

Improving Patient Safety by Examining Pathology Errors

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Abstract

Purpose: To determine the frequency, impact and cause of anatomic pathology screening and diagnostic testing errors and to develop, implement, and evaluate the quantitative and qualitative effectiveness of error-reduction interventions.

Scope: Prior to our investigations, anatomic pathology error detection and quality improvement were vastly unstandardized and the reported error frequency was based largely on biased, single institutional reports.

Methods: A consortium of nine institutions standardized retrospective and prospective error detection methods, classification scheme, clinical harm assessment, and root cause analytic processes. The consortium created a database of multi-institutional error and used these data to design and implement quality improvement initiatives within and across sites.

Results: Up to 67% of all specimens are “defective,” resulting in inefficiencies, high costs, and patient harm. A diagnostic error occurred in 2% to 15% of all specimens, and harm occurred in approximately 50% of diagnostic errors. Using Lean methods, process redesign markedly improved quality in clinical and laboratory processes and specific areas of cancer diagnosis and care (e.g., lung and breast cancer care). Culture plays an enormous role in the ability to implement quality improvement initiatives, and barriers, such as disruptive physicians, can markedly limit quality improvement.

Key Words: Patient safety, laboratory test, cancer

Purpose

The objectives of our project were to:

- 1) Determine the frequency, root cause(s), and clinical impact of anatomic pathology errors at multiple institutions using standardized methods.
- 2) Demonstrate the utility of specific quality improvement process changes developed in the context of the root cause analyses for decreasing errors at multiple institutions.
- 3) Qualitatively evaluate the usefulness and effectiveness of the methods used for error examination and reduction at multiple institutions using direct participant observation, focus groups, and semi-structured interviews of institutional leaders.

Scope

Background

More than 70% of the medical events that affect or change a patient’s clinical course are the result of a pathology laboratory value from a blood, serum, fluid, or tissue (histologic or cytologic) diagnosis. Anatomic pathology is primarily concerned with the fields of tissue diagnosis (surgical pathology) and cell diagnosis (cytopathology, including Pap tests and non-gynecologic tests). Much of the work in anatomic pathology is focused on cancer screening, diagnosis, prognosis, and treatment. A screening test is performed on a symptom-free patient to diagnose early, treatable disease (e.g., Pap test). A diagnostic test is performed on a patient who has signs and/or symptoms of disease in order to rule in and/or out specific pathologies (e.g., lung biopsy to rule in lung cancer).

The exact number of anatomic pathology tests performed per year in the United States is unknown, although the combined number of surgical pathology and cytopathology tests per year may reach as high as 100 million (one per every three Americans). The number of annual Pap tests is estimated at 60-70 million. In the United States, 1.2 million Americans are diagnosed with cancer each year and almost every patient has a tissue or cytopathologic diagnosis. Far more people are tested for signs and/or symptoms of cancer but are found not to have cancer. Many more patients undergo anatomic pathology diagnostic testing for other medical conditions (e.g., gastrointestinal disease or infections). The cost of anatomic pathology diagnostic testing and screening in the United States is most likely in the billions of dollars per year. Even a diagnostic testing and screening error rate as low as 1% would affect at least one million Americans per year.

Process mapping has shown that most anatomic pathology tests involve over 225 unique steps. An anatomic pathology test may be subdivided into a number of phases (each including a number of steps): pre-pre-analytic phase (choice of test), pre-analytic phase (test performance), analytic phase (laboratory processing and evaluation), post-analytic phase (test result reporting), and post-post-analytic phase (post-test clinical decision-making). An anatomic pathology error may occur in any step within any phase, although only a small proportion of these errors may result in a diagnostic testing or screening error.

Clinicians and pathologists have always known that anatomic pathology screening and diagnostic testing is far from perfect.

Sensitivity and specificity metrics of less than 100% clearly reflect test failures, but these metrics have been viewed as static or as “tradeoffs” such that, if the sensitivity of a test increases, the specificity inevitably decreases. This concept oversimplifies the anatomic pathology testing process and does not allow for dynamic, continuous quality improvement (QI) in the testing pathway that may improve/change both the sensitivity and specificity of screening and diagnostic tests and, therefore, change the frequency of diagnostic errors (false-positive and false-negative tests).

In alignment with this relatively static view of laboratory testing, for decades laboratory accreditation agencies have required that anatomic pathology laboratories maintain specific quality assurance (QA) practices. These practices are aimed primarily at assuring that testing in the laboratory is precise (reliable) and commonly involve documentation of calibration of laboratory instruments in the clinical laboratory. Historically, the nature and extent of expected QA activities in anatomic pathology has been ill-defined and, thus, highly variable and without standardization. Additionally, defining, measuring, and longitudinally tracking continuous quality improvement (CQI) indicators has not been performed in anatomic pathology as it has been in many other clinical specialties, despite the plethora of evidence that has accumulated over the past decade; this indicates the continuing significant gaps in the quality and safety of patient care in our health system.

Context

Prior to our investigations, the field of pathology had no standardized criteria for classifying error, and frankly, many pathologists rejected the definition of error offered by the Institute of Medicine (IOM). Consequently, published error frequencies were highly variable, ranging from 2% to over 50%. Patient harm generally was linked to medical-legal assessments, and error root cause analysis was performed in a highly limited manner by retrospectively reviewing microscopic slides to determine whether a pathologist was “at fault” by having rendered an incorrect diagnosis or if the clinician had not sampled a lesion appropriately.

At the start of our project, system-oriented QI practices had been utilized in nonmedical fields, such as business, industry, and engineering, and only recently were being tested in healthcare environments. One such practice is based on the Lean method, which we adopted in our QI efforts. Examples of Lean include the Toyota Production System (TPS) and Perfecting Patient Care® (PPC). Lean organizations adhere to four basic principles of work and culture: 1) decisions are based on long-term philosophy, 2) right processes produce the right results, 3) people and partners add value to an organization, and 4) organizational learning is driven by problem-solving. Theoretically, the successful application of these principles would improve quality (i.e., reduce errors, inefficiencies, and costs), although these concepts had not been tested in any diagnostic testing pathways or screening services.

One major problematic aspect of the current state of anatomic pathology practice, which was a major challenge for us throughout the duration of this study, was the complete lack of standardization of laboratory methods and QA activities. Another was the extensive lack of agreement among individual pathologists, even those working in the same institution, regarding the definitions of medical error and diagnostic error. Finally, there was extensive lack of agreement among pathologists regarding the usefulness of previously reported evidence in the medical literature regarding the importance of systems factors for medical errors, the usefulness of formal root cause analysis for determining multiple underlying causes of errors, the utility of previously published clinical severity scales, and the use of qualitative methods for obtaining information useful for understanding and improving the quality of laboratory practices.

In light of the complete lack of standardization of definitions and methods in day-to-day anatomic pathology practice, prior to beginning the project, all participants reached consensus on a definition of medical error and an initial standard method for detecting errors. We used the IOM's definition of medical error: the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim. In adapting this description to anatomic pathology, we defined a diagnostic or screening error as the occurrence of a test result (final pathology report) that did not accurately represent or describe the actual disease process in the patient (i.e., the planned action [performance and reporting of the test] does not achieve the correct aim [making a correct diagnosis]). We believe this definition of an anatomic pathology diagnostic error is optimal because it allows for mistakes or errors at any point in the diagnostic or screening test pathway and, thus, is consistent with the concept of a laboratory system, within which breakdowns at multiple possible steps may lead to an incorrect diagnosis being rendered. This definition includes the commission of cognitive errors by pathologists as one possible cause of anatomic pathology diagnostic error, but it does not limit error to those events caused by cognitive failure alone. Thus, common events, such as poor specimen collection and lack of clinical information at the time of specimen evaluation (systems factor), were examined, and the rendering of the incorrect diagnosis due to one or more of these factors was also considered a diagnostic error.

Although we used multiple methods to detect errors in the anatomic pathology laboratory, the first and major method we used was cytologic-histologic correlation. We chose this method because it is a federally mandated QA process for all laboratories that perform Pap testing, and all the study sites were already performing this activity at the time we initiated this study. An original purpose of correlation was to detect false-negative Pap tests due to cytotechnologist screening error. However, this method potentially detects both false-negative and false-positive tests in all types of cytology tests and correlating surgical pathology specimens, with errors secondary to pre-analytic, analytic, or post-analytic factors. Due to its potential to identify multiple underlying causes of errors and its widespread use by anatomic pathology laboratories, we agreed on a standardized method for performing cytologic-histologic correlation for both gynecologic and non-gynecologic specimens, which was used by all participating institutions throughout the study. However, due to the initial lack of standardization of this procedure at each institution prior to the initiation of data collection and the lack of agreement among the participant pathologists regarding “best practices” for performing this procedure, our group spent 5 months to reach consensus on a standardized procedure for data collection.

Settings

The eight consortium institutions that participated were all large, tertiary care, teaching institutions: the University of Colorado Denver (UCD), Aurora, CO; University of Pittsburgh Medical Center (UPMC), Pittsburgh, PA; the University of Iowa Hospitals and Clinics (UIHC), Iowa City, IA; Henry Ford Health System (HFHS), Detroit, MI; Wake Forest University Baptist Medical Center (WFUMC), Winston Salem, NC; Drexel University College of Medicine (DUCM), Philadelphia, PA; New York University School of Medicine, New York, NY (NYUSM); Loyola University Medical Center (LUMC), Maywood, IL; and Western Pennsylvania Hospital (WPH), Pittsburgh, PA. All institutions were university-associated institutions, except for HFHS and WPH. Several of these systems consisted of multiple hospitals that contributed effort. For each hospital system, retrospective baseline error data collection and post-intervention (but also retrospective at the time of collection) data collection occurred in the pathology department by dedicated data collectors who entered de-identified data on-site into the web-accessible project database. All analysis was performed at the original applicant site (UPMC) or at UCD (December 2007 – August 31, 2008) where the PI relocated in December 2007. QI initiatives occurred in all phases of diagnostic testing and screening services and, therefore, involved anatomic pathology departments, inpatient hospital services, and outpatient services.

The original applicant site was the University of Pittsburgh, and the initial additional three funded consortium sites were UIHC, HFHS, and WPH. The PI at the WPH consortium site relocated before Year 3 of the project, and the WPH site was replaced by WFUMC. Three sites (DUCM, NYUSM, and LUCM) learned about the project through project result dissemination activities performed by the overall project PI, so they voluntarily joined the project during Years 2 and 3 for institutional QI reasons. These sites did not receive funding to support their participation.

Participants

For each consortium site, a co-investigator pathologist served as consortium site PI, and the overall project PI at UPMC/UCD was Stephen S. Raab, MD. At the coordinating site (UPMC) and several of the other consortium sites, one or more co-investigators with expertise in specific areas (statistical analysis, health information technology, etc.) were key personnel. The consortium site co-investigators were Dana M. Grzybicki, MD, PhD, Michael J. Becich, MD, PhD, Janine E. Janosky, PhD, Dilip Gupta, MD (UPMC); Richard J. Zarbo, MD, DMD, Frederick A. Meier, MD, Chad Stone, MD (HFHS); Kim R. Geisinger, MD, (WFUMC); Chris S. Jensen, MD, Michael B. Cohen, MD, Laila Dahmouh, MD (UIHC), Eva M. Wojcik, MD (LUMC); Marion M. Haber, MD (DUCM); Stanley J. Geyer, MD, Uma Krishnamurti, MD (WPH); and Thaira Oweity, MD (NYUSM).

Data collection and QI initiatives involved large numbers of individuals at each site. These individuals included pathologists, pathologist extenders, clinicians, clinician extenders, administrators, support staff, hospital medical-legal personnel, patient representatives, and payers. For example, more than 40 clinicians and their office staff were involved in a controlled Lean QI initiative at UPMC.

All collected error-related data were pre-defined, and institutional review board (IRB)-approved discrete patient specimen and clinical variables were manually or electronically extracted from electronic medical records. All data were obtained through retrospective review of institutional electronic records and were in existence at the time of collection.

Post-interventional data collection satisfied IRB definitions of existing data because we waited for time periods of 1-6 months after cohort specimen examination dates in order to collect linked clinical outcome data that were complete and comprehensive.

A small, multidisciplinary External Expert Consultant Committee assisted the overall project PI and co-investigators in data interpretation and QI redesign. This Committee consisted of Charles P. Friedman, MD (UPMC), Mark S. Roberts, MD, MPP (UPMC), Joyce C. Niland, PhD (City of Hope), John Thomas Cox, MD (University of California, Santa Barbara), and Robert C. Reiter, MD (ProMedica Health Systems). These individuals had expertise in the domains of clinical medicine, public health, decision-making, and informatics.

A major partner in this process was the Pittsburgh Regional Health Initiative (PRHI) (Karen Feinstein, PhD, president). PRHI provided training for our personnel in Lean methods.

Methods

Study Design and Data Sources/Collection

As mentioned above, most of the research activities for this study involved establishing baseline error rates using cytologic-histologic correlation as the error detection method, measuring post-intervention error rates using the same method, and performing statistical hypothesis testing to compare pre- and post-intervention error rates. Cytologic-histologic correlation may be performed as a retrospective review process or as a real-time process; for the purposes of this study, we performed retrospective reviews. All data entered into the project database were de-identified and satisfied the definition of a Limited Data Set. No linking identifiers were maintained during the course of the study; therefore, study investigators and other key personnel participants were unable to re-identify any patient specimens utilized for the study. Generally, only a single data collector at each site temporarily had access to unique patient identifiers during data mining activities.

Additional error detection methods we utilized during the course of the study were: 1) second pathologist review of cases, 2) generation of an amended report, 3) rendering of a frozen section – permanent section diagnostic discrepancy, and 4) direct observation. Retrospective reviews were performed to collect pre- and post-intervention data similarly to that for cytologic-histologic correlation.

Evaluation studies were performed to measure the validity and reliability of modified error taxonomy and clinical severity scale tools when used by the data collectors and other investigators during the study. A large amount of time and effort was spent during this study on examining the level of diagnostic interobserver variability between the pathologists and pathologist extenders who were rendering final pathologic diagnoses on the specimens analyzed for the study. The kappa statistic with confidence intervals was used to evaluate levels of diagnostic agreement. As we consistently measured high levels of diagnostic variability between pathologists, we also performed interventions to attempt to increase levels of diagnostic agreement.

The major methods we used to perform root cause analyses for errors were a modification of the Eindhoven method (originally used for study of transfusion-related errors) and “Five-why” analysis (Toyota Production System). Methods based on Lean principles were performed by dedicated personnel formally trained by the Pittsburgh Regional Health Initiative and funded by the Jewish Healthcare Foundation. Each distant consortium site sent one or more individuals to a multiple-day, Pittsburgh-based training session prior to utilizing Lean methods for process assessment and improvement. Real-time observational studies were used by the trainees to assess current practices, defects, and process failures. Time motion studies were used to evaluate personnel and work processes. Process mapping and failure modes and effects analysis (FMEA) was used to determine the manner by which failures occurred and the consequences of these failures.

Measurement of the clinical severity of patient outcomes associated with errors was a major activity of this study; previously, severity had never been directly measured through chart reviews and pathologists had only inferred degrees of potential harm. We modified previously described clinical severity scales for use in this study and then measured the inter- and intra-observer agreement between the data collectors and investigators using the instrument prior to its general use in the study.

Evaluation of the usefulness of the methods and process changes utilized during the course of this study was assessed through participant direct observation by one of the study co-investigators (Grzybicki), a physician perception and opinion survey at the initiation of the study, focus groups, and semi-structured interviews with key leaders at the coordinating site.

Interventions

We implemented a variety of process changes during the course of the study to test for their effectiveness in reducing anatomic pathology errors. The process changes we were able to implement and test at each institution were significantly limited by departmental and organizational cultures.

For Project Years 2-5, we performed two cross-site interventions at the four initial consortium sites per year, although additional sites also participated in some implementation processes. These interventions are listed below; for each intervention, we examined specific IOM domains of quality:

1. Implementation of “double” slide viewing procedures (i.e., having two or more pathologists blindly examine slides prior to case “sign-out”) to improve safety
2. Implementation of pre-analytic (tissue procurement) and analytic (tissue accessioning, processing, screening and interpretation) process changes in cervical cancer screening services to improve safety, efficiency, clinical effectiveness, patient centeredness, and timeliness
3. Implementation of “immediate” pathologist interpretation services (using a pathologist at the tissue procurement site to provide feedback) in a variety of clinical services to improve clinical effectiveness, timeliness, safety, and patient centeredness
4. Implementation of wide-scale Lean practice redesign in the laboratory phase of anatomic pathology testing to improve safety, timeliness, clinical effectiveness, patient centeredness, and efficiency
5. Implementation of analytic diagnostic standardization procedures to decrease diagnostic variability and to improve safety and clinical effectiveness
6. Implementation of standardized processes for amended (corrected) report error detection, root cause analysis, and implementation of change to improve safety, clinical effectiveness, and efficiency
7. Implementation of a real-time tracking and an improvement system for specimens with identification and/or information defects to improve safety, timeliness, clinical effectiveness, and efficiency
8. Implementation of slide review protocols to decrease the frequency of “indeterminate” diagnoses to improve safety, clinical effectiveness, patient centeredness, and efficiency

Interventions were based on targeting specific quality failures that were identified by our standardized error detection processes. We used a blended Lean model of problem-solving by including aspects of FMEA and failure cause classification using the Eindhoven model. Using a modified *hoshin* approach, the cross-site interventions were planned at a yearly Project Conference. Each consortium site adapted the intervention to site-specific conditions, although we maintained standardized outcome metric collection across all sites. The adaption to site-specific conditions used variable aspects of a Lean model, with some sites actually constructing Lean A3s for immediate problem-solving. We collected qualitative data on the differences in specific site implementation strategies in order to identify best implementation practices among sites and site-specific cultural differences and barriers that limited effectiveness.

Each site was required to perform at least one site-specific intervention per year. We grouped these interventions into the following categories:

1. Implementation of standardized diagnostic criteria for anatomic pathology specimens
2. Implementation of standardized procedures for specimen collection, transport, accessioning, grossing, processing, and reporting
3. Implementation of rapid feedback loops and critical value reporting for pathologist-clinician handoffs
4. Implementation of rapid root cause analysis with Lean immediate problem-solving
5. Implementation of pathology process changes (stain utilization and tissue processing protocols) in intra-operative services
6. Implementation of wide-scale process changes in clinical services (e.g., radiology) that obtain anatomic pathology tissue specimens
7. Implementation of targeted post-analytic secondary review services to identify error causes

Implementation strategies varied by site and at the yearly Project Conference (held in September or October), each site discussed the successes and failures of the interventions. Some of the successful interventions were then developed into cross-site interventions.

Measures

We classified our measures into three categories: 1) measures related to error detection, 2) measures related to laboratory quality of services, and 3) clinical outcome measures.

Error detection measures: Error frequencies, error proportions, and error rates.

Laboratory quality measures: Specimen turnaround times, laboratory specimen throughput, laboratory worker productivity, laboratory worker overtime, laboratory disposable resource costs and utilization, laboratory section wasted time and services, clinician and patient satisfaction with laboratory services

Outcome measures: Changes in error detection measures, diagnostic performance measures (e.g., sensitivity and specificity), time to treatment, delay in diagnosis, missed or inaccurate diagnosis, unnecessary diagnostic

testing, repeat diagnostic testing, delay in treatment, unnecessary treatment, wrong treatment, and patient harm (psychological or physical harm). Patient harm was classified on an interval scale representing levels of morbidity to mortality. Patient harm occurred secondary to delays in diagnosis or to missed or inaccurate diagnoses as a consequence of clinician providers acting (or not acting) on the faulty information provided.

Limitations

Limitations in data collection included the inability to collect specific data elements based on institutional laboratory and/or hospital information system structure. As Dr. Geyer relocated from WPH, we were not able to collect multiple years of data, limiting conclusions made about that institution. As we added new data collection elements each year of the project, some of the original core institutions did not have the resources to fully collect data using each error detection method. The non-funded institutions were limited by resources in their data collection capabilities.

During interpretation and discussion of inter-site error frequencies at all stages of the study, it became clear that a contributing factor to statistically significant differences in error measures was residual process variations in clinical and laboratory practices. Therefore, aggregated analysis of the study data was not possible, nor was error benchmarking or valid quantitative inter-site comparisons of error measures. As mentioned earlier, a single anatomic pathology test often involves more than 225 steps, and many of the steps are performed outside of the laboratory. We lacked the manpower to fully evaluate sources of error in all process steps. For some individual cases of error, retrospective root cause analysis was limited by the lack of information in the medical records, especially information regarding latent system contributions to error. Some consortium sites lacked a team with broad expertise that could evaluate cross-discipline contributions to error.

Cross-site implementation initiatives also were limited by the inability of some sites to perform complete process mapping of existing practices. Single-site implementation initiatives could not be evaluated in terms of ease of dissemination or if implementations would be successful at other sites. We lacked the ability to measure all quality domain variables for the implementation for some QI initiatives. We also lacked the ability to measure all variables that affected success or failure.

Results

Principal Findings

1. We defined baseline anatomic pathology error proportions based on detection method. The proportions are based on number of cases reviewed:

1. Diagnostic errors detected by cytologic-histologic correlation (i.e., comparing a cytologic diagnosis with a histologic diagnosis obtained from the same anatomic site of a patient): 4.2%-15.1%
2. Diagnostic errors detected by secondary review on cases presented at clinical-pathologic conferences: 1.3%-5.4%
3. Diagnostic errors detected by frozen section-permanent section correlation: 1.1%-7.1%
4. Diagnostic errors detected by secondary review prior to case sign-out: 0%-2.7%
5. Diagnostic errors detected by targeted review practices: 5.1%-32.9%
6. Diagnostic errors detected by random review practices: 1.7%-3.7%
7. Post-analytic errors (including diagnostic errors) detected review of revised (corrected) reports: 0.30%-1.47%
8. Errors (defects in specimen quality, identification, information, or diagnosis) detected in the analytic phase by direct observation: 33%-67%
9. Specimen latent errors detected in the gross room: 100%

The variability using specific detection methods is largely secondary to the lack of standardized work processes, lack of standardization in detection methods, and bias.

We also defined baseline error proportions using other metrics, such as specimen type, organ type, institutional type, provider subspecialty, and phase of testing.

In summarizing these data, we estimate that the diagnostic error proportion in surgical pathology specimens is highly variable and depends on several factors, such as the specimen organ type and the degree of diagnostic standardization within groups of pathologists. We showed that the variability in diagnostic error by organ type ranged from 1%-33%. Error proportions in non-gynecologic cytology specimens fall within a similar range. In cervical cancer screening, our data show that, at a minimum, 10% of women experience a diagnostic error in their lifetime.

Although we spent most of the early time period of the project examining errors in final diagnosis, in the later years, we measured work process errors that some consortium sites preferred to classify as defects. We classified defects into specific categories (specimen, report, or information/identification), which reflected different types of process failures. A subset of these defects resulted in an incorrect diagnosis being reported on the final pathology report. Although most defects did not result in patient harm, they were correlated with poorer laboratory quality measures, such as poorer turnaround times and clinician satisfaction with laboratory services.

We reported that one-third to two-thirds of all anatomic pathology specimens experience at least one process failure in the analytic phase of testing, and many specimens experience multiple process failures. As the analytic phase of testing is the least error prone of all phases, we hypothesize that all specimens undergo multiple process failures in the entire cycle of anatomic pathology testing.

2. We defined baseline levels of harm caused by errors in anatomic pathology diagnosis. Approximately 50% of anatomic pathology diagnostic errors result in patient harm. Most harm (80%) associated with a diagnostic anatomic pathology error was classified as minimal or mild and consisted of repeat noninvasive or minimally invasive testing. We showed that pathologists exhibited acceptable levels of inter-observer agreement in the assessment standardized harm scenarios ($\kappa > 0.6$).

3. We determined the causes of specific types of anatomic pathology error. As mentioned previously, for errors in diagnosis, pathologists traditionally have classified an error's cause as secondary to a pathologist's misinterpretation or to a clinician's error in test procurement. We found that assessments using this binary scale had very low inter-observer reproducibility ($\kappa < 0.4$), as pathologists and clinicians are highly biased in their assessments.

Using our methods of root cause analysis, we found that the causes of diagnostic error are multifactorial and that many diagnostic errors arise from problems in specimen procurement *and* interpretation ($> 75\%$ of all errors in diagnosis). Diagnostic errors generally resulted from pathologists interpreting poor specimens. Most importantly, a large component of diagnostic error resulted from process failures in the pre-analytic steps. These errors are compounded by latent problems affecting the cultural focus on production, training issues, overwork, lack of feedback channels, and numerous other system-related problems.

4. We found that the lack of diagnostic standardization in most areas of anatomic pathology contributed to diagnostic error. The lack of diagnostic standardization is based on a number of factors, including the lack of insufficient diagnostic criteria, inadequate training, and the lack of data correlating diagnostic criteria with clinical outcomes.

5. We measured the cost of diagnostic error in specific areas such as the diagnosis of lung lesions and thyroid gland nodules. We calculated the cost of false negative error as the extra costs of unnecessary testing, delays in diagnosis, and complications. For a false-positive error, we calculated the extra costs of unnecessary treatment. For thyroid gland fine needle aspiration, we compared the differential cost of improved service, following an intervention designed to reduce false-negative and false-positive error. We showed that the implementation of several Lean-based interventions improved diagnostic sensitivity from 70.2% to 90.3% and resulted in a cost savings of \$1,670 per patient. If it were possible to implement this initiative throughout the United States, the annual cost savings would be \$501 million.

For pulmonary cases at one institution, we measured a cytology error rate of 9.4% based on correlation analysis. Fifty-six percent of patients who had a discrepant diagnosis suffered from some form of harm. The mean cost for a lung cytology false-negative diagnosis associated with additional diagnostic procedures was \$11,325. The 1-year total cost for pulmonary cytology false-negative cases was \$199,468. The pulmonary cytology false-negative errors comprised less than 2% of all the false-negative errors collected in our database. At a minimum, 5% of patients undergoing a pulmonary procedure will have a false-negative diagnosis associated with additional testing. We hypothesize that the annual cost of false-negative diagnoses related to pulmonary specimens in the United States results in millions of dollars of additional testing and procedures.

We showed that inefficiencies in laboratories also contributed to high healthcare costs. One consortium site redesigned work processes in the histology section and compared pre- and post-implementation productivity and costs. The pre- and post-implementation productivity ratios were 3,439 and 4,074 work units/FTE, respectively ($P < 0.001$). For comparison, a non-Lean histology section in the same system had a productivity ratio of 1,598 work units/FTE.

The yearly cost change per FTE of the post-implementation Lean laboratory was \$292,210 per FTE (employees in this laboratory had a salary range of \$20,000 to \$45,000).

6. We showed that the implementation of Lean designed process changes in specific diagnostic testing and screening phases improved practice in many quality dimensions. For a full 3 years, project teams implemented changes across multiple institutions, and we experienced many successes and failures. We implemented Lean-based process changes in a number of ways, such as changing a specific work process using Lean principles to attempting work culture change from a “bottom-up” or frontline point of view in which small- and large-scale changes occur continuously. We lack the space in this summary document to fully detail the enormity of specific changes that were made and the entire process of implementation. A few of the successful implementations are listed below:

1. Double slide viewing procedures reduced the number of diagnostic errors in some laboratories
2. The redesign of cervical cancer screening office practice improved turnaround time of Pap test results, improved the quality of Pap tests, and reduced the number of errors
3. The redesign of CT-guided lung fine needle aspiration practice increased diagnostic accuracy
4. The redesign of radiologic breast biopsy services decreased time to treatment by 2 weeks for some patient groups and improved patient satisfaction
5. The redesign of thyroid gland fine needle aspiration services improved diagnostic accuracy and reduced the number of repeat fine needle aspiration procedures
6. Diagnostic reproducibility was improved for some practice groups by the implementation of interactive methods
7. Standardization of error reporting and follow-up processes led to a decrease in error frequency
8. Standardization of laboratory work processes led to fewer specimen defects
9. Implementation of wide-scale Lean practice redesign in the laboratory phase of anatomic pathology improved timeliness, safety, timeliness, clinical effectiveness, patient centeredness, and efficiency
10. Implementation of slide review protocols decreased the frequency of “indeterminate” diagnoses to improve safety, clinical effectiveness, patient centeredness, and efficiency

Several of the successful interventions have been published and/or are being prepared for publication. We experienced failure, or only variable success, in some of the single-site interventions and at some sites for cross-site interventions. We classified failures in terms of causes, which are listed below:

1. Turf issues
2. Lack of organizational commitment
3. Lack of sufficient training
4. Long-term evaluation was not feasible
5. Disruptive physicians
6. Middle management not engaged
7. Up-front costs limited implementation
8. Cultural model (top-down versus bottom-up)
9. Punitive history difficult to eradicate
10. Disincentive for improvement
11. Difficulties in linking improvement with outcome

7. Qualitative results from this study revealed three major findings that are generally consistent with other reports in the literature related to physician and organizational barriers to improving patient safety. First, despite their initial commitment to collaborate on this study with the knowledge that it would involve requests for changes in processes and self-assessments of practice, pathologist consortium PIs were unwilling to agree and act in a consensual manner regarding research activities. Major underlying reasons for these behaviors were individual perceptions that their laboratory was already practicing “best practices” despite a lack of supporting evidence for these perceptions; complaints that implementing given changes would be “too hard” (not necessarily associated with limited resources); lack of human resources; and a seemingly general lack of willingness to prioritize and expend effort on improving practice.

Second, focus group findings showed that a sample of frontline laboratory workers at one site were highly suspicious and fearful of the implementation of process changes aimed at detecting errors and improving practice.

Despite receiving education and assurance regarding the ultimate purpose of the application of Lean principles to their work, they still displayed a significant resistance to change and fear of potential negative consequences consistent with an unsafe organizational culture that persisted throughout the study.

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Third, individual semi-structured interviews with institutional administrators at the one site (laboratory section supervisors, overall laboratory manager, hospital quality improvement director, and vice chair of patient services) revealed a significant disparity between administrators' and frontline workers' perceptions of the value and success of laboratory process changes. All administrators articulated a belief in the value of Lean methods for achieving quality and safety improvements and a perception that implementation efforts were going very well. Laboratory-level administration articulated support for the process change experiments associated with this study.

8. A major finding was that disruptive physician behavior related to our medical error research at the coordinating site resulted in the obstruction of many study activities during Year 5 of the study, the professional demotion of the overall study PI, such that he had no authority to initiate QI activities in the laboratory, the creation of a hostile environment for all study personnel at the coordinating site, and ultimately, a "suggestion" by the Vice-Chancellor that the overall project PI and one of the project co-investigators leave the University.

The primary disruptive physicians who obstructed our work at the coordinating site were the Director of Anatomic Pathology and the Chair of Pathology at UPMC. The most blatant disruptive behavior (professional demotion of the overall project PI) occurred as a consequence of the PI's refusal to re-identify patient data entered into the project database. The Director of Anatomic Pathology issued a direct threatening order in writing to the PI to commit HIPAA violations and re-identify de-identified data. Despite reporting this occurrence to the Chair of Pathology, the Director of Clinical Research, the Dean of the Medical School, the Director of Research Compliance in the office of the Institutional Review Board, the Vice Dean of the medical school overseeing the Office of Faculty Affairs, the hospital legal office, and the CEO of UPMC, the PI's demotion was supported. The leadership in both the University of Pittsburgh and UPMC not only condoned the actions of the Director of Anatomic Pathology but also denied any wrongdoing had taken place. During Year 5 of the study, ongoing disruptive behavior consisted of the harassment of physicians who were integral to implementing QI change, constant coercion to violate HIPAA, refusal to participate in data collection processes or not being provided access to quality data, misuse of AHRQ data, manipulation and elimination of clinical services in which quality work was being performed, and other unprofessional behavior involving slander and threats. Essentially, the Chair's written agreement with AHRQ to support the performance of this research project was broken, as were data sharing agreements, the overall PI's faculty contract with the University, and essentially all University policies regarding the rights and expectations of faculty members. The result of these behaviors was that two co-investigators were forced out of the Department of Pathology, and the Vice-Chancellor suggested that the PI and a physician co-investigator leave the institution.

Although disruptive physician behavior has been described in the patient safety literature, we do not believe the nature and extent of the damage resulting from the condoning of disruptive behavior by institutional leadership is yet appreciated by federal, state, and private agencies promoting, supporting, and funding patient safety programs.

Outcomes

1. We developed a fully functional database to voluntarily store, share, and analyze anatomic pathology errors. This database was designed so that any institution could participate. In addition, this database was designed so that pathology errors detected by other methods could be added. Our database was structured so that even errors from other disciplines (e.g., radiology, internal medicine, pharmacy) could be added and correlated with linked pathology data.
2. We defined baseline rates of anatomic pathology error frequency, cause, and level of harm. The level of error frequency has not been previously defined for multiple institutions across the wide spectrum of error types. We developed a taxonomy for the harm impact of anatomic pathology diagnostic errors. Prior to this development, anatomic pathologists did not have a means to discuss errors in terms of their clinical impact. We have shown that this scale has validity and reproducibility.
3. We developed the use of Lean QI tools within laboratories. We currently are disseminating the use of Lean tools throughout laboratories within the United States and the world. Our core Lean laboratories are viewed as seminal sites for the application and testing of process changes.

4. Based on our findings we planned, organized, and directed two national meetings on medical error that focused on laboratory medicine and anatomic pathology.
5. We widely disseminated our work by publishing 42 manuscripts. We presented 51 conference abstracts and were invited to speak nationally and internationally, providing over 135 lectures. We have provided interviews in numerous lay journals and have been interviewed by local and national television and radio networks.

Conclusions and Discussion

Traditionally, most practicing clinicians and pathologists viewed that anatomic pathology error consisted of a pathologist making a mistake in diagnostic interpretation or a clinician not properly obtaining a sample. Furthermore, many clinicians viewed that the failure to procure a diagnostic sample simply was an inevitable part of the testing procedure.

Our research findings are at odds with this traditional assessment. We believe that the lack of work process standardization is the major cause of anatomic pathology error and that this lack of standardization affects all IOM domains of quality. The lack of standardization exists in every testing phase and is especially pronounced in the pre-analytic and the post-analytic phases. In fact, more problems related to anatomic pathology testing and screening reside outside of the laboratory than do within. Errors in diagnostic testing and screening usually are multifactorial, and a problem in QI is that errors must be targeted from a system point of view and not simply by targeting pathologists or clinicians who fail. The lack of standardization in anatomic pathology has enormous consequences, as it results in variability in outcomes, high costs, and inefficiencies.

The standardization of practice, through the use of systematized QI methods, has the potential to yield remarkable results. For our QI interventions, we utilized Lean methods, although we believe that other methods could be equally effective. We consistently demonstrated improvement in quality metrics, including error reduction, in most areas that we targeted. In retrospect, our findings are not surprising, as most phases in diagnostic testing and screening are not standardized. Our experience with performing this project supports the idea that the largest problem with achieving laboratory medicine (and most likely any medical specialty) QI and patient safety goals is culturally based. This problem results from a lack of training, understanding, commitment, and focus among leaders within the practice of pathology as well as among institutional leadership who support disruptive physician behavior.

Significance and Implications

We believe that we fulfilled the promise of our funding by providing a plethora of foundational information unavailable prior to this study regarding defining, measuring, and categorizing anatomic pathology errors and the usefulness of specific process changes for reducing errors. We constructed the only national anatomic pathology error database that may be used for research and practice. Our work is the first to demonstrate the use and usefulness of systematic root cause analytic methods in anatomic pathology. We created a national network of hospitals and laboratories that use Lean tools for QI. In addition, because of the significant interdependence we demonstrated between the quality of laboratory services and the quality of clinical services, we believe our work supports the necessary integration of pathologists and pathology services in all departmental and institutional QI and patient safety programs involving the use of laboratory information. We believe that the government or private payers must help to reorganize the diagnostic testing and screening communities to create a cross-disciplinary, united approach for diagnostic testing and screening services.

Results from this study include information about significant quality and safety gaps in anatomic pathology that may be used by multiple stakeholders, including research funding agencies, to support further QI and patient safety clinical and research programs. The level of error leading to patient harm, inefficiencies, and high costs in anatomic pathology diagnostic testing and screening is high. We have shown that most of this error is secondary to the lack of standardization within all phases of testing. We also have shown that quality metrics may be improved with well-designed process interventions. The national diagnostic testing and screening community needs to standardize and evaluate the effects of standardization in order for demonstrable changes in anatomic pathology diagnostic errors and other quality indicators to be meaningful.

Our data has shown that the costs and inefficiencies of diagnostic testing and screening errors are enormous. Further analysis of these costs and inefficiencies needs to be conducted. If corroborated, we believe that the government must embrace a national agenda for diagnostic testing and screening QI.

In many settings, laboratories, pathologists, hospital systems, and clinicians are generally reimbursed by the number of diagnostic and screening tests performed. Our data indicate that improvement results in a decrease in the number of tests performed. We believe that the financial reimbursement system must be realigned to pay for diagnostic testing and screening service quality and not number of tests performed. In addition, we propose that pay for performance should be introduced for the entire testing pathway (cross disciplinary) and not just for individual disciplines within the pathway.

Our qualitative findings indicate that culture has an enormous role in either assisting or limiting the performance of QI activities. We believe that more study is necessary to better define the cultural barriers to improvement and the means to eliminate these barriers. In particular, we believe that a major effort needs to be initiated to study disruptive physician behavior and initiate means to eliminate these behaviors.

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Raab SS. Quality assurance and cytology. Annual Iowa Cytology Course; 2005 May 7; Iowa City.

Raab SS. Improving anatomic pathology practice by utilizing the Lean production system. PSA2005 Pathology Business Retreat Conference; 2005 May 13; San Antonio.

Raab SS. Pathology errors: Using reporting system data for action – II. Agency for Healthcare Research and Quality Annual Meeting, Patient Safety and Health Information Technology; Making the Health Care System Safer through Implementation and Innovation; 2005 Jun 6; Washington, D.C.

Raab SS. The impact of gynecologic pathology discrepancy on patient safety. Agency for Healthcare Research and Quality Annual Meeting, Patient Safety and Health Information Technology; Making the Health Care System Safer through Implementation and Innovation; 2005 Jun 6; Washington, D.C.

Raab SS. Information management and reporting capabilities of a pathology patient safety database. Agency for Healthcare Research and Quality Annual Meeting, Patient Safety and Health Information Technology; Making the Health Care System Safer through Implementation and Innovation; 2005 Jun 6; Washington, D.C.

Raab SS. Healthcare costs associated with pulmonary cytology false negative diagnoses. Agency for Healthcare Research and Quality Annual Meeting, Patient Safety and Health Information Technology; Making the Health Care System Safer through Implementation and Innovation; 2005 Jun 7; Washington, D.C.

Raab SS. Use of clinical impact information about urine cytology false negative diagnoses to target this error of root cause analysis and error reduction strategies. Agency for Healthcare Research and Quality Annual Meeting, Patient Safety and Health Information Technology; Making the Health Care System Safer through Implementation and Innovation; 2005 Jun 7; Washington, D.C.

Raab SS. Development of a diagnostic classification system for thyroid fine needle aspirations to reduce false negative frequency. Agency for Healthcare Research and Quality Annual Meeting, Patient Safety and Health Information Technology; Making the Health Care System Safer through Implementation and Innovation; 2005 Jun 7; Washington, D.C.

Raab SS. Training the pathologist as a driver of institutional change. Association of Pathology Chairs Annual Meeting; 2005 Jul 19; Mt. Tremblant, Quebec.

Raab SS. Anatomic pathology error. University of Kansas Medical School Conference Series; 2005 Jul 1; Kansas City.

Zarbo RJ. Error assessment in surgical pathology. Colorado Society of Clinical Pathologists Stars in the Mountains Pathology Seminar; 2005 Jul 8; Vail.

Raab SS. Update on AHRQ data. Henry Ford Hospital Lecture Series; 2005 Aug 4; Detroit.

Tuthill JM. Error reduction, efficiency improvement, and cost savings through automated data entry. Annual Meeting of Advancing Practice, Instruction and Innovation through Informatics; 2005 Aug 24; Lake Tahoe.

Raab SS. Errors in anatomic pathology and participation in a national patient safety database. Drexel University Lecture Series; 2005 Sep 7; Philadelphia.

Meier FA. How can the use of amendments and addenda be safe and consistent? College of American Pathologists 2005 Annual Meeting; 2005 Sep 13; Chicago.

- Raab SS.** Improving pathology practice by reducing errors and inefficiencies utilizing the Toyota Production System. American Society of Clinical Pathology Annual Meeting; 2005 Oct 8; Seattle.
- Raab SS.** Update of patient safety. National Meeting of AHRQ Grant Participants, Improving Patient Safety by Examining Pathology Errors, University of Pittsburgh; 2005 Oct 13; Pittsburgh.
- Raab SS.** The high cost of lab/pathology errors: making a business case for quality. Washington G-2 Reports Lab Institute; 2005 Oct 22; Arlington.
- Raab SS.** Anatomic pathology errors. Pittsburgh Pathology Society Meeting; 2005 Oct 26; Pittsburgh.
- Zarbo RJ.** The QA plan at Henry Ford Hospital. La Qualita in Anatomia Patologia, Presidio Osepedaliero San Eugenio, Azienda USL; 2005 Oct 27; Rome, Italy.
- Zarbo RJ.** Monitoring errors and outcomes in anatomic pathology. La Qualita in Anatomia Patologia, Presidio Osepedaliero San Eugenio, Azienda USL; 2005 Oct 28; Rome, Italy.
- Raab SS.** Patient safety in anatomic pathology. Department of Pathology, Special Conference Series; 2005 Nov 2; Winnipeg, Manitoba.
- Raab SS.** Error reduction in anatomic pathology. Department of Pathology Special Conference Series; 2005 Nov 2; Winnipeg, Manitoba.
- Raab SS.** Utility of immediate interpretation services for breast care. UPMC Shadyside Hospital, Medicine Grand Rounds; 2005 Nov10; Pittsburgh.
- Raab SS.** Approach to systems analysis in pathology. Brigham and Women's Hospital, Pathology Ground Rounds; 2005 Nov 14; Boston.
- Raab SS.** Patient safety in anatomic pathology. New York University, Pathology Grand Rounds; 2005 Nov 21; New York.
- Raab SS.** Improving anatomic pathology practice using Lean production. Inova Fair Oaks Hospital Pathology Conference; 2005 Nov 29; Fairfax.
- Raab SS.** Errors in cancer diagnosis. University of Pittsburgh Modeling Meeting, University of Pittsburgh; 2006 Mar 14; Pittsburgh.
- Raab SS.** Identification errors in the laboratory. CLMA ThinkLab '06; 2006 Mar 18; Charlotte.
- Raab SS.** Improving diagnostic testing by using Lean production principles. Peter M. Winter Institute for Simulation & Education Research, Jewish Healthcare Foundation, Council on Foundations Annual Meeting; 2006 May 8; Pittsburgh.
- Raab SS.** Improving patient safety by examining pathology errors. Improving Hospital and Lab Safety 2nd Annual Meeting; 2006 May 18; Pittsburgh.
- Zarbo RJ.** Henry Ford Production System-continuous quality improvement in pathology based on Ford and Toyota Lean Production principles. Improving Hospital and Lab Safety 2nd Annual Meeting; 2006 May 18; Pittsburgh.
- Zarbo RJ.** Patient safety and diagnostic error in surgical pathology. Ontario Association of Pathologists Annual Meeting; 2006 Jun 2; Collingwood, Ontario, Canada.
- Raab SS.** The effectiveness of congressionally mandated quality assurance practice. Agency for Healthcare Research and Quality 2006 Annual Health IT and Patient Safety Conference; 2006 Jun 5; Washington, D.C.
- Raab SS.** The standardization of the amended report process. Agency for Healthcare Research and Quality 2006 Annual Health IT and Patient Safety Conference; 2006 Jun 5; Washington, D.C.
- Raab SS.** Use of the no-blame box on reaching consensus on the cause of cytologic-histologic correlation discrepancy. Agency for Healthcare Research and Quality 2006 Annual Health IT and Patient Safety Conference; 2006 Jun 5; Washington, D.C.
- Raab SS.** The effectiveness of diagnostic criteria guidelines in thyroid gland fine needle aspiration (FNA). Agency for Healthcare Research and Quality 2006 Annual Health IT and Patient Safety Conference; 2006 Jun 5; Washington, D.C.
- Zarbo RJ.** The impact of multiple versus single interpreter on estrogen and progesterone receptor status. Agency for Healthcare Research and Quality 2006 Annual Health IT and Patient Safety Conference; 2006 Jun 5; Washington, D.C.
- Raab SS.** Root cause analysis for laboratory errors. Seminar Series in Laboratory Medicine, University of Pittsburgh; 2006 Jun 1; Pittsburgh.
- Raab SS.** Transformation of pathology practice. Applications and Advances Through Perfecting Patient Care, Jewish Healthcare Foundation; 2006 Aug 21; Pittsburgh.
- Zarbo RJ.** Transforming to a quality culture: the Henry Ford Production System. Applications and Advances Through Perfecting Patient Care, Jewish Healthcare Foundation; 2006 Aug 21; Pittsburgh.

- Raab SS.** Anatomic pathology patient safety. Grand Rounds Conference, Division of Pathology and Laboratory Medicine, MD Anderson Cancer Center; 2006 Sep 15; Houston Texas.
- Raab SS.** United States national safety databases in anatomic pathology. Patient Safety in Anatomic Pathology Symposium, International Academy of Pathology, XXVI International Congress; 2006 Sep 17; Montreal, Canada.
- Zarbo RJ.** Addressing national patient safety goals in surgical pathology. Symposium SYM13 Quality Assurance- Patient Safety in Anatomic Pathology, 26th International Congress of the International Academy of Pathology; 2006 Sep 17; Montreal, Quebec.
- Raab SS.** Targeting error at the sharp edge of lab care: patient specimen switches in the anatomic and clinical labs. Lab Institute '06; 2006 Sep 27; Washington, D.C.
- Raab SS.** Perfecting patient care in diagnostic testing. Highmark Blue Cross Blue Shield Conference Series; 2006 Oct 3; Pittsburgh.
- Raab SS.** Pathology quality: role of the pathologist in lab quality assurance programs. College of American Pathologists, Virtual Management College Audio Conference 2006-2007; 2006 Oct 10; Northfield.
- Raab SS.** Update on AHRQ consortium: diagnostic testing errors. National Meeting of AHRQ Grant Participants, Improving Patient Safety by Examining Pathology Errors; 2006 Oct 12; Pittsburgh.
- Raab SS.** Diagnostic variability and its impact on care. University of Pittsburgh Center for Research and Healthcare Seminar Series; 2006 Oct 24; Pittsburgh.
- Raab SS.** Agency for Healthcare Research and Quality patient safety update. University of Iowa Seminar Series; 2006 Nov 10; Iowa City.
- Stark A.** Laboratory specimen defects as an observed disparity in health care. National Leadership Summit on Eliminating Racial and Ethnic Disparity in Health Care; 2007 Jan 9; Washington, D.C.
- Raab SS.** Pathology quality assurance and quality improvement. Norwegian Society of Cytology Annual Conference; 2007 Feb 2; Oslo, Norway.
- Raab SS.** Improving pathology practice by reducing errors and efficiencies utilizing the Toyota Production System. ASCP Weekend of Pathology; 2007 Feb 8; Las Vegas.
- Raab SS.** Improving pathology practice by examining and reducing errors. Washington G-2 Reports Audio Conference; 2007 Feb 22; Teleconference Webcast.
- Zarbo RJ.** Henry Ford Productions System: leaning out the surgical pathology laboratory. Pathology Conference Series, University of Miami School of Medicine; 2007 Mar 1; Miami.
- Zarbo RJ.** Custom quality measures in healthcare: beyond Lean. 2007 World Conference on Quality and Improvement, American Society for Quality; 2007 May 1; Orlando.
- Raab SS.** Errors in pathology; Illinois Society of Pathology Spring Meeting; 2007 May 5; Chicago.
- Raab SS.** Cervical cytology: still the most cost effective cervical cancer screening test? 16th International Congress of Cytology; 2007 May 14; Vancouver, Canada
- Zarbo RJ.** Going beyond Lean-transforming to a laboratory quality culture: the Henry Ford Production System. 26th Annual Current Issues in Surgical Pathology, University of Texas Southwestern Medical Center at Dallas; 2007 May 17; Dallas.
- Raab SS.** Sharing our errors in cytology. 16th International Congress of Cytology; 2007 May 17; Vancouver.
- Raab SS.** Organization of screening programs to reduce error and the role of human papillomavirus testing; Belgian Society for Clinical Cytology Conference Series, University of Antwerp; 2007 Jun 2; Antwerp, Belgium.
- Raab SS.** Evaluating patient safety best practices in prostate needle core biopsy diagnosis. AcademyHealth Annual 2007 Research Meeting; 2007 Jun 4; Orlando.
- Raab SS.** Dissemination of Toyota Production System (TPS) methods to improve quality and patient safety in cervical cancer screening. AcademyHealth Annual 2007 Research Meeting; 2007 Jun 4; Orlando.
- Raab SS.** Establishing the frequency and outcome of cervical cancer screening failures in the United States. AcademyHealth Annual 2007 Research Meeting; 2007 Jun 4; Orlando.
- Raab SS.** Redesigning clinical and lab processes to improve thyroid gland diagnostic testing; AcademyHealth Annual 2007 Research Meeting; 2007 Jun 4; Orlando.
- Raab SS.** Designing a "Smart Room" using erecord data and technology. 2006 UPMC CLIQS Grants Committee Conference; 2007 Jul 17; Pittsburgh.
- Raab SS.** Developing quality standards in anatomic pathology; Department of Pathology Seminar Series, University of Colorado Health Sciences Center; 2007 Jul 23; Denver.
- Raab SS.** Improving patient safety by examining pathology errors. AHRQ Project Results Conference; 2007 Aug 24; Pittsburgh.

Raab SS. Improving patient safety – error reduction in laboratory care. American Society of Clinical Pathology Hot Topic Conference; 2007 Aug 29; International Webcast.

Zarbo RJ. Towards zero defects in surgical pathology. Henry Ford Production System manufacturing-based quality improvement in pathology and laboratory medicine. The Banff Pathology Course: Medical Errors in Laboratory Medicine and Pathology-Detection, Prevention and Mitigation; 2007 Sep 8; University of Alberta, Banff, Alberta, Canada.

Zarbo RJ. Surgical pathology in 2007. A quality report. The Banff Pathology Course: Medical Errors in Laboratory Medicine and Pathology- Detection, Prevention and Mitigation; 2007 Sep 7; University of Alberta, Banff, Alberta, Canada.

Raab SS. The Delphi method of agreement. Papanicolaou Society of Cytopathology Afternoon Session, Cells without Borders, 98th United States and Canadian of Pathology Annual Meeting; 2008 Mar 1; Denver.

Raab SS. Proficiency testing in surgical pathology: issues for renal pathology. Proficiency Testing in Renal Pathology and Beyond, Renal Pathology Society/KUFA, United States and Canadian of Pathology 98th Annual Meeting; 2008 Mar 2; Denver.

Raab SS. Practice redesign using patient safety performance metrics. Innovations and Trainees Program, The Royal College of Pathologists of Australasia Pathology Update 2008; 2008 Mar 14; Sydney, Australia.

Raab SS. The Pathologist's working environment panel. Innovations and Trainees Program, The Royal College of Pathologists of Australasia Pathology Update 2008; 2008 Mar 14; Sydney, Australia.

Raab SS. Histopathology errors: frequencies, causes, and outcomes. The Royal College of Pathologists of Australasia Pathology Update 2008; 2008 Mar 15; Sydney, Australia.

Raab SS. Quality assurance with emerging technologies in genetics. The Royal College of Pathologists of Australasia Pathology Update 2008; 2008 Mar 16; Sydney, Australia.

Raab SS. Root cause analysis for pathology interpretation errors. Women's and Children's Hospital Special Conference; 2008 Mar 17; Adelaide, Australia.

Raab SS. Urine cytology: diagnosis, error, and practice management. Australian Society of Cytology Spring Conference; 2008 Mar 17; Kent Town, Australia.

Raab SS. Pathology proficiency testing in the United States. Flinders Medical Centre Quality Conference; 2008 Mar 18; Adelaide, Australia.

Raab SS. Errors in challenging cytology cases. Royal Brisbane Womens Hospital Error Conference; 2008 Mar 19; Brisbane, Australia.

Raab SS. Anatomic pathology failures. The University of Queensland Research and Error Conference; 2008 Apr 19; Brisbane, Australia.

Raab SS. Lean implementation in diagnostic testing services. Healthcare Performance Partners 3rd Annual Lean Conference; 2008 Apr 22; Denver.

Raab SS. The economic and social costs of false positive testing: fine needle aspiration in the diagnosis of thyroid cancer. 3rd Annual "Living with Radiation: Medical and Psychological Consequences of the Chernobyl Nuclear Accident; 2008 Apr 24; United Nations, New York.

Raab SS. Errors in anatomic pathology. Diagnostic Error in Medicine 2008 Conference; 2008 Jun 1; Phoenix.

Raab SS. Quality assurance in pathology. The Royal College of Pathologists of Australasia Internet Video Lecture Series; 2008 Jun 5; International Webcast.

Raab SS. Histopathology errors. The Royal College of Pathologists of Australasia Internet Video Lecture Series; 2008 Jun 5; International Webcast.

Raab SS. Designing best practices in thyroid gland FNA. A Flavour of the 2007 NCI Conference on Thyroid FNA, European Federation of Cytology Societies/Papanicolaou Society of Cytopathology Joint Session, 34th European Congress of Cytology; 2008 Jun 18; Rovaniemi.

Raab SS. Using Lean methods to improve laboratory medicine. Medical Grand Rounds, Northern Michigan Regional Hospital; 2008 Aug 27; Petoskey.

Raab SS. Practice management college: reducing errors and patient risk in the practice of pathology. College of American Pathologists '08; 2008 Sep 26; San Diego.

Raab SS. Reaching consensus in pathology. Department of Pathology Grand Rounds, University of Colorado Denver; 2008 Nov 7; Aurora.

Raab SS. Cognitive error, decision making and tools to improve cytopathology diagnoses. Panel Luncheon, 56th Annual Scientific Meeting of the American Society of Cytopathology; 2008 Nov 9; Orlando.

Raab SS. Error reduction in cytopathology: working smarter, not harder. Innovations & Trends in Cytology, 56th Annual Scientific Meeting of the American Society of Cytopathology; 2008 Nov 9; Orlando.