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| RESEARCH ARTICLE

Quality Management System of Philippine Hospital Laboratories: An Analysis Based on Service Capability and Bed Capacity

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| ABSTRACT

Laboratories play a critical role in assisting the clinical decisions of physicians in providing reliable results to patients. Laboratory Quality Management Systems (LQMS) is the important element that drives the effective delivery of laboratory services. However, problems and barriers to QMS implementation still remains a challenge, especially in resource-limited countries. This research aimed to determine the LQMS implementation of Philippine hospital laboratories of Region XII in terms of laboratory service capability and hospital bed capacity. A Quantitative-Descriptive design was employed and respondents were selected through complete enumeration. Fifty-five respondents who were laboratory managers were surveyed, focusing on the 12 Quality System Essentials (QSEs) as building blocks of LQMS. Data obtained were analyzed using descriptive and inferential statistics. Findings of the study showed that majority of hospital laboratories are categorized as tertiary in terms of service capability and most of the hospitals have less than 100 bed capacity. In terms of implementation, primary, secondary, and tertiary laboratories have implemented LQMS to a very high extent, while hospitals with 100 to 500 beds outperformed those with less than 100 bed capacity. Process Management obtained the highest implementation score across all service capability and bed capacity categories, while Facilities and Safety Management obtained the lowest. A significant difference in LQMS implementation in the area of Customer Focus was observed between hospitals with less than 100 and 100 to 500 bed capacities, while no significant difference was observed across all laboratory service capabilities. On the basis of findings, it is recommended that implementation strategies must be applied, monitored, and evaluated by hospital laboratories targeting QSEs that fall behind other essentials. In the area of Customer Focus, the following must be addressed: meeting regulatory requirements; adhering to contracts; effective communication; monitoring customer feedback; and taking proactive steps to address customer concerns.

| KEYWORDS

Quality Management System, Hospital Laboratories, Philippines, Clinical Laboratories, Quality System Essentials

| ARTICLE INFORMATION

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1. Introduction

The robustness of the healthcare system depends upon the clinical laboratory since the entirety of clinical decisions made by physicians on patients are primarily based on clinical laboratory reports (Chaudry et al., 2023). To guarantee reliability, Laboratory Quality Management Systems (LQMS) and accreditation are implemented by laboratories (Maruta et al., 2024).

LQMS is a vital element for the effective operation of research, clinical, testing, or production/manufacturing laboratories (Pillai et al., 2022). Sufficient evidence that emphasizes laboratory services as crucial in assisting patient care exists. However, in resource-limited nations, the central function of laboratory services has been neglected for decades (Beyanga et al., 2018). Notwithstanding the immense progress made in advancing laboratory medicine in low- and middle-income countries (LMICs), the deficient Quality Management Systems (QMSs) still persist as a challenge and hindrance to providing reliable laboratory services in resource-constrained settings (Tanasiichuk et al., 2023).

Philippines, as reported by World Bank, has been classified as a lower middle-income country (Catilogo, 2024). Furthermore, only a few laboratories in the Philippines are accredited by International Organization for Standardization (ISO) 15189. This is despite the evidence that accreditation results in progress as well as the passing of Executive Order No. 605 in 2007 mandating institutionalization of Total Quality Management programs across all agencies in the government. Accreditation serves as a tool for healthcare providers and payers to ensure that clinical laboratory services are safe, reliable, and of good value for patients. Additionally, it provides a mechanism to gauge quality improvements and support consistency (Badrick et al., 2019).

International standards provide a description of QMS for medical laboratories. Of these, ISO 15189 and Clinical and Laboratory Standards Institute (CLSI) QMS01-A4 are the most widely adopted and are comparable in terms of addressing the three laboratory phases: a) preexamination (test and indication selection, sample collection, transportation, reception and accessioning); b) examination (quality control and analysis); and c) postexamination (interpretation, reporting, archiving, and notification). Additionally, CLSI QMS01-A4 introduced Quality System Essentials (QSEs) (Barbé, 2017).

The 12 QSEs are a series of well-coordinated activities that formed the foundation of quality management. Each must be addressed in order to achieve overall laboratory quality improvement (Patel et al., 2024). Implementation of a QMS that depends on effective management of the 12 QSEs enables the laboratory to achieve the highest level of accuracy and reliability of quality service. These undeniably crucial essentials for the effective provision of quality laboratory services are organization, personnel, equipment, purchasing and inventory, process control, information management, documents and records, occurrence management, assessment, process improvement, customer services, and facility and safety (Mulleta et al., 2021).

The DOH guidelines in the Philippines categorize clinical laboratories based on ownership, institutional character, function, and service capability. According to ownership, a clinical laboratory can be characterized as either government or private. Based on institutional character, a clinical laboratory can be classified as either institution-based or non-institution-based. In terms of function, a clinical laboratory is categorized into clinical pathology, anatomic pathology, and molecular pathology. Lastly, based on service capability, a clinical laboratory can be classified into three types: exclusively molecular pathology; solely anatomic pathology; and clinical and anatomic pathology which can be further categorized into primary, secondary, tertiary, or special (AO 2021-0037). According to Bahati et al. (2022), the number of laboratory tests increases with an increase in hospital bed capacity. Therefore, since a hospital laboratory is institution-based, which means that it is located within the premises and operates as part of a DOH licensed health facility (AO 2021-0037), its services will be influenced by the number of hospital bed capacity. In terms of bed capacity, Lan and Pan (2020) state that primary hospitals have less than 100 beds, secondary hospitals have 100 to 500 beds, and tertiary hospitals have more than 500 beds.

In order to align with the main objective of the Republic Act No. 11223 or the Universal Health Care Act, the Department of Health (DOH) implemented new guidelines in the licensing of diagnostic laboratories in the Philippines (Administrative Order 2021-0037). However, DOH licensing only considers the ability of healthcare facilities to function based on structural inputs (Ulep et al., 2021). This allows hospitals to do anything they see fit as long as they stay under the general standards of DOH, and such practice resulted to a significant variation in the compliance rating for each indicator within the essential quality system between hospitals (Saguil et al., 2023).

Concerning gaps in several areas of the quality management system were found by De Torres et al. (2022) after examining point-of-care testing (POCT) practices in Philippine hospitals using the 12 QSEs. In the area of organization, only one-third (16 out of 50) of hospitals had a dedicated POCT committee, and over half (58%) lacked a POCT coordinator. Under personnel management, while laboratory staff performed tests, they often received no training as POCT operators, and competency assessments were missing for over half (52%) of operators. Supply and inventory management also showed inconsistencies, with different institutions assigning responsibility based only on who oversaw POCT. These variations in POCT implementation across hospitals led to discrepancies in several QSEs, specifically organization, personnel, assessments, nonconforming event management, and documentation.

In the study conducted by Saguil et al. (2023) that assessed compliance with QMS in government laboratories across the National Capital Region, findings revealed areas where practices fell short of expectations. In the area of documents and records management, partial compliance was noted in the indicator on the provision for a list detailing all documents in the QMS as well as in the indicator on archiving discontinued processes and procedures. Information management also showed room for improvement as evidenced by a partially compliant rating on laboratory information management systems, their actual selection, maintenance, and document verification. Furthermore, a significant gap was identified where four respondents said they do not maintain any laboratory information management systems. Customer focus also revealed partial compliance ratings, specifically in terms of availability of a laboratory handbook and the presence of a tool for regular evaluation of client satisfaction. The issue was further highlighted by the fact that four respondents claimed they do not have the availability of a laboratory handbook as indicator

in their system. Equipment management also revealed inconsistencies. While most indicators related to equipment compliance were met, one respondent admitted not complying with the labeling of faulty equipment, routine preventive maintenance of equipment, and routine equipment servicing. Process management showed the lowest compliance in documenting the selection and evaluation of referral laboratories and consultants, as well as comparing results across different procedures and equipment. The assessment area also revealed some deficiencies. Two out of three indicators for evaluation, audits, and assessments received only partial compliance ratings. Notably, the conduct of internal audits and using audit reports for improvement were the areas that lacked compliance. Two respondents even reported having no system in place for these activities. Finally, facilities and safety showed partial compliance regarding the designation of a trained safety officer to implement and maintain the safety of the laboratory.

While existing studies offer valuable insights, a critical gap still remains in the understanding of the specific state of the Philippines' LQMS due to the very limited number of studies exploring this area of the country's healthcare system. Therefore, this study aimed to fill in the gap, specifically by determining the status of LQMS implementation of hospital laboratories in Region XII in terms of the 12 QSEs. Understanding the extent of implementation of hospital laboratories in the region based on demographic variables such as service capability and bed capacity will provide additional information to the scarce body of literature on LQMS in the Philippines and to the existing knowledge about LQMS in resource-limited countries. Furthermore, the findings of the study will serve as the basis for improvement of healthcare quality and patient safety, strengthening of laboratory systems, optimization of resource allocation and management, enhancement of public health outcomes, and building of confidence and trust among healthcare professionals, patients, and the wider community.

2. Methods

A Quantitative-Descriptive design was employed in the study. Complete Enumeration sampling was utilized where a total of 55 laboratory managers composed of chief medical technologists and laboratory quality assurance officers of Philippine hospital laboratories from Region XII were included. The respondents have valid Professional Regulation Commission (PRC) license and are directly involved in the operational continuity of the laboratory's QMS.

The instrument used to assess the LQMS implementation utilized the framework of 12 QSEs adapted from the Next Generation Sequencing (NGS)/QMS Internal Assessment Tool of Centers for Disease Control and Prevention (CDC) and passed a series of validation from experts in the field.

Specific actions were observed by the researchers to ensure the reliability of the study. The informed consent form explicitly addressed: the background of the study that focused on LQMS implementation of hospital laboratories in Region XII; the rights of the participants that specifically conveyed the right to withdraw at any time and right to confidentiality through the study in compliance with Republic Act No. 10173; and the exclusive use of data for academic and research purposes. Survey questionnaire was sent to the respondents and data were analyzed by the statistician using descriptive and inferential methods.

Table 1 shows the range of means, description, and interpretation of scores of the hospital laboratories' extent of LQMS implementation.

Table 1: Quantitative and Qualitative Interpretation of Survey Scores

Range of Means	Description	Interpretation
4.20–5.00	Very High Extent	The extent of Laboratory Quality Management System implementation is very high rated at 80-100%.
3.40–4.19	High Extent	The extent of Laboratory Quality Management System implementation is high rated at 60-79%.
2.60–3.39	Moderate Extent	The extent of Laboratory Quality Management System implementation is moderate rated at 40-59%.
1.80–2.59	Less Extent	The extent of Laboratory Quality Management System implementation is less rated at 20-39%.
1.00–1.79	Least Extent	The extent of Laboratory Quality Management System implementation is least rated at 0-19%.

3. Results and Discussion

3.1 Profile of Hospital Laboratories

Figure 1 shows that majority of the hospital laboratories in Region XII are categorized as tertiary (47%), followed by secondary (46%), and primary (7%). This implies that a number of laboratory procedures are offered to the community by most of the hospital laboratories in Region XII, since AO 2021-0037 emphasizes that tertiary laboratories offer the minimum service capabilities of a secondary category with additional services such as other clinical chemistry examinations, arterial blood gases, any machine-based serological and immunological testing but not limited to tumor markers, thyroid function tests, hepatitis profile, culture and sensitivity testing for aerobic and anaerobic bacteria, and cytologic and histopathologic procedures.

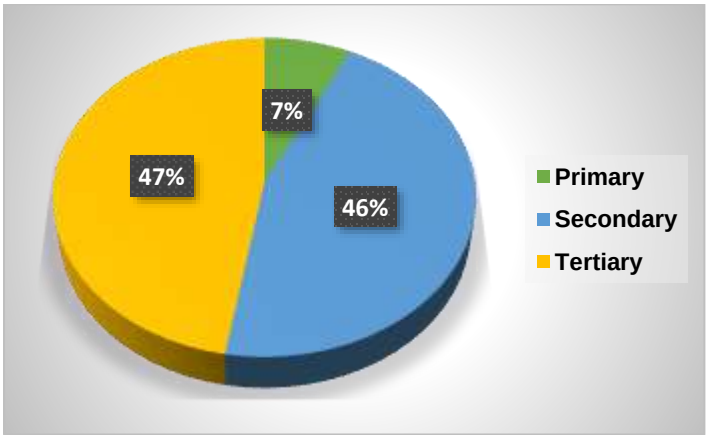

Fig. 1. Frequency of hospital laboratories according to service capability

Figure 2 shows that in terms of bed capacity, most of the laboratories are based in hospitals with less than 100 beds (65%), followed by hospitals with 100 to 500 beds (35%). Interestingly, no hospital in Region XII has a bed capacity of greater than 500 (0%), which is contrary to the statement of the Department of Budget and Management and Department of Health (2022) that more hospitals expanded their bed capacities beyond 500 beds, exceeding the coverage of the 2013 standards.

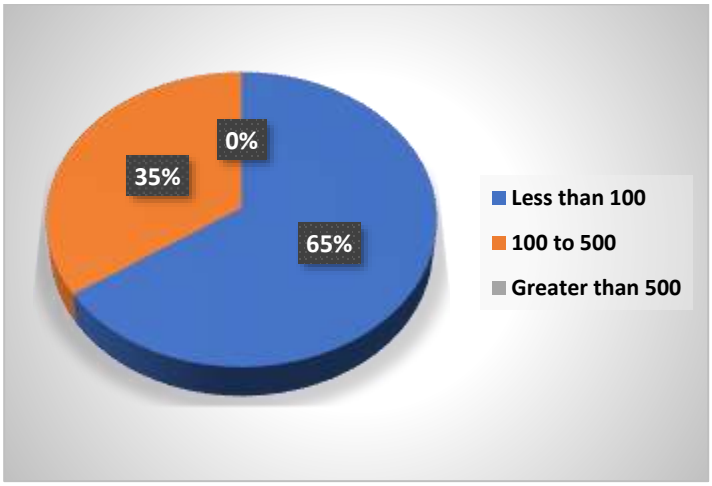

Fig. 2. Frequency of hospital laboratories according to hospital bed capacity

3.2 Extent of LQMS Implementation of Hospital Laboratories

Table 2: Overall LQMS Implementation Based on Demographic Profile

Quality System Essentials	Laboratory Service Capability			Hospital Bed Capacity	
	Primary	Secondary	Tertiary	Less than 100	100 to 500
	Mean	Mean	Mean	Mean	Mean
Organization	4.28	4.35	4.33	4.33	4.31
Customer Focus	4.53	4.58	4.58	4.57	4.59
Facilities and Safety Management	4.16	4.19	4.18	4.17	4.23
Personnel Management	4.63	4.66	4.66	4.65	4.69
Supply and Inventory Management	4.60	4.63	4.62	4.61	4.63
Equipment Management	4.54	4.56	4.55	4.55	4.56
Process Management	4.65	4.68	4.68	4.67	4.70
Documents and Records Management	4.41	4.45	4.45	4.44	4.48
Information Management	4.50	4.50	4.51	4.47	4.52
Nonconforming Event Management	4.41	4.45	4.43	4.44	4.43
Assessment	4.24	4.31	4.28	4.29	4.32
Continual Improvement	4.30	4.32	4.31	4.30	4.33
Overall	4.44	4.47	4.47	4.46	4.48

Table 2 shows that Process Management obtained the highest implementation mean score across all categories of laboratory service capability (primary = 4.65, secondary = 4.68, and tertiary = 4.68) and hospital bed capacity (less than 100 = 4.67 and 100 to 500 = 4.70). This implies that analysis of data and management of nonconforming events, the conduct of quality control, validation, and verification are typically performed to a 'very high extent' by Region XII hospital laboratories. This result aligns well with Moitlhobogi et al. (2024) that reported Process Management as one of the highest scoring critical success factors of QMS implementation.

On the contrary, Facilities and Safety Management shows the lowest mean score across all categories of laboratory service capability (primary = 4.16, secondary = 4.19, and tertiary = 4.18) and hospital bed capacity (less than 100 = 4.17 and 100 to 500 = 4.23). This pertains to the laboratory environment, including physical conditions, documentation, maintenance, incident management, risk assessment, environmental monitoring, and emergency preparedness. According to Abu-Siniyeh et al. (2021), numerous safety-related accidents in laboratories are caused by insufficient regulations, improper application of safety measures, or unaware attitudes and practices toward safety precautions. Therefore, this QSE needs to be accorded attention by hospital laboratories in Region XII.

3.3 Comparative Analysis of LQMS Implementation of Hospital Laboratories Based on Service Capability

Table 3: Comparative Analysis Result According to Service Capability (α = 0.05)

Quality System Essentials	p-Value
Organization	0.778
Customer Focus	0.215
Facilities and Safety Management	0.663
Personnel Management	0.240
Supply and Inventory Management	0.105
Equipment Management	0.750
Process Management	0.380
Documents and Records Management	0.352
Information Management	0.661
Nonconforming Event Management	0.157
Assessment	0.713
Continual Improvement	0.688

Table 3 shows that there is no significant difference in the extent of implementation of the 12 QSEs across primary, secondary, and tertiary hospital laboratories in Region XII at a significance level of 0.05. This indicates that the hospital laboratories implement LQMS to the same degree, irrespective of service capability. However, despite the extensive literature reviewed by the researchers, no study was found that directly compares LQMS or QSE implementation or performance of hospital laboratories in terms of service capability following Philippine classification scheme. Therefore, to the best of the researchers' knowledge, this study is the first to explore this comparison in the Philippines. This finding is very much helpful since a uniform level of LQMS implementation among all hospital laboratories would mean that a unified approach could potentially offer a solution to the persisting challenges faced by the majority of the hospital laboratories in the region.

3.4 Comparative Analysis of LQMS Implementation of Hospital Laboratories Based on Hospital Bed Capacity

Table 4: Comparative Analysis Result According to Bed Capacity (α = 0.05)

Quality System Essentials	p-Value
Organization	0.183
Customer Focus	0.047
Facilities and Safety Management	0.061
Personnel Management	0.833
Supply and Inventory Management	0.927
Equipment Management	0.433
Process Management	0.550
Documents and Records Management	0.761
Information Management	0.355
Nonconforming Event Management	0.895
Assessment	0.292
Continual Improvement	0.190

Table 4 shows that there is a significant difference in the extent of implementation of the 12 QSEs between Region XII hospital laboratories with less than 100 beds and 100 to 500 beds in the area of Customer Focus (p-Value = 0.047) at a significance level of 0.05. This indicates that hospital laboratories belonging to these two categories have differing LQMS implementation. This finding is contrary to the study of Gaughan et al. (2020) which investigated the extent to which small hospitals are associated with lower quality. In their study, it was underscored that small hospitals are commonly not related to lower quality before or after controlling for hospital characteristics. However, it should be noted that they defined small hospitals as those with less than 400 beds. For the rest of the 11 QSEs (Organization, Facilities and Safety Management, Personnel Management, Supply and Inventory Management, Equipment Management, Process Management, Documents and Records Management, Information Management, Nonconforming Event Management, Assessments, and Continual Improvement), the results show that all hospital laboratories in Region XII implement them to the same degree.

In the study of Bahati et al. (2022), who compared hospital bed capacity against the highest number of tests reported by each hospital within two years, the number of tests increases as the bed capacity increases. In terms of LQMS implementation, in this current study, it means that whether the bed capacity is small or large, which basically corresponds to smaller or larger number of tests carried out, hospital laboratories in Region XII implement LQMS to the same degree and based on the general mean score, it is to a 'very high extent'. As to the researchers' extensive review of literature, no study was found that directly compares LQMS implementation of hospital laboratories based on bed capacity, which makes this current study the first to explore this comparison in the Philippines. Furthermore, this finding is significantly valuable since this uniformity in LQMS implementation makes it easier to offer potential solutions to challenges faced by hospital laboratories in the form of a unified approach.

4. Conclusions

Having analyzed the data and discussed the findings, the study was able to draw the following conclusions from Philippine hospital laboratories in Region XII: a) most hospital laboratories have tertiary service capability, indicating increased number of services offered to patients; b) majority of the hospital laboratories have less than 100 beds; c) Process Management stands out as the highest scoring QSE, while Facilities and Safety Management lags behind at the bottom of the rankings; d) QMS implementation does not vary in terms of service capability, suggesting that all hospital laboratories regardless of size and services implement LQMS to the same degree; and e) implemention of Customer Focus significantly differs between hospital laboratories with bed capacity of less than 100 and 100 to 500.

5. Recommendations

Hospital laboratories in Region XII must implement, monitor, and evaluate targeted strategic actions for QSEs who have lower implementation score. Moreover, since Customer Focus varies in implementation between hospital laboratories with less than 100 and 100 to 500 beds, hospital laboratories must address the following: a) meeting regulatory requirements; b) adhering to contracts; c) effective communication; d) monitoring customer feedback; and d) taking proactive steps to address customer concerns.

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