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Pre-analytical phase and causes of variations in the results of hematological laboratory exams: a literature review

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Abstract: Laboratory diagnosis has undergone several changes over time due to automation. In addition to automation, the adoption of a quality assurance program (PGQ), thus resulting in greater accuracy and accuracy in exams. The present study aimed to analyze in the literature the main laboratory errors related to the pre-analytical phase. The same is a literature review, where data collection was composed of scientific articles taken from electronic databases of scientific publications: SciELO, CAPES Journal Portal and MEDLINE, and data analyses were performed between July and August 2021. The main question of the present study was: "What are the main laboratory errors of the pre-analytical phase found in scientific publications?". The search in the database was performed using the combination of the following keywords: Laboratory tests; pre-analytical phase; Laboratory hematology. In view of the findings in the studies, it was possible to notice that pre-analytical variables continue to be an important source of attention for the clinical laboratory. And that it is responsible for most of the errors that occur in the dynamic process of the clinical analysis laboratory, which negatively impacts the laboratory result of the patient.

Keywords: Laboratory tests. Pre-analytical phase. Laboratory hematology.

1. Introduction

Laboratory diagnosis has undergone several changes over time due to automation. In addition to automation, the adoption of a quality assurance program (PGQ), thus resulting in greater accuracy and accuracy in exams. In order to have quality control, the processing of a biological sample is didactically divided into three subsequent phases: pre-analytical, analytical and post-analytical, and in the first one arises to most errors, the disclosure of these failures (OLIVEIRA *et al*., 2011).

Some recent surveys indicate that about 70% of the errors described in the laboratories are associated with the pre-analytical stage, impacting the costs and quality of the results. In view of this, the pre-analytical phase is very fragile and with great difficulties because it is still considered a manual procedure (BERLITZ, 2010; WISLOCKI, 2011).

It is also worth mentioning that the mention of 70% of errors is considered only laboratories that have established a CK, for reasons that those who do not have have no way of knowing if they are missing. If they do not register, there is no way to have indicators, if there are no indicators, there is no control, so there is no way to map, they are outside the statistics (VIEIRA *et al*., 2011).

There are several factors that impact the results of the pre-analytical stage tests, starting with the medical decision regarding the laboratory tests to be requested and what to expect from them, where at this stage, it depends on the knowledge obtained by the professional of the different pathologies and available tests and more pointed to reveal the diagnosis early or adequately monitor the patient (TOMEDA *et al*., 2011).

In addition to the medical choice, the patient's proper preparation, collection, centrifugation, transportation and storage of samples are elementary to impact the quality of the final report. As well as the proper preparation of the patient directly influences the report of the examination. Among the various errors found in the pre-analytical phase, the most incidents are related to the improper preparation of the patient and the time of sample collection (SCHONS; TAVARES, 2010).

A question arose to try to understand what occurs in this important phase: "What are the main laboratory errors of the pre-analytical phase found in scientific publications?". To answer the question raised, it was decided to be a literature review of articles that may present errors related to the pre-analytical phase in hematological tests.

The present study is justified by the fact that bibliographic research is necessary to identify based on pre-analytical factors, which of these have relevant implications for hematological tests. However, the pre-analytical phase is when the highest error index occurs, according to the literature, and this phase will be challenged in this study. From the scenario briefly problematized here, the present study aimed to analyze in the literature what are the main laboratory errors related to the pre-analytical phase.

Finally, the research exposed is divided into four topics, the first being the introduction, the second the chosen methodology, the third the results and discussions of the data and the fourth the conclusions.

2. Methodology

A bibliographic study was developed through a literature review, which is a broader review method, as it allows to include theoretical literature, as well as studies with different methodological approaches (quantitative and qualitative) (SOUZA, *et al*., 2010).

The collection was composed of scientific articles taken from electronic bases of scientific publications, being identified the following: SciELO, CAPES Journal Portal and MEDLINE. The search in the database was performed using the combination of the following keywords: Laboratory tests; pre-analytical phase; Laboratory hematology.

Based on the reading of the title and summary of the files presented by the databases, the ones that were consistent with the theme were selected. Other inclusion criteria were the selection of articles published between 2011 and 2020 (last ten years) and written in the language of Portuguese. And as exclusion criteria, articles were not indexed free of charge in full, articles written in the languages, English and Spanish, theses, dissertations, event summaries and monographs. Finally, data analyses were carried out between July and August 2021.

3. Results and Discussion

The main question of the present study was: "What are the main laboratory errors of the pre-analytical phase found in scientific publications?". Some of the articles, despite having one of the descriptors researched, did not meet the other criteria, because they were not laboratory pre-analysis. There were still those who did not approach the descriptor within the objective of the study, however it was not the focus of this study and those that did not refer to errors in the pre-analytical phase, but to other phases. These restrictions limited to only those articles that met the established criteria. At the intersection of the terms: Laboratory tests; pre-analytical phase; Laboratory hematology using the following databases: SciELO, CAPES Journal Portal and MEDLINE, in all, 11 publications were obtained, of these, 6 studies were in English and Spanish, and 5 in Portuguese. Among these 11, nine were selected to make up the analysis and categorization proposed in this study (table 1).

Table 1. Articles selected to make up the study

Nº	Origin	Article title	Authors	Year
01	J. Bras. Patol. Med. Lab.	Main biological parameters evaluated in errors in the pre-analytical phase of clinical laboratories: systematic review.	COSTA, V. G.; MORELI, M.L.	2012
02	Brazilian Journal of Health Review.	Pre-analitic errors in clinical analysis laboratories: a review.	SOUSA *et al.*	2021
03	SEMPES.	Laboratory tests and the pre-analytical phase.	SANTOS *et al.*	2016

04	Rev. HCPA.	The clinical laboratory and pre-analytical errors	GUIMARÃES *et al*.	2011
05	Health Magazine.	The prevalence of error in the pre-analytical phase in clinical analysis laboratories.	RIVELLO, V.V.; LOURENÇO, P.M.	2013
07	FIOCRUZ	Main errors in the pre-analytical phase of the service provider laboratory at the getúlio vargas hospital in southern sapucaia.	XAVIER, N.G.	2013
08	UFP repository.	Laboratory pre-analytical phase: errors and recommendations.	RODRIGUES, P. H. S.	2016
09	Updates.	Interference of pre-analytical factors in the performance of the blood count.	SANTOS, C.M. A.; Vieira, L.C.	2013

Source: according to data found.

Laboratory exams are complex processes, as they involve several steps, from the request of the examination to the release of the report. It is estimated that about 70% of the diagnoses are made based on laboratory tests, and the results are responsible for 60% to 70% in the medical decision regarding the patient's health status (COSTA; MORELI, 2012; SOUSA *et al*., 2021).

Laboratory tests are increasingly improved, with technological advances that are growing in the health area, reagents and laboratory equipment provide increasingly specific results and in a shorter time, physicians use these facilities considerably increasing the request for tests (XAVIER, 2013).

In this regard, in the study by Rodrigues (2016) elucidated the assistance to health, where failures in the diagnosis can significantly compromise the safety of the patient in severe clinical conditions and those in normal clinical situations as well, because it is based on this scientific and technological information that many decisions are made.

The pre-analytical phase concentrated most errors in the laboratory phase and the consequences can be determinant for the positive-false or negative-false diagnosis. According to the scientific literature, errors occur due to omission of the patient or even the health professional due to lack of knowledge, resulting in a mistaken diagnosis with consequences that may be severe to the patient (SANTOS *et al*., 2016; GUIMARAES *et al*., 2011).

According to Rivello & Lourenço (2013), achieving the goals of reducing errors in the pre-analytical processes and increasing the safety of the same, it is necessary to implement activities aimed at the training, education and culture of all professionals by which they are involved in the process of obtaining and manipulating biological samples.

Thus, for Santos & Vieira (2013), it is necessary to seek a look at the investigations about how people, whether individually or in groups, should carry out their activities, mas not attributing the errors to people, but to the processes that can lead to some failures in obtaining a result. Therefore, it is essential that it be in mind that pre-analytical errors will always exist, however they can be minimized with the support of quality control strategies, adopted by all who work with diagnostic medicine.

4. Conclusions

In view of the findings in the studies, it was possible to notice that pre-analytical variables continue to be an important source of attention for the clinical laboratory. And that it is responsible for most of the errors that occur in the dynamic process of the clinical analysis laboratory, which negatively impacts the laboratory result of the patient.

Thus, one of the solutions to minimize pre-analytical errors comes with the automation of this phase, but especially with training, standardization of activities and continuing education of the professionals involved. Therefore, professional awareness about the importance of the pre-analytical phase and its functions, in order to minimize the inherent errors of this phase.

However, the objective of this research is not to exhaust the subject, which is proven in its development, which is complex and requires careful analysis. However, the implementation of quality indicators is essential for monitoring the execution of the service, which must be standardized, in order to achieve a reduction of errors in the laboratory scope and improve the quality of the reports dispatched.

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