Original Article

Evaluation of Preparedness of Provincial Laboratories in Kenya to Respond to Public Health Emergencies

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Public health laboratories are critical for diagnosing and supporting control of infectious diseases. Concern about Kenyan provincial laboratories' ability to detect and respond to outbreaks and other emergencies has increased in recent times, with cholera and Rift Valley fever outbreaks as examples. These situations have raised questions regarding readiness of laboratories for outbreaks and emergency response, particularly to serious threats such as Ebola. We assessed provincial laboratories to determine their level of preparedness. We selected eight out of ten core functional areas of the World Health Organization's Laboratory Assessment Tool / Facilities (WHO LAT) that are critical for responding to public health emergencies. Managers of the eight provincial laboratories completed the checklist, which assesses preparedness and emergency responses in eight components: equipment; reagents and supply; analysis and test performed biosafety, hygiene and security; total quality; laboratory staffing and working time; reporting, analysis and communication; and outbreak participation. Percentage scores relative to the World Health Organization benchmark were calculated for each of the eight components. Median overall scores across the eight laboratories for five out of eight components were 41-49% of the benchmark level set by the WHO; reagents and supply exceeded the minimum optimal WHO of 50% threshold, attaining median score of 67% (55-85). Lab 6 scored was rated optimal scores of 75% and above on 23 of 32 specific indicators. All of the other provincial laboratories achieved at least 75% on 11 to 16 indicators out of 32 indicators. Provincial laboratories in Kenya are therefore inadequately prepared for public health emergencies. The result of this evaluation illustrated a need to improve the ability of provincial laboratories to respond to public health emergencies.

Key words: Kenya, laboratories, public health, emergencies

Introduction

Functional and adequate laboratories are a critical component of a national public health system for diagnosis, treatment, surveillance and prevention of public health emergencies (1). Because of these roles, laboratories in developing countries should be adequately prepared to provide timely and accurate diagnostic tests to enable effective public health responses and disease surveillance (2). However, inadequate equipment, unreliable diagnostic tests, and under-funding are major factors that prevent laboratories from achieving these goals (3).

In 2005, the World Health Organization's (WHO) member states adopted revised International Health Regulations (IHR), committing them to develop capacities in monitoring, reporting and providing responses to diseases posing public health threats (4). Strengthening

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laboratories is one of the core capacities required by IHR; laboratory services need to be part of every phase of alert and response, including detection, investigation and response to public health threats (5). In Africa, laboratory services are not afforded equal priority to other health services despite the need to improve infrastructure, human resources and modernization of laboratory equipment (6). This has limited laboratories from implementing IHR goals. Recent efforts to improve laboratories have primarily focused on HIV/AIDs, malaria and tuberculosis. As emerging and re-emerging diseases are imminent threats, strengthening laboratories to handle multiple diseases is imperative (7).

In Kenya, provincial public health laboratories support intermediate laboratories in confirming causative agents in an outbreak, and transmitting data to the national public health laboratories and WHO's Integrated Disease and Surveillance Response (IDSR) network. Concerns about the adequacy of these provincial laboratories has been the subject of continuous debate. We assessed provincial laboratories on eight core capacities to determine their level of preparedness and identify gaps in responses to public health emergencies in the provinces.

Materials and Methods

Evaluation tool

WHO has developed a Laboratory Assessment Tool (LAT) to assess the general capacity of laboratories (8). The LAT consists of ten core functional components for laboratory capacity: building facilities and utility service; biosafety, hygiene and security; specimen collection and recording; equipment; reagents and supply; analysis and test performed; laboratory staff and working time; total quality; reporting, analysis and communication; and outbreak participation. To evaluate laboratory emergency preparedness, we selected eight of the above ten core functional components, omitting 'building facilities and utility service' and 'specimen collection and recording'. We further selected specific checklist questions within the eight chosen components that were most relevant to the laboratories' capacity to deal with public health emergencies. Details of the components and specific indicators shown in Table 1. The LAT was scored according to directions in the User Manual (9). We used item scores as a proxy for public health preparedness, adding the scores across specific indicators for eight components to obtain a total item score. The higher the total item score, the better the laboratory preparedness capacity.

Evaluation of laboratories

We evaluated all eight provincial laboratories in Kenya between July and August 2010. Study investigators explained the nature and purpose of the assessment to laboratory managers and obtained permission to conduct the assessments. Verbal informed consent was obtained from laboratory managers prior to interview. We administered the LAT via interviews with laboratory managers and staff, and answers were crosschecked by visual observations and register reviews.

Data were entered, cleaned, checked, and analyzed using Microsoft Excel (Microsoft Corp, Redmond, WA). We calculated scores as percentages of the level set as the ideal benchmark by the WHO LAT (9). After an evaluation, a laboratory components were a score out of 100 percent points in order to determine its threshold from lower optimal, < 24%, minimal optimum, 25-49 %, medium optimal 50-74% and best optimal 75-100% for the 32 specific indicators for the eight chosen components relevant to emergency preparedness and response.

Results

Eight provincial laboratories were evaluated during the period. Of all the laboratories total cumulative tests done daily were 3820 test (range 395-550) and representation of 170 (range 16-32) laboratory staff work force across the labs. On scoring of indicators, the median overall scores on eight laboratories for five out of eight components were between 41% and 49% of the WHO threshold. Reagents and supply, total quality median scores of 50% and 67% respectively which are within sub-optimal threshold .Only laboratory staff and working time attain the optimal threshold as per the WHO LAT tool(Table 2). With regard to personnel, seven labs reported that they have an adequate number of specialized staff and support staff (median score of 100 and range 0-100) and only 1/8 lab score of 0% of the threshold. Half of laboratories registered medium optimal (50%) performance on availability of external quality assurance program and other half scored best optimal performance of 100%. Despite EQA program in place, internal quality control program 5/8 laboratories register low threshold of less than 24%.

Table 1 Selected components and specific indicators for the evaluation of laboratory preparedness and emergency response capability in Kenya (8)

Components	Specific indicators
Biosafety, hygiene and security	• Use of safety equipment
	• Availability of safety procedures
	• Level of safety trainings
	• Availability of biosafety documentation
Equipment	• Percentage of minimal functional equipment available
	• Percentage of optimal functional equipment available
Reagents and supply	• Quality of reagent management
	• Availability of funds for reagents
	• Availability of enteric transport and culture media
	• Availability of meningitis transport and culture media
	• Availability of other transport and culture media
Analysis and test performed	• Availability of screening for targeted diseases
	• Availability of high level identification
Laboratory staff and working time	• Presence of a senior staff
	• Percentage of senior staff
	• Presence of cleaning staff
	• Availability of staff training
	• Availability of formal training
Total quality	• Availability of technical procedures
	• Availability of internal quality control
	• Availability of external quality control
	• Availability of temperature charts
	• Performing of preventive maintenance
Reporting, analysis and communication	• Availability of disease reporting
	• Availability of activity recording
	• Availability of electronic activity recording
	• Availability of sample referral
	• Availability of lab/lab collaboration
Outbreak participation	• Involvement during outbreaks
	• Specific outbreak supply
	• Outbreak participation
	• Specific outbreak guidelines

Table 2 Scores for laboratory preparedness and outbreak response of provincial laboratories in Kenya, August 2010, as a percentage of the WHO benchmark level

Components	Provincial laboratories' pooled scores‡ (as % of WHO benchmark level)		
Indicators	**Median**	**Min**	**Max**
Biosafety, hygiene and security	***49***	***35***	***79***
Safety equipment	40	40	60
Safety procedures	56	0	100
Safety training	100	100	100
Biosafety documentation	0	0	100
Equipment	***41***	***19***	***60***
Minimum equipment available	49	23	63
Optimal equipment available	33	15	60
Reagents and supply	***67***	***55***	***85***
Reagent management	80	50	80
Budget allocation for reagents	75	50	100
Culture media	52	10	75

Components	Provincial laboratories' pooled scores‡ (as % of WHO benchmark level)		
Indicators	**Median**	**Min**	**Max**
Analysis and test performed	***48***	***20***	***74***
Targeted diseases	75	40	100
Specialized diagnosis	13	0	40
Laboratory staff and working time	***86***	***39***	***98***
Presence of a senior staff	100	0	100
Presence of cleaning staff	100	100	100
Availability of staff training	100	0	100
Availability of formal training	100	100	100
Working hours	88	13	88
Critical thinking outside working hours	75	0	100
Total quality	***59***	***31***	***92***
Availability of technical procedures	100	0	100
Availability of IQC	23	0	80
Availability of EQC	75	50	100
Availability of temperature charts	63	0	80
Performing of preventive maintenance	60	0	75
Reporting and communication	***48***	***40***	***83***
Report infectious disease to other institutions	50	20	100
Analyze lab data reporting	75	25	100
Mode of data transmission (electronic)	0	0	67
Sample referral to reference labs	67	0	100
Support from other labs (reagents and technical)	75	50	100
Outbreaks participation	***49***	***10***	***75***
Involvement in outbreaks	75	0	100
Field investigations of outbreak	50	0	100
Have IDSR† guidelines in labs	0	0	100
Receive supplies for outbreaks from Kenyan government/WHO or NGO	50	0	100

‡Scores are presented as percentages of the international benchmark level defined by WHO (i.e. Lower optimal, < 24 %, minimal optimal, 25-49 %, medium optimal, 50-74% and best optimal, 75-100%).

†IDSR, Integrated Disease Surveillance and Response; NGO, non-governmental organization; WHO, World Health Organization

Figure 1 presents the performance across laboratories and highest-scoring laboratory. Lab 6 as per the LAT tool registered best optimal performance of scores 75% and above on 23/32 indicators of eight components. Both lab5 and7 registered lower optimal score of 10/32 indicators indicating the lowest performing laboratories as per LAT assessment tool on level of preparedness and responses to public health emergencies.

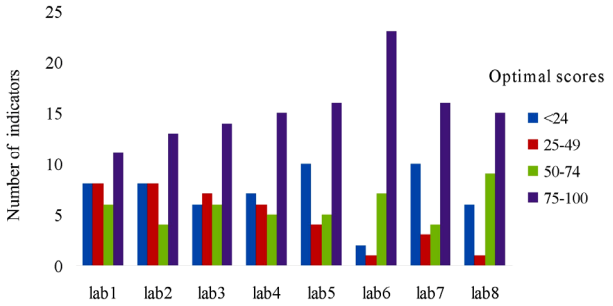

Fig.1 *Performance of laboratories against specific indicators threshold as per WHO LAT assessment tool*

Discussion

Findings from this study suggest that provincial laboratories in Kenya are inadequately prepared for public health emergencies. Several reports and studies have highlighted the gaps in public health laboratories' capacity to offer public health services in outbreak and emergency responses (2, 10, 11). The findings of our study indicate that the laboratories have a low capacity with regard to basic functional equipment, availability of reagents and specialized diagnostic tests, outbreak participation, and reporting and communication of laboratory data.

Similar assessments of the status of public health laboratories in Africa reported inadequate laboratory capacity to diagnose infectious agents, especially due to inadequate functional equipment, culture media and specialized diagnostic tests hampering response efforts to outbreak investigations (2, 3, 12).

A lack of specialized tests – especially molecular testing such as polymerase chain reaction (PCR), enzyme-linked immunoassays (ELISA) and microbiologi-

cal capacity tests – was evident in these provincial laboratories, which scored between 13% and 40% for diagnostic capacity. In addition, a referral system to send samples to other specialized laboratories, such as the Kenya Medical Research Institute, was not in place in all the provincial labs. Therefore, these laboratories do not have the capacity to identify causative agents. Kenya faces a situation in which provincial laboratories are unable to detect pathogens of public health importance and respond to outbreak investigations. These conditions prevail in sub-Saharan Africa, where laboratories are often unable to recognize or confirm pathogens by available laboratory methods (13).

Most of the laboratories scored below the WHO benchmark for biosafety, hygiene and security. However, low scores for biosafety documentation contrast with the optimal score of 100% for safety training. As IHR requires all member states to put biosafety and security precautions in place in public health laboratories handling highly infectious samples or agents (14), further investment in laboratories to ensure adequate resources and equipment is needed to enable provincial laboratories to respond to emergencies and investigate outbreaks.

Despite recent advances in electronic data collection and transmission, most of these laboratories report their data in paper form to national public health laboratories and to IDSR. Hence, analysis of data within the laboratories was minimal, hampering disease-monitoring efforts. However, two laboratories have Laboratory Information Systems (LIMs) in place, although data analysis remained minimal. The six remaining laboratories lack a database for data storage and transmission from provincial to national level, and vice versa. A LIM is critical to enable effective disease surveillance and timely responses to disease outbreaks (5). Rolling out LIMs to link all provincial laboratories to a central database is critical to meet these objectives.

Provincial laboratories performed better in the reagents and supply component, scoring 100% across all laboratories in all the assessed indicators. The reason for this was that some of the laboratories had received supplies from the Kenya Ministry of Public Health and Sanitation and from non-governmental organizations (NGOs) during the 2009 to 2010 cholera outbreaks, which coincided with our evaluation period. Therefore, these positive results might not reflect the true situation in all laboratories under standard conditions.

Most laboratories did not achieve WHO LAT threshold level on outbreak participation and equipment ccomponents. This limits public health laboratories core function as an integral component in responding to public health system especially infectious disease surveillance. Lack of this component are major contributor to delayed or inappropriate responses to epidemics diseases and control (6). Elsewhere for instance, evaluation of laboratories in Sub-Saharan Africa were unable to identify common microorganisms that causes outbreak of high magnitude (15)and this is no different to Kenyan situation. This presents under investment on equipment on public health laboratories and integration of laboratories with public health surveillance systems. Integrating and involving provincial laboratories in outbreak planning and management of outbreaks could play a role in outbreak response.

This report is subject to limitations. The survey was restricted to provincial laboratories, limits generalization to other laboratories. The retrospective nature of the study and self-reported data collected from laboratory staff and line managers is subject to recall bias that may not reflect the true situation. Despite its limitations, this evaluation provides a snapshot of provincial laboratories in Kenya, illustrating that attention is needed on investment of equipment, involving laboratories more on outbreak participation and enhancing the capacity for specialized laboratory diagnostic capability for Kenyan laboratories' to respond to public health emergencies.

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