



momentum

Newsletter of the Global Laboratory Initiative

Issue 2 - April 2014

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Stop TB Partnership

The GLI is a Working Group of
the Stop TB Partnership
with a Secretariat provided by
WHO Global TB Programme





Dr. Christopher Gilpin

World Health Organization, Global TB Programme, Geneva, Switzerland
Secretariat for the Global Laboratory Initiative

Proposed GLI priorities 2014-2015

- Assist countries in the development of the TB laboratory component of National Strategic Plans
- Develop an implementation plan for already developed GLI tools available on the GLI website
- Promote the integrated use of the GLI stepwise process towards accreditation with other tools and checklists for implementation of Quality Management Systems
- Develop guidance on engineering requirement for different risk level TB laboratories
- Develop a strategy to improve human resources for laboratory management
- Finalize the development of new GLI tools

GLI tools under development

- TB laboratory consultant manual
- Xpert MTB/RIF Training package
- Updated SOPs

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FROM THE SECRETARIAT

Restructuring of the GLI Core Group

Since 2008, the Global Laboratory Initiative (GLI) has led the development of several essential tools and guidance within the framework of a multi-faceted, integrated approach to assist TB endemic countries in strengthening laboratory systems through a network of international partners.

The GLI Core Group members have been actively involved in the development and review of several new resources which are available at <http://www.stoptb.org/wg/gli/default.asp>.

The GLI Core Group consists of individuals with expertise in multiple disciplines, representing constituencies of stakeholders and/or institutions involved in global and country-level laboratory strengthening. Recently a call for nominations for new members to represent the GLI Core Group elicited an excellent response with more than 50 applications being submitted to the GLI Secretariat. The selection of new members was performed by the current Core Group members according to the GLI operating procedures ensuring that membership is balanced by gender, region, disease burden and GLI constituency. The GLI Core Group membership for 2014-2015 is as follows:

Current Members

Thomas Shinnick¹, GLI Chair; Rumina Hasan², Vice Chair; Armand van Deun³; Amy Piatek⁴; Heather Alexander¹; Sabine Rüscher-Gerdes⁵; Rick O'Brien, former GLI Chair; Maarten van Cleeff⁶; Maria Alice Telles⁷.

New Members

Levan Gagnidze⁸; Paul Klatser⁹; Richard Lumb¹⁰; Heidi Albert¹¹; Tsehaynesh Messele¹²; Alaine Nyaruhirira¹³; Joshua Obasanya¹⁴.

A number of initiatives and objectives have already been achieved by the GLI in the last few years. The newly restructured Core Group will now guide and direct interventions for the biennium 2014-2015.

Global Laboratory Initiative (GLI) with funding from TBCARE 1 has developed resources to guide national level TB laboratories (NRLs) to meet the requirements for international standards of laboratory accreditation, such as ISO15189, using a stepwise approach (www.gliquality.org). Achieving all of the requirements of ISO 15189 at intermediate and peripheral level laboratories is challenging and impractical in many settings. Consequently, GLI partners have developed an assessment tool for TB microscopy laboratory networks which guides the implementation of national policies that address training, quality assurance, supervision to support the establishment of well functioning laboratory networks. Oversight for the laboratory network is the responsibility of the NRL and hence implementing quality management systems at NRL helps enable best practices be implemented throughout the entire laboratory network. An NRL implementing a quality management system towards accreditation can provide supervision and training to ensure quality-assured diagnostic services at all levels of the laboratory network. Improving the quality of testing throughout the country will increase accurate diagnosis which in turn will contribute to effective treatment of more patients.

GLI strategic priorities for this period include strengthening the TB Supranational Reference Laboratory Network (SRLN) to provide technical assistance and support the implementation of quality management systems. Towards this objective, and in view of the new funding model for application to the Global Fund, under GLI guidance the SRLs are encouraged to proactively and constructively assist countries in the development of the laboratory component of National Strategic Plans.

GLI Stepwise Process towards TB Laboratory Accreditation fully updated

The Global Laboratory Initiative (GLI) Stepwise Process towards TB Laboratory Accreditation is a stepwise plan aimed at guiding national TB (reference) laboratories in implementing a quality management system (QMS) that complies with the international quality standard for medical laboratories: ISO 15189. This is pivotal to assure quality laboratory services. The tool is available as a website and is freely accessible to everyone (www.gliquality.org). In the updated version, the entire tool was adapted to the new ISO 15189:2012 standard.

The first version of the GLI tool was launched in 2011. Between 2011 and 2013 a lot of knowledge and experience for optimization of the tool was gained through feedback of users and by piloting the tool in practice. Furthermore, the ISO 15189 standard was renewed to the third edition (ISO15189:2012). This created a need to develop a new and improved version of the GLI tool.

The new version of the GLI tool, developed with financial support from USAID through the TBCARE I project, is more comprehensive and detailed in providing information for implementation of a QMS. First of all the entire tool was adapted to the new ISO15189:2012 standard. Next, the roadmaps that provide detailed information on consecutive activities for implementation of the QMS were modified to provide a more logical approach towards the day-to-day implementation of the QMS. As a consequence, activities were added and each activity was fitted with a logical framework explaining why it should be carried out (related to the ISO15189 requirement), how and by whom.

Also supplementary materials such as document templates, tools and background reading attached to the different activities were updated or added. Examples are the inclusion of the WHO Tuberculosis Laboratory Biosafety Manual and chapters of the WHO Laboratory Quality Management System (LQMS) handbook. Furthermore, a new feature was added to the laboratory assessment checklists included in the tool. This feature enables the users of the tool to customize laboratory assessment checklists based on the desired focus of their assessment. Finally, the layout was optimized. Overall the quality and user-friendliness of the GLI tool has increased significantly.

During the process of developing and optimizing the GLI tool the Stepwise Laboratory Improvement Process towards Accreditation (SLIPTA) was rolled out in a number of African laboratories by WHO AFRO and the African Society for Laboratory Medicine (ASLM). The SLIPTA approach uses a comprehensive checklist to assess and measure laboratories' performance using a score system which allocates points for each element of a QMS in place. The SLIPTA process and the GLI tool are complementary processes. The GLI recommends and promotes the use of the SLIPTA checklist to determine both baseline performance and measure progress being made by National TB Reference Laboratories in preparation for external audit and designation as an ISO15189 accredited laboratory. In conjunction with the SLIPTA assessment the GLI tool offers TB laboratories detailed guidance for implementing improvement activities.

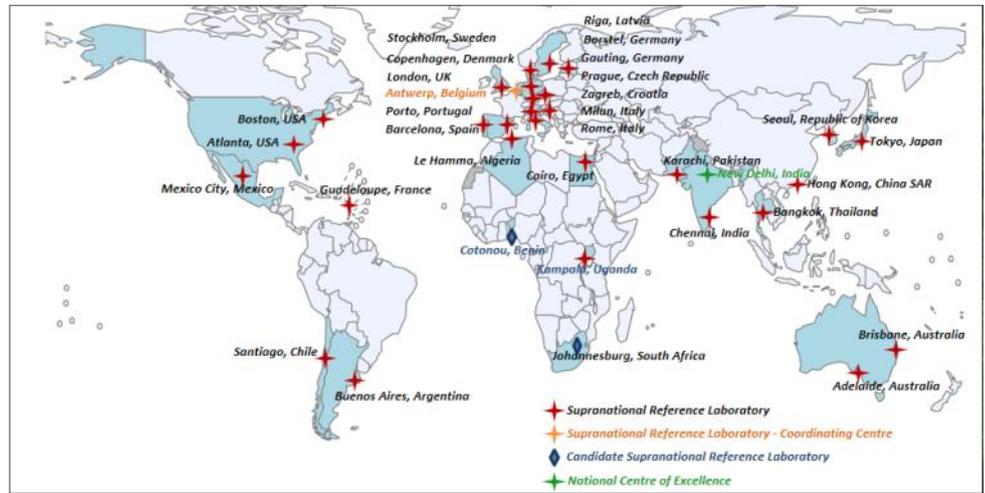
It is envisioned that the refined GLI tool will further facilitate and support implementation of systems to ensure the quality of TB laboratory services worldwide.

Paul Klatser

TB Laboratory Accreditation remains a priority activity of the GLI

The unique GLI tools help countries implement high quality standards for laboratory services.

GLI Stepwise Process towards TB Laboratory Accreditation
<http://www.gliquality.org>



First National Centre of Excellence designated

National Centre of Excellence, India
 National Institute of TB & Respiratory Diseases (NITRD)
 Sri Aurobindo Marg
 New Delhi - 110030
 India

Newly designated SRLs

SRL Pakistan
 Tuberculosis Laboratory
 Aga Khan University
 Karachi
 PAKISTAN

SRL Denmark
 Statens Serum Institut
 5 Artillerivej
 DK-2300 Copenhagen
 DENMARK

STORIES FROM THE FIELD

TB Supranational Reference Laboratory - National Centre of Excellence (SRL-CE)

The World Health Organization (WHO) TB Supranational Reference Laboratory Network (SRLN) is a structure that delivers coordination, identifies synergies among individual SRLs, and serves as a platform to assist National Reference Laboratories (NRL) and National TB Programmes (NTP) facilitate implementation of WHO policy guidance on TB diagnostics and provide a broad range of technical assistance activities to support functional TB laboratory networks. The SRLN is a sub-group of the Global Laboratory Initiative (GLI) Working Group, StopTB Partnership <http://www.stoptb.org/wg/gli/srln.asp>

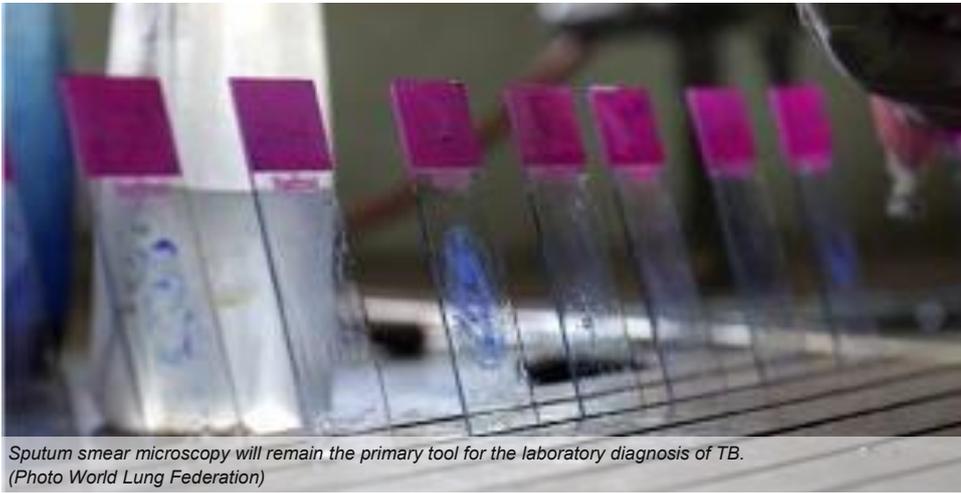
A TB Supranational Reference Laboratory – National Centre of Excellence (SRL-CE) is a new category of the SRLN specifically designed to recognize well-performing National and Regional TB Reference Laboratories in large middle-income countries. A SRL-CE has an equivalent status to a member SRL with similar terms of reference to that of an SRL but with an in-country focus for its laboratory strengthening and capacity building activities.

To be eligible for designation as a SRL-CE, laboratories are expected to meet a set of minimum criteria, similar to the requirements for member SRLs, including being officially recognized by the country's National Health Authority or a National TB Programme, be actively implementing a quality management system towards laboratory accreditation, and be able to demonstrate additional capacity (human resource, infrastructure and equipment) to support other laboratories in their own country's network of TB laboratories. SRL-CE are required to establish a collaboration agreement with an existing member SRL to ensure oversight for quality assurance activities for different diagnostic technologies.

The SRL-CEs will be of particular value for establishing and maintaining high-quality services to support NTPs and partners in PMDT (programmatic management of drug-resistant tuberculosis) scale-up through the coordination of technical assistance, monitoring and supervision, as well as training to laboratory staff involved in MDR-TB control. To meet its objectives, a SRL-CE commits to provide minimum service requirements such as establishing formal links with at least two intermediate level laboratories within the country and undertaking at least one annual technical assistance visit to each laboratory.

Countries with laboratories currently eligible to apply for designation as an SRL-CE include Brazil, China, India, Russian Federation and South Africa. Applications are invited from these countries to nominate well performing laboratories for WHO assessment and designation as SRL-CE. In 2012, these countries collectively accounted for the 41% of global TB burden and as much as for the 60% of global MDR-TB cases and are considered important priority countries for TB control (WHO Global Tuberculosis Report 2013). Applications should be submitted to the GLI Secretariat, Global TB Programme, WHO via email to gli_secretariat@who.int.

All National TB Reference Laboratories are strongly encouraged to establish formal Collaboration Agreements with a partner SRL. The templates for the agreements (English and French versions) are available at: <http://www.stoptb.org/wg/gli/srln.asp>.



Sputum smear microscopy will remain the primary tool for the laboratory diagnosis of TB.
(Photo World Lung Federation)

GLI RESOURCES

Laboratory Diagnosis of Tuberculosis by Sputum Microscopy The Handbook- Global Edition

The handbook story began back in 2002 when an Indonesian colleague requested the Adelaide-supranational reference laboratory (SRL) to produce an Indonesian-specific sputum microscopy handbook in Bahasa Indonesia language. The SRL collaborated with Mark Fitz-Gerald from the Photo and Imaging section of SA Pathology in preparing a design brief for the project.

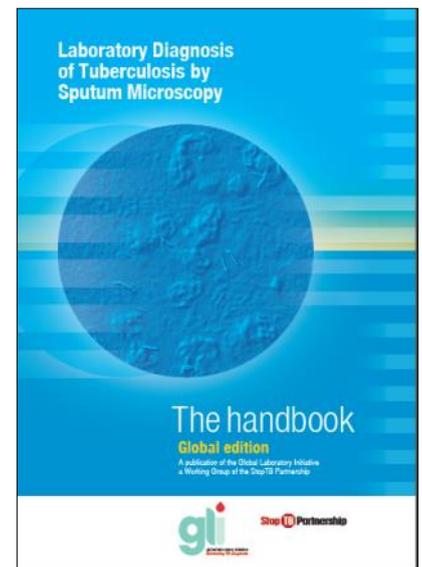
We developed the following design brief:

- Outlines key technical procedures and standards for conducting sputum smear microscopy
- Written for bench-level laboratory technicians and as a training guide for students
- A5 size so that it could fit into the pocket of a laboratory coat and accepting that the bench space available in a microscopy laboratory is often very small
- Spiral binding so that it could be opened flat onto a bench or desk
- Strong emphasis on illustrations rather than text for the protocol parts of the handbook to emphasise the key action(s) of a protocol
- Photographs limited wherever possible to 'what you see' such as reading a sputum smear and to show how acid-fast bacilli appear in a smear
- The main body of the handbook to be limited to daily work activities in the laboratory and for everything else to be included as an appendix
- Liquid-resistant coating on each page to minimise spoiling by water and/or staining reagents

The design brief has passed the test of time by being used for handbooks for Indonesia (2004), Pacific Islands (2005), China (2006), Tanzania (2011), and now, the Global edition (2013).

Sputum smear microscopy will remain the primary tool for the laboratory diagnosis of TB. Therefore, all health workers, especially laboratory personnel are encouraged to use *The Handbook* to improve the standard of smear microscopy in their workplace.

Richard Lumb



The Handbook is available at:
http://www.stoptb.org/wa/gli/assets/documents/TB%20MICROSCOPY%20HANDBOOK_FINAL.pdf

TB Laboratory Biosafety Manual in six languages

All versions are available at:
http://www.who.int/tb/publications/2012/tb_biosafety/en/index.html





Photo MSF

Key data and tools

Global procurement statistics
as of 31 March 2014 (cumulative)

Instruments: 2,343
Modules: 12,103
Cartridges: 6,291,330
Countries: 104

XPERT MTB/RIF UPDATE

Monitoring global roll-out of Xpert MTB/RIF and promoting coordination

WHO policy update on the use of Xpert MTB/RIF

The WHO Global TB Programme has issued updated recommendations on the use of Xpert MTB/RIF. This new policy guidance widens the recommended use of Xpert MTB/RIF, including for the diagnosis of paediatric TB and on selected specimens for the diagnosis of extrapulmonary TB, and includes an additional recommendation on the use of Xpert MTB/RIF as the initial diagnostic test in all individuals presumed to have pulmonary TB. The following updated policy documents on Xpert MTB/RIF may be accessed online at: http://www.who.int/tb/laboratory/xpert_launchupdate/en

- Updated policy statement
- Expert Group meeting report
- Implementation Manual

GLI training package on Xpert MTB/RIF is under development

Combining and updating materials developed by Cepheid, KNCV and FIND, the package will include modules on the Xpert MTB/RIF technology and procedures, installation, biosafety, specimen collection and transport, results interpretation, recording and reporting, troubleshooting and maintenance, and a clinical guide. The package is undergoing piloting and will be published on the GLI website in Q2 2014. For a pre-publication version of modules for piloting, contact gli_secretariat@who.int.

Warranties

Some countries are experiencing higher than expected rates of module failure upon remote calibration and during routine use. Module repairs and replacements can be costly, so implementers may consider obtaining a warranty extension past the initial warranty period of the machine. Details can be found under "FIND-negotiated instrument warranty, support and calibration costs" at http://www.finddiagnostics.org/about/what_we_do/successes/find-negotiated-prices/xpert_mtb_rif.html

Unified Xpert MTB/RIF Forecasting Initiative

In response to the global shortage of cartridges in Q4 2012- Q2 2013, WHO Global TB Programme and the Stop TB Partnership together with donors involved in the buy-down (PEPFAR, USAID, UNITAID and Gates Foundation) started the Unified Forecasting Initiative in April 2013. On a quarterly basis, WHO Global TB Programme and the Stop TB Partnership collect data from major public procurers about orders forecasted to be placed in the coming year. Contributors to the initiative now include South Africa NHLS, Brazil, China, India, the Global Fund, the TBxpert Project, EXPAND-TB Project, TB REACH, PEPFAR, USAID, MSF and UNDP. Unified forecasting aids Cepheid in planning to meet demand, and allows for increased shared leverage among partners to ensure Cepheid timely responds to placed orders that had been forecasted.





GLI for Africa was launched in November 2013 in Addis-Ababa, Ethiopia. From left to right: Jean Iragena, WHO HQ, Philip Onyebujoh, WHO-AFRO, Tsehaynesh Messele and Madeline DiLorenzo, ASLM, Moses Joloba, SRL Uganda, Teferi Mekonen and Ndlovu Nqobile, ASLM.

NEWS FROM GLI PARTNERS

ASLM: supporting implementation of laboratory quality management systems in Africa

ASLM implements the SLIPTA programme in Africa to improve the quality of public health laboratories and achieve ISO 15189 standards. Through standardised processes, SLIPTA measures and evaluates the progress of laboratory systems towards international accreditation and awards a certificate of recognition, and enables laboratories to develop their quality management systems in order to produce timely, reliable and accurate laboratory results.

Laboratories play a crucial role in disease diagnosis. However, while there are 6.37 accredited laboratories per 10,000 people in the United States, there are only 0.003 accredited laboratories per 10,000 people in all of Africa. Therefore, it is very challenging for African laboratories to address the health needs of their population.

To address this need, the African Society for Laboratory Medicine (ASLM) and the World Health Organization's Regional Office for Africa (WHO-AFRO) officially launched the Strengthening Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) programme during a consultative meeting held in Nairobi, Kenya, in 2011. SLIPTA is now implemented throughout Africa by ASLM. The programme uses a standardised process to measure and evaluate the progress of laboratory systems towards international accreditation. Each assessed laboratory is given a score of 0-5 stars (0 is the lowest score, 5 is the highest score), and is awarded a certificate of recognition. ASLM uses ASLM-certified SLIPTA auditors from different countries and organisations, including Ministries of Health, to conduct the audits. ASLM also collaborates closely with partners, including local accreditation associations, to implement SLIPTA. This has enabled country ownership, sustainability and wide-acceptance of the programme.

To date, ASLM has implemented the SLIPTA programme in 11 countries, and has audited 44 laboratories

Since its inception, demand for SLIPTA audits has increased dramatically, which will help ASLM achieve its goal of assessing 2,500 laboratories by 2020. ASLM also anticipates that it will be able to assist 250 of the 2,500 laboratories assessed achieve accreditation by international standards by 2020 through the provision of targeted technical assistance and mentorship. In 2013, a number of SLIPTA-enrolled laboratories were recommended to apply for international accreditation. This includes three laboratories in Ghana, one laboratory in Mozambique, two laboratories in Nigeria, and one laboratory in Tanzania. Two National TB reference laboratories - one in Mozambique and one in Nigeria - have also benefited from participating in the SLIPTA process. Besides auditing, ASLM has provided technical assistance to help these laboratories address their gaps and has connected some of these laboratories to international accreditation bodies.

The recent partnership between ASLM and the GLI will allow for there to be greater synergy between the SLIPTA programme and GLI's efforts to build laboratory capacity, particularly around TB. The GLI tool, in the form of a website, provides a stepwise plan to guide tuberculosis (TB) laboratories towards ISO 15189 accreditation. Laboratories can use the GLI tools as a guide to build and strengthen their quality management systems. The SLIPTA programme complements the GLI tools by providing a means of assessing laboratories. Furthermore, the SLIPTA checklist will be modified to incorporate some elements of the GLI tool in order to tailor it to the needs of TB laboratories undergoing evaluation. Utilising the SLIPTA star recognition will ensure that laboratories mentored by GLI have a means to quantitatively assess their progress.

Launch of GLI for Africa

On 18-22 November 2013, a meeting was convened to discuss modalities for strengthening and supporting TB laboratory services in the African region. The meeting involved representatives from the ASLM, WHO-AFRO, the GLI secretariat, and TB Supranational Reference Laboratory of Kampala, Uganda.

The meeting highlighted the need of creating a Working Group called "Global Laboratory Initiative for Africa (GLI-AFR)", whose main objective is to support countries to achieve quality-assured, accessible and sustainable TB laboratory services in the African region. The GLI-AFR Secretariat will be housed at the ASLM headquarters in Addis-Ababa, Ethiopia.

An interim GLI-AFR Core Group has been appointed. Its priorities are as follows:

1. Development of the Regional framework for strengthening TB laboratory services in Africa.
2. Development of the governance and operating procedures.
3. Call for nominations of the GLI-AFR Core Group members.

momentum

more information

Upcoming Events

4th Advanced TB Diagnostic Research Course

7 - 11 July 2014, Montreal, Canada

Registration forms can be requested at: montreal.course@gmail.com

ASLM Conference 2014

30 November - 4 December 2014, Cape Town, South Africa

Conference website: www.aslm2014.org

45th Union World Conference

28 October - 1 November 2014, Barcelona, Spain

Conference website: <http://barcelona.worldlunghealth.org/>

6th GLI Partners' Meeting

30 April - 2 May 2014

WHO Headquarters, Executive Board Room, Geneva, Switzerland

The programme will include:

- Updates from Partners and on Global Laboratory Initiative activities
- Global Forum of Xpert MTB/RIF Implementers
- TB Supranational Reference Laboratory Consultation

Selected Publications

Steingart K et al. *Xpert® MTB/RIF assay for pulmonary tuberculosis and rifampicin resistance in adults (Review)*. *Cochrane Database Syst Rev*. 2014 Jan <http://summaries.cochrane.org/CD009593/xpert-mtbrif-test-for-diaqnosing-pulmonary-tuberculosis-and-rifampicin-resistance-in-adults>

Nhu NT et al. *Evaluation of Xpert MTB/RIF for the diagnosis of tuberculous meningitis*. *M. J Clin Microbiol*. 2014 Jan Abstract <http://jcm.asm.org/content/early/2013/10/31/JCM.01834-13.abstract?related-urls=yes&legid=jcm:JCM.01834-13v1>

Osman M, Simpson JA, Caldwell J, Bosman M, Nicol MP. *Xpert MTB/RIF version G4 for the identification of rifampicin resistant tuberculosis in a programmatic setting*. *J Clin Microbiol*. 2014 Feb <http://jcm.asm.org/content/52/2/635.long>

Philip C. Hopewell, Elizabeth L. Fair, and Mukund Uplekar. *Updating the International Standards for Tuberculosis Care*. *Ann Am Thorac Soc* Vol 11, No 3, pp 277–285, Mar 2014

Philip C. Hopewell. *Updating the International Standards for Tuberculosis Care*. Editorial, *INT J TUBERC LUNG DIS* 18(3):253, 2014

Jeremiah Chakaya and Mario Raviglione. *Quality Tuberculosis Care. All Should Adopt the New International Standards for Tuberculosis Care*. Editorial *Ann Am Thorac Soc* Vol 11, No 3, pp 397–398, Mar 2014

Kik S. *Tuberculosis diagnostics: which target product profiles should be prioritised?* *ERJ Express*. April 2, 2014

WHO Executive Board recommends post-2015 global TB strategy to Assembly (http://www.who.int/tb/post2015_strategy/en/index.html)

- Resolution developed by the Executive Board
- WHO report on the proposed post-2015 TB Strategy and targets (as presented to the Executive Board)
- Short summary of the proposed post-2015 TB Strategy and targets

TB Care I Annual Report Year 3 (<http://www.tbcare1.org/reports/>)

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Cover page photo: FIND

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GLI website: <http://www.stoptb.org/wg/gli/default.asp>