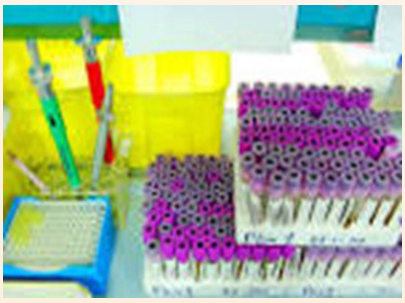
LABORATORY CAPACITY REQUIREMENTS FOR INTERNATIONAL HEALTH REGULATIONS AND THEIR IMPLEMENTATION IN THE WHO AFRICAN REGION

DISEASE SURVEILLANCE AND RESPONSE PROGRAMME AREA

DISEASE PREVENTION AND CONTROL CLUSTER






World Health Organization
REGIONAL OFFICE FOR Africa

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Disease Surveillance and Response Programme Area
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Abbreviations and acronyms

AFP	acute flaccid paralysis
AFR/RC	African Regional Committee
AIDS	acquired immunodeficiency syndrome
BSL	biosafety level
EDP	emerging and dangerous pathogens
EQA	external quality assessment
FELTP	Field Epidemiology and Laboratory Training Programme
HIV	human immunodeficiency virus
IDSR	Integrated Disease Surveillance and Response strategy
IHR	International Health Regulations (2005)
ISO	International Organization for Standardization
PCR	polymerase chain reaction
PHE	public health events
PHEIC	public health emergency of international concern
SARS	severe acute respiratory syndrome
SLIPTA	stepwise laboratory quality improvement process towards accreditation
TB	tuberculosis
UN	United Nations
VHF	viral haemorrhagic fever
WHA	World Health Assembly
WHO	World Health Organization

1. Introduction

1.1 Overview

Brief history of the International Health Regulations 2005 (IHR)

The International Health Regulations (2005), or IHR, are a legally binding international instrument for preventing and controlling the international spread of diseases while avoiding unnecessary interference with international travel and trade (1). The Regulations were first adopted by the World Health Assembly (WHA) in 1969 and initially covered the six diseases of cholera, plague, yellow fever, smallpox, relapsing fever and typhus. They were amended in 1973 and again in 1981 to focus on cholera, yellow fever and plague. Owing to the increase in international travel and trade and the emergence or re-emergence of international disease threats, a substantial revision of IHR was carried out from 1995. The revised Regulations were adopted in 2005 and came into effect on 15 June 2007 (2).

Purpose and scope of IHR

IHR aim to prevent, protect against and control the international spread of disease and to provide a public health response to such diseases in ways that are commensurate with and restricted to public health risks and avoid unnecessary interference with international traffic and trade (3).

All World Health Organization (WHO) Member States are required to have or to develop national core public health capacities for surveillance of and response to the diseases covered under IHR, according to Annex 1A, and to notify WHO of all events that may constitute a public health emergency of international concern (PHEIC). PHEICs are not restricted to communicable diseases with epidemic or pandemic potential but may include emergencies associated with contamination from microbes, toxins, chemicals or radioactive material due to industrial leaks or intentional discharge (2,3).

National IHR core capacities requirements

Based on the provisions of Annex 1A of IHR, a group of technical experts identified eight core capacities needed to be monitored to assess progress towards IHR implementation: legislation and policy, coordination, surveillance, response, preparedness, risk communication, human resources and laboratory. To reflect the multisectoral nature of IHR it was proposed that these capacities would be assessed at points of entry into a country and relating to the five hazards of infectious and zoonotic diseases and food safety, chemical and radio-nuclear events (2).

IHR agenda for strengthening national core capacities

All Member States have committed to develop, strengthen and maintain core public health capacities for surveillance of and response to public health hazards within a stipulated time frame. An assessment of national core capacities, including for laboratories, should have been carried out by June 2009. Based on the results of that assessment, Member States were expected to develop and implement plans of action to ensure that these capacities existed and were functional. Member States were given three years to strengthen these capacities. The implementation period was extended to 2014 for countries that had not met all the requirements within the three years when they requested the extension. An extension to 2016 might be granted in exceptional circumstances, but Member States that need this are expected to develop and submit to WHO an implementation plan for the specific areas concerned. Though WHO supports the IHR implementation process by providing technical advice and direction, it is solely the responsibility of Member States to follow through with the plans of action and report on progress. WHO has developed performance indicators for the assessment of progress in strengthening the core capacities for IHR implementation, and data on these indicators is being collected and analysed to monitor progress in the Region.

1.2 Justification

Challenges of IHR in defining laboratory capacity requirements

IHR outlines the obligations, procedures and requirements for the detection, notification and management of public health events of international significance. Laboratories play a key role in the detection and notification of public health events through accurate and timely diagnosis. Laboratory capacity is one of the eight core capacities that require strengthening for IHR implementation. The fulfilment of the IHR requirements for laboratory capacity is crucial. Laboratory or laboratory-related activities are mentioned in seven articles or annexes in IHR:

(a) Laboratory data, if available, are part of the essential information that should be reported during the initial detection of an event (Annex 1).

(b) Insufficient laboratory capacity is one of the criteria mentioned for classification of an event as "serious" and ultimately as a PHEIC (Annex 2).

(c) The public health response to an event should be supported through the laboratory analysis of samples in either national or collaborating laboratories (Annex 1).

(d) The notification of a PHEIC to WHO should include any laboratory results (Article 6).

(e) Communication channels should be established between all key functions including laboratories for the dissemination of information and recommendations received from WHO (Annex 1).

(f) Recommendations issued by WHO with respect to persons may include the review of laboratory analysis (Article 18).

(g) State Parties are urged to facilitate the transport, entry, exit, processing and disposal of biological substances and diagnostic specimens, reagents and other diagnostic materials (Article 46).

Despite these guidelines for laboratory requirements many challenges remain in the definition and development of the laboratory capacity to fulfil IHR requirements:

(a) The IHR 2005 second edition does not prescribe clear the minimum laboratory requirements, norms and standards to meet the obligations for IHR.

(b) It was left to each Member State to design and put in place the most appropriate laboratory system to meet IHR detection and reporting needs.

(c) The level of health care delivery, i.e. district, intermediate or central level, at which laboratory testing should take place is not specified.

(d) There are no provisions or guidance for sample collection, storage, transportation or preparation.

(e) IHR does not recommend any laboratory standards or accreditation or certification processes for laboratory quality management systems.

IHR recommends that laboratory results be communicated to WHO within 24 to 48 hours but only if they are available and where possible. Not making laboratory results a mandatory component of reports on health events encourages the countries to notify WHO of events in a rapid and transparent manner, even if the laboratory confirmation is not available. In addition, there is flexibility about whether the countries use domestic or outsourced laboratory capacity. A country could decide to entirely outsource its laboratory services and still comply with the IHR requirements. The choice on whether or not to rely on foreign laboratories will depend on many factors, such as the lack of local capacity, concerns over the quality of the testing, resource shortages and cost-effectiveness, as well as the need for national control over biological material property rights and the desire for autonomy.

Expectations for public health laboratories in IHR implementation

Laboratories are key instruments in the detection and investigation of public health events and for monitoring trends of endemic and epidemic-prone diseases and diseases targeted for elimination and eradication. In the WHO African Region, the polio laboratory network is an example of how core laboratory capacity can be developed by countries with WHO technical support for training, setting norms and

standards and resource mobilization. This has been achieved through enabling the functioning of several regional networks of laboratories with specific functions for national, intercountry and regional referencing. The WHO polio laboratory network contributes to the detection of outbreaks and differentiation of the poliovirus types, as well as tracing of poliovirus importations by comparisons of phylogenetic relationships of viruses after sequencing. The data collected from the laboratories also guide health authorities in determining the vaccine type to be used in vaccination campaigns. This network serves as a model for laboratory capacity building for IHR implementation within the African Region. The measles, yellow fever, rubella, influenza and human papilloma virus laboratory networks are already tapping into the resources of this unique laboratory network. The network of emerging and dangerous pathogens laboratories also is drawing lessons from the polio laboratory network. Domestic resources for some of these networks are very limited compared with funds from partners. To ensure sustainability of the laboratories, it is crucial to promote innovative financing solutions following the guidelines provided in section 4 of this document.

IHR does not provide clear guidelines on laboratory capacity requirements, an oversight that prompted WHO to convene a group of experts meeting in May 2006 to define what that core capacity would encompass. The group reached a common position to the effect that the "national public health system should establish the laboratory capacity to identify, monitor and report to the health authorities on agents that may cause epidemics and emergencies, including those of international importance, in a safe, timely and reliable manner" (4). To achieve that objective, "Every national public health laboratory system should institute a national quality assurance programme which must include all laboratories participating in disease surveillance, detection and identification of diseases of public health importance. A quality management system related to the IHR requirements must be part of the laboratory policy in each country, and include standards, quality control, audits, external quality assessment, maintenance of equipment and biorisk management system addressing biosafety/biosecurity" (4).

On a parallel track, through adopting two resolutions in the World Health Assembly, Member States urged WHO to support the development and strengthening of laboratory capacity:

(a) In 2006 a resolution was adopted that called for immediate and voluntary compliance with IHR. WHO was requested to expand and accelerate training efforts to develop laboratory capacity, including by facilitating regional networking of laboratories and skill building on biosafety and quality control (5).

(b) In 2008, through resolution WHA61.2, WHO was urged to provide support to Member States with the most vulnerable health systems to strengthen their core capacity requirements for PHEIC surveillance and response at airports,

seaports and ground border crossings, paying special attention to the sub-Saharan Africa laboratory network (6).

These resolutions clearly emphasize the need for reliable, safe, secure and well-linked laboratories supported by a national laboratory policy and encompassing an external quality assessment process, standards and interconnectivity with national, regional and global laboratory networks. In addition, Member States in the African Region recommended that IHR be implemented in the context of the Integrated Disease Surveillance and Response (IDSR) strategy (7). IDSR and IHR share common elements such as detection, reporting, confirmation, verification and notification of diseases and institution of timely response. Effective implementation of IDSR strengthens the networks of public health laboratories and thus contributes to the building of laboratory capacity for implementation of IHR.

Recognizing the need to strengthen laboratory capacity for detection of all events, Member States in the WHO African Region adopted resolutions AFR/RC58/R2 and AFR/RC59/R4. These resolutions mainly call for strengthening of public health laboratories and establishment of centres of excellence. To meet the obligations of these resolutions, Member States in the African Region have continued to reinforce the implementation of the strategic actions on the laboratory component of IHR. These actions are intended to address the gaps in accuracy of results in disease control and prevention programmes and timely access to highly specialized laboratory facilities.

2. Scope and objectives

WHO continues to provide guidance on surveillance of and response to epidemic and pandemic diseases with a focus on implementing IHR within the context of IDSR (8). IHR requires Member States to strengthen their surveillance and response capacities at all levels including in early detection of and response to national priority events to meet the challenges posed by public health events of national or international concern (2).

Although many countries in the African Region have conducted an assessment of their national core capacities and developed IHR implementation plans, most have reported that they have not achieved the required capacity levels. Since the full implementation of IHR by Member States will help safeguard international public health security (1), there is an urgent need for the countries to enhance and sustain their laboratory capacity for appropriate confirmation of public health events.

This document focuses on the laboratory component of IHR. It can be used in identifying approaches to develop the laboratory capacity for implementation of IHR in the WHO African Region in accordance with the specifications outlined in Annex 1A of IHR. Since IHR does not provide clear guidance on the laboratory component, this document will define specific elements for laboratory capacity requirements to facilitate the monitoring and evaluation of the implementation of IHR, and also will supplement existing WHO reference documents.

Building and maintaining laboratory capacity to meet IHR requirements entails significant resource input, and many countries may find it difficult to fully meet their obligations. The laboratory capacity and services in countries in the WHO African Region are at different levels with respect to IHR requirements. This document will help national policy-makers to prioritize the actions in their national plans pertaining to health laboratories to facilitate laboratory capacity building to meet IHR requirements.

This document is primarily intended to support managers and professionals dealing with and overseeing laboratory services, as well as national authorities and stakeholders responsible for implementing IHR. It is expected that these guidelines will be used by all Member States as they draw their road map for laboratory capacity development and maintenance for IHR implementation.

This guide is laid out in sections that respond to three important questions:

(a) What are the laboratory capacity requirements for IHR?

(b) How do we ensure that stakeholders at the national level have a common understanding of the laboratory capacity requirements for IHR?

(c) What are the approaches for developing and maintaining IHR laboratory capacity?

As the contents of this document take into account the tools available for assessing the national capacities for IHR, the document will contribute to the technical guidance on collection of information from the assessment of the status and progress in laboratory capacity building for IHR implementation. The objectives of this document are:

(a) To provide clear guidance on the laboratory component and specific elements on laboratory capacity requirements for IHR implementation.

(b) To provide approaches for developing the laboratory capacity for IHR.

(c) To facilitate monitoring and evaluation of the implementation of IHR.

3. Pillars of the IHR laboratory core capacity

Laboratory services are part of every phase of health hazard alert and response systems, including risk detection, investigation and response. Laboratory analysis of samples can be carried out in a country or externally through collaborating institutions. Every Member State should establish mechanisms for reliable and timely laboratory identification of infectious agents and other hazards likely to cause public health emergencies of national or international concern. This will not only shorten the turnaround time for responding to health emergencies but also minimize international traffic of specimens and the associated dangers of intentional or unintentional pathogen exposure or release.

Building the local laboratory capacity is also good for sustainability of laboratory programmes and preserving national sovereignty. However, very few countries have full laboratory capacity and therefore the use of regional or global reference laboratories for confirmatory testing has to be organized and maintained.

The organization of laboratory diagnostics should be based on whether sample collection and storage and transportation systems are adequate, the local diagnostic capacity for the priority events, and the ease of use of external capacity when needed. Appropriate biosafety measures and laboratory quality systems should ensure that laboratories release results in a timely and reliable manner. Special attention should be paid to the interaction between the public health laboratory services and the surveillance systems. Each Member State should determine the structure of its laboratory capacity system and assess its proficiency against the IHR requirements.

To help Member States to comply with the IHR requirements, the WHO Regional Office for Africa has proposed six key pillars as the basis for laboratory capacity building for IHR (see in Figure 1).

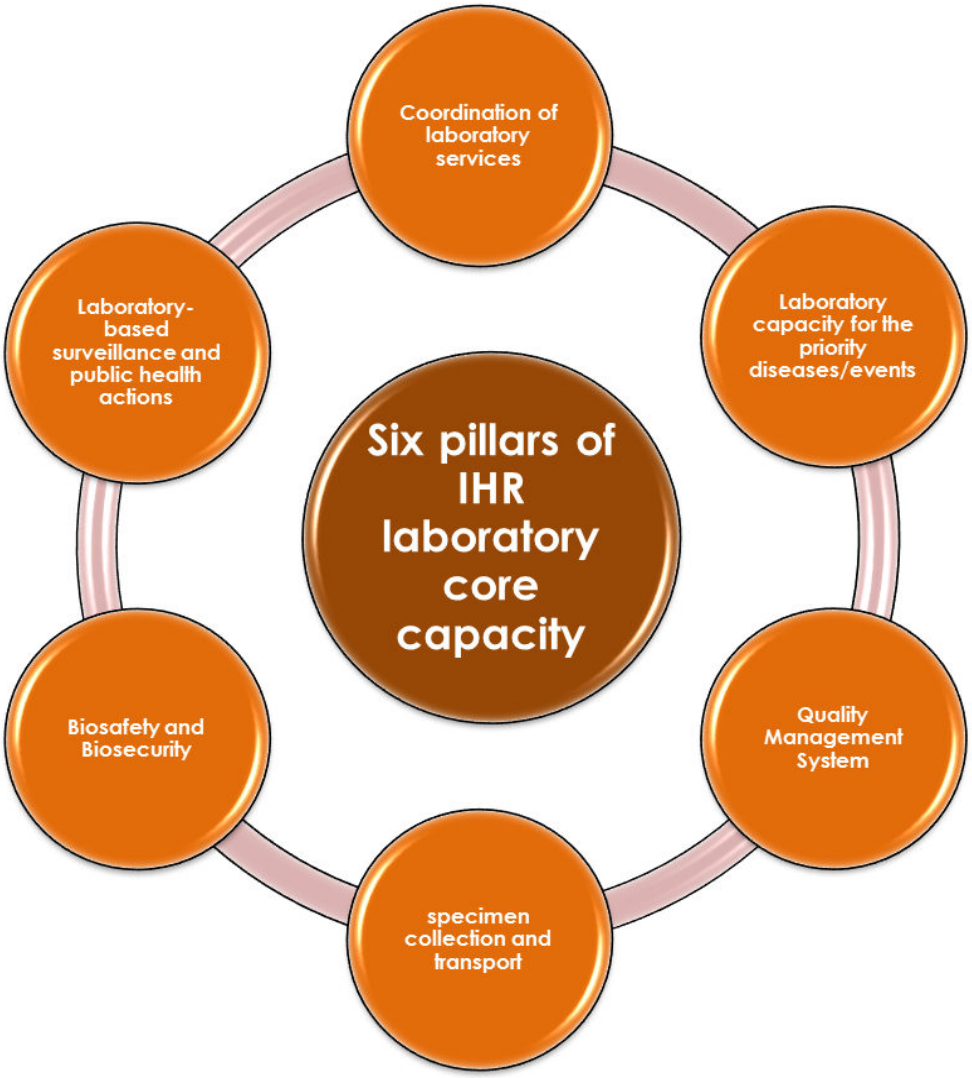

Figure 1: The six pillars of IHR laboratory core capacity

Many Member States in the Region are at different stages in developing their laboratory capacity in as far as the structure provided by the six pillars of IHR laboratory core capacity is concerned. The detailed description of these pillars builds on different tools used for assessment and monitoring of IHR core capacities by Member States. The main activities under each pillar are described in this section. Through the full implementation of the actions under each pillar, the Member States will comply with the IHR requirements for laboratory core capacity.

3.1 Coordination of laboratory services

Organization and management

As with other health departments such as pharmacy and disease control or the ministry of health, to satisfy IHR requirements a laboratory needs to include an office for coordination of its services in its organogram. The coordinator of laboratory

services should ensure constant contact is maintained with the IHR national focal point and the head of national surveillance unit or its equivalent. The laboratory services coordinator should ensure that the laboratory's roles, responsibilities, organization, activities, staffing norms, coverage and other factors related to the laboratory capacity are regularly reviewed and revamped in order to detect and respond appropriately to public health events.

Policy and regulations

A national laboratory legislation or policy should be developed or if it exists be expanded to entrench the optimal functioning and coordination of laboratory services as a critical element within the structure of the ministry of health. The legislation will also guide the development and maintenance of the laboratory component for IHR implementation. The policy document should be regularly updated and should cover the following items at the very least:

(a) Goals and objectives of the national laboratory services.

(b) Registration and licensing mechanisms for public and private laboratories.

(c) Licensing and registration processes for medical laboratory personnel, including scientific officers, technologists and technicians, as applicable.

(d) Definition of roles and responsibilities of laboratories at different levels of health care service delivery, taking into account the country' needs and all priorities related to IHR.

(e) Terms of reference for IHR-designated reference laboratories for confirmation of PHEs and monitoring of antimicrobial resistance for priority pathogens.

Other elements that should be provided for in the national policy document are:

(a) Laboratory service coordination and leadership.

(b) Laboratory structure and organization.

(c) Testing capacity for the laboratories, with the definition of the authorized tests for each level.

(d) Programmes for continuous medical education of laboratory personnel.

(e) Networking mechanisms in public health and the sample referral system, including laboratories at each health service delivery level.

(f) Mechanisms for regular monitoring and supervision of the laboratory network.

(g) The quality management system, including laboratory accreditation by national or international bodies, as well as internal and external audit mechanisms.

(h) Mechanisms for adopting and using the standard operating procedures for laboratory processes.

(i) Equipment inventory and procurement systems, including the process for equipment validation.

(j) The biorisk management system.

(k) Financial and human resource allocation for laboratory services.

The national policy document should be disseminated to all diagnostic laboratories, as it will serve as a key tool for promoting the quality of laboratory diagnostic services. The regulatory authorities should validate or regulate the in-vitro diagnostic devices used in the country.

To meet the diagnostic requirements in all levels of the health care service delivery, an official document is needed dealing with the creation of national laboratory networks for priority diseases and other public health events. In general, a network is composed of laboratories at each level of the health care service delivery such as health centre, district, provincial or national level committed to the proper diagnosis of priority infectious diseases for public health decision-making. Members of a network should establish channels for routine communication, exchange of information and interaction for specified purposes among themselves, and with epidemiology departments involved in disease surveillance and control at the national and subnational levels. In this respect, the official document should define the set criteria and terms of reference for the networks (9).

A formal network will facilitate the exchange of knowledge and expertise among experienced laboratory specialists and practitioners, facilitating timely and appropriate laboratory support for patient management and disease surveillance, prevention and control (10). The relevant ministry in charge of laboratory coordination should continuously promote the participation of members of the network in biannual or annual reviews at subnational and national levels as well as international meetings especially if they are intended to share knowledge and experiences for improved laboratory performance.

National plan of action

A strategic operational plan for strengthening laboratory services countrywide should be developed, financed, implemented and updated regularly. This plan should be an integral part of the national health plan, and indicators should be developed to monitor its implementation. It is crucial that the strategic plan include projects for building, renovating or upgrading laboratory facilities in order to best meet IHR requirements.

3.2 Laboratory capacity for the priority diseases and events

Laboratory assessment

A nationwide inventory of laboratories, both private and government owned, should be carried out by the head of the national laboratory service in conjunction with regulatory authorities responsible for laboratory licensure and registration. The purpose is to identify the capacity in various laboratories whether they are hospital, health centre, dispensary or university laboratories and whether they are used for public health, production, environmental, veterinary, research or food safety purposes or detection of hazards such as chemical, radiological or nuclear events. This inventory should be intersectoral and must cover the relevant ministries such as health, agriculture, livestock, environment, trade, education and defence. The exercise should take into account the laboratories' capacity in all relevant aspects such as clinical chemistry, bacteriology, virology, toxicology and human genetics testing. The inventory needs to include the techniques used for identification of PHEs in each laboratory, but particularly for the national reference laboratories. The inventory should cover the number of laboratory staff, their qualifications and responsibilities. The information collected should be updated yearly.

An official list of reference laboratories designated for surveillance of and response to the priority threats should be disseminated to all levels of the health care service delivery. The list should contain contact information as well as the roles and responsibilities of each reference laboratory.

Diagnostic and confirmation capacity

Despite the existence of substantial evidence on the role of laboratories in disease detection, prevention and control, clinicians may lack confidence in laboratory results if they are not always accurate or are not provided in a timely manner. When results are not available or are unreliable, clinicians often rely on clinical diagnosis and empirical treatment instead of laboratory-confirmed diagnosis (11). Each Member State should, therefore, continue to enhance the laboratory capacity to confirm PHEs such as infectious, chemical, radiological or nuclear events as well as antimicrobial resistance for priority pathogens, based on national priority public health risks. The key tasks for capacity building pertain to confirmation of PHEs, as follows:

(a) In-service laboratory training sessions should be regularly organized by the national authorities with technical assistance from WHO and other partners to cover the relevant topics. These topics may include aspects of basic and field epidemiology (e.g. those covered in the Field Epidemiology and Laboratory Training Programme), laboratory techniques, laboratory management, biosafety, biosecurity, sample management (e.g. shipment of infectious samples), logistics, and information technology. The training should be

designed to promote sustainability of the diagnostic capacity, primarily focus on human resource development, and involve national authorities in designing and customizing laboratory training tools or curricula to address the particular needs of the country while meeting international standards (12). Health facilities should have adequate laboratory staff capacity according to national minimum staffing levels (13). The capacity to plan for and establish an effective public health laboratory system that meets the IHR requirements depends on the availability of appropriately educated personnel (14).

(b) The terms of reference for the various laboratory functions with the required staff qualifications and competence should be developed and kept updated. The job descriptions of all staff should clearly define the required qualifications, duties and responsibilities.

(c) The facilities should be in good condition and with uninterrupted electricity and water supply. Adequate space should be allocated to perform the required work without compromising the quality of the services or safety of patients or personnel. Sample collection should be carried out in space that is separate from the laboratory examination rooms. It is also appropriate to separate adjacent laboratory sections in which incompatible activities are undertaken, such as nucleic acid extraction and amplification, and to designate rooms for specialized testing for example for TB or brucellosis or reagent preparation.

(d) Each country should set up an appropriate equipment management system to cover all levels of the health care service delivery and equipment donations, including those for disease-specific control programmes. A national coordination mechanism with clear guidelines should be established and implemented to ensure appropriate distribution of quality equipment from the government, donors or partners.

(e) A national supply and reagent inventory system with appropriate storage facilities and timely distribution mechanisms should be established to avoid stockouts of reagents and supplies in the laboratories or use of expired products. There should always be a buffer stock of emergency sample collection and transport supplies to be made available when the need arises.

(f) The list of priority diseases, conditions and events for IDSR and pathogens selected for antimicrobial resistance monitoring should be used in the existing integrated plan of action for strengthening the national laboratory capacity.

(g) The national laboratory standards should define the diagnostic tests and methods used by each laboratory at different levels of the health system, such as reference, national, intermediate and peripheral levels.

(h) National reference laboratories should have the capacity to accept samples for diagnosis of PHEs 24 hours a day and 7days a week.

(i) Appropriate resources should be made available to each laboratory involved in identification, investigation and response to public health events according

to their minimum staffing requirements, facility infrastructure, equipment and running costs. These resources should come from the government, donors, grants and other means, with the government providing the largest portion. It is more likely that the initial set-up costs will be supported by donors, but for sustainability of activities, it is crucial that the running costs be the responsibility of the government.

Networking

The network of national laboratories should be established well enough to allow the country to meet its diagnostic requirements and support investigations of outbreaks of events specified in Annex 2 of IHR.

The national laboratory network should promote the development of algorithms by level of health care service delivery for the exchange of specimens and sharing of laboratory data and results and mechanisms for provision of reagents, laboratory supervision, quality assurance and funding. Private laboratories should play a key role in the operationalization of the network. A supervisory mechanism should be developed to facilitate the national laboratory network to operate effectively. Efficient supervision of laboratories at the intermediate and peripheral levels is one of the strategies for ensuring standard laboratory practices are observed and opportunities are provided for continuing education and mentoring of laboratory staff (15).

Collaboration among reference laboratories in the country, including those dealing with human or veterinary diseases, and other specialized laboratories should be fostered in the context of the "one-health" approach. In addition, the national laboratories should be part of the international public health surveillance networks to facilitate disease confirmation, specifically characterization of pathogens.

A memorandum of understanding or other contractual agreement should be entered into and maintained with high quality international collaborating centres when no corresponding domestic capacity is available for referral of specimens for confirmation of public health events. Agreements with these international laboratories aim for specialized investigations of public health events related to infectious diseases, food safety, or chemical or radio-nuclear hazards. The list of external collaborating centres with information on their focal points, addresses and relevant areas of expertise should be regularly updated and disseminated to relevant national institutions. Major public health crises such as the severe acute respiratory syndrome (SARS) or a new influenza strain could become even more serious and difficult to control without their prompt and accurate detection by specialized regional or international laboratories of the existing laboratory networks (10).

One of the IHR requirements for countries is to have access to influenza testing either within or outside the country. The national reference laboratory should play a critical role in the development of the procedures for rapid virological assessment of clusters of cases with acute respiratory illness of an unknown cause or individual cases when epidemiologic risk is high, as stipulated in the IDSR technical guidelines. There is advantage in participating in the Global Influenza Surveillance Network, and to regularly submit viral isolates for analysis by WHO collaborating institutions. In addition, national data or maps on circulating strains of influenza should be available and be shared with the global community. This will help determine the laboratory capacity in each country for detection of public health events.

Given the costs associated with building laboratory diagnostic capacity, it might not be feasible for every country to have such capacity for all pathogens (16). Mapping of the diagnostic capacity of national reference laboratories for each country was carried out in 2012 through the WHO Regional Office for Africa using a self-assessment questionnaire. This survey showed that only a few countries had the appropriate capacity for confirmatory testing for all priority outbreak-prone diseases. From the findings, the 46 countries in the WHO African Region were categorized into four groups based on their self-estimated laboratory capacity to confirm IDSR-defined, epidemic-prone diseases:

(a) Category 1 — countries with the laboratory capacity to confirm 75% or more of the diseases (11 countries or 24%).

(b) Category 2 — countries with the laboratory capacity to confirm 50–74% of the diseases (8 countries or 17%).

(c) Category 3 — countries with the laboratory capacity to confirm 25–49% of the diseases (24 countries or 52%).

(d) Category 4 — countries with the laboratory capacity to confirm less than 25% of the diseases (3 countries or 7%).

With the low laboratory capacity in the Region, pooling of international laboratory resources through networks of local, national, regional and international reference laboratories is encouraged. However, the countries are expected to have the capacity to quickly and reliably conduct certain core diagnostic tests either through their own or a network laboratory to direct disease surveillance and response activities (16).

3.3 Quality management systems

For case management and to respond to internal health emergencies, the lack of laboratory results is preferable to the use of erroneous laboratory results. The lack of confidence in the quality of laboratory results is a significant problem in many countries in the African Region and can lead to the use by surveillance units of case definitions based only on clinical symptoms without specificity. Even when

laboratory testing is available in the country, a confirmation from an international laboratory, particularly for new emerging pathogens, is very often required by the health authorities to determine the best control measures. But sending a specimen outside the country for confirmation is expensive and can be difficult because of transportation logistics issues. Also, occasionally intellectual property issues arise that could delay the process and cost lives. Therefore, a quality management system that engenders trust and confidence in laboratory services is essential.

National norms

The laboratory policy in each country must provide for a quality management system that will define the standards and processes for quality control and audit, external quality assessment, and quality maintenance. National laboratory quality manuals, norms, standards, guidelines and standard operating procedures should be made available for appropriate diagnostics of priority PHEs. These documents should be regularly revised and updated. A system should be set up for the management of laboratory documents and records. Quality manuals in each national reference laboratory should describe the quality system policy and procedures in place to ensure proper laboratory management. A quality officer should be appointed to oversee the national laboratory service quality. In addition, a quality manager should be designated for each laboratory to establish a system for managing laboratory documents and records and other quality assurance components. Standard operating procedures should be developed for each laboratory if they do not exist and be appropriately and regularly validated, with that process being documented according to the defined procedures. The standard operating procedures should be reviewed at least annually and necessary amendments incorporated. They should cover all the key aspects relating to laboratory operations such as pre-examination, examination and post-examination procedures and reporting of results.

Maintenance of laboratory equipment

The laboratories should be equipped appropriately for the tests they perform and should have in place a preventive maintenance programme for the equipment. National public health laboratories should have internal capacity for preventive maintenance and repair of equipment, and only serious equipment problems should be handled by manufacturers. Where local institutional capacity for preventive maintenance and repair of equipment does not exist, the laboratory should have a standing maintenance and repair agreement with an external contractor (15). The maintenance contracts drawn up, including for after-sales service, should cover all the analytical equipment whether purchased or donated (17).

The quality assurance system should include daily recording of the temperature in the refrigerators, freezers and incubators, as well as regular identification and

inspection of the functioning pieces of the critical equipment such as PCR thermocyclers, biosafety cabinets, and chemical analysers. The laboratories should keep the list of functioning and usable equipment updated. The standard operating procedures should provide details on the methods for not only instrument maintenance but also general troubleshooting. Laboratory personnel must be able to perform simple troubleshooting procedures and be conversant with the process to notify service providers of scheduled preventive maintenance and instrument or equipment failures (18).

A corrective action log sheet should be developed to record problems and error messages that occur during or outside testing. The action taken to resolve the problem, including advice or service calls from the manufacturer, should be documented. This log should be reviewed periodically to check for trends, and any technical errors identified should be immediately addressed (18).

Internal quality control and external quality assessment

Countries, institutions and individual reference laboratories should develop an effective mechanism for internal quality control and external quality assessment (EQA) for laboratories and establish links with internationally recognized or accredited EQA bodies (19). A minimum requirement should be mandatory participation of national reference laboratories in international EQA programmes for diagnosis of major PHEs, with satisfactory results. All laboratories should ensure that internal quality control requirements are regularly observed and are incorporated into all procedures as appropriate.

Every national public health laboratory system should institute a national EQA scheme, for example for proficiency or panel testing or systematic rechecking, that must cover all the laboratories participating in surveillance of diseases of public health importance. The national EQA programme should cover but not be limited to bacteriology, virology, serology, immunology, parasitology, biochemistry, haematology, anatomical pathology, cytogenic and transfusion medicine. National level laboratories are typically responsible for implementing comprehensive proficiency testing programmes for a country's laboratory systems (20) but this can also be coordinated by independent entities. The participation in national EQA programmes by public and private laboratories should be a mandatory regulatory requirement. Corrective actions should be institutionalized for each laboratory when assessment results are found to be poor in international or national EQA schemes.

Accreditation

As a first step towards accreditation it is important to establish licensing criteria to define the minimum quality norms. Complying with the minimum standards will be the foundation for potential accreditation. Laboratories play a critical role in

providing reliable information to inform IHR decision-making and guiding public health response, and accreditation of a laboratory significantly contributes to the improvement of the quality of its diagnostic results. In addition, laboratory accreditation bridges the gap between clinicians and laboratory experts in the use of test results by improving the credibility of laboratory results (11). National reference laboratories should aim at complying with the internationally recognized standards such as ISO 15189 or equivalent requirements such as the WHO polio, measles and HIV genotyping accreditation schemes (21,22). The cost of meeting ISO requirements is far too high for most laboratories in developing countries (19). As an alternative, such laboratories should comply with national standards adapted from international standards, but only after they have met the minimum standards. All laboratories should be regularly assessed by independent inspection bodies.

Currently there are very few accredited laboratories in Africa and most of these are owned by the private sector or international research organizations. The accreditation process requires meeting stringent conditions that largely have been unattained by most public health laboratories in Africa. To address the paucity of accredited laboratories in the African Region, the WHO Regional Office for Africa established a stepwise approach (SLIPTA[1]) to help laboratories to attain the required standards. This approach involves providing support to laboratories at all levels through a series of evaluations that recognize and reward demonstrated improvements and progress towards attainment of quality standards (18). Laboratories are assigned a recognition rank based on a percentage score ranging from 1 to 5 stars. Laboratories that receive a 5-star rating are strongly encouraged to transition to an international accreditation scheme. This initiative assists laboratories to progressively improve their quality management systems towards accreditation by internationally recognized standards such as ISO (23).

3.4 Specimen collection and transportation

Infectious substances are transported for a variety of reasons within countries and across international borders. It is incumbent upon shippers to ensure packaging and shipping conditions meet regulatory requirements to preserve the integrity of the materials and facilitate their timely arrival at the destination. The capacity to safely, appropriately and rapidly ship specimens within and outside a country is crucial to detect, investigate and respond to PHEs in a timely manner.

National transport regulations

Laboratories should comply with applicable national regulations for the transport of specimens within national borders. In the absence of such regulations or for international shipment of infectious substances, laboratories need to follow applicable international requirements as described in the *WHO guidance on*

[1] Stepwise laboratory improvement process towards accreditation.

regulations for the transport of infectious substances, 2013–2014 (applicable as from 1 January 2013).

Building a specimen transportation system

A nationwide system should be established to maintain the capacity for appropriate, safe and rapid shipment of biological specimens. Sample collection and packaging materials such as triple packaging meeting P620 and P650 requirements should be pre-positioned at convenient locations to ensure rapid availability to investigation teams and for speedy delivery when needed. This process should be coordinated by the reference laboratories and the surveillance units. Triple packaging materials for categories A and B substances should be available in the reference laboratories for shipment of specimens to outside laboratories.

Shippers of infectious substances are required to maintain valid certification records. The rapid response team or other staff at relevant health care service levels should also be trained in the procedures for collection, storage and shipping of samples.

Local and international couriers should ensure that specimens are transported under appropriate conditions within and outside the country. The list of courier service providers should be available in all relevant institutions at all health care delivery levels. It is crucial that agreements with courier services for shipment of hazardous samples, including biological samples, be kept active.

The IHR assessment showed that multiple programme-based systems existed in some countries for collecting and transporting specimens to the laboratory. These included the Expanded Programme on Immunization (EPI) for measles and polio specimens, the influenza sentinel surveillance process for specimen referral to the national influenza centres, and the postal bus system used for dry blood spots for early diagnosis of HIV in infants. The challenge is to develop an integrated and cost-effective national system for the transport of all specimens from the peripheral to the national level and to ensure that specimen collection kits are available, particularly in emergency situations (13).

A specimen collection and transportation system should facilitate delivery of viable clinical specimens to an appropriate laboratory for investigation of urgent public health events or for transportation to an international reference laboratory within the recommended time frame. Although international cooperation and partnerships are encouraged for laboratory testing, they should be set up in advance so as to address the issues of specimen sharing and intellectual property rights. It is important to monitor the number of specimens referred for laboratory diagnosis, for example the non-AFP (acute flaccid paralysis) hazardous specimens

sent each year to national or international reference laboratories, in order to determine the performance of the laboratory system in the country.

3.5 Biosafety and biosecurity

Laboratory workers were some of those infected with smallpox in 1978 (24) and SARS in 2003 (25) and those infected during outbreaks of the viral haemorrhagic fever (HVF) in the African Region. The first Marburg outbreak in 1967 (26) was associated with a laboratory. These accidents threatened the control of these diseases. Biosafety measures that protect laboratory workers and contain the spread of pathogens from laboratories to communities are crucial to comply with IHR requirements.

Safety organizations

The ministry of health or a relevant ministry should have a dedicated national unit in charge of biosafety and biosecurity. It is crucial to set up a national biosafety committee, association or unit responsible for laboratory biosafety and biosecurity. In addition, there is need to identify an institution or a person responsible for inspection and certification of laboratory biosafety equipment for compliance with biosafety requirements.

Biosafety regulation and risk assessment

A biorisk management system will enable laboratories to effectively identify, monitor and control the biosafety and biosecurity aspects of their activities. Where absent, national biosafety regulations, guidelines, manuals and standard operating procedures should be developed using WHO or other resources and disseminated to all laboratories. Biorisk management systems may need to be implemented based on the normative document, *Laboratory biorisk management standard* (CWA 15793).

An up-to-date national legislation should define the minimum biosafety levels, measures and requirements for laboratory operation. In addition, national regulations or guidelines should be developed for hazardous waste management and disposal. Policies and regulations should be established to protect laboratory workers, for example by providing them with vaccination against the Hepatitis B virus or other diseases and emergency antiviral therapy, and for specific measures for pregnant women. A post-exposure prophylaxis and treatment protocol should be developed and published to enable laboratory workers in all facilities to benefit from the provisions when need arises. A national classification of microorganisms by risk group should be carried out and documented.

Biorisk assessment has to be carried out regularly and at least every two years at the national level and in the laboratories to guide creation or updating of biosafety

regulations, development of infrastructure, acquisition of equipment, development and enforcement of procedures and practices, and conduct of training activities including for decontamination and management of infectious waste. Relevant staff should be trained regularly on laboratory biosafety and biosecurity guidelines.

Laboratories should be routinely inspected for their compliance with biosafety requirements. In addition, appropriate biosecurity measures should be in place to avoid or minimize inappropriate removal or deliberate release or misuse of dangerous pathogens, for example by theft or during earthquakes or flooding.

Biosafety and biosecurity capacity building

Biosecurity is particularly important in the highly dangerous pathogen containment and storage areas, and can comprise various measures such as restricting access to sensitive areas in the laboratory. It is crucial to strengthen capacity for handling pathogens, especially in countries where highly dangerous pathogens recur.

Biosafety cabinets used in the laboratories should be certified preferably by a local certification body if one with the required capacity for this exists. Personal protective equipment should be provided in appropriate locations for immediate mobilization during a public health event. In addition, material safety data sheets[2] should be made available for handling or working with dangerous substances in a safe manner. Laboratories should have appropriate facilities for the biosafety level (BSL) to which they are assigned based on their designated functions and in accordance with recognized standards. For example, reference laboratories handling dangerous pathogens in risk groups 3 or 4 should have functional, high containment facilities per requirements for BSL 3 or BSL 4 laboratories. Each new high containment laboratory should be formally commissioned before beginning operation.

3.6 Laboratory-based surveillance and public health actions

The IDSR strategy brings together data from health facilities and laboratories in systems designed to monitor public health events. The emphasis in the African Region is on integrating surveillance and response with an efficient and effective public health laboratory system using IDSR and IHR recommendations. This approach will promote successful detection, characterization and monitoring of public health events, which are essential for their prevention and control.

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[2] The material safety data sheet (MSDS) is a technical bulletin providing detailed hazard and precautionary information. It is intended to provide workers and emergency personnel with procedures for handling or working with substances in a safe manner, and includes information on the substance's physical data (melting point, boiling point, flash point, etc.), toxicity, health effects, first aid, reactivity, storage, disposal, protective equipment, spill-handling procedures, etc.

Surveillance and response

The national laboratory services unit should be represented on any committee or task force that prepares for and responds to public health events, including the national emergency response committee. The terms of reference for the laboratory unit's participation need to be clearly defined by the members of the committee. It is an asset to have in the country staff trained through the field epidemiology and laboratory training programme (FELTP) or similar programmes as they will facilitate and promote the activities of the emergency response committees.

Operating procedures and algorithms should clearly describe how laboratories, and particularly reference laboratories, will participate in the investigation of an event and interact with the rapid response teams or the national IHR focal points. In addition, all other activities involving the national laboratory services department and the national surveillance unit should be clearly described and catered for allow surveillance of and response to all IDSR priority diseases, conditions and events.

A wide range of laboratory testing environments can be envisaged to support an investigation, such as conducting screening tests in the field using rapid diagnostic tests and confirmatory testing in existing facilities or mobile or deployable laboratories. The efficient shipment of diagnostic kits to where they are needed during epidemics or pandemics is crucial for early identification of the pathogen and close monitoring of the pandemic wave.

Data management

Implementation of IHR requires a smooth and fast communication process between the laboratory and the surveillance and response units in the ministry of health and other relevant ministries. The data management and reporting processes used by laboratory personnel can be a source of error. In view of this it is important to have standard data collection and reporting procedures and formats for use by the laboratory, the health ministry's national laboratory services department and the national surveillance unit. These procedures should include timeliness requirements for each class of pathogens. The standardized forms or other materials for collecting and reporting laboratory data should be disseminated to all laboratories by the relevant department in the health ministry. It is important to disseminate the list of notifiable diseases or events requiring laboratory confirmation to all laboratories as proposed in the national IDSR technical guidelines. In addition, and if possible, it is important to make available to relevant laboratories the list of priority chemical, radiological and nuclear events and syndromes for surveillance.

In many countries laboratory data are stored in formats that make retrieval, analysis and summarization for public health action difficult. Laboratory information is often captured in multiple reports and may be inaccurate, nonstandardized or illegible (14). It is highly recommended that the laboratories use a computerized laboratory

information system to better manage data. All laboratories should be able to at least provide basic data with statistical analysis and periodic activity reports. Support is needed to build the capacity of laboratory staff to analyse and disseminate laboratory information to facilitate early detection of new health problems or outbreaks and provide evidence-based data for policy-making and planning (10). The use of computerized laboratory information systems suitable for surveillance and response requirements should be promoted to track and monitor laboratory data.

Epidemiological and laboratory data for priority diseases, conditions and events for IDSR should be collected, compiled, analysed and disseminated to each level of the health care service delivery using the existing surveillance data flow process. Peripheral, intermediate and reference laboratories should send aggregated data to the surveillance unit at each level at the intervals defined for IDSR and IHR requirements. Each country should regularly promote observance of reporting procedures across the laboratory networks, from peripheral to central laboratories. The surveillance unit in the health ministry or a relevant ministry and the national laboratory services department should receive the overall data from laboratories nationwide.

Laboratories that handle specimens from peripheral centres, and especially reference laboratories, should send the results not only to the central surveillance and response units but also to the laboratory where the specimen originated. The national laboratory services department, in close collaboration with the epidemiological team, should carry out overall analysis of laboratory data and generate regular feedback reports. These reports should be shared with public and private laboratories, surveillance units, decision- and policy-makers, health partners and other relevant parties.

4. Fulfilling IHR laboratory core capacity

This section outlines the key elements in building and maintaining laboratory capacity to fulfil the IHR requirements, categorized under three main topics:

(a) Approaches to building laboratory core capacity.

(b) Roles of stakeholders in supporting laboratory capacity building for IHR implementation.

(c) Overview of tools for monitoring progress in laboratory capacity development for IHR implementation.

4.1 Approaches to building laboratory core capacity

After the revised IHR came into effect in June 2007, all Member States agreed to develop their surveillance laboratories' capacity to meet the IHR requirements within a time frame of five years. Various national approaches to IHR implementation have since emerged, depending on factors such as the sophistication of pre-existing health systems and infrastructure, past and present objectives of health ministries and their external partners, availability of resources, architecture of the health system, and strength of regional commitments to health cooperation and coordination (27). Member States in the African Region also recommended that IHR implementation be addressed in the context of IDSR, which provides a framework for consolidation of and coordinated approaches for rapid disease detection and public health emergency response across sectors, countries and the Region (28). Several factors will influence the process and determine the success of Member States in developing their laboratory capacity to meet IHR requirements:

- National political commitment
- Financing
- Partnerships
- Commitment of laboratory personnel
- Mapping of laboratory capacity and resources
- Opportunities to build on existing capacity
- Collaboration on cross-sectoral issues
- Collaboration among the laboratory unit, IHR national focal points and other entities

National political commitment

All Member States in the WHO African Region missed the deadline of 15 June 2012 for developing the minimum core capacities required under IHR. The main reasons for this included inadequate allocation of human and financial resources, unpredictability in funding for national IHR plans, and attrition of highly trained and skilled health personnel including the national IHR focal points (1). Government commitment and leadership will be essential to reinforce and strengthen the existing laboratory capacity for the implementation of IHR. The Fifty-eighth session of the WHO African Regional Committee (2008) endorsed the necessity of strengthening of health laboratory services through resolution AFR/RC58/R2, which urged Member States to:

(a) Develop a comprehensive national laboratory policy

(b) Formulate a national laboratory strategic plan

(c) Establish or strengthen laboratory leadership

(d) Set up a national public health reference laboratory or laboratories

(e) Strengthen the public health laboratory supply distribution system

(f) Improve public health laboratory quality assurance systems

(g) Strengthen laboratory staff training at all levels

(h) Ensure maintenance of laboratory equipment

(i) Strengthen laboratory information management systems

(j) Monitor and evaluate laboratory services

(k) Ensure adequate funding for public health laboratory services

Leadership is crucial for the success of any programme, health programmes included. Strong laboratory leadership ensures that the laboratory agenda is a central component of national health systems. The creation of a high-level, decentralized and coordinated laboratory structure is key in enabling public health laboratories to play a significant role in disease control and prevention (15). Leadership of a national laboratory coordinator and heads of reference laboratories is required to raise awareness among the national authorities in the relevant government ministries of the need to strengthen public health laboratory services and to propose actions for building national laboratory capacity.

Financial resources from governments or partners cannot have significant impact on the improvement of laboratory capacity unless appropriate skills to manage them exist.

Financing

It is crucial that the government regularly allocate a specific budget for activities of public health laboratories and their network operations. It is fundamental that after the assessment has been undertaken of laboratories' capacity to meet IHR requirements the unit in charge of laboratory coordination provide in the plan of action an appropriate costed budget for laboratory capacity building for IHR implementation. A country may need a specific internal capacity for cost-effectiveness and in order to be able to select technically and financially appropriate laboratory technologies and methods. Minimum standards are mandatory for all laboratories and efforts should be made to ensure that they are met by all facilities. There also may be higher standards that are desirable but not mandatory.

To ensure that the minimum standards are met, an adequate budget should be available for infrastructure, staff capacity building, procurement of consumables and reagents, equipment purchase and maintenance, and laboratory surveillance and response activities. It is also important to establish an appropriate salary structure for laboratory workers taking into account their work load and level of responsibility. It is necessary to motivate laboratory staff and create a conducive working environment for them to minimize attrition.

Ensuring adequate funding from government budgetary allocations is available for public health laboratory services is critical to implement IHR. Several mechanisms may be used to fund laboratory services such as government or public health insurance, user fees and donations. However, the government should remain the key source of funding for improving the capacity of national laboratory services.

Partnerships

A key challenge for countries is to ensure that laboratory strengthening accomplishes the targets defined in six key pillars for IHR laboratory requirements so that individuals and communities will benefit from improved laboratory services for detection of PHEs. This requires strong partnership in all relevant sectors, agencies and organizations and collective effort of all donors and implementing partners, with country ownership and leadership.

Partnerships of relevant sectors such as health, agriculture, travel, trade, education and defence is essential to build coherent alert and response systems that cover all public health threats and that during such events are able to rapidly mobilize the required resources in a flexible and responsive way (29). At the international level, partnership between countries is required to share technical skills and resources to support capacity strengthening at all levels, for support in times of crisis and to promote transparency.

One important question that needs to be urgently addressed is the cost of implementing the laboratory plans developed after the assessment of laboratories' capacity for IHR implementation. Financial, logistical and technical support should be provided by governments and partners. Some of the specific areas for collaboration include development of the national health laboratory policy and strategic plan and strengthening of laboratory services through development of laboratory infrastructure, personnel training, laboratory commodity procurement, supportive supervision, biorisk management and laboratory quality assurance (19).

Coordination of activities between host governments and their external funding partners as well as their interlinkage could be improved. Some donors continue to promote their own agenda in their support choices. The lack of or perceived lack of host country leadership in interaction with donors compounds the problem, creating the opportunity for implementing a donor-driven rather than a country-driven agenda that is in line with the national health plan and responds more directly to national needs (20).

Commitment of laboratory personnel

Laboratory staff, specifically the heads of various units, should be up to date on the necessary information on the IHR requirements for the laboratory component and should be responsible for advising the health ministry on what is needed to enhance laboratory service capacity in relation to IHR implementation. In addition, laboratory managers, supervisors and testing personnel at all levels should commit to:

(a) Staying informed about the national laboratory legislation, regulations and policies.

(b) Contributing to the development and implementation of the laboratory strategic plan.

(c) Efficiently and effectively contributing to the functioning of the national public health laboratory network and to resource mobilization using the existing systems.

(d) Updating their skills in new laboratory technologies for confirming public health events through self-study, on-site training with senior staff within the institution or other means of capacity building.

(e) Implementing a laboratory quality management system that complies with recognized international standards, recommended practices and national regulations.

(f) Acting in a socially responsible manner to ensure that the laboratory environment is safe and secure.

(g) Rendering quality and timely laboratory data through the existing reporting systems.

(h) Keeping their skills updated in order to contribute to the investigation and response to public health events.

Mapping of laboratory capacity and resources

Health authorities in charge of implementing IHR, and particularly the national focal point, should map and identify existing laboratory resources in the country, as often there is no broad knowledge of such resources. This is particularly true when laboratories are managed or supervised by several authorities. For instance, in many countries, animal health, food or environmental laboratories are regulated by ministries other than that of health such as the agriculture, trade and environment ministries. In resource-limited settings these laboratories can sometimes be the unique place in the country with the specific biosafety or diagnostic equipment that could be used for human specimen testing. A research laboratory might be the only one capable of testing animal or human samples for specific pathogens such as avian influenza, anthrax or rabies. It is unlikely that the public health laboratories will be able to cover the wide range of tests required for the identification of all biological, chemical or nuclear threats. For this reason the inventorying process for the laboratory capacity in the country should adopt an all-hazards approach and include human health, veterinary and environmental laboratories, whether they are public, private, hospital, academic or research facilities. Links should also be established among these laboratories to facilitate collaboration. An up-to-date registration or licensure system is essential to achieve the goals of this inventory.

Regular laboratory capacity mapping will determine their ability of implement IHR and help define the plan of action to address the gaps identified in meeting the laboratory requirements for IHR implementation as outlined in Annex 1A. The situation analysis should be conducted using the WHO protocol for assessing national surveillance and response capacity for IHR that includes all the pillars for IHR laboratory requirements, and the WHO laboratory assessment tool (2,30,31). During the mapping exercise it is crucial to identify the strengths, weaknesses, opportunities and threats for each laboratory. The gap analysis should define the most important needs or weakness for each laboratory, particularly in the following areas:

(a) Regulatory framework, organization and service delivery structure

(b) Human resource qualifications, availability and deployment

(c) Equipment adequacy, calibration and maintenance

(d) The supply management system, including quality, availability and delivery of supplies

(e) Specimen collection, storage and transportation

(f) Guidelines on laboratory practices

(g) The quality management system

(h) Safety and security

(i) Data management

(j) Financial resources for laboratory activities

Opportunities to building on existing capacity

The successful implementation of IHR requires a strong national public health system that is capable of providing critical response during a public health event of international concern. Member States should utilize existing national structures and resources to develop their laboratory capacity to achieve IHR standards. This is Member States' responsibility with technical support from WHO if needed. The objective is not to create a new vertical IHR programme but rather to build on existing capacity.

It is essential that the experience from the response to the influenza A(H1N1)pdm09 be capitalized on to develop generic capacity for responding to any unknown, emerging or re-emerging event. Countries could also take advantage of the polio and influenza networks for specimen transport within or their borders (2). But it requires strong intersectoral coordination that goes beyond the programmes for the control of human endemic or epidemic-prone disease to address the capacity development issues for the animal or environmental health laboratories in line with the one-health approach.

Collaboration on cross-sectoral issues

While considerable effort has been made to improve health laboratory services in the WHO African Region, much of the focus has been on programmes for controlling specific diseases such as polio, measles, yellow fever, rotavirus, paediatric bacterial meningitis, influenza, HIV/AIDS and TB. As a result, laboratory services are often fragmented and other sections of the laboratory system are accorded low priority with inadequate allocation of resources. Building the laboratory core capacity for IHR implementation should not consist of a new vertical programme but rather be an opportunity for better coordination of existing laboratory programmes and networks. The cross-cutting elements shared by the health laboratory networks are well described in various guidelines and manuals. A thorough examination of these networks will permit synthesizing of plans and actions for developing the laboratory capacity for IHR implementation.

A comprehensive national laboratory strategic plan should focus on strengthening the core cross-cutting elements of the health laboratory systems including:

(a) The framework for training and retaining laboratory workers and facilitating their career development.

(b) Infrastructure development.

(c) Supply-chain management for laboratory supplies and maintenance of laboratory equipment.

(d) Specimen referral systems for an integrated, tiered national laboratory system network.

(e) Standards for quality management systems and accreditation of laboratories and facilities.

(f) Laboratory information systems.

(g) Biosafety and waste management.

(h) The governance structure to clearly address regulatory issues and define reporting structures, authority and the relationships between private diagnostic and public health laboratories to ensure smooth functioning of the national laboratory service network (11).

Integration of national public health laboratory programmes will ensure sharing and optimal use of available resources (10). The department in charge of the health laboratory services in the country, working in close collaboration with relevant stakeholders, should take advantage of the support from the various disease programmes to coordinate and monitor the implementation of the cross-cutting activities.

Developing a comprehensive national laboratory strategic plan that integrates multiple diseases of public health importance is essential for strengthening national laboratory services (32). The national strategic plan should integrate all IDSR priority diseases, events and conditions. This approach of promoting one laboratory system in the overall efforts for strengthening the laboratory services across the different disciplines, such as bacteriology, virology, biochemistry, will contribute to building laboratory core capacity for IHR implementation and its sustainability. To tackle the challenges confronting national public health laboratory services in the African Region, there is need for combination of complementary measures, actions, strategies and capacity strengthening across departments and sectors (15).

Collaboration among the laboratory unit, IHR national focal point and other entities

Laboratory capacity for IHR implementation should be regularly monitored to identify gaps using the existing WHO tools. The action plan should be reviewed based on the findings from the self-assessment IHR monitoring framework so that identified gaps are properly addressed. In addition, resource mobilization should be ensured to implement the plan for the development and maintenance of the laboratory capacity for IHR implementation. Collaboration between the laboratory coordination unit and the IHR national focal point is crucial in all phases of laboratory capacity strengthening actions outlined under the six-pillar model defined for IHR laboratory requirements. In addition, coordination among the laboratory networks or entities is important, as well as strong collaboration with the

national surveillance units, point-of entry authorities and IHR national focal points. This approach will promote the sharing of existing resources to implement the IHR plan of action.

4.2 Roles and responsibilities of stakeholders in supporting capacity enhancement for IHR implementation

Country responsibility

IHR is a legally binding international instrument for preventing and controlling international spread of diseases while avoiding unnecessary interference with international travel and trade. WHO Member States have agreed to comply with IHR rules in order to contribute to regional and international public health security (1). Each country is required to assess its national resources in disease surveillance and response and develop a national action plan to implement IHR, permitting rapid detection of and response to risks of international disease spread. State Parties may need to mobilize additional resources or re-allocate resources to develop, strengthen or maintain their disease surveillance and response capacities.

Meeting the IHR capacity obligations is not easy even for developed countries and requires considerable investment and commitment at all levels. However, such investment is justified, as developing national core capacity will enable the countries to better protect themselves against public health events arising within their borders or other parts of the world (33).

WHO support for IHR implementation

WHO is working with public and private sector partners around the world to help countries develop their IHR core capacities. WHO support, drawn from all levels of the organization, covers many IHR facets, including:

(a) Provision of guidance and monitoring and evaluation tools and support as required for development of IHR core capacities.

(b) Fostering partnerships.

(c) Dissemination of information gathered about public health risks worldwide that is necessary for Member States to protect themselves.

(d) Directly supporting States Parties to assess and monitor the implementation of IHR.

Specific WHO support for laboratory capacity development focuses on the following elements (see also Table 1):

(a) Leadership and guidance for developing policies, norms, standards and guidelines and assessment tools for laboratory performance within the context of IDSR and IHR.

(b) Enhancement and expansion of regional laboratory networks for surveillance and response to IDSR priority diseases, conditions and events in the Region.

(c) Facilitation of twinning projects between resource-limited and specialized laboratories.

(d) Support for training courses and regional or subregional meetings for laboratory specialists on public health laboratory networks and IHR awareness.

(e) Laboratory accreditation.

(f) Reagent distribution.

(g) External quality assessment and on-site evaluation and planning specifically for vaccine preventable diseases such as polio, measles and rubella.

(h) Support for implementation of appropriate biosafety, biosecurity and biorisk management processes, including for safe transport of infectious substances.

(i) Promotion of collaboration between public health and animal health laboratories within the framework of the one-health concept.

(j) Advocacy and resource mobilization to support the strengthening of public health laboratories in the WHO African Region.

Table 1: Key strategic pillars for building laboratory capacity for IHR implementation

Pillars for IHR laboratory core capacity	Key points to consider	Role of WHO
Coordination of laboratory services	• Laboratory organization in the management structure of the health ministry • National laboratory focal point in the health ministry • National laboratory regulation mechanism • Official documentation for the national public health laboratory network • National laboratory policy and strategic plan	• Advocate through regional committee resolutions • Provide standards and guidelines for enhancing laboratory services
Laboratory capacity for the priority diseases or events	• Up-to-date mapping of all laboratories • National standards for competence, essential infrastructure, equipment, tests and techniques at each level of the network for confirmation of public health events • Memoranda of understanding with external collaborating centres	• Develop standardized tools • Assist in upgrading human resource skills • Facilitate linking of national networks with regional and international networks
Quality management system	• National quality office • National quality norms, standards and guidelines, including standard operating procedures for laboratory practices • External quality assessment • Certification and accreditation	• Assist in setting up a laboratory quality management system using WHO resources • Develop external quality assessment schemes • Develop a step-by-step approach to assist Member States with accreditation process (SLIPTA)
Specimen collection and transport	• National system for sample transportation • Availability of sample collection and transportation kits • Identification of appropriate courier services • Training in transportation of infectious substances, ensuring appropriate levels of staff with valid certification are maintained	• Facilitate transportation logistics • Provide training on shipment of infectious substances
Biosafety and biosecurity	• Risk assessment and legislation • Availability of biosafety manuals • Biosafety training • Availability of safe and secure equipment • Laboratory containment capacity development	• Develop biosafety and biosecurity guidelines • Provide technical support on biosafety and biosecurity issues, for example for training on biorisk management
Laboratory-based surveillance and public health actions	• Laboratory networks • Effective supervision systems • Data management and reporting, including laboratory information management systems • Surveillance, outbreak preparedness, investigation and response • Laboratory financing	• Advocate for and mobilize resources for disease surveillance and response • Enhance and expand the regional laboratory networks • Assist in setting up of a laboratory information management system

4.3 Monitoring IHR core capacity development

The Sixty-first World Health Assembly adopted a resolution in 2008 in accordance with Article 54 of IHR requiring State Parties and WHO to report to the World Health Assembly on progress made in implementing IHR. A monitoring framework was developed for that purpose.

Indicators for progress in laboratory capacity development for IHR implementation

To monitor the development in laboratory capacity across IHR relevant hazards, such as infectious and zoonotic diseases; food, , chemical and radio-nuclear safety; and other hazards, an indicator framework was developed along the lines of the WHO tools used for assessment of other IHR core capacities and the IDSR strategy. States Parties are encouraged to report annually to the World Health Assembly on all 20 indicators to monitor progress in core capacities at a point in time as well as progress over time, and to update their plan of action to address identified gaps. These indicators were developed by a group of technical experts in accordance with the specifications of Annex 1 of the Regulations.

A national laboratory coordinator may be part of the group in charge of supporting the IHR national focal point to complete the monitoring checklist or the electronic data reporting form, but dealing mainly with the laboratory component.

The indicators for monitoring progress in IHR core capacity development are described in the *Checklist and indicators for monitoring progress in the development of IHR core capacities in States Parties, February 2011*. These indicators require the following actions at the country level:

- **Establishment of the coordinating mechanism for laboratory services**
- **Laboratory services are available to test for priority health threats**
- **Influenza surveillance is established as a proxy for diseases in Annex 2 of the IHR**
- **Establishment of the system for collection, packaging and transport of clinical specimens**
- **Laboratory biosafety and Laboratory Biosecurity (Biorisk management) practices are in place**
- **Establishment of Laboratory data management and reporting**

It is important to remember that the 20 indicators for reporting to WHA were selected from the 28 global indicators for monitoring the development of IHR core capacities. Countries are encouraged to report on all 28 indicators. Two of indicators were selected for the laboratory component:

Data collection for monitoring progress in IHR core capacities

The IHR secretariat is required to provide an annual report to the World Health Assembly detailing WHO and States Parties progress on IHR implementation. To assist Member States in their responsibility to report to the Assembly, the IHR secretariat has developed a data-collection tool that will enable each country to provide standardized information about progress in its core capacities in implementation of IHR (34). The data collection tool is designated primarily for use by national IHR focal points for collaborative activities with public health professionals and managers and other sectors and stakeholders responsible for implementing IHR (34). The questionnaire is divided into 13 sections, for each of the eight core capacities, the point of entry and the four hazards. The focal point for the coordination of the laboratory services in the ministry of health and the heads of the national reference laboratories should be fully informed of the laboratory capacity component requirements for IHR implementation in order that they provide appropriate and accurate data for the laboratory section of the World Health Assembly annual report.

Outputs for monitoring the laboratory capacity development for IHR implementation

The checklist for monitoring the laboratory capacity for IHR implementation presents country profiles based on the six pillars proposed for laboratory compliance with the IHR requirements. The data will enable national stakeholders to assess progress, identify capacity gaps and prioritize capacity building activities in policy development, coordination of laboratory services, laboratory diagnostic and confirmation services, specimen collection and transportation, laboratory biosafety and biosecurity, and laboratory-based surveillance. In addition, the data will provide an overview of progress in implementation of IHR at regional and global levels.

National laboratory experts should be able to interpret and use the data on laboratory capacity monitoring from the different IHR tools to take appropriate action to address gaps in the specific elements of the laboratory capacity. WHO support may be requested to assist in interpreting the results, making recommendations for follow-up action and efforts to strengthen specific capacities (35).

References

1. Resolution AFR/RC62/12. Implementation of International Health Regulations (2005) in the WHO African Region. Sixty-second session of the WHO Regional Committee for Africa, Luanda, Angola, 19–23 November 2012.
2. Protocol for assessing national surveillance and response capacities for the International Health Regulations (IHR) in Accordance with Annex 1 of the IHR. A guide for Assessment Team. Geneva, World Health Organization, 2010 (WHO/HSE/IHR/2010.7).
3. International Health Regulations (2005), 2nd ed. Geneva, World Health Organization, 2008.
4. Strengthening national capacities for epidemic preparedness and response in support to national implementation of IHR (2005). Report of a WHO meeting, Lyon, France, 2–5 May 2006. Geneva, World Health Organization. (WHO/CDS/EPR/LYO/2006.4).
5. Resolution WHA59.2. Application of the International Health Regulations (2005). In: Fifty-ninth World Health Assembly, Geneva, 22–27 May 2006. Resolutions and decision and annexes. Geneva, World Health Organization, 2006, 3–6.
6. Resolution WHA61.2. Implementation of the International Health Regulations (2005). In: Sixty-first World Health Assembly, 19–24 May 2008. Resolutions, decisions and annexes. Geneva, World Health Organization, 3–4.
7. International Health Regulations (2005), WHO Regional Committee for Africa, Addis Ababa, Ethiopia, 31 July 2006, Provisional agenda item (10.2. INF.DOC/2).
8. The Work of WHO in the WHO African Region, 2010–2011: biennial Report of the Regional Director. Brazzaville: WHO Regional Office for Africa, 2012. (AFR/RC62/2).
9. Guide for national public health laboratory networking to strengthen Integrated Disease Surveillance and Response (IDSR). Brazzaville, WHO Regional Office for Africa, 2008.
10. Asia Pacific Strategy for Strengthening Health Laboratory Services (2010-2015), WHO South-East Asia Region & Western Pacific Region. 2010.
11. Nkengasong JN et al. Laboratory systems and services are critical in global health. Time to end the neglect? Am J Clin Pathol, 2010, 134:368–373.
12. Specter S et al. ASM LabCap's contributions to disease surveillance and the International Health Regulations (2005). BMC Public Health, 2010, 10(Suppl 1):S7.
13. Wamala JF et al. Assessment of core capacities for the International Health Regulations (IHR[2005]) — Uganda, 2009, BMC Public Health, 2010, 10(Suppl 1):S9.
14. Masanza et al. Laboratory capacity building for the International Health Regulations (IHR [2005]) in resource-poor countries: the experience of the African Field Epidemiology Network (AFENET). BMC Public Health 2010, 10(Suppl 1):S8.

15. Strengthening public health laboratories in the WHO African Region: a critical need for disease control, Regional Committee for Africa, 1–5 September 2008, Younde, Cameroon. (AFR/RC58/R2).

16. Kashef Ijaz et al. International Health Regulations — What gets measured gets done. Emerging Infectious Diseases, 2012, 18(7):1057–1057.

17. Development of national health laboratory policy and plan. WHO South-East Asia Region and Western Pacific Region, 2011.

18. Larry E et al. A quality management system approach for CD4 testing in resource-poor settings, American Journal of Clinical Pathology, 2010, 134:556–567.

19. Opio A et al. Country leadership and policy are crucial factors for implementing laboratory accreditation in developing countries: a study on Uganda, American Journal of Clinical Pathology, 2010, 134:381–387.

20. Olmsted SS et al. Strengthening laboratory systems in resource-limited settings. American Journal of Clinical Pathology, 2010, 134:374–380.

21. Joint WHO-CDC Conference on Health Laboratory Quality Systems, 9–11 April 2008, Lyon, France. Geneva, World Health Organization. (WHO/HSE/IHR/LYO/2008.3).

22. Weekly Epidemiological Record, 8 August 2008, 83(32):285–292.

23. Gershy-Damet G-M et al. The World Health Organization African Region laboratory accreditation process: improving the quality of laboratory systems in the African Region, American Journal of Clinical Pathology, 2010, 134:393–400.

24. Global Alert and Response (GAR): smallpox. http://www.who.int/csr/disease/smallpox/en/.

25. Laboratory confirmation of a SARS case in southern China - update 2, 5 January 2004, Global Alert and Response (GAR) http://www.who.int/csr/don/2004_01_05/en/.

26. Marburg haemorrhagic fever, Fact sheet November 2012. http://www.who.int/mediacentre/factsheets/fs_marburg/en/

27. Katz R et al. Costing framework for International Health Regulations (2005). Emerging Infectious Diseases, 2012, 18(7):1121–1127.

28. Technical guidelines for integrated disease surveillance and response in the WHO African Region, 2nd edition. Geneva, World Health Organization, 2012.

29. International Health Regulations (2005), Areas of work for implementation. Geneva, World Health Organization, 2007 (WHO/CDS/EPR/IHR/2007.1).

30. Laboratory assessment tool, Annex 1: System questionnaire. Geneva, World Health Organization, 2012 (WHO/HSE/GCR/LYO/2012.2).

31. Laboratory assessment tool, Annex 2: Facility questionnaire. Geneva, World Health Organization, 2012 (WHO/HSE/GCR/LYO/2012.2).

32. Nkengasong JN et al. Critical role of developing national strategic plans as a guide to strengthen laboratory health systems in resource-poor settings. American Journal of Clinical Pathology, 2009, 131:852–857.

33. Lyons S et al. Implications of the International Health Regulations (2005) for communicable disease surveillance systems: Tunisia's experience. Public Health, 2007, 121:690–695.

34. IHR core capacity monitoring framework: questionnaire for monitoring progress in the implementation of IHR core capacities in states parties. Geneva, World Health Organization, 2011.

35. IHR core capacity monitoring network: checklist and indicators for monitoring progress in the development of IHR Core Capacities in States Parties. Geneva, World Health Organization, 2011 (WHO/HSE/IHR/2010.1.Rev.1).




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