Science

Most laboratory errors result from the lack of standardization of this preanalytical phase of the overall procedure, particularly patient identification, sample collection, and processing. It has been estimated that more than 80% of all errors in laboratory testing occur in the extra-analytical phase (ie, the combined pre- and post-analytical phases). Moreover, only a few routine procedures exist for the detection of errors in the extra-analytical phase. Clinical laboratories worldwide are now conforming to certification rules outlined in International Organization for Standardization (ISO) publication 15189 or to accreditation programs with standards based on ISO 15189, such as the National System of Accreditation (DICQ) from the Brazilian Society of Clinical Analyses (SBAC). Nevertheless, a major problem in laboratory quality management is that health care professionals still focus excessive attention on the analytical phase of laboratory testing. The extra-analytical phase has previously been defined as the “dark side of the moon” in laboratory medicine because it is unfamiliar and often overlooked by laboratory managers involved with quality assurance. A particularly important aspect of this phase is the lack of uniform standards and indicators sufficient to ensure the quality of phlebotomy, which is a critical procedure for obtaining reliable diagnostic blood specimens but often is not supervised by laboratory personnel. The aim of this study was to evaluate the performance of phlebotomists

Is Phlebotomy Part of the Dark Side in the Clinical Laboratory Struggle for Quality?

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ABSTRACT

Objective: Blood collection is a critical part of the preanalytical phase of laboratory testing. Only a few procedures are evaluable for detecting errors in this non-automatic activity. Information about potential sources of error is frequently absent from quality-control procedures and training materials.

Objective: To evaluate the performance of phlebotomists and to identify the major sources of errors during diagnostic blood collection.

Methods: We evaluated the performance of 3 phlebotomists each from 10 laboratories regarding tourniquet time, request for fist clenching, excessive friction during skin cleaning, sequence of vacuum-tube usage, and mixing of tube contents after specimen collection. The total number of these laboratories represented an equal number of private (ie, owned by private parties) and public (ie, administration by government organizations) settings.

Results: An error rate of greater than 60% was observed in the performance of procedures we examined, and the error rate was not significantly different between public and private settings other than more adequate mixing of the contents of primary collection tubes in private facilities.

Conclusions: Most facilities did not achieve adequate quality standards in phlebotomy. In procedural manuals, training materials, and practices for phlebotomists, greater emphasis should be placed on presenting information on possible sources of error and on the correct implementation of procedures that ensure the quality of diagnostic blood specimens collected for laboratory analysis.

Keywords: phlebotomy, blood collection, ISO 15189, preanalytical variability, quality indicators, tourniquet, venous stasis, phlebotomist

Most laboratory errors result from the lack of standardization of this preanalytical phase of the overall procedure, particularly patient identification, sample collection, and processing. It has been estimated that more than 80% of all errors in laboratory testing occur in the extra-analytical phase (ie, the combined pre- and post-analytical phases). Moreover, only a few routine procedures exist for the detection of errors in the extra-analytical phase. Clinical laboratories worldwide are now conforming to certification rules outlined in International Organization for Standardization (ISO) publication 15189 or to accreditation programs with standards based on ISO 15189, such as the National System of Accreditation (DICQ) from the Brazilian Society of Clinical Analyses (SBAC). Nevertheless, a major problem in laboratory quality management is that health care professionals still focus excessive attention on the analytical phase of laboratory testing. The extra-analytical phase has previously been defined as the “dark side of the moon” in laboratory medicine because it is unfamiliar and often overlooked by laboratory managers involved with quality assurance. A particularly important aspect of this phase is the lack of uniform standards and indicators sufficient to ensure the quality of phlebotomy, which is a critical procedure for obtaining reliable diagnostic blood specimens but often is not supervised by laboratory personnel. The aim of this study was to evaluate the performance of phlebotomists
and to identify the major sources of errors during diagnostic blood collection.

Materials and Methods

Selection of Laboratories and Phlebotomists

We contacted nearly 1000 randomly chosen clinical laboratories in Brazil. The laboratories were asked the following questions:

1) Is the analytical phase in your laboratory performed by automated instruments?
2) Does your laboratory perform internal quality-control procedures on normal and pathological levels at least once daily?
3) Are your technicians trained and certified by the manufacturers or the distributors of the automated instruments?
4) Is there a quality manual in your laboratory?
5) Does your laboratory participate in external quality-assessment or proficiency-testing programs?

These questions addressed elements that are considered to be universally acceptable for quality assurance programs. Overall, 97 laboratories answered affirmatively to all the questions; among these, only 10 institutions formally agreed to participate in this project. Five of the selected laboratories are run privately; the others are run publicly. Appointed representatives from each of the evaluated laboratories gave formal written consent for participation in this study; the project was approved by the Internal Review Board of Dante Pazzanese Cardiology Institute, Sao Paulo, Brazil. Three phlebotomists from each laboratory were randomly selected (phlebotomists represent approximately 60% of the workforce in a typical Brazilian collection site). All venipuncture procedures were performed using vacuum-tube systems from traditional brands with similar characteristics, eg, Becton, Dickinson and Company, Franklin Lakes, NJ; Greiner Bio-One, Kremsmunster, Austria; Guangzhou Improve Medical Instruments Co., Zhejiang, China; Sarstedt, Numbrecht, Germany; and Terumo Europe, Leuven, Belgium.

Evaluation of Phlebotomist Performance

Evaluation of Phlebotomist Performance

To evaluate the performance of the phlebotomists during the collection of diagnostic blood specimens, we followed the checklist proposed by Lima-Oliveira and colleagues. We aimed to evaluate:

1) time of tourniquet application
2) inappropriate requests to patients to clench their fist repeatedly
3) excessively aggressive disinfection of the forearm by the phlebotomist, which can produce venous stasis
4) the order in which vacuum tubes were used in specimen collection
5) adequacy of mixing blood in primary vacuum tubes that contain anticoagulant or clot-activating additives

The checklist allowed us to correlate errors in laboratory results with improper phlebotomy procedures we witnessed, such as increased potassium concentration in the specimen due to fist clenching by the patient. The laboratory quality managers were the only personnel to be informed about this research; the phlebotomists were unaware that data were being collected. The performances of the phlebotomists were analyzed only during procedures that involved blood collection in vacuum tubes containing additives (ie, coagulation activator, sodium citrate, ethylenediaminetetraacetic acid [EDTA], heparin, or sodium fluoride).

Evaluation of Tourniquet Application Time

To standardize the approach and to reduce bias, the performance of each phlebotomist was evaluated when blood was being collected from patients with the following characteristics: between the ages of 18 and 65 years, nonpregnant, nonobese (ie, body mass index [BMI] < 30 kg/m²), neither undergoing chemotherapy nor catheterization, and not afflicted with any apparent vascular disease. All these conditions were carefully excluded because they might be associated with difficulties during the collection of diagnostic blood specimens, which thereby might introduce bias into the evaluation. All phlebotomists were assessed by an expert auditor of quality-control systems, based on ISO 15189. The performance of each phlebotomist was monitored in 5 different phlebotomies; the time of tourniquet application was measured with a calibrated chronometer. The time interval between tourniquet application and removal was recorded in seconds.

Statistical Analysis

Categorical variables were compared by the Fisher exact 2-tailed test using RxC software. Continuous variables with normal distribution were compared using the Student t-test; descriptive statistics were analyzed with SPSS software, version 13 (SPSS Inc., Chicago, IL). A P value of less than .05 was considered significant.
Results

The major errors observed during phlebotomies are summarized in Table 1. The overall rate of errors observed in this study was more than 60%. There were no significant differences observed between public and private laboratories except for adequate mixing of the contents of primary vacuum tubes, for which private laboratories had fewer errors ($P = .04$). Regarding tourniquet time (Figure 1), the overall mean (SD) was 84.4 (14.1) seconds. Private laboratories applied the tourniquet for significantly shorter times than public laboratories (69.9 [10.6] sec vs. 98.9 [17.3] sec; $P < .001$). Nevertheless, only 2 phlebotomists (7% of the total) achieved a mean tourniquet time of 60 seconds or less (Figure 1), which is the maximum time recommended by Clinical and Laboratory Standards Institute (CLSI) publication H3-A6. Additionally, in no single case was the phlebotomist able to locate the vein and collect the blood within 30 seconds after tourniquet application.

Discussion

The first important finding of this study is that only approximately 1% of the 1000 laboratories performing clinical analyses in Brazil that we contacted agreed to participate. The main justification provided was “Should the external expert auditor find some nonconformity in my procedures, either my job or my relationship with the employer might be jeopardized.” This assumption was untrue because the signed informed-consent paperwork ensured the confidentiality of the laboratories and the health care professionals who participated. We believe the results from the 10 participating laboratories reflect the vast majority of laboratories in Brazil, however, and conclude they currently do not consistently achieve adequate quality standards for phlebotomy.

Four major sources of errors were assessed in the 10 laboratories. The sources of error we selected are described by the CLSI; however, this type of information is frequently absent from quality manuals.

Table 1. Main Error Sources Observed During Phlebotomy

<table>
<thead>
<tr>
<th>Error Description</th>
<th>Phlebotomists, %</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All (N = 30)</td>
</tr>
<tr>
<td>Inappropriate request to the patient to clench his or her fist repeatedly</td>
<td>83</td>
</tr>
<tr>
<td>Inadequate friction procedure during the cleaning of the venipuncture site</td>
<td>90</td>
</tr>
<tr>
<td>Incorrect sequence of vacuum tubes</td>
<td>87</td>
</tr>
<tr>
<td>Incorrect mixing of contents of vacuum tubes</td>
<td>83</td>
</tr>
</tbody>
</table>

*aDetermined by Fisher exact 2-tailed testing.  
*bStatistically significant (ie, < .05).
and training procedures. The inappropriate request to the patient to clench his or her fist repeatedly was observed in 83% of the observed phlebotomies (Table 1). This common behavior generates venous stasis and changes the local pH balance, affecting the concentration of potassium, ionized calcium, and some protein-bound analytes.20,21 The inadequate friction procedure characterized by excessive rubbing at the venipuncture site was observed in more than 85% of all blood-collection procedures. Excessive rubbing may increase venous stasis, contaminate the sample with skin microorganisms,18,22 and increase the presence of detached elements of the vascular wall such as endothelial cells in the samples, thus simulating vascular dysfunction.23

The appropriate collection sequence of blood in vacuum tubes, as recommended by CLSI publication H3-A6,18 is as follows: 1) coagulation; 2) serum with clot activator, with or without gel separator; 3) heparin with or without gel separator; 4) ethylenediaminetetraacetic acid (EDTA) with or without gel separator; and 5) glycolytic inhibitor. The modification of this sequence has the potential to introduce a source of contamination into primary collection tubes through carrying over of additives.18,19,24-26 Most of the phlebotomists we observed did not follow the recommended sequence (Table 1). When questioned about the collection sequence, phlebotomists admitted that they had been trained to collect blood in the evacuated tubes in a certain sequence but they did not consider this sequencing to be important. The primary emphasis in training was to fill the tubes completely with blood to satisfy the appropriate blood to additive ratio and to avoid collecting a volume of blood that is inadequate for analysis. Adequate mixing of blood in tubes containing anticoagulants or additives is essential for the effectiveness of those ingredients, as recommended by the datasheets from nearly all manufacturers.19,21 In our study, the lack of compliance with correct tube sequencing was observed in more than 80% (25 of 30) of phlebotomies; a significant difference (P = .04) was also observed between the results from public and private laboratories. The major error we observed was the lack of mixing in serum tubes (with clot activator and with or without gel separator), a practice that several phlebotomists considered to be unnecessary.

The use of a tourniquet is a universally accepted practice to facilitate vein location.27,28 Nevertheless, venous stasis due to prolonged tourniquet placement affects the concentration of several analytes.29-31 The CLSI16 currently recommends that tourniquet time should not exceed 60 seconds; recently, it has been demonstrated4-6 that 30 seconds might be optimal for maximum tourniquet time. All but 2 phlebotomists in this study exceeded the 60-second maximum recommended time in most of the phlebotomies they performed (Figure 1). It is noteworthy that the patients with conditions that might pose potential challenges to easy venipuncture were excluded from this study. Hence, it is plausible that in patients with difficult venous access, the tourniquet might be placed for an even longer period. It is not clear why private laboratories showed a significantly lower tourniquet time (ie, by approximately 40%) compared with public laboratories; one possible explanation is that the pressure for a fast turnaround time might have a greater influence on procedures in private laboratories.

In this study, we showed that performing simple and well-established procedures that affect the quality of the blood sample was not considered a priority in most facilities. Accordingly, quality assurance policies and training procedures do not place the necessary emphasis on the preanalytical factors, including phlebotomy procedures that affect laboratory results. It may appear that phlebotomy is like the dark side of the moon15 because so many best practices that exist in this field are mostly ignored or neglected by its practitioners.

**Conclusion**

In summary, our data show that in laboratories with comprehensive quality management procedures, practices that ensure the quality of diagnostic blood specimens collection by venipuncture were not followed by most phlebotomists. The tourniquet application time was usually long enough to change the concentration of several analytes. Better training for phlebotomists with major emphasis placed on sources of errors, as discussed in this article, would improve the overall quality of clinical laboratory testing.15,32

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