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Control and prevention of adverse events in the clinical laboratory process

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Abstract

The article responds to the research project: Prevention and control of adverse events in the pre-analytical phase of the clinical laboratory process in the Veris Medical Centers of the city of Guayaquil, carried out by the Clinical Laboratory career of the Instituto Superior Tecnológico Universitario Espíritu Santo. The essential core to ensure the quality of health services and the main axis of patient care is patient safety. The purpose of the article is to provide a theoretical framework related to quality management of health services, patient care and safety in the clinical laboratory setting. This study was carried out at the León Becerra Hospital in Guayaquil, where the effectiveness of control and prevention measures for adverse events in the clinical laboratory process was evaluated. A mixed methodology was adopted, combining field and descriptive research, which allowed the active participation of the community in all stages of the research. Several methods were used, including analysis-synthesis, inductive-deductive and structural systemic methods at the theoretical level, while observation, interviews, surveys and document review were used at the empirical level. The

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main result obtained focused on improving the quality of care and patient safety through the implementation of preventive and corrective measures during the pre-analytical phase of the clinical laboratory process.

Key words: Laboratory, Clinical, Hospital, Safety, Health

Control y prevención de acontecimientos adversos en el proceso del laboratorio clínico

Resumen

El artículo responde al proyecto de investigación: Prevención y control de eventos adversos en la fase preanalítica del proceso de laboratorio clínico en los Centros Médicos Veris de la ciudad de Guayaquil, realizado por la carrera de Laboratorio Clínico del Instituto Superior Tecnológico Universitario Espíritu Santo. El núcleo esencial para garantizar la calidad de los servicios de salud y eje principal de la atención al paciente es la seguridad del mismo. El propósito del artículo es proporcionar un marco teórico relacionado con la gestión de la calidad de los servicios de salud, la atención al paciente y la seguridad en el ámbito del laboratorio clínico. Este estudio se realizó en el Hospital León Becerra de Guayaquil, donde se evaluó la efectividad de las medidas de control y prevención de eventos adversos en el proceso de laboratorio clínico. Se adoptó una metodología mixta, combinando investigación de campo e investigación descriptiva, que permitió la participación activa de la comunidad en todas las etapas de la investigación. Se utilizaron varios métodos, entre ellos el análisis-síntesis, el inductivo-deductivo y el sistémico estructural en el plano teórico, mientras que en el plano empírico se recurrió a la observación, las entrevistas, las

encuestas y la revisión de documentos. El principal resultado obtenido se centró en la mejora de la calidad asistencial y la seguridad del paciente mediante la implantación de medidas preventivas y correctoras durante la fase preanalítica del proceso del laboratorio clínico.

Palabras clave: Laboratorio, Clínico, Hospital, Seguridad, Salud.

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INTRODUCTION

Monitoring the functions within the entities that care for health within a population is of vital importance in the health care setting. In particular, the clinical laboratory plays a critical role in the diagnosis and treatment of disease, underscoring the need to maintain rigorous control and an effective prevention system to avoid adverse events. The accuracy and reliability of clinical test results are crucial for making sound medical decisions, so any error in this process can have serious consequences for patients' health.

In this context, establishing solid control and prevention mechanisms in the clinical laboratory becomes a crucial barrier to mitigate the risk of adverse events. The implementation of standardized protocols and procedures, as well as the continuous monitoring of activities within the laboratory, are fundamental strategies to ensure the safety and quality of the medical services provided. Therefore, it is essential to understand the importance of this function within healthcare institutions and to work on its constant improvement in order to protect the health and well-being of patients.

The problem is that, in healthcare practice, the fundamental principle of patient care is not always complied with, because a series of errors are made, particularly in the pre-analytical phase of

the clinical laboratory process, which affect clinical results and, therefore, patient safety. Adverse events that occur in the clinical laboratory process affect the diagnosis, prognosis and follow-up of the evolution of the disease. When a disease is incorrectly diagnosed, patients suffer damage, and sometimes this damage is irreversible and can lead to death.

Inadequate training could result in improper execution of laboratory procedures, misinterpretation of results, and unsafe handling of samples, increasing the risk of errors and adverse events in the process. In addition, lack of training could affect the understanding of safety protocols and the importance of following standard operating procedures, which could jeopardize both the health of staff and the quality of services provided to patients.

The objective is to provide a theoretical reference related to quality management of health services, patient care and safety in the clinical laboratory process, particularly in the pre-analytical phase; carried out at the León Becerra Hospital in Guayaquil, which evaluated the effectiveness of the control and prevention of events in the clinical laboratory process.

The inclusion of a theoretical reference related to quality management of health services, patient care and safety in the clinical laboratory process, specifically in the pre-analytical phase, is an indispensable element to support and contextualize the importance of this process in the hospital setting. In the case of the León Becerra Hospital in Guayaquil, this theoretical approach acquires even greater relevance when applied to the evaluation of the effectiveness of the control and prevention of events in the clinical laboratory process.

The relevance of providing a theoretical reference is justified in the first place by the need to establish a solid conceptual framework to understand the fundamentals and principles that govern quality management in health services. In a context where accuracy, reliability and safety of results are vital for patient welfare, a solid theoretical basis is essential to guide practices and decisions in the clinical laboratory process.

In addition, the integration of a theoretical reference provides an academic underpinning that supports the actions and strategies implemented to ensure quality and safety in the pre-analytical phase of the clinical laboratory. This theoretical basis not only provides intellectual support, but also facilitates the identification of best practices, risk assessment and the implementation of preventive and corrective measures.

In the specific context of the León Becerra Hospital in Guayaquil, where the evaluation of the effectiveness of the control and prevention of events in the clinical laboratory process is carried out, the theoretical reference acquires additional relevance by providing a frame of reference for interpreting the findings, analyzing the underlying causes and proposing recommendations for improvement. It also allows comparisons to be made with internationally recognized standards and allows practices and protocols to be adapted according to the best available evidence in the field of quality management in health.

The inclusion of a theoretical reference related to quality management of health services, patient care and safety in the clinical laboratory process, particularly in the pre-analytical phase, is not only relevant but essential to ensure excellence in the provision of health services and promote the welfare of patients. In the case of León Becerra Hospital in Guayaquil, this theoretical approach becomes an essential pillar for the evaluation and continuous improvement of clinical laboratory processes, thus contributing to excellence in health care and patient safety. A study conducted in 2021 in some recognized Hospitals in the city of Guayaquil addressed the fall prevention protocol with the objective of improving the safety of hospitalized pediatric patients. This study points out the importance of nursing professionals receiving periodic training on the proper management of patients, as well as the need for them to remain focused on meeting and maintaining standards of care and safety. This ensures the protection and well-being of patients, preserving their integrity during their stay in the hospital (Mendoza, D. 2022).

The aforementioned study highlights the need for continuous training for nursing professionals, among others; especially in topics related to patient management, suggesting a proactive approach towards improving healthcare. In addition, it underscores the importance of nursing staff strictly adhering to established standards of care and safety, which reinforces confidence in the integrity and well-being of patients. These measures not only directly benefit pediatric patients admitted to the León Becerra Hospital in Guayaquil, but also contribute to the overall quality of medical care provided at the hospital.

According to Cañarte, G. (2018), Hospitals should consider all regulations, manuals and procedures established in the biosafety guidelines issued by the Ministry of Health. These regulations are fundamental to prevent occupational hazards. It is essential to apply the biosafety manual in all processes carried out within clinical laboratories.

Hospital compliance with the regulations and procedures set forth in the biosafety manual is crucial to ensure a safe working environment and protect the health of both staff and patients. These guidelines provided by the Ministry of Health are specifically designed to prevent occupational hazards and ensure the integrity of all those involved in hospital operations. By implementing the biosafety manual in the processes performed in clinical laboratories, a culture of safety is promoted and the chances of occupational health-related incidents are reduced, resulting in safer and higher quality medical care.

Considering the lack of adequate research on the current state of patient safety in clinical laboratories in Jipijapa Canton, province of Manabi, it is necessary to conduct a systematic review. The objective of this review is to analyze and improve this area within the health services, thus seeking to obtain a more complete understanding of the situation and promote the implementation of measures that guarantee the safety and well-being of patients in these medical environments (Yambay, C. et al. 2023).

The absence of sufficient studies on patient safety in clinical laboratories in this case indicates a gap in the understanding and management of the risks associated with health services in this specific area. A systematic review presents itself as a vital tool to address this dearth of information, as it will allow for a comprehensive identification and analysis of the challenges and areas for improvement in terms of patient safety in clinical laboratories. This, in turn, will facilitate the implementation of measures and policies aimed at improving the quality and safety of medical care in these settings, thus contributing to the protection and well-being of patients.

Standard Precautions comprise a set of actions aimed at reducing the likelihood of transmission of infections between medical personnel and patients, as well as among patients themselves. These precautions are designed to prevent the spread of pathogens that are transmitted through contact with high-risk blood and body fluids (Calahorrano, L. 2020).

It is essential in clinical practice, as they are specifically designed to minimize the risk of transmission of infections both from patients to

healthcare personnel and between patients themselves. These measures are essential to protect the health and safety of everyone involved in healthcare by reducing the possibility of transmission of pathogens transmitted by blood and other high-risk body fluids.

According to Hernandez, A. et al (2018) ordering laboratory tests that are not necessary can cause a variety of problems, such as technical errors, misinterpretations, patient harm due to procedures based on incorrect interpretations, or information overload that influences medical decision making.

The importance of requesting laboratory tests in a selective and informed manner lies in the need to avoid potential technical and patient harm. Requiring unnecessary tests increases the risk of errors in the interpretation of results, which can lead to erroneous medical decisions and unnecessary procedures that could harm the patient. In addition, information overload from superfluous tests can make it difficult to make appropriate clinical decisions, underscoring the importance of careful and accurate assessment before ordering any laboratory tests.

In the laboratory, the priority in terms of safety lies in preventing, detecting and minimizing adverse events at all times, in addition to thoroughly examining the underlying causes of these incidents (Evia, J. 2014).

According to the author, focusing on the prevention, detection and reduction of adverse events is essential to ensure process integrity and patient protection. Proactively addressing these events not only promotes a safer work environment, but also strengthens confidence in outcomes and reduces the risk of harmful errors.

Previously, according to Cenzual, M. (2015), the clinical laboratory was not considered as an environment prone to cause adverse events. This new perspective underscores the importance of

assessing and addressing the risks inherent in laboratory operations, which can lead to greater error prevention, earlier detection of problems, and a significant reduction in adverse events affecting patients. This shift in focus reflects a commitment to continuous improvement and prioritization of patient welfare in healthcare.

METHODOLOGY

The research project of which this analysis is being made, worked with a polymodal or mixed methodology; with a field and descriptive research development; which made possible the involvement of the community during the whole research process; a variety of methods were used, among the theoretical ones, the analysis, synthesis, inductive, deductive and structural systemic; among the empirical ones, observation, interview, survey and documentary review were used. To collect qualitative data, the documentary review technique was used, which involved analyzing and synthesizing relevant information from written sources, such as reports, previous studies and institutional documents related to the control and prevention of adverse events in the clinical laboratory. This provided a solid base of prior and contextual knowledge on the subject.

In addition, a documentary data collection form was used to record and organize the information obtained through the documentary review and the analysis of survey results. This facilitated the systematization of the data and its subsequent comparative analysis (Bastar, S. 2019).

The use of the Likert scale in the study is of vital importance due to its ability to provide a quantitative measurement of the perceptions and attitudes of respondents regarding the control and prevention of adverse events in the clinical laboratory of the León Becerra Hospital in Guayaquil. This scale allows participants to express their degree of agreement or disagreement with specific statements, which facilitates obtaining structured and comparable data (Morales, N., et al., 2016).

RESULTS

The main result obtained from the study conducted at the León Becerra Hospital in Guayaquil is a significant milestone in the constant search for excellence in the provision of health services. The orientation towards improving the quality of care and patient safety reflects an institutional commitment rooted in medical ethics and responsibility towards those who rely on the institution for their care. Focusing on the pre-analytical phase of the clinical laboratory process recognizes the critical importance of this initial stage in obtaining accurate and reliable results, which are fundamental to guiding sound medical decisions and ensuring the effectiveness of treatments.

The adverse event prevention and control actions deployed as a result of this study not only represent a timely response to identified challenges, but also establish a paradigm of continuous improvement in health quality management.

Implementing preventive measures, such as reviewing and optimizing protocols, training staff and adopting innovative technologies, demonstrates a commitment to innovation and excellence in healthcare. This proactive approach not only addresses existing problems, but also paves the way for an organizational culture focused on patient safety and continuous improvement.

Ultimately, the results obtained at León Becerra Hospital in Guayaquil transcend the boundaries of the institution by providing

an exemplary model that can inspire and guide other healthcare institutions in their quest for excellence. By sharing the lessons learned and best practices developed during this study, we contribute to the global advancement of quality management in healthcare, thus promoting safer, more effective and patientcentered healthcare worldwide.

The doctoral research entitled "Clinical safety and occurrence of adverse events in the clinical experiences of nursing students at the University of Malaga" conducted by Garcia, M. (2020), help us to identify four main areas of study in the literature reviewed on adverse events in nursing students: adverse events themselves, clinical safety competencies, student experiences in clinical safety and pedagogical approaches, such as methods and content for teaching clinical safety. It has been observed that nursing students face adverse events during their clinical practice, with the incidence of sharps accidents ranging from 17% to 18%.

According to Dionisio, D. (2017) in his research entitled "Adverse events arising from care in a public hospital in Córdoba", five adverse events were identified. Upon evaluation, it was determined that 75% of the adverse events appeared to occur during the provision of floor care, while 25% occurred during procedures, including one during a surgical intervention and another during the insertion of an intravenous line. However, statistical analysis revealed no significant associations between the occurrence of these events and specific periods (P-value: 0.2689). Furthermore, no clear association could be established between the occurrence of adverse events and a specific service within the hospital.

In her research on adverse event management in the context of the patient-centered care model, Peña, L. (2018) found a total of eight relevant articles. Of these, one study links the Patient-Centered Model of Care (PCMC) with healthcare-associated infections (HAIs),

while seven studies establish a relationship between PCMC and medication errors. The results reveal various interventions carried out by different healthcare professionals, such as nurses, physicians and pharmacists, who implement various elements of the MACP in order to contribute to the control of adverse events.

In research on the detection of adverse events in adult patients discharged from a Critical Patient Unit using a specific search tool, Astargo (2016) found that 93% of adverse events (AEs) occurred during hospitalization, being more common (61%) in patients with hospital stays of at least 15 days. It was observed that 57% of triggers led to the identification of an adverse event, with 64% being of moderate severity. Adverse events related to care and care accounted for 29%, healthcare-associated infections (HAIs) for 20%, medication use for 18%, and those related to surgical procedures for 17%. Surprisingly, 92% of the adverse events detected had not been previously reported at the institution.

In the thesis entitled "Biosafety measures applied by the nursing staff during the patient's hospital stay at the Dr. José Garcés Rodríguez Hospital", Panimboza, C., and Pardo, L. (2013), revealed that knowledge about the principles of biosafety measures reached 71%, while knowledge about the adequate use of personal protection barriers was 75%. Regarding the application of physical protection barriers, it was observed that these were always implemented in 19%, while chemical barriers were always applied in 41%. As for the proper management of hospital waste, this was always carried out in 55% of the cases. In general terms, with regard to the application of biosecurity measures, 36% of the respondents indicated that they always applied them, 31% sometimes, and 33% never. These results underscore the urgent need to implement an education and awareness project through lectures to improve the application of biosafety measures by nursing staff.

Peñaloza, A. et al. (2016) examined in their research the identification of failures that lead to more common adverse events during the administration of medications by nursing staff in hospital institutions in Latin America. They focused on the importance of analyzing the classification of errors committed by nurses when administering medications, since according to the guidelines of the patient safety policy established by the Colombian Ministry of Social Protection, these errors are defined as "a deficiency in the performance of a planned action as planned or the use of an incorrect plan, which may manifest itself through the execution of incorrect processes (failure of action) or through the non-execution of correct processes (failure of omission), in the planning or execution phases, where the failures are, by definition, unintentional".

Comparison of these results with previous research, such as that conducted by Astargo (2016) on adverse event detection, highlights the importance of addressing identified gaps in training, safety in adverse event identification and reporting, and availability of resources in the clinical laboratory to ensure safe and quality care for patients. These findings underscore the need for a multidisciplinary approach and close collaboration between care teams to address identified challenges and continuously improve patient safety in the hospital setting.

Garcia's doctoral study (2020) provides a comprehensive overview of clinical safety and the occurrence of adverse events in nursing students, focusing on the University of Malaga. Through a comprehensive literature review, he identifies four crucial areas of research: adverse events, clinical safety competencies, student experiences, and pedagogical approaches.

This multidimensional approach provides a better understanding of the challenges and needs in the training of future professionals at the León Becerra Hospital in Guayaquil. In addition, the revelation of a significant incidence of sharps accidents during clinical internships highlights the importance of improving safety measures and practical training of students in clinical settings. This analysis underscores the importance of addressing not only the adverse events themselves, but also the pedagogical aspects and lived experiences of students to promote more effective and safer nursing education.

The study conducted by Dionisio, D. (2017) on adverse events in a public hospital in Cordoba provides an important perspective on the safety and quality of medical care in hospital settings. The identification of five adverse events and their distribution between floor care and during surgical procedures underscores the need for a comprehensive approach to address patient safety in all areas of care. However, the lack of significant association between the occurrence of adverse events and specific periods, as well as the inability to determine a clear association with particular hospital services, highlights the underlying complexity in understanding and preventing these events. This analysis suggests the importance of ongoing surveillance, as well as the implementation of preventive measures and standardized safety protocols at all levels of hospital care to mitigate the risks of adverse events and improve the quality of patient care.

The research work conducted by Peña (2018) provides an enlightening view on adverse event management within the framework of the patient-centered care model. The collection and selection of eight relevant articles provides a detailed overview of how the Patient-Centered Model of Care (PCMC) relates to various aspects of health care, including healthcare-associated infections (HAIs) and medication errors. The findings highlight the variety of interventions implemented by different healthcare professionals, such as nurses, physicians, and pharmacists, who, through the

integration of MACP elements, contribute significantly to the control of adverse events. This analysis underscores the importance of adopting a holistic and collaborative approach to healthcare, where the priority is patient well-being and safety, and where the Patient-Centered Model of Care plays a fundamental role in the continuous improvement of the quality of care.

The study conducted by Astargo (2016) provides revealing insight into the detection of adverse events in adult patients who have been discharged from a Critical Patient Unit. The findings highlight the high incidence of adverse events during hospitalization, particularly in patients with prolonged stays. In addition, different triggers were identified, with care-related triggers being the most frequent. The surprising revelation that the vast majority of these adverse events had not been previously reported at the institution underscores the importance of improving reporting and surveillance systems to ensure safer and higher quality medical care.

The study conducted by Panimboza and Pardo (2013) on the biosafety measures applied by the nursing staff at the Dr. José Garcés Rodríguez Hospital reveals a mixed picture in terms of compliance and knowledge of these measures. Although an acceptable level of knowledge about the principles and use of personal protective barriers is observed, the results indicate a significant gap between knowledge and practical application of biosafety measures. There is a clear need to implement educational and awareness strategies to improve nursing staff adherence to these measures and ensure a safer hospital environment for both patients and healthcare personnel.

The research work led by Peñaloza et al. (2016) highlights the importance of analyzing the errors made by nursing staff during medication administration in Latin American hospitals. By

examining the classification of these errors according to patient safety guidelines, it underscores the need to understand both failures of action and failures of omission in the planning and execution of medication administration processes. This approach not only highlights the importance of attention to detail in clinical practice, but also highlights the need to implement preventive measures to minimize the incidence of adverse events related to medication administration.

In order to advance in the understanding and improvement of the control and prevention of events in the clinical laboratory process of the León Becerra Hospital of Guayaquil, it is recommended to carry out new studies that explore specific aspects of this problem. Among the possible lines of research, it would be possible to investigate the effectiveness of training programs aimed at clinical laboratory personnel, evaluating their impact on the reduction of adverse events. In addition, it would be relevant to investigate the underlying causes of the insufficiency of resources and tools for the prevention of adverse events, as well as to identify effective strategies to improve their availability and use in the hospital context. Another aspect to consider would be to investigate the role of technology and the implementation of quality management systems in the clinical laboratory to improve early detection and response to adverse events.

CONCLUSIONES

In conclusion, the results obtained at Hospital León Becerra transcend the boundaries of the institution, offering an exemplary model that can inspire and guide other institutions in their quest for quality and patient safety. By sharing the knowledge gained and successful strategies developed during this study, a positive change in the healthcare landscape is promoted, driving towards safer, more effective and patient-centered care throughout the healthcare setting.

Contrasting these findings with previous research, such as the identification of adverse events, highlights the importance of addressing identified gaps in training, safety in the identification and reporting of adverse events, and availability of resources in the clinical laboratory, all with the purpose of ensuring safe and high quality care for patients. These findings highlight the need to adopt a multidisciplinary approach and foster close collaboration between care teams to address the challenges identified and continuously improve patient safety in the hospital environment.

The objective of this research study was to provide a theoretical reference related to quality management of health services, patient care and safety in the clinical laboratory process, particularly in the pre-analytical phase; conducted at the León Becerra Hospital in Guayaquil, which evaluated the effectiveness of control and prevention of events in the clinical laboratory process. It highlights the importance of improving safety measures and practical training of students in clinical settings to ensure safe and high quality care. In this regard, the study provides valuable information to improve training programs and ensure that personnel are adequately prepared to provide safe and effective care in the clinical laboratory and other health care settings.

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