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Institutionalization of the Philippine Health Laboratory System (PHLS)

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INTRODUCTION

In 1966, Section 3 of Republic Act (R.A.) 4688, entitled "An Act Regulating the Operation and Maintenance of Clinical Laboratories and Requiring the Registration of the Same with the Department of Health, Providing Penalty for the Violation Thereof, and for Other Purposes," provided for the establishment of the Bureau of Research and Laboratories (BRL) under the Department of Health (DOH). The BRL served as the central laboratory that governed the operation of regional public health laboratories. The BRL's function was delegated to different offices in 2000 by Executive Order 102 s. 1999 entitled "Redirecting the Functions and Operations of the Department of Health," which was premised in part with Section 78 of the General Provisions of R.A. 8522 ("General Appropriations Act of 1998") authorizing the President to direct changes in organization and key positions of any department, bureau, or agency.

Towards this direction, the function of the BRL was distributed to different agencies, and the Philippines designated six (6) national reference laboratories that catered to communicable and non-communicable diseases. Five (5) subnational reference laboratories for emerging and re-emerging infectious diseases were established in response to the 2009 Influenza AH1N1 pandemic. The DOH issued Administrative Order No 2012-0021 to establish a national and regional network of laboratories.

NATIONAL LABORATORY CAPACITY IN RESPONSE TO COVID-19

In the early part of the COVID-19 pandemic, the Philippines reactivated its five (5) existing subnational laboratories capable of molecular testing for emerging and re-emerging infectious diseases to augment the testing capacity of the National Reference Laboratory. However, as the demand for testing increased, the Department had to undertake steps to increase the number of laboratories that performed COVID-19 testing both for government and private health facilities.[1]

Compared with the performance of other countries in terms of testing capacity at the start of the pandemic, the Philippines tested a total of 1.44 persons per 1,000 people.[2] This is relatively lower compared to its neighboring countries: 31.82 per 1,000 people for Singapore, 12.98 per 1,000 people for South Korea, 7.94 per 1,000 people for Malaysia, 4.1 per 1,000 people for Thailand, and 2.68 per 1,000 people for Vietnam.[3] The low cumulative testing figures in the Philippines may be attributed to the limited resources and accredited laboratories especially at the outset of the pandemic, low capacity of testing centers, lack

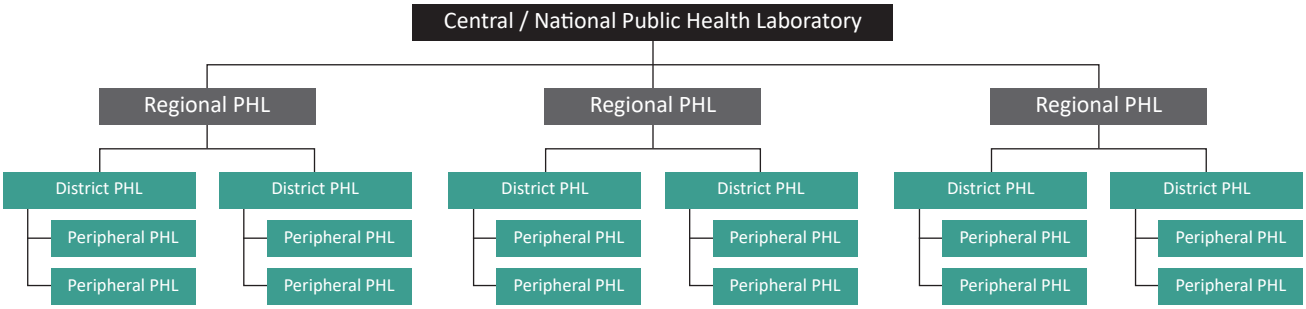

Figure 1. Generic organizational structure of Public Health Laboratories in SEA. 2018.[9]

of trained personnel, inadequate supplies, and distribution of resources across the country, and fragmentation of the laboratory system.[1]

The efficiency and effectiveness of the response of other Southeast Asian countries to the COVID-19 pandemic are associated with their public health preparedness and response plans for communicable disease management.[1] The different approaches among these countries stem from their key interventions (Table 1).

INTERNATIONAL BENCHMARKING AND MODELS OF LABORATORY SYSTEMS

Based on the World Health Organization Report on Establishment of Public Health Laboratories in Southeast Asia, while different countries have different organizational structure for their laboratory network, the generic arrangement of Public Health Laboratories comprises 3-5 levels[1] (Figure 1). In most cases a separate entity / system focuses on public health related services / activities particularly on surveillance, diagnosis, treatment, and control.

Taiwan

At the National Level, the Taiwan Center for Disease Control (CDC) serves as the overall governing body for the national laboratory system. Twelve (12) National Reference Laboratories are directly lodged under the country's CDC (Figure 2).

Thailand

In Thailand, the Bureau of Laboratory Quality Standards under the Department of Medical Sciences focuses on standards development and facilitates the EQAS provisions (Figure 3). This bureau also functions as the National Reference Laboratories. The Bureau of Laboratory Quality Standards has regional counterparts known as Regional Medical Sciences Centers. They are tasked to manage the budget of the network and coordinate with regional, general and community hospitals.

Vietnam

Vietnam's laboratory system consists of approximately 900 laboratories that deal with human infectious diseases including public health diagnostics and reference laboratories, and clinical laboratories at different levels of

Table 1. Approaches of selected Southeast Asian countries in response to COVID-19

Country	Approach/Laboratory Strategy
Vietnam	Vietnam enhanced their surveillance and mass testing approach through target testing of higher risk groups and random testing of households and inpatients. Its maximum testing capacity remains 51,000 tests with 152 laboratories COVID-19 RT-PCR.[4]
Thailand	Thailand is the first country to complete an assessment on how their health system has responded to COVID-19 using a WHO Intra-action Review (IAR) tool. One of their effective systems is integrating epidemiological, laboratory, clinical and logistic data in a new digital information system. Thailand has greatly improved detection through expanding their COVID-19 surveillance as well as their strong capacity to trace and quarantine contacts.[5]
Singapore	Singapore has implemented a whole-of-government, whole-of-society approach to contain the spread of the virus. Singapore's healthcare system provides access to quality healthcare through high government investment in infrastructure, subsidies, financing that has resulted in high coverage of essential health services to support the COVID-19 response. At the start of the COVID-19 pandemic, Singapore performs an average of 8,000 tests per day.[6]
Malaysia	Malaysia has a robust health system with universal health coverage which helped them prepare and respond to the COVID-19 pandemic in a whole-of-government and whole-of-society approach. With a population of 32 million, they have ramped up its testing capacity from 1000 to over 38, 000 tests per day.[7]
Australia	Australia has an expert network of public and private laboratories with the capability to detect SARS-CoV-2 and to securely capture and report results. The Australian Public Health Laboratory Network (PHLN) and Communicable Diseases Network Australia (CDNA) were fast to respond and create guidelines as early as Q1 of 2020 on the testing of SARS-CoV-2 hence a more rapid roll out of testing by the laboratory network.[8]

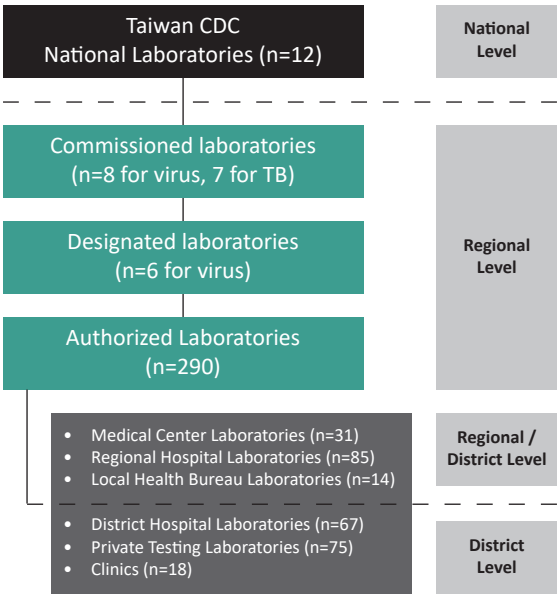

Figure 2. Structure of the National Laboratory System in Taiwan. Adapted from Taiwan's Public Health Laboratory System: success and surveillance, Ji-Rong Yang, Hwa-Jen Teng, Ming-Tsan Liu, et al. 2017.[10]

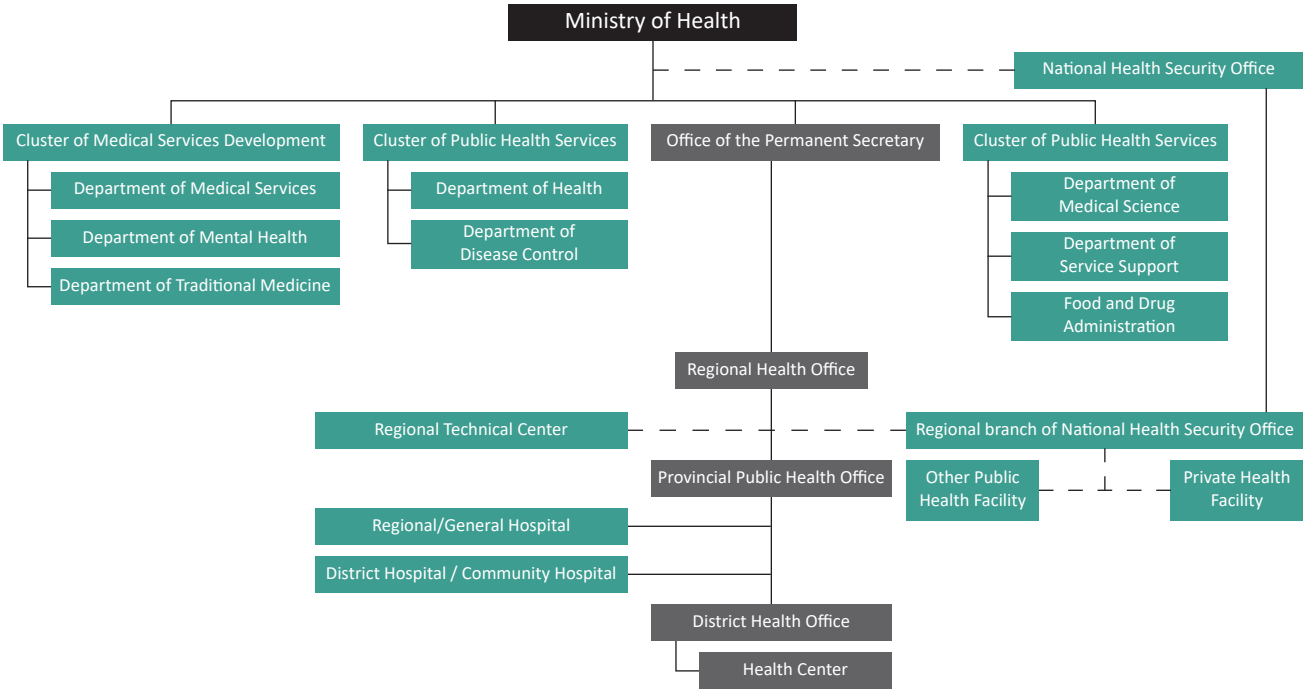

Figure 3. Organizational structure of the Ministry of Public Health, Thailand. Adapted from The Kingdom of Thailand Health System Review. Vol. 5 No. 5, 2015.[11]

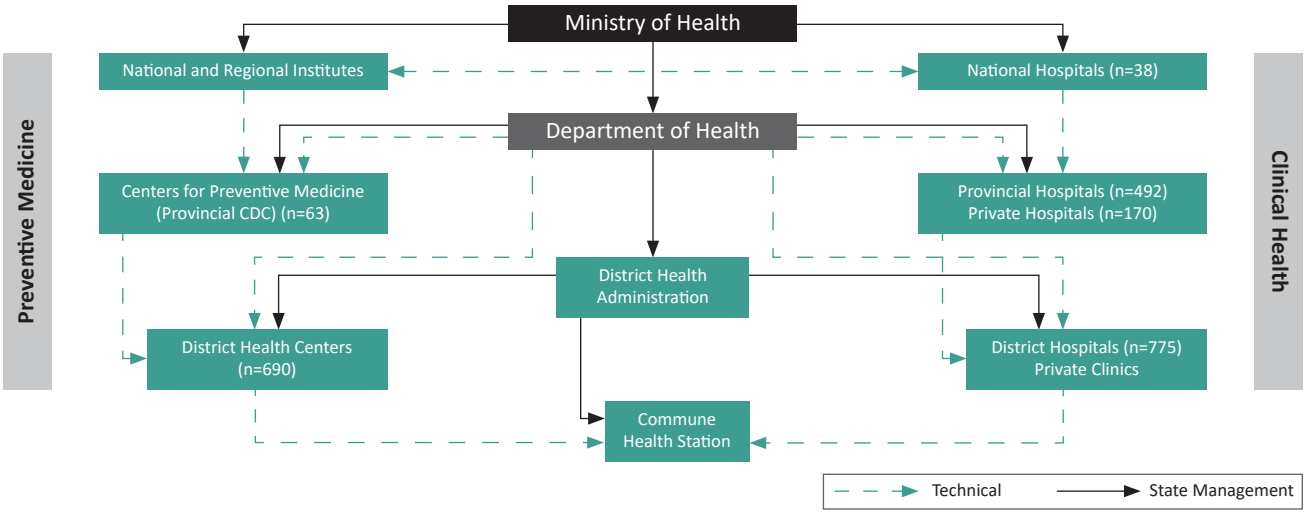

Figure 4. Organizational structure of the health system in Vietnam. Adapted from patient complaints in healthcare services in Vietnam's health system (Bui Thi Thu Ha, Tolib Morzoev, Rosemary Morgan, 2015).[12]

the healthcare system (Figure 4). Of the 73 public health diagnostic and reference laboratories, 4 are national or regional public health laboratories, two non-governmental research laboratories, and two pediatric laboratories. Forty (40) clinical laboratories are at central or regional levels.

Cambodia

Cambodia's laboratory system consists of 94 public laboratories (of which eight are national laboratories) at different levels of the health care system (Figure 5). Aside from laboratories supporting disease-specific programmes (such as HIV/AIDS, tuberculosis, and malaria), Cambodia's National Institute for Public Health supports surveillance and outbreak response for emerging infectious diseases. It is also the representative body of the ministry of health providing public health and laboratory services, training, and research to improve the health of Cambodians. Under the NIPH is the National Public Health Laboratory (NPHL) known as the National Reference Laboratory, which is operated by highly qualified and experienced technical staff and working on promotion and strengthening of quality laboratory services for public health. Laboratory results particularly for disease diagnosis are ensured through up-to-date technologies and use of Laboratory Quality Management System (LQMS).

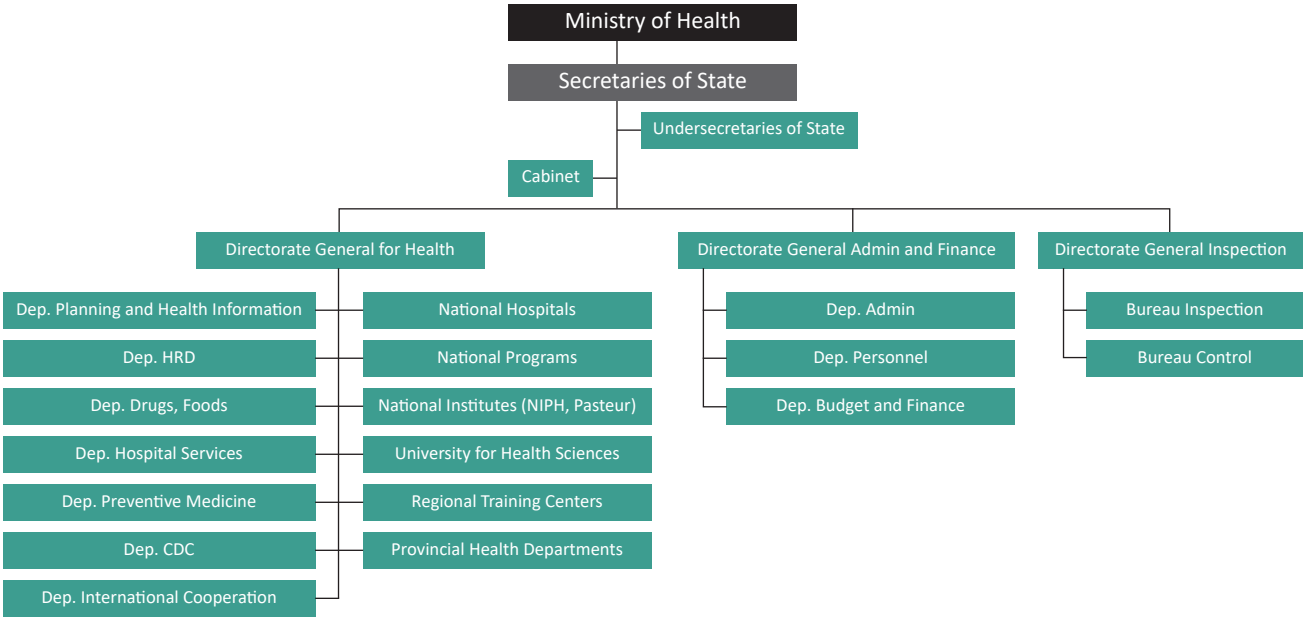

Figure 5. Organizational structure of the Ministry of Health of Cambodia. Adapted from ReBuild Consortium: country situational analysis, Cambodia.[13]

Singapore

The Singapore's Ministry of Health has established the National Center for Infectious Diseases in 2009 under the Communicable Disease Division (Figure 6). Under this division is the National Public Health Laboratory (NPHL) which is currently involved in the laboratory surveillance and preparedness for detection of highly infectious pathogens, such as MERS-CoV, H7N9, and Ebola Virus. The NPHL facilities include a biosafety-level 3 (BSL-3) containment facility which shall be dedicated for surveillance of infections of public health importance as well as the detection and identification of novel pathogens. The mission of NPHL is to use the best possible science for the laboratory surveillance of infectious diseases and investigation of outbreaks. NPHL also works closely with its partners in government agencies, medical laboratories, and research institutions to enable a coordinated and broad-based response to infectious threats.

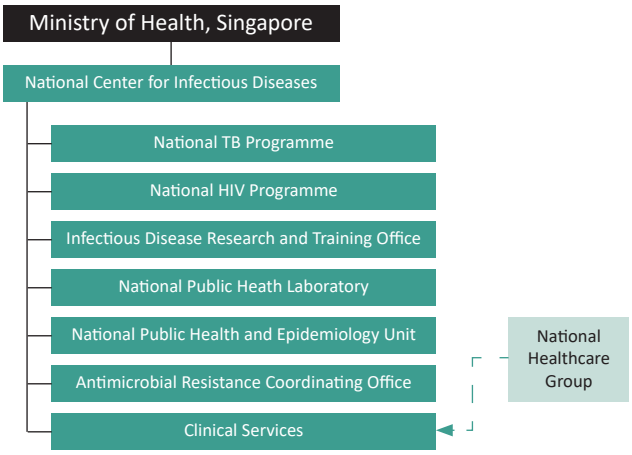

Figure 6. Organizational structure of the National Center for Infectious Diseases, Ministry of Health Singapore.[14]

The marked similarity among these models includes the following:

1. There is a centrally governing body that focuses on the standards, policies, and operations of the laboratory network under the Ministry or Department of Health.[1]
2. National Reference Laboratories in these countries are stand-alone organizations and not lodged under a hospital.[1]
3. There is a delineation between clinical laboratory services and public health services.[1]
4. Quality Management System, Quality Assurance Program, and Network Development are critical components of a responsive laboratory diagnostic services both for medical and public health services.[1]

CREATION OF THE OFFICE FOR HEALTH LABORATORIES

The Office for Health Laboratories (OHL) was created by virtue of Department Order 2021-0421 upon realizing the gaps in our healthcare system during the COVID-19 pandemic. The OHL, under the cluster of the Health Policy and Infrastructure Development Team, shall serve as an interim structure focused on building the foundation of the PHLS, pending the enactment of the Philippine Center for Disease Control and Prevention. At the national level, the OHL shall provide administrative supervision to all Public Health Laboratories and shall stir the implementation of the PHLS with the following core mandates:

- Develop and provide the overall strategic direction, policies, plans, and programs, including infrastructure and equipment investments, in the development of the PHLS;
- Establish and implement systems and programs for (1) national laboratory referral system, (2) nationally coordinated training for HRH Development for clinical and public health laboratories, (3) unified national evidence-based laboratory-related research agenda, (4) national laboratory information system, (5) laboratory

surveillance, (6) chemical safety and security, and (7) administrative supervision and support;
- Serve as the technical authority in developing the laboratory biosafety and biosecurity standards, policies, plans, and measures to prevent/reduce biorisk and bioterrorism;
- Evaluate the performance of public health and clinical laboratories by ensuring compliance with the laboratory quality management system and quality assurance programs;
- Provide technical and administrative standards and guidelines for the NRLs, SNLs, Public Health Laboratories, and Clinical Laboratories; and
- Participate in inter-agency and international networks for laboratory response to uphold national security and prevent international threats.

INSTITUTIONALIZATION OF THE INTEGRATED PHILIPPINE HEALTH LABORATORY SYSTEM

The Philippine Health Laboratory System aims to harmonize the entire laboratory system in the country, specifically, to ensure quality, efficient sustainable and accessible laboratory services; and to ensure a functional, efficient, and harmonious network of health laboratories and referral system across different laboratory facilities paving the way to a more responsive medical and public health diagnosis and surveillance.

In order to address these challenges, the Philippine Health Laboratory System (PHLS) was pursued with the vision of Accessible Health Laboratory Services by 2025, and World Class Services by 2035 (Figure 7). Furthermore, to ensure that the development of the Philippine Health Laboratory System is fully realized, the Office for Health Laboratories under the Health Facilities and Infrastructure Development Team shall be created to serve as the interim structure focused on building the foundation for the PHLS, pending the enactment of the mandate for the Philippine Center for Disease Control and Prevention (PH CDC).

Through the Philippine Health Laboratory System, at least one (1) public health laboratory shall be established in each region. The Philippine Health Laboratory System likewise calls for the institutionalization of Subnational Reference Laboratories (SNL) and Regional Public Health Laboratories (RPHL) to ensure the detection of both communicable and non-communicable diseases and health events as guided by the DOH Resource Stratified Framework for Laboratory Facilities.

THE PHILIPPINE HEALTH LABORATORY SYSTEM STRATEGIC MAP

With a vision of accessible health laboratory services by 2025 and world class services by 2025, the Philippine Health Laboratory System shall ensure the provision of quality, affordable, and accessible laboratory services, and information for the appropriate management of patients and prevention and control of diseases through strengthening key laboratory facilities in the network.

The overall implementation of the PHLS shall have an impact on the daily lives of the Filipinos by providing a responsive clinical and public health diagnostics and surveillance for public health action. The realization of this impact in laboratory diagnostics shall greatly contribute to the overall goals of Universal Health Care.

The following shall be the strategic focus of the PHLS:

1. **Functional and efficient network of Clinical and Public Health Laboratories**
   The following are the strategies to ensure a functional and efficient network of clinical and public health laboratories for appropriate public health and clinical diagnostic response:
   - Resource management through long-term efforts to ensure fundings for the infrastructure development, Human Resource development, and provision of supply and equipment through

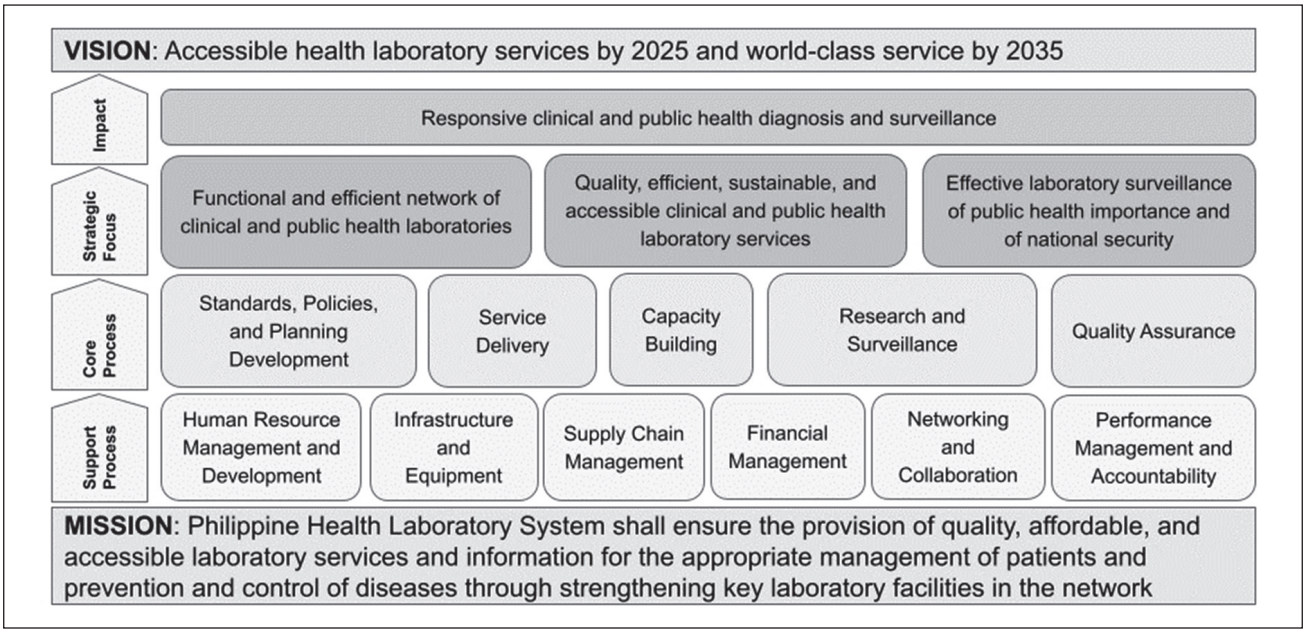

Figure 7. Overall strategic map for the Philippine Health Laboratory System.

the development of a sustainable supply chain management system;
- Partnership with other DOH offices, other stakeholders, different levels of laboratories with clear delineations, roles, and contributions to establish a harmonized network for all DOH programs in terms of laboratory services;
- Provide accessible and quality laboratory services for appropriate management of patients and public health programs;
- Standardize the clinical and public health laboratory policies, operations, and standards aligned with statutory and regulatory requirements, epidemiological criteria, developmental standards, and WHO recommendations.

2. **Quality, efficient, sustainable, and accessible Clinical and Public Health Laboratory Services**
To strengthen this strategy, the following implementing mechanisms shall be enhanced:
   - Laboratory Referral System
   - Public Health Laboratory Network

3. **Effective laboratory surveillance of public health importance and of national security**
To focus on providing effective diagnostic surveillance, the implementing mechanisms shall be strengthened:
   - Laboratory surveillance and management
   - Laboratory biological and chemical safety and security
   - Integrated laboratory information management system

PHLS Core Processes

The following are the principal processes for the Public Health Laboratory System based on its strategic map.

1. **Standards, policies, and planning development**
The Office for Health Laboratories under the DOH Health Policy and Infrastructure Development Team shall lead the institutionalization and implementation of the Philippine Health Laboratory System. The OHL shall develop policies, standards, programs, and plans, and provide the overall strategic direction for the implementation of the PHLS

2. **Service delivery**
Service capabilities of Public Health Laboratories at various levels from the reference laboratory down to the peripheral laboratories shall be determined by the OHL.

3. **Capacity building**
A competency framework for the PHLS shall be set by the OHL to guide development of appropriate and effective trainings, workshops and other learning and development interventions.

4. **Research and surveillance**
The PHLS shall be an important national resource for generation of policy-guiding information through research and surveillance activities.

5. **Quality assurance**
OHL shall ensure that facilities under the PHLS operate within a functional Quality Management System. It shall lead to the implementation of the National External Quality Assurance Scheme (NEQAS) by the reference laboratories.

PHLS support functions

To achieve the overall goal set by the PHLS, the following relevant support functions need to be developed and strengthened:

1. **Human resource management and development**
Capacity building processes needed by the PHLS across all laboratories in the PHLS for continuous professional education shall be supported, to contribute to the improvement and strengthening of the laboratory workforce. This shall include, provision of learning and development interventions, fundings for hiring technical and managerial staff, and strengthening of laboratory interface to support human resources.

2. **Infrastructure and equipment**
Technical standards for physical infrastructure and equipment appropriate for each laboratory level in the PHLS shall be developed to guide investments.

3. **Supply chain management**
National policies, guidelines, and standards on laboratory supply chain management guided by the existing statutory and regulatory protocols, policies, and guidelines, shall be established to support the logistics needs of the PHLS.

4. **Financial management**
The OHL shall work towards obtaining necessary budget to finance the implementation and sustain the operations of the PHLS, to include a dedicated line-item budget in the annual budget appropriations for the Department of Health, retention, and use of income, as well as tapping other potential local and international funding sources.

5. **Networking and collaboration**
   5.1 Partnership
      5.1.1. Other DOH Bureaus
      5.1.2. Other Government Agencies
      5.1.3. Non-Government Organization
      5.1.4. Private sector
   5.2 Laboratory Advisory Groups

6. **Performance management and accountability**
Monitoring and evaluation of the operations and performance of all laboratories in the PHLS through indicators set by the OHL and/or NRL.

COMPONENT LABORATORIES OF THE PUBLIC HEALTH LABORATORY SYSTEM

Public health laboratories are responsible for providing timely and reliable diagnostic results primarily for disease prevention, control, surveillance, and outbreak emergency response. They perform core public health and

environmental activities, including reference tests for diseases of public health importance.

National Reference Laboratories (NRLs)

By virtue of DO 2020-0820 "Institutionalizing and Strengthening the National Reference Laboratories in the Philippines," the National Reference Laboratories (NRLs) serve as the highest level of laboratory in the country performing highly complex procedures, including end confirmatory testing. The NRLs are the responsible entity facilitating National External Quality Assurance Scheme (NEQAS) to ensure compliance of quality standards for regulation and licensing of all laboratories in the Philippines.

The NRLs are housed in six (6) selected host hospitals that cater to disease-specific testing, namely: *1) Research Institute for Tropical Medicine (RITM), 2) San Lazaro Hospital - STD AIDS Cooperative Central Laboratory (SLH-SACCL), 3) East Avenue Medical Center (EAMC), 4) National Kidney and Transplant Institute (NKTI), 5) Lung Center of the Philippines (LCP), and 6) Philippine Heart Center (PHC).* These NRLs shall closely collaborate with the OHL as the highest level of laboratories under the PHLS that is mandated to develop standards and policies pertaining to laboratory operations, personnel competence, quality assurance programs, and product evaluation to ensure quality laboratory results across public laboratories and clinical laboratories. They will also play a key role in diagnostic surveillance, research, monitoring and evaluation, and provision of technical assistance to SNLs, RPHLs, Clinical Laboratories, and other Health Laboratories. The NRLs shall serve as the technical authority in evaluating the quality management system performance of SNLs and RPHLs, including the highly technical services offered by Clinical and other Health Laboratories. These NRLs are currently hosted in selected hospitals and shall be operating as a separate department from its host hospital clinical laboratory, with transfer of its administrative and technical supervision to the OHL. The NRLs shall have their own physical infrastructure, equipment, and personnel to deliver the following services.

Subnational Reference Laboratories (SNLs)

The direction of the PHLS is to establish SNLs across the country with catchment areas according to population density, accessibility, and geographical location, and disease prevalence to streamline services offered by the NRLs into one facility. The SNLs shall be the arm of the NRLs and OHL in rolling out programs, policies, and standards, training, and testing on their catchment area. They shall be technically supervised by the NRLs in conducting selected confirmatory testing by providing accessible laboratory services and decongesting the services of the NRLs down to the regions. In addition, the SNLs shall participate in the conduct of laboratory surveillance and research within their catchment.

Regional Public Health Laboratories

The RPHLs shall also be established in each region, catering to smaller catchment areas with a less complex service capability than the SNLs and NRLs. The RPHLs shall be established in each region, with administrative governance from the Centers for Health Development. The RPHLs shall be technically supervised by the NRLs in conducting routine analysis and priority diagnostic testing to support the different DOH programs. The RPHLs shall facilitate roll-out of training programs provided by the SNLs to the clinical laboratories within their catchment area.

Clinical and other health laboratories

The Philippine Health Laboratory System shall also serve as the overall backbone of the National Framework for Health Laboratories, involving not only public health laboratories but also all clinical and other health laboratories in the country. The Clinical and other Health Laboratories shall comply with regulatory standards to enable an effective and efficient laboratory quality management system as guided by this framework. Delineating its role from Public Health Laboratories, the Clinical Laboratories are mainly focused on individual-based testing and management of patients. In addition, these facilities are involved in the (a) pre-analytical, (b) analytical, and (c) post-analytical procedures and where tests are done on specimens from the human body to obtain information about the health status of a patient for the prevention, diagnosis, and treatment of diseases. These tests include, but are not limited to, the following disciplines: anatomic pathology, clinical chemistry, clinical microscopy, endocrinology, hematology, immunology and serology, microbiology, toxicology, as well as molecular and nuclear diagnostics. All licensed Clinical Laboratories by the DOH shall follow the existing minimum service capabilities for primary, secondary, and tertiary clinical laboratories, as stated in the Administrative Order No. 2021-0037 entitled "New Rules and Regulations Governing the Regulations of Clinical Laboratories in the Philippines."

In addition, other Health Laboratories are laboratories that do not meet the minimum standards of a Primary Clinical Laboratory but are likewise involved in individual-based testing and research, such as but not limited to the following:

1. Analytical Toxicology Laboratories
2. Drug Testing Laboratories
3. Water Testing Laboratories
4. Bureau of Quarantine Laboratories
5. State Universities and Colleges (SUCs), and Other Academic Laboratories
6. Department of Agriculture Laboratories
7. Department of Science and Technology Laboratories
8. Military Clinical Laboratories

CONCLUSIONS AND RECOMMENDATIONS

With the challenges faced by the country in the emergence of infectious diseases and other public health threats, the institutionalization of the Philippine Health Laboratory System is an avenue to deliver an effective public health laboratory network across the country by addressing its geographic challenges, to boost laboratory diagnostic capacities and laboratory referral system when and where they are needed, and to serve gateway to mobilize technical expertise, knowledge exchanges and resources in support of future pandemic response. Through the creation of the Philippine Centers for Disease Prevention and Control, these public health laboratories shall serve as the country's laboratory diagnostic arm in providing surveillance

testing, research, and capacity building in support of the Department of Health's disease prevention and control programs to achieve Universal Health Care.

STATEMENT OF AUTHORSHIP

The authors certified fulfillment of ICMJE authorship criteria.

AUTHOR DISCLOSURE

The authors declared no conflict of interest.

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