Syllabus

The most important component in a successful quality assurance and improvement program is a commitment to the quality principle of continuous quality improvement. This is heavily dependent on a department’s ability to collect data without bias and be able to trust the data sufficiently to make changes. Quality assurance and improvement has its edges and some of its core elements imperceptibly intertwined with laboratory management. This is best demonstrated by understanding the cycle of Plan-Do-Study-Act which is emblematic of QA. Traditional QA programs represent the “Study” aspect of this cycle. To make improvements, successful QA programs repeatedly use the entire cycle of “Plan-Do-Study-Act”. As such, the director of quality assurance and the director of the laboratory need to be on the same page, since QA data is likely to drive a good number of management decisions.

Inherent in the QA cycle is the ability to critically analyze processes and redesign them with policies and procedures that reduce errors. In this continuous assessment and redesign, quality checks must be built into processes so that if errors occur they are detected at the earliest possible point. Adopting these principles also addresses patient safety. Simply defined patient safety may be defined as “freedom from accidental injury” but Joint Commission requirements have expanded that definition to “ensuring patient safety involves the establishment of operational systems and processes that minimize the likelihood of errors and maximize the likelihood of intercepting them when they occur.”

The traditional role of quality assurance may be defined as the function of measuring the quality of a laboratory. In regards to anatomic pathology, a quality product is best defined as an accurate, complete and timely report. Therefore, quality assurance programs must measure report accuracy, completeness and timeliness. The core components of quality assurance and improvement should include active monitors in all the disciplines within anatomic pathology, i.e. surgical pathology, cytopathology, autopsy pathology as well as any number of specialty diagnostic laboratories, among them; electron microscopy, immunohistochemistry, immunofluorescence, and molecular testing.

The existence of a QA program is mandated by the Laboratory Accreditation Program’s standards ANP.10000; “Is the quality management program defined and documented for surgical pathology?” and GEN.13806; “Does the laboratory have a documented quality management (QM) program?” Defining a quality management program is best done in a quality management plan that includes:
1. A quality assurance committee with a clear charge,
2. An assessment of the risks facing the laboratories.
3. Individuals responsible for the various monitors of the plan,
4. A list of study monitors that address laboratory risk with a time table for evaluation and discussion of the results.
5. Inclusion of monitors that cover the entire test cycle (pre-analytic, analytic, post-analytic), turn-around times and customer satisfaction.
6. Defined working relationships with other departmental and institutional QA and other committees.
7. Annual review of the plan.

Selection of study monitors is dependent on multiple factors including:
1. Laboratory accreditation requirements.
2. Institutional accreditation requirements
3. Prevalent and persistent problems
4. Satisfying institutional concerns
5. Resources

Numerous monitors are mandated for accreditation; for example CLIA-88 mandates the majority of the QA monitors in cytopathology. The CAP’s LAP mandates that monitors cover the pre and post-analytic phases of the test cycle. A number of standards also mandate a specific turn-around time for specimens including frozen section results, surgical specimens, autopsy reports and cytology.

Occasionally, there are monitors that satisfy multiple factors. A good example is specimen identification. The Joint Commission has placed heavy emphasis on patient identification which includes specimen identification. This is an opportunity to address a pre-analytic problem that is prevalent and persistent and has become an institutional accreditation concern. Addressing specimen identification also requires working with other departments and enhances better integration of pathology QA activity with other departments.

The LAP standard GEN.20368 states “Have referring physicians' or patients' satisfaction with laboratory service been measured within the past 2 years?” Customer satisfaction surveys are central in the determination of quality of most products in a host of industries. In some instances it is the only determinant of quality. In pathology it is a relatively new tool, although, many pathologists know too well the importance of clinician’s happiness with pathology reports and services. Surveys are particularly helpful when changes or new services are introduced.

Most important in selecting monitors is the choice of an analytic monitor and the method for determining an error rate. Nearly all laboratories monitor frozen section – permanent section discrepancies as well as cytology – histology discrepancies. However, there is no agreement on the best method for determining diagnostic error of the final diagnosis. Follow up is the ultimate judge of diagnostic error, but this is impractical as a QA monitor. By default, peer review has become the standard for judging diagnostic error. But there is no agreement on the best method to review cases. There is also no evidence to demonstrate that one type of review is superior to others. It is difficult to estimate the actual diagnostic error rate without expert second review of all of the cases. This is, however, impractical and time consuming and is only performed in a few laboratories. Most laboratories use multiple methods of directed case reviews such as review of cases for conferences. Many use amended reports for revised diagnosis as a surrogate measure of diagnostic error.

One important aspect of monitors is to set a reasonable range for results while at the same time try to drive improvement. Expectation for QA results should be set by examination of
benchmarks that may be available in the literature. In using published benchmarks, pathologist should be careful to use the same measurement methods.

Multiple new aspects of quality assurance are being introduced and mandated by accrediting agencies including;
1. Proficiency testing in anatomic pathology (cytology, HER2),
2. Maintenance of certification,
3. Emphasis on actual improvement,
4. Emphasis on extra-departmental communication
5. Patient safety and error prevention

In the short term, this has increased the interest in QA programs. In the long term, it is unclear how these new demands will impact the practice of pathology. It is clear that tolerance for the status quo is diminishing as more and more groups and institutions demand improvement.

Reference:

3. The College of American Pathologists’ Laboratory Accreditation Program Laboratory general and anatomic pathology section http://www.cap.org/apps/docs/laboratory_accreditation/checklists/laboratory_general_sep07.doc (accessed 11/20/08)
Core Components of a Comprehensive Quality Assurance Program in Anatomic Pathology

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Disclosure

• None
Learning Objectives

• Address basic concepts of quality and patient safety
• Present the core components of a traditional QA plan
• List the test cycle segments and global measures that should be monitored in a QA program
• Understand new points of emphasis in quality assurance
Agenda

• Overview
• Core components
• QA monitors
• Points of emphasis
Overview

• Quality assurance program
  – A system to monitor the quality of complex processes

• Quality in Anatomic Pathology
  – Accurate diagnosis
  – Complete report
  – Timely delivery
Overview

• Quality management
  – Integration of quality principles into the core values and philosophy of an institution
  – Integration of quality principles and quality monitors into the design of processes
Overview

• Patient safety
  – Renewed focus with JC and CAP goals
  – Addressed within the QA program

• Definition: Freedom from accidental injury; ensuring patient safety involves the establishment of operational systems and processes that minimize the likelihood of errors and maximize the likelihood of intercepting them when they occur.
Quality by Design

• Commitment to quality principles
  – Continuous quality improvement
  – A Systems approach
• Critically analyzing processes and redesigning them to reduce errors
• Build quality checks into processes so that errors are detected at the earliest possible point
Core Components

• Quality Management Plan
  – Quality assurance committee with a clear charge
  – Individual responsibility
  – Risk assessment
  – Monitors with a time table for reporting
  – Relationship to other institutional Quality Programs
  – Patient safety
  – Annual review
Risk

- The Doctors Company
- 166 (61%) false negative
- 73 (27%) false positive
- 10 (4%) frozen section
- 22 (8%) operational
  - 13 mix-ups
  - 3 floaters
  - 2 mislabeled biopsy site
  - One transcription error, “no” omitted before malignant cells
Core Components

• Address all disciplines
  – Surgical pathology
  – Cytology
  – Autopsy

• Address all laboratories
  – Gross room
  – Histology
  – Immunohistochemistry
  – Molecular
  – Electron microscopy
QA Monitors

- Pre-analytic
- Analytic
- Post-analytic
- Turnaround time
- Customer satisfaction
Factors in Selecting Monitors

• Laboratory accreditation requirements
  – CLIA-88, LAP
• Institutional accreditation requirements
  – JC Patient safety goals
• Prevalent and persistent problems
  – Specimen identification
• Satisfying institutional concerns
• Resources
Pre-analytic

- Specimen identification
- Specimen collection
- Specimen labeling
- Specimen fixation
- Specimen transport
- Accessioning
Analytic

• Grossing
• Sectioning and Block labeling
• Tissue processing
• Embedding
• Cutting and slide labeling
• Microscopic interpretation
• Special stains
• Immunostains and other ancillary testing
Analytic

- Frozen section – permanent section correlation
- Cytology – histologic correlation
- Final diagnostic errors
  – amended reports
Post-Analytic

- Communication of significant diagnoses
- Gross and microscopic dictation
- Transcription
- Verification and finalization
- Report completeness
- Report delivery (electronic and paper)
- Comprehension
Turnaround Time

• Frozen section
• Small biopsies
• Large resections
• Autopsy: GAD, FAD
• Cytology: GYN, non-GYN

• Receipt of specimen to report delivery
Customer Satisfaction

- Overall satisfaction
- Diagnostic accuracy
- Frozen section timeliness and accuracy
- Report timeliness
- Report completeness
- Pathologist availability
- Recent changes
Customer or Clinician Satisfaction

- Opportunity to monitor and manage expectations
- Opportunity to understand institutional concerns
- Opportunity to inform and educate
- Opportunity to integrate and be recognized more fully as a service within the larger institution
Measuring Quality

- Benchmark
  - Performance standard most commonly determined by literature

- Trending
  - Performance of laboratory over time
Points of Emphasis

- Proficiency testing
  - HER2
  - Cytology
- MOC?
- Emphasis on continuous improvement
- Emphasis on extra-departmental communication
- Emphasis on patient safety and error prevention
Summary

• Tried to demonstrate the need to integrate quality and patient safety principles into every day processes
• Brief overview of the core components of a comprehensive quality assurance program
• Need to demonstrate improvement
Questions?
Thank you for participating!

Please be sure to complete the course evaluation online after the conference.