Summary report on the

Regional workshop on strengthening health laboratory quality systems

WHO-EM/LAB/383/E

Amman, Jordan
7–9 October 2012

World Health Organization
Regional Office for the Eastern Mediterranean

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1. Introduction

Efficient and reliable health laboratory services are an essential and fundamental component of an effective health system for both clinical and public health functions. WHO provides technical support to Member States in improving laboratory quality through support of regional and national external quality assessment programmes, training of laboratory professionals, and support for laboratory networking through coordination of a laboratory twinning programme.

WHO also supports Member States in the implementation of the International Health Regulations (IHR) 2005 and in maintaining global capacity to detect, verify and rapidly assess public health emergencies of international concern. Member States need to build core capacities to meet the requirements of IHR (2005). One of these core capacities is strengthening health laboratories to detect and report to WHO details of events of international public health importance. A credible and accessible laboratory service producing high quality test results in a timely manner is key to Member States being able to meet this requirement.

An international conference, arranged by WHO and the United States Centers for Disease Control and Prevention (CDC), on health laboratory quality systems, took place in Lyon, France, on 9–11 April 2008. The meeting unanimously endorsed a statement calling for, among other things, implementation of national laboratory quality standards. As a follow-up of the recommendations of the conference, workshops have been held in all WHO regions since 2008. Concrete initiatives are now needed to develop and implement a regional framework for the development and delivery of quality and accessible national laboratory services through national laboratory policies and laboratory strategic plans.

In order to support health laboratory services in the WHO Eastern Mediterranean Region, the WHO Department of Global Capacities, Alert and Response, in collaboration with the WHO Regional Office for the Eastern Mediterranean and WHO Jordan country office, organized a regional workshop on strengthening health laboratory quality systems in Amman, Jordan, from 7 to 9 October 2012. The workshop was organized as a follow-up to a previous WHO regional workshop on strengthening laboratory quality systems and promoting national laboratory planning held in Muscat, Oman, from 4 to 6 October 2010. The workshop was supported by CDC, GIZ (Germany's agency for international cooperation), INSTAND (Germany's institute for standardization and documentation in medical laboratories) and PTB (the German national metrology institute).

The main objective of the workshop was to review and endorse a regional strategic framework and related tools to implement laboratory quality management systems.

The specific objectives were to:

- share country experiences in the implementation of quality management systems;
- identify essential elements of a health laboratory policy and strategic plan addressing quality system elements;
- review draft regional guidelines on the development of a national health laboratory policy and plan that can be adapted according to national needs;
- review and endorse the use of related tools and technical guidelines developed by WHO and other stakeholders to assist in strengthening laboratory quality systems.

The workshop was attended by 46 participants from 14 countries of the Region: Afghanistan, Bahrain, Egypt, Iran (Islamic Republic of), Iraq, Jordan, Lebanon, Libya, Morocco, Oman, Palestine, Qatar, United Arab Emirates and Yemen. The country participants were directors of national public health laboratories and laboratory policy-makers from ministries of health.

The workshop was also attended by international consultants and representatives, including from CDC, DAkkS (the German national accreditation body), GIZ, INSTAND, PTB and the United States Department of State, as well as WHO staff from country, regional and headquarters levels.

2. Summary of discussions

Presentations were given on: WHO global and regional perspectives on laboratory quality systems and laboratory capacity under IHR (2005); the International Standards Organization (ISO) 15189 concept and its implementation in Thailand; the draft guidelines on national health laboratory standards for quality assurance and quality management; the national guidelines for quality assurance for medical laboratories and stepwise implementation of quality objectives according to the Jordanian experience; the external quality assessment (EQA) scheme as a tool for quality improvement (with a focus on virus diagnostics and clinical chemistry in Jordan); a systems approach to supporting preparedness, surveillance and response; and strengthening laboratory quality in a stepwise process.

Country presentations were made on their experiences regarding national laboratory policies, regulation and quality management systems currently in place.

In their efforts to implement laboratory quality management/quality assurance systems, some countries have put criteria in place for establishing and supervising medical laboratories in private and public sectors and licensing of private laboratories, and have established national quality assurance committees, national accreditation committees/bodies, and biorisk management committees. Countries have also established national EQA schemes, and some are participating in international EQA schemes in addition to the regional microbiology EQA programme.

Other achievements described included the development of national standards manuals, biosafety guidelines and manuals, and manuals for sample collection, storage and transport based on international standards, and the adoption of a quality management system based on the 12 quality system essentials.

Furthermore, examples were given of regulatory systems of *in vitro* diagnostic medical devices being established, of private laboratories being regulated by ministerial orders and of private and government medical laboratories being accredited by international accreditation bodies.

Examples were also presented of a cascade training system developed for diverse target audiences (laboratory directors, laboratory personnel, auditors, laboratory trainers), and the adoption of an incentive approach with quality awards for laboratories successfully implementing quality management systems.

Challenges faced by countries include the lack of a national laboratory quality office, a shortage of trained staff, a lack of computerized systems for data management and data analysis of laboratory results/activities, a lack of advocacy for the culture of quality

management among professionals, problems with maintenance of laboratory equipment, as well as cultural problems and a reluctance to make the changes needed to improve/adopt quality management/quality assurance policies.

Overall, there was agreement on the need to have a regional consensus on strategies and plans for strengthening health laboratory quality systems. Country presentations and discussions indicated that while some countries are already implementing health laboratory quality systems and preparing towards accreditation, other countries still need some guidance and support from WHO and its partners to achieve these goals.

Participants worked in groups to review and comment the on the draft regional guidelines on the development of national health laboratory standards for quality assurance and quality management. Feedback from group work and subsequent discussions on the guidelines were incorporated into the final version of the guidelines.

Practical steps for improvement of internal quality control programmes and to establish/improve a regional and national EQA schemes were also discussed.

3. Recommendations

To Member States

1. Establish a national committee for health laboratories.
2. Promote the concept and implementation of quality management systems, especially in health laboratories, throughout the ministry of health and with regulatory authorities/policy-makers, to benefit the whole health care system.
3. Identify focal points to oversee the national quality programme.

4. Include quality and integrated management system aspects into the national academic curricula at graduate and postgraduate level.
5. Establish/strengthen national quality management programmes, especially EQA schemes.
6. Consider setting up a core group for laboratory quality systems in the Region, led by several regional laboratories and facilitated by WHO.
7. Ensure implementation of the guidelines on development of national health laboratory standards for quality assurance and quality management by private and public health laboratories.
8. Organize training courses at national level according to the guidelines and consider translation of the guidelines into local languages.

To WHO

9. Organize training courses on implementation of quality management systems and on EQA schemes for interpretation of results and defining remedial and corrective actions.
10. Establish a regional committee for strengthening laboratory quality management systems in countries.
11. Finalize and publish the guidelines as an official WHO document and provide adequate translations into Arabic and Farsi.
12. Strengthen and support the laboratories network (e,g. through an expert directory) within the Region, and with other WHO regions, by redefining the system of expert laboratories and their functions, and improving and expanding adequate regional programmes for EQA.
13. Encourage laboratories to use the guidelines and to connect this with the forthcoming stepwise implementation toolkit provided by WHO.
14. Support Member States to establish regional EQA programmes for different specialties.
15. Develop mechanisms to address the special needs of countries suffering from political and economic instability to ensure a sustainable total quality management programme.

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