Reducing Errors in Blood Specimen Labeling: A Multihospital Initiative

ABSTRACT

Patient blood specimen identification is critical for quality patient care. Misidentified specimens can result in delayed diagnosis, additional laboratory testing, treatment of the wrong patient for the wrong disease, and severe transfusion reactions. Specimen identification errors have been reported to occur at rates of 0.1% to 6.5%. From August 2009 through October 2010, the Pennsylvania Patient Safety Authority sponsored a multihospital blood specimen labeling collaborative. The Authority worked with the hospitals to measure blood specimen labeling error rates, document hospital-specific interventions to reduce the labeling error rate, and measure the outcome of the interventions. At the end of the collaborative, there was a 37% aggregate statistically significant decrease in specimen labeling errors. This study discusses the collaborative's objectives, methods, and outcomes. (Pa Patient Saf Advis 2011 Jun;8[2]:47-52.)

INTRODUCTION

Background

Accurate patient identification and correct specimen labeling are critical patient safety issues in healthcare. Inaccurately identified specimens can lead to delayed or wrong diagnoses, missed or incorrect treatments, blood transfusion errors, and additional laboratory testing. The Joint Commission has implemented two hospital National Patient Safety Goals related to patient identification: (1) use at least two patient identifiers when identifying patients, and (2) label containers used for blood in the presence of the patient.[1] The College of American Pathologists includes patient and sample identification as one of its five top patient safety goals.[2] Literature reviews have identified specimen labeling error rates of 0.1% to 6.5%.[3-6]

In 2010, the Centers for Disease Control and Prevention's Laboratory Medicine Best Practices Team published the third phase of an ongoing effort by the Division of Laboratory Science and Standards to develop new systematic evidence review and evaluation methods for identifying pre- and postanalytic laboratory medicine practices that are effective at improving healthcare quality.[7] A key objective of this initiative was to examine the utility and feasibility of including unpublished assessments or studies as part of the systematic evidence reviews of laboratory medicine practices. There was enough evidence from published and unpublished sources to support the following best practices for patient specimen identification: the use of barcoding systems versus no barcoding (eight studies, log odds ratio = 2.45; 95% CI 1.6–3.3) and the use of point-of-care-testing barcoding systems (five studies, odds ratio 6.55; 95% CI 3.1–14.0).

However, solutions to the specimen identification problem are not easily accessible to hospitals. Not all healthcare facilities can afford barcode systems, and even in those facilities that have one, many blood draws and labeling activities are performed in units that do not have access to this technology. For example, in a blood specimen labeling collaborative sponsored by the Pennsylvania Patient Safety Authority, several participating facilities used barcode systems, but staff performing venipunctures in the emergency departments (ED) or neonatal intensive care units did not always have access to the systems. The challenge, then, was to discover if other interventions could improve the specimen labeling error rates within the Authority-sponsored collaborative.

Blood Specimen Labeling Collaborative Objectives

The goal of the collaborative was a 50% reduction in blood specimen labeling errors over 18 months. The Authority identified the following scope of activities:

- Educate participants (i.e., reliable design, Just Culture™, human factors engineering, event investigations)
- Provide participants with data collection and event investigation tools
- Provide ongoing aggregate data analysis for participants
- Be available for participant mentoring and coaching
- Facilitate interhospital communication and collaboration to reduce blood specimen labeling errors

MATERIALS AND METHODS

Participants

Hospital representatives in the northeast region of Pennsylvania were invited to participate in the Authority collaborative. Inclusion criteria were reporting blood specimen

labeling errors through the Authority's Pennsylvania Patient Safety Reporting System (PA-PSRS), submitting monthly laboratory reports to an Authority analyst, and investigating mislabeling events using a standardized event investigation tool (see the tool at http://patientsafetyauthority.org/EducationalTools/PatientSafetyTools/Pages/home.aspx). Eight acute care hospitals and one rehabilitation hospital participated in the collaborative. Each hospital assembled a team to participate in the collaborative, and team members included laboratory directors, phlebotomy supervisors, patient safety officers, and risk management, quality and performance improvement, and regulatory compliance personnel. Hospitals selected collaborative participants based on a variety of factors, such as care areas studied, leadership support of the project, and resources available for the time and effort commitment. Because of hospital diversity, the Authority allowed each hospital to select the care areas for study. Hospital collaborative participants decided whether to engage the whole hospital or only certain areas, according to their perception of the greatest problems in blood specimen labeling. Five hospitals engaged the entire facility in the collaborative, and the remaining hospitals chose specific areas: ED, ED and intensive care area, progressive intensive care unit, and medical intensive care unit. Authority representatives included the director of educational programs, the regional patient safety liaison, and a patient safety analyst.

Data Sources

Authority and collaborative members specified numerator data as the number of blood specimen tubes not accepted for testing because of labeling issues. Collaborative participants entered case data (i.e., events) into PA-PSRS on a continual basis as errors were identified, and the Authority analyst validated the monthly totals for each facility against quality assurance data generated by the hospitals' phlebotomy laboratories. Mislabeled blood specimen samples were defined as those not meeting the same local standards for sample acceptance. Types of mislabeling included wrong, missing, incomplete, or illegible labels. Samples that were properly labeled but not accepted for processing for other reasons (i.e., insufficient blood in tube, presence of hemolysis) were not included. Point-of-care testing was not included. Hospitals could report denominator data as any of three variables, depending on the availability of data at each facility: (1) number of venipunctures, (2) number of accessions, or (3) number of tests. For the statistical analysis, denominator data was combined to represent total number of error opportunities.

Blood specimen labeling error data was collected monthly from August 2009 through October 2010. Baseline error rates were calculated as the number of blood specimen labeling errors per 1,000 opportunities for error after 3 months of data collection. Education was provided from August 2009 through May 2010. Various process improvements were implemented at each facility from April through July 2010. Endpoint error rates were calculated for August through October 2010 and compared to baseline error rates at the facility level and in the aggregate. Exclusionary criteria included failure to implement improvement interventions, failure to report mislabeled specimens through PA-PSRS, and failure to submit laboratory data to the Authority; three facilities were excluded from the data analysis.

Education

In September and October 2009, the Authority provided educational sessions about reliable design, Just Culture™, and human factors engineering. Subsequently, each hospital team mapped its blood specimen labeling process, assessed the process for compliance through direct observation, and presented an overview of the processes to the rest of the collaborative participants. This was an opportunity for the collaborative participants to identify barriers to labeling compliance that transcended specific care areas and organizations. Common barriers noted by the Authority were those related to technology, communication, education, staffing, workflow, and leadership.

In September 2009, the Authority developed and distributed a standard event investigation tool, which guided collaborative participants through the event investigation process and asked investigators to identify contributing factors for each error. Many collaborative participants were not clinical personnel familiar with

PARTICIPATING HOSPITALS AND COLLABORATIVE LEADERS

Allied Services Rehabilitation Center
Viewmont Medical Laboratories
Gene Mushak, Patient Safety Officer

Berwick Hospital Center
Joseph V. Bazzarri, MBA, MT (ASCP)

Easton Hospital
Georgiann Gerlach, RN, BSN, Risk Manager/Patient Safety Officer
Shelly Williams, Laboratory Support Service Coordinator

Geisinger Medical Center, Danville
Janine Alexis, MS, MT (ASCP)

Geisinger Wyoming Valley Medical Center
Barbara Booth, MT (ASCP), Laboratory Service Improvement Coordinator

Lehigh Valley Health Network
Kristy Lowery, BS, RN, CPHQ, CPHRM
Lori Izzo, BSN, RN, Patient Safety Coordinator

Sacred Heart Hospital
Diane Guerrero, MT (ASCP), Director of Laboratory Services

Pocono Health Systems
Joanne Reinitz, Manager Regulatory Compliance
Amy Yoblonski, MT (ASCP), Laboratory Supervisor
Lois Wahrmann, Outpatient/Client Services Supervisor

Wyoming Valley Health Systems
Joan DeRocco, MS, RN, CPHRM, CAN, Director, Patient Safety Services

root-cause analysis; therefore, the Authority held an additional training session regarding event investigation in January 2010. This training session included clinical scenarios and role-playing that allowed collaborative participants to gain familiarity with techniques related to respectful investigation of errors, including gaining trust of staff, allowing for gracious space during an interview, refraining from the use of individual blame, and using active listening skills.

Authority representatives analyzed the data monthly and reconciled any discrepancies found between PA-PSRS reports and laboratory data. Quarterly analysis was provided to each facility. Additionally, the Authority organized biweekly conference calls, tapering to monthly, in which interventions, successes, barriers to success, and mutual support and encouragement were exchanged. Several guest speakers were invited to participate in these calls, including laboratory directors and phlebotomy supervisors with direct experience in specimen labeling projects. Authority representatives were available by means of e-mail and telephone consultation for coaching or mentoring throughout the duration of the collaborative. An additional goal of the collaborative was to develop capable and confident mentors within the participating hospitals who could become resource personnel for other Pennsylvania healthcare facilities that may also want to address blood specimen labeling errors.

Event Investigation Data

By October 2010, the Authority had collected and analyzed 485 investigations. Facilities reported 520 different contributing factors associated with the mislabeling errors (see Table 1).

The top three contributing factors were (1) procedures not followed (n = 256), (2) distractions and interruptions (n = 70), and (3) unplanned workload increase

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Table 1. Event Investigations Contributing Factor Data

DOMAIN	FACTOR	NUMBER
Organizational	Procedures not followed	256
	No dedicated phlebotomy	3
	Lack of policies/procedures	2
	Unclear policies/procedures	2
	Other	1
	Total	**264**
Work Environment	Distraction/interruptions	70
	Equipment malfunction	7
	Inadequate equipment availability	6
	Limited access to patient information	4
	High noise	3
	Poor lighting	2
	Other	9
	Total	**101**
Task Factors	Emergency situation	22
	Inexperienced staff	15
	Training issues	9
	Inadequate resident supervision	7
	Cardiac/respiratory arrest	5
	Order entry problem	4
	Other	4
	Total	**66**
Team Factors	Unplanned workload increase	32
	Communication	15
	Shift change	3
	Cross-coverage	2
	Change of service	1
	Other	1
	Total	**54**
Staff Factors	Issue related to proficiency	6
	Agency staff	5
	Float staff	5
	Insufficient staff	5
	Issue related to impairment	4
	Inadequate system for covering patient care	3
	Scheduling issues	1
	Total	**29**
Patient Characteristics	Lack of understanding	3
	Language barrier	1
	Lack of family cooperation	1
	Other	1
	Total	**6**
Grand Total		**520**

Table 2. Summary of Blood Specimen Labeling Collaborative Barriers and Interventions

DOMAIN	BARRIERS	INTERVENTIONS
Technology	Technology issues with label printing Lack of strong wireless signal throughout facility Collection technology used only by phlebotomy staff but nursing staff also collect blood specimens in some locations Lack of financial resources for information technology (IT) equipment updates Inability to print blank labels between patient label sets	Changed to new laboratory IT system Installed laboratory printers for labels in care areas Implemented "hold" labels with patient identification versus patient chart labels Investigated label printing option to add blanks between patient label sets Standardized location of all labels Created a bidirectional interface between multiple IT systems
Communication	Communication issues between nursing and laboratory staff Lack of teamwork and cooperation across service lines	Held monthly meetings with laboratory and nursing staff Addressed staff printing multiple sets of labels at once Shared case studies with staff responsible for laboratory blood specimen draws and labeling Facilitated transferring labels with patients transferred to another department; ensured all labels followed patient to next care setting Implemented a patient-specific binder system for labels
Education	Lack of knowledge regarding phlebotomy policies/procedures Physicians ordering all labs STAT to get timely results	Implemented mandatory competency testing for specimen labeling process Updated laboratory handbook; provided electronic version to all employees Educated staff regarding proper patient identification procedures Addressed printing of multiple label sets at same time Educated physicians regarding STAT orders
Staffing	High turnover in laboratory staff Short-staffed; phlebotomists performing 45 to 50 morning draws from a normal high of 25 morning draws Float pool staff not always aware of proper specimen labeling procedures	Leveled work loads Implemented new processes for student phlebotomists Permitted nursing home phlebotomists to work overtime in mornings to assist with blood specimen collection
Workflow	Lack of care area specific procedures that expedited workflow	Developed mini emergency department (ED) registration to make labels available at time of blood draw in ED Created patient folders to hold labels; patients to give labels to person drawing blood Added third printer to ED to facilitate label printing Began immediate bedside labeling of peripherally inserted central catheter line draws Started hourly batch printing of labels to smooth workflow
Leadership	Lack of management support Lost momentum for collaborative work; other initiatives with higher priority Loss of clinical leadership; difficult to sustain compliance with improved procedures	Created dashboard/scorecard for collaborative team Used dashboard for laboratory draws to focus staff attention on labeling issues Increased awareness via Pennsylvania Patient Safety Authority-sponsored posters and pins

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(*n* = 32). This data indicates that the development of strategies to monitor compliance with existing labeling procedures, as well as strategies to maintain compliance in the face of interruptions and distractions, may be a worthwhile endeavor for hospitals.

Barriers and Interventions

The collaborative participants implemented more than 20 interventions between April and July 2010. They also identified barriers to improvement that they felt affected their hospitals' blood specimen labeling error rates (see Table 2).

There were six major categories of barriers to blood specimen labeling accuracy: (1) technology, (2) communication, (3) education, (4) staffing, (5) workflow, and (6) leadership. The collaborative participants implemented a number of interventions within these domains to improve specimen labeling accuracy.

RESULTS

Error Data

Of participating hospitals, six acute care hospitals submitted data about more than 1.3 million opportunities for error (i.e., number of venipunctures, the number of accessions, and the number of tests). Three hospitals were excluded from data analysis because interventions to reduce blood specimen labeling errors were not implemented. Baseline error rates for the hospitals ranged from 0.1 to 4.1 mislabeling errors per 1,000 opportunities for error. Postintervention error rates ranged from 0.0 to 1.3 mislabeling errors per 1,000 opportunities for error. A test of two proportions (*z*-test) was run to determine the statistical significance of the change in pre- and postintervention blood specimen labeling error rates (see Table 3).

At the facility level, the decrease in blood specimen labeling errors ranged from 57% to 84%. However, one hospital experienced a 67% increase in errors.

From January through March 2010 (see Figure), the aggregate number of error reports peaked. Thereafter, a steady decline in the aggregate number of error reports continued through June 2010, followed by another slight peak in July and August 2010, ending with a mean decrease in error rates of 37%.

Overall, there was a 37% statistically significant decrease in blood specimen labeling errors in the collaborative over the 18-month period (95% CI; $p < 0.04$).

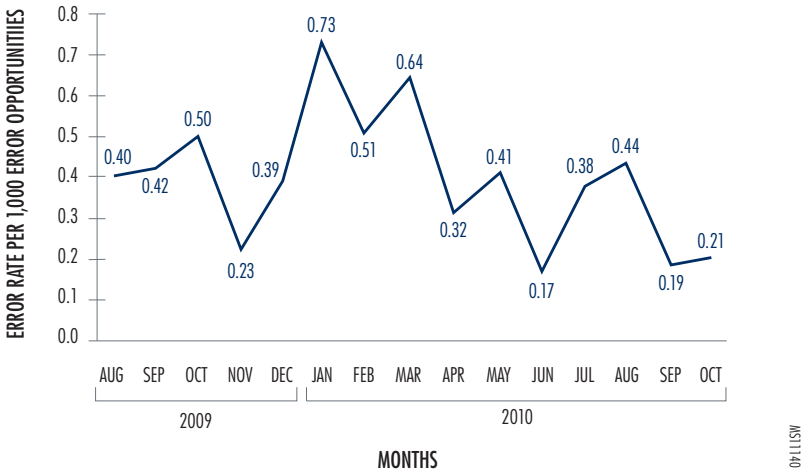
A sensitivity analysis was performed by removing data from each of two facilities with the largest denominator data to test whether the significant decrease observed

Table 3. Reduction in Facility-Specific and Program-Wide Error Rates

FACILITY	BASELINE ERROR RATES (August through October 2009)			POSTINTERVENTION ERROR RATES (August through October 2010)			CHANGE	HOSPITAL-SPECIFIC CHARACTERISTICS
	Rate per 1,000	LCL	UCL	Rate per 1,000	LCL	UCL		
A	4.1	1.8	6.4	0.8	0.0	1.7	-81%*	One care area of focus; adequate leadership support; targeted interventions
B	0.6	0.4	0.9	0.3	0.1	0.4	-57%	Multiple care areas of focus; adequate leadership support; targeted interventions
C	0.1	0.0	0.2	0.0	0.0	0.0	-84%*	Multiple care areas of focus; adequate leadership support; targeted interventions
D	2.5	1.6	3.3	0.7	0.4	1.1	-71%*	Multiple care areas of focus; adequate leadership support; targeted interventions
E	3.2	1.5	4.9	1.3	0.2	2.4	-61%	One care area of focus; adequate leadership support; targeted interventions
F	0.3	0.2	0.4	0.5	0.3	0.7	67%	One care area of focus; inadequate leadership support; targeted interventions
Pooled Mean	**0.44**	**0.36**	**0.52**	**0.28**	**0.21**	**0.34**	**-37%***	

*$p < 0.05$. Test of two proportions (*z*-test).

Figure. Collaborative Aggregate Specimen Labeling Error Rate



in the aggregate was overly influenced by the observations at these larger hospitals. The aggregate results remained statistically significant in these two scenarios: 36% decrease in errors (95% CI; $p < 0.01$) and 61% decrease in errors (95% CI; $p < 0.01$).

DISCUSSION

The peak blood specimen labeling error rates occurred in January 2010 (month 6). This peak likely correlated with increased facilitywide focus and attention to blood specimen labeling issues (shortly after education by the Authority, when surveillance and reporting efforts were likely to be at their highest). If the decrease in error rates was recognized from the peak (January 2010) to the end of the collaborative (October 2010), the decline would be even more significant (i.e., greater than the original goal of a 50% decrease in errors). Additionally, the statistical significance of the collaborative decline (37%) remained even after removing data from the two facilities with the largest denominators, individually, from the aggregate pool.

These positive results apply only to the hospitals that continued to participate in the collaborative and were able to implement some interventions to decrease the blood specimen labeling error rate. Compared to the hospitals included in the study, those hospitals that were excluded experienced a 20% increase in error rates (not statistically significant) (95% CI; $p > 0.05$). Therefore, while the efficacy of sustained attention and implementation of interventions is sound, the effectiveness of this approach cannot be determined through this study.

Lack of standardization of the interventions could be viewed as a limitation of the study. However, the Authority recognized that each of the participating hospitals had unique problems in particular care areas with different patient populations and had varying amounts of resources available for improvement. The hospitals with statistically significant decreases in error rates had in common a sustained focus on the labeling problem and adequate administrative and leadership support. The single hospital that experienced an increase in labeling errors underwent a change in leadership in its care area of focus. According to the hospital leader for the collaborative, this resulted in a lack of follow-through with planned interventions, which may have contributed to the increased error rate.

CONCLUSION

Specimen identification error analysis combined with interventions to reduce specimen labeling errors can decrease rates of specimen identification error and contribute to improvements in patient safety. Leadership support, sustained attention to the labeling issue, and implementation of interventions to reduce error rates are critical components of a specimen labeling error reduction program.

NOTES

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