

Decreasing Mislabeled Laboratory Specimens Using Barcode Technology and Bedside Printers

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Mislabeled laboratory samples has been found to be a high-risk issue in acute care hospitals. The goal of this study was to decrease mislabeled blood specimens. In the first year after the implementation of a positive patient identification system using barcoding and computer technology, the number of labeling errors decreased from 103 to 8 per year. The outcome was clinically and statistically significant ($P < .001$). **Key words:** *barcoding, laboratory, medical errors, mislabeling, patient safety, specimen labeling, technology*

THE rising concern and attention to patient safety in health care create the need for health care organizations to implement, monitor, and revise practices to promote a culture of patient safety and avoid errors. Wrong patient errors can occur in every aspect of patient diagnosis and treatment. The importance of proper patient identification is recognized as an essential element in maintaining a foundation for patient safety.¹ The importance of correct patient identification is recognized by The Joint Commission as a safety goal.² National patient safety goal 1 addresses the need to improve the accuracy of patient identification when providing care, treatment, and services. In addition, this year, The Joint Commission has added new requirements to this goal, which include either a 2-person bedside

patient verification process or an automated identification technology process when collecting blood samples. The College of American Pathologists (CAP) has also recognized patient identification as a cardinal safety goal.³

Correct patient identification and correct specimen labeling are critical patient safety issues in health care. The laboratory testing process plays a key role in the care of patients via diagnostics and therapeutic monitoring.⁴ Errors can occur at any step in the testing process, and it is estimated that 1 of 4 errors can have consequences for the patient.⁵ More than 160 000 adverse medical events per year have been suspected in the United States because of misidentification of patient or laboratory specimen.⁶ Specimen mislabeling can cause errors in diagnosis and lead to inappropriate treatment and possible patient harm⁷ as well as create “near-miss” situations that may cause emotional trauma to patients.⁸

PATIENT AND BLOOD SPECIMEN IDENTIFICATION ERRORS

Proper patient identification and handling of specimens are crucial steps that can have a negative impact on patient safety if performed incorrectly.⁹ Determining the frequency of

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patient misidentification and specimen mislabeling relies on the process of voluntary reporting systems rather than a systematic approach such as a prospective study. It is generally believed that routine error-finding methods underestimate true error rates⁶ and that published error rates are likely to be underestimated because of inconsistent or inadequate detection and reporting mechanisms.¹⁰

Frequencies and types of mistakes throughout the total laboratory testing process have been described with large heterogeneity in study design, data collection approach, time frame, and definition of error.^{4,11} However, there is consensus that a majority of errors occur primarily in the preanalytic phase, which includes the processes of patient identification and specimen labeling.^{4,11-13}

A good source of data on specimen mislabeling is from the CAP, which has performed more than 130 studies constituting the largest database of laboratory errors in this nation.¹⁰ The occurrence of patient identification mistakes with regard to incorrect or missing wristband patient data was found in one study to be as high as 7% across 217 health care institutions.¹⁴ In a longitudinal analysis of blood specimen errors, 11.9% of the errors were due to mislabeling and/or specimen-requisition mismatch¹⁵ and were deemed critical errors because of direct relationship with patient identification.

In one large multicenter study, 55% of specimen identification errors were related to a primary specimen label error.⁶ In that same study, an adverse event resulted in 1 of 18 identification errors. If this rate of adverse event is extrapolated to all the nation's hospital-based laboratories, the authors estimate that 160 900 adverse events per year could result from mislabeled laboratory samples.⁶

STRATEGIES TO REDUCE PATIENT AND BLOOD SPECIMEN IDENTIFICATION ERRORS

The good news is that reducing patient and specimen identification errors has been

demonstrated in several institutions. Creating awareness and monitoring of proper patient identification via checking wristbands prior to phlebotomy demonstrated a decrease in patient identification errors from 7% to 3% across 217 institutions over a 2-year period.¹⁴ In a multi-institutional survey of more than 3 million specimen labels to determine frequency of specimen-labeling errors, it was found that institutions that actively participated in quality monitoring had fewer errors in specimen labeling.¹⁶ Data from CAP also revealed that misidentification mistakes decreased from 4% to 1% with ongoing quality-monitoring processes.¹⁰ The implementation of safety projects such as nursing education and online incident reporting also has been shown to reduce significantly mislabeling errors.¹⁵ Another health care institution demonstrated that tracking and immediate investigation of errors and timely feedback to patient care areas reduced mislabeling incidents from 47% to 14%.¹⁷ Implementation of organizational policy addressing accuracy of specimen labeling also has been shown to be successful, leading to a 75% reduction in laboratory specimen-labeling errors.¹⁸

In addition to implementing labeling policies and educating staff, perhaps the strongest intervention to reduce labeling errors is the addition of barcode technology.⁸ The Food and Drug Administration has proposed barcoding at the point of care for medication and blood product delivery.¹⁹ The use of automated patient identification and specimen collection techniques can be an additional safety net for routines that are vulnerable to error, especially when coupled with strong system designs.²⁰ The clinical applications of electronic and information technology support can assist in the identification, control, and reduction of error rates throughout the laboratory testing process.²¹

Barcode technology has been applied successfully in many aspects of patient care including identification of laboratory specimens,²² blood products,²³⁻²⁵ point of care testing,^{26,27} and medication dispensing and adverse drug effects.²⁸ Patient wristbands

with unique barcoded patient identifiers have the potential to improve the patient identification process throughout the episode of care. Integrating barcode technology at the point of care and throughout the entire testing process adds to the reliability of conventional means of patient identification and provides much potential for decreasing error related to misidentification.²⁴

METHODS

Planning phase

The goal of this project was to decrease specimen-labeling errors in hospital patients who had blood tests ordered. Patients would benefit through enhanced timeliness of laboratory results, fewer delays in treatment because of redundant sampling, and comfort by avoiding redraws of blood specimens. The nursing and laboratory staff would benefit through decreased rework in the specimen drawing and testing process.

Since 1997, this 227-bed not-for-profit acute care community hospital has used decentralized phlebotomy as part of the patient care model. All patient care technicians (PCTs) and registered nurses (RNs) are extensively trained in the importance of patient identification and bedside labeling as well as specimen collection techniques. As part of this decentralized phlebotomy system, specimen labels were printed from a central printer in the nurse's station and were then sorted by patient. The hospital's Lab Variance Committee reviewed data related to mislabeled specimens, identifying and concentrating on the areas most closely related to patient safety. These errors were defined as wrong patient label on specimen or specimens from multiple patients placed in the same specimen transport bag. As a standard procedure, specimens from a single patient were to be placed in a single transport bag, and it was assumed that a bag containing specimens with multiple names had another patient's label applied erroneously. The specimen label printing process at the nurse's station was identified with

both of these types of potentially serious errors.

The plan-do-check-act performance improvement methodology was used. Despite actions including changing the font on the labels to enlarge the name, inserting a blank label between each patient name when printing, and requiring additional staff training and disciplinary action, blood specimen labeling continued to be a problem. Staff accountability cannot be minimized but blaming individuals accomplished little to make the system safer and prevent reoccurrence.

Root cause analysis

Adverse event reports were analyzed to determine the type and frequency of errors. In addition, process steps contributing to the errors needed to be identified to determine possible solutions. Unit observations using an observation tool identified process inputs. A cause-and-effects analysis was developed to prioritize the reasons contributing to errors. The formation of focus groups to review the data helped to prioritize and target improvement efforts. The focus group determined that the centralized nature of the label printing contributed significantly to the problem of mislabeled specimens. The cause-and-effects analysis highlighted the opportunity to explore a technological solution to this high-risk, high-volume, and problem-prone process. On analysis, 9 of the top 10 causes were determined to be addressed by the technology of a positive patient identification (PPID) system. These causes included such issues as patients with similar or the same last names, not checking the armband, no armband on the patient, and the labels not taken into the room when the blood was drawn.

Because methods to improve the process and enhance staff education had failed to decrease significantly specimen-mislabeled errors, we decided that technology could play an important role in enhancing the process and improving compliance. The need for a phlebotomy and laboratory specimen PPID system was identified; this system would enhance patient safety in the process of

collecting, labeling, and processing laboratory specimens, while also improving workflow and communications. Considering this hospital's existing information system, the need to select a PPID system that would fully integrate and interface with the information system was paramount to maximize operational efficiencies and minimize duplicate and redundant data entry. These needs were outlined and expanded upon in detail in the request for proposal .

Process change

The PPID technology changes the processes of labeling specimens through printing of labels on demand at the bedside using a small portable label printer. The labels are generated from laboratory orders that have been entered into the order management system by the prescribing physician. Orders are checked for accuracy by the prescriber and nursing staff who review prescriber orders prior to the point of care. Positive patient identification is accomplished through a wireless infrastructure by using a portable handheld computer that includes a barcode scanner or beside computer with barcode scanner. The patient's barcoded identification band includes name, date of birth, and other identifying information. The labels generated have barcodes specific to that patient. The computer with scanner and handheld printer is brought to the bedside, and the patient's identification band is scanned to confirm the name and date of birth. The labels for the tests print on the handheld bedside printer and are affixed at the bedside; blood specimen tubes are rescanned at the bedside following phlebotomy.

The technology allows for the laboratory to then scan the specimen on receipt. Because this organization is fully equipped with a wireless infrastructure and the technology is portable, it is adaptable to any other area of the hospital. Part of the request for proposal and evaluation process was to ensure that the new technology could be easily integrated into the existing hospital information system, including the order entry and labo-

ratory systems. As this was determined before purchase and implementation, integration was seamless.

Implementation

The completed analysis was presented to the Lab Variance Committee and key stakeholders. A capital budget for the hardware and computer infrastructure for the PPID system was prepared and approved for implementation on 6 inpatient units. A multidisciplinary core team and implementation team were formed. The core team evaluated vendor presentations and participated in site visits about PPID technology. Prior to implementation, the core team determined that the high-risk area of blood bank specimen labeling, which was a handwritten process with double signatures, should be excluded from this new process until additional information was obtained on the success of the program.

One medical-surgical unit was chosen as the pilot unit. After training all the RNs and PCTs, this unit implemented the technology for 1 month and had no blood specimen-labeling errors in that month. The other 5 inpatient units, composed of 2 more medical-surgical, an intermediate care, the psychiatry, and the obstetrics units, implemented the technology the following month after an extensive educational program. With the portable nature of the technology, training classes were held in unit conference rooms with groups of approximately 10 staff members, and training was conducted hands-on, resulting in high attendance. After a week of 24-hour support from the Implementation Team, the units used the technology independently.

Because of the success of this technological solution in the reduction of errors and high staff acceptance and compliance, the capital budget for the next year was approved, expanding the program to the intensive care unit (ICU), neonatal intensive care unit (NICU), and pediatrics and emergency departments. Technology was developed, which attached scanners to bedside computers for the PPID system rather than having

to use only the handheld computer-scanning device. This technology advancement facilitated a more efficient implementation process for the ICU and NICU where bedside computers were already in place. Nine months after implementation on the first pilot unit, implementation was successfully completed in the ICU and NICU with continued positive results.

The system was expanded for use with blood bank specimens for all units using the system. Implementation was again successfully completed in the pediatrics emergency and pediatric inpatient department, and a presentation given to the Board of Trustees on the process and successful results. This prompted an out-of-budget approval to expedite implementation in labor & delivery and newborn nursery by the end of the fiscal year. To complete hospital-wide implementation the capital budget for fiscal year 2009 included resources to implement the technology for perioperative services. This completed a well-planned, phased process of full hospital implementation.

Resources

The staff resources allocated to this initiative included staff time for observations, data collection, review and analysis; time for team members' participation in Lab Variance Committee, vendor demonstrations and site visits; training for each unit staff member; and 24-hour support by staff super users during each unit implementation. The staff training program was 1 hour in length for each RN and PCT on the involved units.

This initiative to reduce patient and blood specimen identification errors had the support of the executive management team, board of trustees, physicians, nursing, and laboratory leadership, and nursing and laboratory staff members. Specifically, a board of trustee member had success with 6-Sigma training at his business and advocated for 6-Sigma training for key hospital staff. This was accomplished in collaboration with his company and our health system. The professional committee of the board reviews all

performance improvement data and specifically recognized and repeatedly expressed the need for improvement in laboratory specimen labeling. The executive management team was involved in reviewing the performance improvement data, recognizing the need and supporting the team's recommendations for technology as a solution. The executive management team, hospital board of trustees, and hospital system board of trustees approved and supported the capital and staff training budget for this important patient safety initiative.

RESULTS

Performance measurement

The performance measurement tools used in this initiative were a process map, cause-and-effect matrix, an observation tool and summary of results, data collection through adverse event reports, plan-do-check-act methodology, and statistical program to assist in data analysis. The process of phlebotomy and specimen labeling was mapped as it existed. A cause-and-effect matrix was used to rank and prioritize the reasons contributing to errors. Adverse event reports were used to determine the number of errors in the base year period prior to implementation and in the 1-year period postimplementation. Statistical software was used for analysis, and measurement biases in the number of errors were addressed using 2 different years of data with the exact same months preimplementation and postimplementation to account for variation related to seasonality. Staff involvement through focus groups was used to validate the ranking process in the cause-and-effect matrix and to decrease biases of management staff.

Baseline mislabeled blood specimen data were collected for a 1-year period November 2005 through October 2006 as the preimplementation period and November 2006 through October 2007 as the initial postimplementation comparison period. Mislabeled specimen data were segregated for the 6 units

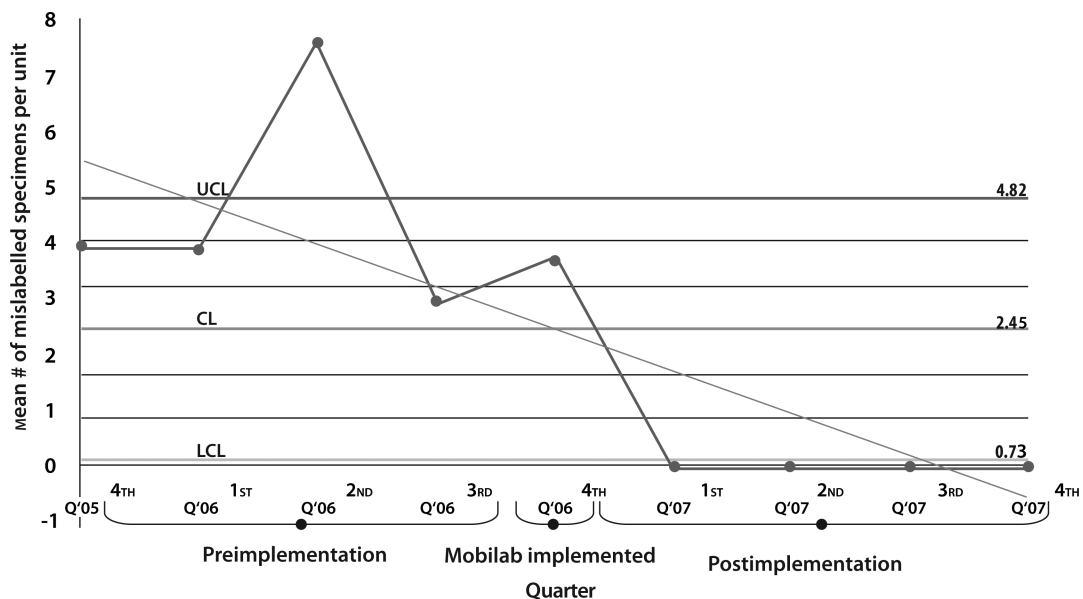


Figure 1. Positive Patient ID Project: Mean Number of Mislabeled Blood Specimens First 6 Units.

that implemented the PPID system and were analyzed by unit. The Laboratory Variance Committee continued to review and analyze each error and the summary data to ascertain the reliability of the data. The data were obtained through adverse events reports, which was a paper-based event-reporting system from prior to 2005 until March 2007. In March 2007, the adverse event-reporting system was transitioned to a Web-based reporting system. Events in both systems are entered by both nursing and laboratory personnel. In conversion to the Web-based system, consistency in categorizing and tracking of events by category was maintained. Mislabeled blood specimens were defined as those having the wrong patient name or specimens with multiple patient names in one specimen bag. As stated previously, blood bank specimens were excluded from the PPID process during the first year following implementation.

Data analysis

The criteria for measuring the success of the project was a decrease in the number of mislabeled blood specimens and maintaining the improvement over time. Blood specimen mislabeling data were analyzed for the 6 in-

patient units. The outcome data include statistically significant findings of a decrease in labeling errors from the baseline preimplementation error frequency of 103 to the postimplementation error frequency of 8. A crosstab with error count by unit and period was completed, which shows that errors decreased for each unit between the pre- and postimplementation periods. The largest decrease in errors on a unit was from 49 to 1.

The mean number of errors per unit per month for the preimplementation year period was 1.49 and for postimplementation year period it was 0.10. A control chart including a trend line demonstrates the decrease in the mean monthly number of errors between the baseline preimplementation period and the first year postimplementation period for all 6 units combined and the continuing trend of no errors in mislabeling blood specimens through December 2007 (Figure 1). To volume adjust the change in the errors, a mean monthly error rate per 1000 patient days was calculated. The preimplementation error rate was 2.02 and the postimplementation error rate was 0.13. Although a *t* test to measure the mean difference in errors in the pre- and postimplementation periods showed

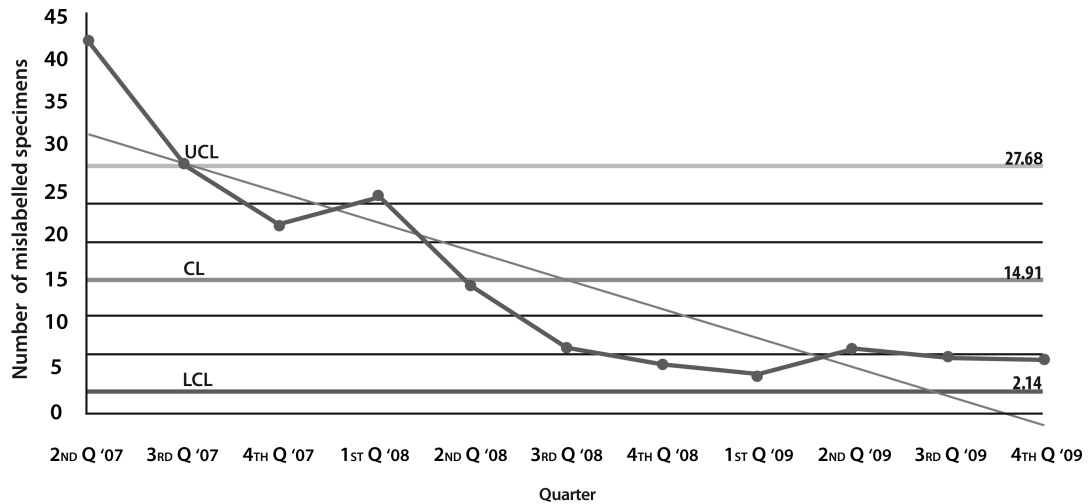


Figure 2. All Mislabeled Specimens, 2007-2009.

significant results, it did not meet the assumption of equality of variance. A Mann-Whitney U Test showed a significant difference in the mean number of errors for the 2 periods ($P < .001$).

DISCUSSION

With the overwhelming success of error reduction on the pilot unit, the decision was made to quickly expand the implementation to the additional 5 inpatient units. The errors continued to decline, and within 2 months following implementation, all 6 units had eliminated blood specimen-labeling errors. This demonstrated a significant improvement in patient safety for the target population. The goal to decrease mislabeled blood specimens and make process improvements to ensure consistent accuracy of patient identification in the usage of 2 patient identifiers was achieved. This accomplished the short-term goal to significantly reduce blood specimen-labeling errors.

The long-term goals included sustaining this improvement and expanding the technology and processes hospital-wide. This was accomplished using a phased 3-year implementation. A control chart of all mislabeled laboratory specimens hospital-wide was used

to demonstrate the success over time in reduction of errors as the technology expanded (Figure 2).

The implementation of this improvement exceeded both the quantitative and qualitative goals and objectives. The quantitative goal to decrease laboratory specimen mislabeling was exceeded because rather than simply a reduction in mislabeling errors, defined as errors involving wrong patient and specimens with multiple patient names in 1 specimen bag, errors were eliminated 2 months following implementation for the initial 6 inpatient units. Subsequently, results have continued to show significant error reduction for each unit implemented with only an infrequent error related to a new implementation or a new staff member. The qualitative objectives of avoiding unnecessary patient discomfort and inconvenience for redrawing specimens and preventing delay in treatment regimens, while eliminating rework on behalf of the nursing and laboratory staff, were also accomplished. Acceptance and utilization of the technology by staff also exceeded qualitative goals and expectations.

Lessons learned were that implementation of this technology in a decentralized phlebotomy model where the nursing staff, rather than laboratory personnel, perform the

phlebotomy is unusual and more complicated requiring extensive education. Success was attributed in part because of the strong advocacy and involvement of the senior director of nursing and support of executive management team. Other obstacles faced included the costs of capital expenditures and staff paid time for training and to support implementation. These obstacles were overcome by phasing implementation over several fiscal years as a necessity to include the total hospital in the solution due to the capital and training resources. The need for sufficient numbers of handheld printers and computers was also determined to be essential. If sufficient equipment is not available, staff will be frustrated and develop work around processes. Initially, the number of handheld bedside printers for the fiscal year 2008 implementation phase was underestimated, and additional funding was requested and approved to fully accomplish the implementation. Lastly, the importance of having a strong wireless network in place was identified because in the beginning several areas of weak signal were noted and had to be upgraded.

The initiative leaders, comprising nursing, laboratory, and information systems leader-

ship, were paramount in the evaluation of the technological solutions and success of implementations. The senior director of nursing was the champion who was most visible in supporting and leading implementation of this system including being involved in many of the staff training sessions. The involvement of staff cannot be underestimated in the success of this project. The nursing staff participated in identifying problems, exploring solutions, education of staff, and serving as super users to support implementation. Staff training and education related to this technology was conducted on a unit basis as each unit approached its implementation date.

This process improvement enhanced patient safety through a significant reduction in misidentified laboratory specimens. Through the elimination of blood sample redraws, patient comfort was improved and possible delays in diagnosis and treatment were avoided. It decreased rework for the nursing and laboratory staff. It involved several departments and many direct care nursing staff members in implementation, making safety efforts very visible and tangible and enhancing the culture of safety.

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