QUALITY IMPROVEMENT REPORT

A multidisciplinary, multifaceted improvement initiative to eliminate mislabelled laboratory specimens at a large tertiary care hospital

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ABSTRACT

Objectives To sustainably reduce the rate of mislabelled laboratory specimens through implementation of a series of interventions as led and coordinated by a multidisciplinary performance improvement team.

Methods The quality improvement project was performed at Cedars-Sinai Medical Center in Los Angeles, an academic care tertiary care hospital. Phlebotomy services are provided by unit-based nursing and dedicated laboratory-based phlebotomists. Baseline mislabelled specimen rate was obtained for a 6-month period prior to the first improvement intervention. Included in the rate of mislabelled specimens were inpatient blood and body fluid specimens. Anatomic pathology and cytological specimens and outpatient specimens were excluded. Mislabelled specimens were identified preanalytically, analytically or postanalytically. A specimen was considered mislabelled under the following circumstances: (1) specimen/requisition mismatch; (2) incorrect patient identifiers and (3) unlabelled specimen. Specimen mislabels were identified and validated monthly by a multidisciplinary team composed of personnel from nursing, laboratory and performance improvement. Performance improvement initiatives were implemented over a 2-year period with control charts used to assess improvement over time.

Results The rate of mislabelled specimens varied by clinical area and decreased significantly over a 24-month time period during the initiative from 4.39 per 10 000 specimens to 1.97 per 10 000 specimens. All clinical areas achieved a significant decrease in the rate of mislabelled specimens except for the operating room and labour and delivery.

Conclusions A multidisciplinary unit specific approach using performance improvement

methodologies focusing on human factors can reliably and sustainably reduce the rate of mislabelled laboratory specimens in a large tertiary care hospital.

INTRODUCTION

Accurate patient identification is the first of the National Patient Safety Goals articulated by the Joint Commission in 2013.¹ This reflects the central role patient identification plays in assuring patient safety, and the contribution of patient misidentification to preventable medical errors.

In laboratory medicine, accurate patient identification and specimen labelling is essential to appropriate diagnosis and treatment. Laboratory specimen labelling errors, defined as samples with either identification incorrect patient (mislabelled), or no patient identification (unlabelled), have been shown to contribute to preventable medical errors and have resulted in unnecessary invasive procedures or other treatments, missed diagnoses, delayed treatment and haemolytic transfusion reactions.² ³ The College of American Pathologists reports that mislabelling events are detected at a rate of 0.04-0.1%, and numerous process improvement initiatives have been devoted to reducing this risk to patient safety.⁴

Mislabelling errors identified either before or after testing allow caregivers to intervene to prevent harm. However, these instances may only represent a fraction of the true incidence as some mislabelled samples escape detection. A mislabelled specimen rate other than zero portrays an environment where patient harm could potentially occur if the





mislabelling is not identified. Recognising that proper patient identification and specimen labelling is a multistep process that can be adversely affected by human factors such as fatigue, distraction and inattention, the Joint Commission has recommended use of automated systems such as barcoding to prevent misidentification.¹ However, automated systems are not a panacea for eliminating specimen mislabelling as workarounds and other process variations have still occurred in institutions that have implemented such systems.⁵ Thus, prior to consideration of electronic methods of patient and sample identification, optimisation of existing manual processes is necessary. In that regard, we initiated a performance improvement project to address these areas.

METHODS

Background

Cedars-Sinai Medical Center is a 958-bed tertiary care hospital that treats adult and paediatric patients with a broad range of clinical conditions including traumatic injury, advanced heart failure and solid organ and bone marrow transplants. The high complexity of disease necessitates frequent evaluation of blood and body fluid for metabolic, haematological, microbiological and other lab investigations. Approximately 80 000 inpatient laboratory specimens are processed monthly. Unit-based nursing personnel collect nearly 70% of the specimens. The majority of the remaining samples are collected by laboratory-based phlebotomists and a small number are collected by physicians and other personnel. The proportion of specimens collected by nursing varies by clinical care unit depending upon factors including patient acuity, need for timed blood draws and the presence of central venous and arterial catheters.

In April 2011, as part of an ongoing Cedars-Sinai institutional goal to eliminate preventable patient harm, an improvement team was formed to assess the current laboratory specimen labelling process with a goal to eliminate mislabelled specimens. The multidisciplinary team included personnel from nursing, clinical laboratory, blood bank, information technology, performance improvement and patient safety departments. Subsequently, the elimination of mislabelled specimens became an institutional goal with monthly progress reports presented to the Cedars-Sinai Quality Council.

According to the policy that stipulates activities constituting research at Cedars-Sinai Medical Center, this project met criteria for operational improvement exempt from ethics review.

Data

A specimen was considered mislabelled when a sample was received in the lab with one or both patient identifiers that were incorrect (name and medical record number (MRN)), for example, a

specimen with a label from a different patient as reported by the phlebotomist or nurse, two contradictory labels on one specimen or labels that did not correspond to a laboratory requisition.⁴ In addition, multiple specimens with different patient identifiers in a single laboratory transport bag were considered mislabelled. Preanalytical specimens that were subsequently identified as mislabelled were included, for example, if a nurse notifies the lab that a specimen is mislabelled prior to testing. Specimens without any patient identifying information were considered mislabelled. Excluded in the data were unconfirmed mislabelled specimens flagged by the lab system's delta-check process. The delta-check process detects laboratory results that differ significantly from a patient's previously reported results. This may result in redrawing the specimen if the test results do not appear to be compatible with the patient's current clinical condition. In these cases, tests to confirm a mislabelled specimen (eg, blood typing) are not routinely done.

Specimens from outpatient clinical areas and anatomical pathology and cytology specimens were also excluded.

Blood bank specimens included those sent for type and screen, type and cross match and cord blood samples from neonates. Mislabelled blood bank specimens were identified when the blood type did not match a patient's historical type on record at Cedars-Sinai. For patients without a historical blood type at our institution, specimens were considered mislabelled if there were a mismatched blood type between the first and second required confirmatory sample.

In addition, the number of unlabelled specimens was tracked and reported. All mislabel events were logged into the laboratory electronic information system in addition to the institution's patient safety event reporting system. The aggregated monthly reported specimen errors were reviewed by the project team leadership for determination of inclusion criteria for the purposes of tracking performance improvement.

Quality improvement tools

Established quality improvement methods were used to map the current process, assess process variation, identify areas for improvement and implement process changes. Methods included developing flow charts, affinity diagrams, run, control and Pareto charts, brainstorming sessions, priority payoff matrix, failure mode and effects analysis (FMEA) and conducting tests of change using plan do study act (PDSA) cycles.⁶ Baseline data were obtained for the period of 6 months prior to initiation of the first improvement intervention.

Improvement interventions

The improvement interventions, organised around four key areas, were implemented over a 20-month

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period and varied by clinical area. The dates of the final implementation of each intervention are presented. Some interventions underwent tests of change for one or more cycles prior to implementation.

- 1. Staff engagement—In March 2011, an improvement team was formed and nurse champions were identified from each inpatient unit, the operating room (OR) and the emergency department (ED). A computer screensaver to be displayed on all clinical work stations in patient care areas was created in August 2011 to remind staff to confirm the required two-patient identifiers on the hospital identification band and printed specimen labels during the specimen labelling process.
- 2. Data transparency-Beginning October 2011 monthly unit-specific mislabelling data displayed on a run chart were emailed to all nurse champions, nurse directors and project executive sponsors. A specimen mislabelling dashboard was displayed on each unit's quality corner. Included were performance data from all inpatient units. An insert on the dashboard allowed for the display of the current month's hospital performance, the hospital's performance over time and the unit specific data. The number of mislabelled and unlabelled specimens was included in the hospital report summarising potentially preventable patient quality and safety issues distributed to nursing managers, directors and executive leadership. In addition, the mislabelling data were included in a report of the weekly summary of events related to nursing practice and care.
- 3. Process changes—A flow map for the existing process was created (figure 1). An FMEA was conducted to identify potential process step failures, the likelihood of occurrence and the risk to patient safety. A priority payoff matrix was developed to assess feasibility and effectiveness of potential improvement interventions. The following changes to the specimen collection process were implemented: (1) September 2011-after testing, bolded and increased the font of the patient name and MRN on the specimen label for easier readability; (2) July 2012-two caregiver verification of two-patient identifiers during the lab labelling process in the inpatient medical and surgical units; (3) August 2012-engage the patient whenever possible in the two-patient identifier process in all areas; (4) implement a process to 'sweep' the OR suite of all patient identifying information after surgical case completion; (5) September 2012-for point-of-care testing, attach barcode readable labels to the patient identification wrist band for electronic scanning. Personnel were instructed to only scan the barcode and never manually enter the patient encounter number; and (6) January 2013—after testing on two units, highlighting the patient name and MRN on the specimen label when it is removed from the printer in the intensive care units (ICUs) and the ED,
- 4. Event review and accountability—Two mislabelling event review processes were created. The initial goals of the reviews were to use front-line staff to identify potential defects in the existing process that may have led to the

mislabel event and to improve and sustain awareness of following proper lab specimen labelling procedures.

- A. Event review
 - 1. Nursing unit review process: In April 2012, a standardised review tool was created that included a series of questions addressing proper completion of each labelling process step (figure 2). In addition, free text providing for narrative event description could be entered. When a mislabelling event occurred, the laboratory notified the unit and respective charge nurse by telephone. The charge or senior unit nurse reviewed the event with the staff involved and completed the event worksheet. The data were then entered into the hospital event reporting system and reports were reviewed by the nursing manager of the involved unit for discussion at the next unit safety huddle.
 - 2. Root cause analysis (RCA): Given the potential serious adverse consequences related to a mismatched blood transfusion, RCA meetings were conducted beginning in March of 2012 for blood bank specimen mislabelling events. Upon identification of a blood bank specimen mislabelling error, a multidisciplinary team meeting was held within 48 h to include unit staff directly involved with the error, unit nurse manager and representatives from the blood bank, patient safety and the specimen mislabelling improvement team. At the meeting, the mislabelling event was reviewed, contributory factors identified and causation established.7 Recommendations for implementing process improvement or tests of change were made when system issues were identified. In addition, retrospective analysis assessed systematic factors for each blood bank mislabelled event using a structured tool.⁸ 9 Contributing factors included those related to the patient, task, provider, team, training and education, information technology, local environment and institutional environment. Each event may have had one or more contributing factor.
- B. Accountability: The event review and mini-RCA processes are designed to assess system issues without assigning blame or individual responsibility. Staff performance issues related to lab mislabelling event occurred and was attributed to a job performance issue, the staff member was given a coaching letter to review and sign that outlined the events and potential contributing factors. A discussion between the manager and staff member occurred to review what happened and how to avoid a repeat event. Repeated errors within a specified time period could result in termination.



Figure 1 Process flow map for the laboratory specimen collection.

DATA ANALYSIS

We compared rates of mislabelled specimens across the institution by grouping patient care units by similar workflow, that is, medical-surgical, ICUs, ED, OR/post-anaesthesia care unit (PACU) and labour and delivery (L&D). Data were available by specific clinical area from August 2011, the time of the implementation of the first improvement intervention.

We used statistical process control charts to assess improvement in the rate of mislabelled specimens over time. Run charts were used to monitor mislabelled specimen rates in the different clinical areas. We used a p chart to evaluate the overall hospital mislabelled specimen rate over time and special cause detection rules to identify when an improvement in the process occurred. Control limits were set at 3- ς . Nine consecutive points below or above the centre line indicated a change in the data and process prompting recalculation of the control limits in September 2011 and August 2012.

RESULTS

Over the 24-month period, more than 1.8 million laboratory specimens were collected (table 1). Slightly more than two-thirds of the specimens were collected by unit-based personnel who had proportionately more mislabelled specimens compared with phlebotomybased personnel.

A series of improvement interventions were implemented over the 2-year period (figure 3). Compared with the baseline period in 2011, the mean rate of mislabelled specimens decreased from 4.39 per 10 000 specimens to 1.97 per 10 000 specimens in the final period. Figure 4 shows the rate of mislabelled specimens over time by clinical area. The specimen mislabelling rate in the medical/surgical areas decreased, ICUs and ED all decreased over time. The rate of mislabelled specimens in L&D and the OR/PACU did not appreciably decline.

Fifteen RCAs for blood bank specimen mislabelling events were conducted. Factors assessed to have contributed to the mislabelling event included, staff training and education (32%), the local unit environment (32%), information technology (24.4%), team issues (12.2%), institutional environment (2.4%) and the provider (2.4%).

DISCUSSION

We have presented the results of a multidisciplinary, multifaceted effort to reduce mislabelled laboratory specimens at a large tertiary care hospital. Over a 24-month period, the rate of mislabelled and unlabelled laboratory specimens steadily declined during a series of interventions designed to improve the specimen collection and labelling process, engage unit staff, increase awareness and education and ensure accountability when errors occur.

Established quality improvement methods were used to map the current process, assess current system performance variation, identify areas for improvement and implement process changes. Methods included use of flow charts, control charts, brainstorming sessions, priority payoff matrix, FMEAs and PDSA cycles.⁶ ¹⁰ We found that the failure modes with the highest risk potential included incorrect labels being picked up from the printer, not taking patient labels into the Downloaded from qualitysafety.bmj.com on July 17, 2014 - Published by group.bmj.com



PATIENT NAME PLATE

1						VES		NO		NA	
2			DECIMENS?		VES	-	NO	<u> </u>	NA		
3						YES		NO		NA	
з. 4	WERE THE DATIENT'S RECORDS ACCESSED AND ORDER VERI		VES		NO		NA				
5							-	NO		NA	
6	WERE THE DRUED FRINTED WHEN TOU WERE READY TO COLLECT THE SPECIMENS:							NO		NA	
7	WERE ALL LARELS AND SUPPLIES TAKEN TO THE PATIENT'S REDSIDE?							NO		NA	
8	DID SOMFONE FLSE HELP COLLECT YOUR LABS OR TAKE LABELS TO LAB FOR YOU?							NO		NA	
9.								NO		NA	
10								NO	<u> </u>	NA	
11							-	NO		NA	
		10 1112/1				120					
IF YOU ANSWERED "NO" TO ANY OF THE ABOVE QUESTIONS, PLEASE USE THE BOX BELOW TO PROVIDE COMMENTS:											
12.	WAS THE ID BAND PRESENT?					YES		NO			
13.	Were 2 patient identifiers used to match orders, labels, and ID band?							NO			
14.	Was each label validated against the ID band when affixing labels?							NO			
15.	WERE THE TUBES LABELED BEFORE LEAVING THE PATIENT ROOM/BEDSIDE?							NO			
16.	WERE INITIALS AND TIME WRITTEN ON THE TUBE AT THE BED SIDE?							NO			
17.	WERE THE LABELED TUBES COMPARED TO THE REQUISITIONS BEFORE PLACING THEM IN THE BAG?							NO			
18.	WERE THE COLLECTION DATE AND TIME DOCUMENTED IN CS-LINK WORKLIST BY THE BED SIDE?							NO			
19.	WERE THE BLOOD BANK SAMPLES, TYPE AND SCREEN/CROS	IS AND SE	COND SAMPLE T	O CONFIRM DRAWN AT TWO DIFFERENT TIMI	s?	YES		NO		NA	
	Contributing Factors			Personal Factors		UNSAFE (Condit	IONS/ACT			
	ACUTE CLINICAL ISSUE WITH PATIENT										
	Acute clinical issues within unit										
	COMPLETER OR DRINTER NOT WORKING										
Additional observations or issues:											
	DATE COMPLETE	D:		MILITARY TIME:							
Tiner											
NAME: SIGNATURE:											

Figure 2 Laboratory specimen mislabelling event review form.

room prior to specimen collection and failure to perform the two-patient identifier process at the patient bedside. In addition, gemba walks were conducted to understand the actual process flow in different clinical areas. Due to physical space parameters, patient clinical characteristics and existing workflow

 Table 1
 Summary of laboratory specimen collection from April 2011–April 2013

Collection source	Specimens, n (% of all specimens)	Mislabelling events, n (% of all events)
Unit based	1 239 978 (67.1)	597 (96.6)
Central phlebotomy	608 951 (32.9)	21 (3.4)
Total	1 848 929 (100)	618 (100)

patterns, the specimen labelling process and potential solutions to reduce errors varied across different clinical areas. While the essential components of proper patient identification and specimen labelling are consistent, the practical implementation of process changes were not uniform.

Given the different workflows in various hospital units, we implemented different strategies to mitigate the risks identified in the FMEA. For example, in the ICUs and ED where patients have high acuity illness and potential for rapid clinical change, highlighters were used to quickly verify the name and MRN on each specimen label. On medical/surgical units where most labs are scheduled, a second nurse check was implemented to verify the correct label was affixed to



Figure 3 Monthly hospital-wide rate of mislabelled specimens per 10 000 specimens collected from January 2011 to April 2013. Improvement interventions are indicated with arrows. Solid lines indicate mean mislabelling rate. Dotted lines indicate upper and lower control limits, set at 3-c. (1) Initiation of improvement team. (2) Hospital Quality Council adopts mislabelled specimen reduction as goal. (3) Mislabelling screensaver implemented. (4) Redesigned specimen label implemented. (5) Nursing unit dashboards. (6) Unit-level mislabelling event review. (7) Blood Bank mini-root cause analysis. (8) Nursing unit event review. (9) Two-caregiver verification. (10) Engage patient. (11) Point-of-care testing process changes. (12) Highlight labels.



Figure 4 Run charts showing rates of mislabelled specimens by clinical area. (A) Medical Surgical, Emergency Department, Intensive Care Units. (B) Labour and delivery, OR/postanaesthesia care unit (PACU).

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the specimen tube. In the OR, a process to 'sweep' the room of all patient identifying information after each case was instituted and interventions to eliminate inadvertent entry of the wrong patient identifier in the point-of-care testing instruments were implemented.

We also implemented processes that would not significantly change the existing nursing workflows. For example, the two caregiver verification was not used in the ICUs or the ED as the acuity level of patients often precludes the immediate availability of a second nurse to validate specimens. At monthly team meetings with unit champions, we received feedback on how process changes were affecting workflow and made adjustments as needed. In addition, the project team leaders conducted gemba walks to directly observe the process and receive feedback at the point of care. For the two caregiver verification, we learned that it was sometimes difficult to find a second staff nurse, thus completion of the second verification by a clinical partner was allowed.

While no generalisable strategies have been shown to directly change organisational culture to improve quality,¹¹ we believe that over time, many of the interventions had a significant effect on staff performance related to proper specimen labelling procedures. Transparent unit-specific data, a uniform process of accountability and front-line staff involvement in identifying potential solutions not only increased awareness of the seriousness of specimen mislabelling but also served to align staff attitudes. Because approaches related to patient safety may vary by clinical area, we observed that monthly team meetings were an effective way to discuss successful improvement interventions. This led to a sense of shared responsibility in the overall hospital mislabelling rate. An anecdotal example of the change in staff culture is exemplified by one of the unit nurses who recounted the following at one the team meetings: "Before when we had a mislabelled specimen we would say, Oh, well, we can just redraw the sample, now we say, uh, oh, we had a mislabel."

Previous studies have shown that a dedicated centralised phlebotomy service has lower rates of important blood specimen quality parameters, such as haemolysis and blood culture contamination compared with decentralised unit-based phlebotomy.¹²⁻¹⁵ Moreover, the presence of 24/7 phlebotomy services is associated with lower rates of mislabelled specimens.^{4 15} We also found that the mislabelled specimen rate was lower when specimens were collected by the laboratorybased collection staff compared with the unit-based nursing staff. The reasons that a dedicated phlebotomy service has lower rates of mislabelled specimens are likely multifactorial. Laboratory personnel have the single task to collect blood from patients and label specimens. In contrast, nurses have multiple patient care responsibilities that can coincide with the important aspects of patient identification and specimen labelling. Given the circumstantial differences,

laboratory personnel might be held to different performance standards with more rigid consequences resulting from specimen mislabelling errors. Recognising these differences, institutions must consider the risks and benefits of centralised and decentralised blood specimen collection processes. Despite the reduced incidence of mislabelling, lab collected samples are often performed during scheduled phlebotomy rounds to improve efficiency, and stat requests will ultimately include additional time to dispatch the phlebotomist from the laboratory. In addition, phlebotomists may not be able to collect blood from indwelling intravenous or arterial lines. Benefits of nurse collections include timeliness of collection and ability to collect from indwelling lines.

We found in the medical and surgical patient care areas, the ED and the ICUs, mislabelling rates declined following implementation of interventions chosen for those areas based on an analysis of workflow. In contrast, the mislabelling rates in the OR and L&D areas did not decline significantly. We recognised that multiple pathways existed for laboratory test ordering and specimen labelling in the preoperative, intraoperative and postoperative settings, and this lack of process uniformity likely contributes to specimen mislabelling events. Implementation of computerised physician order entry with onsite laboratory label printers is planned that will standardise this process. In L&D, workflow assessments suggested that dedicated printers may contribute to more accurate labelling. The additional specimen label printers have recently been installed and are expected to have a significant impact on improving the nursing workflow and reducing mislabelled specimens.

To reduce the rate of mislabelled specimens, we chose to focus initially on process improvement related to human factors. Electronic positive patient and specimen identification systems such as bar code-based technologies have the potential to reduce mislabelling events, particularly when combined with bedside label printers and electronic order verification. However, this technology will not necessarily eliminate all specimen labelling errors since the process ultimately remains dependent on human performance. At one paediatric oncology hospital, patient ID barcode scanning combined with onsite label printing resulted in a significant reduction in mislabelled samples; however, the number of unlabelled samples received by the laboratory was not affected.⁵ In addition, there remained a small number of mislabelled samples due to barcode reading errors and failure to act on system alerts. Based on our results, we believe that careful workflow assessment and design and an emphasis on staff training are crucial to successful efforts to eliminate laboratory mislabelling events. In fact, much of our process improvement efforts reflect the recommendations of the College of American Pathologists for creating a system to ensure proper specimen collection and labelling.¹⁶

A sustainment plan is essential to maintain improvement and was created to monitor the number of mislabelled specimens each month. By analysing control chart data, thresholds for the number of mislabelled specimens that indicated a potential special cause process variation were determined. An important component of the sustainment plan included continued data transparency. Unit-specific mislabelling data are sent monthly to nursing managers. In addition, we continue to conduct unit-level reviews for mislabelled specimens and mini-RCAs for mislabelled blood bank specimens. The goals of the review processes are not only to assess and ameliorate potential system issues by engaging front-line staff for ideas on prevention but also to maintain awareness of the importance of proper specimen collection. Personnel performance review continues to be handled separately through counselling and coaching by unit nursing and laboratory managers with respective staff.

There are several important limitations to our findings. First, the mislabel rate was primarily determined from specimen mislabels that were discovered in the preanalytical period with the exception of some blood bank specimens. The true rate of mislabelled specimens can be difficult to determine because some mislabelled specimens will be resulted and reported and remain clinically undetected. Moreover, some of the improvement interventions may not be generalisable to other institutions. For example, the two-person caregiver verification of correct patient identifiers may not be feasible in some institutions with different staffing models and workloads. Because the rate of mislabelled specimens differed between nursing and phlebotomy, implementing the process changes we adopted may have different effects on the reduction of mislabelled specimens in other institutions depending on the structure of their phlebotomy services. Finally, since other concurrent initiatives to eliminate preventable patient harm were ongoing in the hospital during the period of the specimen mislabelling improvement initiative, there may have been greater attention paid to general safe practices. This enhanced attention to safety may also have resulted in a reduction in the mislabelling rate not directly attributable to the improvement interventions implemented.

SUMMARY AND CONCLUSIONS

A multifaceted, multidisciplinary process improvement effort significantly reduced the rate of mislabelled laboratory specimens at our hospital. Our results demonstrate that the rate of mislabelled laboratory specimens can be significantly reduced by focusing on human factor improvement interventions.

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