The use of indicators in the pre-analytical phase as a laboratory management tool

O uso de indicadores da fase pré-analítica como ferramenta da gestão laboratorial

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ABSTRACT

Introduction: Efficient laboratory services are the basis of modern health systems. Scientific innovations have contributed to substantial improvements in the laboratory environment, but errors still persist. These errors are classified as pre-analytical, analytical and post-analytical, according to the time of occurrence. **Objective:** To evaluate the frequency of pre-analytical errors in the clinical laboratory service of a military hospital. **Methods:** A total of 329,582 tests were performed in the clinical laboratory of Hospital Naval Marcílio Dias (HNMD) from August to October 2012, and pre-analytical errors were documented. **Results:** The most frequent cause of the observed pre-analytical errors was hemolysis (27.54%), followed by samples not received (25.43%) and insufficient sample volume (18.49%). The samples from the Integrated Home Care Service (SIAD) showed the highest frequency of errors (3.38%), followed by those from the inpatient (0.76%) and the outpatient departments (0.21%). **Conclusion:** Our study demonstrates the importance of managing laboratory pre-analytical quality in order to ensure service excellence.

Key words: laboratory error; clinical laboratory; quality; laboratory indicators.

INTRODUCTION

Laboratory processing consists of a sequence of procedures that begins with the ordering of tests by physicians, and ends with the interpretation – also by physicians – of the test results. The three phases of this cycle – pre-analytical, analytical and post-analytical – are subject to innumerable possibilities of error that affect quality and reliability of results[12]. According to ISO/TS 22367:2008, laboratory error may be defined as any defect during the laboratory cycle, resulting from a badly-planned action or a non-achieved aim, which may occur from ordering tests to interpreting their results[9, 14].

The pre-analytical phase comprises all the processes occurring before the sample is processed in the analyzer. In this phase one may observe the highest frequency of errors, the highest risk to professionals' health and the highest rates of human error. Studies indicate that approximately 40% to 70% of errors occur in the pre-analytical phase[1, 3, 7, 8, 15, 16, 21].

Errors in this phase generally occur from high personnel turnover rates, negligence, lack of understanding about good laboratory practices, and ineffective training[8, 12]. They include inappropriate test request, inadequate samples, delays in transport or inappropriate storage, illegible requisitions, improper venipuncture, inadequate instructions to patients (as to previous

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fasting, special diet, medicine use, etc.), incorrect identification of samples, insufficient sample volume, among others[4, 15, 21, 22]. Such errors normally lead to sample rejection, and consequently, they produce insecurity, dissatisfaction, inconvenience and anxiety, in both doctors and patients; unnecessary costs; prolonged turnaround time; rework; loss of laboratory credibility and loss of confidence in the laboratory. Difficulties to control pre-analytical variables and to make process improvements are possible causes for the high prevalence of errors in this phase.

In the health area, quality philosophy does not differ from that applied to industries. Adequacy of the product or service to meet customer needs is a fundamental element of quality, perfectly applicable to the several health care services[14]. Provision of good services implies two basic components of quality: the operational, which corresponds to the process itself; and the perception, or how clients perceive the offered service. These components may be measured by quality indicators (QIs), and recognition is obtained through certification and accreditation processes[14].

QIs allow for internal and external comparisons with other services sharing the same characteristics. They are called, in quality management, control items[21].

OBJECTIVE

The main purpose of this study is to assess the frequency of pre-analytical errors occurring at the clinical laboratory service of Hospital Naval Marcílio Dias (HNMD) in the divisions of hematology, immunology/hormones, biochemistry, parasitology and microbiology. The study also aims at assessing the frequency of errors from different sources: outpatient and inpatient departments, and Integrated Home Care Service (SIAD).

METHODS

Research site

HNMD is a general hospital providing care in approximately 41 specialties. Patients come from the Navy Health System, comprising active duty, retired military personnel, and their dependents. The hospital offers 507 beds, diverse services (dentistry, physical therapy, radiodiagnosis, clinical pathology, anatomical pathology, etc.), modern facilities and a highly skilled clinical staff.

The clinical laboratory service is part of this structure, with a team of phlebotomists qualified for the collection of blood samples.

The laboratory monthly performs 19,500 blood collections and 11,000 exams in the areas of hematology, biochemistry, urinalysis, microbiology, immunology and parasitology. The service operates 24 hours a day, seven days a week, including inpatient ward, emergency department, urgent care, and integrated home care for the elderly and/or those experiencing degenerative diseases. The different divisions are supplied with modern equipment, acquired under a commodate contract, and represent the state of the art in terms of technology and operational capacity.

The laboratory process is daily monitored by internal quality controls, and monthly monitored by proficiency testing by the Sociedade Brasileira de Patologia e Medicina Laboratorial (SBPC/Controllab). After technical validation, all the results are transmitted electronically to the several clinics of the hospital.

All the laboratory divisions have standard operating procedures (SOPs) for their different processes. SOPs are periodically updated.

Criteria for inclusion of data and parameters

The data derived from pre-analytical errors were obtained by analysis of sample rejections and requests of new sample collection for tests in the divisions of immunology/hormones, biochemistry, hematology, parasitology, and microbiology. Data were gathered from August to October 2012. The members of each division were in charge of the criteria for sample acceptability/rejection, based on the internal quality program of the clinical laboratory service.

The rejection criteria in clotted, hemolyzed and lipemic samples were visually applied. Only the clotted samples collected in tubes with ethylenediaminetetraacetic acid (EDTA) and sodium citrate were counted. The samples considered with insufficient volume were those presenting volume lower than the necessary for the conduction of a specific test, previously standardized and/or by consensus of the laboratory staff in this hospital.

The rejection criteria used in this work were:
- total of clotted samples;
- samples affected by an accident;
- insufficient sample volume;
- hemolyzed serum or plasma;
- result confirmed by the technical staff;
- clotted material;
- material collected in an inappropriate tube;
- material lost/not received;
- sample with inadequate anticoagulant/blood ratio;
- misidentification.

These criteria were selected after consecutive meetings with professionals involved in the quality management of the clinical laboratory service at HNMD.

Statistical analysis

The statistical analysis was performed using the program Excel, and the graphs were generated by the program Prism. Frequency and percentage were obtained using univariate analysis. Results were expressed as percentage (%).

Limitations of the study

Data derived from the emergency department could not be computed due to limitations in our laboratory information system. This happened because the ordering of new sample collection created an outstanding issue, interfering with the average release time of results from this source.

RESULTS

A total of 329,582 exams were conducted in the period of this study, of which 806 presented some type of pre-analytical error (0.25%). The three main observed causes of pre-analytical errors were hemolysis (27.54%), material not received (25.43%) and insufficient sample volume (18.49%) (**Table**).

TABLE − Absolute and relative error frequency, by cause

	F	Total of exams	F%	% Pre-analytical error
Accident in the division	27	329,582	0.01	3.35
Insufficient sample volume	149	329,582	0.05	18.49
Result confirmed	108	329,582	0.03	13.4
Hemolysis	222	329,582	0.07	27.54
Clotted material	79	329,582	0.02	9.8
Material not received	205	329,582	0.06	25.43
Others	16	329,582	0.01	1.99
Total	806	329,582	0.25	100

F: absolute frequency; F%: relative frequency.

When analyzing error frequency per source, we verified that the outpatient service carried out 153,460 tests, with 329 presenting pre-analytical errors (0.21%). The inpatient service carried out 44,469 tests, and the absolute error frequency was 336 (0.76%). The SIAD was responsible for 975 tests, whose pre-analytical errors amounted to 33 (3.38%) (**Figure 1**).
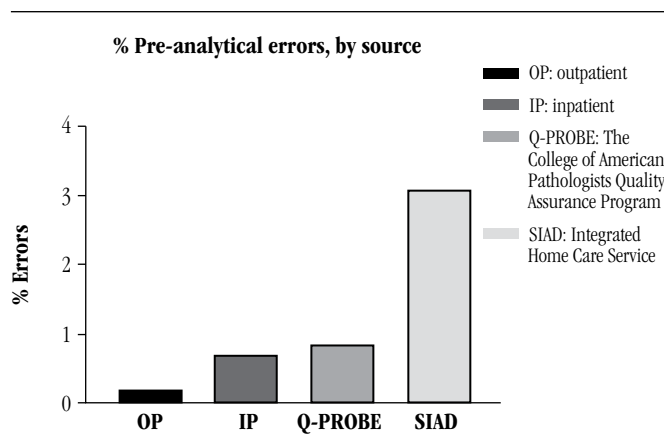

FIGURE 1 − *Relative frequency of pre-analytical errors, by source, compared to the limits accepted in the program Q-PROBE*

DISCUSSION

The relative error frequency in our study is in accordance with the international literature: 0.25%. It contrasts with 1.52% of Chawla *et al.*[4], 0.74% of Stark *et al.*[12], and 1.4% of Goswami *et al.*[6]. The College of American Pathologists Quality Assurance Program (Q-Probe)[5] has xreported xsample/specimen rejection ranging from 0.3% to 0.83% (**Figure 2**).
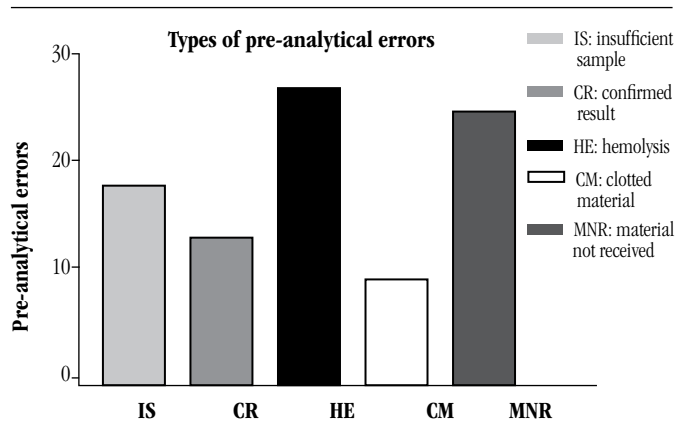

FIGURE 2 − *Relative frequency of the main pre-analytical errors*

We must draw attention to the variety of methods adopted in the several studies, as well as the different ways to quantify these nonconformities: parts per million (ppm) in the studies by Plebani, Zago and Carraro; accumulated and relative frequency in the studies by Chawla, Stark and Goswami. Still, there are some authors who count rejected samples[4, 6, 7], other rejected tests, or tests with nonconformities[20]. In our study, due to questions inherent to our information system, we counted absolute and relative frequency of wrong exams, as well as Stark *et al.*[20] did.

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These method differences decrease the "power" of comparison between studies, and reflect structural differences between diverse laboratories. Attempts at standardization have been the object of study by various societies of laboratory medicine (College of American Pathologists, Sociedade Brasileira de Patologia e Medicina Laboratorial, Sociedade Brasileira de Análises Clínicas), but the search for laboratory QIs still remains[21].

The chief cause of error in the pre-analytical phase was hemolysis, confirming the studies by Chawla[4] and Stark[20]. Hemolysis is responsible for the rejection of countless exams, like lactate dehydrogenase (LDH), acid phosphatase, and potassium tests, aspartate transaminase (AST), alanine transaminase (ALT), prothrombin time (PT), activated partial thromboplastin time (aPTT), among others[11, 13, 17, 23]. According to Jacobs et al.[10], the estimated cost of repeating hemolyzed specimens is approximately €4355 per month, plus additional time and use of equipment, based on an average of 60 admissions/day. Factors related to the collection of diagnostic blood specimens, such as maximum time for tourniquet application, inadequate constriction of the forearm muscles, adequate selection of the needle gauge for venipuncture, may increase the incidence of hemolysis, and, consequently, sample rejection[12].

To our surprise, material not received was the second cause of errors, resulting in 25.45% of pre-analytical errors in this study. Although this QI is not found in the literature, we decided to include it after discussions about the most appropriate indicators for our routine. We defend that this QI works as a process indicator that will bring us information on collection, as a not received blood specimen will forcefully generate an order for new collection. The lack of a specific division for receiving and distributing samples, the low automation of the pre-analytical phase in our routine, and the low level of integration in the divisions of our laboratory may be possible causes for this discrepancy[2].

Insufficient sample volume was the third cause of error, responsible for 18.49% of pre-analytical errors. In the study by Guimarães et al.[7], this cause took second place, representing 24% of total pre-analytical errors. We point up that this study was also conducted in Brazil, in a hospital laboratory similar to ours.

In the study by Stark et al.[20], the relative frequency of error due to insufficient sample volume was 1.2%, very different from the one in our study and from those in most studies in this area. This piece of data may reflect how difficult collection of the blood specimen is from hospitalized patients, or outpatients under chemotherapy, as it is in our routine, although we cannot affirm it confidently, once it is not the aim of our study.

SIAD presented the greatest frequency of errors, followed by inpatient and outpatient services, respectively. The high rate of errors in the SIAD source may result from several factors, like insufficient training of phlebotomist/nursing staff about the best practices of blood collection, the increased prevalence of elderly patients or patients with chronic degenerative diseases with difficult venous access, or inadequate transport of samples from patients' home to HNMD laboratory. We must underline that this service is provided by a third-party company, but under the complete responsibility of HNMD.

We emphasize that there is no reference in the literature to the percentage of pre-analytical errors derived from the home care service, as it is the case of SIAD, nor from a so stratified sample of patients: elderly people, and with chronic degenerative diseases. In the future, this may become a public health problem, as our population ages.

CONCLUSION

In spite of the technological improvements in laboratory medicine, the pre-analytical phase is still the main responsible for laboratory errors[1, 3, 4, 6-8, 12, 15, 16, 20, 21]. In our study, we demonstrated that the frequency of pre-analytical errors in our laboratory routine (0.25%) is in accordance with the international scientific literature. However, when analyzing the different sources of these errors, we observe that SIAD presented the major rate of errors, falling outside the internationally accepted range. This is the first study to analyze the pre-analytical errors arising from a home care service, reinforcing the need of constant training for all the laboratory team members.

RESUMO

Introdução: Serviços laboratoriais efetivos são a base dos sistemas de saúde modernos. Inovações científicas têm contribuído para melhorias substanciais no meio laboratorial, mas os erros ainda persistem. Esses erros são classificados como pré-analíticos, analíticos e pós-analíticos, dependendo do momento de sua ocorrência. Objetivo: Avaliar a frequência de erros pré-analíticos ocorridos no serviço de análises clínicas de um hospital militar. Métodos: Um total de 329.582 exames foram realizados no

*laboratório de análises clínicas do Hospital Naval Marcílio Dias no período de agosto a outubro de 2012, e os erros pré-analíticos documentados. **Resultados:** Os erros pré-analíticos mais observados foram decorrentes da hemólise (27,54%), seguidos de material não recebido (25,43%) e amostra insuficiente (18,49%). As amostras oriundas do Serviço Integrado de Atendimento Domiciliar (SIAD) foram as que apresentaram a maior frequência de erros (3,38%), seguidas pelo setor de pacientes internos (0,76%) e ambulatoriais (0,21%), respectivamente. **Conclusão:** Nosso estudo demonstra a importância da gestão da fase pré-analítica na garantia da qualidade laboratorial, de maneira a assegurar um serviço de excelência.*

Unitermos: erro laboratorial; laboratório clínico; qualidade; indicadores laboratoriais.

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