



CONCEPT NOTE

TECHNICAL LUNCH BRIEFING

Health laboratory strengthening: an essential component of early warning surveillance and response systems and a national core capacity of the International Health Regulations (2005)¹

Introduction

The International Health Regulations (2005) (IHR) requires Member States to develop national capacities for the detection, investigation and reporting to the international community through WHO of potential public health emergencies of international concern (PHEIC). The IHR obliges countries to strengthen national IHR core capacities required to detect, assess, notify and report events, and respond to public health risks and emergencies of national and international concern. To comprehensively meet the early warning and alert requirements of the IHR, there is a need to strengthen and develop both routine, or indicator-based, surveillance and event-based surveillance². The organized mechanism to reach this objective is referred to as Early Warning and Response (EWAR).

Reliable and accessible laboratory services capable of producing results in a timely manner are an essential component of any country's surveillance capacity and early warning and response systems that collect information on epidemic-prone diseases in order to notify WHO of potential PHEIC and trigger prompt public health interventions. That laboratories are in the front-line of the response to epidemics and pandemics has been demonstrated many times, particularly during the 2003 SARS outbreak, the recent Ebola outbreak and the 2009 H1N1 pandemic. In spite of this, the performance of public health laboratories is hindered by a number of challenges including insufficient financial and human resources, equipment and supplies, quality and biosafety and sample referral and transport systems.

The WHO Regional Office for Europe (WHO/Europe) has for many years been providing support to laboratory networks responsible for disease-specific programs and emergency response, through its networks and WHO Collaborating Centres. Based on the premise that nationally managed laboratory systems operating to national or international (ISO) laboratory standards would strengthen IHR core capacities, in 2012 it launched the "Better Labs for Better Health" initiative, an intersectoral

¹ International Health Regulations (2005). Second edition. Geneva: World Health Organization; 2005 (<http://www.who.int/ihr/publications/9789241596664/en/>).

² Protocol for Assessing National Surveillance and Response Capacities for the IHR (2005). Geneva, WHO; 2010.

approach to strengthen laboratory systems as a whole, through the development of national laboratory policies and strategies, the implementation of laboratory quality management systems and improved training programs for laboratory staff.³

Objectives

- a. Inform Member States of the role of laboratory services under the IHR, and WHO's work on strengthening national laboratory capacity in the WHO European Region as part of Better Labs for Better Health;
- b. Exchange of experience and models of good practice in laboratory strengthening;
- c. Discuss the need for a regional framework for laboratory capacity development as a means to successful IHR implementation and national emergency preparedness.

Laboratories strengthening within the International Health Regulations

The International Health Regulations (IHR) are an international legal instrument that is binding on 196 countries across the globe, including all the Member States of WHO, aimed at helping the international community prevent and respond to all public health risks (biological, chemical, radiological and nuclear) irrespective of the source that have the potential of cross-border spread, thereby threatening health of people worldwide. The IHR obliges countries to strengthen national IHR core capacities required to detect, assess, notify and report events, and respond to public health risks and emergencies of national and international concern, as stipulated in Articles 5 and 13, and Annex 1, of the Regulations.

The eight core capacities that countries are required to develop, strengthen and maintain are related to national legislation, policy and financing; coordination and NFP communication; surveillance; response; preparedness; risk communication; human resources and laboratory services. Additionally, the IHR require countries to adopt procedures to be able to report certain disease outbreaks and public health events to WHO.

IHR requires that each country has developed certain core capacities at community, intermediate and national levels:

- At **community level**, the country should be able to Detect events involving disease or death above expected levels and report unusual events to the next level of public health responsibility;
- At **intermediate level** the country should be able to confirm the status of reported events and support or implement control measures, as well as assess reported events immediately and report essential information to the national level;
- At the **national level** the country should be able to assess reports of urgent events within 48 hours, notify WHO immediately through the National Focal Point of all potential PHEICs, determine rapidly the control measures required to prevent further spread, support local investigations, provide information-sharing links with health care facilities, national entry

³ <http://www.euro.who.int/en/health-topics/Health-systems/laboratory-services>

points, and other key operation areas, and establish, operate and maintain a national public health emergency response plan

The International Health Regulations (2005) (IHR) requires Member States to develop national capacity for the detection, investigation and reporting to the international community through WHO of potential public health emergencies of international concern.

The IHR has expanded usual infectious disease notification to include surveillance of public health events from various origins (e.g. nuclear, chemical or unknown), and prompts Member States to develop the capacities of their surveillance systems to detect, assess, notify and respond to all acute health events or health risks that may constitute a threat to human health. As the Regulations note, “To comprehensively meet the early warning and alert requirements of the IHR, there is a need to strengthen and develop both routine, or indicator-based, surveillance and event-based surveillance”.⁴ The organized mechanism to reach this objective is referred to as Early Warning and Response (EWAR). Timely collection of information about public health threats informs and guides public health response to all acute public health events including: unknown, unusual or unexpected diseases or disease patterns of all origins (i.e. biological, chemical, radiological or nuclear), as well as hazards of other nature that could potentially pose a risk to human health, such as environmental or food safety related. Sources of information that can be used for the early warning function go beyond traditional disease-based and syndromic surveillance, and should encompass environmental surveillance and health-related behavioral information.

Reliable and accessible laboratory services capable of producing results in a timely manner is an essential component of any country’s surveillance capacity and early warning systems that collect information on epidemic-prone diseases in order to trigger prompt public health interventions.

Laboratory strengthening at the global level

In support of implementation of the IHR, WHO at the global level works with Member States to strengthen national laboratory system policies and strategic plans, support implementation of laboratory quality systems, enhance networking between laboratories with public health responsibility and with surveillance and response systems, increase domestic testing capacity in range and volume, support laboratory workforce development and contribute to WHO leadership and coordination role in global laboratory strengthening forums. In order to achieve these goals, WHO conducts a series of activities at global, regional and country level, including the development of technical resources (training materials, tools, guidelines); organization of trainings, workshops, meetings or conferences; support to public health laboratory networks through knowledge sharing, training, or the provision of external quality assessment schemes; and technical assistance to public health laboratories through the procurement of essential equipment and supplies.

WHO has advocated for strengthened laboratory capacities during two global meetings held in 2008, the first of which resulted in the **Maputo Declaration on Strengthening of Laboratory Systems**,⁵ and which calls for the recognition for the need to expand and further develop

⁴ Protocol for Assessing National Surveillance and Response Capacities for the IHR (2005). Geneva, WHO; 2010.

(WHO/HSE/IHR/2010.7; http://www.who.int/ihr/publications/who_hse_ihr_201007_en.pdf?ua=1)

⁵ http://www.who.int/diagnostics_laboratory/Maputo-Declaration_2008.pdf

quality-assured laboratory services as part of a greater framework of health system strengthening within resource-limited settings. The declaration also calls on national governments to support laboratory systems as a priority by developing a national laboratory policy within the national health development plan that will guide the implementation of a national strategic laboratory plan.

During a second meeting organized jointly with the US Centers for Disease Control and Prevention (CDC), Atlanta, USA, the **Conference on Health Laboratory Quality Systems** in April 2008, the development of laboratory quality systems within well-organized integrated national laboratory plans was discussed, and successful experiences and challenges of countries that have already made steps towards meeting these objectives were shared.⁶ WHO has since developed tools and training materials to support the assessment of laboratory systems and facilities, the implementation of laboratory quality management systems, training in biorisk management and the international shipment of infectious substances.⁷

Laboratory strengthening at the Regional level

In a number of countries in the Region, laboratory performance is hindered by specific challenges related to insufficient:

- National coordination and oversight;
- Capacity for the detection of emerging pathogens and response to PHEIC;
- Laboratory quality management systems, quality assurance practices, biosafety and biosecurity;
- Resources resulting in underfunded laboratories and lack of trained staff;
- National and international sample transport networks;

Although there has been notable progress in national laboratory capacities in the WHO European Region through activities conducted as part of disease-specific programs (polio, measles/rubella, tuberculosis and HIV) as well as during emergencies and outbreaks (the 2009 H1N1 pandemic, Ebola and ZIKV), activities related to strengthening preparedness and response of laboratory systems were, until recently, lacking.

Better Labs for Better Health

Following the principles of the Maputo Declaration, the conference on Health Laboratory Quality Systems, and to support implementation of the national core capacities under the IHR, the WHO Regional Office for Europe launched the **Better Labs for Better Health** initiative in 2012. This intersectoral approach aims to provide timely and accurate laboratory results from accredited laboratories that are trusted by the user from all laboratories dealing with human and animal health, environmental, food safety, chemical and radionuclear laboratories, both public and private. This is achieved through a three-pronged approach:

- Development of national laboratory policies and strategic plans in countries lacking a legal and regulatory framework for laboratories;
- Improvement of national training programs and implementation of laboratory quality management systems; and

⁶ http://www.who.int/ihr/publications/WHO_HSE_IHR_LYO_2008.3/en/

⁷ <http://www.who.int/ihr/lyon/hls/en/>

- Upgrading critical infrastructure, such as teaching laboratories, national external quality assurance programs, and maintenance and metrology units.

Key activities and achievements

The Better Labs for Better Health initiative has been active in a wide area, with involvement of more than 20 countries throughout south-eastern and eastern Europe and central Asia. Three countries have developed national laboratory policies and strategies (Kyrgyzstan, Republic of Moldova and Tajikistan) and Uzbekistan has developed a national laboratory policy. A fifth country, Turkmenistan, started the process on laboratory policy development in late 2015. All five countries have formally established national laboratory working groups that function as expert resources for laboratory issues at a national level. Better Labs for Better Health has developed a standardized methodology for policy and strategy development, which includes the use of existing WHO laboratory system and individual laboratory assessment tools. Intersectoral partner involvement is essential to Better Labs for Better Health activities, with the aim of utilizing networking to achieve synergies for the implementation of best laboratory practices. Countries are encouraged to include technical partners in their national laboratory working groups. In addition, a first Better Labs for Better Health partners meeting was held in 2014, with eight Member States as well as NGOs, foundations, major donors and supporters represented, to achieve consensus on the Better Labs for Better Health initiative's direction.

The Better Labs for Better Health approach and methodology was endorsed during a recent global meeting held by WHO, during which WHO staff from global, regional and country levels as well as country representatives and partners, reviewed methodologies and experiences in the development of national laboratory policies.

To help countries improve their national training programs for laboratory specialists, five-day interactive curriculum review workshops have been held in the Republic of Moldova, Kyrgyzstan, Tajikistan and Uzbekistan with both laboratory managers and representatives from laboratory education institutes, resulting in recommendations covering strengthening collaboration between the institutes and the laboratories, improving examination methods, developing managerial training, and curricula reviews to ensure that newly-qualified laboratory scientists have been capacitated to work according to modern methodologies.

To help countries implement Laboratory Quality Management Systems (LQMS), Better Labs for Better Health has developed a five day course for quality officers and their managers in laboratory quality and use of WHO's Laboratory Quality Stepwise Implementation (LQSI) tool. Five courses were held in 2014 and 2015 for 110 participants from 75 laboratories in eastern and south-eastern European, as well as central Asian countries. The Better Labs for Better Health initiative follows up on this training in selected laboratories with mentoring that supports national reference laboratories towards ISO accreditation and 10 international laboratory experts have been trained as mentors for this. The aim is to increase from one laboratory mentored in 2015 to eight in 2016 and 12 in 2017. Laboratories that complete all phases of the LQSI stand in good stead to achieve international-level standardization, e.g. ISO 15189 for medical laboratories. Implementing a quality management system also implies management challenges, and the Better Labs for Better Health initiative therefore also provided training for laboratory managers in the Republic of Moldova.

In addition, three laboratory assessment and quality tools have been developed (for influenza, HIV and AMR laboratories); and laboratory experts from across the region have been trained in biorisk management and the shipment of infectious substances.

The above initiatives are now supported by an online forum that supports best laboratory practice through group discussions and the exchange of documents.

Next steps

The Better Labs for Better Health initiative has two major priorities for 2016–2017. Firstly, it will assist Member States in the implementation of their national laboratory strategic and operational plans, in particular by improving regulatory frameworks (licensing and accreditation) and by providing models for the reorganization and centralization of public health laboratory networks. Secondly, it aims to increase the number of laboratories being mentored under LQMS towards ISO 15189 accreditation.