Quality Indicators in the Preanalytical Phase of Testing in a Stat Laboratory

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ABSTRACT

Objective: To quantify performance in the preanalytical phase in a stat laboratory using quality indicators, and compare our results with those in the literature to improve laboratory services.

Methods: We counted the test request forms, samples, and the types of preanalytical errors that occurred in a stat laboratory between January 1 and December 31, 2011. We then compared the quality-indicator scores with the quality specifications mentioned in the literature.

Results: During the 1-year period, a total of 168,728 samples and 88,655 requests forms were received in stat laboratory. The total number of preanalytical errors was 1,457, accounting for 0.8% of the total number of samples received in a year. Of the total preanalytical errors, 46.4% were hemolyzed samples (biochemistry), 43.2% were clotted samples (hematology), 6.4% were samples lost-not received in the laboratory, 2.9% samples showed an inadequate sample-anticoagulant ratio, 0.7% were requests with errors in patient identification, 0.3% were samples collected in blood collection tubes with inappropriate anticoagulant and 0.1% were requests with errors–missing test requests.

Conclusion: The preanalytical performance of a stat laboratory in our setting is favorable and complies with international quality specifications.

Keywords: preanalytical phase, quality indicators, sigma metrics

The 2007 ISO 15189 standard “Medical laboratories: Particular requirements for quality and competence” establishes that the preanalytical phase of the testing process begins with the test request from the healthcare provider and includes the requisition, preparation of the patient, collection of the primary sample, and transportation of the sample to and within the laboratory. The preanalytical phase ends when the analytical examination begins. Clause 4.12.4 of this standard, which is used for medical laboratory accreditation, requires the implementation of quality indicators (QIs) for systematically monitoring and evaluating the contribution of the laboratory to patient care and the identification of improvement opportunities.1 Quality indicators constitute objective measures that can be used to evaluate critical health care dimensions (eg, patient safety, effectiveness, equity, patient-centeredness, timeliness, and efficiency).2 Hence, quality indicators are tools that enable the quantification of laboratory performance based on objective criteria.

Recently, there has been increasing interest among healthcare professionals in quality assurance in the pre- and postanalytical phases of laboratory testing.3, 4 The International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) Working Group on Laboratory Errors and Patient Safety (WG-LEPS) has made an important contribution to developing QIs for the preanalytical phase and specifications for those indicators.5-7 A clear definition of how QIs are evaluated and the development of performance levels (eg, unacceptable, minimum, and desirable) are useful for laboratory performance evaluation, especially in the preanalytical phase. In a project focused on reducing laboratory testing errors, the IFCC WG-LEPS developed a series of QIs specific to clinical laboratories. Of these, 16 focused on the preanalytical phase. Based on data collected from the 39 laboratories involved in the project from February 2008 through December 2009, the following parameters were calculated for each QI: Mean

Abbreviations

QIs, quality indicators; IFCC, International Federation of Clinical Chemistry and Laboratory Medicine; WG-LEPS, Working Group on Laboratory Errors and Patient Safety; DPM, defects per million; EDTA, ethylenediaminetetraacetic acid

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value, median, and an interval delimited by the lowest and highest reported result. Preliminary quality specifications and 3 performance levels—minimum, desirable, and optimal—were determined for each QI. For example, the median value represented the desirable level when the range between the lowest and highest value was very wide. For the QIs for which a lower score represented better performance, a value less than or equal to 25% below the median belongs to optimal level and a value greater than or equal to 25% above the median belongs to minimum level. A poor outcome is counted as an error or defect. The sigma value indicates the frequency of errors in a process. The higher this value, the less likely the laboratory reports incorrect results. Quality is assessed on a sigma scale, from 3 sigma as the minimum allowed for routine performance to 6 sigma as best-in-class quality. World-class quality processes have a Six sigma level, which means around 3.4 errors per million. Average products, regardless of their complexity, have a quality performance value of approximately 4 sigma.

We established 4 levels of laboratory performance according to the sigma values. These facilitate the identification of opportunities to improve laboratory services.

### Table 1. Performance Levels of Certain Quality Indicators for the Preanalytical Phase of Testing

<table>
<thead>
<tr>
<th>Key Activity in the Laboratory</th>
<th>Quality Indicator (QI)</th>
<th>Performance Level</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>QI-5: %age of request forms with errors concerning patient identification/total no. of request forms</td>
<td>Optimum</td>
</tr>
<tr>
<td></td>
<td>QI-7: %age of requests with errors concerning input of tests (missing tests)/total no. of request forms;</td>
<td>&lt;0.40</td>
</tr>
<tr>
<td></td>
<td>QI-8: %age of sample lost–not received/total no. of samples</td>
<td>&lt;0.20</td>
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<tr>
<td></td>
<td>QI-9: %age of samples collected in a blood-collection tube with inappropriate anticoagulant/total no. of samples</td>
<td>&lt;0.07</td>
</tr>
<tr>
<td></td>
<td>QI-10: %age of hemolyzed samples (in biochemistry)/total no. of samples</td>
<td>&lt;1.00</td>
</tr>
<tr>
<td></td>
<td>QI-11: %age of clotted samples (in hematology)/total no. of samples with anticoagulant</td>
<td>&lt;0.50</td>
</tr>
<tr>
<td></td>
<td>QI-13: %age of samples with inadequate sample-anticoagulant/total no. of samples with anticoagulant</td>
<td>&lt;0.20</td>
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*aDeveloped by the International Federation of Clinical Chemistry and Laboratory Medicine Working Group on Laboratory Errors and Patient Safety.*

Another method of quality assessment, which is also applicable in the preanalytical phase, is the use of sigma metrics (ie, the Six Sigma methodology). Developed by Motorola, Inc., this methodology was introduced into industry and business as early as the 1980s. Six Sigma provides principles and tools that can be applied to any process to measure the defect and/or error rate. Bill Smith, known colloquially as the father of Six Sigma, decided to measure the defects per million (DPM) instead of defects per thousand. The number of errors, or DPM, is a measure of laboratory performance. Six Sigma requires the definition of tolerance limits for the objective determination of poor quality or defective products (or, in our report, erroneous laboratory results). The measurement of quality on a sigma scale in the preanalytical phase requires monitoring the outcome process, counting the defects, calculating the DPM, and using statistical tables to convert the DPM into sigma metrics. A poor outcome is counted as an error or defect. The sigma value indicates the frequency of errors in a process. The higher this value, the less likely the laboratory reports incorrect results. Quality is assessed on a sigma scale, from 3 sigma as the minimum allowed for routine performance to 6 sigma as best-in-class quality. World-class quality processes have a Six sigma level, which means around 3.4 errors per million. Average products, regardless of their complexity, have a quality performance value of approximately 4 sigma.

### Organizational and Procedural Conditions for Data Collection

We performed our study in the clinical laboratory of the County Emergency Clinical Hospital in Timisoara, a general teaching hospital that is the largest hospital in Western Romania. The laboratory performs stat and routine tests for the hospital, which has 1300 beds and various medical and surgical care units. The clinical laboratory has several
departments, namely, clinical chemistry, immunology, hematology, molecular biology, microbiology, and stat. The hospital and laboratory use the same electronic information system. In the laboratory, the information system communicates bi-directionally with the automated analyzers that are connected to it. The stat department of the laboratory, which operates with independent staff, processes the specimens collected in the clinical sections of the hospital and the emergency department. Blood samples from inpatients and the emergency department are collected by the clinical ward staff, whereas outpatient samples are collected on site by the laboratory staff.

For stat tests, venous blood samples are collected in plastic tubes with clot activator additive (for clinical chemistry), ethylenediaminetetraacetic acid (EDTA) tubes (for hematology), and buffered sodium citrate tubes (for coagulation testing). All laboratory tests are ordered via the electronic information system, and each request form is assigned a unique identification code. Stat priority can be specified by the provider on the request forms. The request form is printed, stamped by the physician, and sent to the laboratory along with the samples. The emergency specimens are transported by the ward staff to the laboratory reception area, where the laboratory staff checks whether the patient’s identification data on the sample collection tube match those on the request form. The laboratory staff examine samples to find any that are clotted (ie, in hematology or coagulation) or incorrectly collected (ie, insufficient volume or wrong anticoagulant). Samples that meet the acceptability criteria are logged in a register that specifies the time the samples were received and the type and number of tubes collected; then, the samples are processed for analysis. After centrifugation, laboratory professionals visually check the blood samples to detect hemolyzed, lipemic, and icteric plasma. In our laboratory, the sample rejection criteria are as follows: Wrong or missing patient identification, wrong anticoagulant, too much or not enough sample volume, coagulated sample (in hematology and coagulation), and visible hemolysis after centrifugation. The samples that do not meet the acceptability criteria are rejected; data regarding these samples are recorded in a special register, and the staff members who collected them are notified. The date, a unique identification code, the reason for rejection, and the name of the person who rejected the sample are specified in this register. According to the ISO 15189:2007 standard that is implemented in the laboratory, the laboratory staff are trained to identify and register all the errors that may affect the testing process, including those that occur in the preanalytical phase. The clinical section staff have been trained to collect specimens, and a handbook for sample collection has been distributed to these staff members.

Materials and Methods

The aim of our study was to quantify performance in the preanalytical phase of the testing process in a Romanian stat laboratory using quality indicators expressed as a percentage and a sigma metric, and also to compare our results with those reported in the literature. The QIs we used referred to the key activities of the preanalytical phase. To evaluate the input of the test requests in the laboratory information system, 2 indicators were used, namely, request forms with errors concerning patient identification (QI-5) and requests forms with errors concerning input of tests (ie, missing tests) (QI-7). Five indicators were used to evaluate sample collection, handling, and transport: samples lost–not received (QI-8); samples collected in a blood-collection tube with inappropriate anticoagulant (QI-9); hemolyzed samples (in biochemistry; QI-10); clotted samples (in hematology; QI-11); and samples with inadequate sample-anticoagulant (QI-13). We used the percentage and the sigma-scale methods of quality indicator evaluation in our laboratory to quantify the performance of the testing process to detect risks that may lead to errors that cause harm to patients.

During the yearlong period in which our study took place, from January 1 through December 31, 2011, the following were counted on a monthly basis:

- **QI-5**: Request forms with errors concerning patient identification (ie, the identification data on the test-request form [namely, the first name and surname of the patient and the unique identification code] and the data on the sample-collection tube are not the same)
- **QI-7**: Requests with errors concerning the input of tests (ie, missing tests, for samples collected for unrequested tests)
- **QI-8**: Samples lost–not received (ie, requests for uncollected samples)
- **QI-9**: Samples collected in blood-collection tube with inappropriate anticoagulants (ie, the anticoagulants used for blood collection were not those indicated in the sample-collection handbook of the laboratory)
- **QI-10**: Hemolyzed samples (in biochemistry: hemolysis detected by visual examination after centrifugation)
• QI-11: Clotted samples (in hematology: the presence of visible clots or platelet aggregation in the hemat-ology test–collection tubes)
• QI-13: Samples with inadequate sample-anticoagulant (ie, the sample volume exceeds the optimum volume by ±20%).

The QI indicators were as follows:
• QI-5 = Percentage of request forms with errors concerning patient identification/total number of request forms
• QI-7 = Percentage of requests with errors concerning input of tests (missing tests)/total number of request forms
• QI-8 = Percentage of samples lost—not received/total number of samples
• QI-9 = Percentage of samples collected in blood-collection tubes with inappropriate anticoagulants/total number of samples
• QI-10 = Percentage of hemolyzed samples (in biochemistry)/total number of samples
• QI-11 = Percentage of clotted samples (in hematology)/total number of samples with anticoagulant
• QI-13 = Percentage of samples with inadequate sample to anticoagulant ratio/total number of samples with anticoagulant

We developed the following performance levels (similar to the WG-LEPS levels) based on the sigma metrics evaluation:

1. very good : ≥ 5.0 sigma
2. good: 4.0–<5.0 sigma
3. minimum: 3.0–<4.0 sigma
4. unacceptable: <3.0 sigma

To evaluate the performance level of the laboratory in the preanalytical phase, we compared our results with the specifications reported in the literature for QIs.

Results

During the 1-year period from January 1 through December 31, 2011, a total of 168,728 samples and 88,655 test-request forms were received in the stat laboratory. The number of blood samples collected without the use anticoagulant (for biochemical tests) was 69,350; the number of samples collected with anticoagulant (for hematology and coagulation tests) was 80,808. The number of urine samples received in this period of time was 18,570.

The total number of preanalytical errors was 1457, which accounted for 0.8% of the total number of samples received that year. Among the preanalytical errors, 46.4% were hemolyzed samples (in biochemistry), 43.2% were clotted samples (in hematology), 6.4% were samples not received in the laboratory, 2.9% samples showed an inadequate sample to anticoagulant ratio, 0.7% were requests with errors in patient identification, 0.3% were samples collected in blood-collection tubes with inappropriate anticoagulant, and 0.1% were requests with errors–missing test requests.

Of the test request forms received, .01% contained errors with regard to patient identification (sigma level = 5.3) and .002% had errors concerning the samples collected but not tested (sigma level = 5.6).

Of the total samples, 0.4% were hemolyzed (sigma level = 4.2), .05% were not received in the laboratory (sigma level = 4.8), and .02% were collected in blood-collection tubes containing inappropriate anticoagulant (sigma level = 5.6). Among samples with anticoagulant, .77% were clotted (sigma level = 4.0), and .05% were not properly filled (sigma level = 4.8).
Laboratory QA

Table 2 lists the type and number of errors in the preanalytical phase. It also lists the performance levels obtained for quality indicators, expressed as percentages and on a sigma scale.

**Discussion**

Laboratory results are often essential in diagnosis and management of diseases. Studies have shown that most incorrect results originate in the preanalytical phase. Preanalytical errors account for more than 70% of the total number of laboratory errors and have a significant clinical and economic impacts on medical care. Consequently, the preanalytical phase must be strictly supervised so that the laboratory can achieve an adequate performance level. Quality indicators are useful performance monitoring tools for the preanalytical phase of the testing process. Of these, 16 focus on the preanalytical phase. In our study, we selected 7 quality indicators based on the type and frequency of the preanalytical errors detected in our stat laboratory. Other QIs also can be used; however, we did not examine these in the present study. For example, for test ordering practices, the number of requests regarding a given clinical question (QI-1) and the number of appropriate tests (with respect to such a question; QI-2) are relevant QIs. To evaluate activities such as formulation and input of request, the number of requests without physician identification (QI-3), the number of unintelligible requests (QI-4), and the number of requests with incorrect physician identification (QI-6) are pertinent. To evaluate activities such as sample identification, collection, handling, and transport, the number of samples with insufficient sample volume (QI-12), the number of samples damaged in transport (QI-14), the number of samples improperly labeled (QI-15), and the number of improperly stored samples (QI-16) can be used.

Our study may have limitations in QI data collection. QI data collection can be influenced by laboratory vigilance in detecting and recording preanalytical errors, especially during night shifts or very busy times, which typical occur in the stat laboratory.

Our study evaluates only the QIs we considered to be most suitable within our own quality program. We did not...
consider QI-1 to be suitable because clinical information is mandatory regarding test requests for inpatients and outpatients; also, QI-2 was not suitable because it is difficult to determine whether a test request is appropriate or inappropriate for use with a particular clinical condition.

The errors we discovered would not have been detected if we had not established specific acceptance and rejection criteria. We recorded data on a daily basis regarding samples that did not meet the acceptance criteria. Our results confirm the results of other studies,\textsuperscript{15-21} that preanalytical errors include patient identification, sample quality (ie, clotted, hemolyzed, and collected in blood-collection tubes with inappropriate anticoagulant), and the volume of the specimen. Of the total number of biochemistry samples we received in our stat laboratory during the 1-year period of the study, 0.4% were hemolyzed, compared with 0.7%, as reported by Chawla et al\textsuperscript{19} and 0.77%, as reported by Lippi et al.\textsuperscript{21} The coagulated hematology samples occurred at a more frequent rate (0.77%) than the 0.25% figure reported by Lippi et al.\textsuperscript{21}

Most of our results indicated an optimum level of performance; only 1 result (for QI-11) was just within the desirable range, according to the specifications of the WG-LEPS.\textsuperscript{7}

The Six Sigma metrics indicated that our results are comparable to those reported in the literature.\textsuperscript{22} In our study, the sigma value was 4.2 for hemolyzed samples and 4.0 for coagulated samples; the sigma value calculated based on the data reported by Sciaccovelli et al\textsuperscript{23} is 3.6 for hemolyzed samples and 4.4 for coagulated samples.\textsuperscript{23} The sigma values we calculated for inadequate anticoagulants and improper specimen volume were 5.6 and 4.8, respectively, against sigma values of 5.0 and 3.9, respectively, calculated based on the data reported by Sciaccovelli et al.\textsuperscript{23} Sciaccovelli et al reported errors as percentages; for purposes of comparison, their data was converted into DPM.\textsuperscript{22} In the sigma metrics there are no different performance levels, other than acceptable and unacceptable. The literature mentions only a single interval between 3 and 6 sigma, and the performance level in that case is the desirable one.\textsuperscript{9} As a result, we developed the 4-level classification of laboratory performance, as presented herein. We derived the very good, good, minimum, and unacceptable performance levels, based on the sigma value, from the fact that, in evaluating quality in the sigma scale, 3 sigma is the minimum allowed for routine performance and 6 sigma is the goal for world-class quality.\textsuperscript{9} Average products, regardless of their complexity, have a quality performance value of approximately 4 sigma.\textsuperscript{21}

Arbitrarily, we divided acceptability intervals that have a minimum (3 sigma) and a maximum tolerance value (6 sigma) into 3 parts. The lower third corresponds to the minimum level (3.0-3.9 sigma), the median third represents the good level (4.0-4.9 sigma) and the upper third represents the very good level (≥ 5.0 sigma). Any score lower than 3 sigma is unacceptable. This 4-level classification allows laboratories to place the QIs at a certain initial performance level and to discern their progress more easily when their dynamics are evaluated. In this way, performance enhancement measures can be enacted more quickly.

In our stat laboratory, we eliminated some of the possible causes of errors in the test request forms (ie, missing or wrong identification of the doctor requesting the tests, illegible test request forms, and misinterpretation of requested tests) by introducing an electronic request form that is generated as soon as tests are selected in the software application.

Requested tests for which no sample was collected are usually caused by sample collection difficulties, which occur frequently in emergency care settings. The number of samples with inadequate sample-anticoagulant ratio and samples collected in a blood-collection tube with inappropriate anticoagulant are minor; we consider them to be random errors rather than a consequence of the actions of untrained or undertrained medical personnel.

Hemolyzed specimens for biochemical tests, and clotted hematology samples, remain challenges for emergency laboratories. In our study, if any sign of hemolysis was detected visually, the sample was rejected, and phlebotomists were called to collect new samples; hemolysis affects many laboratory tests, making the results unsuitable for diagnostic purposes. The upper reference values for free hemoglobin are 50 mg per L and 20 mg per L for serum and plasma, respectively. Hemolysis is visually detectable when the hemoglobin concentration exceeds 300 mg per L, resulting in a pink to dark-red appearance of the serum or plasma.\textsuperscript{24} Although visual examination of the sample is considered to be an uncertain verification method for hemolysis,\textsuperscript{25} no widely accepted criteria have been developed for evaluating the degree of hemolysis or the thresholds that must be taken into consideration for sample rejection.\textsuperscript{24}

In vitro hemolysis is the most common cause for rejection of specimens by clinical laboratories.\textsuperscript{26} It is usually
caused by the use of small-gauge needles (smaller than 21 gauge), partial obstruction of catheters and other collection devices, application of excessive negative pressure to aspirate blood into the syringe, under filling of the blood-collection tube, excessive shaking or mixing of the blood sample after collection, centrifugation of the sample at too high a speed for a prolonged period of time, and centrifugation of partially coagulated specimens.\(^{24}\) Hemo-
lysis causes prolonged turnaround time for the tests that are ordered; this affects workflow, which could result in harm to critically ill patients.\(^{19}\)

At our hospital, the information provided by QI evaluation for laboratory performance enhancement prompted us to focus on regularly retraining laboratory and hospital personnel in specimen collection procedures. Because none of the quality indicators we evaluated in this study showed an unacceptable performance level in the preana-
lytical phase, no corrections were necessary. However, we continue to collect data regarding preanalytical errors to monitor this critical phase of laboratory testing to ensure ongoing satisfactory performance.

**Conclusion**

To quantify performance in the preanalytical phase, stat laboratories can use quality indicators irrespective of how they are expressed, whether as a percentage or on the sigma scale. These indicators provide a means to compare the performance of the individual laboratory with that of other laboratories, as long as the same parameter (for instance, number of requests, number of samples, or number of samples with anticoagulant) is used as a reference.

In our stat laboratory, we judged the performance level in the preanalytical phase of the testing process to be good. However, according to ISO quality specifications, the performance level of the laboratory at all phases of testing requires continuous evaluation so that health care professionals can readily identify opportunities for improvement in the stat laboratory and other healthcare services departments.  \textit{LM}

**References**


