

ADASP Recommendation for Quality Assurance and Improvement in Surgical and Autopsy Pathology

Introduction

The Association of Directors of Anatomic and Surgical Pathology (ADASP, www.adasp.org), which was founded in 1989, first published recommendations for anatomic pathology quality control and quality assurance in 1991². This paper emphasized surgical pathology and autopsy pathology quality issues and did not address cytopathology or specialized anatomic pathology laboratories such as immunohistochemistry or electron microscopy.

In the decade and a half since the original ADASP recommendations, the emphasis on quality improvement has grown tremendously, and a variety of contributions to this area of anatomic pathology have been made by ADASP, The College of American Pathologists (CAP), and single institutional studies^{1-3, 5-13, 15-18}. The 1999 Institute of Medicine Report, *To Err is Human: Building a Safer Health System*, further focused attention on medical errors and patient safety and also offered specific recommendations for improvement⁴.

The current publication updates and refines the 1991 ADASP recommendations for surgical and autopsy pathology. As in the original paper, these recommendations take into consideration the structure, responsibilities, and needs of academic anatomic pathology laboratories that have an active residency or fellowship. These recommendations can be modified according to specific institutional circumstances and needs.

1. **Quality Assurance and Improvement Plan^{2,7}**: An annual plan should be created with the intent of monitoring quality, but also targeting specific aim(s) each year for improvement.
 - a. Quality assurance in surgical pathology is defined as a program for the systematic monitoring and evaluation of the various aspects of the laboratory service to ensure that standards of quality are being met.
 - b. Quality improvement in surgical pathology is defined as a systematic attempt to improve specific quality measures in laboratory service.

2. **QI Committee^{2,7}**: A quality improvement committee should be formed including most of the anatomic/surgical and autopsy pathologists, selected residents or fellows and sufficient support staff including key laboratory and clerical staff. The committee members should have clear responsibilities. Regular meetings should be held to review QI data and to discuss possible changes in QI plan or changes in practice.

3. **Test Cycle³**: Analytic diagnostic errors have been the focus of most studies, however, errors with possible patient consequences occur with equal frequency in the pre-analytic and post-analytic phases of the test cycle and should be addressed with equal effort.

4. **QA&I Monitors⁷**: A QA&I plan should have at least one component in each of 5 sections listed below, but could be more. Typically, more than one analytic monitor is performed annually. It is not necessary to run QA monitors all the time. If a monitor is running at a satisfactory level, it may be spot checked for a small period of time annually or biannually. Then resources may be directed to areas in need of improvement.
 - a. Pre-analytic
 - i. Specimen fixation
 - ii. Specimen delivery
 - iii. Specimen identification
 - iv. Adequacy of clinical history
 - v. Accessioning errors
 - b. Analytic
 - i. Intra-operative
 1. Frozen section – permanent section concordance
 - ii. Final diagnosis
 1. Peer review error rate
 - iii. Possible histology monitors
 1. Quality of histologic sections
 2. Specimens lost in processing
 3. Histology TAT
 4. Block labeling

- 5. Slide labeling
 - 6. Extraneous tissue
 - iv. Immunohistochemistry
 - 1. Frequency and causes of repeat stains
 - 2. Immunohistochemistry TAT
 - 3. Report audit for integration of stains with morphologic diagnosis
 - 4. Annual review of antibody inventory and frequency of use
 - 5. Enrolment in external proficiency testing should be considered particularly for tests that directly impact patient therapy such as Her2/neu immunostaining.
 - v. Other ancillary study monitors may be used as needed, include monitors for FISH, EM, other molecular studies.
 - c. Post-analytic
 - i. Transcription errors
 - ii. Verification errors
 - iii. Report delivery errors
 - iv. Incomplete reports
 - v. Diagnostic finding correlation with ancillary studies (IHC, EM, FISH)
 - d. Turn-around-time (TAT)
 - i. Frozen section
 - ii. Biopsy
 - iii. Large specimen
 - iv. Preliminary and final autopsy reports
 - e. Clinician satisfaction and/or complaints
5. **Quality assurance case reviews**^{1,2,5-8,10-12,15,16}: No single method of case reviews has been shown to be more effective in detection of errors. As a preventative measure many departments mandate prospective review of selective cases prior to case verification. Depending on departmental resources, a number of methods may serve as quality assurance case reviews including;
- a. Review of a randomly selected % of cases (past recommendations have used 1%, 2%, 5%, 10%, depending on the size of practice and available staff time to conduct reviews)
 - b. Focused internal second review of specific organ system or malignancy type (e.g. breast Cancer)
 - c. Interdepartmental conferences (e.g. tumor board)
 - d. Intradepartmental quality assurance conference
 - e. Frozen section/permanent section correlation
 - f. Cytology/surgical pathology correlation
 - g. Review of previous pathology material
 - h. Intradepartmental review of material prior to release to other institutions.
 - i. Review of outside diagnosis of in-house cases

6. **The gold standard⁷**: The only true gold standard for diagnoses is long-term follow up and response to therapy. This however is impractical. Peer review has become the gold standard to judge diagnostic “correctness” in surgical pathology. There are acceptable ways of adjudicating errors and diagnostic disagreements, e.g. external consultation.

7. **Defining error types and quantification of effect on patient^{2,3,7,11,12,17}**
 - a. Error types
 - i. Change in categorical interpretation (e.g. benign to malignant, malignant to benign)
 1. False positive
 2. False negative
 - ii. Change within the same category of interpretation (change in type of malignancy)
 - iii. Change in threshold (in the past this has referred to differences of opinion such as ADH vs. DCIS: This may also be used for differences in grading and staging)
 - iv. Change in margin status
 - v. Change in lymph node status
 - vi. Change in information unrelated to the diagnosis
 - vii. Case or patient misidentification
 - viii. Site misidentification (right vs. left)
 - b. Effect on patient; many institutions choose to include some type of grading scheme to determine what harm or potential harm may result from an error. Consideration should be given to communicating to risk management any error that has significant harm or impact on patient care.
 - i. No harm or impact on patient care
 - ii. Slight harm or impact on patient care
 - iii. Significant harm or alteration of clinical management

8. **Error correction^{7,8}**: When an error is identified, this information must be directly and promptly communicated to the patient’s caregiver. Because of the presence of an already erroneous report, newly distributed reports must be carefully marked with language that establishes the changes. Most changes fall into 3 categories.
 - a. Change in diagnosis; some have used the terms amended or revised reports to indicate these changes.
 - b. Change of information other than the diagnosis; some have used the term corrected report for this change.
 - c. Additional information, no changes to original report: most have used the term addendum report for this change.

9. **Acceptable error rates^{1-3,5-13,15-18}**: While errors causing patient harm are unfortunate, there must be acknowledgement that a certain error rate is prevalent. Error levels that may be deemed within an acceptable range should

be determined based on the literature for that measure, with the goal of modification by continuous improvement.

10. **Acceptable TAT^{7,18}**: This should be determined based on current literature, keeping in mind that acceptable TAT's are also defined by accrediting bodies. TAT's are variable depending on case complexity as well as other factors such as the presence of a residency training program. These standards may change over time with the advent of new technologies or other factors.
11. **Sentinel event^{2,7}**: It is recommended that incidents in which there is significant patient harm or there is significant breach of known policies and procedures be fully investigated, reviewed and possible changes in policy or procedure be made to address the problem. This should also be referred to the institutional QI committee and risk management.
12. **Pathologist Competence¹⁴**: JCAHO standards state that “at the time of renewal of privileges, the organized medical staff evaluates individuals for their continued ability to provide quality care, treatment, and services for the privileges requested as defined in the medical staff bylaws.” Therefore, pathologists may be required to document evidence of acceptable performance. This may be done by collecting individual performance data on multiple parameters and always submitting these data in the context of peer group comparison. These data may include but are not limited to TAT, diagnostic error rates, clinician complaints, or satisfaction.

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