Espirales
Revista multidisciplinaria de investigación científica

Prevention and control of adverse events in the clinical laboratory process: A literature review

Prevención y control de eventos adversos en el proceso de laboratorio clínico: Una Revisión Bibliográfica

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Received: January 23, 2024
Approved: March 30, 2024

León, L., Cevallos, C., Quimis, R. (2024) Prevención y control de eventos adversos en el proceso de laboratorio clínico: Una Revisión Bibliográfica. *Espirales Revista Multidisciplinaria de investigación científica*, 8 (49), 34-49

Abstract

This is the result of the research project Prevention and control of adverse events in the clinical laboratory process at the León Becerra Hospital in Guayaquil, corresponding to the Higher Technology course in On-Site Clinical Laboratory of the Instituto Superior Tecnológico Espíritu Santo. The prevention and control of adverse events in the clinical laboratory process is essential to ensure quality and safety in the analysis of samples and results. This process involves a series of measures from the reception of the sample to the issuance of the final report. Accurate patient and sample identification, proper labeling, transport and storage are critical steps to avoid errors. In addition, rigorous quality control protocols must be followed at all stages, including equipment maintenance and calibration, as well as ongoing staff training.

Keywords: Prevention, Control, Adverse Events, Clinical Laboratory, Quality, Safety

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Resumen

Se presenta un resultado del proyecto de investigación Prevención y control de eventos adversos en el proceso de laboratorio clínico en el Hospital León Becerra de Guayaquil, correspondiente a la carrera de Tecnología Superior en Laboratorio Clínico Presencial, del Instituto Superior Tecnológico Espíritu Santo. La prevención y control de eventos adversos en el proceso de laboratorio clínico es fundamental para garantizar la calidad y seguridad en el análisis de muestras y resultados. Este proceso implica una serie de medidas desde la recepción de la muestra hasta la emisión del informe final. La identificación precisa del paciente y la muestra, el adecuado etiquetado, transporte y almacenamiento son pasos críticos para evitar errores. Además, se deben seguir protocolos rigurosos de control de calidad en todas las etapas, incluyendo el mantenimiento y calibración de equipos, así como la capacitación constante del personal.

Palabras clave: Prevención, Control, Eventos adversos, Laboratorio Clínico, Calidad, Seguridad

Introduction

The clinical laboratory process plays a critical role in the diagnosis, treatment and monitoring of disease. However, as in any area of healthcare, this process is subject to the possibility of adverse events that can compromise the accuracy of results and, ultimately, patient safety and well-being. Therefore, the prevention and control of these adverse events are critical aspects of ensuring the quality and reliability of clinical laboratory services.

The interest in this topic lies in its direct impact on medical care and in the improvement of quality standards in clinical laboratory services. Although there are numerous studies and protocols dedicated to risk management in the healthcare setting, specific aspects related to the prevention and control of adverse events in the clinical laboratory have not yet been comprehensively addressed.

Although previous work has been done on the subject, many of them have failed to clarify certain key aspects, leaving significant gaps in the understanding of how to effectively prevent and manage these adverse events within the clinical laboratory setting. However, the studies that have addressed the topic have looked at several specific aspects or at particular types of adverse events, which limits their applicability and generalizability to other contexts. Among these, only sample identification errors are mentioned, while others have focused on problems related to the quality of reagents or laboratory equipment. However, the complexity of the clinical laboratory process requires a more holistic approach that addresses a wide range of contributing factors and potential failure points.

The main objective of this study is to investigate the various factors that contribute to the occurrence of adverse events in the clinical laboratory process, as well as to mention

effective prevention and control strategies. By addressing these issues, we seek to improve the safety, quality, and efficiency of clinical laboratory services, which in turn can have a positive impact on overall medical care and public health.

Materials and methods

The research was based on a qualitative approach because it collected, analyzed and synthesized relevant information from various literature sources. This approach was fundamental to obtain a comprehensive understanding of the topic by critically examining the existing literature.

The research is of the documentary type as it refers to a theoretical framework which, according to Bernal (2010) "is a constitutive aspect of all scientific research, whose basic function is to serve as a theoretical basis for scientific research" Page 110, in this case, the prevention and control of adverse events in the clinical laboratory process. Techniques such as the review of bibliographic documents and theoretical methods such as analysis and synthesis, historical logic and induction and deduction were used.
In terms of population and sample, the population consisted of all relevant literature on the importance of the preanalytical phase in the clinical laboratory, for which 68 articles were considered. The sample consisted of the specific literature sources selected for article development. This ensured that a wide range of perspectives and opinions on the topic were considered.

Interventions in this type of research included appropriate selection of literature sources, critical review of texts, extraction of relevant information, and synthesis of findings to respond to the research objectives. The research instruments included systematic literature search using academic databases and selection of relevant sources addressing the importance of the preanalytical phase in the clinical laboratory.

Results

Sources used in the documentary research on the importance of the preanalytical phase in the clinical laboratory included:

- Academic articles, published in Acta Médica.
- Specialized books such as "Good Laboratory Practices (GLP)" by Baggini, S. (2022).
- Master's research papers
- Technical reports
- Scientific journal articles,
- Opinion articles, published in the Journal of Clinical Pathology.
- Specialized magazines,
- Scientific papers from preclinical trials

The analysis of the sources was able to identify the theoretical background, theoretical foundations and a legal framework, which constitute the main result of this article.

Based on the working conditions in clinical diagnostic laboratories, where it is intended to process biological samples, different types of errors are likely to occur, which may

lead to adverse events; an adverse event in the clinical laboratory includes situations that may compromise the patient's life. The authors van Moll et al., (2023)examined 327 reports allowing to analyze in which phase of the testing process the error occurred, showing that 77.1% of the errors occurred in the pre-analytical phase, 13.5% in the analytical phase and 8.0% in the post-analytical phase (1.5% undetermined). In another study by Ballesteros & Trunzo, (2021) detected a total of 818 pre-analytical errors, of which 42% corresponded to coagulated samples, 25% to hemolyzed samples, 23% to inadequate sample volume, 4% to poorly marked samples, 3% to unmarked samples, 2% to samples in inadequate containers and 1% to other causes (such as tube breakage in the centrifuge or failure of the sample to arrive).

According to the authors Pilco et al., (2023) an event can occur at any stage of the laboratory process, these errors being categorized according to their cause, phase of the process in which they occur, responsibility and impact on the patient. However, he mentions that most accidents occur in the preanalytical and postanalytical phase due to the lack of control that still persists in laboratories at these stages, since almost 70% of these incidents do not directly affect the patient and the remaining ones are due to other factors. On the other hand, Plebani et al, Plebani et al., (2021) mentions that the results of a laboratory influence up to 75% in the medical diagnosis, therefore it is necessary to maintain a rigorous quality control at all stages of the laboratory process to ensure the reliability and accuracy of the results. (Jara & Batista, 2023)..

Likewise, the authors. Wang & Ho, (2018) in their study determined a total of 187 incidents in a span10 months, which is equivalent to an error detection rate of 0.26%. The distribution of these incidents was as follows: 17% pre-analytical incidents, 25% analytical incidents and 59% post-analytical incidents. On the other hand Vélez et al., (2023) argue that the incidence of errors, also influenced by data transcription, varies between 3% and 39%, with an average of 13% in some laboratories. These errors can be of various kinds, either due to lack of accurate or diagnostic information.

Likewise, Hidalgo et al., (2022) also consider among the factors to be considered the frequency of incorrect identification of patients or samples, inadequate sample collection and insufficient quantity and quality of samples. Also, the presence of interferences in the samples should be taken into account, which significantly affect the accuracy of the results and, therefore, their interpretation and clinical application.

In another research work carried out by Cespedes et al., (2019) In a retrospective and longitudinal experimental study in the Clinical Laboratory of the Hospital Oncológico Docente Provincial Conrado Benítez García in Santiago de Cuba, with the aim of analyzing the accuracy of analytical procedures by determining the total error and the six sigma metric. The results showed a satisfactory performance in gamma-glutamyl transferase and alanine aminotransferase measurements, while glycemia and cholesterol showed an inferior performance, which guarantees the reliability of the results in the clinical laboratory and, therefore, the quality of the medical care provided to patients.

On the other hand, Lloacana et al., (2023) conducted a study with the objective of examining how patient safety is implemented and contributed to in clinical laboratories

in Latin America. The results of this research highlighted a notable lack of knowledge on the part of healthcare personnel about the criteria related to patient safety. The authors found that crucial aspects such as patient and specimen identification, as well as specimen transport and collection, along with equipment calibrations and maintenance during the analytical phase, and timely reporting of results in the post-analytical phase, were critical areas.

In Ecuador there have been few studies related to patient safety in the clinical laboratory process, the types of errors that occur in the phases of the clinical laboratory process and the evaluation and control of these errors. The studies found during the bibliographic review are generally developed by researchers in the administrative area and are more oriented to the measurement of quality in the clinical laboratory process:

Ortiz, (2022) conducted an investigation in the clinical laboratory with the purpose of reducing errors that may affect the diagnosis of patients. The analysis was carried out at the IESS Ambato Hospital, where the current situation of the pre-analytical phase of the laboratory process was evaluated, especially in terms of the amount of waste generated by defects, which serves as an indicator of the quality of the service offered to the institution's affiliates. It was identified that the critical processes were concentrated in reception and extraction during the pre-analytical phase, with metrics of 2.91 and 4.1 sigmas, respectively. This resulted in the generation of 6583 errors per million opportunities of biological samples analyzed, with consequent economic losses for the hospital.

On the other hand, Matute et al., (2022) conducted a study with the aim of providing clinical laboratory professionals with evidence on adverse events and how to prevent them in order to improve patient safety. As a result of this research, the main risk factors occurring in the different phases of the clinical laboratory were identified in a general way. In addition, a culture of patient safety was promoted among clinical laboratory professionals and a decrease in the variability in clinical practice among the different procedures applied by these professionals in the laboratories was achieved.

Adverse event

An adverse event refers to an undesirable or harmful outcome that arises as a direct or indirect consequence of the medical care a patient receives. These events can be caused by a variety of factors, such as medical errors, failures in the health care system, adverse drug reactions, nosocomial (hospital-acquired) infections, among others. The identification, analysis and prevention of adverse events are essential to improve the quality and safety of health care (Hernandez et al., 2019).

Health systems usually implement specific protocols and procedures to detect, report, investigate and prevent the occurrence of these adverse events. First, screening systems are established to identify potential adverse events by thoroughly reviewing medical records, analyzing reported incidents and evaluating clinical outcomes. Then, a culture of reporting is fostered among medical staff to report any adverse incidents observed (Lima et al., 2019).

Once reported, a thorough investigation is conducted to understand the underlying causes and determine preventive actions, these measures may include changes in treatment protocols, improvements in staff training, and modifications to data recording systems (Mucito, 2020). Finally, ongoing monitoring is performed to evaluate the effectiveness of the implemented preventive measures and adjust protocols as needed, thus ensuring constant improvement in patient safety (Severinsson et al., 2019)..

Adverse events in the clinical laboratory are undesirable situations that can arise during the processing and analysis of biological samples, compromising the quality and accuracy of the results (San Miguel et al., 2018). These events can occur at different stages of the process, including pre-analytical, analytical and post-analytical (Hermosa et al., 2023)..

The pre-analytical stage in the clinical laboratory encompasses all activities that take place before the analysis of biological samples is performed. During this crucial phase, processes such as accurate patient identification, proper sample collection, transport and handling, as well as correct recording of associated information are carried out. However, this stage is also susceptible to a number of adverse events that can compromise the integrity of the results (Briones & Cantos, 2019)

For example, errors in patient identification can result in incorrect assignment of test results, which could lead to misdiagnosis and mistreatment. Also, improper specimen collection, such as contamination during extraction or the use of inappropriate collection tubes, can lead to unrepresentative or inaccurate results. In addition, incorrect or incomplete labeling of samples can lead to confusion and difficulties in traceability, increasing the risk of errors in the interpretation of results (Baggini, 2022).

The analytical stage in the clinical laboratory involves the processing and analysis of biological samples collected during the pre-analytical phase. During this process, the samples are subjected to a series of tests and analyses to detect the presence of certain substances, cells or microorganisms, among other elements of clinical interest(Garcia, 2021). However, this stage is also subject to adverse events that can compromise the accuracy and reliability of the results (Santiago et al., 2021).

For example, errors in the calibration or maintenance of laboratory equipment can lead to incorrect or inaccurate measurements. Likewise, contamination of samples or reagents used in the analysis can introduce interferences and affect the accuracy of the results. In addition, improper handling of samples or failure to follow standardized procedures can generate erroneous results (Gonzales, 2021).

While the post-analytical stage in the clinical laboratory comprises all activities that take place after the analysis of biological samples has been completed. During this phase, test results are reviewed, interpreted and communicated to the clinical staff and ultimately to the patient. However, as with the preanalytical and analytical stages, the postanalytical stage can also be susceptible to adverse events that can affect the accuracy and reliability of the results (Orth et al., 2019).

For example, errors in transcription of test results can lead to incorrect or misinterpreted reports, which could influence clinical and therapeutic decisions. In addition, inadequate communication of results between the laboratory and clinical staff may result in delays in treatment or failure to adequately follow up on certain medical conditions. Likewise, lack of follow-up or inadequate documentation of results can compromise continuity of care and patient health monitoring (Dávila & Parrales, 2023)..

Other adverse events during the laboratory process are failures in quality control in the clinical laboratory are situations in which the processes and procedures designed to ensure the accuracy and reliability of the results do not meet the established standards. (Macias, 2023). These failures can occur at various stages of the analytical process and can have various causes. For example, they may arise due to problems with the calibration or maintenance of laboratory equipment, errors in the preparation or storage of reagents, failures in the execution of internal and external quality controls, or deficiencies in the training or supervision of technical personnel (Alonso, 2021).

These failures can have significant consequences, such as the generation of inaccurate or unreliable results, which can lead to misdiagnosis, inappropriate treatment, or delays in appropriate medical care for patients. Therefore, it is crucial that clinical laboratories establish and maintain robust quality control systems, including regular internal and external monitoring, ongoing staff training, periodic review of standard operating procedures, and taking corrective and preventive action in response to any identified deviations or incidents.

Likewise included are problems with information systems in the clinical laboratory represent a significant concern that can have a direct impact on the quality and safety of medical care (Barba, 2019). Failures in data recording or storage can lead to loss of critical information or corruption of files, compromising the integrity of records and traceability of results. In addition, errors in electronic transmission of results can disrupt seamless communication between the laboratory and other electronic medical record systems, hindering coordination and continuity of patient care.

Quality of care and patient safety in the clinical laboratory process, in adverse events in the pre-analytical phase.

In this regard, the following concepts should be taken into account

- *Quality control:* Refers to actions aimed at ensuring that a product or service meets the standards necessary to satisfy the needs of users. The ultimate goal is to provide optimal, adequate, safe and cost-effective quality. (Benozzi, 2022).

- *Quality assessment: These are* actions aimed at ensuring that quality control activities are carried out effectively, which implies a constant evaluation of the processes and the results or products obtained. (Benozzi, 2022).

- Patient safety: Defined as the absence of unnecessary harm, whether actual or potential, related to medical care. Errors in health care delivery have consequences

for patients and their families as well as for healthcare organizations and society as a whole (Lopez et al., 2020).

For a long time, it has been thought that, in the clinical laboratory setting, quality control and quality assessment were limited to the analysis of control samples along with patient samples, however, over time, the broader concept of quality assurance or quality guarantee has been developed and adopted. (Lopez et al., 2020).

In general terms, quality assurance is the set of activities designed to assure the user that the product meets the established quality standards, this process comprises two main activities: quality control and quality assessment. (Panunzio et al., 2022).. Therefore, its purpose is to prevent and control errors that occur from the moment the physician requests the test until the result is interpreted.

This includes any error that may occur from the time the physician issues the order for analysis until the result is analyzed and interpreted, encompassing both the analytical process and additional aspects outside this process (Ospina et al., 2023).. Quality management refers to the coordinated activities aimed at directing and controlling an organization with regard to quality, where analytical, extra-analytical, management and support processes are clearly identified, as well as their responsible parties (Cazarré et al., 2020)..

Quality presents a different conceptualization according to each type of customer, for the external (consumer of the final product) it can be the offer of a product or service and will be measured according to the functionality and efficiency with which it has been delivered, while, for the internal, that is, an operator, quality will be to comply with the activities aligned to the business objectives and, within the same line, for a production manager, it will be to maintain and improve the business productivity through indicators (Diaz, 2019; Osorio, 2019)..

Quality of care and patient safety in the clinical laboratory process, especially with regard to adverse events in the preanalytical phase, are critical aspects to ensure accurate and reliable results in diagnosis and medical treatment (Madrid & Hernández, 2022). The preanalytical phase spans from the request for the test to the preparation of the specimen for analysis in the laboratory. During this phase, a variety of errors can occur that affect the quality of the samples and, therefore, the reliability of the results (Huyhua et al., 2023)..

This includes inadequate patient identification, which is a fundamental aspect in the clinical laboratory process, especially during the preanalytical phase, this process ranges from the request for tests to the collection and labeling of samples. (Cedeño et al., 2021).. Inadequate patient identification can result in a number of errors that affect the quality of test results and, ultimately, patient safety and well-being (Lino et al., 2023)..

Errors in identification can arise due to a variety of factors, such as similarity of names, lack of communication between clinical and laboratory staff, or the absence of robust identification protocols. These errors can have serious consequences, such as incorrect

sampling, misassignment of test results, delays in appropriate treatment, and even loss of patient confidence in the health care system (Miño et al., 2022)..

Likewise, the erroneous assignment of results in the clinical laboratory process, as a consequence of inadequate patient identification, represents a significant risk to the quality of medical care. This error occurs when test specimens are not correctly labeled due to errors in patient identification, which can have several negative repercussions (Dávila & Parrales, 2023)..

When test results are incorrectly attributed to a patient, there is a risk of misdiagnosis or inappropriate treatment. This scenario can compromise the patient's health and affect their medical prognosis. They can also cause delays in proper medical care, as additional time will be needed to correct the error and provide the correct results to the correct patient (Villalta et al., 2019)

Another of the errors or adverse events is the quality of the sample in the preanalytical process of the clinical laboratory is essential to obtain accurate and reliable results in the analysis. When a poor quality sample is submitted, i.e., a sample that does not meet the required standards, a series of problems can arise that affect the validity of results (Soto & Sáez, 2022)..

One of the main consequences of a poor quality sample is the possibility of errors in the analysis. This may be due to the presence of interfering substances, such as hemolysis, coagulation or contaminants, which alter the measured values and lead to incorrect interpretations of the results (Brun et al., 2021). This situation can lead to misdiagnosis by medical personnel, resulting in inappropriate treatments or lack of treatment for a real medical condition (Acosta et al., 2023)..

In addition, the need for repeat testing due to poor quality samples can lead to delays in proper diagnosis and treatment. This implies an additional expenditure of resources and time for both the patient and the laboratory staff, which can negatively affect the efficiency of the health care system and increase the economic burden for the patient or the health care system in general (O'Hara et al., 2020)..

Incorrect sample mislabeling in the clinical laboratory process is a problem that can have serious consequences for the quality and safety of medical care (Carral, 2021). This error occurs when test specimens are not correctly identified with patient information, which can result in a number of problems: First, incorrect labeling can lead to misassignment of test results. When samples are not labeled correctly, there is a risk that results will be incorrectly associated with the wrong patient, which can result in misdiagnosis and inappropriate treatment (Jorna et al., 2021)..

In addition, mislabeling can cause confusion in the handling of specimens in the laboratory. If specimens are not clearly identified, laboratory personnel may have difficulty tracking and processing specimens properly, which can lead to delays in obtaining results and in patient care (Trujillo et al., 2020).. Another important consequence of mislabeling is the loss of sample traceability; without proper identification, it may be difficult or impossible to trace the origin of a sample, making it

difficult to identify potential problems or errors in the analysis process (Gomez et al., 2020)..

Lack of staff training in the clinical laboratory process can be a significant factor contributing to a variety of problems, including preanalytical errors and patient safety risks. First, lack of training can result in improper sample collection techniques. For example, untrained personnel may not follow standard procedures for venipuncture, which can lead to bruising, hemolysis, or other complications that affect sample quality (Suardíaz et al., 2022)..

In addition, untrained personnel may not be aware of the importance of critical factors in the pre-analytical phase, such as proper patient identification and correct labeling of samples. This can result in identification errors that affect the accuracy of analysis results and jeopardize patient safety (Mera & Lino, 2022).. It can also result in a lack of knowledge about the proper interpretation of laboratory results. Staff may not fully understand reference ranges and the clinical implications of abnormal results, which can lead to incorrect medical decisions or lack of proper follow-up (Baltazar, 2023).

Poor communication between clinical staff and laboratory personnel in the health care setting can have a significant impact on the quality and safety of the clinical laboratory process (Gondres et al., 2022).. First, poor communication can lead to misunderstandings about test orders. If the information provided by clinical staff is not clear or accurate, there is a risk that incorrect tests will be ordered or relevant information will be omitted, which can affect the quality of test results (Mucito & Sanchez, 2020).

In addition, lack of communication can lead to delays in specimen processing. If clinical staff do not provide timely information about specimens to be sent to the laboratory, this can lead to delays in specimen collection and processing, which in turn can delay patient diagnosis and treatment (Marrero et al., 2022).. Poor communication can also make it difficult to resolve problems and manage emergency situations. If unexpected problems arise during the testing process, such as unidentified samples or samples of poor quality, effective communication between clinical and laboratory staff is critical to quickly address the situation and take appropriate action to resolve the issue (Guevara et al., 2022)..

Prevention and control of adverse events in the clinical laboratory process.

The prevention and control of adverse events in the clinical laboratory process is of utmost importance to ensure patient safety and integrity of results. Some of the quality standards in the context of a clinical laboratory:

- *ISO 15189: The* international standard for clinical laboratories. It defines the general requirements for technical competence, quality management and service quality that clinical laboratories must meet to demonstrate that they operate competently and can generate valid and reliable results. (Alvarez, 2022).
- *Laboratory accreditation:* Many countries have specific accreditation systems for clinical laboratories. These accreditation programs evaluate the technical

competence and quality of the services offered by the laboratory, and certify compliance with recognized standards (Carboni & Sáenz, 2019)..

- *Regulatory compliance:* Clinical laboratories must comply with applicable national and international regulations and standards, which may include requirements related to patient safety, waste management, data privacy, and other areas. (Laz & Lino, 2022)..
- *Quality management:* The implementation of a quality management system based on principles such as process approach, continuous improvement and staff involvement is essential to maintain and improve quality in all areas of the laboratory. (Viteri et al., 2023)..
- *Internal and external quality control:* Internal and external quality control programs are essential to monitor and ensure the accuracy and precision of laboratory results. This involves the use of quality control materials, participation in proficiency testing programs, and regular comparison of results with other laboratories (Viteri et al., 2023)..
- *Validation and verification of analytical methods:* Before implementing a new analytical method, it is crucial to validate and verify its performance to ensure its reliability and precision under specific laboratory conditions. (Mendoza et al., 2023).
- *Personnel training and competence:* Ensuring that laboratory personnel are adequately trained and competent in their functions is essential to maintain quality at all stages of the analytical process (Mendoza et al., 2023). (Mendoza et al., 2023).

In Ecuador, clinical laboratory quality standards are regulated and supervised mainly by the Agency for Quality Assurance of Health Services and Prepaid Medicine (ACESS), as well as by the Ministry of Public Health (MSP). Although specific standards may vary, here are some relevant regulations and norms in Ecuador:

- *Ecuadorian Technical Regulation*: This regulation establishes the general requirements for the quality and competence of clinical laboratories, based on the ISO 15189:2022 standard (Curillo, 2022). (Curillo, 2022).
- *Laboratory accreditation:* In Ecuador, there are accreditation and certification programs for clinical laboratories, such as the Ecuadorian Accreditation System (SEA) and the National Health Laboratory Accreditation System (SINACAL). These systems evaluate the technical competence and quality of services offered by clinical laboratories (Curillo, 2022). (Curillo, 2022)..
- *Ministry of Public Health (MOH) Regulations:* The MOH issues regulations and guidelines related to the quality and safety of health services in general, including clinical laboratories. These regulations may include specific requirements on quality management, quality control, patient safety, and data privacy (Pasquel & Burgos, 2020).
- *Waste management:* There are specific regulations on the proper management of waste generated in clinical laboratories, ensuring its treatment and safe disposal to prevent negative impacts on human health and the environment (Gonzales, 2021). (Gonzales, 2021)..
- *Biosafety regulations:* The MOH establishes regulations related to biosafety in clinical laboratories to prevent exposure to pathogenic biological agents and ensure a safe

working environment for laboratory personnel and patients (Baggini, 2022). (Baggini, 2022).

Ecuador can adopt globally recognized standards that address quality, safety and risk management in the field of health and, therefore, in laboratory services. These international standards can come from organizations such as the World Health Organization (WHO) and the International Organization for Standardization (ISO), among others. For example, ISO 15189:2022 establishes specific requirements for the quality and technical competence of clinical laboratories, covering aspects such as quality management, personnel competence, method validation, internal and external quality control, as well as document and record management (Cedeño et al., 2021)..

Biosafety regulations are a fundamental part of laboratory management, as they are designed to protect both laboratory workers and the general public from the risks associated with the handling of hazardous biological and chemical agents (Arias et al., 2021).. In Ecuador, these regulations are usually established by the Ministry of Public Health or other competent authorities, and address a number of key aspects to ensure safety and prevent exposure to risk (Cedeño et al., 2021)..

First, these regulations often include detailed requirements on laboratory infrastructure, ensuring that facilities are designed and constructed in a manner that minimizes the potential for environmental contamination and provides adequate containment of hazardous agents. This can range from adequate ventilation to the provision of security systems and access control (Valles et al., 2024)..

In addition, biosafety regulations establish specific procedures for the safe handling of biological and chemical materials. This may include guidelines on the proper use of personal protective equipment, decontamination of surfaces and equipment, and safe disposal of waste, all with the goal of minimizing the risk of exposure and contamination (Luzuriaga et al., 2020)..

Another important aspect is personnel safety protocols, which establish the responsibilities and training necessary to ensure that those working in the laboratory are adequately informed and prepared to handle the risks associated with their work. This can include everything from training in biosafety practices to participation in emergency drills (Brun et al., 2021).

Finally, biosafety regulations also typically include measures for the management of emergency situations, such as hazardous material spills or accidental exposures. This involves the implementation of clear response protocols, including proper notification and timely medical care, in order to minimize potential health and environmental impacts (Baggini, 2022).

Also included are reporting and follow-up regulations are essential to ensure transparency, accountability and continuous improvement in the management of adverse events in the laboratory process. These regulations establish the procedures and responsibilities for reporting adverse events that occur during laboratory activities,

as well as for adequate follow-up to prevent their recurrence in the future (Luzuriaga et al., 2020)..

Regulations should first establish criteria for determining which events should be reported. This may include events such as sample processing errors, incorrect or unexpected results, contaminations, personnel safety incidents, among others. Next, procedures and timelines for adverse event reporting are detailed. This may include the obligation to report immediately or within a specified period of time, depending on the severity of the event and the potential risk to public health (Carboni & Sáenz, 2019)..

In addition, the regulations establish appropriate communication channels for adverse event reporting, ensuring that information reaches the relevant authorities in a timely and complete manner. This may involve the creation of online reporting systems or the designation of specific points of contact to receive and process the information. Once reported, follow-up regulations establish the mechanisms to investigate and analyze adverse events, with the objective of identifying the underlying causes and taking appropriate corrective actions (Macias, 2023).

Finally, reporting and monitoring regulations may also establish requirements for the maintenance of detailed records of reported adverse events, as well as for the disclosure of this information in a transparent manner to relevant stakeholders (Lloacana et al., 2023)..

Conclusions

The prevention and control of adverse events in the clinical laboratory process are fundamental aspects to guarantee the quality and safety of analytical results, as well as to safeguard the health of patients. First of all, it is essential to implement quality control measures from the beginning of the process, ensuring proper calibration of equipment, use of quality reagents and constant training of technical staff. This helps to minimize pre-analytical errors that could compromise the accuracy of the results.

In addition, efficient management and strict compliance with biosafety regulations are crucial to prevent adverse events related to environmental contamination and occupational exposure to hazardous substances. The implementation of standardized safety protocols and the constant monitoring of their compliance are key aspects to avoid incidents that may endanger the health of laboratory personnel and the environment.

Every clinical laboratory requires a comprehensive approach from the pre-analytical phase to the final waste disposal, involving the application of quality control protocols, biosafety measures and an adequate management of environmental and occupational risks. Only through a continuous commitment to quality and safety can the reliability of analytical results and the protection of patients, laboratory personnel and the environment be guaranteed.

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