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Strengthening public health laboratory capacity in Thailand for International Health Regulations (IHR) (2005)

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ABSTRACT

Introduction: Thailand conducted a national laboratory assessment of core capacities related to the International Health Regulations (IHR) (2005), and thereby established a baseline to measure future progress. The assessment was limited to public laboratories found within the Thai Bureau of Quality and Safety of Food, National Institute of Health and regional medical science centres.

Methods: The World Health Organization (WHO) laboratory assessment tool was adapted to Thailand through a participatory approach. This adapted version employed a specific scoring matrix and comprised 16 modules with a quantitative output. Two teams jointly performed the on-site assessments in December 2010 over a two-week period, in 17 public health laboratories in Thailand. The assessment focused on the capacity to identify and accurately detect pathogens mentioned in Annex 2 of the IHR (2005) in a timely manner, as well as other public health priority pathogens for Thailand.

Results: Performance of quality management, budget and finance, data management and communications was considered strong (>90%); premises quality, specimen collection, biosafety, public health functions, supplies management and equipment availability were judged as very good (>70% but ≤90%); while microbiological capacity, staffing, training and supervision, and information technology needed improvement (>60% but ≤70%).

Conclusions: This assessment is a major step in Thailand towards development of an optimized and standardized national laboratory network for the detection and reporting of infectious disease that would be compliant with IHR (2005). The participatory strategy employed to adapt an international tool to the Thai context can also serve as a model for use by other countries in the Region. The participatory approach probably ensured better quality and ownership of the results, while providing critical information to help decision-makers determine where best to invest finite resources.

Key words: Laboratory assessment, International Health Regulations, Thailand

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INTRODUCTION

The revised International Health Regulations (IHR) (2005) is a critical legal document that focuses on ensuring national public health core capacities, as well as a coordinated and effective response to public health emergencies that may have international dimensions.[1] Laboratory capacity and capabilities are a critical component of IHR (2005) and must be part of comprehensive planning of national as well as international public health response plans. Standardized assessment is key to the development of comprehensive and integrated laboratory capacity, and tracking progress and use of tools

such as those developed by the World Health Organization (WHO) is a preferred method. Thailand, an upper–middle-income country in the WHO South-East Asia Region, and part of recent outbreaks of international importance,[2] has a robust national public health system, including a comprehensive network of laboratories. To guide the development and to provide a framework for strategic investment, the Ministry of Public Health (MOPH), in collaboration with international partners, conducted a comprehensive evaluation of its public health laboratory (PHL) system in 2010. This evaluation used a laboratory assessment tool (LAT) developed by WHO.[3]

The assessed laboratories included the National Institute of Health (NIH) and Bureau of Quality and Safety of Food (BQSF) at the national level and functioning as reference laboratories, and 14 regional medical science centres (RMSCs) that are part of the national PHL network. The RMSCs are located in provinces throughout Thailand.

This paper reports the results of this assessment and discusses the implications of using this approach to guide the strengthening of PHL capacity in Thailand, with implications for other countries, to meet the requirements of IHR (2005).

METHODS

The LAT for facilities was developed by WHO and employs a specific scoring matrix comprising 16 modules, 15 of which had a quantitative output (the general information module is qualitative). Additionally, there was a general indicator score that was the average of all modules.[3] The LAT is a generic, prototype tool for assessment, and requires adaptation to each country's laboratory systems and facilities. Modules included in the assessment were:

- *general information*: name and address and overall type of analyses performed (qualitative output);
- *premises quality*: condition of the premises and availability of utilities (quantitative output);
- *specimen collection*: quality of samples received, availability of sampling procedures, sample tracking and shipment (quantitative output);
- *biosafety*: premises safety, training and procedures, and equipment (quantitative output);
- *quality management*: availability of written procedures, quality-control procedures and accreditation (quantitative output);
- *public health functions*: contact with IHR focal point, participation in disease surveillance, and notification and reporting (quantitative output);
- *supplies management*: availability and quality of supplies (quantitative output);
- *equipment availability*: availability and quality of equipment (quantitative output);
- *budget and finance*: availability of funds (quantitative output);
- *data management*: data recording and reporting, as well as data protection and back-up (quantitative output);
- *microbiological capacity*: capacity and capability to identify and ship selected pathogens (quantitative output);
- *staffing*: staff availability in the laboratory (quantitative output);
- *training and supervision*: job training, continuing education and availability of e-learning (quantitative output);
- *information technology*: availability of laboratory information systems, computer access and internet availability (quantitative output);
- *communications*: internal (laboratory meetings) and external communications (customers, patients, clinicians, and public health services), as well as capacity (availability of phone, fax, and computer) (quantitative output);
- *gap*: identification of the critical needs and limitations within the laboratory systems and their components (quantitative output).

Each module in the LAT had between three and ten indicators. The indicators consisted of several closed questions, which automatically generated a score. For example, "Yes" had a score of 100 and "No" had a score of 0. An "NA" response was not included in the calculations. Some questions had a response of 1 (33.3%), 2 (66.6%) or 3 (100.0%). The module score that is presented is the average of each indicator included in the given module. The 16th module, the gap module, included 18 questions with responses ranging from 0 (positive impact) to 5 (negative impact). These questions were broad aimed at identifying the greatest needs in the laboratory. Finally, there is a general indicator score that is the average of all modules.

The WHO LAT was adapted to Thailand through a participatory process within the MOPH, and in collaboration with the United States (US) Centers for Disease Control and Prevention (CDC) and WHO, which included the following:

- formation of a working group;
- the working group deleted, added and/or modified indicators and questions within each module, to make the LAT relevant to Thailand. Specifically, many questions were made broader, to include BQSF sampling and diagnostics (environmental samples);
- the working group identified the equipment and diagnostic services required at the different tiers within the PHL system. The modules "microbiological capacity" and "equipment availability" were modified to reflect the different levels of services;
- the module "microbiological capacity" was modified to include shipping and/or diagnostics for selected pathogens listed in IHR (2005).[4] The pathogens included *Vibrio cholerae, Yersinia pestis*, smallpox virus, severe acute respiratory syndrome, viruses causing viral haemorrhagic fevers, West Nile fever virus, and *Bacillus anthracis*, as well as diseases of regional and/or national concern: enteroviruses, *Shigella* and *Salmonella*, *Streptococcus*

pneumoniae/suis, Legionella pneumophila, *Leptospira interrogans*, dengue viruses and chikungunya virus;

- the module "equipment availability" was modified to reflect the equipment needed to perform the required diagnostic tests at each tier within the PHL system;
- the LAT was evaluated at the national level before use in the field, and modifications in the use of language were incorporated into the tool as necessary;
- the LAT was made bilingual and had an integrated electronic "switch" to convert between English and Thai, permitting full use by speakers of either language.[a]

Two trained teams composed of MOPH and WHO personnel jointly performed the on-site assessments in December 2010, over a two-week period, in a total of 17 PHLs around the country. At the national level, two divisions at the NIH Department of Communicable Diseases (medical bacteriology and virology) and one division responsible for communicable diseases within the BQSF were assessed, and at the provincial level, all 14 of the regional PHLs (RMSCs) in Thailand (Chiang Mai, Chiang Rai, Chon Buri, Khon Kaen, Nakhon Ratchasima, Nakhon Sawan, Phuket, Pitsanulok, Samut Songkhram, Songkhla, Surat Thani, Trang, Ubon Ratchathani and Udon Thani) were assessed.

The assessment process at a laboratory involved interviewing the head of each laboratory section employing the adapted LAT. Answers to questions were verified, either through visual inspection (e.g. condition of the building) or through inspection of reports (e.g. external quality control reports). The gap module was done last, through interviews with the head of each laboratory and the director of the facility.

RESULTS

Overall, Thailand PHLs scored well on the assessment, as demonstrated by the means of the general indicator and of each module (*see* Table 1). Detailed data for six selected modules (biosafety, quality management, public health functions, microbiological capacity, information technology, and communications) are presented in Figure 1. They were chosen because they represented an overview of the laboratories in Thailand and of the type of data that were collected during the assessment.

Four modules – quality management, budget and finance, data management, and communications – were judged as strong (>90%). Six modules were judged as very good (>70% but ≤90%): premises quality, specimen collection, biosafety, public health functions, supplies management, and equipment availability. Four modules were judged as needing improvement (>60% but ≤70%): microbiological capacity, staffing, training and supervision, and information technology.

The detailed findings from this assessment are presented next.

[a] The modified LAT is available online: Peruski et al.: IHR (2005) and laboratory capacity in Thailand online-only supplementary material.

Table 1. Composite assessment scores (%) for individual modules and the general indicator

Category	Overall mean score	National-level mean score (range)	RMSCs mean score (range)
General indicator	83.0	84.7 (81–87)	82.8 (66–88)
Premises quality	87.2	79.3 (66–91)	88.9 (44–100)
Specimen collection	86.7	84.3 (80–90)	87.2 (64–98)
Biosafety	86.9	76.7 (71–85)	89.1 (71–97)
Quality management	94.1	94.3 (91–100)	94.0 (78–100)
Public health functions	84.0	80.0 (65–94)	84.9 (54–100)
Supplies management	89.8	85.3 (77–90)	90.8 (81–97)
Equipment availability	86.4	93.0 (89–100)	85.0 (62–99)
Budget and finance	94.6	81.7 (45–100)	97.4 (90–100)
Data management	91.8	89.3 (78–96)	92.3 (74–100)
Microbiological capacity	66.0	97.7 (93–100)	59.2 (24–97)
Staffing	68.4	83.3 (67–100)	65.2 (17–100)
Training and supervision	67.0	78.3 (74–82)	64.6 (38–96)
Information technology	70.0	61.0 (53–70)	71.9 (42–92)
Communications	90.1	98.3 (95–100)	88.4 (74–100)

RMSC, regional medical science centres.

Biosafety

Several areas of biosafety were assessed, including availability of training, written procedures, availability and use of personal protective equipment and premises safety, as well as sterilization procedures and waste disposal. As shown in Table 1, overall, the laboratories scored very well (mean score 86.9%). The waste disposal (91.7% and 94.1%, respectively, for national laboratories and RMSCs) and PPE availability indicators (93.3% and 96.8%, respectively, for national laboratories and RMSCs) had the highest overall scores, while the premises safety (44.3% and 81.6%, respectively, for national laboratories and RMSCs) and PPE use (50.0% and 82.9%, respectively, for national laboratories and RMSCs) scored the lowest (*see* Figure 1).

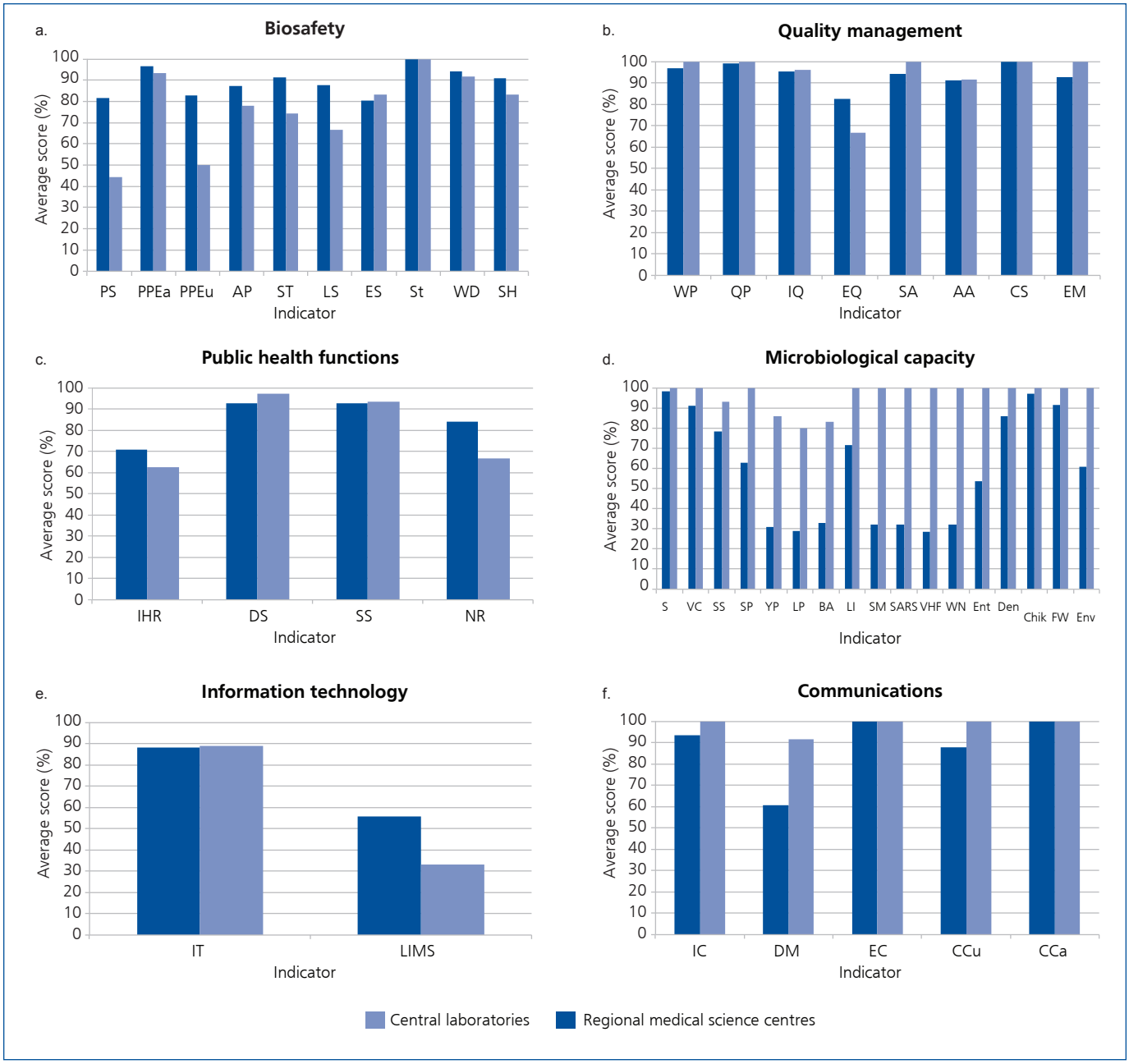

Figure 1: Conceptual framework

a, Average biosafety score on the LAT. The indicators are as follows: PS, premises safety; PPEa, availability of personal protective equipment; PPEu, use of personal protective equipment; AP, availability of procedures; ST, safety training; LS, laboratory safety conditions; ES, equipment disinfection and sterilization; St, sterilization; WD, waste disposal; SH, staff health services.

b, Average quality management score on the LAT. The indicators are as follows: WP, written procedure; QP, quality of procedures; IQ, internal quality control; EQ, external quality control; SA, standards and accreditation; AA, audits and assessments; CS, customer satisfaction; EM, error management.

c, Average public health functions score on the LAT. The indicators are as follows: IHR, relationship with IHR; DS, disease surveillance; SS, sampling and shipping; NR, notification and reporting.

d, Average microbiological capacity score on the LAT. The indicators are as follows: S, sampling; VC, *Vibrio cholerae*; SS, *Shigella* and *Salmonella*; SP, *Streptococcus pneumoniae*/*suis*; YP, *Yersinia pestis*; LP, *Legionella pneumophila*; BA, *Bacillus anthracis*; LI, *Leptospira interrogans*; SM, smallpox virus; SARS, severe acute respiratory syndrome; VHF, viruses causing viral haemorrhagic fevers; WN, West Nile virus; Ent, enterovirus; Den, dengue viruses; Chik, chikungunya virus; FW, food and water samples; Env, environmental sampling.

e, Average information technology score on the LAT. The indicators are as follows: IT, information technology hardware and internet connections; LIMS, availability and use of laboratory information system.

f, Average communications score on the LAT. The indicators are as follows: IC, internal communications; DM, document management; EC, external communications; CCu, communications with customers; CCa, communications capacity.

Quality management

This module examined the quality of diagnostic procedures by evaluating process control, written procedures and internal and external quality control. As shown in Table 1, the laboratories scored very high in all areas (mean score 94.1%). The quality of procedures (100% and 99.0%, respectively, for national laboratories and RMSCs) and customer satisfaction (100% for both national laboratories and RMSCs) had the highest overall scores, while external quality control (66.7% and 82.6%, respectively, for national laboratories and RMSCs) had the lowest overall scores (*see* Figure 1).

Public health functions

The primary aim of this module was to assess the ability of the laboratory to interact with, and participate in, surveillance and disease outbreaks, as well as their relationship with the IHR focal point (number of meetings and the degree of information exchange with the IHR focal point). All laboratories scored very well in public health functions (mean score 84.0%; *see* Table 1). In particular, the laboratories scored very high in the disease surveillance indicators (97.3% and 92.5%, respectively, for national laboratories and RMSCs), while the relationship with IHR focal points (62.7% and 71.0%, respectively, for national laboratories and RMSCs) indicators had the lowest overall score in this module (*see* Figure 1).

Microbiological capacity

This module assessed the laboratories' capacity to perform specified viral and microbiological laboratory tests and/or their ability to transport specimens at the appropriate biosafety level. Diagnostics were assessed for pathogens specified in Annex 2 of the IHR (2005), as well as several key endemic pathogens. Of note for this module is that the diagnostic capacity assessed was modified to the level of laboratory within the public health system. For example, for viral haemorrhagic fever, the RMSCs were only assessed on their ability to collect and transport these pathogens to the national laboratories.

As shown in Table 1, microbiological capacity in Thailand should be strengthened (mean score 66.0%). The highest score was in the sampling capacities indicator (100% and 98.2%, respectively, for national laboratories and RMSCs). Laboratories had the lowest score in the capacity to detect/identify *Legionella pneumophila* (80.0% and 28.9%, respectively, for national laboratories and RMSCs) and viral haemorrhagic fevers (100% and 28.6%, respectively, for national laboratories and RMSCs). Of note in this module is the difference in sample shipment questions. Most laboratories scored 100% in the capacity to ship low-risk clinical samples to the national level. However, most laboratories scored 0% in the capacity to ship high-risk samples (biosafety level 3 pathogens) to the national level. Finally, while the mean score is presented for all indicators, there is a large range of scores for this module.

Information technology

This module assessed the laboratory information management systems, as well as the computer availability and internet connectivity. As shown in Table 1, the mean score for this module was 70.0%. The laboratories scored very well on the computer hardware and internet connectivity indicator (89.0% and 88.0%, respectively, for national laboratories and RMSCs) but scored much lower with regard to availability and actual use of laboratory information management systems (33.3% and 55.6%, respectively, for national laboratories and RMSCs). That is, most laboratories still use paper to report and track samples and results.

Communications

Assessment of laboratory communications included both internal and external communications, such as electronic library (e-library) systems, communications with other laboratories, and communications with customers. Additionally, this module assessed the laboratory's communication capacity (availability of phone, fax and computers). The aim of this module was to assess the ability of the laboratory to communicate internally and externally (through meetings, newsletters and publications) and how these communications were carried out (phone, fax, or electronically). As shown in Table 1, the laboratories scored very high in all areas (mean score 90.1%). The external communications and capacity indicators had the highest overall scores (100% for both national laboratories and RMSCs), while the documents (access to e-library) indicator (91.7% and 60.7%, respectively, for national laboratories and RMSCs) had the lowest overall score (*see* Figure 1).

The gap module (data not shown) posed questions that were broad and aimed at identifying the greatest needs in the laboratory; thus, the findings were more variable across the sites assessed. Most sites reported the need to strengthen human resources. For example, at the national level, the number of permanent staff was capped at insufficient levels; thus, temporary staff were employed, which resulted in a high turnover rate of employees. Additionally, many laboratories reported the need for improvements in the laboratory information management systems. As strengths, most sites reported that they had a good organizational structure and network of laboratories, as well as good sample quality.

DISCUSSION

This assessment of Thailand's PHLs mapped the locations and areas serviced by all RMSCs, NIH and BQSF, using a participatory approach to determine national laboratory core capacities as they relate to IHR (2005). Additionally, 11 Thai nationals were trained as laboratory assessors and successfully completed the assessment, and a fully bilingual, customized LAT was developed. Using this LAT, the assessment found that quality management, budget and finance, data management, and communications scored very high (>90%); premises quality, specimen collection, biosafety, public health functions, supplies management and equipment availability were judged

as very good (>70% but ≤90%); and microbiological capacity, staffing, training and supervision, and information technologies were judged as needing improvement (>60% but ≤70%). Of note is that the quality management module achieved a very high score (94.1%). This is probably the result of in-service training supported by the MOPH and the development of a national laboratory accreditation programme to ensure the quality of laboratory services.[5]

All laboratories scored similarly on the modules; however, some major differences between laboratories are noteworthy. The national laboratories scored much lower in the biosafety module for questions concerning premises safety. This was primarily due to lack of space or poor space utilization in these laboratories. Additionally, while all laboratories had access to PPE, personnel at the national laboratories were much less likely to consistently use it. The assessment also revealed insufficient awareness of IHR among laboratory staff, and a lack of clear and systematic linkage with the officially designated national IHR focal point based in the Bureau of Epidemiology. The large range in scores in this section resulted from some laboratories being more aware than others of IHR. Surveillance functions as linkages between the laboratories and Thailand's surveillance system were weak. While Thailand has a strong public health network, it needs to strategically link its laboratory system with its surveillance system (often referred to as the "506-reporting system"). The 506-reporting system is a health-care-based system. To date, no mechanism exists within Thailand to electronically link strategic information from the two systems, representing a major inefficiency and missed opportunity. IT also had a large range in scores, resulting mainly from the fact that some laboratories lacked laboratory information systems, while others had developed internal home-grown systems. Finally, the assessment found major differences in microbiological services offered for selected pathogens, and identified underutilization of the RMSCs. The low volume of samples analysed and the number of tests performed provided clear evidence of this underutilization. The range of microbiological laboratory services and underutilization of the RMSCs is probably the result of Thailand's lack of clear definitions of roles, responsibilities and services for each level of laboratory as part of its national PHL system. Additionally, an efficient and safe sample-transfer system is greatly needed to transport high-risk pathogens from RMSCs to national-level laboratories, for reference testing during public health emergencies.

Strengths of this assessment included: the formation of a working group with tripartite interactions between the MOPH and its major collaborators – WHO and US CDC. This encouraged country ownership of the assessment process and application of the results for improving the national PHL system. Additionally, the schedule of travel for the assessment teams was well coordinated, and a thorough review of the laboratories' capacities under IHR (2005) was obtained. Finally, national assessors were trained and they can periodically re-review the laboratories to measure changes and progress, as well as refine recommendations.

Challenges of this assessment included insufficient time allowed during the pre-assessment phase to customize the LAT. This affected the translation of the tool and validation of the translation. As a result, the LAT was further modified during the assessment, to further refine language usage. Finally, the number of questions and categories included in the LAT could be consolidated and the time spent at each laboratory increased to 2 days, to permit a more in-depth assessment and improve findings and recommendations.

While the findings of this study highlighted strengths and weaknesses of the national laboratory system as a whole, and of individual laboratories, the quantitative scores are not comparable to those of other countries because of the country-specific nature of the scoring matrix in the customized LAT. The authors' experience of adapting the LAT to the Thai context demonstrates that the generic WHO LAT is sufficiently flexible to assess country-specific laboratory public health capacity. Here, the customized LAT that was developed for this study focused on laboratory capacity relevant to the IHR (2005);[1] however, the LAT could also be used to meet broader health-system goals,[6–9] such at the Millennium Development Goals,[10] or in a more focused manner for specific public health initiatives.

IHR (2005) obliges countries to establish relevant public health core capacity, which includes laboratory core capacity as part of a global effort to ensure global public health security. Health laboratories have long been considered an essential component for evidence-based clinical care. In recent decades, global initiatives have been launched to control, eliminate or eradicate specific diseases (e.g. polio, measles, HIV, tuberculosis and malaria), and resource-poor countries have benefited greatly from these initiatives to build laboratory capacity related to these specific diseases and also introduce a "public health approach" in laboratories.[2,8] These disease-specific programmes have helped to highlight the "system bottlenecks" that must also be addressed in order to have high-performing and sustainable laboratory services that meet national public health needs. The participatory approach probably improved the quality of the process and results, as use of the LAT in a participatory way enables countries to take ownership of this process and results, and uses a systems approach to assessing and building laboratory capacity. In Thailand, use of the adapted LAT elucidated strengths and weaknesses of the national PHLs from a "systems" and "core capacity" perspective. The next step is to use these findings strategically to guide the next practical steps in strengthening laboratory capacity and capabilities to improve public health surveillance and disease control.

In summary, this assessment highlighted considerable strengths, but also weaknesses and opportunities to further develop a national laboratory network to help meet the public health priorities of Thailand and ensure compliance with IHR (2005). The participatory strategy, which employed an adaptation of an international tool to the national needs and local context, can serve as a model approach for similar initiatives in other countries and regions. The results of the assessment provide critical information to guide decisions, using a systems approach for the next steps to maximize the efficiency and effectiveness of laboratory services, which are critical to meeting public health needs in Thailand.

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