Preanalytical interferences in laboratory tests: a narrative review

Interferências pré-analíticas em exames laboratoriais: uma revisão narrativa

Interferencias preanalíticas en pruebas de laboratorio: una revisión narrativa

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Abstract
Laboratory errors can occur in any of the three phases of laboratory testing, being preanalytical, analytical or postanalytical. The preanalytical phase occurs before the examination is performed, being characterized as the phase with the most errors. Preanalytical errors account for 60% to 90% of the interferences that occur in laboratory test results. The collection of information available in the literature on the subject can help to minimize this occurrence. Given the above, the present study aims to present the knowledge discussed in the literature about preanalytical interferences in laboratory tests. This is a narrative review of the literature. The data sources consulted were SCIELO and Google Scholar, in December 2020. The total number of studies revealed in both data sources was 9,635 studies, of which 28 manuscripts were included. Among the main results found, errors related to the preanalytical phase of the laboratory stand out, which can directly interfere with the interpretations of professionals who request the exam. In addition, having knowledge of the equipment present in these biochemical sectors is essential for a better conduction of the preanalytical phase. The dissemination of laboratory quality indicators can encourage the team to visualize actions and investigations with corrective objectives and the prevention of preanalytical errors. Therefore, the conclusion is that errors in the preanalytical phase interfere with laboratory results and can cause poor results due to possible misinterpretations. Quality control is essential for the prevention or elimination of preanalytical errors in laboratory biochemical tests.

Keywords: Clinical analysis; Quality control; Preanalytical phase; Laboratories.

Resumen
Los errores laboratoriales son clasificados de acuerdo con las tres fases de los testes laboratoriales: pré-analíticos, analíticos e pós-analíticos. A fase pré-analítica ocorre antes da realização do exame, caracterizando-se como a fase com mais erros. Os erros pré-analíticos são responsáveis por 60% a 90% das interferências que ocorrem nos resultados dos exames laboratoriais. O levantamento de informações disponíveis na literatura sobre o assunto pode ajudar a minimizar essa ocorrência. Diante do exposto, o presente estudo tem como objetivo apresentar o conhecimento discutido na literatura sobre as interferências pré-analíticas em exames laboratoriais. Trata-se de uma revisão narrativa da literatura. A busca foi realizada nas fontes de dados SCIELO e Google Acadêmico, em dezembro de 2020. O total de estudos revelados em ambas as fontes de dados foi de 9.635 estudos, dos quais 28 manuscritos foram incluídos. Dentre os principais resultados encontrados, destacam-se: erros relacionados à fase pré-analítica do laboratório podem interferir diretamente nas interpretações dos profissionais que solicitam o exame; ter conhecimento dos equipamentos presentes nesses setores bioquímicos é essencial para uma melhor condução da fase pré-analítica; a divulgação de indicadores de qualidade laboratorial pode estimular a equipe a visualizar ações e investigações com objetivos corretivos e de prevenção de erros pré-analíticos. Portanto, conclui-se que erros na fase pré-analítica interferem nos resultados laboratoriais e podem causar desfechos ruins devido a possíveis interpretações errôneas. O controle de qualidade é essencial para a prevenção ou eliminação de erros pré-analíticos em testes bioquímicos laboratoriais.

Palavras-chave: Análise clínica; Controle de qualidade; Fase pré-analítica; Laboratórios.

1. Introduction
Laboratory tests, according to the Brazilian Society of Pathology and Clinical Analysis, are a set of tests and exams requested by qualified health professionals that serve to verify health, make therapeutic decisions in treatment, as well as for
follow-up of patients. Clinical analysis laboratories usually perform and analyze these tests. However, its collection can take place in any environment, as long as the procedure guarantees maximum safety and comfort for the patient, although this practice alone increases the possibilities of errors (Shcolnik et al., 2019; Lopes et al., 2022).

Modern clinical analysis laboratories, as pointed out by Shcolnik et al. (2019), are an important part of the health system. They directly contribute to the prevention, diagnosis, treatment and management of pathologies (Codagnone et al., 2014). In addition, they provide laboratory results that can be responsible for up to 75% of the information needed to choose the best therapeutic approach for a given patient with a given pathology.

The execution of laboratory tests takes place in three phases: pre-analytical, analytical and post-analytical. The first phase consists of preparing the patient, identifying, collecting, handling and storing the biological sample, that is, all the activities that precede the laboratory analysis. The second phase consists of carrying out the procedures and tests themselves, as well as interpreting the results of these tests. In this phase, the methods used, before being implemented in the routine, are analyzed in relation to the type of sample, duration of the assay, precision, accuracy, sensitivity, specificity, linearity, stability of the reagents, thus guaranteeing the reliability and precision of the results. The last phase, in turn, begins with a quantitative and/or qualitative result obtained after analysis by a specialized clinician and ends with the delivery of the report. At some stage within these described phases, it is possible that errors in laboratory quality control, direct assistance to management, jeopardize the analysis of the collected material and consequently make it impossible to issue a reliable and accurate report (Barbosa & Mansour, 2019).

Laboratory errors can occur in any of the three phases of laboratory testing, being preanalytical, analytical or postanalytical. In the pre-analytical phase of the exam, these errors occur before the exam or test. Analytical errors generally occur due to miscalibration of the collection equipment, collection in inappropriate circumstances, incorrect techniques, and expired reagents, among others. Finally, errors that occur in the post-analytical phase are associated with the post-examination stage, involving processes such as typing and delivery of reports (Oliveira et al., 2011).

However, the phase that presents the most errors is the pre-analytical one, being responsible for 60% to 90% of the interferences that occur in the results of laboratory tests and 60 to 70% interfere in medical decisions (Fernandes et al., 2021; Souza, 2020). These errors can cause rework, expenses with supplies, anxiety, medical non-compliance and customer dissatisfaction, in addition to discrediting the contracting laboratory in the diagnostic and therapeutic market. Errors at this stage usually occur between the moment of requesting the test and the moment of its analysis in the laboratory (Fernandes et al., 2021). High rates of refusal of laboratory tests, due to non-compliance with requirements in the pre-analytical phase, prove such sensitivity that there is in this phase. These indices also point to the need to seek to recognize the items most vulnerable to errors at that time. Due to its high sensitivity, if this phase presents considerable minimal flaws, the others (analytical and post-analytical) may also experience errors in the analysis and interpretation of the exam. Errors in any steps of this process generate analyzes and results that do not reflect reality (Burtis et al., 2016).

All aspects that make up the initial laboratory phase are important. It is especially noteworthy the collection of information regarding the patient, the main causes related to errors in this phase, such as chronobiological characteristics, pathophysiological characteristics, age, physical exercise, eating behavior, drug use, alcohol and cigarette consumption, and underlying pathologies such as diabetes and hypertension. Therefore, considering all aspects inherent to this phase contributes to the development of a pre-analytical phase in accordance with the indicated standards, bringing reliability and security to users and the diagnostician professional (Ramos et al., 2020).

It is also clear that there are many laboratory quality control errors. The laboratory quality control, in short, is a good practice and a requirement of ANVISA (National Health Surveillance Agency). This quality control is carried out based on the requirements of a laboratory or collection point, public or private, to carry out pathology tests, clinical analyzes and cytology.
The total elimination of errors in the pre-analytical phase is practically impossible, since its accomplishment depends on manual tasks and often involves the cooperation of the patient (Santos et al., 2020). This directly interferes with the laboratory quality of the establishment. Thus, taking into account the repeated fragility that exists in the pre-analytical phase and the high occurrence of errors attributed to this stage, the need for studies focused on this knowledge is evident.

The development and publication of studies on the most recurrent errors are necessary, given that their results can reveal the means of tracking and resolving errors of any nature in the various clinical laboratories, and consequently improve the laboratory quality of these establishments. Gathering the information available in the literature on the subject is also important, as it may help to minimize this occurrence. Given the above, the present study aims to present the knowledge discussed in the literature about pre-analytical interferences in laboratory tests.

2. Methodology

This is a narrative literature review. Cordeiro et al. (2007) describe that this method does not impose on researchers the obligation to present a specific research question, thus allowing a broader search and without deepening on a particular topic. The selection of articles and literature materials is subject to the researchers' subjectivity, in view of the exhaustive exhaustion of data sources (Cordeiro et al., 2007). However, despite not being a requirement of the narrative review method, the researchers of the present study previously determined the data sources. They also decided to establish inclusion and exclusion criteria for the selection of manuscripts available in the literature.

The search was carried out in the following data sources: SCIELO (Scientific Electronic Library Online) and Google Scholar, in December 2020. Here are the keywords used for the search: Clinical Analysis, Pre-Analytical Phase and Quality Control. The search strategies were independent, in SCIELO, in view of the low number of articles found from the mechanisms using Boolean operators. In Google Scholar, the search happened as follows: [Clinical Analysis] and [Pre-Analytical Phase] and [Quality Control].

In the SCIELO database, with the descriptor ‘Pre-Analytical Phase’ a total of 21 articles were found (Search Strategy 1); with the descriptor ‘Quality Control’, 2,955 scientific materials were found (Search Strategy 2); and with the descriptor ‘Clinical Analysis’ 3,289 studies were found (Search Strategy 3). Thus, the search in the database revealed 6,265 scientific materials. In Google Scholar, in turn, the search revealed 3,370 results, based on the strategy described in the previous paragraph. Thus, the total number of studies revealed in both data sources was 9,635 studies. All articles and materials found had their titles and abstracts read. The researchers of this research read in full all the materials that responded to the objective of the present study.

The researchers of the present strategically organized themselves to read all the materials found in both data sources, in view of the collection of works found. Due to the large amount of material found from the search strategies used, it was not possible to control and describe, through a PRISMA flowchart, the entire process of selection, eligibility and inclusion of studies. However, as this process is not a requirement for this review method, there was no negative interference in the methodological aspects of the present study. Below is a brief flowchart of how the process of selecting studies for analysis took place (Figure 1).
Here are the inclusion criteria listed for the study: being a scientific manuscript, published in the last 15 years, being freely available on the internet, and available in Portuguese, Spanish and/or English. Duplicate studies in the same data source and repeated in both were excluded.

After reading and analyzing the manuscripts, the result was 35 studies selected for further analysis. All the articles were read again and after this reading seven (7; 20%) of these manuscripts were not used, as they did not address the issue “quality errors in clinical analysis laboratories”. Thus, the remaining 28 articles were included in the sample of this narrative literature review.

3. Results and Discussion

3.1 Laboratory tests

The importance of laboratory tests in clinical practice is essential. They generate reliable results, help in the prevention, diagnosis and treatment of diseases, whether in the hematological, hormonal, microbiological, serological, cardiovascular, lymphatic, mycological, endocrine and genetic areas (Szwarcwald et al. 2019; Xavier et al., 2016). Health professionals authorized to prescribe them depend on the results of these laboratory tests in a complementary way to provide an effective answer regarding the patient's clinical condition (Tekkesin et al., 2010; Júnior, 2020; Souza, 2020). Information from laboratory tests contributes to more than 70% of medical decisions (Shcolnik et al., 2012; Souza, 2020). In this sense, errors related to the pre-analytical phase can interfere with the interpretations and reports of professionals who request the examination. Pre-analytical errors can interfere with the analysis and issuance of adequate reports.

Reference values of laboratory tests can support health professionals in interpreting the results (Andriolo, 2010; Rosenfeld et al., 2019; Rosa, 2019). Many laboratories choose to accept the values provided by the test manufacturers, forgetting that the values attributed by scientific studies are more reliable. This is because the scientific studies that attest to
these parameters are generally multicenter cross-sectional or longitudinal studies, carried out rigorously (Szwarcwald et al., 2019; Roncalio et al., 2019). Furthermore, in Brazil, some laboratories still use reference values from other countries for their laboratory tests. This can generate unreliable results in the exams, since the Brazilian population has diverse miscegenation characteristics. Brazil is a country with different races, ages, ethnicities, peoples and social and economic realities (Munanga, 2015). Thus, it is important that the reference values used in the country come from studies in that country (Szwarcwald et al., 2019).

Thus, the professional responsible for carrying out the pre-analytical phase of laboratory tests, from the provision and forecasting of materials to the performance of the exam, must have sufficient knowledge about the parameters of the laboratory tests that their health service adopts. Because some tests lack specific recommendations and verifications to be carried out before collecting the biological sample to be analyzed. When considering the references that help to understand the blood glucose test, for example, it is clear that the patient who performs it needs to be fasting, but there are several fasting times established in the literature recommended for this test. Therefore, every professional who composes the analysis team must be aware of these specificities even before obtaining and analyzing the sample.

It is necessary that the entire professional body of the pre-analytical phase is attentive to the parameters and recommendations that guide the laboratory tests offered by the laboratory (Souza, 2020). Furthermore, it is essential that clinical analysis professionals, especially biomedical and pharmaceutical professionals, or other professionals trained for this purpose, properly manage the laboratory pre-analytical phase, in order to avoid errors and inconvenience to the patient. The supervisors of these professionals need to be attentive to the pre-analytical quality control, that is, to the moment before the exam.

3.2 Biochemistry Sector

The biochemistry sector in a laboratory or in a health institution is the place that performs any interpretation of chemical compounds in the blood, through automated and calibrated devices. They process serum or plasma samples, providing important information about the patients' metabolic and productive clinical status (González & Silva, 2008). This information is useful for the professional to draw, from them, therapeutic approaches aimed at the patient's problem. However, it is important to emphasize that although laboratory profiles are relevant in the diagnosis, physical examination and clinical history are also necessary for the final decision on this diagnosis and procedures (Melo et al., 2021; Pagliarini, 2021).

This sector is capable of evaluating more than 400 different types of laboratory tests. They range from the most common, such as sodium analysis, to highly complex ones, such as DNA testing, drug testing, differentiation of lipoprotein variants, and identification of intermediate metabolites. Many of these tests are performed on automated machines; others are performed manually with industrialized reagents (Gaw, 2015; Simões, 2019; Corrêa, 2019; Pimenta & Júnior, 2016).

These machines require maintenance control by a qualified professional, so it is important that their operating conditions are adequate to process the collection of biological samples. In addition, knowing which equipment is present in these biochemical sectors is essential for the execution of the pre-analytical phase, with quality and effectiveness. This is because certain conducts, prior to collection, are directly related to the type of machines that the laboratory has. It is important to emphasize that the basic mistakes made in this phase happen mainly due to the inadequate control of these machines, not being possible to maintain their operational quality.

There are two reasons why biochemical measurements vary so much, one is analytical and the other is biological. The first has the function of analytical action. The second refers to the actual changes that take place in the patient's body fluids over time. These measures lead analysts to observe some important requirements: precision, accuracy, sensitivity, specificity and reference intervals of the exams; and age, diet, time of day, stress level, pregnancy condition and medical history of the
patient (Gaw et al., 2015). Therefore, making basic preanalytical errors related to one of these points mentioned may even cause organic damage to these patients, which may or may not be reversible.

3.3 Laboratory errors

The articles point out that the main most common laboratory errors are: incorrect interpretations of medical prescriptions; incorrect identification of biological samples; insufficient volume of blood collected; and inadequate conditioning of the samples. The most prominent causes: lack of information about the patient's pharmacological treatment; contamination of the sample by bacteria or artifacts; and hemolysis from careless handling (Guimarães et al., 2011; Fernandes et al., 2021; Machareth & Messeder, 2018). Many of these errors occur due to failure in the manual processes performed by health professionals. Some of these errors happen even before the collection, as from the misinterpretation of the medical or nursing request, for example. The creation of protocols consistent with the reality of each laboratory can be an alternative to minimize pre-analytical errors.

Total eradication of laboratory errors, especially pre-analytical errors, is practically impossible. Therefore, Vale & Miranda (2015) suggests that it is necessary for scholars in the area to develop efficient measures to reduce and prevent these errors. For this, the insertion of means of professional qualification and training (courses, lectures and audits) for categorization and control of these incidents are necessary. It is an effective way that can intensify in the learning of these professionals the culture of good practices of conduct in all the laboratory phases.

The consequences of these errors can cause irreparable inconvenience to the patient, such as hemodynamic instability, discomfort, undue costs, unnecessary serological repetitions, expense with reagents and laboratory materials and delay in releasing their results (Codagnone & Guedes, 2014; Holanda, 2019). These errors certainly delay the prescription and implementation of urgent therapeutic approaches. In addition, they can generate dissatisfaction and discredit on the part of professionals requesting tests and users, disqualifying the services offered by the laboratory, and even civil and criminal damages for the institution.

To reduce the number of memories due to some inadequacy in the pre-analytical phase, the authors Oliveira et al. (2009) described the standards for sequencing vacuum collection tubes. These authors showed, at the time, how much it is worth following this strategy as an important parameter in everyday life. The order is as follows: blood culture flask, tubes without additives, tubes with sodium citrate, tubes with separator gel, tubes with heparin, tube with EDTA and tubes with glucose inhibitor, the well-known sodium fluoride (Oliveira, 2009). Thus, seeking to standardize operational activities such as this one can be effective in minimizing pre-analytical errors and reorganizing routines and processes.

Another interfering item, not much commented on by some authors, is the intense use of pharmacological products by patients. Drugs administered daily can react together with reagents and thus intervene and modify test results. Many drugs provide effects in vivo by a physiological mechanism and in vitro when some physical or chemical property of the drug blocks the test reaction (Ramos et al., 2020). Therefore, in the pre-analytical phase, the screening of the patient regarding the drugs he uses is extremely considerable, as well as the time of ingestion of these drugs and how often he uses them. It is worth mentioning that many exams can have their results altered due to the use of medications.

3.4 Quality Control

The concept of quality started to have great prominence from the 20th century, due to the evolution of large companies in offering services that corroborate with the needs and hopes of their customers, in a satisfactory and safe way. In the field of health, quality must also guarantee and maintain, in its fairness, the primary rights of patients (Morita et al., 2010; Nunes & Scaff, 2021). Dr. Feigenbaum in 1956 described that the entire responsibility for the product belongs to the entire
organization and not only to the quality control sector (Vieira et al., 2011). The last area that accepted the quality processes was health; however, it has presented decisive results (Mendes et al., 2006).

According to ABNT NBR NM ISO 15.189:2015 standards, laboratories must carry out research work to find processes that do not meet the requirements of their quality system, both in non-conformities and in improvement actions (SBPC/ML, 2012). The inclusion of quality control represents the guarantee of a reliable health service (Garrido & Souza, 2021). In line with the pre-analytical phase, the professional practice of the researchers of the present research allows us to infer, from these findings, that the periodic review and discussion with the entire laboratory team, about these processes, can be useful for the knowledge and strengthening teams. This can strengthen the clinical practice of those involved, reducing the occurrence of errors at this stage.

In Brazil, due to the search for quality in laboratory methods, the Brazilian Society of Clinical Pathology/Laboratory Medicine (SBPC/ML) created the Clinical Laboratory Accreditation Programs (PALC). The Department of Inspection and Quality Accreditation (DICQ), the Brazilian Society of Clinical Analysis (SBAC) were also included. In addition, in the mid-1970s to 1980s, they created the Proficiency in Laboratory Examinations (PELM) and the National Quality Control Program (PNCQ) (Fiorenzani, 2011). These programs and institutions were essential for improving the quality of control of laboratory tests, contributing significantly to the reduction of errors in all laboratory phases. In the pre-analytical phase, the actions became more rigorous in execution, starting from the reading of the exam prescription until its execution. Notably, due to the quality control required by these institutions, the services have become safer and more rigorous technically and scientifically. Thus, studies and mapping of strategies for quality control in laboratory methods are necessary. Furthermore, implementing this quality sector in health institutions that offer clinical analysis services is essential.

With the evolution of quality control, laboratory medicine has advanced a lot, as shown by the indicators. Indicators are essential tools that allow users to quantify the quality of laboratory services. They are objective measures that allow the person in charge of the sector to analyze all critical domains of their processes, including the pre-analytical phase (Plebani, 2012; Borrecho, 2018). Therefore, it is important that laboratories and hospital institutions increasingly invest in this sector. Its contribution to the promotion of safety and quality in the performance of laboratory tests is of fundamental importance for the effective performance of its services.

3.5 Importance of quality control in minimizing biochemistry laboratory errors

When it comes to quality in error minimization in the biochemical sector, two well-known definitions usually appear, they are certification and accreditation. Accreditation is the approval of the laboratory health service, by the accrediting entities, for carrying out laboratory tests. The Certification of these services, in turn, is based on the recognition of the institution as a health laboratory unit that meets existing national and international standards for a complete or excellent laboratory service offered (Gerônimo et al., 2018; Ferreira, 2019).

In the laboratory environment, it is necessary to monitor all errors in biochemical tests, from the initial phase to the end of each procedure. For this, laboratory quality indicators are used (Santos et al., 2020; Magalhães, 2020). In the presence of errors or circumstances that require attention to prevent errors, they enable the identification and subsequent accurate assessment of the event. It is suggested that the results of these indicators be disseminated to motivate the professionals involved and so that they have detailed feedback on the work that the team has been developing in the unit (Ferreira, 2019). The dissemination of these results may encourage the researchers of the team to envision actions and research with corrective and error prevention objectives, especially for existing problems that significantly interfere with these results.

Analysts can perform continuous quality analysis of their own unit of work – internal quality control. Internal quality control is responsible for the continuous monitoring of the reproducibility of the laboratory analytical phase. It identifies and
eliminates errors inherent in the process of analyzing quantitative and qualitative assays. Its purpose, finally, is to keep the variability of the assay analysis process under control and offer an opportunity to improve the activities carried out in the laboratory (Machado et al., 2018).

External quality control is the system used by clinicians to define laboratory performance through interlaboratory comparisons. In this case, the laboratories involved verify the control samples of unknown concentrations released by the sponsor of the laboratory institution's external quality control program. This control compares the accuracy of the exams of a given laboratory with the others, thus verifying the performance of the analysts of the laboratories involved (Dias et al., 2017).

To reduce or avoid errors in the biochemistry sector, internal and external quality controls have been used (Gonçalves, 2020). Both reinforce and ensure that the reference data of the exam results are within the established norms, during all phases, pre-analytic, analytic and post-analytic. This process aims to improve the credibility of the institution and the safety of users, from the identification and tracking of the data involved in the procedure, to the prevention of errors and unnecessary discomfort/damage (Manso & Seabra, 2020). The biochemical professionals responsible for the sector need to be graduates or postgraduates to perform the function. They are trained and trained by the laboratory to adapt the processes developed (Silva, 2018; Teodoro, 2013).

4. Final Considerations

Quality control is essential for the prevention or elimination of preanalytical errors in biochemical laboratory tests. Errors in the preanalytical phase interfere with laboratory results and can cause poor prognosis due to possible misinterpretations. In addition, the involvement of the entire laboratory team in the prediction and correction of errors and avoidable situations is of fundamental importance, as this phase comprises manual activities and processes, and is subject to failures. For clinical analysis laboratories, we suggest continuous implementation of courses, lectures and internal and external audits in order to seek improvements to their monitoring, evaluation, care, and management operationalization processes. Finally, we suggest the production and publication of studies on the most common errors in each of the stages of laboratory tests, as well as the most effective measures to correct these incidents.

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