The Henry Ford Production System

Measures of Process Defects and Waste in Surgical Pathology as a Basis for Quality Improvement Initiatives

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Abstract

We implemented a continuous quality improvement initiative in pursuit of a "zero-defects" performance goal in surgical pathology that required design of novel data collection tools to assess our current condition and sources of defects and waste. We defined defect as a flaw, an imperfection, or a deficiency in specimen processing requiring delaying or stopping work or returning work to the sender. These defects were noninterpretive, nondiagnostic defects critical to quality. Through a blameless work environment and contributions from all workers, we defined a baseline surgical pathology case defect rate of 27.9%, mostly arising in the laboratory (89.3%); only 8.3% were preanalytic; 2.4% resulted in amended reports. Additional focus on fidelity of patient and specimen identification allowed us to define defective identification in 1.67% of cases, with blocks and slides accounting for 78% of the defects. The misidentification defect rates per million opportunities for all sources were 4.3 to 4.8 sigma. These misidentification defects for 3 weeks required 159 hours of manual rework, or an annualized 1.3 full-time-equivalent employees. We found that through deep and honest exposure and the concerted effort of all workers, we could identify numerous sources of waste in our processes. This knowledge formed the structure for effective changes to strive toward a zero-defect performance goal.

"The old way was to guess. We cannot afford to guess. We cannot afford to leave any process to human judgment."

—Henry Ford[1]

The management adage of "You can't manage what you can't measure" has also been offered as a truism when speaking of quality improvement initiatives. The health care accreditation requirement for meaningful data collection to define indicators of clinical quality arose from the Joint Commission on Accreditation of Healthcare Organizations quality initiative of the late 1980s that evolved into the Indicator Measurement System and ORYX.[2,3] Laboratories are even now expected to maintain meaningful continuous indicators of quality in each laboratory discipline with associated reference benchmarks to trigger action when performance falls below acceptable levels.

In pathology and laboratory medicine, the challenge to define indicators and data collection methods was met by the College of American Pathologists Quality Assurance Committee that provided voluntary, subscription quality indicator programs known as Q-Probes[4] and Q-Tracks[5] that enabled laboratories to collect data in a standardized manner for interlaboratory comparison and benchmarking of best achieved performance. The drawback of benchmarking, however, is that laboratories may become complacent, accepting average or, more likely, mediocre performance, rather than pushing to continually improve.

Another approach to quality is driven by the expectation of zero defects rather than that of an acceptable, even if benchmarked, deficiency rate. The quality level of zero defects is often expected in activities associated with potentially high risk, such as air travel and, in medicine, anesthesia. Oddly, it is also the culture of very successful, superior performers in the manufacturing arena. For this reason,

manufacturing-based approaches to quality such as Six Sigma[6] and Lean[7] are being introduced in medical disciplines.

Evaluating the effectiveness of quality improvement changes on the basis of scientific measurement is one of the tenets of the Toyota Production System,[8,9] a manufacturing-based approach to continuous quality improvement that is only now being adapted to anatomic pathology.[10,11] By using these quality management principles, we created the Henry Ford Production System in early 2006 to transform our laboratory culture by formalizing our approach to implementing continuous changes in a blameless environment, improving our work and work product.

In preparation for redesigning our work processes, we realized that we had little information, let alone quantitation, of defects and sources of waste encountered throughout surgical pathology. The opportunity to know how a complex system of numerous manual processes such as surgical pathology works in real time is a challenge, even with current laboratory information systems. In this article, we share simple yet novel approaches to data collection in our implementation of a Toyota Production System–style continuous quality improvement initiative in the surgical pathology laboratories of the Henry Ford Health System, Detroit, MI, that enabled us to define worker-identified sources of waste, defects, misidentifications, and other opportunities arising in all phases of production.

Materials and Methods

Quantitating Process Defects and Waste in Surgical Pathology

Figure 1 graphically illustrates the change management process in the Henry Ford Production System, enabling empowered work cell teams to make numerous quality process improvements targeting identified defects and waste. Initially, we sought to identify a baseline state of all defects

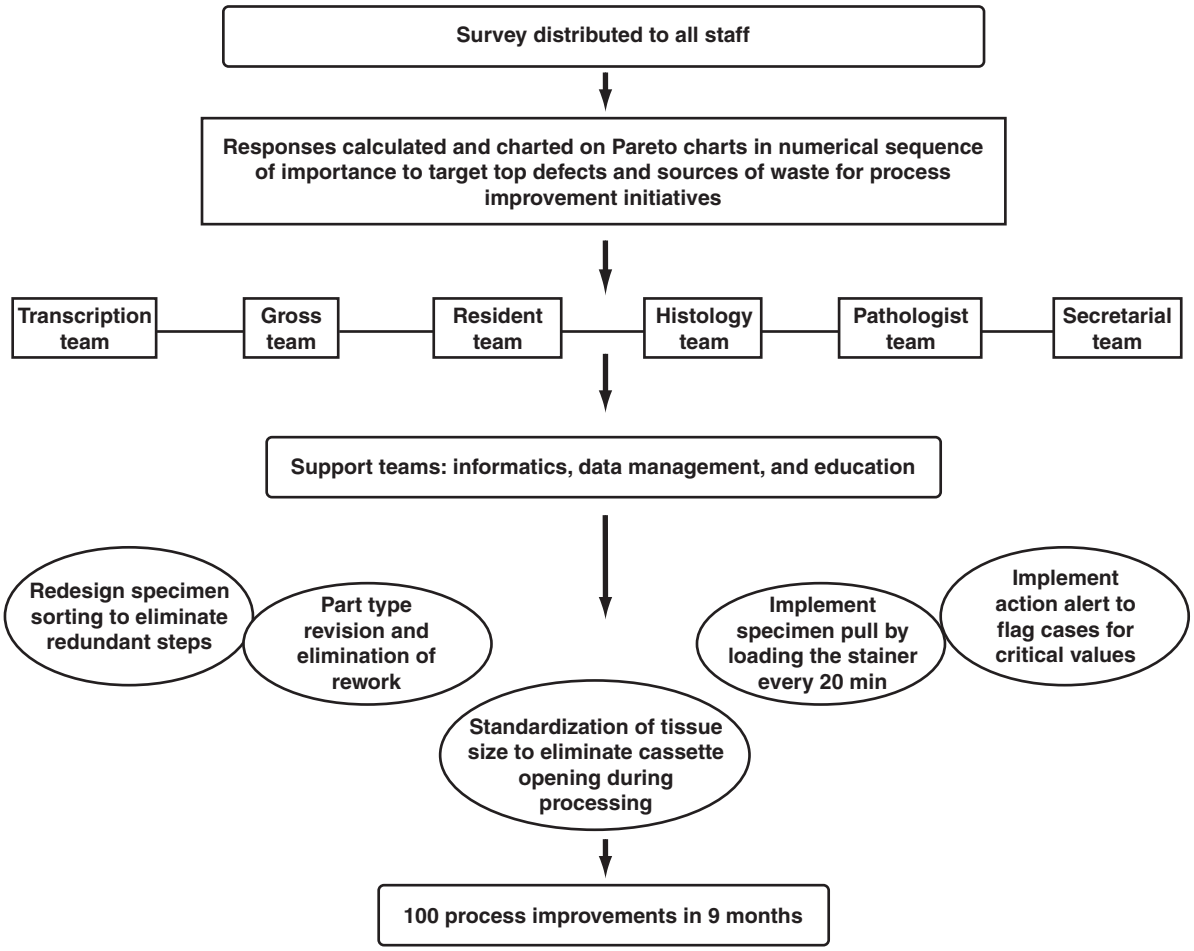

Figure 1 Change management in the Henry Ford Health System quality improvement initiative from identification of defects and waste to resultant improvements made by empowered work cell teams.

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arising throughout the surgical pathology processes, from specimen collection to report generation. From a staff survey of all workers in surgical pathology, we gained insight into defects commonly encountered and used this information to define 100 indicators of these potential defects. We structured our data collection process to include sources of waste and defects that occur from specimen accessioning to case sign-out, while focusing on the definition of a true defect. We defined defect as a flaw, an imperfection, or a deficiency in specimen processing that requires us to delay or stop our work or return work to the sender. The defects determined to be critical to quality were noninterpretive, nondiagnostic defects. Types of waste included process flaws associated with overproduction, time waiting, transportation, processing, stock on hand, movement, and defective products **Table 1**.

After unsuccessful attempts to collect complete data by assessing global overall changes associated with rapid process improvements through laboratory information systems, we sought to design a data collection tool based on our definitions of defects and waste that had the following 10 specifications: (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. We devised 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 processes being evaluated. These visual data displays (VDDs) were affixed to the walls of each work-cell area to facilitate compliance with data capture by all employees.

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 57 staff documented defects they encountered in routine practice on VDDs placed in each surgical pathology work unit in real time for a defined interval in early 2006.

Defining Misidentification Defects in Surgical Pathology

Before implementing a bar code–specified approach to workflow in surgical pathology, we sought to define the baseline state of all defects associated with misidentification arising throughout the surgical pathology processes from specimen collection to report generation. A VDD, illustrated in **Image 1**, was specifically created to capture all misidentification defects encountered in a defined interval. The main

Table 1
Defect Types in Surgical Pathology by Process Steps

Process Step	Defect Type
Specimen receiving	Not on manifest/batch
	No specimen in container
	Misplaced specimen
	Specimen and tag information discrepant
	No physician and/or service documented
	Wrong physician code
	No International Classification of Diseases, Ninth Revision code
Specimen accession	Wrong part type
	Wrong description
	Wrong physician or staff name
	Block discrepancy
Specimen gross examination	No or wrong gross description present
	Unfixed block or too large
	Wrong measurement
	Wrong No. of pieces
	Poorly sampled or labeled
	Clarification needed
Slides	Wrong case No.
	Wrong level
	Wrong stain label
	Poor stain quality
	Section too thick
	Section not deep enough
	Orientation incorrect
	Bar code not readable
Stains, including special and immunostains	Wrong stain ordered
	Wrong label
	Wrong pathologist name
	Poor quality
Recuts	Not deep enough
	Embedded incorrectly
	Not received or misplaced or lost
Amended reports	Additional specimen received
	Misidentification
	Report errors

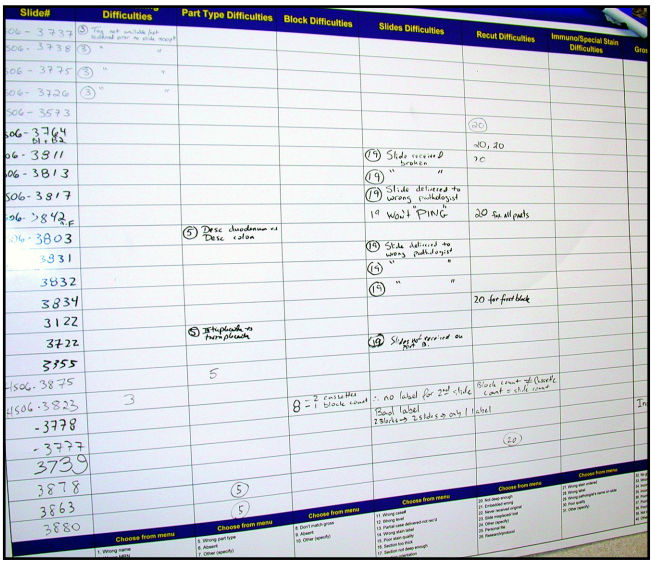

Image 1 Visual data display poster showing data entries by pathologists that captured detail on misidentifications arising in the surgical pathology process.

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VDD menu was composed of the following variables identifying origin of the misidentification defect: case number, accession, cassette generation, laboratory tag, scanning of the laboratory 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 was composed of the following parameters: name, medical record number, surgical pathology case number, laboratory tag, container, cassette, slide level, special stain, immunostain, recuts, gross tissue description, tissue, laterality, gross [examination] dictation, number of pieces of tissue, and other.

Results

Quantitating Process Defects and Waste in Surgical Pathology

Data were collected for 2 weeks of routine service from January 30 through February 10, 2006, by 57 personnel (20 senior staff pathologists and 37 technical staff) in surgical pathology for 1,690 accessioned surgical pathology cases. Of the 1,690 accessioned surgical pathology cases, 472 cases resulted in 494 defects encountered internally within the laboratory. Multiple defects were present in 22 cases. The overall case defect frequency was 27.9% for the 2 weeks of data collection (32.2% in the first week and 23.5% in the second week). The majority of defects (441/494 [89.3%]) were encountered in the analytic phase, including defects in accessioning (n = 123), gross examination (n = 99), histology slides (n = 151), recuts (n = 66), and immunostains or special stains (n = 2). Of the 494 defects, 41 (8.3%) were derived from providers in the preanalytic stage who passed the defects on to the laboratory where they were detected and corrected. Amended reports were generated because of 12 defects (2.4%). These data are presented in **Table 2**. Pathologists acquired data on 326 defects (66.0%); 8.3% were captured by personnel at accession, 8.7% at the gross examination station, and 14.6% in histology. Amended reports correcting erroneous information that resulted after examination of additional tissue, tumor board case review, or clinician query accounted for 2.4% of the defects.

Defining Misidentification Defects in Surgical Pathology

Internal identification defects were documented during a 3-week period in July 2006 in the surgical pathology laboratory of Henry Ford Hospital. Data were collected by 59 surgical pathology personnel (21 senior staff pathologists and 38 technical staff). The data were recorded on publicly displayed posters placed in key areas of the laboratory—accession and transcription, gross tissue and frozen section laboratories, histology laboratory, and pathology suite. Defects were categorized by defective part (ie, laboratory tag, specimen container, block, 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). Defect frequencies and sigma values were calculated for different error opportunities (ie, cases, specimen parts, blocks, and slides) **Table 3**.

Table 2
Sequence of Testing Phases and Accumulation of Data Collected*

Testing Phase/Site of Defect	No. (%) of Defects (n = 494)
Preanalytic	
Specimen receipt	24 (4.9)
Specimens requiring rework	17 (3.4)
Total	41 (8.3)
Analytic	
Accessioning	123 (24.9)
Gross examination	99 (20.0)
Histologic slides	151 (30.6)
Immunostains and special stains	2 (0.4)
Recut	66 (13.4)
Total	441 (89.3)
Postanalytic	
Amended reports	12 (2.4)
Total	12 (2.4)

* For a 2-week period. The majority of defects found were in the analytic phase of processing.

Table 3
Misidentification Detail by Type and Origin Depicting the Frequency of Identification Defects Within the Analytic Phase of Testing

Process	Blocks (n = 8,776)	Slides (n =14,270)	Specimen Parts (n = 4,413)	Cases (n = 2,694)
Accession (n = 10)				
Laboratory tag				
Case No.				2
Medical record No.				1
Name				1
Part type				2
Laterality				1
Tissue site				
Container				1
Manual block tissue site label				1
Recut slide labeling				1
Gross examination (n = 3)				
Block incorrect	3			3
Histology (n = 30)				
Block incorrect	2			2
Pencil slide label		2		2
Affixed slide label		26		26
Case sign-out (n = 2)				
Selected wrong slide		2		2
Total (n = 45)	5	30		45
Sigma value	4.7	4.8	4.5	4.3
Defect rate (%)	0.06	0.21	0.00	1.67

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From 2,694 case accessions, there were 4,413 individual specimen parts, 8,776 blocks, and 14,270 slides. There were 45 individual identification defects resulting from 45 cases, producing a defective case rate of 1.67%. Of the defects, 10 were found in the accessioning process, 5 in blocks, and 30 in slide identification. Slide labeling alone accounted for 67% of defects (30/45), and blocks and slides together accounted for 78% of the defects (35/45). The defect rates per million opportunities for all sources were in the range of 4.3 to 4.8 sigma. The accessioning defects were attributed to laboratory tag or container identification errors of case number, medical record number, part type, laterality, and tissue site and manual block generation with wrong tissue site label. The block 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 tags, blocks, and slides. The correction of these misidentification defects required 159 hours of manual rework.

Discussion

Surgical Pathology Process Defects and Waste

The frequency of process defects and waste encountered within the analytic phase of any surgical pathology operation from the point of the specimen receipt to final report transmission is usually not tabulated in a comprehensive manner, and, therefore, measures of inefficiency in the current approach to surgical pathology operations are undefined in the literature. Review of the existing literature based on amended pathology reports does not adequately address the internal defects that may be repaired if detected but are not often recorded.[12] It is our impression that numerous defects are encountered daily as product is passed sequentially to many technical and professional staff involved in the largely manual processes of surgical pathology. Knowledge of what these defects are and how they arise in the process is key to planning quality improvements in surgical pathology.

We report, for the first time, the frequency of surgical pathology case defects encountered to be nearly 1 of 3 cases moving through the surgical pathology process. Although alarming, this is not to be misconstrued as a tabulation of defects or errors of a diagnostic nature that would affect patient care. Rather, this is a reflection of the amount of waste in the surgical pathology system requiring correction, rework, and delay before an acceptable product can be released. These data confirm that the most common defects and corresponding waste encountered in surgical pathology are generated within rather than passed into the laboratory. Furthermore, pathologists have a key role on the team as the "catcher" of the majority of these defects. Heretofore, this inefficiency was quietly recognized, corrected, and passed on within the supply chain without systematically being made visible as a focus of process improvement activities.

Surgical Pathology Misidentification Defects

Perhaps one of the most critical defects in medicine is that of patient misidentification. Accuracy of patient identification is a prime national patient safety goal for laboratory services as described by the Joint Commission on Accreditation of Healthcare Organizations.[13] For laboratories, this involved a College of American Pathologists 2006 checklist question requirement to evaluate and monitor the processes involved in accuracy of patient and sample identification at specimen collection, analysis, and result reporting (question TLC.11100).[14] This critical quality requirement would seem to have extended the laboratory's span of control beyond the accepted physical boundary and was, unfortunately, deleted from the October 2006 revision of the checklist.

In surgical pathology, identification process activities encompass the total testing process from the preanalytic (ie, specimen collection, labeling, and transport) through analytic (ie, specimen accession, gross and histologic processing, microscopic interpretation, and report generation) and postanalytic (ie, report transmittal and clinical interpretation) phases. The frequency of misidentification within the surgical pathology domain is believed to be low, but this impression often reflects passively acquired knowledge rather than active examination of patient and specimen identity throughout the laboratory processes. We undertook this study to better understand identification defects made by the laboratory within the analytic phase of testing (internal misidentification errors) as a prelude to implementation of bar code–specified work processes in surgical pathology. The potential to misidentify cases and parts in surgical pathology exists at numerous points of identity transfer in sequential processes, including opportunities at the following points of identity transfer: laboratory tag, information system, cassette, tissue embedding, slide, and report.

This is the first documentation of the frequency and root causes of identification defects occurring within the mostly manual work processes of surgical pathology. We found no benchmarks for comparison, and with a zero-defect expectation, none would be acceptable. From the root cause analysis, more than two thirds of the misidentification defects arose in slide labeling processes, such as manual pencil writing on glass slides and affixing labels to glass slides after staining.

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With the addition of defects related to mislabeled blocks (cassettes), histology-derived misidentifications accounted for 78% of the total. We believe that these data strongly support investment in a laboratory initiative to develop a better process designed to eliminate these common human-derived and potentially critical misidentification errors with an integrated identification system of bar-coded laboratory tags, blocks, and slides. The inefficiency of these misidentification defects documented during 3 weeks of practice required 159 hours of manual rework. This equates to an annualized 1.3 full-time-equivalent employees dedicated to this rework task and defines the human cost of this form of system waste. The cost of this quality investment to maintain patient and specimen identity in the common sequence from paper requisition and container label to laboratory information system to tissue cassette to glass slide to paper report may be offset by the avoidance of the labor required to correct these defects and the avoidance of potentially harmful patient outcomes from misidentification.

VDD Effectiveness as Measurement Tool

The VDD poster is similar to an Andon board used by manufacturing plants as a measurement tool or a scoreboard to track daily production of actual vs target defects, line of location, and other quality issues in real time. Scoreboards and Andon displays are traditionally a basic display of fixed data to capture target and real-time production numbers as a snapshot view of what is currently happening on the shop floor. Unlike the Andon board, VDD posters provide standardized menus for team members to readily use in identifying root causes. Similar to the Andon board, VDD posters capture manual data by the discoverer in real time closest to the defect. Unlike data input on an Andon board by supervisory staff, the worker at the bench who finds the defect contributes the VDD poster data.

We considered other mechanisms of data collection such as e-mail and paper tabulations of copies of posters. However, the public presentation of data acquired in real time in the VDD had distinct advantages. These VDD measurement tools were very effective in allowing numerous workers to participate as defect detectors in quantifying the amount of waste commonly encountered and quietly accepted in the complicated sequence of mostly manual laboratory processes in surgical pathology. The psychological benefit of the VDD approach was seen in the sense of teamwork and involvement in data collection that informed and stimulated the staff to recognize and accept the defects and then make directed changes. The cohesive effort of data collection promoted not only team spirit but also competition between work cells. Team members often strove to capture as many defects as possible. The public sharing of defects between work cells illustrated ownership and consequences of defects passed on to other work cells. This anonymous method of data collection also removed any possible blame associated with defect identification.

There are several cautions to be considered when using data collection from so 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 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. We have considered 2 analyses when comparing processes separated by time and the implementation of numerous process improvements. It is not unreasonable to compare the frequency of total defects again and to make an "apples-to-apples" comparison of identical indicators that remain common to the temporally separated yet somewhat different processes.

Data Collection for Continuous Improvement

In our experience, the VDD posters were very effective in measuring the current condition as a basis for identifying and implementing effective quality improvement changes. We used this method to collect specific data 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. In practice, data are collected and monitored daily and a summary is tabulated for presentation of the current condition when the full board is cleared of data. Graphs representing data collection results are created, updated, and posted weekly near the VDD as another communication tool to update the team members. The data are then erased to make way for new collection set criteria. Because detailed defect data are not usually obtained in many information systems, the VDD technique of data collection is a practical tool to analyze current process conditions, whereas defects of this nature would usually be undetected or buried.

Six Sigma

Sigma is a performance metric referring to the variability defined by statistical deviations from the performance goal at the opportunity level. For example, six sigma (99.99966% yield) reflects 3.4 defects per million opportunities and is commonly accepted as a manufacturing goal. It is imperative to choose the correct opportunity and measure the right indicators so the process can be improved. The VDD posters we describe herein identify numerous opportunities that must go right, the right way, at the right time to obtain a defect-free product. Defects per opportunity are the number of defects

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within the total number of opportunities in a unit.[6] In surgical pathology, these opportunities have been specified in the menu and detail of the posters we created that reflect our processes. Opportunities are those usually critical to customer requirements because they have a direct effect on the sigma value. For example, in our evaluation of misidentifications, we identified 9 key opportunities for a defect that were critical to quality. To calculate the sigma, the total number of defects per opportunity was obtained by multiplying this number by the denominator based on cases (n = 2,694), parts (n = 4,413), blocks (n = 8,776), and slides (n = 14,270). This resulted in sigma performance values of 4.3 for cases, 4.5 for parts, 4.7 for blocks, and 4.8 for slides. Although this may be meaningful to some, we find this method of performance comparison cumbersome and unfathomable by workers. This is especially frustrating because most endeavors in health care function in the range of 3 sigma (99.32% yield) to 4 sigma (99.38% yield) or 66,800 to 308,000 defects per million.

Conclusion

Based on our successes described herein in defining our current system state, we have now adopted the VDD measurement technique in our goal of targeting a zero-defect laboratory environment. We believe that it is only through identification of the numerous sources of waste, in its many forms as described by manufacturing pioneers Ford[1] and Ohno,[9] that this zero-defect performance goal can be achieved.

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