The cost of poor blood specimen quality and errors in preanalytical processes

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**ABSTRACT**

**Objectives:** The increase in the prevalence of medical errors represents a disturbing trend; hospital-based errors are the eighth leading cause of death in the United States. For the clinical laboratory, errors that occur in the preanalytical phase of testing may account for up to 75% of total laboratory errors; 26% of these may have detrimental effects on patient care, which contribute to unnecessary investigations or inappropriate treatment, increase in lengths of hospital stay, as well as dissatisfaction with healthcare services. This review focuses on these errors, particularly those observed in the preanalytical phase, and how they may affect clinical and financial outcomes.

**Introduction**

The complexity of the current healthcare environment has increased the potential for medical errors. Statistics provided by The Institute of Medicine (IOM) showed that medical errors contribute to more than 1 million injuries and approximately 44,000-98,000 deaths in hospitals annually [1,2]. These numbers make hospital-based errors the eighth leading cause of death in the United States, ahead of breast cancer, Acquired Immunodeficiency Syndrome (AIDS), and motor vehicle accidents [1]. In addition, these errors have been shown to result in 2.4 million extra days of hospitalization and possibly increase hospital costs by $17 billion [3,4]. A study of medical errors published in the New England Journal of Medicine showed that 11% of patients received potentially harmful care and that 46% of patients did not receive the recommended care [5]. “Preventing Medication Errors”—a 2006 report from the IOM—estimated that more than 1.5 million preventable adverse drug events occur annually in the United States [6].

Eliminating or reducing these errors requires a concerted effort by healthcare organizations, product manufacturers, and policy makers. This effort should begin with a review of potential causes of these medical errors and their effect on both the institution and the patient. Medical errors can occur anywhere in the healthcare system—hospitals, clinics, surgical centers, physicians’ offices, and nursing homes. They may also occur during the laboratory testing process. This review will focus on these errors, particularly those observed in the preanalytical phase, and how they may affect clinical and financial outcomes.

**Errors in laboratory testing**

Laboratory testing provides essential information used by physicians in medical decision making with an estimated 60–70% of these decisions based on laboratory test results [7]. This critical component of healthcare, however, is also a vital source of errors which may affect patient safety. A laboratory error has been defined as any defect that occurs during the entire testing process, from ordering tests to reporting results, and in any way influences the quality of laboratory services [8]. Moreover, these errors may be evident in each phase of the testing process—preanalytical, analytical, and postanalytical. The preanalytical phase refers to all of the steps from the time of test ordering by the physician until the sample is ready for analysis; the analytical phase includes the actual specimen analysis, and the postanalytical phase encompasses test reporting and interpretation. The preanalytical phase is also a complex process, encompassing steps that occur outside as well as inside the laboratory (Table 1). Attempts to reduce errors should begin with a review of the sources of these errors. As discussed in the next section, the majority of errors that occur during laboratory testing are the result of preanalytical variables.

**The root causes of preanalytical variables**

Review of the literature has documented that preanalytical variables may account for up to 75% of total laboratory errors [8–12] (Table 2). While most of these occur outside of the laboratory, any incident that may present a risk for the patient requires investigation,
Errors are evident in each phase of the testing process—preanalytical, analytical and postanalytical—with the majority occurring in the preanalytical phase.

### Evaluating the clinical effects of the most prevalent preanalytical errors

#### Hemolysis

The presence of hemolysis accounts for up to 40–70% of unsuitable specimens provided to the laboratory [15,16]. Vigorous mixing of the specimen, pneumatic tube transport of the specimen, or forcing of blood through a large-bore needle of a syringe may cause the red blood cells to rupture, resulting in hemolysis [17]. Even a mild degree of hemolysis may influence test results for several analytes (e.g., lactate dehydrogenase, creatine kinase-MB, potassium, aspartate aminotransferase, alanine aminotransferase) by falsely elevating these levels [18–20], and thus may not present an accurate picture of the patient’s condition.

#### Incorrect patient identification

Errors in patient identification can result in delayed diagnosis, additional laboratory testing, or treatment of a patient for the wrong medical condition. These errors may even be fatal, particularly if an acute hemolytic transfusion reaction results [21]. One study in the literature found that 40%–50% of transfusion morbidities were the result of errors in patient identification or the blood component [22].

#### Clotted specimens

Specimens that are inappropriately mixed may cause clotting and cannot be processed for complete blood count testing [23]. Clotting may produce false leukopenia, low red cell counts, aberrant red cell indices and low hematocrit results [23]. Micro-clots also contributed to instrument probe aspiration and clogging, leading to service calls and downtime [24], which delay processing of specimens and test reporting.

#### Insufficient sample volume

All blood collection tubes must be filled to the correct volume to ensure the proper amount of blood for the amount of additive in the tube (blood to additive ratio) [25]. For example, if a 5 mL-draw heparin tube is only filled with 3 mL of blood, the heparin concentration may be erroneously elevated and potentially interfere with some chemistry analytes. In addition, a “short” draw of an EDTA tube may cause erroneous results for intact parathyroid hormone due to a chelation of the magnesium cofactor in some assays [26]. An insufficient quantity specimen is also problematic, as all testing ordered by the physician often cannot be completed. This may potentially require the patient’s blood to be redrawn and the delay in receipt of test results can lengthen the patient’s stay in the hospital.

A preanalytical error that is detected by the laboratory can require re-collection of specimens, adding to processing time and time to result reporting. Instances in which the error is not readily identified by the laboratory but is detected after the result has been reported to the patient is also problematic, as all testing ordered by the physician often cannot be completed. This may potentially require the patient’s blood to be redrawn and the delay in receipt of test results can lengthen the patient’s stay in the hospital.

### Table 1

<table>
<thead>
<tr>
<th>Complexity of the preanalytical phase.</th>
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<tbody>
<tr>
<td>Preanalytical phase outside the laboratory</td>
</tr>
<tr>
<td>Order test</td>
</tr>
<tr>
<td>Collect sample</td>
</tr>
<tr>
<td>Transport sample to lab</td>
</tr>
<tr>
<td>Preanalytical phase inside the laboratory</td>
</tr>
<tr>
<td>Receive sample in lab</td>
</tr>
<tr>
<td>Prepare sample for testing</td>
</tr>
<tr>
<td>Transport sample to lab section</td>
</tr>
<tr>
<td>Preanalytical error that is detected by the laboratory can require re-collection of specimens, adding to processing time and time to result reporting. Instances in which the error is not readily identified by the laboratory but is detected after the result has been reported to the patient is also problematic, as all testing ordered by the physician often cannot be completed. This may potentially require the patient’s blood to be redrawn and the delay in receipt of test results can lengthen the patient’s stay in the hospital.</td>
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</table>

### Table 2

<table>
<thead>
<tr>
<th>Study results</th>
<th>Study time interval</th>
<th>Preanalytical (%)</th>
<th>Analytical (%)</th>
<th>Postanalytical (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole laboratory:</td>
<td>6 years</td>
<td>53.0%</td>
<td>23.0%</td>
<td>24.0%</td>
</tr>
<tr>
<td>Total 133 errors [6]</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary care:</td>
<td>6 months</td>
<td>55.6%</td>
<td>13.3%</td>
<td>30.0%</td>
</tr>
<tr>
<td>160,714 patients, 0.11% of patients [9]</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>STAT laboratory: 40,490 tests, 0.47% error rate of test results [10]</td>
<td>3 months</td>
<td>68.2%</td>
<td>13.3%</td>
<td>18.5%</td>
</tr>
<tr>
<td>Whole laboratory: 676,364 tests, error rate of 0.61% of test results [11]</td>
<td>3 years</td>
<td>75.0%</td>
<td>16.0%</td>
<td>9.0%</td>
</tr>
<tr>
<td>Molecular genetic testing: 88,394 patients, error rate of 0.33% of test results [12]</td>
<td>1 year</td>
<td>60.0%</td>
<td>15.0%</td>
<td>15.0%</td>
</tr>
</tbody>
</table>

Errors are evident in each phase of the testing process—preanalytical, analytical and postanalytical—with the majority occurring in the preanalytical phase.
Physician may adversely affect patient diagnosis and/or treatment. It is important to note that correctly ordering laboratory tests, as well as interpreting analytical results, can have an influence on clinical outcomes as well.

As demonstrated, there is considerable evidence regarding the clinical impact of preanalytical variables. However, no quantifiable evidence exists that clearly illustrates the financial impact of these variables on the laboratory and the hospital and subsequently, on patient care.

Calculating the financial impact of preanalytical errors

Many preanalytical errors occur prior to the arrival of the specimen in the laboratory. These findings are not unexpected, since there may be many healthcare professionals who are involved in the blood collection process, presenting more opportunities for errors to occur. A preanalytical error may be as simple as an unlabeled or mislabeled specimen or an improper collection technique. But even one small failure in the blood collection process can affect patient treatment and multiply into significant costs for the hospital (Fig. 1).

A model to estimate the costs of poor specimen quality

In conjunction with healthcare economist Frost & Sullivan, BD Healthcare Consulting Services developed a model to quantify the cost of poor blood specimen quality for the healthcare institution on total operating costs and patient care. It also provides a metric for tracking preanalytical errors and setting targets to reduce or eliminate them.

Building the model

Baseline data are collected from key hospital personnel to calculate the impact of preanalytical errors on operating costs. The data required for the model are based on three categories: 1) financial/institutional, 2) laboratory, and 3) clinical.

Financial and institutional data obtained quantitatively include the financial status of the facility (e.g., total hospital/facility operating costs), number of institutional beds, total liability insurance costs and total number of patients seen per year. Laboratory data are obtained through interviews with laboratory staff and incorporate factors that may influence these costs, including total pathology operating costs, disposable blood collection device costs, total number of laboratory tests, total time to perform tests from patient to result in providers’ hands, total hours/week of laboratory operational hours, analyzer downtime (hours/week), total number of blood tests rejected, total number of blood tests flagged as either abnormal or with no result, number of specimen errors and number of tests repeated.

Finally, clinical practice data are obtained through qualitative feedback from hospital physicians and acute care nurses from the Emergency Department and from intensive care units. These clinicians are interviewed to identify the frequency in which they receive laboratory test results that they perceive as erroneous. Clinicians are also asked to describe the perceived impact of these errors on patient flow and clinical practice. These are presented using case study scenarios (Table 3). Fortunately, the majority of preanalytical errors are detected by the laboratory and do not critically impact the patient. In most scenarios, when an error...

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Potential impact on clinical practice</th>
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<tbody>
<tr>
<td>Hospitalized critical patient: A 55-year-old male patient arrived in the Emergency Room complaining of chest pains and shortness of breath. The patient was overweight with a history of elevated cholesterol and cardiac disease. A preanalytical error presented when false positive troponin results for acute myocardial infarction were obtained from the laboratory. Routine outpatient testing: A 40-year-old female type 1 insulin dependent diabetic patient was admitted to the hospital for an outpatient clinic to monitor a number of routine tests, including potassium. The sample was hemolyzed. Hospitalized elective surgery patient: A 55-year-old male patient was admitted for appropriate critical laboratory testing following thyroid surgery due to a cancerous growth. An incorrect result was obtained, which required additional testing.</td>
<td>Low</td>
</tr>
<tr>
<td>Hospitalized critical patient: The laboratory detected the error and corrective action was taken; the troponin test was re-run after 1 h. A proper diagnosis could then be made, which minimized the patient’s length of stay.</td>
<td>Error was not identified by the laboratory and the result was reported. However, the error was detected by the patient’s physician. The patient was re-tested, which translated into another venipuncture for the patient and additional laboratory time for redraw and re-testing. Further collaborative testing may be required, particularly if the first result was positive and the second was negative (&lt;24 h).</td>
</tr>
</tbody>
</table>
occurs, another test must be ordered to confirm the result. If different from the initial result, a third test might be ordered, which may lengthen the patient’s stay in the hospital. Critical test results may also warrant transfer of the patient to an intensive care unit. Extended stays in an intensive care unit have been associated with higher expenses, both in dollars and in resources, such as nursing care [27].

The model also takes into account costs by dividing all patients into three categories: hospitalized critical patients, routine outpatients, and elective surgery patients, since the costs of an error vary greatly among the three categories. Using financial, laboratory and clinical data, a weighted proportion of costs based on type and severity of patient is calculated to estimate the total financial impact of erroneous test results.

To date, this model has been used to estimate the cost of poor specimen quality in seven hospital organizations in four countries (U.S., Canada, Germany, and Ireland). A descriptive analysis of key economic outcomes from these assessments is summarized in the following section.

The estimated cost of preanalytical errors

The estimated average costs of a preanalytical error in North American and European institutions were estimated at $208.00 (USD) and 157€ (~$204 USD), respectively. Average preanalytical error costs by type of patient in North American hospitals are $162.18 for inpatient (critical), $357.15 for inpatient (other), and $377.05 for outpatient (which includes Emergency Department patients). In Europe, the average preanalytical error costs by type of patient are €177.98 for inpatient (critical), €245.37 for inpatient (other), and €107.62 for outpatient.

On average, preanalytical specimen error costs represent between 0.23% and 1.2% of total hospital operating costs. For a US hospital with approximately 650 beds, this cost is extrapolated to approximately $1,199,122 per year.

The cost of preanalytical errors and their impact on efficiency can also be assessed by the hours lost as a result of required redraws and delayed follow-up care. An estimated 24,027 total patient hours (redraw and treatment) was lost by an 850-bed hospital in the US in one year. Of these hours, 2,507 (10%) was lost due to laboratory redraw/processing time, and an additional 21,519 (90%) of hours was lost due to additional patient treatment. In an 850-bed hospital in Europe, an estimated 16,047 patient hours was lost; 730 (4%) due to laboratory redraw/processing time and 16,047 (96%) due to additional patient treatment.

The total cost of specimen rejection can also be quantified by cost category (Fig. 2). In most facilities, patient treatment costs represent the largest cost category at approximately 72%, laboratory investigation and redraw costs at 26%, the cost of instrument downtime at 2%, and blood collection consumables at less than 0.5%.

Despite potential limitations caused by differences in clinical practices between regions, the descriptive analysis demonstrates that preanalytical errors are a significant burden to total hospital operating costs, across all hospitals. Preanalytical errors not only increase redraw costs within the laboratory, but also impact the time and resources required for follow-up or as a result of delays in patient care. The financial impact of a preanalytical error can vary depending on the severity of the patient.

How do we prevent or reduce these errors and conserve valuable resources? Since the majority of errors that occur during laboratory testing are the result of preanalytical variables, reducing these errors should begin with an evaluation of current blood collection practices to identify the root causes of these variables. Establishing best practices for blood collection may achieve the greatest gains for improving the quality of blood specimens (Table 4). Improving blood specimen quality in the preanalytical phase is the key to error prevention or reduction.

Conclusion

Errors in the provision of health services, whether they result in injury or expose the patient to the risk of injury, are events that should not occur. These errors damage the institution’s reputation, diminish confidence in healthcare services and contribute to increase in total operating costs, both for the hospital and laboratory. With rising healthcare expenses and financial constraints, it behooves hospital and laboratory administrators to prevent or reduce the incidence of these errors. While it is understood that human errors cannot be completely eliminated, compliance with best practices for blood collection may help in these endeavors. As healthcare professionals, we can all do our part in reducing errors, improving productivity and enhancing the care provided to our patients.

Acknowledgments

The author wishes to thank Julie Ravo, BD Franklin Lakes and Eva Baginska, BD Canada for their assistance in the development of this article.

Table 4

<table>
<thead>
<tr>
<th>Blood collection consumables</th>
<th>Redraw costs</th>
<th>Lab investigation costs</th>
<th>Instrument downtime costs</th>
<th>Patient treatment costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>80%</td>
<td>60%</td>
<td>40%</td>
<td>20%</td>
<td>0%</td>
</tr>
</tbody>
</table>

Fig. 2. The total cost of specimen rejection can be quantified by cost category.
References

[14] Baumann NA. QC notes at each phase of the analytical process are explored. ADVANCE for Administrators of the Laboratory, 20; 2011 26.