Standardized patient identification and specimen labeling: A retrospective analysis on improving patient safety

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Background: There is an increased risk of specimen labeling errors with the generation of a high volume of pathology specimens. Measuring specimen labeling accuracy has been suggested as a possible measure for patient safety.

Objective: We sought to identify operational areas for improvement around specimen handling with the institution of a standardized specimen labeling protocol in the Duke University Medical Center Department of Dermatology. The average rates of specimen labeling events before and after implementation of this protocol were analyzed to determine the efficacy of this systematic approach.

Methods: We collected the monthly aggregated rates of specimen labeling events occurring with skin specimens processed through the Duke University Medical Center Department of Pathology from December 2008 through June 2011. The average monthly rates of events per 1000 cases for the time periods from December 2008 through March 2010 and June 2010 through September 2011 were compared.

Results: The data collected showed a statistically significant decline in the average monthly rate of specimen labeling errors after institution of the protocol. Before implementation, specimen labeling events occurred at a rate of 5.79 events per 1000 with a decrease to 3.53 events per 1000 after integration of this system ($P = .028$).

Limitations: Limitations of this study include possible sampling error and regression toward the mean.

Conclusions: Low-cost, process-driven interventions are effective in the reduction of specimen handling errors. (J Am Acad Dermatol 2013;68:53-6.)

Key words: labeling errors; pathology specimens; patient safety; safety protocol; specimen identification; specimen labeling errors.

Specimen handling errors may occur in several settings, with varying degrees of potential clinical impact.[1] Most dermatology practices generate a high volume of specimens destined for pathology review, presenting multiple opportunities for specimen handling errors that may range from inaccuracies with anatomic site, patient information, and provider information, to the absence of the actual specimen, among others. Developing a standardized specimen handling system has the potential to reduce such errors, with evaluation of specimen labeling accuracy suggested as a possible measure for patient safety.[2]

The Department of Dermatology, Duke University Medical Center, Durham, NC, has seen significant growth over the past 4 years with a resultant increase in the number of surgical specimens generated; when an upward trend in specimen

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labeling errors was noted, a physician-led safety committee was formed. Through the process of work-flow mapping, a 5-step clinical protocol was developed to standardize the specimen handling policy. The aim of the current study was to examine the efficacy of this system by measuring the variance in specimen labeling events before and after implementation of the protocol.

CAPSULE SUMMARY

- A standardized process-driven patient identification and specimen labeling protocol, including a low-cost critical double-check, significantly reduced the rate of specimen labeling events.
- Creation of a physician-led safety committee facilitated an environment of continuous process improvement where each safety event was viewed as a learning opportunity to further modify protocols.
- Refinement of processes in one department may facilitate identification of opportunities for improvement in other departments that also handle patient specimens.

METHODS

To address the upward trend in specimen labeling errors within our department of dermatology, a safety committee composed of attending physicians, resident physicians, registered nurses, and certified medical assistants was formed. At the time of committee formation, each provider's method of ensuring accurate labeling was individualized. Through work-flow mapping, 17 steps were outlined from the provider's decision to perform a biopsy to submission of the tissue for courier pickup and transportation to surgical pathology.

Five of these steps were considered essential to accurate specimen labeling (Fig 1), and each step was designated as either a physician-specific or nursing staff–specific responsibility. For planned surgical procedures, a formalized time-out process occurred to mitigate the additional potential risk for wrong-site, wrong-patient excisions. For all specimens, a critical double-check mechanism was standardized: before matching the paper requisition to the biohazard bag containing the specimen, the nursing staff verified concordance of patient identification and specimen site between the requisition form and the label, the presence of provider initials on specimen label signifying the provider's double-check, and the visualization of tissue in the specimen container. Once this critical double-check is performed, the nursing support staff place their initials on the paper requisition form, taking ownership for the double-check process, and assisting with follow-up should any specimen handling errors occur. The proposed steps were presented at several departmental grand round meetings to solicit feedback, encourage faculty buy-in, and solicit ideas for iterative process improvement.

Additional improvements beyond the 5-step standardized process included placing label printers in every examination room. Performing label generation at the patient bedside reduces the opportunity for patient identification errors and laterality errors (ie, right leg vs left leg) in site identification. For cutaneous biopsy specimens that are arbitrarily deemed by any health care team member as small, we developed a bright-green sticker labeled "small specimen" to be placed over the container lid to alert the surgical pathology staff to exercise additional care when opening the specimen container.

The standardized specimen labeling protocol was implemented in April 2010. We obtained institutional review board approval for this retrospective study in which we calculated the monthly aggregated rates of specimen labeling events occurring with skin specimens processed through the department of pathology from December 2008 through September 2011. The numerator of the error rate calculation included all specimen labeling events recorded by surgical pathology. Specimen labeling events included: any discrepancy between the paper requisition form and the label on the specimen container; absence of an appropriate label; absence of tissue; absence of a paper requisition; or incorrectly labeled anatomic site. The electronic summary log for these labeling events was available for review, but the summary log did not include the department of origin or attending provider. The denominator of the error rate calculation included all cutaneous specimens received by surgical pathology independent of the department of origin. Thus, the error rate calculation reflects the specimen labeling errors for cutaneous specimens generated at Duke University Medical Center across all specialties.

We calculated the average monthly rate of specimen labeling events per 1000 specimens for 2 periods: (1) before the protocol implementation, December 2008 through March 2010; and (2) after the 2-month implementation period, June 2010 through September 2011. The data from April through May 2010 were excluded to account for institution of the safety protocol. A 2-proportion

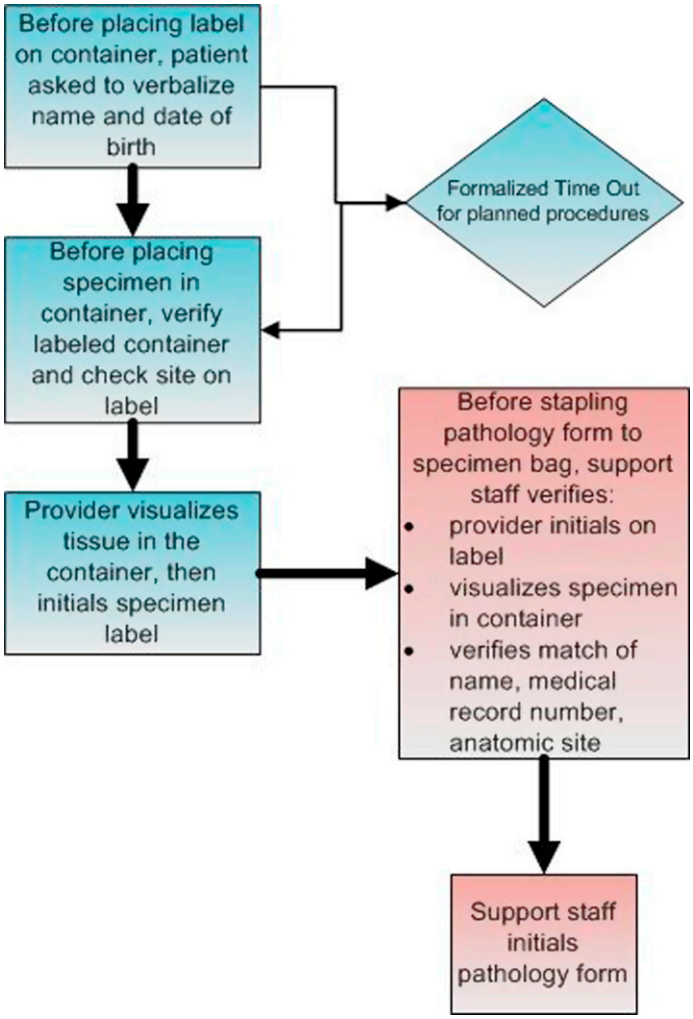

Fig 1. Essential specimen handling steps. Blue items are physician-specific responsibilities; pink items are nursing staff–specific responsibilities.

Z-test was then performed to determine the statistical significance of the variance in event rates before and after institution of the safety protocol.

RESULTS

A total of 8288 skin specimens were processed through surgical pathology from December 2008 through March 2010 with an average monthly rate of 5.79 specimen labeling events per 1000. After institution of the safety protocol, a total of 9072 skin specimens were processed from June 2010 through September 2011, with a decline in the average monthly rate of specimen labeling events to 3.53 events per 1000 (P = .028, 2-proportion Z-test).

DISCUSSION

As health care is an inherently human operation, errors may be expected. And when errors occur, using a systems-based evaluation of the event, rather than a person-based evaluation, greatly facilitates an objective evaluation of the inherent conditions under which the error occurred. Unfortunately without this analysis, the same errors may recur, regardless of personnel changes; said another way, the same errors are destined to repeat themselves unless the fallible system is changed.

The Swiss-cheese model of system failure, represented by multiple stacked slices of holey cheese, provides a very useful visual analog to many health systems errors: if each slice is a defensive layer in the system, and each hole in that slice is an opportunity for an error to occur, a resilient system will formalize multiple layers of defense to assure that the holes do not line up, successfully avoiding the error.[3] This layered defense approach serves as an effective tool to visualize development of a high-reliability

specimen handling policy; the Joint Commission has pinpointed accurate specimen labeling and improved patient identification as important ways to maintain patient safety.[4]

After refinement of the clinical specimen handling process, we began to identify opportunities for process improvement once the tissue left the dermatology clinic: when the paper requisition is separated from the specimen for copying, 2 patient identifiers are now used to rematch the 2; all small specimens are now grossed-in at a defined small-specimen grossing station that is completely broken down at the end of the work day; and when a specimen container is found to contain no tissue, an immediate time-out is called where the pathology assistant brings another staff member to the area to canvas the area and attempt to recover the tissue that may have been inadvertently misplaced through the opening of the container itself. At least 3 specimens have been recovered through this time-out process. The implementation of small-specimen stickers is one example of the increased communication between dermatology and surgical pathology that resulted from this initiative.

There remains the question of whether the application of computer technology, such as the incorporation of bar codes in the specimen labels, may be effective in reducing these errors.[5,6] One study showed that it failed to demonstrate a significant benefit in terms of decreasing identification errors and may not prove to be cost-effective.[7] The interventions of our committee have proven to be low cost (additional incremental time for the nursing double-check and the small-specimen labels; the bedside label generation could also be performed manually with handwritten labels).

Limitations of this study include possible sampling error. The data set for both specimen volume and number of errors consisted of all cutaneous specimens processed through pathology and were not exclusive to those generated by the dermatology department and could not be exactly divided by specialty, although our dermatopathologist estimates that 80% to 90% of cutaneous specimens originate in dermatology (written personal communication, April 20, 2012, M. Angelica Selim, MD, Departments of Dermatology and Pathology, Duke University Medical Center). However, despite the inability to exclude specimen volume and errors generated by other specialties, the statistical significance of error reduction for all cutaneous specimens perhaps underrepresents the true dermatology-specific error rate reduction. Regression toward the mean may also have affected the results of the study; in other words, if the error rate was more extreme on our first measurement (before implementation of the specimen labeling protocol), then the second measurement (after implementation of the protocol) may be closer to the average without actually being affected by the intervention. In addition, the Hawthorne effect theoretically could have contributed: the resultant improvement may have resulted solely from the knowledge that individuals were being monitored rather than from institution of our protocol.

A complex process was fully mapped, distilled to its essential components, then presented at grand rounds to leverage the collective faculty wisdom and experience to address work flow. The double-check process has reinforced a culture of iterative safety improvement with all clinical team members: generation of a specimen labeling error cues a prompt safety debriefing with the involved parties to determine whether additional opportunities for process improvement exist.

This study shows that low-cost, process-driven interventions are valuable in detecting and preventing errors that could result in patient harm. Attention toward standardized patient identification and inclusion of an independent double-check on submitted specimens has led to a dramatic reduction in specimen labeling errors occurring in an outpatient dermatology clinic.

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