World Health Organization
REGIONAL OFFICE FOR Europe

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

Copenhagen, Denmark
25 August 2017

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 TB high-priority countries of the Region. The third face-to-face meeting of the renewed ELI core group was held on 25 August 2017 in Copenhagen, Denmark. The meeting objectives were to: (i) discuss the outputs and achievements of the renewed core group since February 2017; (ii) brainstorm on future activities; (iii) exchange experiences and discuss the challenges and opportunities of joint TB/HIV diagnostic services; and (iv) discuss the requirements to ensure full implementation of the Genotype MTBDR*s*/ assay version 2 in the Region. A range of possible future activities and areas of work were discussed and three immediate tasks were agreed upon. These were to: (i) produce a briefing document to support the integration of HIV and TB testing using the GeneXpert platform; (ii) produce a draft outline on the training of laboratory staff for setting up and using line probe assays for resistance to second-line anti-tuberculosis drugs and; (iii) prepare a concept note describing data management systems for laboratories. A number of other potential areas of interest for future activities were also discussed and plans will be developed further at subsequent meetings of the group.

Keywords

TUBERCULOSIS – DIAGNOSIS
TUBERCULOSIS, MULTIDRUG-RESISTANT – DIAGNOSIS
HIV INFECTIONS – DIAGNOSIS
COINFECTION – DIAGNOSIS
CAPACITY BUILDING
CLINICAL LABORATORY TECHNIQUES
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Abbreviations

ELI	European Tuberculosis Laboratory Initiative
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GLI	Global Laboratory Initiative
PLHIV	people living with HIV
rGLC	regional Green Light Committee
MDR-TB	multi drug-resistant tuberculosis
SL-LPA	line probe assay for resistance to second-line anti-tuberculosis drugs
TB	tuberculosis

Executive summary

The European Tuberculosis Laboratory Initiative (ELI) was set up in 2012 by the WHO Regional Office for Europe and the Global Laboratory Initiative (GLI). The overarching aims of the initiative are to accelerate and expand access to quality-assured tuberculosis (TB) diagnostic services across the WHO European Region, particularly in the 18 high-priority countries. The Regional Office hosts the ELI secretariat, and ELI core group members include individuals from national and supranational TB laboratories as well as international partners and experts.

The ELI core group was renewed on January 2016: 11 members were chosen from 10 countries by a selection committee of representatives from GLI, WHO GTP, the Stop TB Partnership and the WHO Regional Office for Europe. During their first meeting on 25 February 2016 in Copenhagen, Denmark, the group discussed priority areas of work and agreed outputs. The second meeting of the core group took place on 30 November 2016 and the core group along with other ELI members met with partners from the "Better Labs for Better Health" initiative on 1–2 December 2016. The regional laboratory diagnostic algorithm was approved during that meeting and the feedback obtained from the members of the "Better Labs for Better Health" initiative was incorporated into the laboratory maintenance plan. Overall, the joint meeting served as a useful exchange of knowledge and experience.

At the third face-to-face meeting on 25 August 2017 in Copenhagen, Denmark, the achievements and outputs of the ELI core group were reviewed. All three outputs agreed by the core group in 2016 have now been delivered: regional diagnostic algorithms; a technical document that provides guidance on TB laboratory maintenance, biosafety and quality assurance; and supporting tools on the correct use and reporting of WHO-recommended rapid molecular tests for TB and MDR-TB. Strengthening collaboration between HIV and TB diagnostic services in the Region was seen as a key area for future activities, and discussions around this topic evolved into a strengths, weaknesses, opportunities and threats (SWOT) analysis. Factors that can accelerate the introduction and implementation of Genotype MTBDR*sl* assay version 2 (MTBDR*sl* VER 2) were also identified. Members volunteered to take responsibility for three immediate tasks, which were to: (i) produce a briefing document for integrating HIV and TB testing using the GeneXpert platform; (ii) produce a draft outline on laboratory staff training for setting up and using line probe assays (LPAs) for resistance to second-line anti-TB drugs (SL-LPA); and (iii) prepare a concept note describing data management systems for laboratories. A number of other potential areas of interest for future activities were also identified.

Meeting background, scope and expected outcomes

Efficient, high-quality laboratory diagnostic services that comply with recommended biosafety measures are of key importance to Region-wide efforts aimed at controlling, detecting and treating TB and MDR-TB. Despite the ongoing decrease in the number of TB cases in the WHO European Region, TB remains an important threat to public health and is becoming increasingly difficult and expensive to treat. Recent surveillance data from the Region show that only 61% of TB cases are bacteriologically confirmed, rifampicin resistance is high (at 44% of new cases and 49% of previously treated cases) and an estimated 23.4% of all MDR-TB patients tested for second-line drug sensitivity have extensively drug-resistant strains. Regional coverage of second-line drug sensitivity testing has improved significantly; however, scaling up of WHO-recommended rapid molecular tests must be further accelerated to reach the 100% target set in the TB Action Plan 2016–2020.

The objectives of the third face-to-face meeting of ELI core group members on 25 August 2017 were to:

- discuss the outputs and achievements of the renewed ELI core group (2016–2018);
- generate ideas about future activities; and
- present and lead a discussion on two main topics (two discussants from the ELI core group):
- challenges and opportunities for TB/HIV diagnostic services; and
- what is needed to ensure full implementation of the MTBDRsl VER 2 diagnostic test?

Expected outputs from the meeting were a summary of achievements, a list of future priority activities and a meeting report.

Welcome

Dr Masoud Dara welcomed ELI core group members and commended the group on the achievements made since its first meeting in February 2016. He lamented the loss of Dr Sabine Ruesch-Gerdes, who had tirelessly given her time and expert support to ELI and the regional Green Light Committee (rGLC). Although the group have successfully identified gaps in laboratory capacity within the WHO European Region, the current challenge is to address these issues to make an even stronger impact is now needed in countries. More active collaboration with the rGLC would be a practical step forward since the rGLC has operational access to countries. Additional new resources also need to be mobilized. New donors could assist in sponsoring ELI activities and a larger active network extending beyond the core group could include academics, researchers, nongovernmental organizations and other partners. Participation in the network needs to be encouraged and volunteers can form an online community to share information on laboratory-related issues in the Region.

Part 1. Achievements and discussant sessions

ELI achievements and the way forward

Dr Soudeh Ehsani, ELI core group secretariat, briefly summarized the achievements of the ELI core group since the first face-to-face meeting in February 2016 (she had presented a full account the previous day at the ELI Regional TB and MDR-TB diagnosis workshop). She congratulated the core group on achievement in delivering all three outputs since February 2016: the Algorithm for laboratory diagnosis and treatment-monitoring of pulmonary tuberculosis and drug-resistant tuberculosis using state-of-the-art rapid molecular diagnostic technologies (2017)[1]; the technical document, Tuberculosis laboratory maintenance plan (LMP) for preventive and routine maintenance of laboratory equipment[2]; and training tools on the correct use and reporting of WHO-recommended rapid molecular tests (i.e. LPAs) for TB and MDR-TB. Five training sessions on the practical application of the diagnostic algorithm at WHO collaborating centres in Riga, Latvia and Novosibirsk (Siberia, Russian Federation) were attended by over 90 TB specialists from six high

[1] Algorithm for laboratory diagnosis and treatment-monitoring of pulmonary tuberculosis and drug-resistant tuberculosis using state-of-the-art rapid molecular diagnostic technologies (2017). Copenhagen: WHO Regional Office for Europe; 2017 (http://www.euro.who.int/en/publications/abstracts/algorithm-for-laboratory-diagnosis-and-treatment-monitoring-of-pulmonary-tuberculosis-and-drug-resistant-tuberculosis-using-state-of-the-art-rapid-molecular-diagnostic-technologies-2017, accessed 5 November, 2017).

[2] Tuberculosis Laboratory Maintenance Plan (LMP) for preventive and routine maintenance of laboratory equipment. Expert opinion of the European Tuberculosis Laboratory Initiative 2017. Copenhagen: WHO Regional Office for Europe; 2017.

MDR-TB burden countries. In 2016, subregional training on biosafety cabinet maintenance in Armenia was attended by engineers and technicians from Armenia, Belarus and the Republic of Moldova. A similar training session will be held in Tbilisi, Georgia, in September 2017 in collaboration with an expert from the Centres for Disease Control and Prevention, Atlanta, Georgia, the United States of America, and Vladimir Regional TB Control Centre, Vladimir, Russian Federation. In December 2016, a joint meeting between ELI members and their partners from the "Better Labs for Better Health" initiative was held in Tbilisi, Georgia. It included representatives from over 20 countries in the Region and representatives from the United States Centres for Disease Control and Prevention, the Foundation for Innovative New Diagnostics and the European Reference Laboratory Network for TB of the European Centre for Disease Control and Prevention. This was followed by a short discussion on future activities on the practical and operational aspects of ELI-related activities, in which the following points were raised:

- ELI has received specific requests to provide information on the new diagnostic methods and more training sessions.
- A clear description of the modus operandi for core group members is available on the ELI webpage of the WHO Regional Office for Europe website[3] but the terms of reference for non-core group members still need to be formulated.
- The added value of ELI is that it includes experts from a range of countries with varying disease burdens. This contrasts with expert groups of the European Union and European Centre for Disease Prevention and Control, which tend to focus on low-burden countries for TB.
- ELI represents a valuable expert resource that could be deployed more effectively to support rGLC missions. The ELI secretariat can currently accept requests from the rGLC for technical support in laboratory services. In the future, ELI core group members will provide support for rGLC missions and report review.
- The ELI brand should be strengthened and junior "support experts" need to become more actively involved.
- In the role of external expert, ELI can contribute to periodic (three- to five-yearly) reviews of countries' National TB Programmes and thus bring greater balance to the review reports.

[3] http://www.euro.who.int/en/health-topics/communicable-diseases/tuberculosis/areas-of-work/laboratory-diagnosis/about-the-european-tuberculosis-laboratory-initiative-eli.

- Understanding of the mechanisms and consequences of genetic mutations in the bacterium *Mycobacterium tuberculosis* is incomplete. A database that collects and archives this data would be a useful repository and could be used to study dynamic shifts in disease patterns within the Region.

Discussant session

Addressing TB/HIV coinfection: challenges and opportunities

Dr Gulmira Kalmambetova, ELI core group member, described her observations on the increasing interest in Kyrgyzstan in using GeneXpert machines to manage HIV-infected patients. Although HIV programmes appear to be well funded, in practice HIV laboratories in ex-Soviet countries are highly centralized compared with TB services. This results in long delays for HIV specialists in receiving test results and incurs high transportation costs. The additional use of GeneXpert machines in HIV testing is creating extra demand on TB laboratories. According to Dr Kalmambetova, the experience has proven to be very positive and has encouraged good communication between laboratory staff and clinicians. However, she suggested that laboratory services would be best served by incorporating HIV testing in a gradual stepwise manner.
The role of the Cepheid GeneXpert platform in HIV testing was explained. This technology can be used to measure HIV-1 RNA concentrations in blood plasma (HIV viral load). For example, molecular diagnostic tests such as the Xpert HIV-1 viral load assay can be used to assess the prognosis of HIV-positive patients and their response to antiretroviral therapy. However, the test is not used for HIV diagnosis or screening. Cepheid received WHO prequalification for the Xpert HIV-1 viral load test in July 2017.

This topic generated much interest and debate among core group members. A distillation of the presentation and discussion is presented as a SWOT analysis in Fig. 1.

Fig. 1. SWOT analysis of the use of GeneXpert for combined TB/HIV testing

Strengths	**Weaknesses**
Positive patient perspective More robust data Efficiencies and cost savings	Vertical HIV and TB programmes No WHO policy recommendation for Xpert HIV-1 viral load testing of PLHIV Added responsibility for TB laboratories Lack of experience in HIV laboratories Separate logistics Separate data flows Low throughout Not a point-of-care TB test
Opportunities	**Threats**
WHO is setting an example Funding Natural link between TB and HIV services Data for mapping is available	Biosafety concerns Staff reluctance Poor communication Competing interests Weak HIV data Mixing MDR-TB with PLHIV

PLHIV: people living with HIV.

Strengths

Positive patient perspective. TB/HIV coinfection is emerging as a growing challenge in the Region, and the prevalence of HIV infection among TB patients is growing at alarming rates. Coinfected patients will receive better care because clinicians will be able to access test results more quickly.

More robust data. Data from HIV and TB patients can be more accurately generated and reported, thus improving epidemiological surveillance.

Efficiencies and cost savings. Currently, GeneXpert machines might not be used to maximum capacity to diagnose TB and detect rifampicin resistance. Using the same platform for HIV can thus lead to cost savings (e.g. shared maintenance costs, discounted cartridges from the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM)). TB laboratories have also established good contacts with the engineers needed for the regular maintenance of these machines.

Weaknesses

Vertical programmes. In many countries, HIV and TB programmes are managed in separate administrative silos, with separate streams for public financing and state budgeting, for human resource and service planning, and for consumable procurement and recording (e.g. reagents, cartridges).

WHO policy and recommendations. WHO only recently endorsed the implementation of Xpert HIV-1 viral load assays and has not yet released recommendations and guidance for countries to incorporate this technique into national TB programmes.

Added responsibility for shared equipment. TB laboratories will have added responsibility for the day-to-day care and operation (e.g. calibration, maintenance, communication with supplier) of shared GeneXpert machines, but it is unclear which staff members will be assigned these tasks.

Lack of experience. Workers in TB laboratory are experienced in all of the relevant operation/maintenance and external quality assessment procedures, but workers in HIV laboratories are lacking this experience.

Separate and parallel logistics. Different countries transport and deliver biological samples from HIV and TB patients using different systems and routes. Pathology samples from TB patients are often handed in by patients themselves at peripheral TB dispensaries or hospitals. In contrast, HIV laboratories are more centralized and samples are often transported across long distances and difficult terrain. In addition, the delivery of blood samples is increasingly being outsourced to private companies.

Separate data flows. HIV and TB reporting is done via different data channels and recording methods. Confidentiality is a high priority in both HIV and TB reporting, but especially for people living with HIV (PLHIV). A degree of integration in reporting systems would be necessary, for example development of an online request form that can be used for both HIV and TB samples.

Low test throughput. GeneXpert machines cannot be used to test large numbers of samples because of limited throughput. This technology is therefore not useful for HIV screening within the population.

Not a point-of-care test for TB. The GeneXpert platform is useful for point-of-care testing in managing PLHIV, but not as point-of-care testing for TB diagnosis.

Opportunities

WHO can set an example. The WHO Regional Office for Europe has recently created a Joint TB, HIV and Hepatitis Programme, which can set a good example to encourage countries to jointly address HIV and TB.

Funding. The major donor in the Region remains GFATM, which has declared a special interest in supporting combined HIV and TB activities. This is important given the gradual withdrawal of GFATM funding for TB services in the Region.

Natural link. The GeneXpert diagnostic platform can link together existing HIV and TB health services and serve as a natural point of entry for joint services that can better serve the needs of TB/HIV-coinfected patients. This move has been already observed in Armenia, Belarus and Kyrgyzstan.

Data for mapping is available. Countries with a high TB burden currently keep good, accurate records on the location of GeneXpert machines, how many tests are performed and the size of the population that is served. This information is useful for mapping efforts to strategic aims, but may not readily be available in western part of the European Region.

Threats

Biosafety concerns. In many countries, TB laboratories are designed to protect against airborne pathogens and contamination, while HIV laboratories are designed to prevent viral transmission. Staff in the different laboratories also may receive different training on biosafety. Safety measures to reduce the risk of transmission of blood-borne pathogens will be needed (e.g. at reception areas and work benches, including spill kits, sharps containers, waste disposal) if TB laboratories are to receive blood samples from HIV patients for GeneXpert assays.

Reluctance of staff. To address concerns handling patient samples, laboratory staff will need to be fully prepared and informed about protecting themselves against both HIV and TB and the different modes of disease transmission.

Poor communication and competing interests. Different programmes often have to compete for the same scarce resources. Competition for dominance may also hinder communication between the between the two sets of health care professionals.

Weak HIV data. Many countries do not have complete epidemiological HIV data or complete coverage for HIV testing. Moreover, country data is not uniformly reported. As a result, international donors often do not get a full picture of the HIV and TB situation in the country.

MDR-TB and HIV. Exposure of HIV patients to MDR-TB can have lethal consequences. Although this is unlikely to happen at the laboratory level, patient flow needs to be seriously considered.

Strengthening MTBDR*s*/VER 2 implementation

Dr Natalia Shubladze, ELI core group member, shared her practical insights into MTBDR*sl* implementation in different countries. This new technique is very user-friendly and can theoretically be mastered after only a few days of training; however, she observed that laboratory technicians do not always fully understand the procedure. Moreover, interpreting test results can be problematic, especially for clinicians, and is a major challenge in many countries. As an example, Georgia addressed the difficulty by providing joint training sessions for laboratory technicians and clinicians. The clinicians she met in Belarus expressed great interest in this type of training, and made a specific request to attend the regional training sessions organized for laboratory technicians and other National TB Programme staff.

This informal session discussed the following topics that could be relevant to implementation of this diagnostic test by other countries.

Training in interpretation of test results. Interpreting test results can be difficult and requires specific training for both laboratory technicians and clinicians. Separate, more detailed training on the laboratory procedure is also advisable for technicians.

Proper documentation, record keeping and quality control. These are essential factors for efficient implementation of the technique. WHO has received some requests from countries to provide support in implementing a laboratory maintenance plan and a list of laboratory requirements. In addition, standard operating procedures may still not be in place in many countries.

Laboratory-specific databases. Few laboratories have a dedicated database in place for reporting on the implementation of this technique or a quality management system that includes set indicators and monthly reporting. Such a database would be useful for extracting epidemiological information. The difficulty of tracking and identifying patients under

confidentiality constraints was mentioned. An added complication is that several test results from different laboratories can be generated for each patient, but these cannot be tracked by the e-TB Manager software used in several high-burden countries.

Clear requirements and competencies. Countries and donors have asked WHO to outline the laboratory facility requirements needed to implement MTBDR*sl* testing. A commonly held view is that new laboratories are needed to accommodate the new technology. However, this is not the case and could lead to misuse of donor aid. ELI can provide further guidance on implementation by producing a short document on the facility requirements and laboratory competencies needed to deliver an appropriate test.

Risk management strategy. The risk of samples being contaminated by extraneous DNA needs to be clearly understood. Steps should be taken to identify possible sources of contamination and mitigate their effect on test results. Countries may choose to adopt their own risk management strategies to address this issue. Separate testing areas, rigorous staff training and strict procedures to avoid bad practice are practical steps for reducing this risk.

Quality assurance of results. Minimizing the proportion of invalid test results in high-burden countries is very important for preventing high costs that could hinder implementation. Rigorous care is needed to prevent contamination sources from affecting test results.

Strengthening the knowledge base. The current level of molecular biology teaching in laboratory technician courses may be insufficient for staff to fully understand how the test works. Curricula need to be revised to keep abreast with the rapid advances in this field.

Part 2. Round table discussions on future activities

During this session, brainstorming by the core group identified future activities, new areas of work and potential points of interest.

The possibility of TB/HIV coinfection in high-burden countries of the WHO European Region was noted as a cause of concern, and the practical implications for laboratory staff were again mentioned. Some definite suggestions for addressing this issue were made. The need for stronger collaboration and communication with groups working in HIV was stressed and the added value of recruiting an expert with a background in HIV to the group was mentioned. This was accepted as a significant move that could strengthen collaboration between HIV and TB experts and increase the

impact of both programmes. In addition, the group recommended that next revision of the diagnostic algorithm should include a specific diagnostic pathway for PLHIV.

The widespread use of rapid diagnostic tests in high-priority countries and the ways in which ELI can strengthen their implementation was also a point of focus. All group members agreed that ELI can further support countries to ensure that well-trained workforce and efficient data management systems are in place. These efforts could increase the confidence of the medical community in the new rapid diagnostic tests and also reduce additional expenses resulting from contaminated test runs. ELI could also lead systematic efforts to map the availability of rapid diagnostic tests within the Region and explore ways to strengthen links with rGLC consultants.

The reliance of new methods on specific genetic information from antibiotic-resistant mycobacterial strains and the paucity of such data were also discussed. Group members agreed that greater efforts need to be made to collate the genetic information of the various resistant mycobacterial strains prevalent in the Region. Furthermore, ELI members should explore how mechanisms to systematically collect this information from countries in the Region could be introduced. According to some discussants, not all countries in the Region are willing to share this data.

Core group members volunteered to undertake work on the following three documents:

1. a short briefing document that describes how laboratories can better integrate and accommodate HIV and TB testing using GeneXpert –four members volunteered to produce a first draft, which will be shared among the whole group;
2. a summary draft document on training laboratory staff on the use of SL-LPAs and setting up SL-LPAs in laboratories to be based on the detailed HAIN operating manual and on European Centre for Disease Prevention and Control laboratory maintenance plans – three members volunteered for this task; and
3. a concept note describing data management systems for laboratories take account of patient confidentiality and the exclusive rights of the countries as owners of the data – one core group member volunteered for this task.

A number of other possible future activities were discussed and will be revisited by the group in the coming months (with no commitment to specific time frames). These were to:

1. revise the next version of the ELI algorithm to include PLHIV as an entry point;
2. amend the practical template used to facilitate the interpretation and reporting of second-line drug sensitivity testing to include the results of first-line drug sensitivity testing;
3. collect a set of good practice examples of the integration of HIV and TB care into laboratory services across the Region with a view to producing a publication on best practices;
4. undertake a mapping exercise on the current availability and use of GeneXpert across the Region, to be linked to the expected demand in line with the epidemiological burden and disease patterns, and including an extensive analysis of current usage and spare capacity;
5. communicate with colleagues working on HIV to perform a SWOT analysis on integrating TB/HIV laboratory services in countries with a high TB burden;
6. review teaching requirements and address existing gaps in the current training of laboratory staff in molecular biology and new rapid techniques; and
7. produce a simple, user-friendly leaflet on the laboratory and other requirements for implement this new testing method, to be based on the expert opinion of ELI core group members.

Dr Masoud Dara closed the meeting by thanking core group members for their active participation in the meeting through the free exchange of experiences and ideas. He also reminded the group of the upcoming review of the TB Action Plan, which also includes a laboratory component, and that a progress report needs to be submitted by March 2018 in anticipation of the 68th session of the Regional Committee for Europe, due to take place in 2018.

Annex 1. List of participants

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Annex 2. Meeting agenda

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ВСЕМИРНАЯ ОРГАНИЗАЦИЯ ЗДРАВООХРАНЕНИЯ
ЕВРОПЕЙСКОЕ РЕГИОНАЛЬНОЕ БЮРО

ELI core group members meeting	**1/1**
Copenhagen, Denmark	**Meeting room**
25 August 2017	**Original: English**

Time	Topic	Speaker
13:30–14:00	ELI achievements	**Dr Masoud Dara**, Coordinator, Communicable Diseases and Programme Manager, Joint Tuberculosis, HIV/AIDS and Hepatitis Programme, WHO Regional Office for Europe **Professor Francis Drobniewski**, ELI Core Group Chair, Imperial College London **Dr Soudeh Ehsani**, ELI Core Group Secretariat, Joint Tuberculosis, HIV/AIDS and Hepatitis Programme, WHO Regional Office for Europe
14:00–14:30	Addressing TB/HIV coinfection: challenges and opportunities	**Discussant: Dr Gulmira Kalmambetova, ELI core group member**
14:30–15:00	How to strengthen MTBDR*sl* VER 2 implementation	**Discussant: Dr Natalia Shubladze, ELI core group member**
15:00–15:30	**Coffee break**	
15:30–17:00	Round table discussion: future activities	**ELI core group members**
17:00–17:30	Closing remarks	**Dr Masoud Dara**