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Tools to Reduce Discordance in Cancer Diagnostic Imaging a Review of Pathology and Radiology Quality Assurance Programs

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Abstract

Objective: *To review Quality Assurance (QA) Case Review programs that focus on reducing cancer diagnostic discordance in ana- tomic pathology and medical imaging and validating their ability to detect case based interpretive error.*

Design: *From an extensive number of published studies, the rate of major discrepancies identified for cancer patients referred to another institution occur from 4.6% to 14.7%, depending on type of tissue and 12% for medical imaging. However, published data indicates the current intra-laboratories QA programs' ability to detect these discrepancies is only 0.8% to 1.7%. To help understand the cause of this gap, four formal anatomic pathology and diagnostic radiology QA case review programs, both inter- and intra- laboratories, were reviewed for their ability to satisfy a set of selected design attributes known to help identify interpretive error. Peer reviewed literature was researched to support claims for each program's compliance percentage to the attributes, strengths, drawbacks and best demonstrated practices were identified.*

Results: *No program met the selected attribute listing 100%, compliance ranged from 29% (met 2 of 7) to 86% (met 6 of 7) for each program.*

Conclusion: *Pathology laboratories and radiology departments should be aware of the limitations of each QA program and take into consideration their case and medical specialist mix and current on-site concerns in order to select a program with attributes that best match their QA goals [Table 3]. In general, programs that are standardized, include external review by subspecialists and are performed close to the final sign-out date may offer the greatest amount of error discovery and potential to positively influence patient outcomes and continuous improvement. Although this study focused on discordance in cancer related surgical pathology and radiology, case review can also be an effective tool in discovery of all histology/cytology and medical imaging diagnostic and clerical discrepancies.*

Keywords: *Quality Assurance; Interpretive Error; Case Review, Surgical Pathology; Diagnostic Radiology; Diagnostic Error; Prospec- tive; Retrospective;*

1. INTRODUCTION

A 5% reduction in diagnostic error for cancer can impact 80,000 patients and affect $1.6 billion in costs on a annual basis [5]. In both Anatomic Pathology (AP) and Medical Imaging (MI) settings, there are significant recent publications calling our attention to the need for enhanced focus on diagnostic quality along with the AP, MI contribution to diagnostic discordance. One sentinel report from the Institute of Medicine (IOM) "Improving Diagnosis in Healthcare", November 2015, identified "improving the diagnostic process is not only possible, but also represents a moral, professional and public health imperative".

The IOM goes on to promote that "Pathologist and Radiologist are diagnosticians who provide information and consultations that are critical to diagnosing patient's health problem …" and as a result both medical specialists should facilitate and support collaboration among themselves and other diagnosticians. A support article by Johns Hopkins estimates medical errors may result in 250,000 deaths per year, making medical errors the third most common cause of death in the US [1]. Errors in diagnosis were the

most common cause of litigation against radiologists. For cancers, the majority of such cases arose from failure to diagnose breast cancer and lung cancer [19]. When it comes to AP and MI, getting the diagnosis right the first time is imperative, especially in the diagnosis of cancer. The accurate diagnosis and resulting appropriate treatment plan and therapy is critical to successful patient outcomes.

The Joint Commission through its required Ongoing Profession- al Practice Evaluation (OPPE) and Focused Professional Practice Evaluation (FPPE) credentialing of medical specialties identifies peer review, case review, as a process to support on-going credentialing. Medical Societies are also taking action; the College of American Pathology (CAP) completed an 18-month meta study on interpretive diagnostic error reduction in surgical pathology and cytology (Table 1). The expert panel reviewed over 200 published studies on diagnostic discrepancy in AP. The findings document an 18% median discrepancy and 7.4% major discrepancy rate for surgical pathology. When these studies are reviewed closer, it was found that external case review is 5-fold more sensitive in detecting discrepancies than internal review [2]. Case review data for radiology tract to pathology for inter and intra review comparisons [20] (Table 2).

As a result of these findings the CAP has added recommendations to include case review as part of a complete QA program for AP laboratories [19]. MI sees similar findings with 33% increase in discordance discovery between intra and inter radiologist variability with focused breast cases. [British J. of Radiology In medical imaging], the American College of Radiology (ACR) requires institutions to participate in physician peer review to maintain accreditation [18].

Table1. *Summary of studies on the frequency of interpretive errors.*

Pathology	Discrepancy rate %	Major discrepancy rate %
Surgical pathology (All)	18.3 (7.5-37.4)	6.3 (1.9-10.6)
Inter-laboratory case review	23.0 (10.6-40.2)	7.4 (4.6-14.7)
Intra-labortory re- view	10.9 (3.8-17.6)	1.2 (0.3-3.1)
Medical Imaging	**Intra-radiologists**	**Inter-radiologists**
Discordance (Breast)	33%	44%
Discordance (All)	8-10%	12% [20]

Table2. *Accrediting and Certification Bodies QA Case Review.*

Body	Pathology	Radiology
Joint Commission OPPE and FPPE	Required	Required
CAP Guidelines (College Am Path)	Recommended	NA
ACR Accreditation (Am College Radiol)	NA	Required
MOC Credentialing (Am Board of Path/Rad)	Satisfies Part IV	Satisfies Part IV

Every year, over 60 million surgical biopsies and companion radiology images are performed and 1.6 million Americans are diagnosed with cancer [3]. As pathology and radiology play a significant role in the diagnostic process, it is important to note that radiology has targeted a <2% major discrepancy rate as their quality goal [4]. Current quality tools and programs may have topped out in AP.

Over the past 15 years, laboratories have made significant investments in quality initiatives. Certainly, in pathology, on the clinical side, with increasing adoption of automation and sample handling, quality has improved proportionally. On the AP side, with more subjectivity, far less automation and only recent introduction and acceptance of digital imaging, these investments have a less significant impact, as quality has only marginally improved. Plotting the work of Raab, reporting on major discrepancies identified by year of study, there is only a minor negative slope tracking our progress.

Clearly, next generation quality tools and processes need to be implemented to make any significant improvement in reducing diagnostic discrepancies. Evidence indicates that in AP there is a compelling gap in our current quality practices and there is an opportunity to improve QA initiatives (Figure 1).

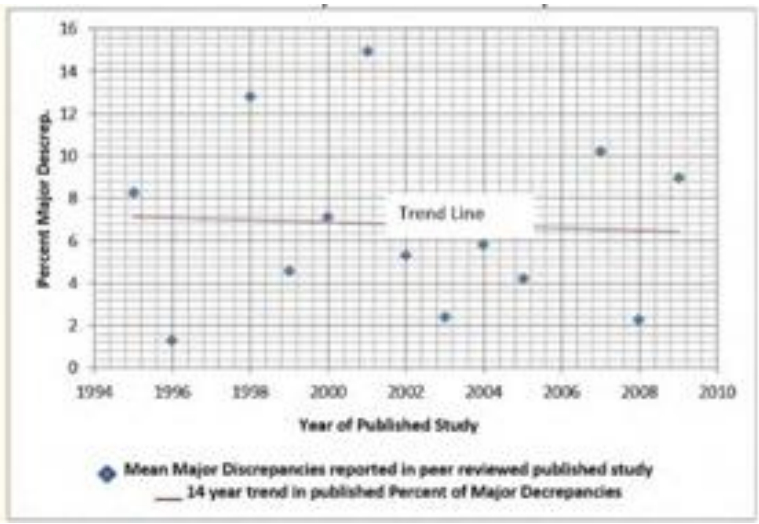

Figure1. *Major discrepancies in surgical pathology identified by year of published study [3].*

2. Marginal Quality Progress has a High Cost

Major medical institutions are focusing on quality metrics of diagnostic accuracy and publishing their results and efforts to re- duce them. The University of Pittsburgh Medical Center (UPMC) estimates the average annual treatment cost due to interpretive errors in AP costs $21,444 ($10,803-26,661) per occurrence and occur at the rate of 281 cases annually within their institution [5,6]. MD Anderson Cancer Center reported after reviewing 2,718 patient cases referred to them during September of 2011, inter- institutional review discovered, 18.7% presented with minor discrepancies and 6.2% (169 patients) with major discrepancies. The financial review of 8 major breast discrepancies identified an average cost impact of $70,000 ($18,560-$115,800) per case [5, 6].

3. Outcomes of an External, Inter-laboratories QA Program Implementation

In actual practice, implementing an external QA case review program utilizing subspecialists as reviewers, showed a significant reduction in deferral rates over time. The QA program spanned over 51 months and totaled 354 QA cases reviewed by 10 subspecialties. The longitudinal change in deferral rates started with an initial assessment rate of 10% deferrals, improving over time to 3% at the end of the 51-month study. The greatest gain in defer- ral reduction came in the first two years of program implementation and remained relatively stable for the remaining two years of the study (Figure 2) [7]. Although this example was focused on AP, vRad a Teleradiology company offering QA case review reports similar findings in their white paper, "Five Elements of an Effective Quality Assurance Program in Radiology".

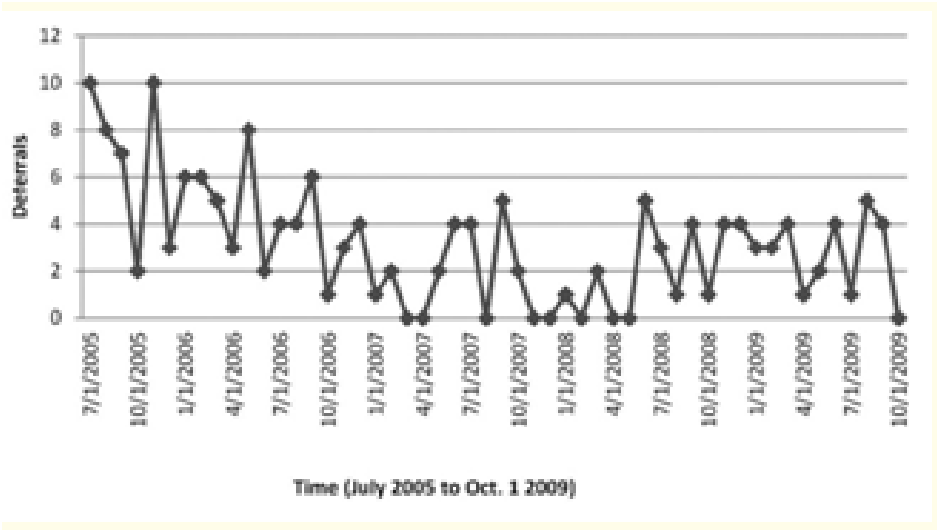

Figure2. *Overall deferral rates percent over time (1-month intervals).*

4. Cost of Readmission

Measuring 30-60-day readmission rates is a required quality metric by CMS. In a recent study on the examination of 30-day readmissions at the Ohio State University Wexner Medical Center Comprehensive Cancer Hospital, of 2,531 inpatient admissions in CMS patients over 6 months, 11% of patients experienced at least one readmission [8].

The most common causes for first readmission were new diagnoses not present at first admission (n=43, 23%), new or worsening symptoms due to cancer progression (n=40, 21%) and complications of procedures (n=25, 13%). There were 38 (21%) initial readmissions classified as potentially preventable.

The study did not attempt to propose the impact of diagnostic pathology and radiology discrepancies but did note the contributing impact of misdiagnosis [8].

When looking at the cost of read- missions, the Cleveland Clinic found that each readmission in general medical oncology costs on average $18,365 [9].

5. Methods

For most laboratories, the quality strategy is made up of multiple QA/QC programs that best fit the institutions patient-mix, staff experience and specialty status. QA programs can be Formal those that are scheduled, (volume and time) predictable and under your control; or Informal having programs that apply as QA but do not have a formal schedule, frequency or under your control (Table 3).

Table3. *QA Programs for anatomical pathology.*

Formal Quality Assurance Programs	Informal Quality Assurance Programs
Retrospective case review (intra and inter)	Autopsy
Proficiency testing	Diagnostic consult (internal or external)
Prospective case review (prior to sign-out)	Patient/Pathologist referral

For this discussion, focus will be on the formal QA programs, although the informal programs can also offer a wealth of quality information and should be tracked and documented as part of the overall quality program, the informal programs lack the ability to be fairly apply and routinely schedule. In addition, such programs only apply to known positive cases missing the opportunity for discovery in false negative cases. Although CLIA has implemented QA requirements for slide review of 10% in gyncytology, no such mandated QA exists for surgical pathology. In a CAP Q-probe (May 2012) with 73 laboratories responding, of those reporting (56), 45% of the laboratories reported using post (retrospective) sign- out case review as the means to help detect defects, followed by Don't Know 29%, Clinician Request 21% and Tumor Conference of 5% (Table 4).

In MI the ACR has implemented an internal case review program, RADPEER [18], with approximately 46% of radiologists reporting. It is unclear as to what QA programs are being practiced with the remaining pathologists and radiologists currently in practice

Table4. *Current Formal Quality Assurance Programs for AP.*

Attribue	Proficieny testing	Internal case review (retrospective)	Internal case review (prospectiv)	External peer case review by subspecialist (retrospective)
Standardized	*	-	-	*
Benchmarking	*	-	-	*
Subspecialty review	*	?	?	*
Detects false negative and positive cases	-	*	*	*
QA total process	-	*	*	*
Influence the diag. in real/ near-real-time	-	?	*	?
Does not add to the Pathologist Workload	-	-	-	*
Attribute Score	**3 of 7(43%)**	**2 of 7(29%)**	**3 of 7(43)**	**6 of 7(86%)**

Key positive feature/s	Established minimum quality tool	Most common QA practice	Real time	External subspecialist review, does not use pathologist time, eliminates bias
Negative consideration	Does not QA the full case detail from gross to report	Demanding on pathologist and tech- nologist time, limited subspecialty coverage, bias and conflict	Most demanding on pathologist and technologist time, requires a significant depth of on-site subspecialty and IT support	Program needs to be double blinded for confidentiality
Best demonstrated practice	CAP and ASCP proficiency programs	ADASP guidelines on QC and QA in AP quality assurance	UPMC	QualityStar™ external QA case review by subspecialist

6. RESULTS

6.1. Proficiency Testing (PT)

This compares a laboratory's test results using unknown specimens (usually digital images), to results from other laboratories. It is the most established QA program and should be considered the minimum requirement for AP laboratory QA. Clinical feedback and reference to subspecialists are provided and standardization allows for national benchmarking capabilities. PT programs from CAP, ASCP and others are approved by the American Board of Pathology and meet part IV requirements for Maintenance of Certification (MOC) (American Board of Pathology website for a complete listing of PT programs that are level IV compliant.

Drawbacks, adds to pathologist workload, does not offer full case review from gross to clinical report, and is not representative of pathologist or laboratory caseload. To gain the added value of a subspecialist review requires a significant volume and depth of pathology specialty.

6.2. Internal Case Review (Retrospective)

A random selection of 1% to 10% of cases, for secondary QA case review including negative cases is desired. False negative cases account for a significant percentage in litigation. The objective of peer review is to not focus on which diagnosis is right or wrong but on why the diagnoses are different. This is the most common practice today for QA case review in both pathology and radiology, allows for complete case review and represents the physician's workload. If performed prior to final sign-out, may be able to influence the diagnosis. This program can also be utilized for Maintenance of Certification (MOC) Part IV.

Table5. *Current Formal Quality Assurance Programs for MI.*

Attribute	Proficiency testing	Internal case review (retrospective)	Internal case review (prospective)	Internal private, peer case review by subspecialist (prospective/retrospective)
Standardized	*	-	-	*
Benchmarking	*	-	-	*
Subspecialty review	*	?	?	*
Detects false negative and positive cases	-	*	*	*
QA total process	-	*	*	*
Influence the diag. in real/near-real-time	-	?	*	?
Does not add to the Radiologist Workload	-	-	-	*
Attribute Score	**3 of 7(43%)**	**2 of 7(29%)**	**3 of 7(43%)**	**6 of 7(86%)**
Key positive feature/s	Established minimum quality tool	Most common QA practice	Real Time	External subspecialist review, does not use pathologist time, eliminates bias

Negative consideration	Does not QA the full case detail from image to report	Demanding on radiologist time. limited subspecialty coverage, bias and conflict	Most demanding on radiologist time	Program needs to be double blinded for confidentiality
Best demonstrated practice	ACR proficiency programs	RADPEER ACR	Diagnostic Imaging, McMaster University, Hamilton Health Sciences, CA [17]	red Quality Assurance MEDNAX Company

Best example in MI can be found with RADPEER offered as a QA tool by the ACR and required for ACR accreditation. Cases are randomly selected for peer review and scored using a four-point scale then reviewed by administration and forwarded electronically to the ACR database [18].

Drawbacks, it cannot identify on-site biases and avoid personnel conflicts as cases are re-read by on-site staff. In AP it is not standardized, so benchmarking is difficult between institutions. Most laboratories also lack true peer review from sub-specialists in all tissue types or specialty and it adds to the physician's workload.

6.3. Internal Case Review (Prospective)

Case reviews like above but performed prior to sign-out in real time to allow findings to influence the final diagnosis and add additional comments that may contribute to enhance patient care. An elegant example was presented by the UPMC in AP [13]. The presentation demonstrated similar error rates pre- and post-sign- out with no effect on case turnaround time. Can be used for MOC Part IV.

Drawbacks, programs like this for AP and MI require a significant depth of staff with subspecialty, software and development support that is not found in most hospitals. As the program is not standardized, it is difficult to receive the benefits of benchmarking with similar programs nationally. It is also subjected to on-site biases and personnel conflicts and has the highest application of physician time.

6.4. External (Peer) Case Review by Sub-Specialist (Retrospective)

This is a comprehensive AP/QA program that is built around case review outside the institution (inter-laboratory) as a new level, next generation of quality intelligence. It offers a significant enhancement (5X) in the ability to provide quality feedback for guidance and continuous improvement [2]. If performed prior to final sign-out, may be able to influence the diagnosis. Two characteristics stand out when comparing the sensitivity of error detection between intra- and inter- laboratory case review: 1. the difference in the ability to gain incremental case scrutiny by using subspecialists for review (when compared to using generalist pathologists) and 2. The difference in moving the review outside the institution to reduce on-site bias and feedback confrontation.

In this program, cases can be submitted via glass slides or digital images (Cases are de-identified prior to submission and cases with digital images are uploaded to a secure cloud). Academic medical centers which are also National Cancer Institute (NCI) sites provide blinded subspecialist case review. The benefit is a standardized program that allows benchmarking at an increased level of granularity without adding to the pathologist's workload. The program is also ABP approved for MOC part IV and is the only Patient Safety Organization (PSO) recognized by the Agency for Healthcare Research and Quality (AHRQ).

Drawbacks, requires additional effort to blind each case prior to submission and uploading of multiple WSI images takes time and may need to be coordinated within the laboratory. Laboratories without digital imaging are required to mail case slides to a secure confidential site for digitizing.

6.5. Integrated Pathology/Radiology Case Review, Way of Future QA Case Review?

With the understanding that 46% of diagnostic errors in cancer comes from pathology/radiology, it is easy to understand the IOM's focus on these two medical specialties for quality improvement. It is encouraging to see pathologists and radiologists take the initiative on working to establish a correlation between histological

diagnosis and the image findings. In one study, working together in case conferencing affected decision-making in 34% of cases and 16% had a major impact on the clinical decision patient follow-up and recommended by the IOM and CAP [21, 22]. Organizations are working to take advantage of this enhanced level of review to combine the imaging of radiology and pathology in one format for review by sub-specialists. The objective is to share the value of such expanded reviews to the benefit of the patient and AP/MI continuous improvement. [23, 24].

7. DISCUSSION

The strongest impact for reducing interpretive diagnostic error in AP and MI would be to truly transform QA for better patient outcomes. The data supports external peer review, by subspecialty, close to sign-out, as the primary benchmark for measuring diagnostic accuracy for improved quality. The combination of AP with MI in the quality process may additionally enhance the value of case review programs. However, most QA programs lack one or all of these attributes. To make a meaningful change in quality, the bar needs to be raised on quality metrics and challenge a 1% improvement over 15+ years as acceptable.

Figure3. *Proficiency.*

It is very difficult for pathologists and radiologists alike to stay current in all organ systems and cancer types. As with all disciplines, frequency of interactions builds confidence and skills, and helps keep practitioners current with evolving diagnostic tools. Lacking case volume, a good external case review QA program can help benchmark performance and identify areas of both improvement and excellence. Having subspecialists on-site is rare in the average hospital setting, and having multiple subspecialists to provide QA peer review is extremely rare. Laboratories should feel comfortable in going outside of their institution to seek bench- marking and learning opportunities. In MI mammography readings by subspecialists were found to identify 34-75% more cancers in early stage, drastically impacting survival rates and overall costs of care [15, 16].

Quality intelligence cannot impact current interpretive diagnosis behavior however. In itself, quality intelligence has no value unless it is reviewed, presumptive corrective action implemented, follow-up monitoring provides confirmation of improvement and surveillance monitors the adoption of the corrective action. A good review of managing the process can also be found in publication [14].

Diagnostic accuracy is often claimed, but less often measured. If diagnostic accuracy is not measured, then accuracy is unknown. Today, a broader, next-generation quality measurement is voluntary-but nearing compulsory. Treat quality intelligence with confidentiality and re-establish best practices to raise the bar for diagnostic accuracy and better patient care. The original laboratory or department is in the best position to;

- Determine whether a discordant diagnosis has already been identified through other quality or clinical review mechanisms.
- To assess whether a clinical follow-up is needed, and whether an opportunity exists for improved care for a particular patient.
- Set the goals for best practices. Knowing the clinically meaningful diagnostic discordance frequency of the laboratory or pathologist/radiologist and department gives the ability to accept the current quality metric or establish a new goal of quality improvement

- Implement corrective action in the form of training, policies and/or procedures.
- Establish longitudinal tracking with external benchmark- ing of related cases to measure effectiveness and tuning needs of the corrective action process.

As professionals in the healthcare system, focusing on quality is imperative. The facts that this article is being read is attestation that healthcare professional do not enter the healthcare field to simply maintain status quo. When thinking about the programs reviewed in this article, each professional will make contributions to quality initiatives. The goal is to build quality tool set with the most effective and cost saving programs that will most rapidly close the gap on diagnostic errors in AP. Taking out 5% of diagnostic error by moving the major diagnostic discrepancy rate from 7-8% to 2% can impact 80,000 patients and save $1.7 billion annually in healthcare costs. With all the responsibilities of healthcare professions, certainly taking action to close this gap is worthy of attention.

This review generated additional questions that future studies may address. Is the value of outside review from the reduction of internal bias or from expertise usually found in outside review do to volume? How much did the digitizing in PACS support the acceptance and adoption of radiology case review and should pathology expect to see the same adoption now that whole slide digital imaging is recently approved for diagnosis?

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