for ELI Core Group members, applications were received from 19 countries of the Region. Members were then selected on the basis of their technical expertise, work experience, background and geographical location. The selection process was led by a committee comprising representatives of the Global Laboratory Initiative (GLI), WHO headquarters, the Stop TB Partnership and the WHO TB and M/XDR-TB Programme of the WHO Regional Office for Europe. The committee subsequently selected 12 members from ten countries of the Region (see Annex 1).

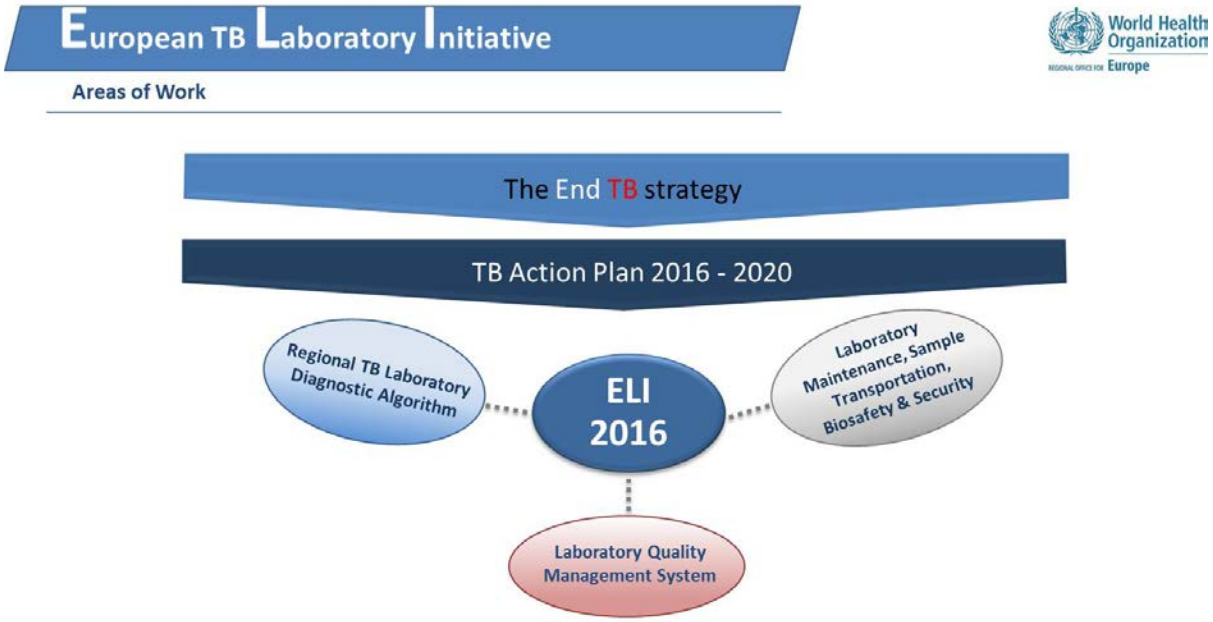
On 25 February 2016 the first meeting of the renewed ELI Core Group was held in Copenhagen, Denmark. Prior to this first face-to-face meeting a teleconference had been held during which Core Group members were divided into paired working groups, comprised of individuals from similar settings, in order to discuss and agree upon the major areas and topics that ELI would prioritize. The outcome of this initial work led to the identification of ten priority areas.[1] These priority areas include TB-specific areas as well as general areas important for any clinical microbiology laboratory and laboratory services. During the meeting in Copenhagen these areas were further discussed with all Core Group members and related topics merged. At the end of the plenary discussions the group agreed upon the following three key ELI activity areas (see Figure 1 and section 2.2):

A. Regional laboratory and clinical TB diagnostic algorithms
B. Quality management systems and biosafety
C. Laboratory maintenance and sample transportation.

[1] The ten identified priority areas were: finalization of a regional TB diagnostic algorithm; laboratory quality management system strengthening; laboratory biosafety and biosecurity; laboratory maintenance; clinical sample transportation; development of laboratory targets and indicators; laboratory advisory services; strengthening ELI and ECDC ERLN-TB collaboration; laboratory information systems; and laboratory human resource development plans.

Meeting participants were then divided into three working groups in order to develop and refine these proposed priority areas, and to determine the time frame for their completion. Prior to the meeting, consideration had been given to the optimum composition of each working group in terms of the backgrounds, technical skill sets and stated priorities of individual members. Such efforts were intended to ensure that the most appropriate mixture of expertise was available to each group, while also bearing in mind the need for geographical representativeness.

Figure 1: ELI's three major focus areas and working groups



To ensure progress in the activity areas identified, responsibilities were assigned to individual Core Group members and a working agenda and time frame developed for the furthering of these activities in the coming months. It was agreed that the progress made in each of the proposed actions listed below in section 2.2 would be reported on via regular teleconferences between WHO and the responsible ELI Core Group members.

In order to identify potential synergies and collaboration areas with ELI, presentations were given prior to the working group sessions on the European (ECDC) national TB reference laboratory network (ERLN-TB); GLI/WHO headquarters' strategic priorities and the post-2015 WHO End TB Strategy; the role of laboratories from a health systems perspective (WHO Regional Office for Europe Division of Health Systems and Public Health); the "Better Labs for Better Health" initiative (Influenza and Other Respiratory Pathogens Programme WHO Regional Office for Europe); and on national antimicrobial resistance (AMR) surveillance and associated CAESAR network (Antimicrobial Resistance programme WHO Regional Office for Europe).

Meeting background, scope and expected outcomes

Tuberculosis (TB) and particularly multidrug-resistant TB (MDR-TB) remain major public health concerns in the WHO European Region. Timely and accurate laboratory diagnostic services play a key role in detecting TB and providing patients with appropriate treatment. There is a need to improve TB and MDR-TB detection and to expand quality-assured susceptibility testing for second-line drugs. Similarly, rapid TB diagnostic methods need to be available and performed within laboratory networks that are rationally organized and tailored to country contexts. Such scaling up of TB diagnostic laboratory capacity is a key element highlighted in the *Tuberculosis action plan for the WHO European Region 2016–2020* which was endorsed by the WHO Regional Committee for Europe in Vilnius, Lithuania in September 2015. Successfully addressing the challenges in this area, including those associated with at-risk groups such as prisoners and people living with HIV, will require a paradigm shift in laboratory policy development and implementation. Such a shift will require the setting of laboratory norms and standards, the guiding and coordinating of technical assistance and the accelerating of knowledge transfer.

In response to this recognized public health need, the Global Laboratory Initiative (GLI) was established in 2008 as one of the seven main Working Groups of the Stop TB Partnership. Since then GLI membership has continued to grow, with more than 100 international partners joining forces to accelerate and expand access to quality-assured TB diagnostic services within integrated laboratory systems. In light of the specific needs and high MDR-TB rates in the WHO European Region, and the corresponding need to scale up TB diagnostic capacity in Member States, the WHO Regional Office for Europe and the GLI launched the European Tuberculosis Laboratory Initiative (ELI) in 2012.

The specific objectives of the meeting were: (a) to exchange information and know-how on TB laboratory development and to review and discuss relevant laboratory activities in the Region; (b) to review ELI priority areas and evaluate and further develop the outcome of paired-group work conducted in advance of the meeting; and (c) to reach consensus on at least three ELI priority actions. During the advance paired-group work a "wish list" of potential activity areas in which the ELI could potentially make significant contributions had been developed.

Expected meeting outcomes included strengthened group collaboration arising from the face-to-face discussions between ELI Core Group members and from engagement in the working group process. As a result of this process, three high-priority areas and seven sub-areas were proposed and agreed upon (see section 2.2).

Welcome and introduction

On behalf of the WHO Regional Office for Europe and Dr Nedret Emiroğlu, Director of the Division of Communicable Diseases, Health Security and Environment, Dr Masoud Dara welcomed participants to this first face-to-face meeting of the renewed European Tuberculosis Laboratory Initiative (ELI) Core Group.

The adoption and signing of the *Tuberculosis action plan for the WHO European Region 2016–2020* by the WHO Regional Committee for Europe at its 65th session in September 2015 represented a key event. This plan sets out the agreed milestones for the coming years in full alignment with the global WHO End TB Strategy and the European Health 2020

policy framework. Among the areas of intervention identified for action, strengthening the laboratory diagnosis of TB represents a vital component, with up to half of all cases of MDR-TB currently being missed. Addressing this and other challenges will require the application of a wide range of laboratory-specific and broader health system access approaches.

Dr Dara reminded the ELI Core Group members that every other year the WHO Regional Office for Europe prepares a progress report on the implementation of the TB action plan, and that the inputs of the group would be vital not only in reviewing the indicators but also in contributing to the qualitative assessment of progress, challenges and next steps. He also emphasized the need for the group to have close links with the WHO Regional Office for Europe Technical Advisory Group (TAG) for TB. Dr Dara also indicated that although there is currently no specific funding stream for ELI activities, limited funding for strengthening laboratory biosafety in selected countries was foreseen under the WHO Regional Office for Europe–USAID Regional Platform mechanism.

There is a pressing need to make progress and to address the currently fragmented technical assistance offered by various agencies and organizations, and in this respect the ELI can play a vital role in improving the situation. Strengthened collaboration with other WHO programmes and initiatives already under way will be a key determinant of success, and presentations were to be given at this meeting on a number of such activities and intended synergies. Dr Dara also stressed the need for intersectoral collaboration as efforts will need to extend beyond the health sector in line with the European Health 2020 policy framework and implementation of the Sustainable Development Goals.

Dr Francis Drobniewski was elected as Chair of the meeting and provided participants with an overview of the meeting structure. In line with WHO policy, Declarations of Interest and Confidentiality Undertakings had been completed, signed and returned by all participants, with none of the declared interests deemed to constitute a conflict of interest. Participants were reminded that they were being asked to act in their capacity as experts to WHO and not as representatives of their organizations or national governments. Dr Drobniewski emphasized that the round-table face-to-face discussions at this meeting would provide a valuable opportunity to identify key priorities for action. Despite the challenge of limited funding in many settings, there was a need to be ambitious in setting out proposed new activities, and to identify how best to harness and expand upon efforts currently under way.

Part 1: Presentations and discussion

1.1 The European TB Laboratory Initiative (ELI)

Dr Soudeh Ehsani highlighted the mission of the ELI to strengthen TB laboratory capacity in the WHO European Region, with a focus on the 18 high-TB-priority countries. ELI priority areas had been consolidated, aligned with the global post-2015 WHO End TB Strategy and reflected in the *Tuberculosis action plan for the WHO European Region 2016–2020*. Dr Ehsani then outlined the three "pillars" of the *Tuberculosis action plan for the WHO European Region 2016–2020* which taken together constituted a comprehensive range of areas of intervention. Dr Ehsani continued by presenting an overview of some of the gains made in strengthening TB laboratory activities in recent years, including the increased performing of rapid molecular methods and drug-susceptibility testing (DST). Dr Ehsani underlined the mismatch between DST performance increases and the unchanged number of laboratories participating in, and successfully completing an EQA programme. Dr Ehsani

then presented the ten identified ELI priority areas which had emerged during paired group work conducted prior to the meeting both during and following a previous teleconference. This showed a range of activity areas in which the ELI could potentially make significant contributions.[1] Dr Ehsani concluded by introducing the 12 newly elected ELI Core Group members for the period 2016–2018 (see Annex 1).[2]

During discussion a number of potential obstacles to the participation of some countries in EQA programmes were identified by meeting participants. These included staff and other laboratory costs needed to process, score and return the panel, the need for legal and other documentation during shipping and lack of staff training in the required administrative processes. In light of the recognized benefits of participation in EQA programmes there was agreement that significant potential benefits might be gained by establishing a more coordinated and sustainably funded strategy for supporting laboratory participation. This could include improved communication of the purpose and benefits of such participation to laboratories and ministries of health, along with training support in shipping and associated procedures. Laboratories could then potentially cut participation costs by reducing their dependence upon external logistics support. It was agreed that a number of these and related issues constituted relevant ELI activity areas, and that efforts were now needed to accurately determine the precise issues involved and identify the best way forward.

1.2 The European national TB reference laboratory network (ERLN-TB)

Dr Drobniewski emphasized the need to coordinate efforts in areas where ongoing activities and resources could efficiently be utilized. One such potential synergy existed with the ERLN-TB. Established in 2010 this network now consisted of 38 National Reference Laboratories and key regional centres from the European Union/European Economic Area (EU/EEA) and candidate countries. In 2012, designated representatives of laboratories involved in the European Centre for Disease Prevention and Control MDR/XDR molecular surveillance project joined the network representing a major collaborative achievement. The network provides a sustainable platform for the open discussion of issues, problems and best practices relevant to EU/EEA countries, for the establishment of procedures for identifying and taking corrective actions, and for the improved harmonization of activities.

Since 2010 there had been three meetings of the ERLN-TB. Key network outputs had included the strengthening of TB control, laboratory diagnosis and management within the EU/EEA and beyond. Approaches used had included training activities, the establishment and maintaining of high standards in TB laboratory diagnosis, and the developing and implementing of EQA schemes. Dr Drobniewski then outlined a range of ERLN-TB resources and support activities. In addition to the publication of reports and handbooks, a range of technical guidance had been developed and an innovative programme of training rolled out involving 14 support experts from 10 EU countries. This was supported by assessment visits and by an external EQA programme involving more than 30 laboratories. A strategy for the integration of molecular genotyping into ERLN-TB activities to improve and maintain high-quality molecular genotyping had also been developed, involving the implementing of universal standards for molecular genotyping EQA and proficiency testing across EU/EEA countries based on international guidelines and strategies. Dr Drobniewski also highlighted a number of resilience and continuity arrangements that had been put in

[2] For further details see also: http://www.euro.who.int/en/health-topics/communicable-diseases/tuberculosis/activities/european-tuberculosis-laboratory-initiative/core-group-members-of-the-european-tuberculosis-laboratory-initiative-eli,-2016-2018

place, along with the establishment of a reference strain collection for use as an EU resource. The issue of securing funding beyond the current four-year ERLN-TB contract was highlighted.

1.3 Global Laboratory Initiative (GLI) strategic priorities in line with the post-2015 WHO End TB Strategy

Mr Wayne van Gemert provided an overview of the structure and mission of the GLI and of its strategic priorities 2016–2017. In its capacity as one of the seven main Working Groups of the Stop TB Partnership, the GLI operates as a network of international partners dedicated to accelerating and expanding access to quality-assured laboratory services in response to the diagnostic challenges of TB. Coordinated by the GLI Core Group with support from the Secretariat, the mission of the GLI and its network of international partners is to serve as a collaborative platform for the development and uptake of practical guidance and tools for building and sustaining high-quality TB diagnostic networks. Towards this objective, specific activities are being undertaken in the areas of: (a) implementation of WHO policy guidance on TB diagnostics and laboratory strengthening; (b) health system solutions and innovations for ensuring rapid and accurate testing, and linkage to appropriate patient management; (c) continuous quality improvement at all levels of the laboratory network; (d) integration of laboratory diagnostic networks; (e) human resource capacity development; and (f) advocacy and resource mobilization.

After outlining the broad membership of the GLI Core Group, Mr van Gemert provided an overview of its achievements during the period 2014–2015. These include guidance on the provision of technical support to TB laboratories in low- and middle-income countries, an online tool to facilitate stepwise laboratory accreditation, training and support materials, face-to-face meetings and the formation of GLI Africa. GLI strategic priorities for 2016–2017 were then presented and included the development, introduction and monitored implementation of a range of further guidance, training and technical resources. It is intended that an assessment would be made of the current uptake of GLI tools in order to inform their further modification and strategic promotion.

Mr van Gemert then drew attention to the longer term goals of both the recently launched United Nations Sustainable Development Goals and of the WHO End TB Strategy. Building on the gains made to date concerted efforts would continue to be directed towards supporting the attainment of the clear milestones that had been set out over the coming two decades. Mr van Gemert then reiterated the overlapping activity areas of the GLI and of the three pillars of the WHO End TB Strategy, and concluded by outlining a number of planned WHO review activities scheduled for 2016–2017 in relation to the development of policy guidance on diagnostic strategies.

During discussion, the issue of tailored guidance on biosafety in TB laboratories was raised. It was highlighted that generic WHO guidance in this respect already existed and the GLI was always open to suitable tools in this and other areas that could be recommended. It was further noted that research initiatives would be a key part of progress in areas such as the development of diagnostic strategies, and the use of short-course treatment regimens and associated leveraging of international funding. In relation to the development of diagnostic strategies, the need for diagnostic algorithms was also highlighted along with the key importance of involving not only laboratory technicians but also clinicians as this was also a key target group for training and support efforts.

1.4 Role of laboratories from a health systems perspective

Ms Regina Winter, speaking on behalf of Dr Hans Kluge, Director of the Division of Health Systems and Public Health (DSP), highlighted the recent Ebola epidemic as an example of the central role of health systems not only in delivering services to improve, maintain or restore health but also in areas such as the prevention and control of communicable disease. WHO efforts to support health system strengthening in the WHO European Region was informed by the twin strategic priorities of transforming health services to meet the health challenges of the 21st century while moving towards universal health coverage for a Europe free of impoverishing out-of-pocket payments. These strategic priorities had recently been endorsed by the 65th session of the WHO Regional Committee for Europe. Furthermore, the DSP operational approach, which rests on the three pillars of expected results, core services and removal of health-system bottlenecks, and is used for supporting Member States in health system strengthening, was outlined.

In the specific case of TB, health system strengthening was one of several parallel processes and initiatives under way aimed at making a coherent contribution to targets and policy at different levels. In support of activities in eastern European and central Asian countries, a consortium including the Center for Health Policies and Studies, the WHO Regional Office for Europe and other partners had initiated a proposal to the Global Fund for a TB regional project for health system transformation and financing reform (TB-REP). Ms Winter outlined a number of ways in which both health systems strengthening activities and TB-REP would support the strategic directions of the *Tuberculosis action plan for the WHO European Region 2016–2020*. Specific TB-REP expected outcomes included the adoption of key policies and strategies by countries to improve models of care and health-financing mechanisms, improve the cost-effectiveness of TB activities, reduce reliance on external donors, and reduce hospitalization rates and average length of hospital stay. Ms Winter concluded with an overview of a number of key health-system bottlenecks in the functioning of laboratory services within national TB programmes. The key areas identified for attention were governance, service delivery, health financing and resource generation.

Discussions then centred around the ways in which the high-level aims of TB-REP and other health systems strengthening activities could best be translated into the practical steps needed. It was clarified that TB-REP was at an early stage and that efforts would now be made to develop national roadmaps for health systems strengthening, including through the convening of high-level working groups and other advocacy efforts to engage national political support. It was further clarified that national health plans were already in place in many countries and that the intention was to support these through the identification and broader application of successful approaches. Support would also be given to ongoing national efforts in relation to specific aspects of health system strengthening such as health-finance reform.

1.5 “Better Labs for Better Health”

Dr Caroline Brown presented an overview of laboratory-related activities of the Division of Communicable Diseases and Health Security at the WHO Regional Office for Europe which include a laboratory coordination group, a dedicated WHO laboratory services website (http://www.euro.who.int/en/health-topics/Health-systems/laboratory-services) and networks for surveillance and response activities. Established laboratory networks included those for poliomyelitis, measles/rubella, influenza and emerging pathogens, with more recent initiatives having being set up for TB and HIV. Typical activities included the development

of standards for laboratory surveillance and a range of training, EQA and accreditation activities.

Dr Brown then introduced the recent "Better Labs for Better Health" initiative and its mission to improve health by providing timely and accurate laboratory results from accredited and trusted laboratories. The rationale behind this initiative included the need to address the frequently fragmented and duplicated services provided by laboratories which often lacked robust quality and safety standards, oversight and supervision. In many countries there are currently no initiatives aimed at improving the national laboratory system as a whole. The coordinated three-pronged approach of the "Better Labs for Better Health" initiative consists of the development and implementation of national laboratory policies and strategic plans, the improving of national training programmes and implementing of quality management systems, and the upgrading of critical infrastructure. The central mechanism for achieving the desired outcomes is the establishment in each country of a National Laboratory Working Group. Such groups had now been set up in five countries and significant progress made in areas such as national policy and strategy development and endorsement, and curriculum evaluation. Among the key priorities identified was the need to improve laboratory quality by developing training for laboratory managers, senior biologists and technicians in quality management systems based upon the WHO Laboratory Quality Management System Training Toolkit, and its complementary Laboratory Quality Stepwise Implementation tool – which itself had been modelled on the GLI tool used for TB laboratory accreditation. Dr Brown concluded by outlining recent progress and guiding principles in the implementation of such training, and highlighted the key role of suitably qualified mentors in ensuring the success of the initiative at laboratory level. As mentoring was an intensive activity, a training-of-trainers process was now under way.

Discussion topics included the importance of ensuring sustained funding for such a key activity that enjoyed a high level of interest given the acknowledged role of public health laboratories in all countries, including in the crucial area of preparedness and response to emerging threats. It was also clear that there was much overlap between this broad new initiative and the specific objectives of the ELI and significant potential synergies could be harnessed. In many settings, the implementing of non-disease-specific approaches would be the key to building up laboratory capacities. Attention would however need to be paid to ensuring that better laboratories did indeed equate to better health and that improvements in laboratory services were linked to improved accessibility and use. Given the unavoidable expense of investing in and operating laboratories any strengthening of laboratory performance must be demonstrably linked to improved health outcomes. Dr Brown pointed out that indicators for assessing progress and impact in this respect were being developed.

1.6 National antimicrobial resistance (AMR) surveillance and CAESAR

Dr Danilo Lo Fo Wong presented an overview of the importance of AMR surveillance in informing local, national and regional actions, guiding patient treatment, monitoring intervention effectiveness, and detecting and understanding the spread of resistance. As part of expanding AMR surveillance throughout Europe, the Central Asian and Eastern European Surveillance of Antimicrobial Resistance (CAESAR) network had been established as a joint initiative of the WHO Regional Office for Europe, the European Society of Clinical Microbiology and Infectious Diseases and the Dutch National Institute for Public Health and the Environment. Acting as a network of national AMR surveillance systems CAESAR incorporated all countries in the WHO European Region that were not part of the European

Antimicrobial Resistance Surveillance Network, coordinated by the European Centre for Disease Prevention and Control.

The organizational structure and methodology underlying the network was outlined, and the three distinct phases involved in the establishment of national AMR surveillance set out. Recent CAESAR activities had included country situation analysis and follow-up activities, the convening of national and multi-country workshops and a recent EQA programme involving 250 laboratories in 15 countries. The first annual CAESAR report had been published in October 2015 based upon results from five countries, with the available data graded according to degree of reliability and representativeness. The annual report also presented the results of a 2013 EQA programme conducted in nine countries.

During discussion there was broad recognition of the high profile of AMR surveillance activities on the political agenda, and of its relevance to MDR-TB. It was also recognized that building a culture of EQA in this area was at an early stage, and that there might be benefit at some point in adding to the six strains used in the latest panel in order to increase the current level of detail captured in the results. Information on the methodologies used by participating laboratories was currently obtained using associated questionnaires.

Part 2: Working group sessions

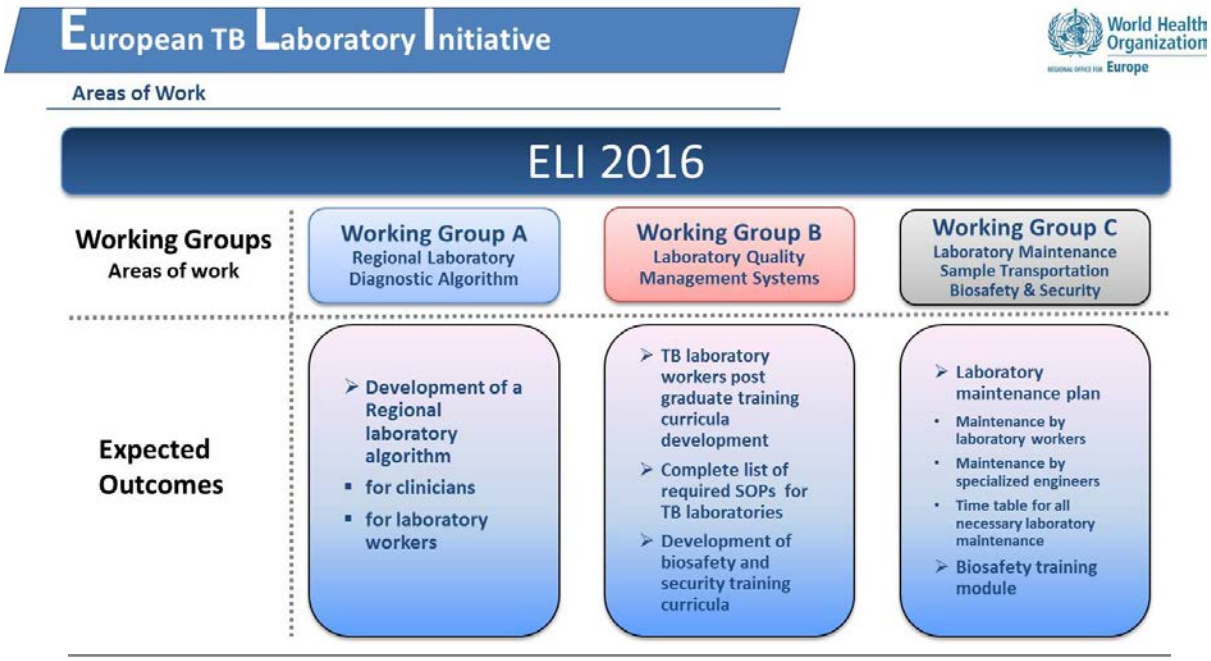
2.1 Introduction

Following the Part 1 presentations and associated plenary discussions, meeting participants divided into three working groups (Figure 2) in order to develop and refine a number of proposed priority actions, and to determine the time frame for their completion. Prior to the meeting, consideration had been given to the optimum composition of each working group in terms of the backgrounds, technical skill sets and stated priorities of individual members. Such efforts were intended to ensure that the most appropriate mixture of expertise was available to each group, while also bearing in mind the need for geographical representativeness.

A teleconference had also been held in advance of the meeting in order to identify candidate priority actions that could most effectively be addressed by the working group process. During the working group discussions these were further refined and proposed action points finalized. Key issues arising during feedback discussions included the crucial need for quality management systems to promote trust in laboratory findings among clinicians and other users, and to support the case for investing in the human and other resources required. It was recognized that promoting such trust would be dependent upon robust quality-assurance processes being in place. As the quality management system concept was very broad and potentially onerous, attention would need to be given by the ELI working groups to which aspects of laboratory activities could feasibly be strengthened immediately and to clearly setting out the purpose of such a system.

It was agreed that the progress made in each of the proposed actions listed below in section 2.2 would be reported on via monthly teleconferences between WHO and the responsible ELI Core Group members.

Figure 2: ELI Working Groups, their areas of work and expected outcomes



2.2 List of proposed actions and implementation time frame

ELI Working Group A

- **Proposed action A.1 – Develop and finalize a regional algorithm for the laboratory diagnosis of TB**

Intended outcome would be an updated algorithm to reduce the length of time and costs involved in confirming the diagnosis of TB, MDR-TB and XDR-TB. Following on from work initiated by the previous ELI Core Group it was envisaged that the algorithm would incorporate accelerated quality-assured new diagnostic technologies. Although global algorithms developed by GLI already exist there is a need to take regional factors into consideration as part of increasing their applicability. There is also a need to expand the content areas covered by the algorithm to include important biosafety, logistical and other aspects of activities such as sample transportation, and to inform procedures for the laboratory interpretation and communication of conflicting results.

Time frame: first draft to be prepared by end of April 2016 with completion by end of August 2016.

- **Proposed action A.2 – Develop and finalize an algorithm for use by clinicians**

Intended outcome would be an algorithm tailored for use by clinicians to strengthen and support collaboration and understanding with TB laboratory workers in terms of requesting the correct diagnostic technique and interpreting its result, supported by accordingly developed TB clinical protocols and other guidance.

Time frame: first draft to be prepared by end of April 2016 with completion by end of August 2016.

ELI Working Group B

- **Proposed action B.1 – Development of a comprehensive list of all TB-specific activity areas, procedures and circumstances for which laboratory SOPs are required as part of strengthened quality management systems**

It was indicated that such an overarching listing covering a wide range of operational aspects already exists and that this could be the basis for the development of an updated, expanded and completed resource. This could then be used to "map" available up-to-date SOPs in individual areas and help ensure their use in key identified areas. A key element of success in this area would be the harnessing of the already existing SOP resources covering almost all operational aspects. This would also provide a platform for emphasizing the paramount importance of such internal checking procedures as part of a quality management system that would then complement the use of EQA in facilitating external accreditation, while at the same time reducing over-reliance on EQA alone.

Time frame: first draft to be prepared by end of April 2016 with completion by end of June 2016 for presentation to national tuberculosis programmes.

- **Proposed action B.2 – Develop training curricula for laboratory workers in nursing and medical schools, post-graduate colleges and other relevant teaching institutions**

With the introduction of new techniques the updating of training curricula is important to guarantee the sustainable development of new laboratory workers. Furthermore, there is currently a lack of specific TB-related content in national medical and microbiology training courses and curricula. The development of an updated and where required specific training module could be a first step in moving towards national recommendations on TB-related training.

Time frame: decision on initial target groups (laboratory technician, doctor or manager), collection and analysis (differences versus similarities) of representative existing relevant training curricula and gap analysis. First draft to be prepared by end of June 2016 for presentation to the meeting of national tuberculosis programme (NTP) managers in Bratislava in June 2016.

ELI Working Group C

- **Proposed action C.1 – Develop a maintenance plan systematically listing all daily, weekly, monthly and other periodic TB laboratory maintenance requirements, and indicating the level of both internal and external expertise required for the safe and effective completion of each of the identified actions**

This was viewed as an opportunity for ELI to make the case for the primacy of safety and of the fundamental importance of established maintenance procedures. Potential approaches in this area included the training of individuals to cover specialist servicing requirements across several laboratories, the use of regional level resources and the coupling of equipment purchasing to manufacturer maintenance support contracts.

Time frame: first draft to be prepared by end of April 2016 with completion by end of June 2016 for presentation to national tuberculosis programmes.

- **Proposed action C.2 – Develop a biosafety training module for laboratory technicians and other personnel**

Consideration should be given to the scope and purpose of such a module and to the time and likely extent of external expertise required to deliver its content. It was pointed out that WHO guidance exists in this area but that this could usefully be clarified and made more user friendly in relation to a number of specific aspects of TB laboratory biosafety.

Time frame: first draft to be prepared by October/November 2016 for discussion at the next ELI Core Group meeting.

- **Proposed action C.3: Develop guidelines on all aspects of the transportation of potentially hazardous and time-critical clinical TB samples, cultures and DNA**

It was envisaged that this would include guidance on key topics such as the optimum timing and frequency of shipping of such materials.

Time frame: first draft to be prepared by October/November 2016 for discussion at the next ELI Core Group meeting.

Closing comments and next steps

Dr Dara thanked the ELI Core Group members for all their voluntary efforts and valuable contributions. He reminded meeting participants that in addition to operational activities to strengthen TB laboratory networks there was also a vital need to map efforts to current strategic approaches, to help catalyze other ongoing initiatives and to engage with all relevant partners to promote a broad sense of ownership around ELI activities. In these endeavours ELI Core Group members would play a crucial role in providing state-of-the-art policy papers, strategic direction and technical guidance. Dr Dara noted the intention of ELI Core Group members to hold regular teleconferences both within the working groups and with all ELI members, and welcomed the aim of presenting the inputs and selected outcomes of the ELI working groups at the upcoming meeting of national tuberculosis programme (NTP) managers in Bratislava in June 2016.

Annex 1: List of participants

ELI Core Group members

Dr Francis Drobniewski (Chair), *Imperial College London,* ***the United Kingdom***

Dr Irina G Felker, *Novosibirsk TB Research Institute,* ***Russian Federation***

Dr Sven Hoffner, *Head of the WHO Supranational TB Reference Laboratory Sweden, Karolinska Institute,* ***Sweden***

Dr Gulmira I Kalamambetova, *National Reference Laboratory,* ***Kyrgyzstan***

Dr Katharina Kranzer, *Head of the WHO Supranational TB Reference Laboratory, NRL and Research Centre Borstel,* ***Germany***

Dr Hasmik Margaryan, *National TB Control Centre,* ***Armenia***

Mr Evgeni R Sahalchyk, *WHO Supranational TB Reference Laboratory,* ***Germany***

Dr Elina V Sevastyanova, *Central TB Research Institute,* ***Russian Federation***

Dr Natalia Shubladze, *National Centre for TB and Lung Diseases of Georgia,* ***Georgia***

Ms Nukra Sinavbarova, *Republican Public Health Reference Laboratory,* ***Tajikistan***

Dr Alena Skrahina, *Republican Research and Practical Centre for Pulmonology and Tuberculosis,* ***Belarus***

Dr Rasim Tahirli, *WHOCC on Prevention and Control of Tuberculosis in the Penitentiary System*, ***Azerbaijan***

World Health Organization

WHO Regional Office for Europe

Dr Caroline Brown, Programme Manager, Influenza and Other Respiratory Pathogens

Dr Masoud Dara, Programme Manager a.i., Tuberculosis and M/XDR-TB control programme, and WHO Senior Advisor, WHO Office at the European Union

Dr Soudeh Ehsani, TB and M/XDR-TB Laboratory Focal Officer

Dr Danilo Lo Fo Wong, Programme Manager, Control of Antimicrobial Resistance

Ms Regina Winter, Consultant, Division of Health Systems and Public Health

Ms Anne-Birgitte Gradman, Secretary, Tuberculosis and M/XDR-TB control programme

Ms Elizabeth Neville, Programme Assistant, Tuberculosis and M/XDR-TB control programme

WHO headquarters

Mr Wayne van Gemert, Technical Officer, WHO Global TB Programme

Rapporteur

Dr Anthony L Waddell, Freelance, the United Kingdom

Annex 2: Meeting agenda

Time	Topic	Facilitator/speaker/chair
09:30–09:45	Welcome and introduction	**Dr Masoud Dara**, Acting Tuberculosis Programme Manager, Joint Tuberculosis, HIV/AIDS and Hepatitis Programme, WHO Regional Office for Europe
09:45–10:00	Overview on ELI, its past activities and achievements and presentation of the new Core Group (CG) members 2016–2018	**Dr Soudeh Ehsani**, ELI CG Secretariat, Technical Officer, Joint Tuberculosis, HIV/AIDS and Hepatitis Programme, WHO Regional Office for Europe
10:00–10:15	Proposed areas for ELI to focus on in line with the new TB-Action Plan 2016-2020	**Professor Francis Drobniewski**, ELI CG Chair, Professor of Global Health and Tuberculosis, Imperial College London, Professor of International Health and Mycobacterial Diseases (Hon), Queen Mary and King's College London
10:15–10:30	Introduction of GLI goals in line with the Post-2015 Global End TB Strategy	**Dr Wayne van Gemert**, GLI CG Secretariat, Technical Officer, WHO Global TB Programme, Geneva, Switzerland
10:30–10:45	Role of laboratories from a health systems perspective	**Ms Regina Winter**, Consultant, Division of Health Systems and Public Health, WHO Regional Office for Europe
11:15–11:30	Update on Better Labs for Better Health	**Dr Caroline Brown**, Programme Manager for Influenza & other Respiratory Pathogens, Lab Coordinator for Division of Communicable Diseases and Health Security, Lead of the WHO/Europe “Better Labs for Better Health” Initiative, WHO Regional Office for Europe
11:30–11:45	Update on AMR Lab activities	**Dr Danilo Lo Fo Wong**, Programme Manager, Control of AMR, Communicable Diseases and Health Security, WHO Regional Office for Europe
13:00–14:30	Discussion with all CG members on the ELI focal points	ELI CG Chair Prof Francis Drobniewski & ELI CG Secretariat Dr Soudeh Ehsani
14:30–16:00	Working group session group A	Four CG members
14:30–16:00	Working group session group B	Four CG members
14:30–16:00	Working group session group C	Four CG members
16:30–17:30	Feedback from the working groups	ELI CG Chair Prof Francis Drobniewski & ELI CG Secretariat Dr Soudeh Ehsani
17:30–17:45	Next steps and final remarks	**Dr Masoud Dara**, Acting Tuberculosis Programme Manager, Joint Tuberculosis, HIV/AIDS and Hepatitis Programme, WHO Regional Office for Europe