Analysis of preanalytical errors by different autoanalyzer and sample types

Abstract

Aim: In this study, it was aimed to determine the causes of preanalytical errors according to the different autoanalyzer and sample types. Material and Method: The rejected biological samples were analyzed in the laboratory information system of Mengücek Gazi Training and Research Hospital between January 1, 2017 and December 31, 2017. According to device types, reasons for rejection and rejection rates were identified. Results: At the indicated dates, 748758 samples were reached in the laboratory, of which 4245 (0.56 %) were rejected. The reasons for rejection are mostly following: incorrect test request (53.6 %) and hemolysis (22.6 %) in the biochemistry samples, inadequate sample (61.5 %) and incorrect test request (30.2 %) in hormone samples, clotted samples (76.9 %) and incorrect sample container (7.9 %) in hemogram samples, level error (38.5 %) and clotted sample (31.3 %) in coagulation samples, clotted sample (89.1 %) and inadequate sample (5.7 %) in the blood gas samples, incorrect sample container (53.7 %) and incorrect test request (21.1 %) in the nephelometer samples, incorrect sample container (37.4 %) and clotted samples (34.1 %) in the sedimentation samples were identified. Discussion: The preanalytical error sources vary according to the sample types and autoanalyzers. These results should be stated in personnel training and necessary precautions should be taken.

Keywords

Preanalytical Error; Hemolysis; Clotted Samples; Insufficient Sample; Incorrect Test Request; Incorrect Sample Container

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Introduction
The process of requesting a test to completion is roughly divided into pre-analytic, analytical and post-analytic phases in the clinical laboratory. In this process, the main goal is to present accurate, reliable and precise laboratory results to service areas in time. Any disruption to any of these processes inevitably leads to errors in the test results [1]. The preanalytical phase includes testing the test requests, verification of identity information, collection of blood, collection of samples and transport to the laboratory in appropriate conditions. The analytical phase is the analysis when the analytical sample is analyzed by suitable analytical methods. The post-analytic stage is defined as the phase when the test result obtained from the analysis of the sample is transferred to the information management system, the results are evaluated, and the clinician receiving the test result is delivered [2].

A large majority of laboratory errors (70%) occur in the preanalytical phase [3]. The major sources of error that can be seen at this stage are incorrect test requests, identification of incorrect identification information, use of inappropriate material (tube, needle bar), long-time tourniquet applications, inadequate bulk samples, haemolysis, samples taken from intravenous infusion, fasting status, samples taken at inappropriate times, specimens transported in laboratory under inappropriate conditions [4].

Due to the importance of investigation of the sources of error and performing root analyzes in terms of preventing or minimizing these mistakes, in this study, we aimed to determine the causes of preanalytical errors according to the different autoanalysers and sample types.

Material and Method
In this retrospective study, rejected biological samples were analyzed in the laboratory information system (LIS) of Mengucek Gazi Training and Research Hospital between January 1, 2017 and December 31, 2017. According to device types, reasons for rejection and rejection rates were identified. The samples from the blood collection unit and the services are evaluated in the sample acceptance unit and the appropriate samples are accepted. Inappropriate samples are evaluated within the scope of the preanalytical error and rejected by entering the LIS in the sample acceptance unit. The preanalytical faulty samples (hemolysis, lipemia, etc.) detected during the analysis phase are rejected by the technicians and new samples are requested. The samples evaluated as incorrect are recorded in the system. Sample rejection reasons defined in our laboratory are empty sample container, incorrect sample container, incorrect test request, sample clotted, sample collection from the wrong patient, inadequate sample, hemolyzed sample, lipemic sample, level error.

Firstly, the total and rejected number of samples were obtained by LIS. Then the rejection frequency was calculated as a percentage according to the reason using the following formula: sample rejection frequency according to the cause of rejection = (number of rejected samples based on rejection + total number of samples) × 100

Statistical analysis
For each group, sample numbers, error numbers, and percentages are given. Percentage values of the data obtained from error numbers in the calculation were reevaluated using Microsoft Office Excel program.

Results
Of 748758 samples reached in the laboratory, 4245 (0.56%) were rejected between January 1, 2017 and December 31, 2017. The sample numbers rejected according to the rejection reasons defined in our laboratory and the percentages are shown in Table 1. In this study, the ratio of the number of rejected samples to the total number of samples in one year in our laboratory was found to be 0.56%. The number of rejected samples and percentage of the total number of samples in their group were as follows: biochemistry 597 (0.289%), hormone 743 (0.504%), hemogram 930 (0.460%), coagulation 456 (0.977%), blood gas 1137 (0.505%), nephelometer 227 (0.316%) and sedimentation 155 (% 0.277). The reasons for rejection were mostly following: incorrect test request (% 53.6) and hemolysis (% 22.6) in the biochemistry samples, inadequate sample (22.6%) and incorrect sample container (7.9) in hemogram samples, level error (38.5%) and clotted sample (31.3%) in coagulation samples, clotted sample (89.1%) and

<table>
<thead>
<tr>
<th>Rejection reason</th>
<th>Biochemistry n (%)</th>
<th>Hormone n (%)</th>
<th>Hemogram n (%)</th>
<th>Coagulation n (%)</th>
<th>Blood Gase n (%)</th>
<th>Nephelometry n (%)</th>
<th>Sedimentation n (%)</th>
<th>Total n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Empty sample container</td>
<td>3 (0.5)</td>
<td>2 (0.2)</td>
<td>5 (0.5)</td>
<td>-</td>
<td>9 (0.7)</td>
<td>2 (0.8)</td>
<td>7 (4.5)</td>
<td>28 (0.00)</td>
</tr>
<tr>
<td>Incorrect sample container</td>
<td>28 (4.6)</td>
<td>40 (5.3)</td>
<td>74 (7.9)</td>
<td>56 (12.2)</td>
<td>11 (0.9)</td>
<td>122 (53.7)</td>
<td>58 (37.4)</td>
<td>389 (0.05)</td>
</tr>
<tr>
<td>Incorrect test request</td>
<td>520 (83.6)</td>
<td>225 (30.2)</td>
<td>5 (0.5)</td>
<td>13 (2.8)</td>
<td>10 (0.8)</td>
<td>48 (21.1)</td>
<td>2 (1.2)</td>
<td>623 (0.08)</td>
</tr>
<tr>
<td>Sample clotted</td>
<td>9 (1.5)</td>
<td>2 (0.2)</td>
<td>716 (76.9)</td>
<td>143 (31.3)</td>
<td>1014 (89.1)</td>
<td>8 (3.5)</td>
<td>53 (34.1)</td>
<td>1945 (0.25)</td>
</tr>
<tr>
<td>Sample collection from the wrong patient</td>
<td>24 (4.0)</td>
<td>4 (0.5)</td>
<td>58 (6.2)</td>
<td>9 (1.9)</td>
<td>9 (0.7)</td>
<td>9 (3.9)</td>
<td>5 (3.2)</td>
<td>118 (0.01)</td>
</tr>
<tr>
<td>Inadequate sample</td>
<td>42 (7.0)</td>
<td>457 (61.5)</td>
<td>54 (5.8)</td>
<td>-</td>
<td>65 (5.7)</td>
<td>26 (1.1)</td>
<td>130 (19.3)</td>
<td>674 (0.09)</td>
</tr>
<tr>
<td>Hemolyzed sample</td>
<td>135 (22.6)</td>
<td>4 (0.5)</td>
<td>23 (5.0)</td>
<td>-</td>
<td>7 (3.0)</td>
<td>-</td>
<td>169 (0.02)</td>
<td></td>
</tr>
<tr>
<td>Lipemic sample</td>
<td>3 (0.5)</td>
<td>-</td>
<td>-</td>
<td>8 (1.7)</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>11 (0.00)</td>
</tr>
<tr>
<td>Level error</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>176 (38.5)</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>176 (0.02)</td>
</tr>
<tr>
<td>Unspecified</td>
<td>33 (5.5)</td>
<td>9 (1.2)</td>
<td>18 (1.9)</td>
<td>28 (6.1)</td>
<td>19 (1.6)</td>
<td>5 (2.2)</td>
<td>-</td>
<td>112 (0.01)</td>
</tr>
<tr>
<td>Total rejected sample number</td>
<td>597 (100)</td>
<td>743 (100)</td>
<td>930 (100)</td>
<td>456 (100)</td>
<td>1137 (100)</td>
<td>227 (100)</td>
<td>155 (100)</td>
<td>4245 (100)</td>
</tr>
<tr>
<td>% of rejected samples to total sample</td>
<td>0.289</td>
<td>0.504</td>
<td>0.460</td>
<td>0.977</td>
<td>6.05</td>
<td>0.316</td>
<td>0.277</td>
<td>0.56</td>
</tr>
</tbody>
</table>

Table 1. The sample numbers rejected according to the rejection reasons defined and the percentages.
inadequate sample (5.7%) in the blood gas samples, incorrect sample container (% 53.7) and incorrect test request (% 21.1) in the nephelometer specimens, incorrect sample container (37.4%) and clotted samples (34.1%) in the sedimentation samples. It was found that according to the total number of samples in their group, the most rejection was in blood gas and coagulation samples. Clotted samples and inadequate samples were the most common causes of rejection when all samples were evaluated together.

**Discussion**

The role of medical laboratories in clinical diagnosis and treatment management is about 70% [1,5]. This rate signifies the necessity of proper execution of the laboratory processes. Because of the mistakes made in these processes, the consequence of the wrong test will put patient safety in jeopardy [6]. The majority of laboratory errors are in the preanalytical phase and errors, in this case, are usually due to unsuitable samples for analysis. Since these samples are rejected by the laboratories, they cause a new sample requirement and therefore cause the test to lengthen the yield period [7].

In this study, the 0.56% value of the sample rejected within one year in our laboratory is similar to the values reported in the literature [8,9,10,11]. Although it is important to reduce this rate to a minimum, it is not realistic to be 0% [11]. However, there is no clear information about what this minimum ratio is. Very different values of sample rejection rates were found in the studies conducted. For example, in a multicenter study, hemolyzed sample rejection ranged from 0.3% to 3.4%, clotted sample rejection ranged from 0.013% to 1.7%, and blood anticoagulant ratio of non-compliance rejection rates ranged from 0% to 1.09% [12]. Guimaraes et al. [8] and Lay et al. [13] found that the most common reasons for rejection were clotted sample and inadequate sample similar to our results. The first study found as close to our conclusion that gained 0.57% rejection rate but a higher value of 2.7% was found in the latter. Goswami et al. [14] found hemolysis and inadequate sample rejection as the most frequent causes of rejection and 1.1% rejection rate. Grecu et al. [9] found hemolysis and clotted sample as the most frequent causes of rejection and found 0.8% rejection rate. Chawla et al. [15] found hemolysis and blood-anticoagulant incompatibility and rejection rate as 1.33%. In another study [10], the most common reasons for rejection were inadequate samples and clotted samples, and the rejection rate was 0.65%. Such different ratios indicate the importance of each laboratory doing its own rejection analysis. Because the causes of rejection in each laboratory may be different. Therefore, the precautions to be taken against it will be different too.

The highest rejection rate in the present study was found in blood gas specimens as clotted sample because blood gas samples should be delivered to the laboratory in a short time and immediately studied. However, due to the operational difficulties, the clot rate is increasing because this period is prolonged. The second frequency is found to be in coagulation samples as the level error. As the ratio of the amount of anticoagulant in the coagulation tubes to the amount of the sample directly affects the outcome of the patient, which can put the safety of the patient at risk, so the staff member takes care of the problem of level rejection especially in anticoagulant tubes. The use of an injector instead of a vacuum tube during blood collection and mistakes in the amount of vacuum in the tubes are the main reasons for the level error in the sample quantity, because when the tubes have the proper vacuum and the blood is taken from the vacuum tube, each tube is automatically filled up to its level. However, it is not always possible to catch the appropriate level when the injector is taken and the blood is transferred by opening the cap on the tube. Clotted sample rate in hemogram samples was the highest because hemogram samples should be mixed up at least 8-10 times after taking them. However, the clotted sample rate is increasing because of the intensity of the work or from carelessness or lack of knowledge about this process. In hormone samples, insufficient samples were the most common rejection. This is due to the need for a partly larger sample volume for hormone tests. The most common causes in biochemistry samples were incorrect test request and hemolyzed samples. Reason for rejecting the test for incorrect test request is often due to especially the ones that are requested from the emergency laboratory but not carried out in the emergency laboratory (such as cholesterol). Because all the emergency and routine laboratory results are evaluated together in this study. The most frequent causes of hemolysis are blood collection by the injector, the emptying of the needle with strong pressure before removing the needle, the removal of blood from the alcohol used for the blood still wet cleaning the blood collection area and not the gentle movement of the tubes in the vertical position during the sample transportation.

Due to the fact that hemolysin affects biochemical tests, in particular, the sensitivity of the working personnel is another cause of the high rate of hemolysis-induced rejection in biochemical specimens. In nephelometer specimens, the highest rejection was due to the incorrect sample container. The reason for this may be that the carrying out of nephelometer samples from EDTA tubes in the emergency laboratory but from gel tubes in the routine laboratory may have caused the confusion from time to time. The highest rejection in sedimentation samples was due to the incorrect sample container and clotted sample. This may be due to the fact that the sample staff does not comply with the rules, inadequacy of information, lack of obedience, not obeying the procedures, especially sedimentation samples which are carried out from the EDTA tube coagulate after ingestion due to they are not sufficiently mixed up.

Ozcan et al. [16] found the highest rates of rejection in coagulation and sedimentation samples. However, unlike our study, in their study, blood gas samples were not included in the study. Ankan et al. [17] found that the most common reasons for rejection were clotting and hemolysis, and the most frequently rejected samples were hemogram and biochemistry. However, this study was done in the public health laboratory and blood gas and coagulation samples were not included.

Ogz et al. [18] found the most frequent error rates in the central laboratory in hemogram samples and blood gas samples in the emergency laboratory. In the same study, the rejection rate of blood gas samples was found to be 11.43%, whereas it was found to be 20.87% in coagulation samples. However, as this study was done in pediatric laboratories, these rates may have been so high because of the difficulty of taking blood in...
children.

Küme et al. [19] found the most common reasons for rejection level error in coagulation samples, hemolysis in biochemistry samples, clothed samples in blood gas and hemogram samples. In some studies [20,21], hemolysis is the most frequent cause of rejection, whereas in this study the most important reason for the lesser cause of hemolysis-induced rejection is the fact that the partial hemolyzed sample is not rejected by the laboratory technician in most cases. Sometimes it is necessary to find and study samples taken for other types of devices that use the same sample pattern for an insufficient sample (e.g. finding and studying from a biochemical sample of a patient with an insufficient hormone sample). Therefore, the exact false sample rate is higher than the value found, given these circumstances. But that comes with a special injector, such as blood gas samples with no alternative, work even in such cases the asking coagulation a high error rate was found in samples without the possibility of work and probably closer to the actual value.

As a result, preanalytical error sources in this study were found to be different according to sample types and autoanalyses. These results should be stated in personnel training and necessary precautions should be taken. It is very important to keep the preanalytical processes under control for the correct result that have the most effect on the result of the laboratory and the most mistakes being observed. It is important for the laboratory and the hospital to keep the conditions of the patient in view and to make the necessary plans for error correction.

Scientific Responsibility Statement

The authors declare that they are responsible for the article’s scientific content including study design, data collection, analysis and interpretation, writing, some of the main line, or all of the preparation and scientific review of the contents and approval of the final version of the article.

Animal and human rights statement

All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. No animal or human studies were carried out by the authors for this article.

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Conflict of interest

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