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Analysis of the pre-analytical phase in a private pathology laboratory of Maringá city-PR, Brazil

Análise da fase pré-analítica em laboratório privado da cidade de Maringá-PR, Brasil

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ABSTRACT

Introduction: The pre-analytical phase involves most of the errors of clinical analysis laboratories. Information characterizing the occurrence of these errors can be useful to provide prevention and reduction strategies. **Objective:** The aim of this study was to identify the main errors in the pre-analytical phase of a private laboratory in the city of Maringá-PR, and their occurrence rate. **Materials and methods:** Data were collected from sample recollection orders from June 2013 to May 2015. A total of 707,449 exams collections were registered, and 1,274 (0.18%) of these had ordered a new collection based on some criteria adopted by the laboratory. **Conclusion:** The pre-analytical phase represented 70.8% of the orders for new collection. According to the reports from the Quality Control Database, the most frequent reason of recollection in the preanalytical phase was insufficient sample volume (58.54%), followed by clotted sample (19.29%), hemolyzed sample (9.43%), incorrect labeling of sample (8.21%), lipemic sample (3%) and improper sample (1.56%). Although the results of nonconformity forms presented different records, both clearly point to problems in collection and patient registration sector, sustaining that the main problems of clinical laboratories arise from the failure in quality specifications for pre-analytical phase.

Key words: blood samples collection; quality management; patient safety.

INTRODUCTION

The clinical analysis laboratory has been undergoing great modifications over the past decade, which are fundamental to help in diagnostic and therapeutic decisions, in order to ensure a more efficient and safer service within a shorter period of time. Automation and computerization have made the service offered more productive, efficient and systematic, outlining a new profile of professionals involved in the process as well as a routine that follows protocols and procedures with the hopes of reduce and avoid errors⁽¹⁻¹¹⁾.

Despite all these improvements and the abundant scientific literature on improving the quality of the services offered by Clinical Laboratories, errors are still present; furthermore, detecting these errors will lead to data rejection and the collection of new biological samples. The re-collection of samples causes numerous inconveniences to the laboratory and to the patient, not to mention additional costs due to duplication of the materials used, staff hours and time consuming; consequently it also leads to loss of credibility, trust and confidence. An important

management strategy is to quantify the frequency and identify causes that leads to sample recollection and the errors associated with a specific service, so that quality control measures can be implemented^(3, 4, 9, 12-15).

In order to assure an effective quality control, it is essential to know the stages involved in the process, which embrace the pre-analytical, analytical and post-analytical phases. The pre-analytical phase includes the medical order, the stages of sampling and collection biological material, and ends at the onset of the analytical phase. The analytical phase includes the analytical process itself and the set of operations related to achieve an analytical result. The post-analytical phase is immediately after the acquisition of the tests results and ends with the release of the report^(3, 4, 6, 8-10, 13-18).

The pre-analytical phase is related to the higher incidences of clinical laboratory analyses errors, mainly due to the many variables in this process, such as samples labeling and patient preparation; collection, identification, transportation and storage of biological samples. However, this stage still requires indicators by the quality management system in clinical laboratories, and

also there are little knowledge about the impact of these factors on health care^(4, 5, 10, 12, 14, 18).

This study can contribute with relevant information in order to characterize the occurrence of a particular error in the pre-analytical phase of the clinical laboratory analysis, which will be useful to enable error prevention strategies, reducing error occurrence.

OBJECTIVE

The main objective of this study was to identify the main errors in the pre-analytical phase of a private laboratory in the city of Maringá-PR, as well as the frequency of occurrence. Secondly, we aimed to investigate the rate of medical order for recollection during the studied period and their distribution according to the phase of process analysis, evaluating if the number of rejected samples and recollections are within the acceptable values for the laboratory and if there were pending recollections.

MATERIALS AND METHODS

This is a retrospective, descriptive and exploratory study, from June 2013 to May 2015, developed in a private clinical analysis laboratory in the city of Maringá-PR. The laboratory has 17 outpatient care units throughout the city of Maringá and six units on the outskirts of the city, four of which are ambulatory units and two inpatients units.

The data was collected from forms of two natures, from the Quality Control Database reports of recollection and the non-compliance (NC) forms, all data is from the laboratory selected for the research. We considered the recollection of biological materials of all unit of Maringá and its surroundings, exclusion criteria were not applied. Regarding the NC forms, only those related to the pre-analytical procedures that led to errors were considered, the remaining forms were discarded.

The first data collection instrument was the Quality Control form from the selected laboratory, which includes information about the rejection criteria of the samples with a recollection order according to the total process phase, as shown in **Table 1**. These criteria were selected after consecutive meetings with the professionals involved in the quality management of the laboratory, including: clotted samples for hematology (tubes containing ethylenediaminetetraacetic acid [EDTA]) and coagulation tests; hemolysed or lipemics samples; unlabeled

TABLE 1 – Reason leading to recollection of biological sample according to the total testing process

Pre-analytical	Analytical	Post-analytical
Clotted sample	Inconclusive result	Confirmation of results
Hemolysed sample		
Lipemic sample		
Incorrect labeling		
Improper sample		
Insufficient specimen sample volume		

Source: Quality Control Database of the selected laboratory.

or incorrectly labeled samples; improper specimen (anti-coagulant or unsatisfactory tubes, collection tubes that did not follow adequate proportions of blood and anticoagulant); insufficient specimen sample; inconclusive results and confirmation of results. For this latter situation, the laboratory endorse that a new sample should be performed if the patient presents a medical history that contradicts the result obtained in the clinical trials, thus, the recollection is only required after the analysis of results, in the post-analytical phase.

The second form for collecting data was the NC form from the laboratory, containing: number, date, responsible personnel, description of the occurrence, corrective measure taken, deadline for implementation of corrective measure, whether the corrective measure was in fact helpful and signature of personnel in charge.

The recollection rate evaluated corresponds to the percentage of tests that required new collection and was used in the calculation for the biennium.

Descriptive statistics was used to evaluate data by using distribution and frequency, then showing the results as percentages.

The research project was approved by the Ethics Committee of the Centro Universitário Cesumar (UniCesumar), research under code 1.092.341.

RESULTS

During the period from June 2013 to May 2015, 707,449 tests were performed from samples collected from 111,604 patients. From the total, 1,274 tests had recollection order based on one of the criteria adopted by the laboratory, which represented a sample recollection rate of 0.18% for the studied period. **Figure 1** shows the sample recollection rate stratified by semester: from June to November 2013, 0.15%, in the following semester, 0.17%, in the third semester 0.20% and, in the last semestre, 0.19%.

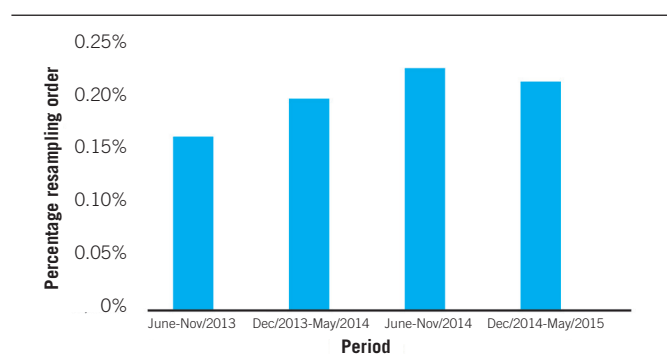


FIGURE 1 – Distribution of resampling percentage orders per semester

From 1,274 tests indicated for sample recollection, 199 (15.62%) could not be collected, representing 0.028% of the all tests performed during the studied period. Although the number of pending tests is small, when considering the number of patients involved in the sample recollection process, it was found that from a total of 1,049 individuals, 171 (16.30%) did not return to the laboratory to recollect the sample, which corresponds to 0.15% of the total patients attended during the study period. According to the reports of the Laboratory Quality Control Database, this fact is due to incorrect and/or incomplete registration of patients, so that it would be impossible to contact them, or due to lack of patient interest in returning to recollect the sample.

Figure 2 shows the distribution of recollection orders according to the total testing process. The pre-analytical phase represents the highest rate of sample recollection orders (70.80%), following the pre-analytical phase is the post-analytical phase (27.79%), and finally, with lower results when compared to the previous stages, the analytical phase (1.41%).

New collection orders were described for the analytical and post-analytical phases and showed inconclusive results and confirmation of results, as part of the criteria of the Laboratory Quality Management. Nevertheless, the causes for sample recollection of 902 tests in the pre-analytical phase involved

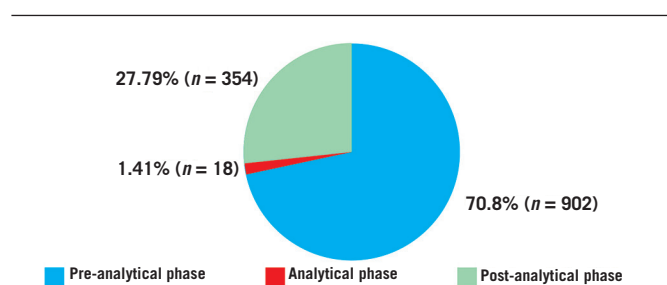


FIGURE 2 – Percentage distribution of recollection orders according to the total testing process of analysis

processes that could be avoided, these factors arisen due to: insufficient specimen sample, clotted and hemolysed samples, incorrect labeling of samples (Table 2).

When evaluating the NC forms records, 153 errors involving the pre-analytical phase were found during the studied period. Table 3 shows these records according to samples rejection criteria. Incorrect storage of specimen sample had the greatest occurrence, followed by discarded sample and improper sample. There was a homogenous distribution for all other parameters except for the hemolysed sample which represented only 3.27% of error records.

When comparing the records from the Quality Control Database recollection reports (Table 2) with the data obtained from the NC forms (Table 3), we observed that some criteria presented in these latter reports are not found in the new collection records, such as: incorrect storage of specimen sample, which led to collection of a sample that was not ordered; tests left undone, referring to tests in which samples were collected but not tested, according to the NC reports, they were just kept at the refrigeration room, or were discarded before testing; discarded specimen sample that was collected but was not sent to the sector; sample not collected, this item reflects the incorrect storage of specimen sample. Analogously, there was no NC record for the criterion regarding “lipemic sample”, identified in Table 2.

TABLE 2 – Distribution of sample recollection orders in the pre-analytical phase from June 2013 to May 2015

Justification	n	%
Clotted sample	174	19.29
Hemolysed sample	85	9.43
Lipemic sample	27	3
Incorrect labeling of sample	74	8.21
Improper sample	14	1.56
Insufficient specimen sample volume	528	58.54
Total	902	100

TABLE 3 – Non-compliance records involving the pre-analytical phase in the period from June 2013 to May 2015

Justification	n	%
Clotted sample	16	10.46
Hemolysed sample	5	3.27
Incorrect storage of specimen sample	27	17.65
Tests left undone	14	9.15
Incorrect labeling of sample	13	8.5
Improper sample	20	13.07
Discarded specimen sample	21	13.72
Insufficient specimen sample volume	26	16.99
Sample not collected	11	7.19
Total	153	100

DISCUSSION

Although sample recollection rate may be the quality indicator most commonly used by clinical laboratories, since it shows possible problems that require preventive actions, there is no agreement regarding its acceptable limit⁽³⁾. The goal set by the Laboratory Quality Management involved in this research was 0.25% maximum sample recollection rate, this threshold was based on personnel and processes costs. The rate achieved in this research was 0.18%, thus demonstrating that the laboratory is within the expected range of acceptable values. This value is very close to that found in the study of Codagnone *et al.* (2014)⁽¹⁵⁾, which reported 0.25%, however they are very low when compared to the study of other researchers that observed 2.7% of sample recollection⁽¹⁶⁾. A similar study carried out by Coriolano (2015)⁽¹⁸⁾ resulted in a rate of 0.62%; on the other hand, the author observed very few sample recollection orders in the second year of the study. In contrast, in this study, the sample recollection rates registered a slight increase of sample recollection orders in the second year, indicating that the strategies implemented were not effective or were not performed as originally planned. This is an important factor that must be considered, since these errors represent a threat to patient's welfare, potentially causing delays or failure in diagnosis; furthermore, it generates additional costs, increases the workload and compromises laboratory's image^(2, 4).

However, 15.62% of the tests ordered for sample recollection were not performed due to registration failure or lack of awareness of patients; this indicates the need to adjust strategies to reduce these errors. One option would be to offer extra laboratory sampling to the patient who has not returned the sample recollection form. This kind of specialized service can result in improving patient satisfaction, even if there are delays in releasing the results.

Wislocki (2011)⁽¹⁷⁾, when analysing some studies on laboratory error, observed variability of occurrence and distribution of them as dictated by stage process. However, all researches indicated that the pre-analytical phase concentrates the highest error rate associated with laboratory tests, which can reach up to 84.50% of general laboratory error; followed by the post-analytical phase, reaching up to 47%, and the analytical phase with less error rate, presented maximum occurrence of 13%.

The data found in this research have also proven that the pre-analytical phase is responsible for the vast majority of laboratory errors.

The main reason for this high incidence is the difficulty in controlling the variables of this phase, the majority of errors are concentrated in patient prepare and the moment of collection,

sectors that are not always under the control and supervision of the clinical laboratory, and that also depend on the patient's information and collaboration. Another important characteristic is the non-automation of most processes, which involves manual operations. However, high errors rates in this stage can indicate high turnover of personnel, negligence, lack of proper protocols and standardization of the service, or even failure in understanding the good practices on laboratory and ineffective professional training^(2, 4, 6-9, 11, 14, 15, 17).

Several studies describe that the pre-analytical errors mainly involve: 1) conflict when filling out the information – missing or inaccuracy of medical demand, misunderstanding or misinterpretation of medical demand, inaccuracy of patient's form and/or test, mislabelling of samples; 2) problems with sample gathering – inadequate patient prepare (fasting verification, diet, rest, time of sampling collection, when necessary), use of improper tube, hemolysis, clotted sample, lipemic sample, insufficient volume, exchange of specimen sample; 3) transport condition or improper storage – no observation of temperature, centrifugation and aliquoting problems, discarded samples^(3, 4, 7-9, 11, 13-15).

The information above described are consistent with data extracted from the report of the Laboratory Quality Management system in which the main reasons for sample recollection are mainly related to the collection process, for example, insufficient specimen sample volume and clotted samples. Other rejection criteria for the pre-analytical phase were: hemolysed sample, lipemic samples, and erros related to collection and identification of sample. The three last situations may involve more than issues related to the collection sector, problems with forms and patient records, as well as instructions to patients.

Insufficient sample volume can hinder the performance of all tests ordered. Clotting sample can result from incorrect mixture in the tubes or due to incorrect volume collected; since for the anticoagulant having the desired action it is necessary that blood/ anticoagulant ratio is observed as specified by the manufacturer. Hemolysed samples may occur due to improper collection or use of narrow diameter needles, shaking tube during transportation, storage at incorrect temperatures for long periods⁽¹⁸⁾.

According to Guimarães *et al.* (2011)⁽⁴⁾, before sample collection, the patient must receive written or verbal instructions that are easy to understand. The phlebotomist is responsible for observing the records and which tests were ordered, establishing communication with the patient, checking relevant data and information. The phlebotomist must follow the correct sequence of tubes to be used and the volume of blood that must be placed in each respective tube. Therefore, some authors recommend

that to minimize errors in the collection sector, the manual of procedures for biological sample collection should be prepared by the phlebotomists' team together with the laboratory quality department. Moreover, it is important to have other programs such as continuous education with training and professional capacity-building, enabling the professionals involved in this process to understand that this stage is crucial to ensure good quality of service^(4, 5, 9, 10, 19).

Another method used to manage quality in the clinical laboratory, besides the use of quality indicators, is the management of "non-compliance" which is a document that must be filled when there is failure in complying requirement specified by the policy and procedures, and thus requiring correction of a particular process stage. It originates in one or more "roots", which is considered as such when the correction eliminates the problem and its recurrence. However, for the evaluation of these causes and the standardization of corrective measures, the error registration is mandatory. Therefore failure in documentation causes the perpetuation of these errors^(9, 13, 17, 18).

The NC records from the studied laboratory involving pre-analytical errors showed different results from those presented by the recollect reports of the Quality control database. The number of NC in the pre-analytical phase for the studied period was lower for recollection data. Incorrect filing of specimen, tests not performed, loss of specimen, and specimen sample not collected, were the reasons that led to a new collection which are not present on the laboratory's virtual Quality Control report. Accordingly, there were no NC forms for lipemic samples, and probably most professionals consider this condition as inherent to the patient.

However both records agree that pre-analytical errors found in this study are rooted in patients' recording and collection sectors.

It was observed that the data identified in the virtual report of the Quality Management system and the NC records work as two different types of reporting. The study carried out by Mugnanol and Ferraz (2006)⁽¹⁾ warned that laboratory systems were thought to be satisfactory for operational activities, but not enough to manage activities. Therefore, it is recommended that a more accurate method for detection and classification of error during the pre-analytical phase, with proper use of technology. A solution to unify data and the correct form would be to register on system the reasons behind a sample recollection, and the same system would generate the NC form. From the identification and correct documentation of the pre-analytical error nature, corrective measures can be implemented so that the error can be overcome also avoiding recurrences^(5, 17).

CONCLUSION

The results of this study clearly point out the problems in collection and patient record sectors, corroborating the main problems faced by clinical laboratories regarding failure in quality specification of the pre-analytical phase. Honestly, evaluating and managing the pre-analytical errors in the clinical laboratories is a complex process since it involves many variables and professional services. However, these errors can be reduced where there are quality control strategies that focus on development, education and training of professionals involved.

RESUMO

Introdução: A fase pré-analítica envolve a maior parte dos erros dos laboratórios de análises clínicas. Informações que caracterizem a ocorrência desses erros podem ser úteis para disponibilizar estratégias de prevenção e redução. **Objetivo:** O objetivo principal deste estudo foi identificar os principais erros na fase pré-analítica de um laboratório privado da cidade de Maringá-PR e sua frequência de ocorrência. **Materiais e métodos:** Foram coletados dados dos pedidos de coleta de junho de 2013 a maio de 2015. Ao todo, foram cadastradas coletas de 707.449 exames; destes, 1.274 (0,18%) tiveram pedidos de nova coleta com base em algum critério adotado pelo laboratório. **Conclusão:** A etapa pré-analítica representou 70,80% dos pedidos de nova coleta. Segundo os relatórios do Banco de Dados do Controle de Qualidade, o motivo mais frequente de coletas na etapa pré-analítica foi material insuficiente (58,54%), seguido por amostra coagulada (19,29%), amostra hemolisada (9,43%), identificação errada (8,21%), amostra lipêmica (3%) e material errado (1,56%). Embora os resultados dos formulários de não conformidades apresentassem registros diferentes destes, ambos apontam claramente problemas no setor de coleta e cadastro do paciente, confirmando que os principais problemas dos laboratórios clínicos provêm da falta de especificações de qualidade para a fase pré-analítica.

Unitermos: coleta de amostras sanguíneas; gestão de qualidade; segurança do paciente.

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