ABSTRACT

Objectives: Specimen labeling defects within the perioperative environment are a known patient safety risk that carries the potential for adverse outcomes. These outcomes are a result of errors that occur when unsuspecting providers operate within poorly designed processes with little control over the specimen collection context. Many costly outcomes resulting from labeling errors may include patient harm, inappropriate treatments, lengthy investigations, corrective actions, and, at times, legal action.

Methods: This improvement initiative to identify and reduce the risk of specimen labeling defects includes the application of a disciplined Lean problem-solving approach with the engagement of employees who actually perform the work.

Results: By listening to the voice of our internal customers, we collectively redesigned the workflow by collaboratively linking work teams of the operating room and Pathology Department of Henry Ford Hospital, Detroit, over a 2-year period.

Conclusions: We illustrate successful interventions achieved by Lean process management by streamlining, standardizing, and mistake proofing the processes and eliminating waste and inefficiency through systematic problem solving.

All patients expect that the results of their diagnostic tests should indeed be their own and do not belong to another patient. In health care today, these uncertainties are valid concerns reflected in a national patient safety goal for accurate patient identification both for diagnostic testing as well as treatment. This extends from patient identification to accurate specimen tracking and significantly affects error rates inherent in current health care processes.

Specimen labeling defects in the perioperative environment are a known safety risk for sometimes serious adverse patient outcomes and unnecessary costs from both rework of investigations and corrective actions. It is estimated that 17% of specimen misidentification defects result in incorrect therapies, and almost 6% result in adverse events.1,2 Bixenstine et al3 noted that the “correction of such identification defects consumes valuable resources; each may take an average of 3.5 hours to correct.”

Although the frequency of these defects may not be very high, they are not insignificant. In the largest comprehensive voluntary study of 1 million outpatient and inpatient specimens from 417 hospitals in 1998, specimen container and requisition labeling defects occurred in 6% of cases or 60 of 1,000.4 In a more focused study in 2007 of the operating room (OR) specimen identification process at Johns Hopkins Medical Center, Makary et al5 documented specimen labeling deficiencies with inaccuracies such as absence of patient name, omission of details regarding tissue site, or inaccurate details to be 3.7 per 1,000 specimens.

Health care is faced with many challenges, and that includes current barriers that inhibit our ability to effectively design and provide safe, reliable, cost-effective, quality care.
to the patient. The Institute of Medicine addressed this challenge prominently in 2011, describing the need to transform poorly designed processes in health care as “the gap between where health care is and where it needs to be.” There have already been numerous attempts to correct process defect issues within OR and pathology departments. This article presents a method that enabled this implementation to be successful where others lacked sustainability.

Description of the Problem

In 2009, we initially began the project to examine mislabeled specimens for the Statewide Keystone-Surgery Patient Safety Initiative of the Michigan Hospital Association. This collaborative of 85 hospitals voluntarily participated in a 3-month pilot of OR specimen labeling accuracy with an overall specimen defect rate of 2.9% or 29 of 1,000. These are poor levels of quality, equating to 3 sigma, with a significant potential to affect patient safety. This raised awareness of our own internal process flaws at Henry Ford Hospital.

Rationale for Improvement

The focus of the study at Henry Ford Hospital was to assess the presence/absence of seven specific required specimen requisition and container information elements such as misidentification, lack of required data, and incorrect laterality. In addition to the statistical analysis aligned with the Keystone initiative, we saw significant opportunities for data capture that fell outside of the specific project requirements. These data sets were tallied and included as the “other” category that later proved to be a rich data source for process improvements.

The Setting

The endeavor to redesign safer processes for specimen collection and delivery began with a multidisciplinary team initiative from the OR and then moved to the pathology department over a 2-year period (2010-2012). The 802-bed inner-city tertiary care hospital includes surgical teams operating within specialties of expertise across 31 ORs. Most important, for this quality improvement initiative, the process variation within these surgical teams was further complicated by lack of standards for specimen collection and processing. The variations within the surgical processes required a collaborative effort to coordinate standardization across 31 ORs. This effort enlisted the representation of nurses, surgeons, pathologists, technologists, technicians, and managers, as empowered employees who took ownership for the redesign of the processes.

Materials and Methods

The methods described within this quality improvement initiative were based on a “step-by-step” approach for Lean continuous improvement through data collection, observation techniques, and customer-supplier interaction. The method for initial data collection included the focus on 14 specific defects associated with testing orders (requisition) and associated specimen containers. We also analyzed the improvement opportunities that were identified as a result of the “other” category of data collection. We then used these data collection results as an impetus for redesign and standardization of processes between the two departments, OR and Pathology. The effort focused on areas that exhibited a lack of efficient, standardized handoffs and direct connections. The following paragraphs describe improvements implemented as a result of the process standardization.

Data Collection

The initial data collection plan was developed to identify and document the current state of specimen defects within the laboratory. The average number of specimen containers received within the laboratory was 800 per month, with 700 specimen testing orders formally known as requisitions. Defects were documented by a pathologist’s assistant in the laboratory at the point of specimen receipt. An electronic form with built-in logic was used to enter data for each requisition, specimen, and subpart. All “other” defects were identified, analyzed, and tabulated for root cause analysis in addition to the mandated elements. The “other” designations, unrelated to an existing category, carried the potential and opportunity for further improvement and were categorized as inefficiencies or lack of process integrity.

The defects categorized within the “other” category are shown in Table 1.

Using the Lean Approach

Our approach for process improvement with OR services was based on the Lean method. This application of Lean problem solving and continuous improvement was adapted from manufacturing as implemented in systems such as the Ford Production System and the Toyota Production System.
The Lean Enterprise Institute\textsuperscript{12} describes Lean as a system for “maximizing customer value while minimizing waste to create more value for customers and using fewer resources.” It is estimated that more than 90\% of Lean efforts fall short of expectations. This is due to a method that is superficial with regard to culture change.\textsuperscript{13} This project therefore aimed to focus on a Lean approach based on strong leadership collaboration to introduce a philosophy, structure, processes, and incentives that enabled the teams to work together to design and implement solutions. Our clinical colleagues, although not previously educated in the significance of waste reduction through Lean, were included in an adaptation of this approach with just-in-time training as the project progressed. Our core method was based on Plan, Do, Check, Act (PDCA) or scientific data-driven hypothesis and test problem solving. We also employed direct observation, process flow and value stream mapping (a high-level view of the entire process to identify opportunities for improvement and redesign a more efficient process), work redesign, error and mistake proofing (a process designed to avoid human error), customer-supplier integration between separate work groups, and employee engagement in process improvements based on “go and see” (it is necessary to observe the process and deeply understand the root cause to understand the significance of the problem). We labeled the identified issues as in-process defects to classify all nonstandard and unexpected work outcomes that caused any employee to stop, fix, or delay the work; work returned to sender; or where internal customers just were not satisfied, indicating that the work could have been done better.

**Cross-Functional Teams: “Customer-Supplier” Meetings**

To address in-process defects and opportunities for improvement, weekly customer-supplier meetings consisting of nurses, residents, surgeons, pathologist assistants, the quality manager, and nurse managers were initiated between the OR and pathology Table 2. The specimen labeling concerns with the potential to affect patient safety were prioritized and discussed at each weekly meeting.

**Observation Sessions**

The Lean principle of “go and see” was critical for identifying defects, wastes, and redundancies within processes involved in collection and processing of specimens. Each member of the team was instructed to physically follow one specimen through the specimen collection process from the OR to the pathology department to better understand how defects originated within the handoff process. The team documented their findings and photographed pertinent events that were later reviewed and used as the impetus for improvement.

**Table 2**

<table>
<thead>
<tr>
<th>Process Defects Identified Within the “Other Category”</th>
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<tbody>
<tr>
<td>Defects within pathology</td>
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<tr>
<td>Lack of laboratory standard process in laboratory</td>
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<tr>
<td>Lack of laboratory employee competency and training in laboratory</td>
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<tr>
<td>Quality control check not performed—container: requisition verification</td>
</tr>
<tr>
<td>Defects along the value stream</td>
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<tr>
<td>Lack of communication/process between operating room (OR) and pathology</td>
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<tr>
<td>Matching specimen parts/requisitions</td>
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<tr>
<td>Lack of chain of custody upon specimen drop-off</td>
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<tr>
<td>Defects originating within the OR</td>
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<tr>
<td>Number of specimens did not match the requisition</td>
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<tr>
<td>Incorrect information documented on the requisition</td>
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<tr>
<td>Patient identification not on all specimen parts</td>
</tr>
<tr>
<td>Missing complete clinical history</td>
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<tr>
<td>Most requisitions missing the time of procedure</td>
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<tr>
<td>Failure to establish and/or follow a standard process</td>
</tr>
<tr>
<td>Poor communication or poor handoffs</td>
</tr>
<tr>
<td>Human error</td>
</tr>
<tr>
<td>Staffing not matching workload</td>
</tr>
<tr>
<td>No rotation of staff duties to eliminate fatigue</td>
</tr>
<tr>
<td>Failure to educate and assess competency</td>
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\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{figure1.png}
\caption{The number of specimen and requisitions defects per month for January 2010 through August 2011.}
\end{figure}

\begin{table}[h]
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\begin{tabular}{|l|}
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Table 2: Process Defects Identified Within the “Other Category”
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Observation Within the OR

In addition to defects captured with the data collection tool, the “other” category, illustrating unclassified process inefficiencies, waste, and variation, became quite significant. Although well-intentioned, employees innocently contributed to in-process variation as a result of informal training inherited from their former colleagues throughout the years. It became apparent that tasks relating to specimen collection, delivery, and processing included significant variation, and one standard across-the-board approach was necessary. On the basis of observation, we identified numerous redundancies within the manual processes. In fact, many nurses developed their own personal work-around in the form of handwritten notes that they carried in their pockets [Figure 2] and [Table 3].

Their intent was to defensively record specimens for which they were personally responsible for transporting to Pathology. This was a form of “cover your tail” rather than a standard work expectation, illustrating the fact that there was little confidence or trust in a poorly defined system of work.

By observation, it was determined that the specimen collection process included a total of nine steps to collect, document, label, and deliver each specimen to the laboratory. This process is depicted in [Table 4] and [Figure 3].

Specimen Read-Back Procedure Within the ORs

Although the OR had adopted the World Health Organization (WHO) guideline for a perioperative read-back procedure between the surgeon and OR staff, there was lack of any standard regarding how the patient/specimen information was to be communicated as part of the specimen handoff process. To verify information, the WHO recommends the circulator to perform read-back with the surgeon to confirm that all specimens were labeled correctly.7 Because of the lack of a standard, the nurses had some difficulty in performing the read-back procedure with the surgeons. To establish a standard, we enlisted the involvement of the chair of Surgery to align and educate surgeons on the importance of the read-back procedure. The specimen read-back education was provided to surgeons through video segments played through the closed-circuit OR television to be viewed while the surgeon scrubbed. The improved instruction for surgeons now integrated processes, people, and procedures to achieve one standardized read-back message that emphasized the surgeon’s role in patient and specimen safety based on a surgeon speaking to his or her surgical peers. Additional instructional videos were developed for OR staff to communicate requirements and to solidify the standardized read-back process during specimen collection. The specimen handoff and read-back procedure standardized in the OR was captured in video and used initially to train 200 OR staff. The video was later developed into an educational module, as an annual refresher for existing staff as well as training for new staff.

Implementation of Labels to Identify Special Handling

One of the identified key root causes of defects were specimens that required special handling but contained no specific instructions. We addressed the top five most common tissue sample processes or work streams containing critical defects: (1) specimens for routine pathologic examination,
To identify unique laboratory testing, a color-coded specimen label was developed that contained processing information associated with each work stream. The special handling requirement was front-loaded for each specimen stream and used as a standard and to ensure mistake-proof processing. “Label Stations” were developed and installed in each of the ORs. Each “Label Station” contained rolls of color-coded labels for use by the circulator nurse to immediately label the specimen containers and file requisitions, as well as expedite processing.

**Approach to Implementation: One Standard Process**

On the basis of the noted nonstandard processes whose variation contributed to the documented defects, the team was instructed to adopt one standard pathway to collect, label, and deliver specimens to the laboratory. This process redesign would serve as a standardized process within the OR in the absence of an electronic specimen tracking system and in preparation for the new information system.

The teams performed the following sequence of events:

- Review the results of multiple observations and identify commonalities of waste, including non-value-added steps, process variation, and redundancy
- Identify opportunities for improvement
- Create the future state by standardizing the value-added steps
- Implement and monitor the perfected process for effectiveness
- Educate super-users, who will then train all staff on the new processes
- Adjust the process based on user feedback

**Table 4**

<table>
<thead>
<tr>
<th>Steps of a Surgical Nurse</th>
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<tbody>
<tr>
<td>1. Check patient file for correct order of anatomic site/procedure</td>
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<tr>
<td>2. Complete laboratory requisition</td>
</tr>
<tr>
<td>3. Enter specimen information in Surgical Information System</td>
</tr>
<tr>
<td>4. Write specimen description on the containers</td>
</tr>
<tr>
<td>5. Write specimen description on the container labels</td>
</tr>
<tr>
<td>6. Write specimen description on the laboratory requisition</td>
</tr>
<tr>
<td>7. Keep adding a running tab (notepad) of all of the above specimens</td>
</tr>
<tr>
<td>8. Write identical information (specimen description) on the logbook</td>
</tr>
<tr>
<td>9. Multiple frozen-section specimens are delivered at different times</td>
</tr>
<tr>
<td>10. Create multiple laboratory requisitions if the original has run out of space</td>
</tr>
<tr>
<td>11. Photocopy the requisition in lieu of writing multiple times in the logbook (the photocopy machine not located nearby)</td>
</tr>
</tbody>
</table>

(2) frozen-section specimens, (3) specimens for lymphoma workup, (4) open lung biopsy protocol specimens, and (5) tissue specimens for microbiologic examination. **Figure 4.**

**Figure 3** The specimen collection process includes a number of redundancies and wastes. Each picture represents one of nine steps in the process.
On the basis of the significant variation, redundancy in documentation, and feedback from nurses, the teams developed one standardized specimen collection process. This process included the concept of using a single multipart label packet with multiple copies [Figure 5]. The form was tested and iteratively modified through numerous PDCA cycles until all users were satisfied with the new tool. This three-part label packet contained label information intended for the requisition and transferred this information through to the container copy and a final reconciliation page. The reconciliation copy was designed for OR staff to confirm that all specimens were accounted for and were correct. This reconciliation page eliminated the need for the personal running list that had previously been tabulated by many nurses. The surgeon or his or her designee provided the final approval required on the label.

The specimen requisition was also revised to include placeholders for chronological label placement [Figure 6].

The Piggyback Labeling Pilot

A pilot to test the piggyback label packet was conducted in partnership with the four gynecology-oncology (GYN-ONC) surgeons of Women’s Health Services who
performed their procedures within the OR. Since the surgeons had been previously Lean trained as part of the Lean management culture development program, it was ideal that they should serve as champions for the pilot to guide the ultimate success of the project.

**Surgeon-Driven Standard Work**

To further assist the nurses and to standardize the designation of the specimen part type names and surgical procedures, the GYN-ONC surgeons reviewed and, by consensus, revised and developed a master terminology list [Table 5]. This list was adopted for use as a surgeon-nurse communication tool used within the GYN-ONC operating rooms and served as a standardized and consistent identification method for specimens submitted for specific tests to be performed by pathology. This standardization by the surgeons allowed the surgical team to reliably and accurately comply with the WHO’s guidelines for safe surgery requiring verbal confirmation of the correct patients and their specimen information.7

**Data Analysis and Results**

[Table 6] lists implemented improvements and significant changes that resulted from this quality improvement initiative.
Impacts of Results

Numerous impacts were identified as a result of the entire process improvement efforts; these are summarized below.

The application of the Lean method yielded several benefits:

- Process simplification
- Removal of waste and inefficiency
- Increased employee satisfaction
- Standardized processes and development of standard work
- Increased surgeon involvement
- Improved communication through multidisciplinary teams working toward common goals

The Lean principles that were applied, as foundations, for achieving these results included the following:

- Color coding (visual controls)
- Customer-supplier integration
- Process and value stream mapping
- Process restructuring to incorporate pull, process flow, and load leveling
- Worker empowerment within cross-functional teams

Discussion

To our knowledge, there is no comprehensive literature demonstrating how health care institutions have successfully dealt with the universal potential patient safety problem in the OR–pathology department process, using Lean methods. As noted by Simon et al., finding publications that discuss Lean theories and tools within the literature is plentiful; however, few publications actually describe how to apply the tools and at what phase of the process reformulation. In our study, we attribute the significant accomplishment of a sustained reduction in specimen labeling defects to the collaborative Lean system redesign by OR and Pathology work group owners committed to finding common ground in redesigning their work to make a difference for patient safety.

The number of defective processes at the onset of the initiative was frustrating for those who were held accountable for the outcomes but had very little control or input into improving the process. As a raw number, the actual number of defects seemed to be quite few, and this made creating a “burning platform” case for change very challenging.
The most profound challenges when implementing these Lean initiatives were those of garnering support and navigating through the silos of control to improve the existing out-worn legacy processes. In addition, efforts of this nature required leaders to prioritize, manage, and dedicate resources to issues that were historically considered “pathology’s problem.” Regardless of the originating department, in our experience, the most effective leaders for change exhibited perseverance, passion, and dedication despite inevitable setbacks and frustrations inherent in the team approach.

Another significant challenge to change in any OR setting is the lack of surgeon involvement. Few surgeons had the time or interest to assist with new process design efforts, but their participation was invaluable once recruited on the team. The success of some of these initiatives was directly related to the involvement of the chair of women’s health services, who directed the piggyback label pilot, and the chair of surgery, who was instrumental in developing the read-back training video for surgeons.

The complex processes we encountered that were once fraught with waste and inefficiency were tackled by the consistent application of one process improvement resolution at a time over a 2-year period. The observation sessions or “go and see” were instrumental in placing the observer employee directly within the dysfunctional OR process as “one of the team” to identify wasteful steps firsthand. We found that the OR teams were shocked to learn of their wasteful non–value-added work steps, but they were also pleased to collaboratively eliminate several redundant steps involved in collecting, labeling, and delivering a specimen. This resulted in significant time savings for the OR employees and gave them more confidence in the reliability and consistency of their new system of work. The creation of the piggyback label packet and process also resulted in significant reductions in handwritten documentation and increased accuracy of specimen collection by forcing a standardized “collect one, label one at the bedside” process. The nurses’ handwritten personal lists and tallies of specimens delivered to the laboratory were no longer required as a defense since the responsible nurse now had a specimen reconciliation page for each patient as he or she filled out the multipart piggyback label packet in real time. The creation of a standardized specimen job-aid by the surgeons, listing all common procedures with the associated specimen part types, was also beneficial to the OR staff responsible for accurate specimen documentation.

Conclusions

The three most important lessons that have been learned here in achieving a sustained reduction in specimen labeling defects are the following:

- Change requires leadership support and cross-functional team involvement to effectively improve across boundaries of control.
- Every process redesign requires the involvement of those who actually do the work; these are the people who understand the nitty-gritty details of exactly how the defects arise and are often “expert” in suggesting how successful changes can be made.
- Focused changes require not one but numerous PDCA cycles with identification of root causes and countermeasures that must be consistently and carefully identified and sustained.

Our baseline specimen defect rate of 2.25% corresponds closely to the overall rate of 2.9% of surgical cases lacking the correct patient/specimen information (specimen requisitions and containers) that was documented in the pilot of the 2009 Michigan Keystone-Surgery collaborative pilot study, which used a similar but slightly less comprehensive data collection tool compared with the one that we used here, which included an additional “other” defects category. From May 2010 to March 2012, the surgical specimen defect rate for hospitals participating in the Michigan statewide collaborative decreased 30%, from 2.64% to 1.85% or 18.5 per 1,000. By comparison, our specimen defect rate over this same timeframe was reduced by 89% to 0.25% or 2.5 per 1,000 cases. We have shown here that the power of embracing a culture of continuous improvement results from leveraging innovations that come best from those directly involved in performing the work. We believe that employee empowerment in a continuous improvement culture is the foundation of Toyota’s historical Lean successes, and this applies just as well to other work cultures outside of manufacturing. It is certainly now time for health care leaders to embrace the Institute of Medicine’s call for “continuous improvement—incorporating innovation, disciplined quality improvement, and evaluation . . . [to] meet the goals of optimizing patient experience and outcomes, improving the health of the population, and controlling cost.”

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