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LITERATUR REVIEW: SCOPE OF QUALITY CONTROL AND INTRODUCTION OF LEVELS OF QUALITY CONTROL

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Quality Control,
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Abstrak

Quality control is a fundamental aspect of ensuring high standards in various industrial and service processes. This article discusses the scope of quality control and introduces the key stages in the quality control process. The scope of quality control includes planning, implementation, and evaluation to ensure that products or services meet the established standards. The stages of quality control involve identifying quality needs, formulating standards and procedures, monitoring and measuring performance, and taking action for continuous improvement. By effectively understanding and applying these stages, organizations can enhance operational efficiency, minimize errors, and ensure customer satisfaction. This article aims to provide a comprehensive guide on quality control, facilitating implementation and ensuring optimal results across various sectors.

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INTRODUCTION

All activities aimed at ensuring the accuracy and precision of laboratory test results are known as laboratory quality monitoring. In laboratory quality assurance there are two activities, namely internal quality assurance activities and external quality activities (Mawarni, 2023). In laboratory quality assurance there are two activities, namely internal quality assurance activities and external quality activities. Internal quality assurance is an activity carried out in laboratory management in the form of checking, prevention and supervision which is carried out continuously starting from the pre-analytical, analytical and post-analytical stages in order to obtain accurate and precise examination results (Achmadi et al., 2021). External Quality Assurance is a type of QC (Quality Control) procedure where the laboratory periodically obtains specimens for analysis which are also sent to laboratories participating in the External Quality Assurance program (Anggraini et al., 2022).

Quality control, or quality control, refers to the steps or processes undertaken to ensure that test results are accurate and reliable. As a primary healthcare facility,

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laboratory management must ensure that test results are reliable (Wicaksono et al., 2019). In the laboratory quality control stage, it is important to pay attention to factors that can affect the quality of laboratory tests, such as the examination method and the calibration of laboratory instruments (F. Kahar, 2022). Routine calibration of laboratory equipment is crucial to produce reliable, accurate, and precise test results (F. Kahar et al., 2025). For example, regarding the examination method used, namely the urine protein examination, an assessment carried out using the Westgard chart resulted in all methods, including the dip strip method, the 6% acetic acid heating method, and the sulfosalic acid method, having a reasonable level of accuracy for use in conducting the examination (Sari et al., 2023). By routinely conducting quality assurance in the laboratory, it will improve work safety and reduce the risk of accidents in the laboratory (Hadipranoto et al., 2022).

The laboratory must carry out, monitor and document quality control for each laboratory test. The role of the organization in policy making, the existence of supporting facilities and good knowledge of ATLM are factors that also support the implementation of quality control in the laboratory (Ministry of Health of the Republic of Indonesia, 2015). The laboratory must document for each function that affects the results of laboratory examinations, namely the requirements for education, qualifications, training, technical knowledge, skills, and experience. The laboratory must monitor, control and record (record) the conditions of the test environment in accordance with the requirements of the relevant methods and procedures or if it affects the validity of the results (Subamia et al., 2023). Each stage of examination in the laboratory refers to GLP (Good Laboratory Procedure) so that each examination gets accurate results. Pre-analytical errors are errors that occur and begin when a laboratory examination is ordered by a doctor until the examination sample arrives at the laboratory and is ready for analysis (Wijayati & Ayuningtyas, 2021).

This article aims to understand the implementation of QC in laboratories, evaluate the relationship between management policies and QC implementation, and the relationship between ATLM knowledge and QC implementation.

METHOD

This study uses a systematic literature review method. This article aims to assess the implementation of quality control (QC) in laboratories and evaluate the relationship between management policies, equipment availability, and ATLM knowledge related to QC implementation. The primary literature search process was conducted electronically through three leading databases, namely Google Scholar for broad coverage, the Directory of Open Access Journals (DOAJ) for quality-assured and globally indexed open access sources. The search strategy was developed using a combination of critical keywords in English and Indonesian, such as "quality control (QC)" and "quality control stages".

RESULTS AND DISCUSSION

Results

The results of the review of articles related to the implementation of quality control in laboratories are research conducted by (Wicaksono et al., 2019) in Bandung. This research is a descriptive analytical study. The research design is a survey by administering a questionnaire to the Laboratory of UPT Puskesmas in Bandung. The

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questionnaire contains 9 questions regarding the overview of QC implementation in the laboratory adopted from The Great QC Global Survey 2017 conducted by Westgard, 13 questions regarding management policies adopted from the management requirements clause of ISO 15189:2012, 10 questions regarding the availability of facilities and infrastructure adopted from the Regulation of the Minister of Health Number 37 of 2012 concerning the implementation of laboratories in health centers and 22 questions to measure ATLM knowledge adopted from laboratory quality control teaching materials published by the Health PPSDM Agency. In this descriptive analytical study, the survey design was applied by sending questionnaires to 29 laboratories of UPT Puskesmas in Bandung.

Data analysis was conducted to illustrate the frequency distribution of QC practices in the laboratory, presented in pie or bar charts. The chi-square test, a nonparametric comparison test, was used to identify and classify research data into numerical or symbolic scores, while scores were assigned by categorizing respondents' answers to the questionnaire according to predetermined categories (Wicaksono et al., 2019)

This study aimed to understand the implementation of QC in the laboratory, evaluate the relationship between management policies and QC implementation, and the relationship between ATLM knowledge and QC implementation. Furthermore, this study also aimed to determine the effect of facility availability on QC implementation in the laboratory (Wicaksono et al., 2019).

The results of the article review conducted by (Wicaksono et al., 2019) showed the following results:

Table 1. Cross tabulation of QC implementation with management policies

		Management Policy		
		Not enough	Enough	
QC Implementation	Implemented	17	4	21
	Not implemented	3	5	8
Total		20	9	29

Table 1 shows the distribution of the frequency of QC implementation in laboratories based on the assessment of management policies. There are two categories of management policy assessment, namely "Poor" and "Sufficient." Of the total 29 laboratories, 21 laboratories implemented QC well, while 8 laboratories did not implement it. Among the laboratories that implemented QC, 17 laboratories were rated "Poor" in the management policy, while 4 laboratories were rated "Sufficient." For laboratories that did not implement QC, 3 laboratories were rated "Poor" and 5 laboratories were rated "Sufficient."

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Table 2 Chi-Square Test of QC Implementation with Management Policy

	Value	Df	Asymptotic Significance (2-sided)
Pearson Chi-Square	5,110	1	0,024
N of Valid Cases	29		

Table 2 shows the results of the Chi-Square test showing a significance value of 0.024 (sig < 0.05), which indicates a relationship between management policies and QC implementation in the laboratory.

Tabel 3 tabulasi silang pelaksanaan QC dan sarana prasarana

		Infrastructure		Total
		Not Enough	Enough	
QC Implementation	Implemented	6	15	21
	Not implemented	3	5	8
Total		9	20	29

Table 3 shows the assessment categories of facilities and infrastructure, namely "Poor" and "Sufficient." Of the total 29 laboratories, 21 laboratories implemented QC well, while 8 laboratories did not implement it. Among the laboratories that implemented QC, 6 laboratories had a "Poor" assessment in facilities and infrastructure, while 15 laboratories were assessed as "Sufficient." For laboratories that did not implement QC, 3 laboratories were assessed as "Poor" and 5 laboratories were assessed as "Sufficient."

Table 4 Chi-Square Test of QC Implementation with Infrastructure

	Value	Df	Asymptotic Significance (2-sided)
Pearson Chi-Square	0,216	1	0,642
N of Valid Cases	29		

Table 4 shows that the chi-square test obtained a significance value of 0.642 (sig <0.05), which indicates that there is no relationship between facilities and infrastructure and the implementation of QC in the laboratory.

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Table 5 Cross Tabulation of QC Implementation with ATLM Knowledge

		ATLM Knowledge		Total
		Not Enough	Enough	
QC Implementation	Implemented	8	13	21
	Not implemented	4	4	8
Total		12	17	29

Table 5 shows that there are 4 laboratories with ATLM knowledge that is considered "sufficient" and QC implementation that is "implemented." A total of 13 laboratories have ATLM knowledge that is "sufficient" but QC implementation is "not implemented." In addition, 4 laboratories with ATLM knowledge that is "poor" successfully implemented QC, while 8 laboratories with ATLM knowledge that is "poor" did not implement QC.

Table 6 Chi-Square Test of QC Application in ATLM Knowledge

	Value	Df	Asymptotic Significance (2-sided)
Pearson Chi-Square	0,338	1	0,561
N of Valid Cases	29		

Table 6 shows the chi-square test obtained a significance value of 0.561 (sig <0.05) which indicates that there is no relationship between ATLM knowledge and the implementation of QC in the laboratory.

Discussion

Cross-tabulation results of QC implementation with management policies

Of the 29 laboratories studied, 69% or 20 laboratories indicated that their management policies were inadequate in encouraging the implementation of laboratory quality control (QC). In contrast, 31% or 9 laboratories had adequate management policies to support effective QC implementation. This suggests that suboptimal management policies can be a significant barrier to effective QC implementation (Wicaksono et al., 2019).

In addition, all laboratories have written personnel job descriptions, which is an important step in ensuring clarity of responsibility. However, of the total laboratories, 16 laboratories have adequate personnel, namely more than 2 personnel, to carry out their duties. In contrast, 13 laboratories experience a shortage of personnel, with less than 1 personnel per laboratory. This shortage of personnel has the potential to affect the laboratory's ability to carry out the QC process effectively and adequately (Wicaksono et al., 2019).

Executor competence is the ability that must be possessed by the executor including knowledge, expertise, skills, and experience. Laboratories need to improve

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management policies and ensure adequate personnel numbers to improve the effectiveness of QC implementation and, in turn, the overall quality of laboratory services (Hartoyo & Ruliyanta, 2024).

According to the SNI-19-17025-2017 standard document on the competency requirements of calibration and testing laboratories, laboratory competency can be assessed technically, including through the availability of technical personnel with adequate capabilities and in accordance with the scope of testing, appropriate and calibrated equipment and clear traceability to SI units, appropriate testing methods, and the existence of mechanisms implemented to ensure the quality of test results. One effort that can be made to ensure the quality of test results is to participate in comparative tests between laboratories (Harjito, 2019).

Chi-Square Test Results of QC Implementation with Management Policy

The Chi-Square test results show a significance value of 0.024 (sig <0.05), which indicates a significant relationship between management policy and implementation of quality control (QC) in the laboratory. A significance value of less than 0.05 means that the relationship between management policy and QC implementation does not occur by chance, but rather shows a real influence (Wicaksono et al., 2019).

The quality of laboratory services is determined by an overall assessment of the examination results, with the main focus on the quality of the parameters tested. Each examination goes through a complicated process and takes time before the results are announced by the laboratory. This process includes pre-analytical, analytical, and post-analytical stages. In addition, the quality of the examination is also influenced by materials, tools, methods, and other factors. Therefore, it is important to implement the right strategy to achieve the desired examination quality (H. Kahar, 2005).

Cross-tabulation results of QC implementation and facilities and infrastructure

A total of 5 laboratories that had facilities and infrastructure assessed as "adequate" successfully implemented quality control (QC). However, there were 15 laboratories with facilities and infrastructure assessed as "adequate" that did not implement QC. On the other hand, 3 laboratories with facilities and infrastructure assessed as "poor" still successfully implemented QC. Meanwhile, 6 laboratories with "poor" facilities and infrastructure conditions were unable to implement QC. This finding shows that although "adequate" facilities and infrastructure do not always guarantee the implementation of QC, "poor" facilities and infrastructure conditions also do not completely hinder the implementation of QC. This highlights the need for additional factors such as management policies and personnel training in determining the success of QC implementation in laboratories (Wicaksono et al., 2019).

Adequate health care facilities that are in accordance with service needs can significantly improve the quality of services in health institutions. With complete and standard facilities, health institutions can provide more effective and high-quality services, better meet patient needs, and support the performance of health workers in providing optimal services (Navis et al., 2020).

Chi-Square Test Results for QC Implementation with Facilities and Infrastructure

The results of the Chi-Square test showed a significance value of 0.642 (sig> 0.05), which indicates that there is no significant relationship between facilities and infrastructure and the implementation of quality control (QC) in the laboratory. A significance value greater than 0.05 indicates that the relationship between facilities and

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infrastructure and the implementation of QC may occur by chance and does not show a consistent effect (Wicaksono et al., 2019).

This is in line with Mohandesi's research that service standards in Puskesmas units in general still have weaknesses and obstacles with limited facilities and infrastructure. Limitations can be seen from the service facilities in the laboratory room where the medical equipment used is still limited so that it hampers the work of officers and causes the length of the examination process (NIM, 2015).

Laboratory personnel may need to undergo additional training to understand the requirements of ISO 17025:2017 and develop the skills needed to run a quality management system effectively. This training can include an understanding of technical requirements, internal audits, and method validation (Hartoyo & Ruliyanta, 2024)

Cross Tabulation Results of QC Implementation with ATLM Knowledge

Table 5 shows the distribution of quality control (QC) implementation based on the level of ATLM (Medical Laboratory Assistant) knowledge in the laboratory. From these data, there are 4 laboratories with ATLM knowledge that is considered "sufficient" that have successfully implemented QC. However, there are 13 laboratories that also have "sufficient" ATLM knowledge but do not implement QC. This shows that "adequate" ATLM knowledge is not always followed by effective QC implementation, indicating that other factors may also influence the success of QC in the laboratory (Wicaksono et al., 2019).

On the other hand, 4 laboratories with ATLM knowledge that was considered "poor" were still able to carry out QC. Meanwhile, 8 laboratories with "poor" ATLM knowledge did not carry out QC. This finding highlights that although "poor" ATLM knowledge can affect QC implementation, some laboratories with insufficient knowledge can still carry out QC, while others cannot (Wicaksono et al., 2019).

Education is related to a person's knowledge and breadth of insight. In the health sector, education is an important benchmark for someone to work. The education of the ATLM who work is D3 and DIV, which is in accordance with the Regulation of the Minister of Health of the Republic of Indonesia No. 42 of 2015 (Pemantapan et al., n.d.).

Chi-Square Test Results of QC Implementation in ATLM Knowledge

The Chi-Square test results show a significance value of 0.561 (sig> 0.05), which indicates that there is no significant relationship between ATLM (Medical Laboratory Assistant) knowledge and the implementation of quality control (QC) in the laboratory. A significance value greater than 0.05 indicates that the relationship between ATLM knowledge and QC implementation may occur by chance and does not show a consistent effect (Wicaksono et al., 2019).

The workload capacity must be adjusted to the number of staff and level of training, the size of the laboratory and the availability of laboratory facilities. Ideally, microscopic work (which is universal for all levels of laboratories) per day should not exceed a total of four hours. If the amount of work requested is beyond the laboratory's capabilities, specimen testing becomes unreliable (NONPF, 2018).

CONCLUSION AND SUGGESTION

Conclusion

Based on the results of the study, it can be concluded that management policy plays a significant role in the implementation of quality control (QC) in the laboratory.

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Table 1 and Table 2 show a significant relationship between management policy and QC implementation, with a significance value of 0.024 indicating that good management policy can increase the likelihood of QC implementation.

On the other hand, facilities and infrastructure and ATLM knowledge do not show a significant relationship with QC implementation. Table 3 and Table 4 show a significance value of 0.642 for facilities and infrastructure, while Table 5 and Table 6 show a significance value of 0.561 for ATLM knowledge. This indicates that although facilities and infrastructure and ATLM knowledge are important, these factors do not have a consistent influence on QC implementation in the laboratory.

These results emphasize the importance of effective management policies in encouraging QC implementation. Laboratories need to ensure that the management policies implemented actively support QC implementation. Although facilities and infrastructure and ATLM knowledge did not show a significant influence in this study, they are still important elements that need to be considered in efforts to improve laboratory quality. Therefore, a comprehensive approach that includes good management policies, improving infrastructure, and developing ATLM knowledge can contribute to the effectiveness of QC implementation and improving the overall quality of the laboratory.

Suggestion

Laboratories should address the absence of SOPs by preparing clear, detailed SOPs that comply with applicable quality standards. The SOP preparation process must involve all relevant parties, including laboratory personnel and management, to ensure that the resulting SOPs can be implemented effectively. In addition, laboratories need to conduct periodic training to ensure that all staff understand and comply with established procedures. Routine evaluation of the effectiveness of SOPs is also important so that they can be updated according to technological developments and operational needs. Thus, laboratories can maintain and improve service quality sustainably.

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