Patient Safety in the Clinical Laboratory
A Longitudinal Analysis of Specimen Identification Errors

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Context.—Patient safety is an increasingly visible and important mission for clinical laboratories. Attention to improving processes related to patient identification and specimen labeling is being paid by accreditation and regulatory organizations because errors in these areas that jeopardize patient safety are common and avoidable through improvement in the total testing process.

Objective.—To assess patient identification and specimen labeling improvement after multiple implementation projects using longitudinal statistical tools.

Design.—Specimen errors were categorized by a multidisciplinary health care team. Patient identification errors were grouped into 3 categories: (1) specimen/requisition mismatch, (2) unlabeled specimens, and (3) mislabeled specimens. Specimens with these types of identification errors were compared preimplementation and postimplementation for 3 patient safety projects: (1) reorganization of phlebotomy (4 months); (2) introduction of an electronic event reporting system (10 months); and (3) activation of an automated processing system (14 months) for a 24-month period, using trend analysis and Student t test statistics.

Results.—Of 16,632 total specimen errors, mislabeled specimens, requisition mismatches, and unlabeled specimens represented 1.0%, 6.3%, and 4.6% of errors, respectively. Student t test showed a significant decrease in the most serious error, mislabeled specimens (P < .001) when compared to before implementation of the 3 patient safety projects. Trend analysis demonstrated decreases in all 3 error types for 26 months.

Conclusions.—Applying performance-improvement strategies that focus longitudinally on specimen labeling errors can significantly reduce errors, therefore improving patient safety. This is an important area in which laboratory professionals, working in interdisciplinary teams, can improve safety and outcomes of care.

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Improving the safe care of patients has recently evoked national attention. Although recognized for centuries, patient safety first made major headlines in 2000 with the publication of “To Err Is Human: Building a Safer Health System.” This extensive review recognized earlier research showing that preventable adverse events leading to death occur as frequently as 44,000 to 98,000 times per year, according to 2 studies in New York and Colorado and Utah. Patient safety is affected by the frequency and seriousness of errors that occur in the health care system. Accurate specimen identification is a challenge in all hospitals, and a mislabeled specimen can lead to devastating consequences for patients. In an effort to decrease the risk of potential harm caused by labeling errors, some hospitals have implemented a zero tolerance laboratory specimen labeling process.

Error rates in laboratory practices are routinely collected for a number of performance measures in clinical pathology laboratories in the United States; however, a critical performance measures list has not yet been recommended. The most extensive databases describing error rates in pathology were developed and are maintained by the College of American Pathologists. These databases include the College of American Pathologists’ Q-Probes and Q-Tracks programs, which provide information on error rates from more than 130 interlaboratory studies.

A recent article identified 17 types of errors associated with invasive procedures, 10 of which were directly related to failure to verify the patient’s identity. The Joint Commission for the Accreditation of Healthcare Organizations (JCAHO) standard for “improving the accuracy of patient identification” was accepted as 1 of 6 National Patient Safety Goals for 2003, shortly thereafter. Patient identification continues as a major priority for the JCAHO laboratory patient safety goals for 2006.

A key clinical care delivery concept is the emphasis on “patient-centeredness.” Clinical laboratories are, in many ways, models of “patient-centered” services. Laboratory
results provide diagnostic clues, assist in therapeutic decision-making, and determine clinical progress for multiple disease entities. The clinical laboratory is also an area where errors in patient identification can potentially result in significant harm. In a typical hospital clinical laboratory, thousands of specimens are received and analyzed daily. These specimens require correct identification of the patient from phlebotomy through reporting of results to the requesting health care provider.

Recognizing the importance of clinical laboratories to patient safety, the Institute for Quality in Laboratory Medicine was organized in 2003 and incorporated in 2005, with the assistance of the Centers for Disease Control and Prevention. The College of American Pathologists recognized the importance of specimen and patient identification by initiating a series of quality measurement tools for clinical laboratories; for example, a 2-year Q-Track study of continuous wristband monitoring that demonstrated a decrease, 7.4% to 3.05%, in wristband errors from voluntarily participating institutions. Increased attention to and awareness of these errors likely contributed to the decline during the 8 quarters of the study.

Despite this heightened attention and interest in patient safety in the clinical laboratory, many institutions are unsure of the best approach for reducing laboratory-related patient errors. Also, each institution faces unique longitudinal effects on patient safety projects related to shifting priorities at the local, regional, and national levels.

MATERIALS AND METHODS

Beginning in November 2002, University of California, Los Angeles (UCLA) Clinical Laboratories initiated a study to determine a baseline frequency for blood specimen errors. From this baseline data collection grew the full development of a specimen/patient identification project examining 3 blood specimen identification errors: (1) unlabeled specimens, (2) specimen/requisition mismatch, and (3) mislabeled specimens. Error trends and statistical analyses were followed through the course of 3 patient safety interventions: (1) reorganization of phlebotomy services, (2) implementation of an electronic event reporting system, and (3) installation of an automated specimen processing system.

To assess patient identification and specimen labeling improvement, the faculty, nurses, and staff at UCLA established guidelines and definitions to create 15 specimen error categories (Table). The UCLA Clinical Laboratories began collecting baseline specimen error information for each of these error categories from November 2002 to March 2003. Implementation data for total specimen error information for each of these error categories from specific tabulated throughout the project implementation phase, during which more than 4.29 million specimens and 2.31 million phlebotomy requests were received. The 3 categories of critical patient identification errors were (1) specimen/requisition mismatch, (2) mislabeled specimens ("wrong blood in tube"), and (3) unlabeled specimens (including specimens labeled with only 1 of 2 required identifiers).

Three patient safety activities were introduced at 4, 10, and 14 months:

1. The laboratory began providing phlebotomy services around the clock (4 months); nursing in-service education was performed for ICU nursing phlebotomy. Prior to the implementation of 24-hour phlebotomy service, 13 to 16 phlebotomists performed early morning blood draws. There were no phlebotomists on the evening or night shifts. Twelve additional phlebotomists were hired to provide the 24-hour phlebotomy service. During the early morning rounds (4:00 AM to 7:00 AM), 13 phlebotomists perform the blood draws. Four phlebotomists serve the day shift hourly and timed draws, 4 work the evening shift, and 3 operate on the night shift. Prior to implementation of the patient safety projects, the nursing staff ordered all tests for the timed and hourly draws just before they drew blood from the patient and ensured that all orders were accounted for at the time. Under the revised process, nursing clerical staff enter orders into the hospital information system for phlebotomy to draw blood from the patients.

2. In 2003, at 10 months, the University of California completed an effort to implement an online electronic event reporting

### Specimen Error Information

<table>
<thead>
<tr>
<th>Specimen Error Category</th>
<th>Definition</th>
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<tbody>
<tr>
<td>Clotted specimen</td>
<td>A specimen received that otherwise should have been received in an unclotted state.</td>
</tr>
<tr>
<td>Container leaking</td>
<td>A specimen received that is leaking or otherwise has breached the integrity of the container.</td>
</tr>
<tr>
<td>Contaminated</td>
<td>A specimen that otherwise should be received using sterile collection techniques that has obvious contamination through handling or appearance.</td>
</tr>
<tr>
<td>Duplicate order</td>
<td>A specimen received after a first specimen has been received within a time frame established by the laboratory when repeat specimens are not typically required for patient evaluation.</td>
</tr>
<tr>
<td>Hemolyzed specimen</td>
<td>A specimen received that has evident hemolysis of red blood cells as evidenced by pink/red discoloration of the serum or plasma.</td>
</tr>
<tr>
<td>Improperly collected specimen</td>
<td>A specimen received that has been collected in the wrong container or tube required for the type of testing ordered.</td>
</tr>
<tr>
<td>Improperly handled specimen</td>
<td>A specimen received that may not have been transported or handled in a proper manner, for example, transport at an inappropriate temperature.</td>
</tr>
<tr>
<td>Mislabeled specimen</td>
<td>A specimen that is not labeled with appropriate patient identifiers.</td>
</tr>
<tr>
<td>Quantity not sufficient (QNS)</td>
<td>A specimen received in a quantity not sufficient for proper testing.</td>
</tr>
<tr>
<td>Requisition mismatch</td>
<td>A specimen received with a requisition that does not match the request or patient identified on the tube or container.</td>
</tr>
<tr>
<td>Specimen not received</td>
<td>Recording of an order, either electronically or manually, not matched with an actual received specimen at the time or subsequent to the order receipt.</td>
</tr>
<tr>
<td>Specimen not suitable for required testing</td>
<td>Some specimen types or tubes/container are not suitable for a given test.</td>
</tr>
<tr>
<td>Tube overfilled</td>
<td>Blood collected in a tube that has been overfilled, excluding some testing.</td>
</tr>
<tr>
<td>Tube underfilled</td>
<td>Blood collected in a tube that has been underfilled, excluding some testing.</td>
</tr>
<tr>
<td>Unlabeled specimen</td>
<td>A specimen received in the clinical laboratory with no label or without 2 identifiers on a label.</td>
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system at all 5 medical center campuses, including UCLA. The system was built from scratch, and initially developed as an early risk management notification system at University of California-Davis. The system was redesigned to incorporate important patient safety concepts by a consortium of University of California quality management, risk management, and performance improvement staff. This electronic event reporting system now allows nurses, physicians, and other health care professionals to easily report adverse events and near misses from any computer within their organization. Errors are entered into the Event Reporting System for unlabeled, mislabeled, and specimen/requisition mismatch. Error information is taken from the Cancel Comment reports printed daily for issues that occurred the preceding day.

A unique feature compared to other event reporting systems is the ability for each organization to customize the event reporting system to meet their specific performance improvement goals. Migration to an electronic event reporting system has resulted in a 2-fold to 3-fold increase in reported events compared with those that were reported using the previous paper system.

3. Prior to the installation of the Beckman Coulter Power Processor (Los Angeles, Calif), specimens were received in the laboratory, ordered in the laboratory information system, labeled, sorted, centrifuged, aliquoted, and sorted again for different testing areas. The receiving to final sort and delivery of specimens required a minimum of 6 to 7 full time equivalents. On January 23, 2004, the UCLA began a laboratory automation project. As part of this project, in May 2004, at 14 months, an automated processing system was activated in Specimen Receiving in the UCLA Clinical Laboratories. At present, specimens are still received, ordered, and labeled manually, but they are sorted, centrifuged, aliquoted, and sorted again by the automated processor. Instead of the minimum 6 to 7 full time equivalents that were required prior to automation, we are now able to function with 4 to 5 full time equivalents for the basic processing operation per shift (with the exception of night shift when fewer specimens are processed). The Beckman Coulter Power Processor implementation has consolidated centrifugation, aliquoting, and the sorting steps of specimen processing.

Statistical analyses were performed on the data collected by 2 methods. The paired Student $t$ test was conducted to measure and compare the numbers of unlabeled and mislabeled specimens before (November 1, 2002 through July 31, 2003) and after (June 1, 2004 through August 31, 2005) interventions by the 3 patient safety activities to assess whether a statistically significant difference existed between the two under different conditions. The paired $t$ test is used to compare preintervention and postintervention measurements in a single group for a time period. It is appropriate when the variable of interest is continuous and approximately normally distributed. The paired $t$ test is suitable for our study because it is a statistical test commonly used in situations in which subjects are tested in a pre-post situation, that is, across time, with some intervention occurring such as the 3 patient safety activities (phlebotomy services around the clock, electronic event reporting system, and automated processing system, introduced at 4, 10, and 14 months, respectively).

The second statistical tool applied to this study was linear trend analysis. Linear trend analysis (indicating a statistical trend) was conducted on the collected data to allow us to plot aggregated response data related to time and determine if the interventions resulted in a statistical trend. This is especially valuable when conducting a long-running survey and measuring differences in perception and responses for a period of time. If an experiment contains a quantitative independent variable, then the shape of the function relating the levels of this quantitative independent variable to the dependent variable is of interest. To apply this analysis to our study, we considered the effect of the 3 patient safety activities (independent variables) on the incidence of critical errors (dependent variable). Trend analysis can be used to test different aspects of the shape of the function relating the independent variable (patient safety initiatives) and the dependent variable (incidence of critical errors). Trend analysis consists of testing 1 or more components of trend. These components are tested using specific comparisons. The linear component of trend is used to test whether there is an overall increase (or decrease) in the dependent variable as the independent variable increases.

**RESULTS**

The total number of specimens in the 3 critical identification error categories (mislabeled, requisition/specimen mismatch, unlabeled specimens) represented 11.9% of all specimen errors from September 1, 2003, through August 31, 2005 (1978 critical errors, $N = 16632$ total errors) (Figure 1). More than 4.29 million specimens and 2.31 million phlebotomy requests were received in the same time period. Critical identification errors occurred in fewer than 1 in 1000 of all procedures or specimens received.

Major external factors during the entire study period (November 1, 2002, through August 31, 2005) included...
outside hospital management consultant oversight beginning fall 2002; an institution-wide JCAHO accreditation survey in April 2004; departure of the outside consultant, June 2004; and a chief executive officer leadership change, July 2004. There was no change of leadership within the laboratory during this period. No significant differences were distinguishably associated with any of the external factors (Figure 2, A).

Initially after the implementation of in-service educational activities and full-time around-the-clock phlebotomy, there was an increase of 33.7% in reported errors (data not shown), because of process changes and higher reporting rates related to the educational activities. The total number of blood draw errors decreased after implementation of the electronic error reporting (March 2004) and installation of an automated specimen processor (September 2004) (Figure 2, A). Of the total specimen errors (N = 16,632) (September 1, 2003 through August 31, 2005), mislabeled specimens, requisition mismatches, and unlabeled specimens represented 1.0%, 6.3%, and 4.6%, respectively (Figure 2, B).

Intensive care units had a disproportionate frequency, 31.2% (range, 21.6%–37.7%) of specimen errors even though they accounted for only 16.1% of total beds (Figure 3, A). Within the ICUs, requisition mismatches were the most common category of misidentification (55.1%) followed by unlabeled specimens (38.2%) (Figure 3, B).

The trend analysis data for 26 months (July 1, 2003–August 31, 2005) are shown in Figure 4. The incidence of critical errors decreased as the patient safety initiatives were introduced. Linear trend analysis shows a general decline during this time in errors for mislabeled specimens, requisition mismatch, and unlabeled specimens. The numbers in all 3 categories decreased after interven-
tions by the 3 patient safety activities (June 1, 2004–August 31, 2005) compared to performance before any of the patient safety projects were implemented. Statistical analysis using paired Student t test showed $P < .001$, for mislabeled specimens, and $P = .15$ for unlabeled specimens when compared to November 1, 2002, through July 31, 2003.

COMMENT

Correct patient identification is an important patient safety initiative. Its prominence is validated by the recognition of patient identification by JCAHO as a primary patient safety goal. Analysis of the frequency and risk factors for patient identification errors, however, is infrequently reported in the literature. We present here an analysis of specimen errors, including an in-depth study of patient identification errors during the course of 3 patient safety implementation projects. Although these data represent the experience of a single academic institution, the results share commonalities with many other clinical laboratories.

Of the 3 categories of critical patient identification errors, the most frequently documented occurrence was the receipt of a mismatched requisition with a specimen labeled with another patient's name. This probably represents the ease with which this type of error is recognized. As soon as a specimen is received, the mismatch is readily apparent in the clinical laboratory. The second most frequently occurring specimen identification error was the receipt of an unlabeled specimen, also easily recognized...
Figure 4. Trend analysis: critical errors by type/month (July 1, 2003–August 31, 2005). Longitudinal data for the 3 critical identification errors by month demonstrates a decrease in errors by trend analysis. The 3 patient safety initiative implementation dates are noted by dotted lines.

by laboratory personnel. For purposes of this study, a partially labeled specimen missing 1 of 2 identifiers was also considered unlabeled, to emphasize the importance of the 2-identifier initiative by JCAHO in our institution.

The most infrequently reported specimen identification error was the notorious “mislabeled” specimen. Sometimes referred to as “wrong blood in tube,” this specimen represents blood from 1 patient accompanied by both a requisition and label that indicates another patient. In the current study the reduction of this type of error post patient safety interventions was greater than the reductions of the other 2 error types (Figure 4). The other 2 error types are more apparent and hence more easily recognized, documented, and controlled. The detectability of such errors as mislabeled specimens is very low, because the errors generally are not discovered until a clinician questions a result that is highly atypical for a given patient (eg, a highly elevated glucose level in a nondiabetic patient). Hence with the introduction of the patient safety interventions, the most significant decrease was seen with this error type. These errors are probably the most severe of patient errors, because there is no reason to question a clinical action taken in response to the laboratory result. This type of error would score high for severity and low for detectability using assessments such as the failure mode and effects analysis.11 It is reasonable to conclude that the number of mislabeled specimens observed in this study underestimates the actual frequency of mislabeled specimens.12

An important observation of this study was that patient identification errors occur more frequently on specimens received from ICUs (Figure 3, A and B). This is somewhat anticipated, given that many critical care specimens are drawn from lines and by nurses, in more complex care environments. When the percentage of specimens for all 3 identification error types was compared to the percentage of ICU beds, 21.6% to 37.7% of errors were noted in ICU locations (ICU beds represent 16.1% of total inpatient beds at UCLA). The increase in ICU errors was also observed when patient days were analyzed (ICU patient days vs total patient days, data not shown). Higher acuity care frequently requires nursing performance of phlebotomy from peripheral and central lines. These processes are inherently more complicated with more process points at which errors can occur (failure mode and effects analysis data not shown), possibly contributing to increased error rates in ICUs.

When viewed from the perspective of all types of specimen errors, critical identification errors occurred in fewer than 1 in 1000 procedures or specimens. This information may seem somewhat reassuring; however, it still represents approximately 3 to 4 “recognized” errors per day. The absolute magnitude of unrecognized mislabeled spec-
Patient Safety and Specimen Identification

Patient identification can be improved for clinical laboratory specimens. Institutions considering such projects for improving their patients’ safety should consider data-driven longitudinal models. Also, awareness is a key factor in ensuring successful implementation; awareness may additionally be a key component of patient safety sustainability.

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References