Reduction in Specimen Labeling Errors After Implementation of a Positive Patient Identification System in Phlebotomy

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Abstract
Ensuring accurate patient identification is central to preventing medical errors, but it can be challenging. We implemented a bar code–based positive patient identification system for use in inpatient phlebotomy. A before-after design was used to evaluate the impact of the identification system on the frequency of mislabeled and unlabeled samples reported in our laboratory. Labeling errors fell from 5.45 in 10,000 before implementation to 3.2 in 10,000 afterward (P = .0013). An estimated 108 mislabeling events were prevented by the identification system in 1 year. Furthermore, a workflow step requiring manual preprinting of labels, which was accompanied by potential labeling errors in about one quarter of blood “draws,” was removed as a result of the new system. After implementation, a higher percentage of patients reported having their wristband checked before phlebotomy. Bar code technology significantly reduced the rate of specimen identification errors.

The recognition that preventable medical errors cause tens of thousands of US deaths annually has spurred a patient safety movement that seeks to create systems that are inherently error-preventing.1,2 The application of technology is considered integral to this process.3 Within laboratory medicine, as analytic quality has improved, the preanalytic and postanalytic stages of testing have emerged as the largest sources of laboratory error and, thus, prime targets for improvement.4,7 Accurate patient and specimen identification within the preanalytic stage is crucial; misidentification can have numerous consequences, such as an invasive procedure performed on the wrong patient,8 a result reported for the wrong patient, and missed or delayed diagnoses. Worst-case scenarios include missed cancer, unnecessary mastectomy,9 and hemolytic transfusion reactions.10 Specimen identification errors, such as mislabeled or unlabeled specimens, are detected at a rate of 0.04% to 0.1%,11-13 and many more may go undetected.14 In 2003, the Joint Commission announced accurate patient identification as the first of 6 National Patient Safety Goals.15 The Joint Commission also suggests the use of automated systems to prevent patient misidentification.16

Positive patient identification (PPID) refers to the correct initial identification of a patient and the absolute linking of all specimens to that patient throughout the entire testing process, including collection, analysis, and reporting.17 Two major technologies, bar coding and radiofrequency identification, are currently used for electronic PPID (EPPID). A typical bar code–based EPPID system consists of bar coded patient wristbands, handheld computers onto which orders are downloaded, bar code scanners used to confirm patient identity before
blood specimen collection, and portable printers to generate labels at the bedside. Early results from hospitals that have implemented EPPID systems seem promising.\textsuperscript{18-22} In 2000, the Valley Hospital, Ridgewood, NJ, implemented an EPPID system and reported an 82\% decrease in the rate of incorrect or incomplete labels from 0.017\% to 0.003\%.\textsuperscript{18} St Jude Children’s Research Hospital, Memphis, TN, reported an 84\% decrease in the incidence of mislabeled specimens from 0.032\% to 0.005\%.\textsuperscript{22} However, no study that we are aware of has shown a statistically significant effect of using EPPID for general specimen collection in a nonpediatric, large, academic hospital. Therefore, we evaluated the impact of a bar code–based bedside labeling system on the rate of specimen labeling errors within the inpatient phlebotomy service of a large, academic medical center.

Materials and Methods

Study Site

The study was performed at Brigham and Women’s Hospital, Boston, MA, a 777-bed academic medical center. The inpatient phlebotomy service at Brigham and Women’s Hospital is a deployed team that covers all inpatient care areas except the neonatal intensive care units and obtains approximately 50\% of inpatient blood samples. In 2008, nearly 215,000 blood samples were drawn by the inpatient phlebotomy team. The Partners Human Resource Committee found this study exempt from board oversight.

Tracking Mislabeled and Unlabeled Specimens

The primary outcome measure for this study was the number of inpatient phlebotomy samples reported as mislabeled or unlabeled by the laboratory. The laboratory typically recognized an incorrectly labeled sample at the time of specimen receipt when laboratory staff compared identifiers on the specimen label with those on the accompanying requisition form. The sample was recorded as mislabeled if patient identifiers on the specimen label did not match those on the requisition form or patient identifiers on the label and requisition matched but it was later determined that the sample was obtained from a different patient. If a specimen arrived with no label, it was recorded as unlabeled.

The percentage of total inpatient phlebotomy blood samples incorrectly labeled was calculated for each study period: preimplementation, from October 1, 2007, to July 31, 2008; implementation, from August 1 to 31, 2008; and postimplementation, from September 1, 2008, to June 30, 2009. Only errors committed by the inpatient phlebotomy team were included in the data.

Estimation of Prevented Mislabeling Events

We used 2 different methods to estimate the number of mislabeled specimens prevented by the EPPID system in 1 year. For the first estimate, we assumed that any difference in the number of errors per accession postimplementation vs preimplementation was attributable to errors prevented by EPPID. Accordingly, we calculated the number of errors that would have occurred in the 10-month postimplementation period if the preimplementation error rate had persisted unchanged. We then deducted the actual number of errors reported in the 10-month postimplementation period and extrapolated the result to 12 months.

We used audit data collected by EPPID to produce the second estimate. If, when scanning a patient’s wristband before specimen collection, the system detected a mismatch with the patient initially selected in the personal digital assistant (PDA) whose sample was to be drawn, an alert sounded and the phlebotomist was required to resolve the mismatch before proceeding. We compiled a tally of all cases during the 10-month postimplementation period in which this alert prevented a wrong-patient “draw” and extrapolated this number to 12 months.

Phlebotomy Workflow

The specimen labeling policy before EPPID implementation relied on a nurse or unit coordinator to manually generate patient addressograph labels and attach each to its correct requisition in preparation for phlebotomy rounds. A phlebotomist making rounds would check that the preprinted labels matched the requisition, were legible, and were of sufficient number, and create new labels if necessary. After EPPID implementation, the practice of preprinting labels was discontinued and new steps specific to EPPID were introduced Figure 1.

Frequency of Mistakes Associated With Label Preprinting

Before EPPID implementation, we assessed the frequency of mistakes made at any point during the label preprinting process. Very few of these mistakes actually resulted in a mislabeled or unlabeled specimen that reached the laboratory, but they were disruptive with respect to workflow and elevated the risk of labeling errors, which was the reason for measuring them. We observed 265 draws and determined the frequency of 4 mistakes: (1) The requisition provided by the unit had no preprinted labels or an insufficient number of preprinted labels. (2) One or more of the preprinted labels was illegible. (3) Too many preprinted labels were provided with the requisition. (4) The wrong patient’s labels were provided.

Time Required for Specimen Collection

After implementation, we determined the time required to perform specimen collections using the handheld system. Ten phlebotomists collecting a total of 116 inpatient blood
samples were observed in May 2009. The time required for specimen collection was defined as the interval between obtaining the paper requisition and finally placing the properly labeled tubes in a biohazard bag. Times were recorded on a form during observation.

Patient Survey

We developed a 5-item survey to monitor the effect of EPPID on patient satisfaction during phlebotomy. The first round of surveys was conducted in September and October 2008; 49 patients were surveyed. At that time, EPPID had been implemented but was not being used for patients on contact precautions; thus, these patients were considered EPPID-naive and acceptable candidates for initial surveys. The second round of surveys was conducted in April 2009; 50 patients were selected from across all inpatient services. Each patient was surveyed in person and asked to report whether his or her wristband had been checked or scanned and whether the specimens had been labeled at the bedside. The patient also rated the following on a 5-point Likert scale: (1) the professionalism of the phlebotomist, (2) the adequacy of the labeling technology, and (3) the overall experience during phlebotomy relative to expectations. From the survey responses, we calculated the percentage of optimal responses before and after EPPID. Optimal responses were defined as “Yes” for the 2 yes-no questions and “5” (“agree” or “excellent”) for the Likert items.

Implementation and Use

Several EPPID systems were evaluated by a multidisciplinary group that included members from pathology, nursing, information technology, and administration. After considering performance characteristics, reliability, information technology considerations, and goodness of fit regarding our workflow, we selected the Lattice mobile handheld system (Lattice, Wheaton, IL). The equipment included a Symbol MC70 handheld computer with bar code scanner, a Zebra mobile thermal printer, and an integrated wireless radio. Twenty handheld systems were purchased for a team of 39 inpatient phlebotomists covering 3 daily shifts.
We elected to implement EPPID in 2 phases, the second
of which had not been implemented as of manuscript submis-
sion. The main difference between the 2 phases concerns the
percentage of specimen collections in the hospital that are
performed using EPPID and the extent to which the EPPID sys-
tem communicates with other hospital information systems.

In the first phase, completed in August 2008, all inpatient
phlebotomy blood collections were performed using EPPID,
except for neonates, whose data could not be interfaced.
Patients on contact precautions were also excluded initially
while the appropriate procedures were being developed in
collaboration with the Infection Control Department. In this
phase, the handheld system interfaced with the hospital infor-
mation system to receive an admission/discharge/transfer feed
with current inpatient demographic information. However,
we were not able to interface with electronic physician order
entry to download orders directly to the handheld system and
continued to use paper requisitions.

In the second phase, the identification system will
interface with electronic physician order entry, and paper
requisitions will no longer be used. We will also expand
EPPID to all inpatient specimen collections, including those
performed by nursing and other health care professionals.

Training

Training consisted of eight 1.5-hour group introductory
sessions, followed by individual training in which each phle-
botomist was accompanied by a “super-user.” Phlebotomists
were then “shadowed” for up to 1 week, as needed. Following
the initial training, some phlebotomists required additional
education.

Statistical Analysis

The analyzed data consisted of the aggregate number of
mislabeled and unlabeled samples and aggregate accessions
for 21 one-month periods. For our statistical analyses, the
main outcome was the rate of incorrectly labeled samples
(estimated as the number of errors per 10,000 accessions)
during each of the 21 one-month periods. Logistic regression
was used to model the rates over time. In the logistic models,
we tested for trends over time and changes before and after
implementation of the EPPID system via Wald statistics. We
also calculated rates, rate ratios, and 95% confidence intervals
(CIs) via logistic regression. All analyses were conducted
using Proc Genmod in SAS, version 9.2 (SAS Institute, Cary,
NC). All tests were 2-tailed, and a $P$ value less than .05 was
considered statistically significant.

Results

Specimen Identification Error Rates

Labeling errors became less frequent after implementa-
tion Table 1 and Figure 2. Of 181,758 phlebotomy accessions in
the preimplementation period, 55 (0.030%) were reported as
mislabeled and 44 (0.024%) as unlabeled (Table 1). This com-
pares with 32 (0.017%) mislabeled and 27 (0.015%) unlabeled
of 184,043 accessions after implementation; the percentage
decreases were 43% and 38%, respectively.

Combining mislabeled and unlabeled samples revealed
an average labeling error rate of 5.45 per 10,000 phlebotomy
samples.

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<tr>
<th>Table 1</th>
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<tr>
<td>Number of Mislabels and Missing Labels Before and After Implementation of a Positive Patient Identification System in Phlebotomy*</td>
</tr>
<tr>
<td>Mislabeled samples</td>
</tr>
<tr>
<td>Unlabeled samples</td>
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<tr>
<td>Total No. of accessions</td>
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* Data are given as number (percentage).
Morrison et al / Reduction in Labeling Errors in Phlebotomy

accessions preimplementation (95% CI, 4.47-6.63) and 3.20 per 10,000 phlebotomy accessions postimplementation (95% CI, 2.48-4.14). The error rate decreased significantly postimplementation vs preimplementation (rate ratio, 0.59; 95% CI, 0.43-0.81; \( P = .0013 \)). Before EPPID, the labeling error rate was on an increasing trend; errors were increasing by an average of 9% per month (rate ratio, 1.09; \( P = .0118 \)). After implementation, the labeling error rate took on a downward trend; this rate fell by an average of 16% per month (rate ratio, 0.84; \( P = .0003 \)).

Estimated Prevented Mislabeling Events

Based on the reduced error rate after implementation, we estimated that EPPID prevented 28 mislabeled samples during 1 year. From auditing records, we estimated that use of the EPPID prevented 108 wrong-patient draws during 1 year.

Observed Label Preprinting Mistakes Before EPPID

Before EPPID, an insufficient number of preprinted labels was provided in 10.9% of draws (29/265) (Table 2). Illegible preprinted labels were provided in 8.7% of draws (23/265), too many in 4.5% (12/265), and labels for the wrong patient in 0.4% of draws (1/265). In total, a mistake was made during the preprinting process in about one quarter of draws before EPPID.

Median Time Required for Specimen Collection

The median time required to collect specimens using the handheld device in the postimplementation period was 6 minutes (\( n = 116; \) interquartile range, 5-8 minutes).

Patient Survey

The percentage of patients who reported being treated in a courteous, professional manner at their last phlebotomy increased from 67% (33/49) to 84% (42/50) after implementation (Figure 3). The percentage who could confirm that their wristband had been checked or scanned by the phlebotomist increased from 69% (34/49) to 92% (46/50). After implementation, 68% (34/50) as opposed to 49% (24/49) of patients preimplementation agreed that the equipment and techniques used by the phlebotomist seemed sufficient to prevent their specimens from being mislabeled. The percentage of patients who could confirm that their specimens were labeled at the bedside was similar preimplementation and postimplementation. Responses about the overall experience did not change substantially.

Discussion

We evaluated the effects of implementing EPPID and found it to be an effective technology for reducing specimen labeling errors within our hospital, as supported by the statistically significant decrease in mislabeled and unlabeled specimens reported by our laboratory and the record of 108 wrong-patient draws prevented by the EPPID system. Only

<table>
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<th>Specimen Label Preprinting Mistake</th>
<th>Observed Frequency</th>
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<tr>
<td>Insufficient No. provided</td>
<td>10.9</td>
</tr>
<tr>
<td>Illegible labels provided</td>
<td>8.7</td>
</tr>
<tr>
<td>Excessive No. provided</td>
<td>4.5</td>
</tr>
<tr>
<td>Wrong patient’s labels provided</td>
<td>0.4</td>
</tr>
<tr>
<td>Total</td>
<td>24.5</td>
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</table>

* Observed frequencies are the percentages of 265 blood “draws.”

Figure 3 Responses to patient satisfaction surveys. The percentage of optimal (“yes” or “excellent”) responses for each survey item is shown before (white bars) and after (black bars) electronic positive patient identification (EPPID) implementation.
a few studies on the effects of such a system for general specimen collection have been published.18,22 Our study, performed at a large, academic teaching hospital, should assist other large institutions considering implementation. Although most EPPID studies report on systems interfacing with electronic order entry, we report on a phase 1 implementation that used paper requisitions. Considering that 50% of institutions do not have electronic requisitions,13 phased implementation may be more realistic for some, especially those attempting to increase patient safety in a setting of limited resources.

Subtypes of Mislabeling Errors

Within what we have called “mislabeled specimens” at least 3 types of errors exist,11,12 2 of which were primarily addressed by the first phase of EPPID and 1 that will be further addressed by phase 2. These 3 types of mislabeling events result from specific breakdowns in the labeling process and have different levels of detectability Table 3.

The labeling process can be reduced to 3 items—the requisition, patient specimen, and specimen label—linked in a way that allows or prohibits errors Figure 4. A weak link between the requisition and patient specimen allows one to start with patient A’s requisition and draw a specimen from patient B, making “specimen-requisition mismatch” and “wrong-blood-in-tube” errors possible. In the same way, a weak link between the patient specimen and the specimen label allows one to label patient A’s specimen as patient B’s, making “wrong-label” and wrong-blood-in-tube errors possible.

Before EPPID, these links depended on human performance and were, thus, vulnerable to human error. For example, a match between the requisition and specimen label depended on the phlebotomist’s ability to visually inspect each preprinted label. EPPID implementation removed preprinting, a step that was problematic in about one quarter of draws, and established a technology-based specimen-label link, only allowing labels to be printed for the patient whose wristband is scanned. This strong link helps to prevent wrong-label and wrong-blood-in-tube errors. More patients reported having their wristband checked when specimen collection was performed with EPPID, confirming the ability of EPPID to enforce critical steps in the specimen identification process.

Recurring Errors

Following implementation, approximately 72% of labeling errors (23/32) were committed when using the handheld system, the majority being specimen-requisition mismatch errors. EPPID can prevent errors only insofar as key steps within the standard operating procedure are followed. Because the identification system did not yet interface with
Morrison et al / Reduction in Labeling Errors in Phlebotomy

electronic order entry in phase 1, the phlebotomist still had the job of selecting the correct patient in the PDA based on identifiers on the paper requisition. It was possible to select the wrong patient in the PDA and subsequently obtain a specimen from this patient, especially if his or her name or room number resembled that of the correct patient. The patient’s tubes would be labeled correctly as belonging to him or her, but the specimen should not have been obtained from this patient. This existing weak link in the labeling process, which will be replaced by electronic order entry in phase 2, partially explains why we saw a 43% decrease in our mislabeling rate, whereas other hospitals have seen reductions of more than 80%.18 While still in the first phase of implementation, further education on proper use of the labeling system should help to reduce recurring errors.

Discrepancy Between Two Estimates of Prevented Errors

The 2 methods we used to estimate mislabeling errors prevented by the EPPID system produced 2 considerably different figures. This is likely because the first method relied on the rate of reported errors, whereas the second method included errors that most often are not reported, such as wrong-blood-in-tube errors, which are difficult to detect within our laboratory. Thus, although the number of errors reported in our laboratory may have decreased by 28 during 1 year, the number of actual prevented errors may be as high as 108. Most identification errors are thought to go undetected.14

Additional Benefits of EPPID

Before EPPID, the phlebotomist ID and blood collection time were manually inscribed and often illegible or inadequate. EPPID has ensured that 100% of labels are legibly printed with this information and that accurate auditing data are automatically recorded.

EPPID did not slow our collection process or negatively affect the patient experience during phlebotomy. The time required for specimen collection using the system was comparable to published times, which were 5.8 minutes18 and 6 minutes20 in other studies.

Technical Issues

Use of the handheld system was 85% in the eighth post-implementation month. Less than 100% use was due partly to technical issues; in particular, when the PDA battery was low, the scanner did not work. A phlebotomist at the end of his or her shift with a low battery might revert to the manual labeling method instead of traveling to the laboratory to pick up a new PDA. Phlebotomists now carry backup batteries on rounds, which should help to raise use of the system to 100%. Such issues occur routinely following implementation of electronic solutions, underscoring the importance of postmeasurement evaluation and trouble-shooting.

Benefits of the Second Implementation Phase

In the second phase of implementation, the system will automatically download electronic orders to PDAs. Paper requisitions will be eliminated, and phlebotomists will no longer be able to mistakenly obtain a specimen from a patient who has no orders, thus reducing the frequency of specimen-requisition mismatch errors. Furthermore, by implementing the bar code labeling system only within our phlebotomy service, we were targeting only 15% of all inpatient mislabeled specimens, the rest being committed primarily by health care professionals other than phlebotomists. Our aim is to expand the technology to all specimen collection in our hospital.

Conclusion

EPPID represents an effective technology for preventing specimen identification errors in a clinical laboratory without slowing the collection process or negatively impacting the patient experience during phlebotomy. Even without interfacing with electronic order entry, the system reduced error rates significantly. This technology represents a key to ensuring patient safety in laboratory medicine.

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References


