Clinical Laboratory Specimen Rejection—Association With the Site of Patient Care and Patients’ Characteristics

Findings From a Single Health Care Organization

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Context.—Programs to track laboratory quality have reported aggregated specimen rejection rates ranging from 0.30% to 0.83%. Because the performance of the laboratory, rather than errors, has been the focus, reasons for specimen rejection or demographic characteristics of individuals at risk for specimens of poor quality may not be fully understood.

Objective.—To calculate the proportions of rejected specimens stratified by point of collections and demographic information of patients.

Design.—Retrospective cross-sectional study. Data were retrieved from the intrainstitutional electronic databases.

Results.—The proportions of specimens that were rejected in the emergency department and inpatient services were 2-fold and more than 5-fold higher, respectively, than for the outpatient services. Assessment of data by patients’ ethnic heritages yielded no significant differences among African Americans (0.38%), Caucasians (0.38%), or “Other” (0.35%) in the outpatient services (P = .07). In the emergency department, the proportions of rejected specimens for African Americans (2.24%) were almost twice that of Caucasians (1.39%) and 30% higher than for Others (1.70%). A similar finding was observed for the inpatient services.

Conclusions.—The effect of ethnicity on the proportions of rejected specimens was significant for samples that were collected in the emergency department and inpatient services, even after adjusting for the total number of specimens. A constellation of factors, that is, disease severity and seriousness, practice of blood sample collection, and lesser proficiency of the nursing staff in phlebotomy may be reasons for this observation. However, the likelihood of differential care, although unlikely, cannot be refuted by the present data.

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Voluntary national programs to track laboratory quality, Q-Probes and Q-Tracks, have reported aggregated specimen rejection rates across multiple facilities ranging from 0.30% in outpatient facilities to 0.83% in hospital-based laboratories.1-2 Because the general performance of the laboratory, rather than errors, is the focus of the accreditation processes, reasons for specimen rejection may not fully be understood. In 1997 Jones et al3 reported that preanalytical errors constituted between 25% and 50% of the total errors in the clinical laboratory with hemolysed specimens as the primary error. Although the authors had stratified the reasons for specimen rejection by work shift and training background of the medical staff, they had not evaluated reasons by site of patient care or by patients’ demographic characteristics. More recently, Bonini et al,4 using the literature review approach, reported that a higher proportion of specimens that were collected at either inpatient or emergency department (ED) locations were rejected primarily because of hemolysis. However, as the authors stated, their findings were limited by the variations in the study design and the heterogeneity of error definitions. In view of these findings, we conducted a retrospective cross-sectional study to evaluate reasons for rejected blood specimens by the site of service (ED, outpatient, and inpatient services) in a single health care organization. In addition, data were analyzed separately by work shift of the laboratory personnel, patients’ ethnic heritages, and gender.

MATERIALS AND METHODS

Setting

The Henry Ford Health System (HFHS), the largest health care provider in southeastern Michigan, is a comprehensive, integrated self-contained health care system, organized so that each person in the system can receive every level of care from preventive and primary care to subspecialty services. Laboratory testing is performed at either the central laboratory facility that is housed within the Department of Pathology and Laboratory Medicine or the laboratories located within the premises of the satellite hospitals or clinics.

When a patient is first seen at any of the HFHS facilities for any reason, he or she is assigned a permanent and unique lifetime medical record number (MRN) which is entered into the...
Master Patient Index. The Master Patient Index resides within a larger relational database, the Corporate Data Store, which serves as the central repository for data on patient encounters. Among the other databases within the Corporate Data Store are information on the date and time of service, the physician at the clinical encounter, the place of the encounter, the primary diagnosis, and the laboratory services data. Most of the medical information generated from patient encounters is fed into the CarePlus, which is the electronic version of the medical record that contains physician notes, pathology diagnoses, radiology, and clinical laboratory results. Access to the databases is tightly monitored and is restricted to clinical and research staff members. In 2003, more than 560,000 people were cared for by HFHS, of whom 35% had declared their racial/ethnic heritage as African American and 60% as Caucasians. The ethnic heritage of the remaining 5% included Native American, Hispanic, Asian American, or biracial.

The data collection component of this project was exempt from requiring written informed consent as stipulated in the Department of Health and Human Services regulation 45 CFR 46, Nos. 3 and 5, because data were collected from a database that already existed and no participant was contacted for the study. The institutional review board at HFHS approved this study protocol (IRB No. 3554). This study is in compliance with the US Congress Health Insurance Portability and Accountability Act of 1996.

Data Collection and Statistical Methods

Laboratory (n = 10,186,745) and demographic (n = 135,665) data for the first quarter of year 2004 were retrieved from the Corporate Data Store (Figure). The laboratory data set included the following variables: (1) patients’ MRN, (2) specimen type (blood, urine, feces, etc), (3) laboratory service (blood bank, microbiology, transplant, biochemistry, etc), (4) ordering physicians’ internal codings, (5) laboratory personnel work shift, (6) specimen status (specimen unsuitable for analysis, specimen was not evaluated, or specimen was rejected), and (7) reasons for rejection (hemolysis, wrong information on the label, missing information, coagulated specimen, significant delay in transportation, inadequate specimen, improper container or collection, empty container, significant platelet clumps). The demographic data set contained information on (1) patients’ MRNs, (2) patients’ ethnic heritages, (3) patients’ gender, and (4) date of birth. The 2 data sets were then merged using patients’ MRNs.

Through an iterative data cleaning process, 39% of data (n = 3,981,623) were determined to be unrelated to the study hypothesis (point-of-care, blood gases, transfusion products, and urinalysis) and therefore deleted (Figure). Further review of the remaining data (n = 6,205,122) revealed that 27% of data (n = 1,679,801), collected between January 1 and February 28, 2004, were incompletely transmigrated from the old to the new computational system and therefore were removed from the data set. In addition, we deleted data pertaining to patients who had been referred to the HFHS and for laboratory tests that were outsourced and data related to microbiology, transplant, and blood bank laboratory testings also were removed (n = 3,161,204). The final data set, which contained a total of 1,364,117 blood specimen data, was merged with the demographic data set (n = 135,665) using the variable MRN (Figure).

We used the HFHS internal coding system for physicians to
Table 1. Proportions of Specimens Evaluated and Rejected by Sites of Patient Care

<table>
<thead>
<tr>
<th></th>
<th>Inpatient, No. (%)</th>
<th>ED, No. (%)*</th>
<th>Outpatient, No. (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specimens evaluated</td>
<td>483,958 (99.00)</td>
<td>137,819 (98.03)</td>
<td>732,246 (99.65)</td>
</tr>
<tr>
<td>Specimens rejected</td>
<td>4763 (1.00)</td>
<td>2767 (1.97)</td>
<td>2564 (0.35)</td>
</tr>
<tr>
<td>Total Specimens Received</td>
<td>488,721 (100.00)</td>
<td>140,586 (100.00)</td>
<td>734,810 (100.00)</td>
</tr>
</tbody>
</table>

* ED indicates emergency department.

identify the site of service, where requests for laboratory services were generated and, therefore, the specimens were collected (point of collection). The sites then were categorized as ED, outpatient service, or inpatient service. The variable work shift was categorized into 3 groups: midnight (12:00 AM to 7:59 AM), day (8:00 AM to 3:59 PM), and evening (4:00 PM to 11:59 PM).

Ethnic heritages of the patients were classified as Caucasians, African American, or Others. The classification of Others includes, Asian American, Native American, Hispanics, and individuals who had described their ethnic heritages as biracial. The 3 classifications were justified because Caucasians and African Americans constitute about 95% of the patient population at the HFHS.

The distribution frequencies between the point of collection and specimen rejections first were evaluated using Mantel-Haenszel chi-square test of significance. This test is based on 2 ¥ 2 contingency distribution tables. We then applied multivariate logistic regression to determine the variables that were best associated with the likelihood of specimen rejection. In developing the best-fitted model, we first estimated the individual effect of each variable (gender, work shift, and ethnicity) and their interactions on specimen rejection. Variables with a P < .05 from the univariate analyses were considered as the candidate variables. Interactions between variables also were tested at P = .05. The initial model was built using the forward selection approach. The interactions between ethnicity with site of service and between gender and site of service, and between work shift and site service were statistically significant (P < .01) and therefore were included in the final model. All statistical tests were 2-sided and analyses were performed using SAS version 9.1 (SAS Institute, Cary, NC).

RESULTS

We identified a total of 1,364,117 physicians’ test orders, corresponding to 1,356,665 patients’ visits, of which 0.74% (n = 10,094) were rejected because of errors in the preanalytical phase of laboratory medicine. Stratification of data by the site of service revealed that the proportions of rejected specimens was the highest in the inpatient services (47.15%) followed by ED and outpatient services with 27.40% and 25.39%, respectively (Table 1). However, after adjusting for the total number of specimens submitted by each site, the proportion of rejected specimens from the ED was almost twice that of the inpatient services and more than 5-fold higher than the outpatient services (P < .001). Further evaluation of data showed that 93.2% (n = 2,579) of the rejected specimens from the ED were because of hemolysis, 3.32% (n = 92) because of improper method of collection, 1.55% (n = 43) because of empty specimen containers, 1.19% (n = 33) because of mislabeling, and the remaining 0.74% (n = 21) were rejected because of inadequate quantity of specimen, clotted specimens, delay in transportation, or significant platelet clumps or general unspecified problems. Of the total specimens that were collected in the inpatient services, 79.2% (n = 3,773) were rejected because of hemolysis, 10.67% (n = 508) because of improper method of collection, and 5.64% (n = 269) because of labeling problems. The remaining 4.47% (n = 213) were rejected because specimens were clotted, were delayed in transportation, or had significant platelet clumps or other general unspecified problems. Finally, of the blood specimens drawn in the outpatient services, 80.49% (n = 2,063) were rejected because of hemolysis, 8.50% (n = 218) because of improper method of collection, 4.33% (n = 111) because of mislabeling, and the remaining 6.63% (n = 172) because of the other mentioned problems (Table 2).

Rejection by the Demographic Characteristics

We also assessed whether the proportion of rejected specimens differed by gender and ethnicity of the patients. For the 3 service sites combined, 0.81% specimens for women and 0.67% specimens for men were rejected (P < .001). Stratification of data by the site of service indicated that the difference in the proportions of rejected specimens collected in the ED was not statistically significant between women (2.03%) and men (1.89%) (P = .07). However, for the inpatient services, the proportions of rejected specimens for women and men were 1.08% and 0.88%, respectively (P < .001). Similarly, the proportions of rejected specimens generated by outpatient services was higher for women (0.42%) than for men (0.27%) (P < .001). Evaluation of rejected specimens by patients’ ethnic heritages yielded that the proportion of the rejected specimens for African American patients was more than 2-fold high-
er than for Caucasians. The proportion of rejected specimens for patients with the Others ethnic heritages was 1.5-fold higher than for Caucasians (Table 3). We further evaluated the proportions of rejected specimens by patients' ethnic heritages, adjusting for the site of service. For the outpatient services, we did not find statistically significant differences in the proportions of rejected specimens among the 3 ethnic classifications (P = .07). However, for specimens drawn in the ED the proportion of rejected specimens for African Americans (2.24%) relative to Caucasians (1.39%) was about 60% higher (P < .001, 95% confidence interval [CI] = 1.49–1.79). Although the proportion of rejected specimens for individuals in the ethnic category of Others was about 22% compared with Caucasians, this difference did not reach the level of statistical significance (P = .08, 95% CI = 0.97–1.55). Finally, for specimens that were drawn in the inpatient services, the proportions of rejected specimens for African Americans was twice that of the Caucasian patients (P < .001, 95% CI = 1.97–2.24) and 1.5-fold higher for patients in the Others ethnic category compared with the Caucasian patients (P < .001, 95% CI = 1.27–1.83).

The proportion of specimens that were collected in the inpatient services was slightly more than 2-fold for African Americans (1.28%) compared with the Caucasian patients (0.61%) (P < .001, 95% CI = 1.97–2.25) or the Others ethnic categories (Table 3).

### Rejection by Work Shift of Laboratory Personnel

We also assessed the proportion of rejection by the work shifts of the laboratory personnel. About 66% of rejections occurred during the evening shift. Laboratory personnel working during the day and midnight shift accounted for 19.8% and 14.2% of rejected specimens, respectively. Proportion of rejected specimens was then adjusted for the total number of specimens that were submitted to the laboratory during each shift. The proportion of rejections was the highest for the evening shift (0.82%), followed by the day shift (0.66%) and the midnight shift (0.59%), respectively (P < .001).

### COMMENT

We conducted a cross-sectional study with the primary objective of identifying the proportions of blood specimen that were rejected by the point of collection and by patients' demographic characteristics. Identification and documentation of a problem is a first step in the multistep process of reducing errors and improving the quality of health care.

We detected an overall specimen rejection rate of 0.74% in our institution, which was almost twice as high as the median rate (0.35%) that was reported by the College of American Pathologists Q-Probe study of 453 laboratories in 1997.2,3 It is imperative to state that about 10% of the participants in the Q-Probe study had reported a rejection rate of more than 1.35%.7,8 We ascribe the differences between these 2 reports to the variations in the number of institutions involved in each study, the method of data collection and reporting, and the definition of errors. Our finding is derived from practitioners, policies, and procedures used in one single medical group; whereas, the previous study was the result of cooperation of a total of 453 different laboratories. The heterogeneity in the definition of errors has been reported as one of the difficulties in assessing the true rates of errors in the preanalytic phase of laboratory medicine.4

Our finding that the proportions of rejected blood specimens that were collected in the ED and in the inpatient services was higher concur with previous reports.4 We attribute the present finding to a combination of several factors such as the practice of blood sample collection in the ED and the inpatient services, the higher complexity of the examination performed and multiple drawings, and the number of physicians involved with the care of a patient.5,6 Also, it is common for the medical staff at the ED and inpatient services to collect a blood specimen through an intravenous catheter at the time of its insertion to minimize the patient's discomfort and to save clinical time.6 However, this practice has been reported to increase the likelihood of hemolysis because of flow through the narrow tube and the tendency of the conduit to tighten or even collapse in response to the negative partial pressure exerted by the suctioning pressure.6 In addition, the lesser proficiency and training of the nursing staff in phlebotomy relative to the trained laboratory phlebotomist may be another reason for the higher specimen rejections in ED and inpatient services. Findings from the Q-Probe study yielded a significant increase in the probability of rejection if the specimen was drawn by an in-hospital nonlaboratory personnel.3

Our data indicated that the proportions of rejected specimens collected at ED or inpatient services were about 2-fold higher for African American patients compared with the Caucasians patients and individuals in the Others ethnic category. Yet, we detected no significant difference for specimens that were drawn in the outpatient services. Because we evaluated the proportion of rejected specimens using the retrospective data, we were unable to reasonably discern the reasons. However, we hypothesize that the severity and seriousness of the diseases and comorbidities of patients admitted to ED or inpatient services are the likely contributing factors for the higher proportion of specimens rejected from these 2 locations. Also, in general, African American patients are more likely to

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**Table 3. Proportions of Rejected and Evaluated Specimens by Ethnic Heritages of Patients and Sites of Patient Care**

<table>
<thead>
<tr>
<th>Specimens</th>
<th>African Americans</th>
<th>Caucasians</th>
<th>Others</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rejected, No. (%)</td>
<td>Evaluated, No. (%)</td>
<td>Rejected, No. (%)</td>
<td>Evaluated, No. (%)</td>
</tr>
<tr>
<td>ED*</td>
<td>2071 (2.24)</td>
<td>90,293 (97.76)</td>
<td>580 (1.39)</td>
</tr>
<tr>
<td>Inpatient</td>
<td>3198 (1.28)</td>
<td>246,684 (98.72)</td>
<td>1,257 (0.61)</td>
</tr>
<tr>
<td>Outpatient</td>
<td>968 (0.38)</td>
<td>254,708 (99.62)</td>
<td>1,499 (0.35)</td>
</tr>
<tr>
<td>Total†</td>
<td>6,237 (1.04)</td>
<td>5,916,85 (98.96)</td>
<td>3,336 (0.49)</td>
</tr>
</tbody>
</table>

* ED indicates emergency department.
† A total of 39,904 laboratory specimen data (3%) were deleted from the analysis because of the missing values for the variable ethnicity.
choose the ED, independent of health insurance status, as the port of entry into the health care system, therefore increasing the probability of errors in specimen collection and handling for them. However, we cannot refute the competing hypothesis of differences in the delivery of quality of care, although quite unlikely, in these 2 locations.

When the quality of a blood specimen is poor, it cannot be processed by the laboratory. This leads to a second request for blood specimen and therefore to an increased turnaround time for the laboratory, which is positively correlated with the delay in diagnosis. About 90% to 96% of the diagnostic delays have been attributed to problems associated with errors in preanalytic phase of laboratory medicine.9–12

Patients’ perception of quality of care is based on the timely access to and discharge from the health care facility, safety, efficient care coordination, and the number of specimens collected.13 Given that the proportions of rejected specimens is significantly higher for African American patients, the delivery of quality of care then may be misconstrued and exaggerated. Additionally, ED physicians’ dissatisfaction is positively correlated with the turnaround time of the laboratory.9 Physicians’ dissatisfaction with the health care organization indirectly can influence the delivery of quality of care. Again, if in general, African American patients are more likely to choose the ED, independent of health insurance status, as the port of entry into the health care system,7 then the likelihood of perception of disparity in the delivery of quality of care also can be exaggerated.

In a recent report the US health care industry ranked the highest in the rate of laboratory errors and duplicate tests compared with 5 other industrialized countries.14 This observation was attributed to a more fragmented health care system and more frequent ordering of tests by multiple physicians involved in the care of a patient.14 We argue that the quality of specimen delivered to the clinical laboratory is another contributing factor to the higher laboratory errors and multiple testings in the United States.

The main strengths of our study are its sample size and its data that were generated by practitioners, policies, and procedures used in one single medical group. Our study also had 2 limitations. First, its retrospective cross-sectional design did not permit us to adequately discern factors that were contributing to specimen rejections. Second, we were limited to speculate the reasons for the observed higher proportion of rejected specimens for African American patients. However, our findings further shed light on the magnitude of errors in the preanalytic phase of the laboratory medicine. The influence of “quality of specimen” and other errors of preanalytic phase of laboratory medicine on the total laboratory errors, delays in diagnosis, and disparity in the quality of medical care deserve a more in-depth scientific evaluation.

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References