CME/SAM

The Henry Ford Production System

Reduction of Surgical Pathology In-Process Misidentification Defects by Bar Code–Specified Work Process Standardization

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Upon completion of this activity you will be able to:
- list aspects of lean manufacturing–based techniques that can be effective in laboratory process redesign.
- describe means of measuring misidentification defects arising within processes of the surgical pathology laboratory.
- discuss applications of bar codes in surgical pathology that reinforce processes designed on the basis of manufacturing principles of efficiency and minimize the creation of misidentification defects.

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Abstract

Misidentification defects are a potential patient safety issue in medicine, including in the surgical pathology laboratory. In addressing the Joint Commission's national patient safety goal of accurate patient and specimen identification, we focused our lens internally on our own laboratory processes, with measurement tools designed to identify potential misidentification defects and their root causes. Based on this knowledge, aligned with our lean work culture in the Henry Ford Production System, we redesigned our surgical pathology laboratory workflow with simplified connections and pathways reinforced by a bar code technology innovation to specify and standardize work processes. We also adopted just-in-time prestain slide labeling with solvent-impervious, bar-coded slide labels at the microtome station, eliminating the loop-back pathway of poststain, batch slide matching, and labeling with adhesive paper labels. These changes have enabled us to dramatically reduce the overall misidentification case rate by approximately 62% with an approximate 95% reduction in the more common histologic slide misidentification defects while increasing technical throughput at the histology microtomy station by 125%.

"Quality means doing it right when no one is looking."
—Henry Ford[1]

In previous articles in this *Journal*, we shared our cultural approach to continuous work improvement,[2] measurement tools established to identify the frequency and root causes of in-process work defects,[3] and our successful reductions of defects and waste in the surgical pathology laboratory.[4] This laboratory-wide effort to continually eliminate waste in all its forms while perfecting processes and advancing patient safety is known as the Henry Ford Production System (HFPS). It is based on adapting techniques highly effective in manufacturing production espoused by Henry Ford in the early years of the Ford Motor Company[1] and more recently innovated in the Toyota Production System.[5-7]

The form of lean management that we practice is notable for changing the underlying leadership approach and culture of the laboratory worker to create a continuously learning, empowered workforce, making scientifically based rapid process improvements as a means of continually striving toward higher performance. We have embraced not only the Toyota Production System principles, but, more important, the rules of work, focused on standardization of tasks, defined connections between workers, and simplified process pathways.[8] Therefore, our purpose in the HFPS environment is to continually examine our work, striving to achieve standardized tasks and workstations, conversion to defect-free, continuous "pull" process flow through smaller batches, a leveled workload, with just-in-time production and adoption of new technology that reinforces those principles. Moreover, the ongoing change decisions are made by an educated and empowered

workforce in autonomous yet integrated work cells based on scientific study of their work.

Misidentification defects are a potential patient safety issue in medicine, including in the surgical pathology laboratory. We are often challenged to know in real time their magnitude, where they occur in the process, and how and by whom they arise. In addressing this Joint Commission national patient safety goal of accurate patient and specimen identification,[9] in 2006 we focused our lens internally on our own laboratory processes, with measurement tools designed to identify potential misidentification defects and their root causes. Our discovery of preventable in-process potential misidentifications taking place daily informed us that it was time for a change in "business as usual." Through the eyes of the workers, we identified key opportunities targeted for redesign as work was passed from one work cell to another in the mostly manual work processes of surgical pathology.

Based on this knowledge, aligned with our lean work culture for achieving change in the HFPS, we redesigned our surgical pathology laboratory workflow with simplified connections and pathways reinforced by a bar code technology innovation to specify and standardize work processes. We also adopted just-in-time prestain slide labeling with solvent-impervious, bar-coded slide labels at the microtome station, eliminating the loop-back pathway of poststain, batch slide matching, and labeling with adhesive paper labels. These changes have enabled us to dramatically reduce the overall misidentification case rate by approximately 62% with a reduction in the more common histologic slide misidentification defects arising in-process by approximately 95% while increasing technical throughput at the histology microtomy station by 125%. Herein, we present our experiences with these work innovations in the lean environment.

Materials and Methods

Measuring Misidentification Defects in Surgical Pathology

As previously described and illustrated, misidentification defects arising within laboratory processes were documented during a 3-week period in July 2006 (baseline) in the surgical pathology laboratory of Henry Ford Hospital, Detroit, MI.[3] These data were compared with misidentification defects measured during a 3-week period a little more than 1 year later, in August 2007, after numerous process improvements and a bar code innovation redesign were adopted, using the same data collection design and personnel. We applied χ^2 tests (Fisher exact test adjusted for small counts and Mantel-Haenszel test) to the 2 data sets to test for significant differences.

Data were collected and recorded by 59 surgical pathology personnel (21 senior staff pathologists and 38 technical staff) as they were encountered in routine practice on publicly displayed posters placed in key areas of the laboratory. These were designated as work cells, each with an HFPS team leader and colleagues referred to as team members—accession and transcription, gross tissue examination, and frozen section laboratories; histology laboratory; immunohistochemistry and molecular pathology laboratories; and pathologists' sign-out suite. Defects were categorized by defective part (eg, laboratory requisition [lab tag], specimen container, tissue cassette [block], glass slide, or report) and further classified by root cause of the misidentification (patient label, name, medical record number, surgical pathology number, specimen part number, original slide level and recut number, tissue, and diagnosis). Frequencies were calculated for different defect opportunities (eg, cases, specimen parts, cassettes, and slides).

For data collection, we created a tool called a visual data display (VDD) poster. VDDs are laminated, dry-erase data collection posters, 4 × 5 ft, composed of horizontal fields bordered at the top and bottom by defined menus of independent and dependent defect variables specific to the potential misidentifications that could arise. The main VDD menu arranged in vertical columns was composed of the following variables identifying origin of the misidentification defect: case number, accession, cassette generation, lab tag, scanning of the lab tag, gross tissue examination, tissue embedding, microtome cutting, slide labeling, tray assembly, tray delivery, case sign out, and report transcription. The submenu of qualifying variables arranged at the foot of the columns was composed of the following parameters: name, medical record number, surgical pathology case number, lab tag, container, cassette, slide level, special stain, immunostain, recuts, gross tissue description, tissue, laterality, gross (examination) dictation, number of pieces of tissue, and other. These VDDs were affixed to the walls of each work-cell area to facilitate compliance with data capture by all employees.

This VDD tool for the worker had the following 10 specifications that enabled defects to be tabulated as they were detected: (1) ease of use, (2) data capture in real time, (3) equal access by all employees, (4) standardized menu driven to identify root causes, (5) data capture closest to the defect encounter by its discoverer, (6) visual presentation and public exposure of defects, (7) anonymous and blameless participation, (8) promotion of team spirit, (9) promotion of compliance with total data capture, and (10) reusable.

After a group education session, ensuring all staff members were in unison on the goals and time frame of the data collection and how to use the VDD, each worker was empowered to be a sensor identifying defects encountered throughout his or her work shift. To enhance compliance, team leaders used daily e-mail reminders and "walk-arounds" in each work-cell area. All defects were evaluated daily for validity and root cause by the quality improvement coordinators.

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Designing a Bar Code Intervention to Standardize Workflow

What follows are descriptions of the surgical pathology workflow pathway that evolved from a simple-logic, bar-coded slide label only condition in 2006 through a 2007 redesign and implementation of a complex-logic, bar-coded workflow pathway tying together 4 work cells and then a subsequent 2008 empowered worker driven lean evolution at the microtome bench of that bar-coded condition. The changes impacting work steps in the histology work cell from 2006 through 2008 are illustrated in **Figure 1**.

The ultimate purpose was to provide computer-readable information encoding not only identification of parts but also standardization of specific work processes at accession, gross dissection, histology/microtomy, and pathology sign-out stations. We designed this bar code system to produce bar codes at 2 work stations. It begins at the accession station with generation of 3 types of bar code labels for each specimen container (adhesive label), paper requisition (adhesive label), and plastic tissue cassettes (laser-etched). Then, at the histology microtome station, the cassette bar code drives generation of just-in-time–produced adhesive, chemically resistant, bar-coded slide labels bearing standard work instructions for the histology technician. This redesigned process also includes manual quality control checks by workers at each station. At the accession station, this check includes a verification step that uses optical scanning to archive and associate the laboratory requisition to the case in the laboratory information system. It is at this opportunity that patient identification entered in the accession process is validated to ensure the integrity of a case before processing. These measures further ensure that all subsequent processes are bar code driven and not subject to character transposition or typographic defects in case numbering, selection, and handling. These work cells, connected and standardized by bar-coded information with their manual quality control checks, are illustrated in **Figure 2**.

2006 Workflow Pathway

"Before everything else, getting ready is the secret of success."

—Henry Ford[1]

Specimens are accessioned on receipt in the surgical pathology laboratory into the laboratory information system (LIS; Sunquest CoPath Plus, version 2.4.1, Sunquest Information Systems, Tucson, AZ) as a specific part type. Because we do not have an electronic order interface into

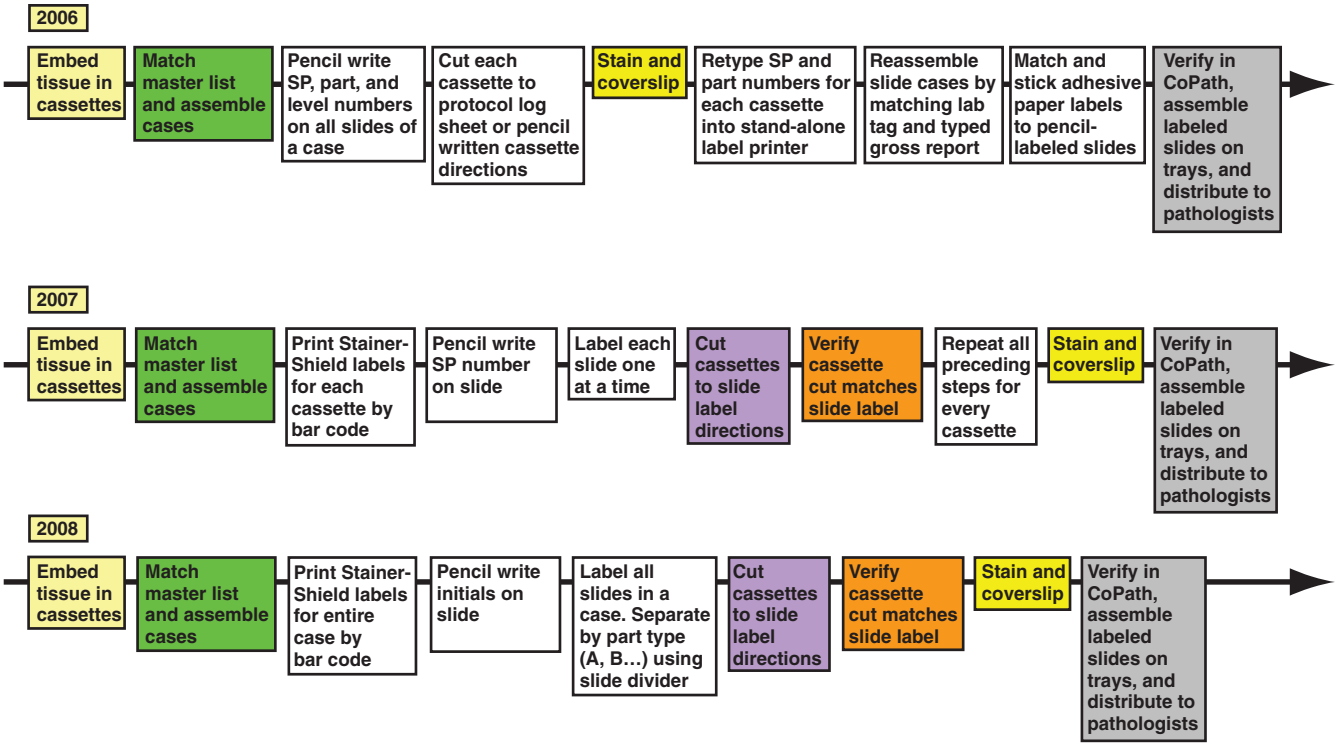

Figure 1 Process flow map of the work steps in the histology laboratory of the 3 workflow conditions of simple bar-coded (2006), bar code work-specified processes (2007), and lean evolved bar code work-specified processes (2008). Processes within the same colored boxes are identical, and processes within uncolored boxes differ. SP, surgical pathology.

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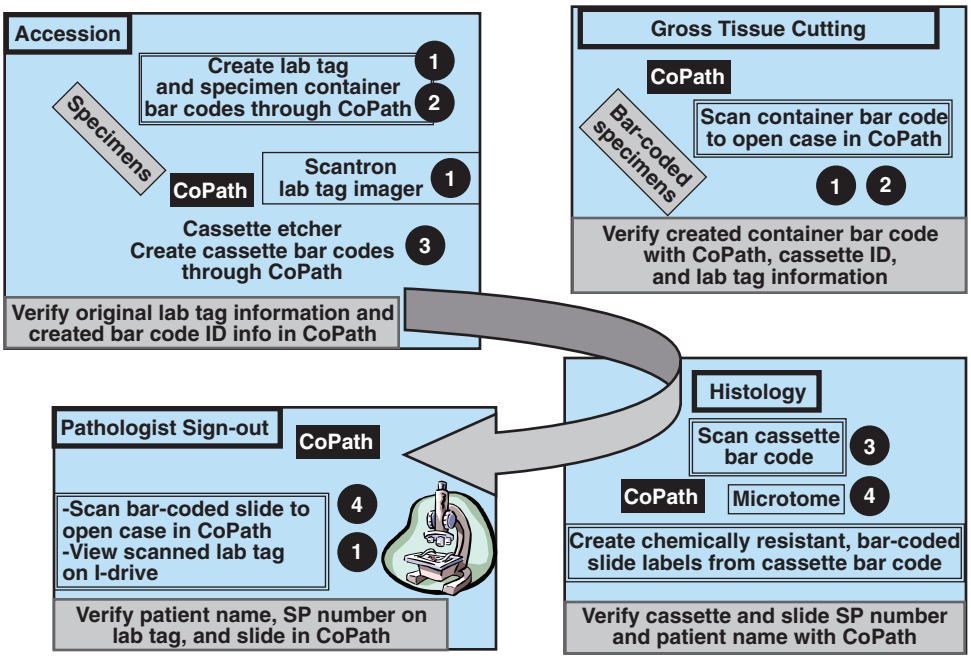

Figure 2 An "electronic kanban" of bar codes connects work cells and defines, standardizes, and mistake-proofs the work processes of surgical pathology. Bar code number key: (1) laboratory requisition (lab tag), (2) specimen container, (3) tissue cassette, and (4) glass slide. Manual quality control checks are described in the lower shaded box of each work station. SP, surgical pathology.

CoPath Plus, nor does our health system use clinical provider order entry at this time, information about a case is received on a handwritten "requisition" that includes patient, provider, billing, and specimen data that must be manually entered into CoPath Plus.

We have designed the part type in CoPath Plus to encode many parameters that include the tissue type received, its topology, the surgical procedure, and the way it will subsequently be handled and processed in the surgical pathology laboratory, eg, colon, sigmoid, biopsy, cut 2 levels, stained with H&E. We use more than 600 part types in our system, defined as explicitly as possible. Within CoPath Plus, we also associate each part type with a default Current Procedural Terminology billing fee code, the number of tissue cassettes to be laser etched, a histology protocol for sections and stains, and text templates for use at the gross examination station. We use electronic histology ordering for all initial and future stain orders on a given case. Defaults at the time of accession may be modified at any time in the process, most typically at the time of gross dissection.

While we had a Leica cassette label printer (Leica Microsystems, Bannockburn, IL), unfortunately, when we began this project, there was no interface available to CoPath Plus. Therefore, to label cassettes for a case, manual double entry of case data into the cassette printer software was required. Labels for requisitions and specimen containers are generated through CoPath Plus and include bar-coded accession numbers using the code 128 symbology. These labels with simple-logic bar codes are placed on containers and requisitions and used to drive future case access through the bar code. In this manner, rather than typing the assigned case number, patient name, or medical record number into CoPath Plus, one reads or "pings" the bar code label on the requisition or the container using a bar code reader.

Subsequently, the labeled tissue cassettes and specimen containers with tissue to be processed are moved to the gross bench for prosection and recording of gross findings. Gross data are entered into a specific text template tied to a given part type. Data entry is by keyboard (in simple cases) or dictation to cassette tapes for large or more complex cases. At the gross examination station, examined, described, and dissected tissues are placed in cassettes for subsequent processing in histology. Histology processing is done per usual procedure with formalin fixation, paraffin embedding, and cutting of sections for a given case. All histology orders are received via electronic log from CoPath Plus and run as scheduled in the histology laboratory. Once a given case is assigned to a histotechnologist, slides are labeled by hand using a pencil to indicate the case number, part letter, subpart number, and cutter's initial before sections are cut from each cassette.

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Once hand-labeled, slides are batch-stained as appropriate to the histology order log. Stained, hand-pencil-labeled slide sections are now reassembled in order on a table and relabeled with CoPath Plus–printed adhesive paper labels. These paper labels include bar-coded accession numbers in addition to other patient identifiers. This approach allows all subsequent users to "open" the case in CoPath Plus by pinging the bar-coded slide, rather than keying in the patient name, accession number, or medical record number.

2007 Workflow Pathway

"We know from the changes that have already been brought about that far greater changes are to come, and that therefore we are not performing a single operation as well as it ought to be performed."

—Henry Ford[1]

We adapted new technology and implemented 3 new workflow processes (Figure 1) to support our lean work principles, improve our workflow efficiency, and eliminate work defects: (1) CoPath Plus–interfaced bar code cassette labeling; (2) chemically resistant, just-in-time bar code slide labeling; and (3) bar code–specified case retrieval with encoded work process standardization.

Interfaced Cassette Labeling

We designed and implemented a custom interface from CoPath Plus, version 2.4, to a new cassette labeler (model CL-12, General Data, Cincinnati, OH) using Labelase software (General Data) that would print cassettes using CoPath Plus accession data and part type defaults, eliminating the former inefficient and defect-prone process of dual entry of this information. The new cassette printers use laser etching to rapidly engrave a high-resolution, 2-dimensional bar code on the cassette along with other identifiers and key information **Image 1**. The cassette bar code encodes not only the case accession number (eg, HS08-1234) but also the part letter corresponding to the specimen container letter (eg, A) and the subpart block number (eg, 1).

Chemically Resistant, Just-in-Time Bar Code Slide Labeling

We replaced our current paper slide labels with StainerShieldDT direct thermal prestainer slide labels (General Data). These labels are resistant to most chemical processes used in tissue staining. Thus, slides can be labeled once, before staining, eliminating the poststaining slide-labeling process. The print algorithm was originally designed to print only the slide labels for that individual cassette in line with the lean philosophy of 1-piece flow or just-in-time when the cassette bar code was pinged. By outfitting slide label printers and slide readers at each histotechnologist's microtome cutting bench, final slide labels are now created and affixed at the time a cassette is cut. The 2-dimensional bar codes etched on the cassettes are read at the microtomy stations using Dell Optiplex 745 PCs (Dell, Roundrock, TX) and Symbol bar code scanners (Motorola, Holtsville, NY) to generate the chemically resistant slide labels on Intermec C4 direct thermal printers (Intermec, Everett, WA). A report was developed in CoPath Plus that retrieves stain orders for each cassette. The histotechnologists, who designed their own standard work and standardized workstation layouts, initially elected to retain pencil labeling of the slides as a manual quality control check

Image 1 Laboratory information system–interfaced 1-dimensional bar codes are printed on adhesive labels for attaching to specimen containers and laboratory requisitions, and 2-dimensional bar codes are etched by laser on tissue cassettes. This case is submitted in 3 specimen containers: left, sigmoid colon biopsy specimen; center, transverse colon biopsy specimen; and right, stomach biopsy specimen with standing order for *Helicobacter pylori* immunostain. Protocol-driven information is reflected in the slide labels that dictate 2 levels cut for each part. The stomach biopsy protocol, right, calls for 2 additional blank slides to be cut, one for the immunostain and a fourth level left unstained.

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should there be issues with loss of the StainerShield label downstream or miscassetting of the part upstream at the gross examination station.

2008 Workflow Pathway

"Our own attitude is that we are charged with discovering the best way of doing everything, and that we must regard every process employed in manufacturing as purely experimental. If we reach a stage in production which seems remarkable as compared with what has gone before, then that is just a stage of production and nothing more."

—Henry Ford[1]

In 2008, the histology staff tested and then eliminated the tedious manual process of prelabeling by handwriting in pencil the case and part identification numbers and letters on the uncut slides. Instead, they relied on a standard work protocol using the StainerShield label only for slide case and part identification but retained their handwritten initials on each blank slide. They also redesigned the label printing process to produce all labels for the entire case when pinging the first cassette of a case rather than 1 label at a time. The subsequent process of affixing labels to slides within a case was written as standard work at the microtome station. The histotechnologists also designed a slide-divider work tool that facilitated separation and orientation of multiple parts of each StainerShield-labeled blank slide within a case. The goals of these changes were to simplify and standardize the labeling process, increase the fidelity of labeling, decrease the time spent per cassette, enable a good working rhythm, eliminate within-case misidentifications, and adopt a work standard that was more likely to be adhered to consistently.

Bar Code–Specified Case Retrieval

The end result of these changes is a surgical pathology workflow that is driven (specified) by reading bar codes. This is true from the point of accession, where the first bar code labels are created, through the final pathologist sign out. In each step in the process, cases are opened for further processing by reading a bar code on a requisition, a tissue sample container, a tissue cassette, or a glass slide. At the point of microtomy, the histotechnologist's work is also specified by cassette bar code as to the number of levels to be cut on each cassette and which stains are to be performed.

Verification of Patient Identification

We do not currently use electronic orders for surgical pathology requests, so cases must be initially accessioned manually from a paper requisition. As an identification quality control check at the point of accession, we instituted a step in our workflow that uses optical character recognition to validate that the bar-coded accession label placed on the paper requisition matches the patient identification information submitted. This is accomplished by scanning the paper requisition after a pathology bar code label is placed on the requisition and comparing this label with the patient information entered on the form. By using high-speed scanning and Teleform optical character recognition software (Autonomy Cardiff, Vista, CA), the pathology label placed on the requisition is read and compared manually with the patient label placed by the clinical team. To verify the identification, a minimal amount of patient data must be rekeyed. If the labels do not match, the case is reaccessioned using the correct information. This approach ensures that all subsequent bar codes produced from that case match the patient information received.

Measurement of Histology Workflow Throughput

The process steps of histology from tissue embedding to slide labeling and delivery were flow-mapped to assess tasks eliminated and/or created (Figure 1). The microtomy cutting times of 4 histotechnologists assigned to cut 2 prostate cases composed of 12 tissue cassettes each were measured in the 2007 bar-coded workflow pathway that printed slide labels per cassette and retained pencil labeling of slides and in the modified 2008 pathway that printed labels per case and eliminated the pencil-writing step. Rates of production in average slides cut per minute were calculated. Production time savings were measured and extrapolated to the number of slides cut in the histology laboratory per day, month, and year. Labor savings were then calculated based on a full-time equivalent (FTE) staffing of 2,080 hours worked per year.

Bar Code Validity Assessments

Validity assessments, or what is more commonly described as bar code validation, are a critical part of bar code production and utilization. Our validity assessment consisted of 2 parts: input validation (scanning) and output validation (printing valid labels).

Input validation was accomplished early in the project by choosing bar code scanners and configuring them to read the planned formats. Bar codes in our system were of 2 types: (1) code 128c with a reported error rate between 1 error in 2.8 million (worst case) and 1 error in 37 million (best case) and (2) data matrix 2-dimensional bar codes with a reported error rate between 1 error in 10.5 million (worst case) and 1 error in 612.9 million. These formats were chosen for the internal error checking inherent in both technologies, eg, checksum as used in code 128. Once the scanners were configured using vendor-provided specifications, they were tested for their ability to consistently read the code 128 and data-matrix bar codes. The vendor of label stock (General Data) also validated the integrity of our scanner configurations. Multiple rounds of iterative testing and ongoing quality assurance have revealed no instances of input failure.

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Output validation consisted of iterative testing that the bar codes on our slide labels (code 128) and our tissue cassettes would read (ping testing) and that they gave consistent values (data validity testing). Output testing is most pertinent to validation of bar code utilization as slight variations in print quality, font size, and stock changes can impact not only pinging, but also potentially the data read-out from the bar code. During setup, we tested ping and data quality through sequential iterative testing. Furthermore, our process is to test output quality on a daily basis as histology slides are released.

Owing to the highly specified data entry fields being used in the CoPath system, data quality that is further constrained as "nonsense data" would be highly unlikely to result in valid data; therefore, any such look-up would be unsuccessful. To date, we have had no reports by end users of bar codes being incorrectly read or produced. Taken in conjunction with our practices requiring users to verify multiple identifiers when interacting with case material and confirming that on-screen displays match labeling of materials, we are confident that such errors would be identified and brought to our attention.

Results

Misidentification Defects

"Every well thought-out process is simple. And with the simplicity and the absence of hand labour has come a greater safety."

—Henry Ford[1]

The 2 measurement intervals roughly 1 year apart in 2006 and 2007 had comparable numbers of cases (2,694 vs 2,877), specimen parts (4,413 vs 4,725), tissue cassettes (8,776 vs 9,167), and slides (14,270 vs 17,927). In comparing misidentification rates arising in the 2 workflow pathways, we documented an approximately 62% overall case reduction from the baseline rate of 1.67% in 2006 (45 defects in 2,694 cases) to 0.63% of cases in 2007 (18 defects in 2,877 cases) **Table 1**. Further examination by category detail showed no reduction in the rate of specimen part defects (including requisition information defects), a 3.5% reduction in tissue cassette defects, and an approximately 95% reduction in glass slide misidentification defects. The reductions in overall cases and glass slides were statistically significant ($P < .001$; χ^2), but that of tissue cassettes was not.

Of the 45 defects in 2006, 10 arose or were detected in the accession station, 3 in gross examination, 30 in histology, and 2 at pathologist case sign out. Misidentified tissue cassettes (5) and glass slides (30) accounted for 78% of the defects, with the remainder in defective specimen parts and requisitions. The cassette misidentification defects were derived from 3 cases generated at the point of specimen gross examination and 2 cases in histology. Of the 30 slide misidentification defects, 28 originated from having the incorrect slide label, and in 2 additional cases, the pathologist transposed the slide numbers when opening the case in the computer system by selecting the bar code of the wrong slide. All misidentification defects would have been potentially addressed by use of an integrated identification system of bar-coded laboratory requisitions, cassettes, and slides. These data have been presented in more detail in our earlier article.[3]

The 18 defect types remaining in 2007 were composed of 12 encountered in the accessioning station (4 of which were misidentification defects submitted by clinician suppliers to the laboratory), 3 arising from gross tissue examination, 2 in histology, and 1 from the sign-out pathologist transposing slides when opening the case in the computer. As a root cause, slide labeling alone accounted for 2 defects, one with a label affixed to the slide of another case and the other a slide mislabeled because cassettes were out of sequence when cut. Problems with cassettes accounted for 5 defects. The latter included transposed numbers, duplication of cassette labels, and wrong number of cassettes generated per part. These 7 slide and cassette misidentifications accounted for 39% of the 18 defects. These sources of misidentification defects, specifically targeted by bar code redesign, formerly accounted for 78% of the total defects in 2006.

Table 1
Changes in In-Process Misidentifications From Before (2006) and After (2007) Bar Code–Specified Workflow Conditions

	2006		2007			
Analytic Category	Volume by Category	No. of Defects (Rate, %)	Volume by Category	No. of Defects (Rate, %)	Reduction (%)	*P**
Surgical cases	2,694	45 (1.67)	2,877	18 (0.63)	62.3	<.001
Specimen parts	4,413	10 (0.23)	4,725	11 (0.23)	0	NS
Tissue cassettes	8,776	5 (0.057)	9,167	5 (0.055)	3.5	NS
Slides	14,270	30 (0.21)	17,927	2 (0.01)	95.2	<.001

NS, not significant.
* χ^2 test.

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Workflow Efficiency

"Our first motive…was to improve the manufacturing processes to increase the output and decrease the prices…. There is nothing incompatible between quality and mass production."

—Henry Ford[1]

Compared with 2006, the only step eliminated in the 2007 and 2008 workflow pathways was the poststaining batch labeling of slide cases with paper labels. This resulted in the elimination of a task previously assigned to 1 FTE. In the 2007 bar-coded workflow pathway that included pencil labeling and prestaining adherence of StainerShield labels, the 4 histotechnologists were able to cut an average of 3.6 slides per minute (range, 1.4-4.1 slides per minute). This rate more than doubled to 8.1 slides per minute (range, 5-10.3 slides per minute) in the 2008 bar-coded workflow process that evolved to eliminate the pencil-labeling quality control step, an increased production on average of 4.5 slides per minute (125%).

Based on the daily laboratory slide cutting workload of 1,322 slides, this new process resulted in a collective daily time savings of 3.4 hours, or 68.2 hours per month, or 773.8 hours per year in slide production. In other words, in a month, 8.5 workdays were saved, and in a year, 96.7 workdays were saved.

Based on the annual worked time of 2,080 hours per FTE, the time saved equated to 0.37 FTE. The time savings were attributed solely to the elimination of the repetitive manual labeling of each slide in pencil. Figure 1 demonstrates the number of histology work steps for the 2 conditions and those that were eliminated in process simplification with the bar-coded systems.

Discussion

"Your methods are formed by what you are trying to do; they do not determine your purpose. To my mind it is starting wrong to put methods ahead of purpose."

—Henry Ford[1]

From our previous studies, we know that 89% of the defects and waste encountered in the surgical pathology laboratory are produced internally and are associated with great manpower cost to remedy.[3] The defects we have targeted and dramatically reduced here are misidentifications arising in-process related to tissue samples and the production of diagnostic glass slide materials in the surgical pathology laboratory. We recognize that when properly designed, bar codes are a powerful tool that can encode information to maintain identification between transfers in production. To serve our purpose, however, we innovated the bar code information to include the definition and standardization of work product as it evolves and is passed from worker to worker in the sequential work-cell processes of the surgical pathology laboratory. This model calls for laboratory creation of bar codes at the very first encounter with tissue specimens at the accession station. This means application of adhesive bar codes on specimen containers and laboratory requisitions, as well as generation by protocol of the proper number of laser bar code etched cassettes via LIS interface.

Impediments to automating or computerizing the surgical pathology labeling process have largely been due to the lack of materials that can survive histology processing, the complexity and unpredictability of surgical pathology workflow, technologic barriers to implementing computer technology at the microtome cutting bench, and the inability to implement anatomic pathology LIS interfaces to cassette and slide labelers. Implementation of such processes has also been hampered by technical difficulties in generating high-fidelity bar code labels on tissue cassettes and slide labels in a just-in-time manner. Recent advances in technology and materials have surmounted several of these barriers, allowing for our design and implementation of end-to-end, bar code–specified surgical pathology workflow to eliminate labeling defects and improve efficiency in tissue processing.

Specifically, bar codes in combination with human readable text can now be rapidly printed on tissue cassettes. These can then be used to drive the generation of specific slide labels that are durable enough to survive many histology processing and staining procedures. This allows tissue slides to be labeled definitively before staining, eliminating manual prestain and poststain slide labeling. Durable slide labels are generated by reading the bar code of a specific cassette at the microtome. Labels are then immediately attached to slides, definitively labeling them before staining. This just-in-time labeling by the histology technologist at the point where slides are created eliminates defects and creates efficiencies.

Our system of bar code–specified work processes and work redesign can be viewed in the context of our lean work culture. A "kanban" in Japanese is a card or sign attached to in-process inventory as a communication or visual control to workers that controls workflow and eliminates overproduction waste or inventory. In essence, we have created an "electronic kanban" using bar codes to define, standardize, and mistake-proof the work processes of surgical pathology. The core of this system makes use of LIS-interfaced and embedded work protocols with bar codes to communicate the next step in production between work cells, not only to maintain identity of parts but also to standardize work (Figure 2). These bar code–specified work processes are tied together in defined pathways in work cells and connections between workers that reduce work variation and, therefore, defects. The additional use of StainerShield solvent-impervious, bar-coded slide labels has enabled us to adopt just-in-time, prestain slide labeling at the histology microtome station, eliminating the loop-back

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pathway and steps of manual poststain, batch slide matching, and labeling with adhesive paper labels (Figure 1). With these redesigns, we have minimized aspects of our process responsible for product defects. We have also eliminated manual slide-labeling tasks, increasing throughput and opening capacity to accommodate volume growth without adding additional staff.

Despite the advantages of this bar code redesign and the successes we report, defects yet arise, most commonly from staff not following standard work. Consistent with Deming's emphasis on building in quality,[10] we have insisted that each work cell retain or adopt new manual quality control checkpoints to detect and prevent defective work. One such example is the verification step at the accession station that uses optical scanning of the laboratory requisition to validate patient identification entered in the accession process, ensuring the integrity of a case before processing. This step further ensures that all subsequent processes are bar code driven and not subject to transposition and typographic defects in case selection and handling.

There is no doubt that despite the best of intentions, humans err, over and over again. Intelligent redesign of the systems and processes in which we toil can eliminate opportunities for a well-intentioned and trained workforce to deviate from expectations.

We often attempt to create these improved work conditions as top-down leaders and managers. The one lesson that we have learned in the HFPS is that for change to be sustained and new work standards to be consistently observed, workers must be involved in the design of the work that they do. Furthermore, it is extremely important to involve staff at the point of service or production to be responsible for identifying the sources of defects and waste encountered and then effectively targeted for elimination. Thus, in the HFPS, it is the expectation that an educated, trained, and empowered worker will identify sources of defects, design quality control verification steps, and assist in the design of not only standard work that can be adhered to consistently but also that of the workplace layout itself.

The VDD data collection method, whereby team members identify actual defects from their work environment in real time in a publicly shared and blameless manner, has been described in much detail in our previous article in this *Journal*.[3] We used this method to collect specific data regarding misidentification defects on a time-limited basis as a spot check, but the technique may also be used to monitor an existing condition for continuous improvement. Once this standard measurement tool is perfected, remeasurement after process improvement changes have been implemented serves to complete the scientific basis for accepting or rejecting the process change.

We have shared several cautions to be considered when using data collection from many workers connected in a complex sequence of processes. The secondary variables that may affect complete data capture are especially important to control when attempting to compare processes over time. These dependent variables include staffing levels; education of personnel in the use of the measurement tool; leadership involvement; team member motivation, participation, and compliance; and identification of unique indicators based on changed or newly improved processes. No significant changes in personnel, practice, case mix, complexity, or volumes were applicable to the comparison intervals in 2006 and 2007, only the implementation of numerous process improvements.

Our root cause analysis of misidentified cases remaining after bar code redesign revealed that 22% of them arose outside the laboratory at the point of specimen collection in the preanalytic test phase. This challenge identifies yet another prime opportunity for the laboratory, as a "customer" to extend its physical boundary and work with clinicians to standardize clinical collection and labeling of specimens from "suppliers" with similar bar-coded processes.

A number of challenges and lessons can be gleaned from our foray into melding bar-coding with lean processes. Implementation of bar code–specified surgical pathology was not as easy as it might seem. This project required careful analysis of specimen workflow, tissue processing, the accessioning process, and user activities at the histology microtome cutting bench. Furthermore, we needed to carefully test new materials (StainerShield labels and laser etched cassettes) for our particular histology processes to determine their reliability and impact. Finally, there were significant technical challenges, including fee-for-service work with Sunquest to develop interfaces to the General Data cassette etcher and customization to the CoPath Plus LIS to allow for just-in-time label generation by cassette.

Deploying computer workstations at 2 accession stations and each of 15 histology cutting benches was complex and ultimately forced us to redesign these workstations into more efficient U-shaped work cells. Unexpected requirements always arise in such a project, one of which was the requirement for the new laser etchers to be vented into the surgical pathology exhaust system. However, the technical design barriers were not nearly as complex as communication of the ideas and workflow changes. To accomplish this, we worked as a multidisciplinary team involving the work cells of histology, pathology assistants, surgical pathology leadership, the office of the chair, transcription and accession, and pathology informatics. Pathology informatics integrated user feedback and design vision to communicate a workable solution to vendors and end users and to implement the required technology.

We were significantly enabled in this effort by the detailed design work that went into implementing our CoPath Plus LIS initially. For example, we had highly specified part types,

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histology processing protocols, and default cassette numbers for cases. We implemented and use only the electronic ordering process for all histology requests. Furthermore, as we generated bar code labels and placed them on requisition forms, containers, and glass slides from the outset, much of the bar code reading technology was already in place. Thus, in many ways, the workflow changes were incremental and not overwhelming. Finally, we planned this project in such a way that generating bar code–labeled cassettes and generation of StainerShield labels could proceed independently as they were implemented in different areas and addressed unique workflow issues.

Other considerations for those contemplating this approach to workflow are the high dependence on reliable technology and hardware, the positioning and availability of spare back-up hardware, firm expectations and commitments of vendor service standards, and the fail-safe of a sound downtime procedure when all else fails. In the HFPS, as we become a culture that relentlessly pursues the eradication of process defects by making opportunities visible and causes transparent to workers empowered to fix them, we hear the voice of our founder, Henry Ford, telling us to stay the course: *"There are no big problems, there are just a lot of little problems."*

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References

1. Ford H. *Today and Tomorrow*. New York, NY: Doubleday; 1926.
2. Zarbo RJ, D'Angelo R. Transforming to a quality culture: the Henry Ford Production System. *Am J Clin Pathol*. 2006;126(suppl 1):S21-S29.
3. D'Angelo R, Zarbo RJ. The Henry Ford Production System: measures of process defects and waste in surgical pathology as a basis for quality improvement initiatives. *Am J Clin Pathol*. 2007;128:423-429.
4. Zarbo RJ, D'Angelo R. The Henry Ford Production System. Effective reduction of process defects and waste in surgical pathology. *Am J Clin Pathol*. 2007;128:1015-1022.
5. Ohno T. *Toyota Production System: Beyond Large-Scale Production*. Portland, OR: Productivity Press; 1988.
6. Womack JP, Jones DT, Roos D. *The Machine That Changed the World: The Story of Lean Production: How Japan's Secret Weapon in the Global Auto Wars Will Revolutionize Western Industry*. New York, NY: Rawson Associates; 1990.
7. Liker JK. *The Toyota Way: 14 Management Principles From the World's Greatest Manufacturer*. New York, NY: McGraw-Hill; 2004.
8. Spear SJ, Bowen HK. Decoding the DNA of the Toyota Production System. *Harvard Bus Rev*. September 1, 1999.
9. Joint Commission on Accreditation of Healthcare Organizations. 2007 Laboratory Services National Patient Safety Goals. http://www.jointcommission.org/PatientSafety/NationalPatientSafetyGoals/07_lab_npsgs.htm. Accessed January 5, 2007.
10. Deming WE. *Out of the Crisis*. Cambridge, MA: Massachusetts Institute of Technology; 1986.

DOI: 10.1309/AJCPPTJ3XJY6ZXDB