

Research Article

Quality Management System Implementation of Hospital Laboratories in the Philippines

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Abstract: Ensuring accuracy, timeliness, and reproducibility of results depends on robust laboratory quality management system (QMS). However, QMS in laboratories remains a global challenge in resource-limited settings. This study aimed to determine the extent of QMS implementation of Region XII hospital laboratories in the Philippines. A Quantitative-Descriptive design was utilized and selection of respondents was achieved through complete enumeration. A total of 55 laboratory managers were assessed through a survey in terms of implementation of the 12 Quality System Essentials (QSEs). Data were analyzed using descriptive and inferential statistics. Results indicated a significant difference in implementation in the areas of organization, customer focus, facilities and safety management, assessments, and continual improvement. In terms of overall implementation, hospital laboratories implemented QMS to a very high extent with private hospital laboratories showing higher mean score compared to government hospital laboratories. However, since QSEs are set of interconnected indicators, low-rated indicators were significantly pulled by higher-rated implementation. This implies the necessity for strategic actions by hospital laboratories for the lower-scoring indicators to address the weak areas of the laboratory's QMS.

Keywords: quality management system; quality system essentials; hospital laboratories

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1. Introduction

Laboratories are an important component of hospitals that play a critical role in providing accurate results. To ensure that data and results are accurate, timely, and reproducible, laboratories must maintain a strong laboratory quality management system (QMS) that supports laboratory activities, records management, a path for continuous improvement (1), and must comply to standardized quality management essentials (2).

Quality management is a system of continuous analysis, improvement, and re-evaluation of an organization's resources, processes, and services (3). The implementation of QMS in the laboratory has the potential to revolutionize laboratory services and ultimately enhance patient care in these settings (4). A framework of 12 components known as the Quality System Essentials (QSEs) developed by Clinical and Laboratory Standards Institute (CLSI) is utilized in the tool of QMS (5). The 12 QSEs are contained in document QMS01-A4 of CLSI approved guideline and is fully compatible with the standards set by International Organization for Standardization (ISO). Since both CLSI and ISO used the same definition of QMS in laboratory practice, ISO 15189:2013 policy recommends the assessment and monitoring of QMS in medical laboratories as a quality improvement effort towards quality laboratory services (6).

The 12 QSEs that form the foundation of QMS are organization, personnel, equipment, purchasing and inventory, process control, information management, documents and records, occurrence management, assessment, process improvement, customer service, and facilities and safety (7). By managing and addressing equal importance of these 12 QSEs within the laboratory's QMS, in a way that best suits the laboratory, accuracy and reliability along the workflow path are assured (8).

However, ensuring QMS in clinical laboratories still persists as a challenge worldwide. This is evident among developing countries especially in resource-limited settings (9). In the Philippines, it was highlighted that 469 out of 1,300 licensed hospitals are not using relevant quality and efficiency indicators for performance evaluation (10). Furthermore, several studies in the Philippines revealed issues in the laboratory QMS. Variations in quality indicators across government hospitals in the National Capital Region were highlighted (2). Concerning practices of laboratories reporting errors and unreliable test results suggesting problems with process control were also found (11). Such problem still persists despite the passage of 2007 Executive Order mandating the institutionalization of Total Quality Management program in all government agencies (12). Furthermore, physicians highlighted slow and inconsistent turn-around times for test results, likely due to staffing shortages (13). Therefore, assessing the levels of implementation of laboratory QMS components is critical for identifying gaps that require further improvement (14). Moreover, it is advised that practical recommendations of a QMS be implemented to improve laboratory operations and generate reliable results (8).

While existing studies offer valuable insights, a critical gap still remains in understanding the specific state of the Philippines' laboratory QMS due to the very limited number of literature exploring this area of the country's healthcare system. Additionally, licensing of DOH only considers the ability of healthcare facilities to function based on structural inputs but not taking into account other quality components (10). Therefore, this study aimed to bridge identified gaps in the Philippine laboratory QMS, specifically by assessing the extent of QMS implementation of hospital laboratories in Region XII in terms of 12 QSEs, since the lack of data that hinders efforts to accurately assess the problem's scope begins from the local level.

2. Materials and Methods

The study employed Quantitative-Descriptive design, passed fullboard ethical review, and was issued ethical clearance. The study population was composed of 77 hospital laboratories in Region XII taken from the National Health Facility Registry of the DOH website. A Complete Enumeration sampling was employed in the selection of hospital laboratories. Only 74 hospital laboratories have active license to operate in year 2024 and 55 of which responded to the survey. Qualified respondents were laboratory managers who were either chief medical technologists or laboratory quality assurance officers, have Professional Regulation Commission license valid in year 2024, with at least one year of experience in laboratory management or quality assurance, and who were directly involved in the implementation and maintenance of the laboratory's QMS.

The survey questionnaire contained 12 QSEs adapted from the Next Generation Sequencing (NGS)/QMS Internal Assessment Tool of Centers for Disease Control and Prevention. It was modified by converting the items from interrogative to declarative form, removing NGS-related items, dividing a few single items that measured multiple information, and utilizing a 5-point Likert scale to measure responses. The scale from 1 to 5 was identified with the score range to fit in the mean rating and the defined interpretation under data analysis.

A series of validations was conducted to ensure content and face validity of the survey questionnaire. First validation was done by the research adviser and corrections were applied. The revised survey questionnaire was submitted to an external validator who was a medical technology professor from the Notre Dame of Marbel University, City of Koronadal, South Cotabato. It passed another validation by three internal validators who were graduate school professors from the Notre Dame of Dadiangas University, General Santos City. The adapted and validated survey questionnaire was converted into Google Forms for ease of administration.

Pilot testing was conducted among 25 laboratory managers from hospital laboratories outside Region XII who share similar characteristics set in the study’s inclusion and exclusion criteria. Data was submitted to the statistician for analysis of Cronbach’s alpha to determine the instrument’s internal consistency. Result showed that all QSEs were above the score of 0.60 with an overall internal consistency of 0.72. Survey questionnaire in Google Forms were sent to respective respondents and data obtained were analyzed using descriptive and inferential methods by the statistician.

3. Results

3.1. Demographic Profile of Hospital Laboratories

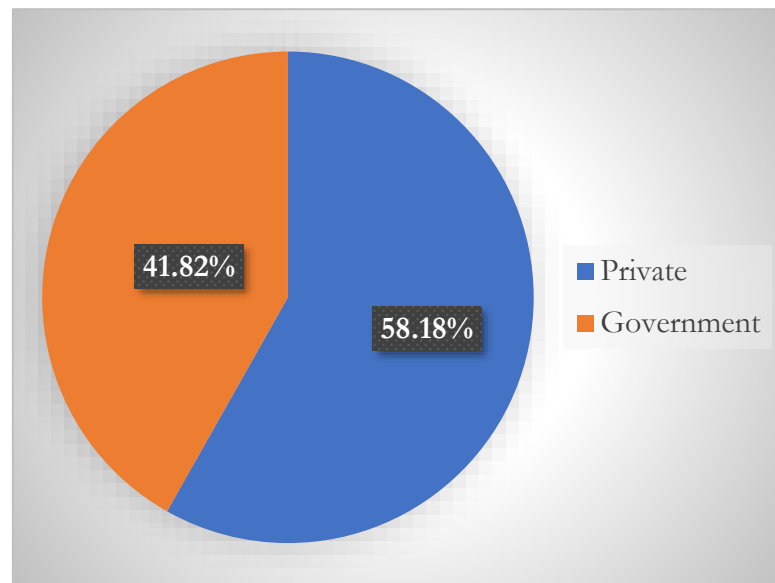


Figure 1. Demographic Profile of Hospital Laboratories Based on Ownership.

3.2. QMS Implementation of Hospital Laboratories

Table 1. Mean Scores of Hospital Laboratories’ Extent of QMS Implementation.

Quality System	Government	Private	Average	Interpretation
Essentials				
Organization	4.10	4.52	4.33	Very High Extent
Customer Focus	4.45	4.67	4.57	Very High Extent
Facilities and Safety Management	3.94	4.36	4.17	High Extent
Personnel Management	4.58	4.70	4.65	Very High Extent
Supply and Inventory Management	4.54	4.67	4.61	Very High Extent
Equipment Management	4.43	4.66	4.55	Very High Extent
Process management	4.59	4.73	4.67	Very High Extent

Documents and Records Management	4.28	4.58	4.44	Very High Extent
Information Management	4.27	4.64	4.47	Very High Extent
Nonconforming Event Management	4.28	4.57	4.44	Very High Extent
Assessments	4.05	4.49	4.29	Very High Extent
Continual Improvement	4.05	4.51	4.30	Very High Extent
Overall	4.30	4.59	4.46	Very High Extent

Table 2. Comparison of QMS Implementation Between Private and Government Hospital Laboratories ($\alpha = 0.05$).

Quality System Essentials	p-value
Organization	0.019
Customer Focus	0.007
Facilities and Safety Management	0.009
Personnel Management	0.118
Supply and Inventory Management	0.213
Equipment Management	0.038
Process management	0.190
Documents and Records Management	0.125
Information Management	0.011
Nonconforming Event Management	0.054
Assessments	0.014
Continual Improvement	0.038
Overall	0.019

4. Discussion

Figure 1 shows that majority of the hospitals in Region XII are privately owned at 58.18%. This finding is consistent with Badrick et al. (12) indicating that majority of their surveyed hospitals in the Philippines were privately operated at 58%, as well as with the recent study of Alibudbud (15) indicating that private hospitals are dominant in the Philippines.

Concerning the extent of QMS implementation, Table 1 shows that 11 out of 12 QSEs are implemented by hospital laboratories in Region XII to a 'very high extent' with an overall mean score of 4.46. This implies that QMS implementation is very high rated. Although the results indicated a very high extent result, it should be noted that since QSEs are set of interconnected indicators, low-rated indicators of each of the 12 QSEs were significantly pulled by higher-rated implementation. This finding is consistent with the study of Saguil et al. (2) on QSE compliance of government hospital laboratories in the National Capital Region of the Philippines. The study revealed a generally compliant result of QSE implementation, however underscored that the overall largely compliant performance of hospital laboratories' was due to the no and partially compliant ratings being compensated by the majority of other indicators' largely and fully compliant ratings.

Interestingly, in this current study, it showed that government hospital laboratories with an overall mean score of 4.30 performed inferior to private hospital laboratories that obtained an overall mean score of 4.59 in QMS implementation despite the passage of 2007 Executive Order mandating the institutionalization of Total Quality Management program in all government agencies (12). In particular, the 11 QSEs that showed a 'very high extent' implementation result in descending order were Process Management, Personnel Management, Supply and Inventory Management, Customer Focus, Equipment Management, Information Management, Documents and Records Management and Nonconforming Event Management, Organization, Continual Improvement, and Assessment. Implementation of Facilities and Safety Management, on the other hand, scored 4.17 described as 'high extent'. Although one score range lower than the rest of the QSEs, this result is still considered to be very good.

Process Management implementation obtained the highest mean score of 4.67, which indicates that hospital laboratories perform validation, verification, quality control, data analysis, and management of nonconforming events to a 'very high extent'. This finding agrees with the previous study of Moithobogi (16) wherein Process Management obtained 4.49 mean score considered one of the highest among the identified critical success factors of QMS implementation.

Personnel Management obtained the second highest mean score of 4.65 which implies that hospital laboratories evaluate and document effectiveness of training, and keep records of job descriptions, personnel's training, continuing education, competencies, and professional qualifications to a 'very high extent'. However, this result is contrary to Mulleta et al. (17) in which personnel management came out as one of the lowest-scoring QSEs at 23.5%. However, it should be noted that the indicator assessing evaluation and documentation of training effectiveness obtained the lowest mean score of 4.40 in this area.

Supply and Inventory Management obtained the third highest mean score of 4.61, which underscores that hospital laboratories receive, inspect, use, dispose, and document supplies to a 'very high extent'. This finding agrees with the previous study of Moithobogi (16) wherein this QSE obtained a mean score above 3.0 which qualifies it as a critical success factor of QMS implementation and with Mulleta et al. (17) where this QSE also ranked second highest in implementation score.

Customer Focus obtained the fourth highest mean score of 4.57, which indicates that hospital laboratories meet regulatory requirements, adhere to contracts, practice effective communication, monitor customer feedback, and take proactive steps to deal with customer concerns to a 'very high extent'. This finding agrees with Almatrafi et al. (18) that customers were satisfied with the laboratory services provided for them.

Equipment Management obtained the fifth highest mean score of 4.55 suggesting that hospital laboratories maintain equipment accuracy, prevent equipment failures, ensure regulatory compliance, improve efficiency, and enhance data quality to a 'very high extent'. Ranking fifth, this challenge agrees with Tanasiichuk et al. (9) who highlighted concern about deficit of equipment maintenance providers among medical laboratories of developing countries.

Information Management obtained the sixth highest mean score of 4.47, which indicates that hospital laboratories ensure data security, accessibility, accuracy, and backup to a 'very

high extent'. However, it is essential to note that the top two indicators with the lowest mean scores in this QSE were those which assessed if alternate methods for managing data during computer downtime is available and if backup and recovery systems are in place, with mean scores of 4.27 and 4.38, respectively.

Ranking seventh on the record are Documents and Records Management and Nonconforming Event Management that both obtained a mean score of 4.44. For Documents and Records Management, the result shows that hospital laboratories implement control, retention, distribution, and review of documents to a 'very high extent'. This finding is contrary to the study of Mulleta et al. (17) in which documents and records only obtained 43.5% equivalent to an average QSE implementation score. However, it is crucial to note in this current study that 'archival of obsolete original documents and destruction of their copies' was the indicator that obtained the lowest mean score of 4.05, followed by 'control documents are assigned a unique number and revision number' with a mean score of 4.29, and 'document distribution is controlled to prevent the use of invalid documents through the use of established procedures' with a mean score of 4.35. These findings agree with the study conducted by Mesfin et al. (19) in Addis Ababa, Ethiopia where laboratory documentation (documents and records) system in accordance with the standard was found unpracticed by 45 (21.1%) health facilities. Nonconforming Event Management, on the other hand, indicates that hospital laboratories implement corrective and preventive action plan, analyze trends, and document and maintain records of nonconforming events to a 'very high extent'. While this finding is consistent with the result of Saguil et al. (2) showing a largely compliant rating, it contradicts the findings of Mulleta et al. (17), wherein occurrence management obtained the lowest average of 17.6%.

Organization obtained the eighth highest mean score of 4.33, which highlights that hospital laboratories define organizational structure, set clear roles and responsibilities, review complaints, nonconforming events, corrective and preventive actions, and consistently review and improve QMS to a 'very high extent'. However, indicator for consistent review and improvement of QMS obtained the lowest mean score in this QSE. This concern also proved to be a challenge as highlighted in the study of Makokha et al. (20) wherein management reviews was one of the 12 QSEs identified as most challenging to improve.

Continual Improvement obtained the ninth highest mean score of 4.30, which implies that hospital laboratories identify key performance indicators, monitor performance, develop improvement plans, and implement changes to a 'very high extent'. The findings agree with Saguil et al. (2) wherein process improvement was given largely compliant ratings.

Assessment obtained the tenth highest mean score of 4.29, which implies that hospital laboratories maintain readiness to audit, perform corrective actions, and maintain records of all audits to a 'very high extent'. The result agrees with Carey et al. (21) that mentioned performance of evaluations and audits guarantee effectiveness and achievement of desired results for processes in the laboratory.

Finally, the QSE with the lowest implementation score among the 12 essentials was Facilities and Safety Management that obtained a mean score of 4.17. In general, this suggests that hospital laboratories have well-maintained environment that include physical conditions, documentation, maintenance, incident management, risk assessment, environmental monitoring, and emergency preparedness to a 'high extent'. However, six indicators have mean scores of less than 4.20 equivalent to 'high extent'.

Table 2 shows that a significant difference exists in the QMS implementation in terms of Organization, Customer Focus, Facilities and Safety Management, Assessments and Continual Improvement between government and private hospital laboratories in Region XII indicated by p-values of less than 0.05. This indicates that government and private hospital laboratories vary in the implementation of each of the seven QSEs. Concerning this, it should be recalled in this study that in terms of implementation mean scores, private-owned hospital laboratories are better than government-owned hospital laboratories. These findings are supported by Akpan et al. (22) who found that private hospital laboratories exhibited better adherence and commitment to delivery of quality services exemplified by overall higher Total

Laboratory Quality Score compared to public hospital laboratories. Furthermore, their study's most significant finding is in the area of Facility and Safety wherein private hospital laboratories showed significantly higher improvement than public hospital laboratories. They also found that private hospital laboratories strictly conform more to standard requirements for equipment maintenance than public hospital laboratories. The researchers cited reason that private hospitals have greater inclination to quality standards to retain their clients because their survival largely depends on market profitability. In the study conducted by Lleshi (23), it was mentioned that while the private sector is subject to all planned market rules by adapting the management in the function of success, the public sector falls behind and currently bears the bulk of the responsibility for providing healthcare services to the population. On the other hand, Personnel Management, Supply and Inventory Management, Process Management, Documents and Records Management, and Nonconforming Event Management are implemented by both government and hospital laboratories to the same degree. The findings for Process Management and Supply and Inventory Management agree with Akpan et al. (22) that highlighted Internal Quality Assurance and External Quality Assurance and inventory control of both public and private hospital laboratories needing ongoing technical support and continuous quality improvement.

This study will be useful for DOH in monitoring quality of hospital laboratories' and ensuring better and safe laboratory services are provided to patients. Hospital laboratories will be guided in formulating strategies that will address the weaknesses in the implementation the 12 QSEs for overall improvement, especially among hospital laboratories who are gearing towards accreditation with the drive to elevate the level of quality services offered to the community. This study also adds to the scarce body of knowledge about QMS implementation in the Philippines and serves as a reliable basis for future research endeavors related to QMS.

This study has some limitations. The instrument used to assess the extent of QMS implementation may not have been comprehensive enough to accommodate all the quality indicators of each of the 12 QSEs. Increasing the number of indicators, preferably ones that conform with international guidelines such as ISO, will enhance the comprehensiveness of the result of the QMS implementation among hospital laboratories. Another is that the responses were obtained solely from laboratory managers (Chief Medical Technologists and Laboratory Quality Assurance Officers). Including patients and physicians as respondents or participants in the study will increase the scope of evaluation and draw comprehensive findings in the area of Customer Focus.

5. Conclusions

Having analyzed the data and discussed the findings, the study concludes that hospital laboratories in Region XII of the Philippines implement QMS to a very high extent using the 12 QSE indicators. Private laboratories significantly performed better than government laboratories across all 12 QSEs and differ significantly in implementation in the areas of Organization, Customer Focus, Facilities and Safety Management, Assessments, and Continual Improvement. Low-rated indicators exist in each of the 12 QSEs which underscores the need for a strategic action by hospital laboratories to address the challenged QMS areas.

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Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

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