Quality of care and patient safety in the clinical laboratory process

Calidad de atención y seguridad del paciente en el proceso de laboratorio clínico

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Abstract
This study is part of a result of the research project Prevention and control of adverse events in the pre-analytical phase of the clinical laboratory process at the Hospital León Becerra of Guayaquil. It is focused on offering a theoretical, analytical and comparative contribution of previous research carried out at the León Becerra Hospital in Guayaquil. Principle of the form The general objective of this work is to evaluate the quality of care in the clinical laboratory processes of different studies and to provide feedback for the quality of care and patient safety in the clinical laboratory process.

Keywords: Hospital, Laboratory, Laboratory Clinical, Care

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Resumen
Este estudio forma parte de un resultado del proyecto de investigación Prevención y control de eventos adversos en la fase preanalítica del proceso de laboratorio clínico en el Hospital León Becerra de Guayaquil. El mismo se centra en ofrecer un aporte teórico, analítico y comparativo de investigaciones previas realizadas en el Hospital León Becerra de Guayaquil. Principio del formulario El objetivo general de este trabajo es evaluar la calidad de atención en los procesos de laboratorio clínico de distintos estudios y realizar una retroalimentación para la calidad de la atención y la seguridad del paciente en el proceso de laboratorio clínico.

Palabras clave: Hospital, Laboratorio Clínico, Atención

Introduction
Exploring the inner workings of hospital institutions is fundamental to understanding their essential operations and functions, including the work performed by the clinical laboratory department. This study focuses on providing a theoretical, analytical and comparative contribution of research conducted on patient care and safety in the clinical laboratory process.

The purpose is to provide an assessment of satisfaction levels with respect to service in these areas, as well as to examine the instruments used to analyze samples and determine their reliability. In addition, it seeks to analyze the necessary infrastructure for a hospital and each of its units, with the aim of identifying areas for improvement and strengthening the quality of care offered to patients.

The quality of care in the clinical laboratory is crucial to ensure accurate and reliable results, which directly influences the diagnosis and treatment of patients. Therefore, it is essential to identify possible areas for improvement and propose recommendations to optimize the quality of the services provided by the clinical laboratory for the León Becerra Hospital in Guayaquil (Huamán & Guevara, 2023).

One of the problems identified was the absence of clear protocols and established quality standards to ensure consistency and accuracy in the performance of laboratory tests, which could lead to variations in the quality of care between different procedures and laboratories.

The lack of clear protocols and quality standards in clinical laboratory processes has become a significant concern in the healthcare setting. This absence of established guidelines can lead to inconsistencies and variations in the quality of care between different laboratories, compromising the reliability of the results obtained. The lack of standards also makes it difficult to compare and evaluate services between institutions,
which can affect patient confidence in laboratory services and ultimately impact the overall quality of care provided.

In addition, few clear protocols and quality standards can lead to confusion and ambiguity among clinical laboratory personnel (Bazán, M., & Valencia, E. 2023). Without defined guidance on how to perform certain procedures and maintain the quality of results, practitioners may be less certain about the best practices to follow. This can lead to a lack of consistency in internal laboratory processes, increasing the risk of errors and negatively affecting the accuracy and reliability of test results. Ultimately, this lack of clarity can undermine laboratory efficiency and its ability to provide quality patient care and safety.

The general objective of this work is to evaluate the quality of care and patient safety in the clinical laboratory process, based on different studies and to provide feedback for the clinical laboratory processes of the León Becerra Hospital in Guayaquil. To achieve this objective, an investigation will be carried out to analyze the quality of the services provided by the clinical laboratory, identifying both strengths and areas for improvement. In addition, the results obtained from different existing scientific documents will be compared in order to identify possible gaps in terms of quality standards. Based on the findings, specific recommendations will be proposed to improve the quality of care in the clinical laboratory of the León Becerra Hospital in Guayaquil and other clinics.

The study "Analysis of the quality of attention to clinical laboratory processes for the León Becerra Hospital in Guayaquil. " is relevant for several fundamental reasons. First, the overall objective of the study, which is to evaluate the quality of care in clinical laboratory processes, is crucial to ensure the accuracy and reliability of medical test results. This analysis will provide valuable information on the effectiveness of current procedures and practices in the hospital’s clinical laboratory, identifying areas for improvement and opportunities to strengthen the quality of care offered to patients. In addition, conducting this study will provide significant feedback to the clinical laboratory processes at Hospital León Becerra de Guayaquil, by comparing the results obtained in different studies on quality of care in clinical laboratories, best practices and successful strategies implemented elsewhere can be identified. This feedback will help laboratory staff to better understand areas for improvement and to implement effective and sustainable changes to raise quality standards at Hospital León Becerra de Guayaquil.

Ultimately, the purpose of this study is to improve the quality of care provided to patients at the León Becerra Hospital in Guayaquil. By identifying and addressing deficiencies in clinical laboratory processes, it ensures that patients receive accurate and reliable results from their medical tests. This not only improves the patient experience, but also contributes to more effective and safer medical care at the hospital, thus promoting the health and well-being of the community it serves.

According to Panunzio, A. (2022), the vulnerability of the borderline stages of the clinical laboratory process, i.e. the pre-analytical and post-analytical phases, is pointed out, and
the importance of external quality assessment in the laboratory is highlighted. This is based on the experiences shared by expert researchers in the field.

The text by Panunzio, A. (2022) highlights the vulnerability of the preanalytical and postanalytical phases in the clinical laboratory process, emphasizing the importance of external quality assessment today. This evaluation is based on the experiences shared by researchers specialized in the field, which underlines the need to strengthen quality controls at all stages of the laboratory process to ensure the reliability and accuracy of analytical results.

During their operation, clinical laboratories, also known as the total examination process, use medical devices and are therefore subject to the possibility of failures that can lead to incidents and affect patient safety. These incidents can result in direct or indirect harm, as errors in the laboratory can lead to medical errors (Mucito, E., 2020).

The text highlights the importance of recognizing that clinical laboratories, when using medical devices during their operation, are exposed to the possibility of failures that can jeopardize patient safety. This underscores the need to implement effective quality control and risk management measures in these environments to prevent incidents that may result in direct or indirect harm to patients. Furthermore, it emphasizes the relevance of continuous monitoring and constant improvement of laboratory processes to ensure the reliability and accuracy of analytical results, thus minimizing the risk of medical errors associated with laboratory failures.

Quality in the clinical laboratory is defined as the ability of laboratory processes and services to meet established standards and requirements, both in technical terms and in terms of patient care. This encompasses the accuracy and reliability of the results obtained, as well as the reliability of the equipment and reagents used. It also encompasses patient satisfaction in aspects such as waiting time, courtesy in the treatment received and access to relevant information. Optimal quality in the clinical laboratory is essential to ensure adequate diagnosis and treatment for patients (Sanchez & Juseth, 2023).

The text highlights the importance of quality and safety in the clinical laboratory, emphasizing that this is related to the capacity of the laboratory’s processes and services to comply with technical and patient care standards. This quality encompasses the accuracy of the results, the reliability of the equipment, and patient satisfaction in aspects such as waiting time and treatment received. It is fundamental to ensure proper diagnosis and treatment, highlighting its crucial role in medical care.

It is of great importance to ensure accurate and safe results, which in turn contributes to appropriate medical decision-making. A clinical laboratory that meets high quality standards can provide accurate and timely data for disease diagnosis, treatment monitoring and prevention of complications. In addition, optimal quality in clinical laboratory processes promotes patient confidence and satisfaction, which enhances the hospital’s image and reputation (Litardo, 2021).
The text highlights the importance of maintaining high quality standards in the clinical laboratory, as this ensures the reliability of results and facilitates appropriate medical decision-making. A laboratory that meets these criteria can provide accurate and timely information for diagnosis, monitoring and disease prevention, which ultimately improves the quality of medical care. In addition, quality in clinical laboratory processes not only benefits patients by generating confidence and satisfaction, but also contributes to strengthening the reputation and image of the laboratory and the hospital or clinic in general.

The analysis of patient samples in laboratories is a highly complex process in which errors can occur at any stage. Therefore, it is essential that laboratories implement measures to ensure the reliability and accuracy of the results obtained. It is necessary for the laboratory to thoroughly examine its procedures for possible weaknesses or risks that may lead to errors, and to take the corresponding measures to detect and prevent such errors before they influence the test results (Lino, W. et al, 2021).

The text underscores the critical importance of ensuring accuracy and reliability in the results of laboratory testing of patient samples. Given the complexity of the process and the potential for errors at any stage, it is essential that laboratories conduct a thorough assessment of their procedures to identify potential weaknesses or risks. Taking proactive steps to detect and prevent errors before they impact test results is critical to ensuring the quality and reliability of clinical laboratory services, which ultimately contributes to optimal patient safety and care.

**Materials and methods**

The research process on the analysis of the quality of care of clinical laboratory processes for the León Becerra Hospital in Guayaquil was carried out using a documentary research approach. In this type of research, data are collected and analyzed from various documentary sources to obtain relevant information on the topic under study (Vargas. I, et al, 2021). In this case, documents, government reports and previous studies related to quality of care in clinical laboratories were used.

The study sample included patients and hospital personnel from the different studies performed at the León Becerra Hospital in Guayaquil. Patients who had used the hospital’s clinical laboratory services and medical and laboratory personnel involved in the provision of these services were selected. This selection made it possible to obtain an integral perspective of the quality of care in clinical laboratory processes, both from the patients’ experience and from the hospital staff’s perspective.

To carry out the research, content analysis and documentary review techniques were used (Rodríguez, A. et al, 2021). These techniques made it possible to examine in detail the documents collected and extract relevant information related to the quality of care in clinical laboratory processes. In addition, data collection sheets were applied to organize and record the information obtained from documents and government sources. These cards provided a structure for collecting specific data related to quality
of care in the clinical laboratory, safety and facilitated the analysis and interpretation of the results obtained. In summary, the research process was conducted in a systematic and rigorous manner, using a variety of techniques and tools to obtain a complete understanding of the quality of care in the clinical laboratory processes at the León Becerra Hospital in Guayaquil.

Results
The studies by different authors offer a broad and varied view of the quality of care in clinical laboratory processes, providing a solid basis for feedback at the León Becerra Hospital in Guayaquil.

In the doctoral research by Cantero, F. (2015) on “Analysis of excellence criteria in laboratory tests performed at the point of patient care”, considerable error rates were observed in tests performed at the point of patient care (POCT), with medians reaching up to 25.8% for patient identification and 15.2% for aborted samples in neonatology. However, monitoring of these indicators revealed a significant decrease thanks to the implementation of our quality assurance program. It is important to note that POCT stands for Point Of Care Testing.

In contrast, the criteria established in the delivery room, with medians reaching up to 11% for parity error and up to 39.2% for air detection in fetal calyx samples, did not exhibit a notable decrease. The late inclusion of this analyzer in the POCT quality assurance program and the challenges experienced in training personnel in this area may account for these findings.

In the results of his research entitled "Level of satisfaction of users with requests for urgent examination in the clinical laboratory of the Type B Health Center No. 1 in the city of Esmeraldas", Chila, A. (2020) found that 55% of users expressed dissatisfaction. This is attributed to the fact that laboratorians present delays in the preparation, sampling and processing stages, which generates a negative perception. On the other hand, it was observed that 27% of the users indicated that teamwork helps to improve the chemical analysis process, since it coordinates activities in a

In the study entitled "Perspective of Emergency users of the National Institute of Child Health - 2016" conducted by Mendivil, A. (2017) on the quality of care in the clinical laboratory, it is observed that users describe confidence in the results issued by the clinical laboratory as reliability. This aspect of care is highly valued by medical professionals, since the results of complementary tests play a crucial role in determining the therapeutic approach. Therefore, these professionals identify two components that contribute to the reliability of the results: verification of results and diagnostic utility, which provide them with the certainty that the results obtained accurately reflect the patient’s clinical condition and relate to their diagnostic impression or therapeutic follow-up, as appropriate.

Principle of the form
In their thesis entitled "Evaluation of the quality of health care using the Avedis Donabedian model in the emergency area of Hospital Paravida from July to December 2014", Chávez, A., and Molina, J. (2015), point out that when evaluating the quality of health care in the emergency area, the results related to the process reveal that of the total number of surveyed internal users working in this sector, 48% have been employed at the hospital for less than one year, 38% from one to four years, and 14% more than five years. However, it is of concern that the majority of the human resources stated that they were unaware of the processes related to user care in the emergency unit. It is important to note that 67% of these resources state that they have received training in customer service, while the remaining 33% have not. On the other hand, the results also show that a large percentage of employees indicate that the institution offers annual training, but 10% are unaware of this fact, which is worrisome, given that all institutions are expected to have fully trained personnel.

Principle of the form

Within the findings of the study conducted by Navas, M., & Ulloa, M. (2013) on the "Evaluation of the quality management of health services offered by the Hospital San Sebastián de Cantón Sígsig", it is observed that users in general show a moderate level of satisfaction. This was perceived positively by patients. However, with regard to the laboratory equipment and material available at the hospital, the evaluation is negative in terms of satisfaction.

In his thesis, Calderón, R. (2018) found that regarding the quality of care variable, 71.6% of the cases were classified as "Very good", 22.7% as "Good", and 5.4% as "Fair". These results indicate satisfactory levels of quality. These data are similar to those obtained in Zamora’s research, where 87.65% high quality was recorded, and in Jinez’s study, where 82% of the quality was reported as "Very good" and 18% as "Good". In contrast, Tuesta reported a “fair” rating for quality in 86.2% of the cases in its evaluation.

Intriago, S. (2022) established quality criteria in two stages of sample processing for shipment to participating laboratories. In the pre-analytical stage, SERISCANN from QCA was used to obtain high quality samples. In the analytical stage, calibration of the automated equipment and pipettes was performed, emphasizing the importance of temperature control. After analyzing and distributing the samples in Eppendorf tubes, they were kept at controlled temperature to guarantee the quality of the results, since this depends on each phase of the analytical process.

Calderon (2018) presents a mostly positive assessment of the quality of health care, with a high percentage of cases classified as "Very good" and "Good". This suggests that the hospital could be obtaining satisfactory results in the provision of services. On the other hand, Navas and Ulloa (2013) identified a discrepancy in user satisfaction in relation to the laboratory equipment and material available in the hospital studied. This finding indicates a specific area that may require improvement to align the quality of laboratory services with user expectations.

Intriago (2022) highlights the importance of establishing quality parameters at the sample processing stages to ensure accurate and reliable results. His focus on quality
control in the pre-analytical and analytical phases, along with maintaining proper sample temperature, provides valuable guidance for improving clinical laboratory processes at Hospital Guayaquil. In addition, Chavez and Molina’s (2015) research reveals a critical need to improve staff training and internal communication in the emergency area, which could be applied to clinical laboratory processes to strengthen the quality of care at the hospital. Principle of the form.

The studies analyzed provide a variety of perspectives on the quality and safety of care in clinical laboratory processes. While some aspects, such as overall user satisfaction, appear to be in line with expectations, others, such as equipment availability and staff training, point to specific areas that require attention. Feedback from these findings can serve as an important starting point to identify areas for improvement and strengthen clinical laboratory processes in the hospital, with the aim of improving the quality of care offered to patients.

The study presented by Cantero, F. (2015) highlights the importance of examining quality indicators in laboratory tests performed at the point of patient care (POCT). The results reveal significant error rates, particularly in patient identification and sample management in the context of neonatology. The analysis also highlights a positive aspect: the implementation of a quality assurance program has led to a significant reduction in these errors. This underscores the importance of a proactive approach to monitoring and improving the quality of laboratory testing at the point of patient care.

The results presented by Chila, A. (2020) in his study on the level of user satisfaction with urgent examinations in the clinical laboratory of the Type B Health Center No. 1 of Esmeraldas offer a detailed view of the perceptions and experiences of users in relation to the services provided. Factors such as delays at different stages of the process by laboratorians, the importance of teamwork to improve chemical analysis, and lack of communication leading to lack of knowledge of technical procedures were identified. These findings highlight critical areas that require attention and improvement, underscoring the need for greater operational efficiency, internal coordination and effective communication to ensure satisfaction and quality in health care.

The author Mendivil, A. (2017), highlights the fundamental importance that users of emergency services assign to the reliability of the results issued by the clinical laboratory. These results are considered as fundamental pillars in therapeutic decision making by medical staff. Confidence in the accuracy and relevance of these results is closely related to the laboratory’s ability to verify the results and provide effective diagnostic assistance. This confidence is essential to ensure that the results accurately reflect the patient’s health status and can be used effectively in the diagnostic and treatment process.

The results presented by Chávez, A., and Molina, J. (2015) point out important areas of concern regarding the quality of health care in the emergency area of Hospital Paravida during the period from July to December 2014. They highlight the lack of knowledge on the part of the staff about the processes related to user care in the emergency unit, as well as the need to improve staff training in customer service. In addition, they
highlight the importance of ensuring that all facilities have an effective training program and that staff are fully informed about procedures and regulations to provide quality care. These findings underscore the importance of investing in ongoing staff training and implementing effective knowledge management policies to improve the quality of health care.

The results of the study conducted by Navas, M., & Ulloa, M. (2013) regarding the evaluation of the quality management of the health services offered by the Hospital San Sebastián de Cantón Sígsig, reflect a mixed perception on the part of the users. Although there is a moderate degree of overall satisfaction with the services provided, a specific concern stands out in relation to the laboratory equipment and material available at the hospital, which is evaluated as unsatisfactory. This discrepancy suggests that, while some aspects of the care received are perceived favorably, there are still areas of critical improvement that require immediate attention, particularly in the infrastructure and technical resources used in the health care process. This argument underscores the importance of addressing as a priority the deficiencies identified in the laboratory equipment to ensure the quality and effectiveness of the health services offered to patients.

The results obtained by Calderón, R. (2018), and the research by Zamora, Jinez and Tuesta provide a varied but comprehensive view on the quality of care in the context studied. While Calderón highlights a predominance of high and good quality levels, mainly represented by a "Very good" rating, the studies by Zamora and Jinez reinforce this perception by recording notable percentages of high and very good quality. These findings suggest a general trend toward satisfactory and positive quality of care in the setting investigated. However, the Tuesta report presents a different perspective by showing a significant percentage of "fair" quality. This discrepancy underscores the importance of considering a variety of perspectives and methodologies when assessing quality of care, and highlights the need to identify and address specific areas that require improvement to ensure optimal and consistent care for all patients.

The approach established by Intriago, S. (2022) to ensure quality in the sample processing stages of his research is crucial to obtain accurate and reliable results in the laboratory. By establishing quality parameters at both the pre-analytical and analytical stages, rigorous control over fundamental aspects such as sample collection and calibration of the equipment used in their analysis is ensured. In addition, attention to temperature and maintenance of the samples in cold chain after preparation are essential measures to preserve the integrity of the specimens and guarantee the quality of the final results. This comprehensive approach underscores the importance of each step in the analytical process and highlights the need to implement rigorous quality control practices at all stages of the study to obtain reliable and meaningful data.

Conclusions
After analyzing the results obtained from the different authors, it can be concluded that the objective of the study to evaluate the quality of care in clinical laboratory processes and provide feedback for the León Becerra Hospital in Guayaquil was met. The findings reveal a range of perspectives on quality of care in the clinical laboratory, from positive assessments to identified areas for improvement. The research has identified key issues, such as the lack of clear protocols and quality standards, the need for staff training, and the importance of quality control at all stages of the laboratory process.

Studies by authors such as Calderón (2018), Navas and Ulloa (2013), Intriago (2022), and others provide a comprehensive view on the quality of care in clinical laboratory processes. Through the analysis of these results, valuable feedback has been provided to the hospital. Areas for improvement have been identified and possible strategies have been suggested to strengthen the quality of care in the clinical laboratory, such as implementing clear protocols, training staff, and maintaining rigorous quality standards.

In conclusion, the study has successfully met its overall objective by providing a comprehensive assessment of the quality of care in clinical laboratory processes and by providing meaningful feedback to the hospital. These findings can not only serve as a guide for improving clinical laboratory services at the hospital, but can also contribute to the continued advancement of overall health care quality.

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