

Introduction

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Quality Management in Anatomic Pathology: Promoting Patient Safety Through Systems Improvement and Error Reduction has been produced by the College of American Pathologists (CAP) to provide pathologists with a framework for a complete and organized approach to quality improvement in the anatomic pathology laboratory. This new text is based on the CAP's *Quality Improvement Manual in Anatomic Pathology*, which was originally published in 1988 and has served as a valuable resource for pathologists throughout the world.

Since the last *QI Manual* was published in 2002, there has been increased public pressure to continuously assure patient safety and reduce medical errors. This text provides more detailed analyses of error reduction strategies in anatomic pathology and includes guidelines and quality assurance and improvement monitors for areas not previously discussed, including immuno-histochemical and molecular pathology laboratories. There is also a more extensive discussion of issues related to histology laboratories.

Quality Management in Anatomic Pathology maintains the structure and organization of the previous manuals. Our goals are to review error reduction strategies that have been well established in other industries, discuss how some of these strategies may be applied to the anatomic laboratory, and provide valuable benchmark data that can be incorporated into routine quality monitors.

In keeping with the earlier CAP publications, this text provides pathologists with the tools necessary to develop and maintain a comprehensive quality improvement plan for anatomic pathology. Since the scope of pathology practice varies widely, the manual includes many different types of recommendations, not all of which are necessary for each laboratory. Although an attempt was made to be as complete as possible, new approaches or modifications of existing approaches to quality improvement continue to be tested and implemented. Consequently, not every discussion presented here is necessary for every lab, and no single plan should be considered comprehensive or definitive for all labs.

Historical perspective

The clinical laboratory, with its focus on accuracy and precision of analytic procedures, developed and implemented effective quality control measures earlier than anatomic pathology. Anatomic pathology as a specialty developed in the patient care setting, with an emphasis on clinical correlation, interpretation, and differential diagnosis. These activities lagged in traditional quality control testing. Quality assurance was brought into focus in this country during the 1980s when American manufacturers realized the quality gap between their products and those of Japanese producers. Prior to this, quality assurance was primarily the domain of industries with the potential for major disasters (eg, aviation). By many measures, the health care industry as a whole has only recently begun to adopt concepts of quality improvement and deal effectively with medical error. This is highlighted in the Institute of Medicine report on medical error,¹ which has stimulated greater focus on quality improvement, error reduction, and patient safety.

Traditionally, the analysis of quality has been divided into three levels: quality control, quality assurance, and quality improvement.

Quality control activities evaluate the uniformity of specific processes and basic functions to assure that they are operating within acceptable parameters. These processes include the ways in which laboratories accession, process, interpret, report, and retain submitted specimens. Quality control monitors are typically designed to compare the actual performance of the process with the process set forth in the departmental procedure manual. Examples of quality control activities in the anatomic pathology laboratory include such things as:

- Routine checking of instruments
- Maintaining temperature logs of water baths and cryostats
- Controls for special stains
- Maintaining procedures for obtaining specimens
- Determining the quality of sectioning and staining

Quality assurance, a term used to indicate a system designed with internal quality checks, encompasses a higher level of oversight and relies upon the collection of outcome data. Typically, these outcomes encompass multiple processes or procedures. These activities often monitor such things as report timeliness or diagnostic error rates. Examples of quality assurance monitors in anatomic pathology include:

- Frozen section accuracy
- Frozen section turnaround time
- Rate of specimen identification errors
- Diagnostic accuracy
- Completeness of information for tumor staging (eg, tumor size, status of surgical margins) included in the report.

Quality improvement activities seek to improve outcomes such as those listed above. Thus, a department's quality improvement goals might include such things as *reducing* diagnostic error rates, *shortening* turnaround time, and *improving* customer satisfaction. Quality improvement activities use quality assurance monitors to determine the effectiveness of an intervention. Typical steps in this process include:

1. Identify an indicator or process to improve.
2. Measure current level of performance for that process.
3. Determine target or desirable level of performance for that process.
4. Design and implement an intervention.
5. Re-evaluate level of performance for that process.
6. Repeat steps, as necessary, to achieve desired level of performance.

Focus on patient care

Pathology is not considered a primary care specialty, but is directly involved in patient care by helping to provide information that is essential for evaluation and management. Since many pathologists interact with patients infrequently, it can be easy to forget that the primary purpose of developing a quality improvement plan is to improve patient care. Regardless of the size or scope of a pathology practice, the primary goal of these activities must be to improve patient care.

The systems approach to quality improvement

The basis of a systems approach lies in accepting that most errors occur due to poor system design and not the individual working within that system. Mistakes are unintended human actions, and the natural response is to blame the individual for his or her action or inaction. Many of these errors are thought to be due to “latent system errors.” Latent system errors are inadequacies of a system that are not manifested when a system is designed, but which ultimately result in errors or mistakes. Examples of latent system errors include inadequate staffing for a particular task or job, defective equipment, ineffective communication, and poor training. Many systems operate reasonably well until stresses are placed on the system. Those stresses may come in the form of more work than anticipated, unexpected absences, or unfamiliar situations, and increase the chance that employees, in their diligence to keep up with the work, will make mistakes.

While human fallibility can be mitigated with knowledge and training, most experts agree that this approach must be accompanied by system enhancements and modifications. Furthermore, focusing on individuals through blame and shame for having made mistakes is frequently counterproductive and can damage morale and trust, factors necessary for team-building and an effective workplace. Education and training in all areas, including error reduction strategies, must be conducted in a healthy nonpunitive environment. Effective error reduction must encompass critical analysis of the systems involved, with system redesign and enhancements encompassing proven techniques, as discussed in chapter 4.

While the essence of anatomic pathology remains tissue diagnosis, enhancements in obtaining, processing, and examining tissues, and in formatting and delivery of diagnostic reports have improved the overall quality of pathology practice. Pathologists should embrace system enhancements that reduce errors, increase efficiency, reduce costs, improve accuracy, and improve timeliness and completeness. The introduction and acceptance of synoptic reports is one example of a successful system enhancement that can improve patient care by reducing the chance of error. The evolution of information technologies has begun to transform many aspects of pathology and will likely drive further changes in our field. Pathologists should continuously strive to adopt such enhancements when they improve patient care.

Developing a quality program

Quality improvement activities consume a significant amount of laboratory resources. Developing and implementing an annual quality improvement plan requires coordinating the desired goals with the resources needed to carry it out. Since resources are often limited, quality improvement activities for any given year must be selected prudently. Just as a plan that is too limited to identify significant problems would be inadequate, attempting to accomplish too much can also result in incomplete or inadequate information.

Too often, quality assurance programs are thought of as isolated activities assigned to select individuals. In this view, quality assurance is often considered only as the quality assurance meeting is approaching and selected data have to be collected and presented. Ideally, quality assurance and improvement are incorporated into the overall mission of the department and are everyone’s responsibility. Every individual in the department should be convinced that maintaining quality at each step leads to the best possible outcome.

In this manual, we have attempted to cover the areas traditionally considered quality improvement activities, namely, ongoing checks or monitors of systems and processes. However, one must

remember that many individual elements are necessary for a quality program in anatomic pathology. A quality program requires competent and informed people at each level, continuous education, uniform methodology, uniform criteria and application of criteria where interpretation is necessary, orderly work flow, accommodating systems that assure tasks are easily and fully completed, ongoing checks or monitors of systems, regulatory compliance, and, finally, a product that meets the needs of customers. As such, quality assurance needs to be integrated into the normal daily workflow of the laboratory and should be considered part of everyone's job. Along with other responsibilities, written job descriptions should include a description of specific quality assurance responsibilities, and completion of these activities should be part of employment evaluations. This integration provides greater efficiency and makes quality improvement an integral part of the laboratory.

Reference

1. Kohn LT, Corrigan JM, Donaldson MS, eds. *To Err Is Human: Building a Safer Health System*. Washington DC: National Academy Press; 2000.