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Pre-analytical Errors in Clinical Laboratories: An Integrative Review

Errores preanalíticos en laboratorios clínicos: revisión integrativa

Erros pré-analíticos em laboratórios clínicos: revisão integrativa

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Abstract: Introduction: Adequate management of the preanalytical phase is crucial for nursing professionals because it guarantees the accuracy and reliability of laboratory results, which are essential for effective diagnosis and treatment. Objective: To identify preanalytical errors in clinical laboratories in the available literature. Methodology: Integrative review through PubMed, Scopus and Scielo databases. PRISMA criteria were used to select and evaluate relevant studies published between 2019 and 2024. Selected studies were critically appraised and synthesized using the constant comparison method: data reduction, data visualization, data comparison, drawing conclusions. Results: The initially identified articles were 80 (PubMed = 66, Scopus = 14, Scielo = 0) and 34 studies that met the selection criteria for this review were included. Pre-analytical errors are identified as predominant, representing a high percentage of errors in the laboratory, with poor sample preparation and handling being the most common causes. These errors increase costs and compromise diagnostic quality. Conclusion: Standardization of procedures and staff training are essential to reduce these errors and improve patient safety.

Keywords: blood chemical analysis; quality of health care; pre-analytical phase; laboratory test.

Resumen: Introducción: Un adecuado manejo de la fase preanalítica es crucial para los profesionales de enfermería porque garantiza la precisión y confiabilidad de los resultados de laboratorio, fundamentales para diagnósticos y tratamientos efectivos. Objetivo: Identificar en la literatura disponible los errores preanalíticos en laboratorios clínicos. Metodología: Revisión integrativa a través de las bases de datos PubMed, Scopus y Scielo. Se utilizaron los criterios PRISMA para seleccionar y evaluar estudios relevantes publicados entre 2019 y 2024. Los estudios seleccionados fueron evaluados críticamente y sintetizados utilizando el método de comparación constante: reducción de datos, visualización de datos, comparación de datos, elaboración de conclusiones. Resultados: Los artículos identificados inicialmente fueron 80 (PubMed = 66, Scopus = 14, Scielo = 0) y se incluyeron 34 estudios

que cumplieron los criterios de selección para esta revisión. Se identifica que los errores preanalíticos son predominantes, representando un alto porcentaje de errores en el laboratorio, siendo la mala preparación y manejo de muestras las causas más comunes. Estos errores aumentan los costos y comprometen la calidad diagnóstica. Conclusión: La estandarización de procedimientos y la capacitación del personal son esenciales para reducir estos errores y mejorar la seguridad del paciente.

Palabras clave: análisis químico de la sangre; calidad de la atención de salud; fase preanalítica; prueba de laboratorio.

Resumo: Introdução: Um manejo adequado da fase pré-analítica é crucial para os profissionais de enfermagem, pois garante a precisão e a confiabilidade dos resultados laboratoriais, fundamentais para diagnósticos e tratamentos eficazes. Objetivo: Identificar na literatura disponível os erros pré-analíticos em laboratórios clínicos. Metodologia: Foi realizada uma revisão integrativa por meio das bases de dados PubMed, Scopus e Scielo. Foram utilizados os critérios PRISMA para selecionar e avaliar estudos relevantes publicados entre 2019 e 2024. Os estudos selecionados foram avaliados criticamente e sintetizados utilizando o método de comparação constante: redução de dados, visualização de dados, comparação de dados e elaboração de conclusões. Resultados: Foram inicialmente identificados 80 artigos (PubMed = 66, Scopus = 14, Scielo = 0), dos quais 34 estudos cumpriram os critérios de seleção para esta revisão. Identificou-se que os erros pré-analíticos são predominantes, representando uma alta porcentagem de erros laboratoriais, sendo a má preparação e o manejo inadequado de amostras as causas mais comuns. Esses erros aumentam os custos e comprometem a qualidade diagnóstica. Conclusão: A padronização de procedimentos e a capacitação da equipe são essenciais para reduzir esses erros e melhorar a segurança do paciente.

Palavras-chave: análise química do sangue; qualidade da atenção à saúde; fase pré-analítica; testes laboratoriais.

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Introduction

Evidence-based practice is the quality instrument that supports clinical practice. Therefore, it is necessary to investigate and review the literature to update concepts and identify strategies that improve the quality of patient care. (1)

This is directly linked to the nursing care role, where a logical and standardized process for blood sample collection in various healthcare contexts is fundamental. (2)

Laboratory medicine is defined as a science that generates clinical information by analyzing the concentration, composition, and/or structure of various analytes in biological

fluids, which, thanks to technological and management advances, have made a fundamental contribution to health care with significant contributions in clinical medicine, epidemiological surveillance, and scientific research. [3]

The total analytical process of laboratory tests was defined 50 years ago by George Lundberg as the "brain-to-brain" cycle, and it has been divided into three phases: pre-analytical, analytical, and post-analytical. [4]

ISO 15189:2012 defined the pre-analytical phase as the steps that consider the healthcare personnel's request, patient preparation, sample collection, transportation to and within the laboratory, and this phase ends with the start of the analysis process. [5]

The International Organization for Standardization (ISO), under ISO 15189:2012, included the definition of thresholds and improvement criteria in pre-analytical quality management. [5] In its update, ISO 15189:2022 established the requirement for clinical laboratories to implement these indicators to monitor and evaluate their performance, ensuring reliable healthcare services. [6]

The World Health Organization (WHO) defines Patient Safety as "the reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum". [7] The International Organization for Standardization (ISO) defines a laboratory error as: a failed operation during the pre-analytical, analytical, and post-analytical phases of laboratory work that was planned but not completed or performed incorrectly. [8]

It is also worth mentioning that quality indicators, closely related to patient safety, are objective tools that provide solid evidence of quality at all stages of the analysis process, ensuring patient safety by reducing error rates and guaranteeing reliable and accurate results. [9]

A pre-analytical error occurs when laboratory acceptability criteria are not met, such as when an analytical test is not performed or results are not provided, which can lead to sample rejection for not being able to generate reliable results for the requested tests. [10]

Moreover, the literature describes that laboratory errors are common and widespread, affecting patient safety, causing unnecessary stress and anxiety. They also contribute to erroneous or delayed diagnoses, unjustified costs for the patient and the healthcare network, inadequate therapies, repeated samples, unnecessary follow-up investigations, as well as affecting clinical effectiveness, generating patient dissatisfaction, and discrediting the clinical laboratory. [11]

The research problem posed was: What evidence is available on the errors that occur in the pre-analytical phase of clinical laboratory tests? The objective was to identify the available literature on pre-analytical errors in clinical laboratories.

Materials and Methods

An integrative review was conducted to gather and synthesize information that would allow for a broad and deep understanding of this phenomenon. [12, 13] To ensure the quality and transparency of this report, the criteria included in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) were used. [14]

The methodological approach guiding this integrative review follows the guidelines proposed by Broome (2019), who emphasizes the importance of integrating various types of evidence to develop robust concepts in the field of nursing. This method allows the inclusion of studies with heterogeneous designs and facilitates a broader and deeper understanding of complex phenomena, such as pre-analytical errors in clinical laboratories. [15]

First, the research question was formulated: What evidence is available on the errors that occur in the pre-analytical phase of clinical laboratory tests? Rigorous inclusion criteria were established to select relevant studies. The articles had to be related to the topic, published in English, Spanish, or Portuguese, available in full text, open-access, and peer-reviewed. Among the limitations of the study are:

- Inclusion criteria limited to open-access articles: This decision restricts access to publications from high-impact journals that could offer more relevant studies or higher methodological quality.
- Temporal limitation of the search (2019-2024): Although this temporal restriction ensures that only recent studies are used, it may also exclude previous research that has provided fundamental data on pre-analytical errors.
- Limited use of databases: While important databases such as PubMed and Scopus were used, the exclusion of other key sources may have restricted the search to a partial view of the available literature. Additionally, no articles were found in Scielo, which may be relevant for studies in specific regions such as Latin America.
- Potential publication bias: By including only peer-reviewed, open-access studies, relevant studies that do not meet these criteria may have been excluded.

The literature search was conducted in databases recognized for their relevance in health and biomedical sciences. These databases included Scielo, PubMed, and Scopus. Additionally, reference lists of relevant articles were reviewed, and specialized organizations on the topic were consulted.

To ensure a comprehensive search strategy, specific terms such as “blood chemical analysis”, “quality of health care”, “pre-analytical phase” and “laboratory test” were used, applied in the title, abstract, or full text of the articles. The complete search strategies were documented for each database, including the filters and limits applied to restrict the results to peer-reviewed studies published within the specified period. The Boolean operator AND was included. The last search in each of these sources was conducted in June 2024.

The study selection process involved a meticulous review to determine if the articles met the inclusion criteria. Two reviewers independently evaluated each record and each retrieved report. Automation tools, such as bibliographic management software, were used for duplicate removal and the initial selection of studies. In case of discrepancies, discussions were held until a consensus was reached. The evaluation of the data by the level of evidence was carried out using the GRADE approach. This process included the assessment of the methodological quality of each study according to previously established criteria, such as study design, result consistency, and clinical applicability. [16]

Data collection from the selected reports was carried out independently by two reviewers, following a standardized protocol. Processes were included to obtain or confirm data directly from the study investigators when necessary, and automation tools were used to facilitate this task. The data were critically evaluated to ensure their validity and relevance. A standardized tool was used to assess the quality of the studies, and each study was evaluated independently by at least two reviewers. The data analysis included the reduction, visualization, comparison, and synthesis of the results. The methods used to tabulate and visually display the results of individual studies and syntheses were described in detail. For each result, the effect measures used, such as risk ratio or mean difference, were specified.

Additionally, the risk of bias in the included studies was assessed, describing the tools employed, the number of reviewers, and their independence in the process. The methods used to assess the certainty or confidence in the body of evidence for each result were detailed.

Finally, the results were presented in a structured manner, in five categories: 1) Patient Preparation, 2) Test Request, 3) Sample Collection, 4) S Sample Storage and Transportation, and 5) Pre-Analytical Errors, highlighting the main conclusions and recommendations for clinical practice and future research. A PRISMA flowchart was used to document the study selection process, showing the number of studies identified, included, and excluded, and the reasons for exclusion.

Results

From the review of the articles, 80 records were initially identified in databases, with 14 from Scopus and 66 from PubMed. No articles related to the topic were found in Scielo. Of these records, 20 were eliminated before the review: 7 due to duplication and 13 due to language. Subsequently, 60 records were reviewed, of which 26 were excluded for not being related to the study topic. Finally, 34 studies were included in the final review (Figure 1).

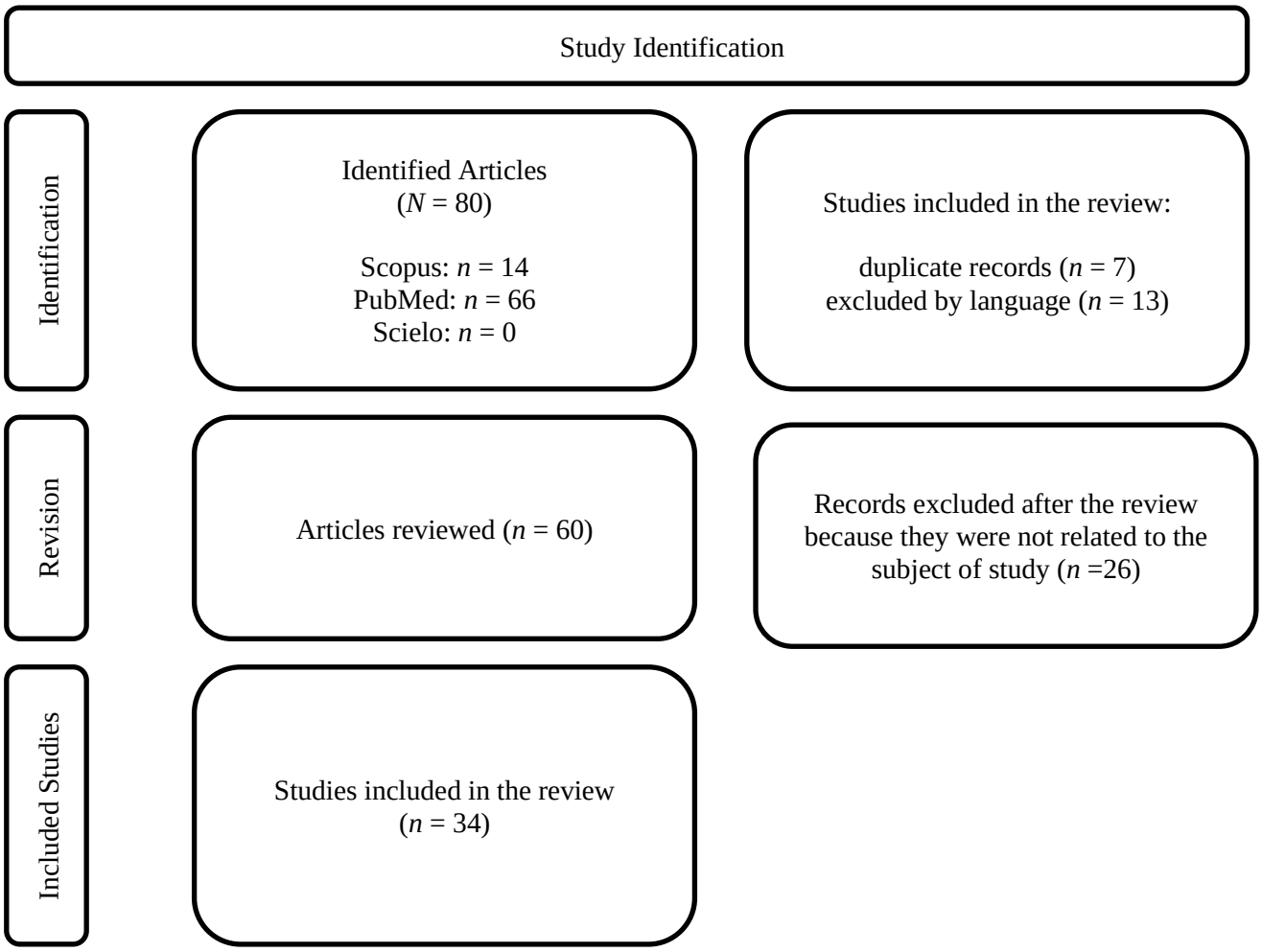

Figure 1. PRISMA Flowchart: Summary of the Study Selection Process

With the purpose of organizing the data for analysis, a table was created that includes the general information of each article (Table 1). This table details the objective of each study, in order to carry out an inductive categorization based on thematic axes in the next phase.

Table 1 – Characteristics of the selected studies

Authorship	Country	Year	Database	Objective	Method
Stonys & Vitkus	Lithuania	2024	PubMed	To determine the level of compliance of venous blood sampling (VBS) in Lithuania with the joint recommendations of the European Federation of Clinical Chemistry and Laboratory Medicine and the Latin American Confederation of Clinical Biochemistry (EFLM-COLABIOCLI), and to analyse possible causes of errors.	Quantitative cross-sectional Descriptive
Stonys & Vitkus	Lithuania	2024	PubMed	To investigate the attitude of non-laboratory health professionals in Lithuania regarding the importance of patient preparation for laboratory tests and its impact.	Quantitative cross-sectional Descriptive
Shinde & Dhanve MJ	India	2021	Scopus	To evaluate the pre-analytical and analytical phases of surgical histopathology in a tertiary care center.	Retrospective quantitative
Arrendondo et al.	Chile	2019	PubMed	To evaluate the effect of breakfast on routine hematology and coagulation laboratory tests.	Experimental
Tashkandi et al.	Saudi Arabia	2021	PubMed	Implement competency assessment programs to improve pre-analytical phase indicators and reduce costs in clinical laboratories.	Pilot Study
Alshaghdali et al.	Saudi Arabia	2022	PubMed	Review quality indicators and detect laboratory errors in the pre-analytical phase of haematology tests in a clinical laboratory.	Quantitative observational descriptive
Zorbozan & Zorbozan	Türkiye	2022	PubMed	Determine the performance of the extra-analytical phase of a biochemistry laboratory.	Quantitative retrospective audit
Fenta & Ali	Ethiopia	2020	Scopus	Identify factors that affect the quality of laboratory results.	Quantitative observational descriptive
Reddy, Cassim, Treurnicht & Makatini	South Africa	2022	Scopus	To identify factors of rejection of HIV samples and evaluate costs associated with delayed centrifugation and alternating transport of clinical decision-making in cancer patients.	Quantitative observational descriptive with cost analysis
Kadić, Ismić & Hasić	Bosnia and Herzegovina	2019	PubMed	Identify the rates of the most common preanalytical errors and document potential differences in error rates between inpatients and outpatients.	Quantitative observational descriptive
Ottestad et al.	Norway	2019	PubMed	Explore patients' knowledge and application of the fasting requirements in the HMGB1 exam	Analytical observational study
Codish, Amichay, Yitshak-Sade, Gat, Liberty & Novack	Israel	2020	PubMed	To assess the clinical impact of reduced transit time and early centrifugation of glucose laboratory specimens.	Quantitative
Leonard, Chin-Yee, Delport, Crozier & Abdulsatar	Canada	2023	PubMed	Improve the success rate of wound swabs.	Mixed quality improvement project
Keppens et al.	Europe	2021	PubMed	Investigate causes and frequency of incidents in the total biomarker testing process in non-small cell lung cancer and colorectal cancer.	Quantitative observational descriptive
Mesganaw, Hassen, Molla & Misganaw	Ethiopia	2024	PubMed	Investigate the rejection rate of laboratory samples and identify their causes in a hospital.	Quantitative cross-sectional prospective
Kopcinovic, Culej, Jokic, Bozovic & Kocijan	Croatia	2019	PubMed	Provide recommendations for the pre-analytical, analytical, and post-analytical phases for the analysis of extravascular body fluids.	Review of clinical guidelines or national consensus
Simundic et al.	Croatia- USA-Austria - Italy	2019	Scopus	To analyze causes and effects of hemolysis in laboratory samples and provide recommendations.	Literature review

Grzych, Roland, Lezier, Beauvais, Maboudou & Lippi	France	2019	PubMed	To analyze the influence of sample transport by pneumatic tubes on potassium levels.	Retrospective quantitative
Grankvist, Gómez, Nybo, Kima-Oliveira & Von Meyer	Europe	2019	PubMed	Inspect pre-analytical aspects of short- and long-term plasma/serum storage.	Literature review
Nordin et al.	Malaysia	2024	PubMed	Review factors that contribute to preanalytical errors in clinical laboratory tests and propose measures to reduce them and explore measures to improve these errors.	Literature review
García-Del-Pino et al.	Spain	2020	PubMed	To investigate under which pre-analytical conditions routine and diagnostic glucose tests are performed in Spanish laboratories.	Quantitative cross-sectional Descriptive
Niedrist et al.	Austria	2023	PubMed	Evaluate the impact of different storage conditions to maintain analyte's stability.	Observational Experimental
Compton et al.	United States	2019	PubMed	Develop evidence-based recommendations to ensure the molecular integrity of biospecimen samples from cancer patients, thereby ensuring the quality and reliability of data obtained for ºprecision medicine.	Literature review
Lippi et al.	Europe	2020	PubMed	Provide a specific checklist to prevent pre-analytical errors in clinical trials.	Literature review
Cool et al.	Belgium	2020	Scopus	Assess whether at-home test samples affect clinical decisions.	Quantitative Observational Retrospective
Chang et al.	South Korea	2023	PubMed	To investigate the current state of pre-analytical quality management in laboratory medicine in primary care clinics in Korea.	Quantitative Observational
Potter, Hickman, Oakman, Woods & Nolan	Australia	2020	PubMed	To investigate the effect of switching from late to early centrifugation on the diagnosis rate of gestational diabetes mellitus.	Experimental
Šálek, Schneiderka, Studená & Votroubková	Czech Republic	2020	PubMed	Investigate current practice and policies for requesting and reporting results of therapeutic drug monitoring.	Quantitative cross-sectional Descriptive
Troiano et al.	Italy	2020	PubMed	Investigate the pre-analytical error of samples not received in a hospital.	Pilot Study
Van Moll, Egberts, Wagner, Zwaan & Ten Berg	Netherlands	2023	PubMed	Investigate the nature, causes, and clinical impact of laboratory errors.	Quantitative observational descriptive
Kadić, Ismic, Hasic & Bosnjak	Bosnia and Herzegovina	2021	PubMed	Explore patient awareness and application of fasting state requirements for blood sampling.	Quantitative cross-sectional Descriptive
Eren, Tuncay, Oguz, Neselioglu & Erel	Türkiye	2021	PubMed	Discuss adapting laboratories during the pandemic to maintain quality in clinical laboratories.	Quantitative descriptive retrospective
Mukhopadhyay, Subramanian, Pandey, Madaan, Trikha & Malhotra	India	2021	PubMed	To determine, characterize and compare the types of pre-analytical errors that occurred during the pandemic and pre-pandemic.	Descriptive observational study
de Laat-Kremers, Ninivaggi, Devreese & de Laat	Belgium	2020	PubMed	To evaluate the methods used to measure thrombin by applying a survey.	Quantitative

After the content analysis, five thematic axes were identified in which the characteristics of the pre-analytical phase are evident. The categories that emerged are the following:

1. **Patient preparation**: It consists of the delivery of the prerequisites for taking exams, which will depend on the analyte to be studied.

2. **Test Request:** Corresponds to the issuance of the request for the examination by the doctor.
3. **Sample Collection**: A controlled, standardized procedure that involves the collection of blood or other body fluids for clinical analysis, diagnosis, or treatment.
4. **Sample Storage and Transportation:** Sample storage implies adequate conditions to preserve the stability of the collected samples until the analysis is performed. Sample transfer is the transport from the collection site to the laboratory for analysis.
5. **Pre-Analytical Errors**: This category corresponds to the failed operation during the preanalytical phase of the laboratory work, which was planned but is not fulfilled or is performed incorrectly. This situation can lead to the rejection of the sample when one or more of the requested results cannot be delivered.

Table 2 shows the different articles grouped according to categories or thematic axes.

Table 2 – Thematic axes that emerge from the selected articles

Thematic axes	Title	Authorship	Country	Year
Patient preparation	Breakfast can Affect Routine Hematology and Coagulation Laboratory Testing: An Evaluation on Behalf of COLABIOCLI WG-PRE-LATAM	Arrendondo et al.	Chile	2019
	PREDICT: a checklist for preventing preanalytical diagnostic errors in clinical trials	Lippi et al.	Europe	2020
	Assessing Non-Laboratory Healthcare Professionals' Attitude towards the Importance of Patient Preparation for Laboratory Tests	Stonys & Vitkus	Lithuania	2024
	A survey on the practice of phlebotomy in Lithuania and adherence to the EFLM-COLABIOCLI recommendations: continuous training and clear standard operating procedures as tools for better quality	Stonys & Vitkus	Lithuania	2024
Test Request	The experience of Careggi Hospital (Florence) regarding Not Received Samples (NRS): a pilot study of Risk Management in the Clinical Laboratory	Troiano et al.	Italy	2020
	Laboratory testing of extravascular body fluids: National recommendations on behalf of the Croatian Society of Medical Biochemistry and Laboratory Medicine. Part I - Serous fluids	Kopcinovic M., Kopcinovic, Culej, Jokic, Bozovic & Kocijan	Croatia	2019
	Factors Affecting Quality of Laboratory Result During Ordering, Handling, and Testing of the Patient's Specimen at Hawassa University College of Medicine and Health Science Comprehensive Specialized Hospital	Fenta & Ali	Ethiopia	2020
	A survey on the practice of phlebotomy in Lithuania and adherence to the EFLM-COLABIOCLI recommendations: continuous training and clear standard operating procedures as tools for better quality	Stonys & Vitkus	Lithuania	2024
Sample Collection	Preanalytics and Precision Pathology: Pathology Practices to Ensure Molecular Integrity of Cancer Patient Biospecimens for Precision Medicine	Compton et al.	United States	2019
	Preanalytical issues related to routine and diagnostic glucose tests: Results from a survey in Spain	García-Del-Pino et al.	Spain	2020
	Towards standardization of thrombin generation assays: Inventory of thrombin generation methods based on results of an International Society of Thrombosis and Haemostasis Scientific Standardization Committee survey	de Laat-Kremers, Ninivaggi, Devreese & de Laat	Belgium	2020
	Managing hemolyzed samples in clinical laboratories	Simundic et al.	Croatia-USA-Austria-Italy	2019
	Preanalytical aspects on short- and long-term storage of serum and plasma	Grankvist, Gómez, Nybo, Kima-Oliveira & Von Meyer	Europe	2019
Sample Storage and Transportation	HMGB1 concentration measurements in trauma patients: assessment of pre-analytical conditions and sample material	Ottestad et al.	Norway	2019
	Improvement of Blood Samples Preanalytic Management Alters the Clinical Results of Glucose Values: Population Study	Codish, Amichay, Yitshak-Sade, Gat, Liberty & Novack	Israel	2020
	Pneumatic tube system transport and false hyperkalemia related to leukocytosis: a retrospective analysis	Grzych, Roland, Lezier, Beauvais, Maboudou & Lippi	France	2019

	Preanalytical stability of SARS-CoV-2	Niedrist et al.	Austria	2023
	Quality of blood samples collected at home does not affect clinical decision making for the administration of systemic cancer treatment	Cool et al.	Belgium	2020
	Status of Pre-analytical Quality Management of Laboratory Tests at Primary Clinics in Korea	Chang et al.	South Korea	2023
	Strict Preanalytical Oral Glucose Tolerance Test Blood Sample Handling Is Essential for Diagnosing Gestational Diabetes Mellitus	Potter, Hickman, Oakman, Woods & Nolan	Australia	2020
Pre-Analytical Errors	Audit in surgical histopathology at a tertiary healthcare center: Study of preanalytical and analytical phase	Shinde & Dhanve	India	2021
	Clinical laboratory services for primary healthcare centers in urban cities: a pilot ACO model of ten primary healthcare centers	Tashkandi et al.	Saudi Arabia	2021
	Detecting Preanalytical Errors Using Quality Indicators in a Hematology Laboratory	Alshaghdali et al.	Saudi Arabia	2022
	Evaluation of preanalytical and postanalytical phases in clinical biochemistry laboratory according to IFCC laboratory errors and patient safety specifications	Zorbozan & Zorbozan	Türkiye	2022
	Factors influencing the high rejection rates of HIV 1/2 serology samples at Charlotte Maxeke Johannesburg Academic Hospital and the cost implications	Reddy, Cassim, Treurnicht & Makatini	South Africa	2022
	Fasting state requirements for blood sampling: a survey of patients in Cantonal Hospital Zenica, Bosnia and Herzegovina	Kadić, Ismić & Hasić	Bosnia and Herzegovina	2019
	Improving wound swab collection in paediatric patients: a quality improvement project	Leonard, Chin-Yee, Delport, Crozier & Abdulsatar	Canada	2023
	Incidents in Molecular Pathology: Frequency and Causes During Routine Testing	Keppens et al.	Europe	2021
	Laboratory specimen rejection rate and associated factors among referred specimens at Debre Markos Referral Hospital, Ethiopia: prospective cross-sectional study	Mesganaw, Hassen, Molla & Misganaw	Ethiopia	2024
	Preanalytical Errors in Clinical Laboratory Testing at a Glance: Source and Control Measures	Nordin et al.	Malaysia	2024
	The Nature, Causes, and Clinical Impact of Errors in the Clinical Laboratory Testing Process Leading to Diagnostic Error: A Voluntary Incident Report Analysis	Van Moll, Egberts, Wagner, Zwaan & Ten Berg	Netherlands	2023
	The prevalence of pre-analytical errors in the laboratory of the Cantonal Hospital Zenica in Bosnia and Herzegovina	Kadić, Ismic, Hasic & Bosnjak	Bosnia and Herzegovina	2021
	The response of total testing process in clinical laboratory medicine to COVID-19 pandemic	Eren, Tuncay, Oguz, Neselioglu, & Erel	Türkiye	2021
	The rise in preanalytical errors during COVID-19 pandemic	Mukhopadhyay, Subramanian, Pandey, Madaan, Trikha & Malhotra	India	2021

Discussion

The management of laboratory tests is essential for safe and quality care. For this reason, nurses must know the evidence that supports their practice in this area. Below are the thematic axes organized into five categories.

Thematic Axis 1: Patient Preparation

Stonys and Vitkus mention that only a minority of patients tend to arrive well-prepared for blood sample collection, which is a problem in Lithuania. The causes of inadequate preparation include misinformation and variability in recommendations provided by laboratories, which affects the quality of the results . [17] Arredondo evaluated the importance of fasting in hematology and coagulation tests. Samples were taken while fasting, after the consumption of a standardized breakfast of carbohydrates, proteins, and lipids, and then at the first, second, and fourth hours post-consumption. The results showed no return to baseline values in the 4 hours following food intake, leading to the conclusion that, for the analytes included in the study, fasting time should be considered important. [18]

This is corroborated by Lippi et al., who, in their publication on the importance of the pre-analytical phase in clinical studies, emphasized the relevance of patient preparation so that the blood sample effectively reflects the subject's real conditions. Therefore, it is indicated that precise information should be collected on medication and supplement use, as well as the pathologies affecting the patient, reinforcing the importance of fasting time, the time of sample collection, abstinence from tobacco, avoiding coffee consumption, and refraining from strenuous physical activity for 48 hours. Moreover, patients should be seated for at least 10 minutes before extraction. [19]

Continuing with Lippi, among the important steps he also recommends are the confirmation of the patient's identity with at least two indicators, defining the sample matrix, specifying the sample volume, applying the tourniquet for less than one minute, defining the venipuncture site, performing venipuncture by phlebotomists, following the recommended order of extraction, and standardizing the mixing of samples. [19]

Stonys and Vitkus, in their study on the attitude and lack of understanding of non-laboratory health professionals about the importance of patient preparation, applied an anonymous questionnaire that revealed that these professionals consider patient preparation in laboratory tests significant, such as fasting, alcohol, tobacco, or medication consumption (nurses more so than doctors). However, the attitude towards the impact of physical activity, the menstrual cycle day, and circadian rhythm showed significant differences depending on years of work experience (more or less than 20 years) and whether they had received relevant training. [20]

Thematic Axis: Test Request

Kopcinovic and colleagues, in their study on body fluid analysis, made a recommendation to professionals involved in the collection and processing of these samples to standardize the procedure at a national level. For this, they conducted a survey and reviewed evidence through the literature, reinforcing the importance of the test request form and order of analysis, which should include: patient's name and surname, gender, date of birth, unique identifier, date and time of collection, hospital unit, doctor's identification and contact details, the identifier of the sample taker, collection procedure and site, and the anatomical origin of the sample. [21]

In a study conducted by Fenta and colleagues to evaluate pre-analytical errors, they observed that 87.5 % of the test requests were incomplete regarding clinical diagnosis,

12.5 % did not include gender, and 15 % were missing age. [22] According to Kadic et al, errors in patient identification were associated with a higher occurrence of laboratory errors. In addition, 85 % of the requests did not have the time of sample collection. [23]

A study conducted by Salek and colleagues, which consisted of a survey to investigate test request forms and result reports in the therapeutic drug monitoring service in laboratories, found that only 12 % implemented all the necessary elements for optimal therapeutic drug monitoring. These elements included age, body weight, sample timing, date of first administration, time of last administered dose, dose, dosing interval, route of administration, purpose of the test, and other co-administered medications. [24]

Thematic Axis 3: Sample Collection

Compton and colleagues, in the case of tissues for molecular tests, estimate that the ideal sample thickness is up to 5mm due to the penetration speed of formalin. For blood samples, factors such as the type of collection tube (EDTA tube or specialized tubes for cell stabilization), the tube fill level as per the manufacturer's recommendation, and the tube order in multiple collections to avoid cross-contamination are emphasized. The recommended order is: tube without additive, coagulation tube with sodium citrate, tube with clot activator, tube with clot activator and serum separator, heparin tube (either sodium heparin or lithium heparin), EDTA tube, and tubes with other additives like citrate, dextrose-acid; oxalate/fluoride, and anti-glycolytic agent. Additionally, an adequate number of inversions should be performed for proper mixing of the analyte with the tube additive. [25]

On the other hand, García del Pino and colleagues, in their study on pre-analytical conditions in glucose tests, sent a survey to different laboratories and observed that the conditions under which the tests were performed were not ideal. The largest percentage of samples was performed in serum tubes, followed by plasma tubes with lithium heparin and plasma tubes with glycolysis inhibitor such as sodium fluoride on a smaller scale (19 %). The importance of the selected serum tube does not meet the conditions of the fasting plasma glucose diagnostic criteria. [26]

De Laat-Kremers and colleagues observed significant diversity among laboratories in the pre-analytical phase for thrombin generation measurement. They conducted a study through a questionnaire to laboratories in different locations around the world to understand these differences. 68 % of laboratories use only platelet-poor plasma, 4 % use only platelet-rich plasma, 24 % combine both types, 1 % use whole blood, and 3 % combine all three types. 40 % draw blood using a butterfly needle, and 39 % with a straight needle. 73 % use plastic collection tubes and 14 % use glass. The preferred anticoagulant is trisodium citrate (83 %), and 71 % discard the first blood tube. [27]

Simundic and colleagues observed that among the most important causes of hemolysis during phlebotomy were the use of inadequate equipment, such as syringes instead of evacuated tubes, needle diameter favoring turbulent flow, blood transfer from the syringe to the collection tube, and blood tubes with less volume than recommended. Phlebotomy from the antecubital fossa and gentle mixing of the tubes is recommended. [28]

The importance of documenting collection time is emphasized by Grankvist and colleagues in their study, as several factors can influence the integrity of biomarkers in serum and plasma samples. In the clinical biochemistry laboratory, samples are usually kept in their collection tubes until analysis, pending transport to the laboratory. Many analytes are stable for several hours without centrifugation; however, unstable ones require centrifugation and refrigerated transport or, in some cases, freezing before analysis. This is important to consider in peripheral sample collection centers, which should have supplies available to

perform these pre-transport procedures. The stability of the analyte must be ensured by the laboratory. Laboratories requiring long-term storage should redouble their efforts to manage pre-analytical variations such as fasting, medication instructions, collection time restrictions, sample volume, maximum centrifugation time, and freezing. [29]

Thematic Axis 4: Sample Storage and Transportation

Niedrist et al. evaluated the impact of routine storage time and temperature conditions on anti-nucleocapsid (NC) antibodies, finding that their levels after approximately 3 months at less than -70°C or during 14 days at temperatures between 2-10°C did not decrease significantly from a statistical standpoint. However, for storage periods longer than 1.5 years, relevant deviations were observed, potentially increasing positivity rates in convalescent COVID-19 patients. [30]

Codish et al. reported that prolonged time between blood extraction and the separation of the cell mass can decrease glucose levels, influencing the diagnosis of hyperglycemia and hypoglycemia. Through the evaluation of fasting glucose tests in an adult population before and after an educational intervention, the establishment of five centrifugation centers at key city locations, and changes in transportation routes, samples were kept in insulated coolers with polystyrene at 20°C for a maximum of 2 hours until centrifugation. The transportation temperature was monitored using a barcode tracking system. After the implementation of these changes, glucose results over 100 mg/dL increased significantly from 9.83 % to 25.91 %, and hypoglycemia (below 50 mg/dL) decreased. [31]

Another study on glucose variation was conducted by Potter et al. on pregnant women. In a protocol of delayed centrifugation versus early centrifugation (within 10 minutes of sample collection), higher glucose levels were obtained with early centrifugation, demonstrating variation in the rate of gestational diabetes diagnosis depending on the centrifugation time. [32]

Ottestad et al. conducted a study to evaluate the pre-analytical handling of HMGB1 (a mediator of systemic inflammation in sepsis and trauma) by taking arterial and venous samples, with delayed centrifugation times of 15 minutes, 3, 6, 12, and 24 hours stored at room temperature. They found that the samples were stable up to 6 hours, and arterial samples presented 40 % lower concentrations than venous samples. [33]

A study by Grzych et al. also evaluated this type of transportation, suggesting that plasma potassium levels can be influenced, which could lead to erroneous diagnoses. [34] Cool et al. explored whether pre-analytical quality was affected in blood samples taken at the homes of cancer patients undergoing treatment due to delayed centrifugation and transportation. They concluded that these interventions do not affect clinical decision-making in this case. [35]

Another study conducted by Chang et al. used a questionnaire to evaluate the functioning of primary care clinics in relation to pre-analytical phase management. Since most clinics do not have their own laboratories and send samples to reference laboratories, inadequate practices were found: 29.1 % of respondents reported a lack of centrifuges at the clinic, almost half had instructions on sample storage, and the samples were transported once a day during workdays. [36]

Thematic axis 5: Pre-Analytical Errors

Nordin et al. [37] observed that 82.6 % of pre-analytical errors are caused by human error, while technical errors account for 4.3 %, which is also consistent with Van Moll et

al., [38] who found that human factors were more frequent (58.7 %) while technical causes accounted for 12.5 %. Additionally, they agree with the literature that pre-analytical errors are more frequent than analytical and post-analytical errors, with rates of 77.1 %, 13.5 %, and 8 %, respectively.

Mukhopadhyay et al. conducted a study comparing pre-analytical errors before and after the COVID-19 pandemic, finding that the rejection rate for blood samples was significantly higher during the pandemic (3 % vs. 1.1 %). Coagulated samples were the most common indicator of pre-analytical error in both stages, along with a significant increase in the rate of mislabeled samples. Hemolysis was the second most common error before the pandemic and the fourth most common during the pandemic. [39]

A similar study conducted by Eren et al. showed that samples not received were significantly more common during the pandemic, concluding that the pre-analytical phase was the most affected during the pandemic. [40]

Tashkandi et al., in their study on a pilot model of Advanced Care Organization, mentioned that rejected samples corresponded to 68.3 % for requests without a sample, 6.95 % for incorrect tube usage, and 2.85 % for hemolysis. [41]

In the study by Alshadhdali et al., of the total samples analyzed, 9.3 % presented pre-analytical errors, with the most common being coagulated samples (3.6 %) and samples not received (3.5 %). [42] The former is repeated in the study conducted by Kadic et al., where the error rate was 1.7 % of samples, with the causes being coagulated samples (39.87 %) and hemolysis (48.5 %). [43]

Hemolysis is a widespread error worldwide, as found in the study conducted by Zorbozan and Zorbozan, with a pre-analytical error rate of 0.22 %, highlighting samples with excessive transport time and samples collected in incorrect containers. [44] Mesganaw et al. also observed hemolysis as a primary error in pre-analytical rejection, along with insufficient volume. [45]

Other studies have shown that errors can occur at different stages of the pre-analytical phase. Keppens et al. noted missing or incorrect information on the test request form, [46] and Troiano et al. studied samples not received (3.7 %), which mostly occurred in the emergency department, following up with interviews with the involved staff to evaluate the cause. [47]

Studies have also mentioned the issue of fasting in laboratory tests. Kadic et al. found that only 37.5 % of patients arrived adequately prepared at the laboratory. [48]

Laboratory errors are not exclusive to blood samples. There are also pre-analytical phase problems in the collection of culture swabs, where incorrect labeling has been evidenced in a study by Leonard et al. [49] and in tissue samples, as seen in the study by Shinde and Dhanve. [50]

According to Reddy et al., the pre-analytical phase is mainly responsible for 97.4 % of the rejections of HIV serology samples, with the need for a separate sample being the most common cause (57.44 %). These errors are attributed to deficiencies in sample collection and handling, leading to increased costs and representing 82.6 % of total rejections. Additionally, the need to improve healthcare staff training is highlighted to minimize these errors, improve laboratory efficiency, reduce costs, and ensure accurate and timely diagnostic results. [51]

Šálek et al. observed that only 67 % of laboratories specified the type of sampling tube on their request forms, which is critical to avoiding pre-analytical errors, such as drug absorption by serum separator gels. Furthermore, it was observed that the manual entry of data from paper forms into electronic systems is prone to transcription errors, which can

compromise result quality. These deficiencies in the pre-analytical phase underscore the need to improve harmonization and therapeutic drug monitoring practices in laboratories. [24]

Conclusions

Pre-analytical laboratory errors are a widespread global issue, in which several international organizations have studied guidelines to ensure a good process in its various stages. Among the different stages of the testing cycle, the pre-analytical phase has the highest percentage of errors, which is associated with the large number of participants involved in this stage and the human errors that may occur.

It is important to highlight that most pre-analytical stage errors are avoidable with proper training of the healthcare personnel involved. Improving these pre-analytical errors would be fundamental to the testing cycle, as it would bring benefits to the staff, patients, and healthcare facilities.

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