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ASSESSMENT OF QUALITY SYSTEM ESSENTIALS AND COMPLIANCE OF GOVERNMENT HOSPITAL LABORATORIES IN THE NATIONAL CAPITAL REGION, PHILIPPINES

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Abstract

The majority of people in the Philippines patronized the services of government hospitals with particular emphasis on affordability and health care services, including laboratory tests. Laboratories are a crucial component of hospitals and should provide accurate results. To deliver reliable findings, laboratories comply with standardized quality management essentials. The standards include detailed instructions about the laboratory setting, human resources, tools, and supplies. This study investigates the level of compliance of national government hospitals with the existing quality management essentials before the pandemic. Government hospitals in the National Capital Region (NCR) were assessed by employing surveys and interviews with key laboratory personnel. The results show that hospital laboratories in NCR largely complied with the implementation of quality system essentials, particularly with the local licensure standards but significantly lower in compliance with WHO standards. The compliance rating of each indicator within the quality system essential is substantially different from one hospital laboratory to another; however, since the quality improvement process is a system of interconnected indicators, the lower-rated compliance indicators were significantly pulled by the higher-rated compliance. From the observation, a continuous improvement model is crucial for the standard examination of

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laboratories in the country for a persistent rise in medical services accessible and reliable for Filipinos.

Keywords: Laboratory, quality management essentials, quality assessment, government hospitals, Philippines

INTRODUCTION

The Philippines has a growing population of 109 million (Philippine Statistics Authority, 2020), with 18.1% under the poverty line (Philippine Statistics Authority, 2022). Due to the increasing cost of basic needs (Philippines Statistics Authority, 2022), most people in the country patronize the services of government hospitals with particular emphasis on healthcare services and affordability (Dela Cruz & Ortega-Dela Cruz, 2019). However, the regulation of government hospitals is plagued by a lack of funds, equipment, personnel, and other input (Kanchanachitra et al., 2011; Dayrit et al., 2018).

Hospitals in the country provide good quality services despite the facilities not being as impressive as those found in private and high-end hospitals in the United States and Western Europe. One of the things that makes the quality of high-end hospitals abroad outstanding is the attention given to their laboratories. Laboratories play a very vital role in the health care system of any country, particularly in aiding physicians in the proper diagnosis of illnesses. Medical care becomes comprehensive with the support of results from of laboratory facilities. Additionally, the presence of laboratory support influences the utilization of health services (George, 2011). In the Philippines, clinical laboratories are utilized by physicians in their diagnosis and management of patients. Laboratories are an integral component in health care provision in the country (AO 2007-0027, recently updated to AO 2021-0037). The Department of Health asserts that it is imperative for laboratories to provide accurate results. Particularly, the Health Facilities and Services Regulatory Bureau of the department is the one that foresees and functions to ensure compliance of hospitals (HFSRB, 2023). The passage of Republic Act Number 4688 in 1966 sought to provide a framework for regulating, operating, and maintaining laboratories in the country (RA 4688, 1966). The recently improved AO 2021-0037 provides a set of minimum requirements for the licensing and regulation of clinical laboratories in the country. This set of standards provides specific guidelines regarding human resources, equipment, supplies, procedures, policies, and the laboratory environment itself, among others. Improvement in processes, techniques, procedures, and protocols paved the way for the standardization of these processes. Currently, the standards set forth by the International Organization for Standardization serve as the most common and sought-after standards, be it in management or processes, specifically ISO 9001 - Quality Management and Quality Assurance, is the best-known standard (Heires, 2008; Koppell, 2011). Moreover, fairly recently, laboratory management (Quality Management Principles, 2015), ISO 15189, specific for medical laboratories, was established. The World Health Organization also has set guidelines for laboratory quality management similar to these ISO standards.

The spread of the Covid-19 virus started in January 2020, infecting people all over the world. The rapid transmission of this respiratory virus caused worldwide chaos, affecting and bluntly revealing the weaknesses of healthcare systems (Ciotti et al., 2020). The quality of laboratory testing of the virus was emphasized more than others then (Durant et al., 2020). In the

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Philippines, the gaps in the healthcare system become even more jarring. Thus, the integrated Philippine Health Laboratory System was institutionalized, and another office through the Department Ordedr 2021-0421 focused on building a foundation for laboratories in the Philippines (Balderama et al., 2022). However, government hospital laboratories' assessments in the Philippines before the COVID-19 pandemic have yet to be reported on their compliance with the quality management system. Thus, this study determined the level of compliance of national government hospitals with the existing quality management essentials and the adequacy and appropriateness of the existing quality system essentials. Since the country adopted a new system, the results of this study may be used as a point to determine improvements that can be introduced in government hospital laboratories' quality system essentials for continuous quality management.

METHODOLOGY

A one-time, one-shot evaluation research design was used to establish the status of the national government hospital laboratory capability and level of performance to achieve continuous technical and management quality maturity. The quality management system was used as the framework of analysis. Quantitative and qualitative approaches were employed to identify the internal and external factors that enable and limit the accomplishment of the national government hospital laboratory's mission and functions as preemptors of policy recommendations to enhance and strengthen the capability of hospital laboratory operations.

Description of Respondents and Sampling

A purposive sampling was implemented in this study, with key hospital laboratory personnel chosen as respondents to confirm compliance with the quality system essential in question.

The sample population came from DOH-retained national government hospitals in the National Capital Region (NCR) with corresponding laboratories. NCR was geographically selected due to its highest concentration of DOH-retained hospitals with corresponding laboratory services. The sample size was limited to 20 respondents, one each for every government hospital laboratory. Each respondent is a full-time, permanent employee of the hospital laboratory with at least five (5) years of hands-on experience in laboratory management.

Instrument and Methods

A survey questionnaire for laboratory managers, chief medical technologists, or senior medical technologists was used to generate information on the queries. The survey questionnaire has two parts: Part 1 - General information about the respondents; Part 2 determines the level of compliance to WHO recommendations regarding quality system essentials.

The second part of the questionnaire, composed of 115 questions corresponding to the compliance ratings of national government hospital laboratories, was grouped into four significant headings following Deming's Plan-Do-Check-Act model (Deming, 1986).

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These four major classifications are the following:

1. Management responsibility (Act-Plan)
2. Resource Management (Plan-Do)
3. Service Realization (Do-Check)
4. Measurement, Analysis, Improvement (Check-Act)

Each of the major classifications has its sub-classification wherein a set of questions seek to address the level of compliance of the laboratory to their respective quality systems essentials. To define the quality system essentials and their subcomponents, uniform quantitative values were assigned for every set of questionnaires following the Likert scale with values ranging from 1 to 5, which is as follows:

Table 1: **Quantitative and Qualitative Interpretation of Survey Scores**

Score	Scale	Level of Compliance
5	4.21-5.00	Fully Compliant
4	3.41-4.20	Largely Compliant
3	2.61-3.40	Partially Compliant
2	1.81-2.60	Non-Compliant
1	0.8-1.80	Not Applicable

Note: ***Fully compliant*** *denotes the laboratory meets all compliance obligations, and no gaps are required to be addressed;* ***Largely compliant*** *denotes the laboratory meets most compliance obligations but minor gaps have been identified;* ***Partially compliant*** *denotes the laboratory meets some compliance obligations but major gaps have been identified;* ***Non-compliant*** *denotes laboratory does not meet compliance obligations;* ***Not applicable*** *denotes compliance obligation is not relevant.*

Data Collection and Management

Data was sourced from national government hospital laboratory managers, chief medical technologists, and physician customers. These data focused primarily on processes related to technical and management aspects of laboratory operations as described by quality system essentials from the World Health Organization and from responses of physician customers. The data was also generated using closed and open-ended questions to determine the strengths and weaknesses of laboratories and the instruments to measure quality. Moreover, probing questions were asked to validate the responses to the survey. The answers were also used to complement the research findings and to determine the respondent's perception of the QSE. The data were analyzed using the triangulation approach.

Statistical Treatment of Data

The weighted mean for the group of responses was used for the descriptive part to summarize the respondents' responses. The standard deviations of scores were computed to determine similarities and differences in the responses. A standard deviation of less than one means commonality in a situation, while a standard deviation of greater than or equal to 1 means that

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the samples are differently situated. Moreover, the scores of hospitals relative to compliance were subjected to the Mann-Whitney U Test, Mann-Whitney U Test Calculator (Mann-Whitney U Test Calculator, 2018) was used to facilitate computation. This was used to determine the significance level of the difference with standards.

RESULTS

Seventeen respondents answered the survey questionnaires and three of the targeted 20 respondents declined to participate for various reasons. All 17 government laboratories are tertiary level in terms of their service capability. For their function, all offer both anatomical and clinical pathology services. The average number of years in service for the respondents is 16 years. Three respondents have been in their position for over 30 years.

In the assessment of compliance of the laboratories, six quality systems essentials are used: documents and records, management reviews, organization and personnel, information management, client management and customer service, and purchasing and inventory are under the major heading of Management Responsibility.

Documents and Records

The government laboratories in NCR largely comply with the indicators of Documents and Records. Only two indicators received a partially compliant rating. The "laboratory has all the legal documentation to operate" indicator was rated at 4.18. This is unsurprising as all government laboratories need legal documents to operate. Legal documentation is one of the first requirements for operating a government laboratory. The lowest indicator received a rating of 3.29, partial compliance with the provision for a list detailing all documents in the QMS. Similarly, the indicator on archiving discontinued processes and procedures also received partial compliance.

Management Reviews

Of the four indicators, only one indicator was considered partial compliance for the management reviews component. The results from the management reviews section detail the need for a routine review of records and quality systems, which must be relayed to relevant staff. The ratings given, mainly described as largely compliant, indicate that the laboratory conducts regular reviews. However, in the indicator for compiling findings and recommendations from the reviews within a given timeframe, the ratings for the government hospitals are only partial compliance. Furthermore, two respondents said they do not have any of the given indicators for the whole management reviews component.

Organization and Personnel

For organization and personnel, there are eight indicators, with almost all being given a largely compliant and fully compliant rating, except for one. Two indicators were given a fully compliant rating, the indicator wherein the laboratory has the organizational chart in the laboratory and a duty roster that covers normal and after-office hours. Tertiary-level hospitals, particularly those in NCR, have a laboratory that is open 24 hours. The rest of the indicators

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received a largely compliant rating except for the conduct of regular staff meetings for laboratory personnel, which was given a partially compliant rating. This may mean that either staff meetings are not to be held regularly or that the agreements in the past meetings are not complied with or addressed. Most of the time, government hospitals and laboratories are swamped with work and patients. Therefore, the absence of regular staff meetings is understandable given such a scenario.

Information Management

For information management, of the ten (10) indicators, there is an almost equal distribution of compliance ratings between partially compliant, largely compliant, and fully compliant.

The indicators that received a partially compliant rating must deal with laboratory information management systems, their actual selection, maintenance, and document verification. Four respondents said they do not maintain any laboratory information management system. Those indicators that received a largely compliance rating pertain to the actual functioning and processes involving the information management systems. The indicators that received fully compliant ratings include those that have to deal with laboratory procedures' actual outputs and results. For example, the person who performed the testing is named in the reports generated, the laboratory reports contain pertinent information like the name of the patient and tests conducted and the test results that have been validated and interpreted by the appropriate personnel.

Client Management and Customer Services

For the client management services component, two indicators received partially compliant ratings, the availability of a laboratory handbook and the presence of a tool for regular evaluation of client satisfaction. The availability of a laboratory handbook received the lowest compliance rating, of 2.94 on average. There was a high variation in the answers of the respondents, four claimed they do not have this indicator in their system, while three respondents gave this indicator a fully compliant rating.

Purchasing and Inventory

For the purchasing and inventory component, almost all of the indicators received largely compliant ratings except for one. The respondents' rating showed that they have partial compliance in maintaining an uninterrupted service due to non-disruptions due to stockouts. Moreover, though it was recorded as largely compliant, one respondent said that they do not forecast the need for supplies and reagents. Also, there was another respondent who said that they do not monitor the performance of suppliers. The indicators dealing with the expiration of the laboratory supplies received a relatively higher rating than the others.

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Table 2: Mean for Compliance Rating for Indicators for the major headings of Management Responsibility

INDICATOR	COMPLIANCE RATING	LEVEL OF COMPLIANCE
DOCUMENTS AND RECORDS		
Laboratory has all the legal documentation to operate	4.18	Largely Compliant
Current and updated laboratory quality manual	3.41	Largely Compliant
System in place to control all documents and information from internal and external sources	3.47	Largely Compliant
There is a list that details all documents in the quality management system with editions and distributions	3.29	Partially Compliant
Standard operating procedures for laboratory functions, technical and managerial procedures are current, available and approved by authorized personnel	3.76	Largely Compliant
Policy and SOPs are easily accessible/available to all staff and written in a language commonly understood by respective staff	4.00	Largely Compliant
Documented evidence that all relevant policies and SOPs have ben communicated to and are understood and implemented by all staff as related to their responsibilities	3.65	Largely Compliant
Policies and procedures dated to reflect when it was put into effect, its location when it was reviewed and when it was discontinued	3.50	Largely Compliant
Invalid or discontinued policies and procedures clearly marked/identified and removed from use and one copy retained for reference	3.41	Largely Compliant
Test results, technical and quality records invalid or discontinued policies and procedures are archived for a specified time period in accordance to national/international standards	3.38	Partially Compliant
Archiving system that allows for easy and timely retrieval or archived records and results	3.53	Largely Compliant
MANAGEMENT REVIEWS		
Laboratory routinely performs a documented review of all quality and technical records	3.65	Largely Compliant
Laboratory routinely performs a review of the quality system at least annually	3.65	Largely Compliant
Findings and actions from the management review are communicated to the relevant staff	3.53	Largely Compliant
Laboratory management ensure actions from management review are completed within defined timeframes	3.24	Partially compliant
ORGANIZATION AND PERSONNEL		
Laboratory has a duty roster that covers normal and after hours	4.41	Fully Compliant
Organization chart available that indicates the relationship between laboratory and its parent organization	4.29	Fully Compliant

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Laboratory is directed by person(s) with the competency, delegated responsibility to perform leadership, budgeting and planning	3.53	Largely Compliant
Quality officer/manager with delegated responsibility to oversee compliance with quality management system	3.41	Largely Compliant
Records of personnel are maintained and updated (education, competencies and immunizations)	3.53	Largely Compliant
A system of training that covers QMS, ethics, processes, procedures, tasks, confidentiality	3.41	Largely Compliant
A system of staff competency assessment according to defined criteria	3.41	Largely Compliant
Staff meetings held regularly and do the meeting address previous agenda, system problems, SOPs, feedback, improvement topics/projects	3.29	Partially Compliant
INFORMATION MANAGEMENT		
Test results are legible, technically verified by an authorized person and confirmed against patient identity	4.18	Largely Compliant
Testing personnel identified on the result report or other records	4.41	Fully Compliant
Laboratory report contains the following: test requested, patient identification, requester, sample, unit used, date and time, page number, accession number, revisions done	4.24	Fully Compliant
Test results are traceable to the equipment used for testing	4.12	Largely Compliant
Archived results properly labeled and stored in a secure location, accessible only to authorized personnel	3.65	Largely Compliant
Laboratory defined and implemented authorities and responsibilities for the management and use of the laboratory information system-paper based and electronic, including maintenance and modifications that may affect patient care	3.65	Largely Compliant
Laboratory has evidence of how the Laboratory Information Management System was selected	3.12	Partially Compliant
Test results are validated, interpreted and released by appropriately-authorized personnel	4.29	Fully Compliant
Documented verification of Laboratory Information Management System (paper/electronic)	3.35	Partially Compliant
Laboratory Information System properly maintained to ensure continued functions	3.25	Partially Compliant
CLIENT MANAGEMENT AND CUSTOMER SERVICES		
Staff members with appropriate professional qualifications provide clients with advice and/or training regarding required types of samples, choice of examinations, repeat frequency and interpretation of results	3.94	Largely Compliant
Laboratory investigate (review) and resolves customer complaints	3.76	Largely Compliant
Laboratory handbook is available for laboratory users	2.94	Partially Compliant

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Timely, documented notification provided to customers when the laboratory experiences delays or interruptions in testing or finds it necessary to change examination procedures when testing resumes	3.53	Largely Compliant
Tool for regularly evaluating client satisfaction, staff suggestions and utilization of feedback to improve services	3.35	Partially Compliant
PURCHASING AND INVENTORY		
A system for accurately forecasting needs for supplies and reagents	3.47	Largely Compliant
Laboratory provide specification for their supplies and consumables that are required when placing a requisition	3.82	Largely Compliant
Laboratory monitors the performance of suppliers to ensure that the stated criteria are met	3.41	Largely Compliant
Laboratory maintains records for each reagent and consumable that contributes to the performance of examinations	3.82	Largely Compliant
Budgetary projections based on personnel, test, facility and equipment needs, and quality assurance procedures and materials	3.59	Largely Compliant
Laboratory management review/approve the finalized supply request	3.53	Largely Compliant
Laboratory system records complete and accurate consumption rates and stock levels routinely	3.53	Largely Compliant
Storage areas are set up and monitored appropriately (easy access, ventilated, shielded from sunlight, proper temperature, dust and pest free)	3.53	Largely Compliant
First expiration-First out practiced for organization and wastage minimization	4.06	Largely Compliant
All reagents/test kits in use and in stock currently within manufacturer-assigned expiration or within stability	4.18	Largely Compliant
Expired products labeled and disposed properly	4.00	Largely Compliant
Laboratory provides uninterrupted testing service with no disruption due to stockouts in the last year	3.18	Partially Compliant

Facilities and Safety

For the facilities and safety component, eight indicators were given a partially compliant rating, with the lowest rating given only a 2.94 compliance rating. This indicator pertains to the vaccine and medical surveillance offered for laboratory personnel. Moreover, there is also partial compliance with the designation of a trained safety officer to implement and maintain the safety of the laboratory. The indicators that received largely compliance ratings were those that deal with the handling and management of hazardous materials and components. These include the proper handling of hazardous chemicals and materials, the presence of appropriate biosafety cabinets, and the proper handling and disposal of sharp materials.

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Equipment

All the indicators under the component of equipment were given largely compliance ratings. There were no indicators that received partially compliant ratings. However, one respondent said there were indicators for equipment that they did not comply with. These include labeling and removing faulty equipment from the laboratory, routine calibration of equipment, routine preventive maintenance of equipment, and routine equipment servicing. There were also respondents who gave a consistent, fully compliant rating to all the indicators for equipment.

Process Control

Process control is another of the strong points of the laboratories surveyed. All indicators were given positive compliance ratings, with two being fully compliant. The indicator on the verification and documentation of new reagents, new lot numbers, and new shipments, as well as the performance of internal quality control before the release of patient results, were given the highest compliance ratings. While the lowest compliance rating provided was for the indicators on the documented selection and evaluation of referral laboratories and consultants on laboratory comparison of results with different procedures and equipment.

Table 3: Mean for Compliance Rating for Indicators for the Facilities and Safety, Equipment, and Process Protocol

INDICATOR	COMPLIANCE RATING	LEVEL OF COMPLIANCE
FACILITIES AND SAFETY		
Documented evidence the laboratory has evaluated the adequacy of the size and overall layout of the laboratory and organized the space so workstations are positioned for optimal workflow	3.47	Largely Compliant
Patient care and testing area of the laboratory distinctly separate from one another	3.94	Largely Compliant
Individual workstation maintained free of clutter and set up for efficient operation	3.53	Largely Compliant
Physical work environment appropriate for testing (ventilation, lighting, free of hazards, appropriate safety signage, clerical work outside of testing are)	3.53	Largely Compliant
Laboratory secure from unauthorized access with appropriate signage	3.65	Largely Compliant
Laboratory-dedicated cold and room temperature storage free of staff food items and are patient samples stored separately form reagents and blood products in the laboratory refrigerators and freezers	3.71	Largely Compliant
Work area are clean and free of leakage and spills and disinfection procedures conducted and documented	3.41	Largely Compliant
Biosafety cabinet required in work is certified and appropriate	4.12	Largely Compliant
Laboratory safety manual available, accessible and up-to-date	3.63	Largely Compliant
Sufficient waste disposal available and adequate; separated into infectious and non-infectious waste with infectious waste autoclaved	3.65	Largely Compliant
Hazardous chemical/materials properly handled	4.00	Largely Compliant

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Sharps handled and disposed of properly in appropriate "sharp" containers	4.18	Largely Compliant
Fire safety included as part of the laboratory's overall safety program	3.94	Largely Compliant
Safety inspections and audits conducted regularly and documented	3.35	Partially Compliant
Standard safety equipment available and in use in the laboratory (biosafety cabinet, covers, caps, gloves, handwashing station, eye wash, emergency showers, spill kits, first aid kit)	3.29	Partially Compliant
Personnel protective equipment easily accessible at the work station and utilized appropriately and consistently	3.29	Partially Compliant
Laboratory personnel offered appropriate vaccination and employee medical surveillance	2.94	Partially Compliant
Post-exposure prophylaxis policies and procedures posted and implemented after possible and know exposures	3.27	Partially Compliant
Adverse incidents or injuries from equipment, reagents, occupational injuries, medical screening or illnesses, documented and investigated	3.29	Partially Compliant
Drivers/couriers and cleaners working with the laboratory trained in biosafety practices relevant to their job tasks	3.18	Partially Compliant
Trained safety officer designated to implement and monitor the safety program in the laboratory, including training of other staff	3.00	Partially Compliant
EQUIPMENT		
Equipment install and placed as specified in the operator's manual and uniquely labeled or marked	3.76	Largely Compliant
Equipment operated by trained, competent and authorized personnel	4.12	Largely Compliant
Equipment and methods validated/verified on-site upon installation and before use and documented evidence is available	4.00	Largely Compliant
Laboratory has documented estimates of measurement of uncertainty (Internal QC minimum of 6 months)	3.59	Largely Compliant
Current equipment inventory data available for all equipment in the laboratory	3.82	Largely Compliant
Relevant equipment service information readily available in the laboratory	3.88	Largely Compliant
Defective equipment, waiting for repair not used and clearly labeled	3.65	Largely Compliant
Non-functioning equipment appropriately labeled and removed from the laboratory or path of workflow following the equipment management policies and procedures	3.59	Largely Compliant
Routine calibration of laboratory equipment with schedule that follows manufacturer recommendations and is regularly reviewed	3.65	Largely Compliant
Routine user preventive maintenance performed on all equipment and recorded according to manufacturer's minimum requirement	3.76	Largely Compliant
Equipment routinely serviced according to schedule as per minimum manufacturer recommendations by qualified and competent personnel and is documented in appropriate logs	3.59	Largely Compliant
Equipment malfunction resolved by the effectiveness of the	3.59	Largely Compliant

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corrective action program and associated root cause analysis		
Equipment repair and monitoring documentation for completeness and verification before use	3.94	Largely Compliant
Functional back-up system that prevents interruption of lab services	3.53	Largely Compliant
Manufacturer's operator manuals readily available to testing staff and available in the language understood by staff	4.12	Largely Compliant
Laboratory provides for uninterrupted testing service, with no disruptions due to equipment failure in the last year	3.47	Largely Compliant
PROCESS CONTROL		
Guidelines for patient identification, specimen collection, labeling, and transport readily available to person responsible for primary sample collection	3.94	Largely Compliant
Laboratory adequately collects information needed for examination performance	4.12	Largely Compliant
Adequate sample receiving/evaluation procedures are in place and criteria followed routinely	4.06	Largely Compliant
Specimens stored appropriately when testing does not occur immediately upon arrival in the laboratory	3.94	Largely Compliant
Specimens either received or referred packaged appropriately according to local and or international regulations and transported within acceptable timeframes and temperature intervals	3.76	Largely Compliant
Documented selection and evaluation of referral laboratory and consultants	3.65	Largely Compliant
Examination procedures documented in a language commonly understood by all staff and available in appropriate locations	4.06	Largely Compliant
Each new reagent preparation, new lot number, new shipment of reagents or consumables verified before and documented	4.24	Fully Compliant
Internal quality control performed, documented and verified for all tests/procedures before releasing patient results	4.24	Fully Compliant
Quality control results monitored and reviewed with corresponding documentation of corrective actions	3.88	Largely Compliant
Laboratory compare results of the same test performed with different procedures and equipment	3.65	Largely Compliant
Environmental conditions checked and reviewed accurately (room and equipment)	3.88	Largely Compliant
Acceptable ranges been defined for all temperature-dependent equipment with procedures and documentation of action taken in response to out-of-range temperatures	3.76	Largely Compliant
Laboratory participate in interlaboratory comparison program or alternative assessment system for all tests	3.94	Largely Compliant

Occurrence Management and Process Improvement

All of the indicators under occurrence management and process improvement were given largely compliant ratings. The highest rating was on the indicator wherein the laboratory regularly communicates with the upper management regarding the need for continual improvement. There were around 5 respondents who consistently gave relatively largely

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compliant ratings for all the indicators under occurrence management and process improvement.

Non-conformities, Corrective, and Preventive Action

The five indicators under non-conformities, corrective and preventive action received mixed compliance ratings. Three indicators received largely compliant ratings, while the other two were given partially compliant ratings. The indicator that received the lowest rating was the documentation of the effectiveness of the preventive actions implemented. On the other hand, the indicator that received the highest rating also dealt with the adequate documentation of non-conforming activities.

Evaluation, Audit, and Assessments

Two out of the three indicators were given partially compliant ratings for the evaluation, audit, and assessments. The ratings on the conduct of internal audits, as well as the use of the audit reports to correct/prevent future issues, received a partially compliant rating. In addition, two (2) respondents claimed they had no system for the mentioned indicators.

Table 4: Mean for Compliance Rating for Indicators for the Occurrence Management and Process Improvement; Non-conformities, Corrective, and Preventive Action; and Evaluation, Audit, and Assessments

Indicator	Compliance Rating	Level of Compliance
Occurrence Management and Process Improvement		
Graphical tools (charts, graphs, tables) used to communicate quality findings and identify trends	3.47	Largely Compliant
Laboratory identify and undertake continual improvement projects	3.59	Largely Compliant
Laboratory communicate with upper management regularly regarding needs for continual improvement	3.82	Largely Compliant
Quality indicators (TAT, rejected specimens, stock-outs, etc.) are selected and tracked	3.71	Largely Compliant
Outcome of review of quality indicators used to improve laboratory performance	3.53	Largely Compliant
Actions taken are checked and monitored to determine the effectiveness of improved quality of laboratory performance	3.59	Largely Compliant
Non-conformities, Corrective, and Preventive Action		
All identified non-conforming activities/work identified and documented adequately	3.71	Largely Compliant
Documented root cause analysis performed for non-conforming work before corrective actions are implemented	3.47	Largely Compliant
Corrective action performed and documented for non-conforming work	3.59	Largely Compliant
Implemented corrective actions monitored and reviewed for their effectiveness before closure/clearance	3.35	Partially Compliant
Documented preventive actions implemented and monitored for their effectiveness	3.29	Partially Compliant
Evaluation, Audit, and Assessments		

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Internal audits conducted at intervals as defined in the quality manual and these audits address areas important to patient care	3.35	Partially Compliant
Generated audits reports are used for documented corrective/preventive actions	3.35	Partially Compliant
Assessment for potential pitfalls performed for all laboratory processes including pre-examination, examination, post examination	3.53	Partially Compliant

DATA ANALYSIS

Data for each of the twelve indicators were summarized (Table 5). The weighted mean scores calculation results reveal that in most of the Quality Standard Essential Aspects, laboratories largely comply with local licensure standards. However, despite their commonality, the Mann-Whitney Test reveals that the weighted mean of the scores is significantly different or lower than the Quality System of the World Health Organization. Likewise, the aspect of Management Review and Evaluation, Audits, Assessment have disparity in the level of compliance in each indicator, resulting in the weighted mean scores significantly different or lower than QS of WHO after the Mann-Whitney Test. The compliance with the indicators under this Quality System Essentials was noted to be different between hospital laboratories. Thus, there exist differences in compliance levels in Quality System Essentials among the observed hospital laboratories.

Table 5: Weighted Mean, Standard Deviation and U test Result of Quality Standard Essential Aspects

QSE Aspect	Weighted Mean	SD of Scores	U-value	z-score	Findings	Interpretation
Documents and Records	3.602	0.832	8.5	The Z-Score is -4.6671. The p-value is < .00001. The result is significant at p < .05.	Weighted mean of scores is high relative to compliance with licensure standards but significantly below QS of WHO.	Laboratories are largely compliant with indicators for local licensure standards yet significantly different/lower from WHO standards
Management Review	3.515	1.200	25.5	The Z-Score is -4.08156. The p-value is < .00001. The result is significant at p < .05.	Weighted mean of scores is high relative to compliance with licensure standards but significantly below QS of WHO	Laboratories are largely compliant with indicators for local licensure standards but their level of compliance in each indicator significantly differs from one another and the compliance in general significantly different/lower from WHO standards
Organization and	3.662	0.876	25.5	The Z-Score is -4.08156. The p-value	Weighted mean of scores is high relative to compliance with	Laboratories are largely compliant with indicators for local

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Personnel				is < .00001. The result is significant at p < .05.	licensure standards but significantly below QS of WHO	licensure standards yet significantly different from WHO standards
Information Management	3.812	0.752	17	The Z-Score is -4.37433. The p-value is < .00001. The result is significant at p < .05.	Weighted mean of scores is high relative to compliance with licensure standards but significantly below QS of WHO	Laboratories are largely compliant with indicators for local licensure standards yet significantly different/lower from WHO standards
Client Management and Customer Service	3.506	0.810	8.5	The Z-Score is -4.6671. The p-value is < .00001. The result is significant at p < .05	Weighted mean of scores is high relative to compliance with licensure standards but significantly below QS of WHO	Laboratories are largely compliant with indicators for local licensure standards yet significantly different/lower from WHO standards
Purchasing and Inventory	3.676	0.783	0	The Z-Score is -4.95987. The p-value is < .00001. The result is significant at p < .05.	Weighted mean of scores is high relative to compliance with licensure standards but significantly below QS of WHO	Laboratories are largely compliant with indicators for local licensure standards yet significantly different/lower from WHO standards
Facilities and safety	3.543	0.696	8.5	The Z-Score is -4.6671. The p-value is < .00001. The result is significant at p < .05.	Weighted mean of scores is high relative to compliance with licensure standards but significantly below QS of WHO	Laboratories are largely compliant with indicators for local licensure standards yet significantly different/lower from WHO standards
Equipment	3.754	0.780	8.5	The Z-Score is -4.6671. The p-value is < .00001. The result is significant at p < .05.	Weighted mean of scores is high relative to compliance with licensure standards but significantly below QS of WHO	Laboratories are largely compliant with indicators for local licensure standards yet significantly different/lower from WHO standards
Process Control	3.937	0.565	17	The Z-Score is -4.37433. The p-value is < .00001. The result is significant at p < .05.	Weighted mean of scores is high relative to compliance with licensure standards but significantly below QS of WHO	Laboratories are largely compliant with indicators for local licensure standards yet significantly different/lower from WHO standards
Occurrence	3.618	0.812	25.5	The Z-Score is -4.08156.	Weighted mean of scores is high relative	Laboratories are largely compliant with

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Management and Process improvement				The p-value is < .00001. The result is significant at p < .05.	to compliance with licensure standards but significantly below QS of WHO	indicators for local licensure standards yet significantly different/lower from WHO standards
Nonconformities, Corrective actions	3.482	0.816	0	The Z-Score is -4.95987. The p-value is < .00001. The result is significant at p < .05.	Weighted mean of scores is high relative to compliance with licensure standards but significantly below QS of WHO	Laboratories are largely compliant with indicators for local licensure standards yet significantly different/lower from WHO standards
Evaluation, Audits, Assessment	3.412	1.115	17	The Z-Score is -4.37433. The p-value is < .00001. The result is significant at p < .05.	Weighted mean of scores is high relative to compliance with licensure standards but significantly below QS of WHO	Laboratories are largely compliant with indicators for local licensure standards but their level of compliance in each indicator significantly differs from one another and the compliance in general significantly different/lower from WHO standards

Perception of Respondents on the Quality System Essentials

All respondents indicated that the QSE System is relevant and objective. It is in the area of completeness of the QSE system where there is no unanimity. Specifically, the respondents who indicated "No" have concerns about resource support – funding. These respondents indicated that funding is insufficient in maintaining or modernizing the equipment of their respective laboratories and that this should be included in the standards.

Furthermore, the survey also revealed that there is a difference in the level of compliance among the respondents. Table 6 reveals that it is in the aspect of Process Control where the laboratories are largely compliant is common to the majority (82.35%) of the respondents, followed by Information Management (70.59%), and then Documents and Records, Management Reviews; Equipment; Occurrence Management and Process Improvement (64.7% each). This means that the implementation of the QSE system is not uniform among the sample hospitals.

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Table 6: Distribution of Hospital Laboratories Based on Level Compliance to Quality System Essentials

Quality System Essentials	Non and Partially Compliant Hospital Laboratories	Percentage	Largely and Fully Compliant Hospital Laboratories	Percentage
Documents and Records	6	35.29	11	64.71
Management Reviews	6	35.29	11	64.71
Organization and Personnel	7	41.18	10	58.82
Information Management	5	29.41	12	70.59
Client Management and Customer Service	8	47.06	9	52.94
Purchasing and Inventory	7	41.18	10	58.82
Facilities and Safety	9	52.94	8	47.06
Equipment	6	35.29	11	64.71
Process Control	3	17.65	14	82.35
Occurrence Management and Process Improvement	6	35.29	11	64.71
Identification of Non-Conformities, Corrective and Preventive Action	11	64.71	6	35.29
Evaluation, Audits and Assessment	10	58.82	7	41.18

DISCUSSION

Hospital facilities directly and greatly affect patients' health outcomes (Dela Cruz & Ortega-Dela Cruz, 2019). Laboratory facilities are vital for public health and environmental activities as they provide diagnostic results primarily for disease prevention, control, surveillance, and outbreak emergency response (Balderama et al., 2022). For this reason, test results from laboratories must be reliable and accurate. The ultimate goal for government hospital laboratories, and public health care in general, should be towards total quality management. Total quality management has been used since the 1980s to improve business and organizations as it concerns the workers and the work process that focus on the satisfaction of customers and improvement of performance (Al-Shdaifat, 2015; Aggarwal et al., 2018). Strengthening laboratories, especially in government hospitals, would give Filipinos a reliable service they can afford. According to Krunk and colleagues (2018), improving the quality of health care in third-world countries would need a system-wide action that includes not just the availability but excellence in the facilities of hospitals. However, to reach total quality management, quality control and assurance in the laboratory should first be extensively implemented. In the Philippines, AO 2021-0037 provided local clinical laboratories with licensing and regulation requirements and guidelines regarding the operation, equipment, policies, and laboratory environment.

This study assessed the compliance of the government hospital laboratories to the quality system essentials before the pandemic. The level of compliance with the local standard was also compared to the international quality standard essentials set by WHO and ISO 15189.

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Based on the results, hospital laboratories in the National Capital Region then were generally largely compliant with the implementation of quality system essentials, particularly with the local licensure standards but significantly lower in compliance when compared with WHO standards. The indicator of each quality system essential to local licensure requirements complements most of the WHO's 12 essential indicators. However, as the WHO standards are geared towards international accreditation, the standards are more numerous, and compliance levels are expected to be higher than local licensure standards (AO 2021-0037; WHO, 2011). Furthermore, the hospital laboratories' overall largely compliant performance was due to the no and partially compliant ratings being compensated by the majority of other indicators' largely and fully compliant ratings. The quality improvement process is an interconnected indicator; thus, the lower-rated compliance indicators are expected to be pulled by the higher-rated compliance within the same quality system essential.

After quality system management, quality cost management is a level before attaining total quality management. This was not directly measured during the assessment in this study since the basis used, WHO and ISO 15189, did not include such principle. However, the survey revealed that most of the respondents believe that funding is a factor in their compliance with the indicators of quality management essentials. Respondents find the quality management essentials relevant and objective, but since resources to support such system is not secure, they find it incomplete. The respondents indicated that continuous improvement requires continuous resource support. Government hospitals secure their funding through a tax-based budgeting system from the National or local government (Lavado et al., 2010; Dayrit et al., 2018). Due to this, funds are mainly allotted too many other functions of the hospital, making equipment modernization of laboratories and other facilities difficult to achieve (Dela Cruz & Ortega-Dela Cruz, 2019). However, public hospital funding has continuously increased in recent years, targeting to fund facilities and laboratories (Ager, 2022). Moreover, based on the General Appropriations Act, 25% of the hospitals' income should be allocated to improving and purchasing their equipment (Dela Cruz & Ortega-Dela Cruz, 2019). Thus, the of government hospitals must prioritize upgrading their laboratory and other facilities' equipment to comply with all the quality system management indicators completely. Currently, the Office for Health Laboratories was assigned to secure appropriate funding for the Philippine Health Laboratory System. By doing so, the quality of the laboratories will be assured (Balderama et al., 2022).

Additionally, it was observed that each indicator's compliance rating within the essential quality system significantly differs from one hospital laboratory to another. This reveals that there is a lack of a tool for examining laboratory performance and comparing it to standards, benchmarks, or the performance of other laboratories. Ulep et al. (2021) mentioned that the licensing of DOH only considers the capacity of health facilities to operate based on structural inputs and not the other quality elements. Such practice makes the hospitals do what they see fit as long as they are still within the general standard of DOH. Hence, benchmarking hospital laboratories in the country may be a great option. Benchmarking elevates the quality of laboratory performance over time as it identifies the best practice (Badrick et al., 2019). Further, a quality maturity model should be adapted for the laboratories for them to continue to maintain or improve their quality management. Nevertheless, this standard should not be

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rigid that it hinders adapting to new developments, especially since the quality standard has shifted due to the pandemic.

CONCLUSION

This study presents the compliance assessment of government hospital laboratories to the quality system essentials before the pandemic, making a point of comparison to the situation now. The government has continued to improve its guidelines and standard for the quality system of laboratories in the country. With the pandemic, the laboratories in the country are given more attention after proving to be a significant component of the healthcare system. Thus, it is necessary to continuously track and review the government hospital laboratories' performance and compliance and the quality management essentials in place.

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