The Henry Ford Production System

Effective Reduction of Process Defects and Waste in Surgical Pathology

Richard J. Zarbo, MD, DMD, and Rita D'Angelo, MS, ASQ CQE, SSBB

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Abstract

*By adopting a cultural transformation in its employees' approach to work and using manufacturing-based continuous quality improvement methods, the surgical pathology division of Henry Ford Hospital, Detroit, MI, focused on reducing commonly encountered defects and waste in processes throughout the testing cycle. At inception, the baseline in-process defect rate was measured at nearly 1 in 3 cases (27.9%). After the year-long efforts of 77 workers implementing more than 100 process improvements, the number of cases with defects was reduced by 55% to 1 in 8 cases (12.5%), with a statistically significant reduction in the overall distribution of defects (*P = *.0004). Comparison with defects encountered in the preimprovement period showed statistically significant reductions in preanalytic (*P = *.0007) and analytic (*P = *.0002) test phase processes in the postimprovement period that included specimen receipt, specimen accessioning, grossing, histology slides, and slide recuts. We share the key improvements implemented that were responsible for the overall success in reducing waste and rework in the broad spectrum of surgical pathology processes.*

"Well, less is more…."
—Robert Browning[1]

The work processes of surgical pathology are analogous to manufacturing processes in the creation of value in its work product. In early 2006, the Henry Ford Production System was created, based on the philosophy of our founder Henry Ford, as our laboratory focused adaptation of the continuous process improvement discipline of the Toyota Production System. Our laboratory-based quality effort melded a cultural transformation of management's role and the employees' approach to work to go beyond simple approaches of leaning out operations, aiming to reduce commonly encountered defects and waste. In this *Journal,* we have previously described the organizational structure, philosophy, and operational aspects of the Henry Ford Production System.[2] The tenets of the Toyota Production System have been well described in manufacturing, and select aspects are beginning to be applied in health care, often under the rubric lean.[3,4] However, full application of the Toyota approach in transforming the culture of management and workers is a challenge in the context of health care delivery systems.

In this article, we share the key strategies and improvements implemented in the Henry Ford Production System during a period of 1 year that were responsible for the success in markedly reducing waste and rework in the broad spectrum of surgical pathology processes. To measure progress in this effort, we compared our baseline preimprovement with postimprovement rates and types of process defects encountered throughout all processes and test phases of surgical pathology. The numerous continuous quality improvements were accomplished by empowered workers in a blame-free environment using innovative tools for real-time data collection, also previously detailed in this *Journal.*[5]

The forms of waste that we sought to eliminate in our surgical pathology processes have been well articulated in the manufacturing arena by Ohno[6] in his description of the Toyota Production System. In the laboratory environment, the defects we have measured were forms of waste defined as flaws, imperfections, or deficiencies in specimen processing that required work to be delayed, stopped, or returned to the sender. These in-process defects are not typically quantified and should not be confused with quality assurance measures attempting to quantify diagnostic discrepancy or error. Rather, these data form a baseline to understand the magnitude and sources of waste within processes that can be targeted for elimination. Our focus has been to improve laboratory efficiency and value with the eradication of the more frequent and vexing defects as we strive toward our "zero defect" performance goal.

Materials and Methods

The organizational and management structure, methods and materials used in the Henry Ford Production System, and the continuous quality improvement initiative of Henry Ford Hospital Department of Pathology and Laboratory Medicine, Detroit, MI, were described in detail previously in this *Journal*.[2,5] This formed the foundation for all quality improvement changes in the division of surgical pathology described herein. Briefly, data were collected on visual data display posters in real time, as previously detailed, by all workers in the division of surgical pathology for 2-week periods of routine service to document the baseline preimprovement state (January 30–February 10, 2006) and to evaluate the postimprovement state approximately 1 year later (December 18-22, 2006, and January 8-12, 2007).

The division typically accessions roughly 48,000 surgical cases per annum and is staffed by 18 anatomic and surgical pathologists who also educate and train 16 pathology resident house staff and 2 cytopathology fellows. The precautions to be considered when using data collection from many workers connected in a complex sequence of processes were discussed in detail in a previous publication in this *Journal*.[5] Daily staff e-mail reminders, postings, and "walk-arounds" were used to maintain worker compliance and resolve in documenting defects. As an indicator of postanalytic defects, amended reports recorded in this study were generated in a standardized manner according to departmental quality management plan policy by 1 quality coordinator and restricted to amended reports arising from the cases accessioned during the measurement intervals only.

Data Collection and Statistical Methods

The selected days for the preintervention and postintervention data collection were essentially within the same period, 1 year apart. It is well accepted that the use of health care services is cyclical. Therefore, by limiting the data collection to similar periods, the potential confounding effect of variation in health care utilization was prevented.

Application of the usual statistical methods to estimate sample size in making inferences about diagnostic tests was applied to the present research design. Estimates of a minimum improvement of 15%, 20%, and 30% in the proportion of defects before and after the intervention justified the sample sizes of 1,690 and 1,791 surgical cases and provided a 90% statistical power and type I error at 0.05.

Data were entered into the Excel database (Microsoft, Redmond, WA) and converted into SAS language (Statistical Analysis Software, SAS Institute, Cary, NC), using the DBMS software (version 8) (DataFlux, Cary, NC). Dummy variables were created to convert alphabetic into numeric variables. Descriptive statistics were used to summarize the frequencies of different types of defects during preintervention and postintervention periods. We applied the McNemar test to evaluate the statistical significance of the overall change between the preintervention and postintervention periods. This test is based on 2×2 contingency distribution tables, while adjusting for nonrandom variations in paired samples. This method was justified because the study design was a paired intervention design and data were collected from the same 77 workers during the preintervention and postintervention periods. The differences in the proportions of defects in the preanalytic, analytic, and postanalytic phases were compared using the χ^2 test of significance. Finally, we applied the Wilcoxon rank sum test to compare the proportions of defects within each phase.

Results

From the baseline measurement state of 1,690 surgical pathology case accessions in early 2006, there were 494 defects arising from 472 cases, compared with the postimprovement evaluation of 1,791 case accessions productive of 288 defects from 223 cases. At project inception, the baseline in-process defect rate was measured at nearly 1 in 3 cases (27.9%). After 1 year of effort by 77 workers and implementation of more than 100 process improvements, the number of cases with defects was reduced by 55% to 1 in 8 cases (12.5%) **Table 1**. The overall reduction in total defects was significant ($P = .0004$). The distribution of total defects by test phase in the evaluation periods is shown in **Table 2**. A significant reduction was achieved in preanalytic phase defects ($P = .0007$) and in analytic phase defects ($P = .0002$) **Table 3**. There was no significant difference in postanalytic defects assessed as amended reports.

The number and types of defects observed in these 2 test intervals are categorized and compared by aspect of the testing

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Table 1
Reduction of Surgical Pathology Defect Frequency After 1 Year of Process Improvements in the Henry Ford Production System*

	Early 2006	Late 2006-Early 2007
Surgical pathology cases in measurement interval	1,690	1,791
Cases with defects	472	223
Total defects	494	288
Defective case frequency (%)†	27.9	12.5
Proportion of defective cases	1 of 3	1 of 8

* Data are given as number of cases or defects unless otherwise indicated.
† Significant at $P < .0001$; McNemar test.

Table 2
Overall Distribution of Defects by Test Phase in Surgical Pathology Comparing Preimprovement and Postimprovement Measurement Intervals*

	Early 2006	Late 2006-Early 2007	P†
Total	494 (100.0)	288 (100.0)	.0004
Preanalytic defects	164 (33.2)	136 (47.2)	
Analytic defects	318 (64.4)	144 (50.0)	
Postanalytic defects	12 (2.4)	8 (2.8)	

* Data are given as number (percentage).
† χ^2 test of significance.

Table 3
Comparison of Defects and Improvements Within Specific Aspects of Testing Phases Encountered in Surgical Pathology During 2-Week Measurement Periods After 100 Process Improvements Were Adopted in the Henry Ford Production System

Types of Defect by Testing Phase	No. (%) of Defects at Baseline (n = 494)	No. (%) of Defects After Improvements (n = 288)	P†
Preanalytic	164	136	.0007
Specimen receipt	24 (14.6)	1 (0.7)	
Specimens rehabilitated	17 (10.4)	85 (62.3)	
Accessioning	123 (75.0)	50 (36.8)	
Analytic	318	144	.0002
Grossing	99 (31.1)	72 (50.0)	
Histology slides	151 (47.5)	61 (42.4)	
Immunostains/special stains	2 (0.6)	9 (6.3)	
Recuts	66 (20.8)	2 (1.4)	
Postanalytic	12	8	.6
Amended reports	12 (100)	8 (100)	

* Data are given as number (percentage).
† Wilcoxon rank sum test.

cycle (preanalytic, analytic, or postanalytic) in **Figure 1**. Most process defects were encountered in analytic-phase activities, especially the grossing section and slide production aspects within the preimprovement and postimprovement periods (64.4% and 50.0%, respectively). Improvements in the histology section reduced that component of waste from 44% of total defects in the preimprovement period to 25% in the postimprovement period, whereas the percentage of total defects in the grossing section remained essentially the same, at 20.0% and 25.0% during the same intervals, respectively.

Comparison of the number of defects encountered in the preimprovement period showed marked reductions in most processes in the postimprovement period, as shown in Table 3. These improvements were obtained throughout the testing process from specimen receipt (24 defects vs 1 defect), specimen accessioning (123 vs 50 defects), grossing (99 vs 72 defects), histology slides (151 vs 61 defects), slide recuts (66 vs 2 defects), and amended reports (12 vs 8 defects). However, increased numbers of defects were observed in special stains/immunostains (2 vs 9 defects) and specimens rehabilitated at receipt (17 vs 85 defects). The latter increase resulted from newly adopted laboratory discipline during the year requiring provision of additionally desired information before the specimen would be accepted.

The specific types of common process defects encountered are listed in **Table 4**. The changes implemented that had the most significant impact on reducing these defects are detailed in the following sections.

Specimen Receipt

Defects in the preanalytic aspect of specimen receipt were targeted by education to standardize specimen collection and labeling practices of clinician suppliers and laboratory requisition redesign to enhance provision of information for required accreditation. Lost specimens were addressed by clinician collaboration to standardize and implement a tracking log created to travel with the specimen from remote clinics and specimens generated within the hospital-based clinics to the laboratory to ensure specimen arrival and receipt.

The rehabilitation aspect of specimen receipt (no surgical specimen is rejected) was improved by development of a process to identify deficient specimens with a color-coded sticker notification system. This was a kanban used to label deficient cases returned to the sender. The brightly colored

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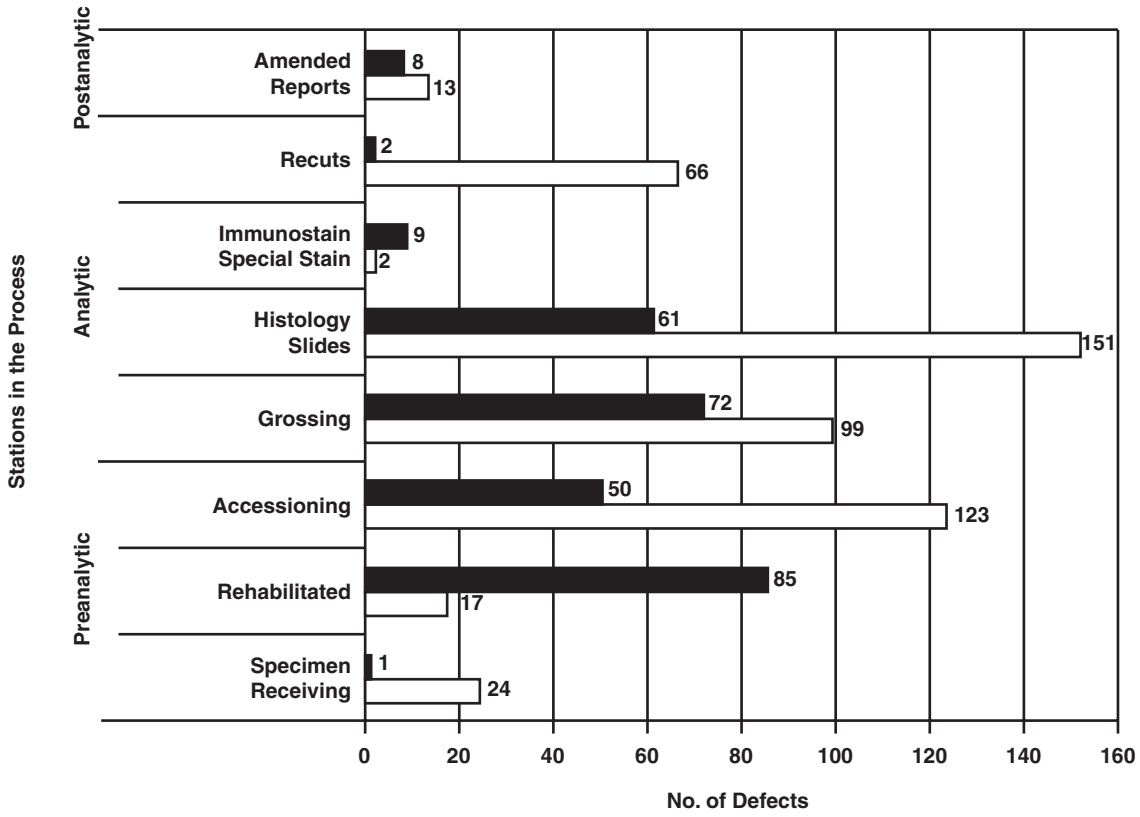

Figure 1 Raw number of defects arising during measurement intervals of 1,690 cases in 2006 (baseline; white bars) compared with 1,791 cases in late 2006–early 2007 (black bars).

labels visually designated different types of missing patient or specimen information for clinicians to immediately correct and return before specimens would be accepted **Image 1**. The specimen rehabilitation process was also redesigned to enhance communication between clinics and the specimen receipt work cell in pathology.

Other improvements to specimen rehabilitation included use of computer software to flag, track, and report patient information discrepancies in the system and to print monthly reports of types of patient information discrepancies, accessioning personnel training to standardize the entering and flagging of information discrepancies in the database, and quality control specimen container label checks comparing information with laboratory tags at the point of specimen receipt.

Specimen Accessioning

The internal assignment of a wrong part type name or description to specimens entered within the anatomic pathology computer system was documented to be a large component of defects arising from the accessioning work cell. This resulted in downstream rework to revise part types, often by pathologists. Customer-supplier meetings were used to define the specific problems, their root causes, and solutions. The informatics team was assigned an ongoing effort to eliminate and revise hundreds of part types in the database after the pathologist team reviewed, revised, and obtained departmental consensus with the transcription and pathologist assistant teams to retain the most commonly used part types while adding clearly defined unique part types. These defect types were nearly eliminated by the 5 customer-supplier teams that reduced the complexity of the part-type dictionary while refining the list to provide an opportunity to specify part types with site laterality. This enhancement reduced the downstream workload of pathologists who often edited diagnostic line information to reflect laterality. Intradepartmental education and training was also held to reinforce the revisions, and external education on the nomenclature of tissue part types was provided to all clinician suppliers to standardize their labeling of laboratory tags.

The manner in which specimens were initially handled at receipt was cumbersome. Specimen transport bags, specimen containers, and laboratory tags were rehandled up to 4 times before primary accessioning took place. A process improvement team changed the approach to specimen receipt by organizing, standardizing, and reducing the steps from specimen receipt to accession. Organizational changes

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Table 4
Specific Surgical Pathology Defect Types by Process Step, Preimprovement vs Postimprovement

Specimen Receiving
2006
Specimen not on manifest batch
No specimen in container
Misplaced specimen
Specimen vs laboratory tag information discrepant
No physician or no service documented
Wrong doctor code
No *ICD-9-CM* code
2007
No specimen in container
Missing any of the following:
  Name
  Medical record number
  Sex
  Encounter number
  Physician code
  ICD-9-CM code
Formalin spill
Labeling defect

Specimen Accession
2006
Wrong part type
Wrong description
Wrong physician/staff name
Block discrepancy
2007
Incorrect number of blocks generated
Wrong part type
Laboratory tag not scanned into laboratory information system
Out of sequence
Container incorrect
Gross description incorrect

Specimen Gross Examination
2006
No gross description or wrong gross description present
Unfixed tissue in block, tissue too large
Wrong measurement
Wrong number of pieces
Poorly sampled
Poorly labeled
Gross dictation needs clarification
2007
Cassette opened in processor
Cassette not labeled
Unfixed tissue in block, tissue too large
Tissue underprocessed
Tissue too big for cassette
Tissue does not match gross
Tissue not inked
Alopecia improperly handled
Incomplete section
No gross description
Wrong gross description
No margin assessment
Incorrect number of labels
Wrong number of cassettes
Lab information system case assignment not edited
Protocol not run
No PA initials on protocol
Missing cone
Lost cassette
Tissue escapes cassette, floating in processor

Histology Slides
2006
Wrong case number
Wrong level
Wrong stain label
Poor stain quality
Section too thick
Section not deep enough
Orientation incorrect
Slide bar code not read
2007
Block not marked for level
Block mislabeled
Block level information incorrect
Wrong physician name on block
Wrinkled section
Wrong level cut
Wrong level stained
No levels
Missing level
Slide delivered late
Slide delivered to wrong pathologist
Section orientation defect
Section not deep enough
Section too thick
No coverslip
Partial case delivered
Slide misplaced
Slide mislabeled

Special Stains and Immunostains
2006
Wrong stain ordered
Wrong label
Wrong pathologist name
Poor quality
2007
Recut or stain log discrepancy
Poor stain
Heavy hematoxylin
Wrong level stained
Wrong stain ordered

Recuts
2006
Not deep enough
Embedded incorrectly
Not received, misplaced, or lost
2007
Recut slide lost

Amended Reports
2006
Misidentification of patient or tissue, clinician- and laboratory generated
Report typographic or nondiagnostic information errors
2007
Report typographic or nondiagnostic information errors

ICD-9-CM, International Classification of Diseases, Ninth Revision, Clinical Modification; PA, pathologist assistant.

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Image 1 Color-coded labels were designed as kanbans to convey different types of missing patient or specimen information for clinicians to immediately correct and return before specimens would be accepted.

at the specimen receipt work cell contributed to streamlining the handling process and simplifying the work of the next accession work cell **Image 2**. This served to level the workload and reduce setup time, contributing to continuous flow at accession and segregation of specimens by type into specific time-sensitive streams for subsequent prioritized gross examination. These changes largely eliminated waste in the forms of overprocessing and incorrect processing. Front-end personnel were then trained to read and interpret laboratory tag information provided by clinicians so that biopsy cases could be segregated into color-coded work streams by customer expectation (eg, transplant service) and case type (eg, biopsy of apple-core lesion of colon) for prioritized processing and subsequent enhanced report turnaround time.

Specimen Gross Examination

The tissue-related defects noted during this phase of processing were addressed by standardization of tissue section sizes submitted in cassettes and standardization of cutting protocols. Other improvements associated with tissue defects were addressed by enhancing workers' knowledge and skills. Visual guides were posted to standardize and reinforce resident and pathologist assistant education and training. Tissue standardization placards included pictures and diagrams in all cutting areas. New residents were trained with visual guides for correct loading and operation of tissue processors. Customer-supplier meetings were held to determine proper cutting protocols for suppliers whose tissue sampling requirements were specified by pathologist customers. These changes served to highly specify work and reduce ambiguity and its resulting variation contributing to defects.

Histology Slides

The voice of the pathologist customer was overwhelmingly heard and resulted in a focus on standardization and revision of histology cutting protocols to meet defined quality requirements. The customer-supplier interaction resulted in better understanding to satisfy commonly identified defects of tissue thickness, tissue orientation, and section thickness. New methods of tissue fixation to inject large solid organs like prostate resections were adopted that also improved

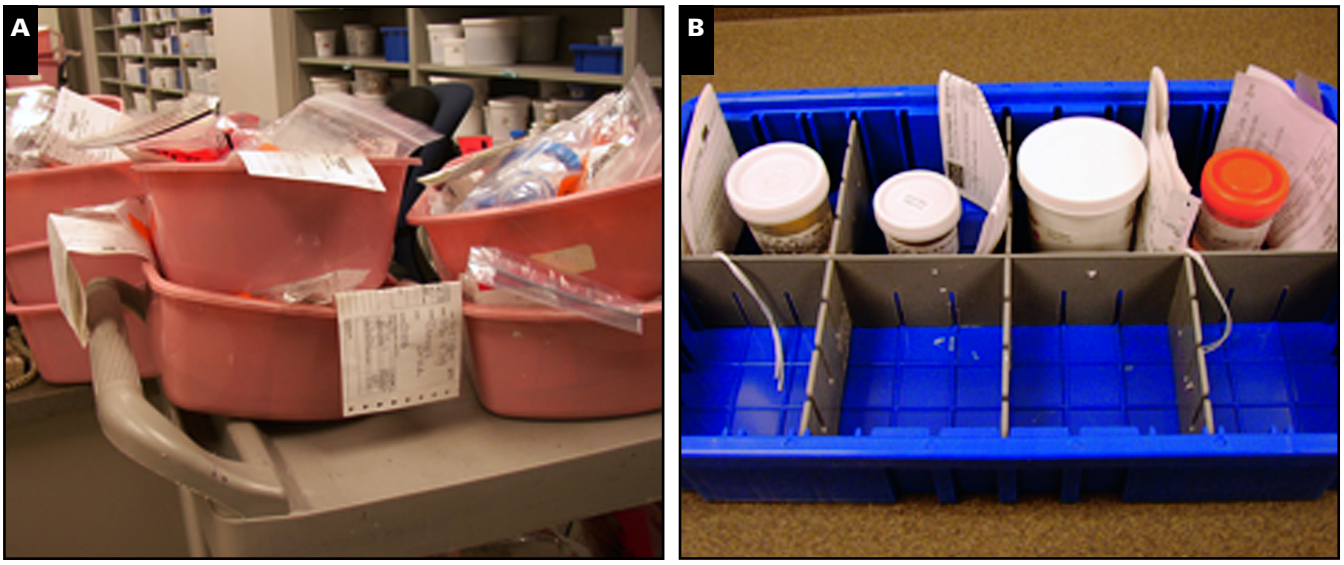

Image 2 Sorting of surgical pathology specimens at receipt work cell in preimprovement period (**A**) in buckets changed in the postimprovement period (**B**) to trays organized by workload.

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microscopic tissue slide quality. The process step from completed microtomy to the combined stainer-coverslipping instrument was revised to accomplish "pull" production with a timer set for 20-minute intervals regardless of batch size. This reduction in batch size contributed to faster throughput and more timely slide delivery to pathologists. Slides delivered to pathologists were organized in smaller batches placed into clearly labeled, stacked, waist-high shelves. Reordering of all special stain inventory was organized with a kanban system for visual cues to the need for reordering as the item was consumed.

Recuts

The recut process pathway was disorganized, and the connections were inconsistent. Recuts were often delayed or orders missed entirely. Teams collected data to establish the baseline condition of lost and missing orders and wrong and poor quality stains delivered. The state of transmitting orders for recuts in the histology laboratory was that of computer-generated logs of orders within the laboratory information system that were manually printed by histotechnologists every 4 hours. Newly printed logs did not clear completed recuts and included additional orders for special stains and molecular laboratory requests for paraffin sections. These defects were addressed by a simple redesign by the informatics team to separate recut logs from other log orders and force an automatic default printing of the log for histology recuts every 2 hours.

Discussion

Any system of processes contains inherent waste that can be evident in many forms, as described by Ohno,[6] chiefly overproduction of materials; time waiting; delays associated with transportation, movement, and processing; excess stock on hand, and production of defective products. The amount of defects or waste encountered in pathology work processes is not typically quantified. We have designed methods to measure this waste as a scientific basis for the changes made in the Henry Ford Production System, our laboratory-focused adaptation of the continuous process improvement discipline of the Toyota Production System.[2,5] In our pilot study in surgical pathology, we initially documented the frequency of surgical pathology in-process case defects from the point of specimen receipt to final report transmission to be nearly 1 of 3 cases.[2] In this article, less than a year after initiating the effort, we document a 55% reduction in that case defect rate to roughly 1 in 8 cases. This was accomplished by transforming our management style, the resulting culture of work, reconnecting with the philosophy of our founder Henry Ford, and applying manufacturing-based quality improvement principles and tools. As we found that the most common defects and corresponding waste were generated within rather than passed on to the laboratory, the key to this success was driven by creating a structure for empowered workers to be accountable for identifying defects and making effective changes to improve the work processes they truly owned.

Sources of defects and waste, as enumerated in Table 4, were targeted for reduction in processes from all phases of testing in surgical pathology. We defined the preanalytic phase as the processes of specimen receipt, acceptance, and accession, including cassette generation and numbering; the analytic phase as the processes of gross tissue examination, dissection and cassette submission, histology slide generation, routine and special staining and immunostaining, recuts, and slide case delivery to pathologists; and the postanalytic phase as generation of an amended report. This study was not designed to examine pathologists' accuracy in the interpretation of primary or secondary diagnostic characteristics as defined previously in a taxonomy of pathology error.[7] None of the amended final surgical pathology reports arising from the cases enrolled in the periods of this study were diagnostic changes but resulted from process defects that required correction of nondiagnostic report information or patient or tissue identification. All but 2 of the defects arose within the laboratory (analytic phase) in the production of specimen-related computerized information at the initial accession step to the subsequent dissection of gross tissues, production of blocks and slides, and report generation. In the postimprovement period, no identification defects were recorded as amended reports.

What is most striking is that specific elements of the preanalytic and analytic phase processes were markedly reduced. There was a marked reduction in defects at specimen receipt related to an intervention of targeted education standardizing specimen collection and labeling practices of clinician suppliers. Laboratory requisition redesign also contributed to a reduction of deficiencies of information required for accreditation. The greatest overall improvement was achieved in defects arising in the intralaboratory steps of case accessioning, gross tissue examination, initial histology slide production, and subsequent slide recuts. The increased rate of preanalytic defective specimens that were rehabilitated resulted from newly adopted laboratory discipline during the year requiring provision of additionally desired information before the specimen would be accepted. Although this change avoided downstream laboratory rework, it resulted in a marked increase in specimens stored for so-called rehabilitation, requiring clinicians to correct deficiencies before specimen acceptance. The increase in special stain defects is a reflection of comparing relatively few numbers of defects encountered in the 2 periods.

As we reflect on the magnitude of these improvements that took place across many work cells, one theme recurs. We believe that the most effective cultural change implemented

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and emphasized in the Henry Ford Production System was to create an employee expectation of constant communication and learning around blamelessly identified defects that led to solutions through customer-supplier meetings.

So, can this approach to continuous quality improvement be effective in eliminating waste and enhancing value in surgical pathology? The data presented here are proof of concept in our surgical pathology laboratory that when melded with a transformation to a new leadership style, adoption of manufacturing-based quality improvement methods can be very effective. We have taken great strides forward in our cultural quality transformation, but we are reminded in the voice of our founder, Henry Ford, on whose vision most of these quality principles are based, that: "The progress has been wonderful enough, but when we compare what we have done with what there is to do, then our past accomplishments are nothing." [8]

From Pathology & Laboratory Medicine, Henry Ford Health System, Detroit, MI.

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Address reprint requests to Dr Zarbo: Pathology & Laboratory Medicine, Henry Ford Health System, 2799 West Grand Blvd, Detroit, MI 48202.

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