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(6,12). They include inappropriate test request, inadequate samples, delays in transport or inappropriate storage, illegible requisitions, improper venipuncture, inadequate instructions to patients (as to previous
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[11].

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

*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).

When comparing error frequency per source, it is observed that outpatient service showed the lowest frequency of pre-analytical errors, 0.21%, while the inpatient service showed 0.76%, which is higher. The SIAD showed 3.38%, which is significantly higher compared to the other sources.

**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 reported sample/specimen rejection ranging from 0.3% to 0.83% (Figure 2).

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, 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.
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 serviço de análises clínicas de um hospital militar. O objetivo era avaliar a frequência de erros pré-analíticos ocorridos no serviço de análises clínicas de um hospital militar.

RESULTADOS

A frequência de erros pré-analíticos foi de 25,4%. Os principais erros foram: inadecuada consistência do braço, insuficiência de volume amostral, eletrocardiograma e declaração de hemólise.

CONCLUSÃO

Os erros pré-analíticos são uma das causas principais de erro no laboratório. É essencial que as equipes de laboratório estejam sempre treinadas e conscientes dos erros que podem ocorrer.
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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