
بسم الله الرحمن الرحيم

Quality Control Of Surgical Pathology Services

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Outline

- Definition of Quality Assurance, Quality Control, and Quality Improvement
- Phases of Quality Control
- Approach to Quality Control in Surgical Pathology
- Standardization of Surgical Pathology Reports
- Incorporation of IHC Results into a Pathology Report

Definition of Quality Assurance, Quality Control, and Quality Improvement

- Quality assurance in pathology and laboratory medicine is the practice of assessing performance in all steps of the laboratory testing cycle including pre-analytic, analytic, and post-analytic phases to promote excellent outcomes in medical care.

- **Quality control is an integral component of quality assurance and is the aggregate of processes and techniques to detect, reduce, and correct deficiencies in an analytical process.**

- **Quality improvement is the practice of continuously assessing and adjusting performance using statistically and scientifically accepted procedures.**

Phases of Quality Control

Pre-analytic phase
Analytic phase
Post analytic phase

Turn around times

A. Pre-analytic Phase:

1. Specimen fixation
2. Specimen delivery
3. Specimen identification
4. Adequacy of clinical history
5. Accessioning errors

B. Analytic Phase:

1. Intra-operative frozen section
2. Frozen section – permanent section concordance
3. Final diagnosis
4. Peer review error rate
5. Quality of histologic sections
6. Specimens lost in processing
7. Histology turn around time (TAT)
8. Block labeling
9. Slide labeling
10. Extraneous tissue
11. Immunohistochemistry

Analytic Phase (cont.):

12. Frequency and causes of repeat IHC stains
13. Immunohistochemistry TAT
14. Integration of IHC stains with morphologic diagnosis
15. Annual review of antibody supply and frequency of use
16. Enrolment in external proficiency testing should be considered particularly for tests that directly impact patient therapy such as Her2/neu immunostaining.
17. Other ancillary study monitors may be used as needed, include monitors for FISH, EM, other molecular studies.

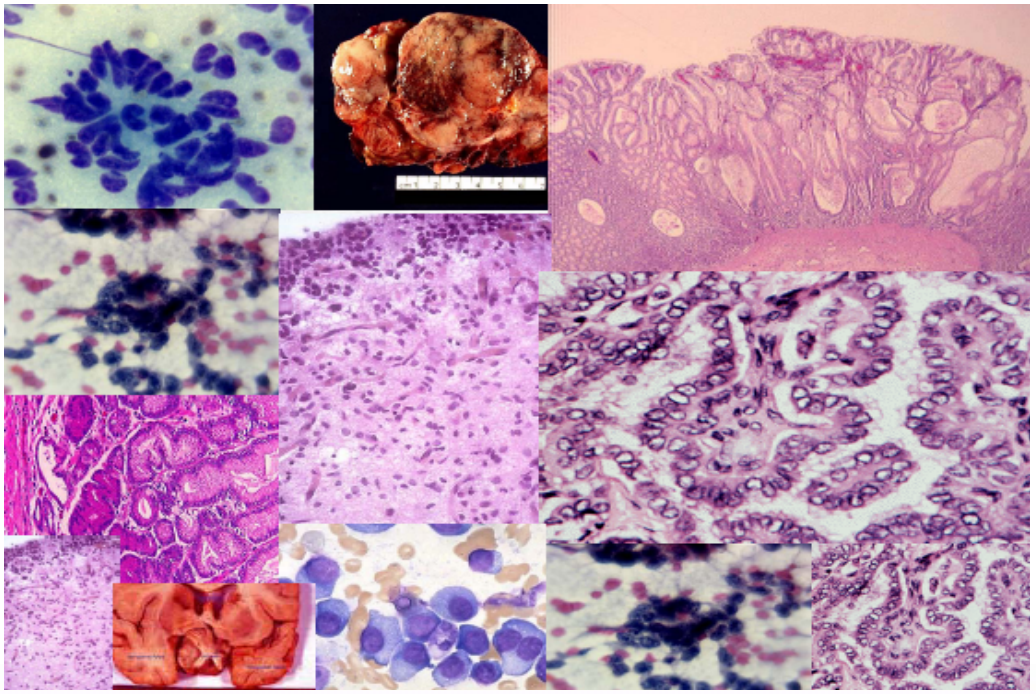
C. Post-analytic Phase :

1. Transcription errors
2. Verification errors
3. Report delivery errors
4. Incomplete reports
5. Diagnostic finding correlation with ancillary studies (IHC, EM, FISH)

D. Turn Around Times (TAT) For:

1. Frozen section
2. Biopsy
3. Large specimen
4. Preliminary and final autopsy reports

Approach to Quality Control in Surgical Pathology



Approach to Quality Control in Surgical Pathology

Intradepartmental Consultation

Intraoperative Consultation

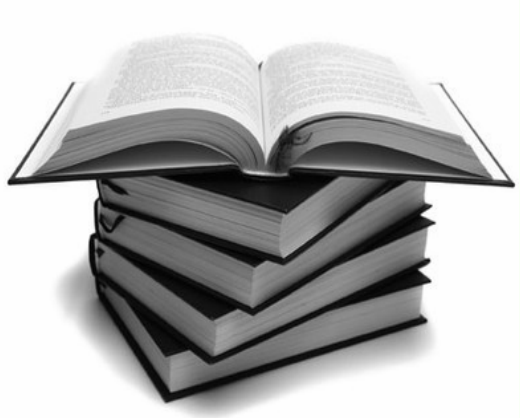
Random Case Review

Clinical Indicators

Intra- and Interdepartmental Conferences

Pathology Turn around Times

Specimen Adequacy and Histology QC



A. Intradepartmental Consultation:

This function is to be carried out through one or both of the following mechanisms:

1 . Review of selected cases by the diagnostic staff as a group, either through a periodic session ("consensus conference") or a written consultation form.

The fact that this exercise has taken place should be indicated in the pathology report.

2. Review of selected cases by a second staff pathologist ("consultant"). For those cases in which the entire case is evaluated by the consultant, it is recommended that both pathologists sign the report; for cases in which only a portion of the cases has been reviewed, it is recommended that a note to that effect be added to the report.

B. Intraoperative Consultation:

It is recommended that all cases in which an intraoperative consultation has been carried out be reviewed on a regular (i.e., weekly) basis and be placed according to their final disposition in one of the following categories:

1. Agreement
2. Deferral - Appropriate
3. Deferral - Inappropriate
4. Disagreement - Minor
5. Disagreement - Major

For all cases in the " Disagreement -- Major" and "Deferral - Inappropriate" categories, it is recommended that the reason for this occurrence be categorized as one of the following:

1 . Interpretation

2. Block sampling

3. Specimen sampling

4. Technical inadequacy

5. Lack of essential clinical or pathologic data

6. Other (indicate)

It is further recommended that the medical consequence of the cases included in the "Disagreement-Major" or "Deferral-Inappropriate" categories be listed as one of the following:

1. None
2. Minor/questionable
3. Major

An acceptable accuracy threshold for intraoperative consultations (as measured by the number of "Disagreement Major" cases and determined per case) is 3% ; an acceptable threshold for "Deferred-Inappropriate" cases is 10%.

C. Random Case Review:

It is recommended that the following cases be reviewed on a random basis:

- Surgical Pathology: 1% or 25/month, whichever is larger
- Autopsy: 10% or two/month, whichever is larger

The review on the randomly selected cases should include all material related to them, including final report, microscopic slides, turnaround time, and special procedures, if any.

D. Clinical Indicators:

It is recommended that a clinical indicator be selected on a regular basis on the basis of organ/ lesion (i.e., carcinoma of endometrium) or procedure (i.e.. TUR), and that all cases belonging to that indicator in a given period be evaluated by checking them against a list of predetermined criteria. This activity should be rotated among surgical pathology and autopsy cases.

E. Intra- and Interdepartmental Conferences:

For all cases presented at intra- and interdepartmental conferences, it is recommended that the diagnosis as listed in the final report be compared with that made by the presenter when reviewing the case for the conference.

F. Inter-institutional Review:

For cases in which an outside review has been carried out at the request of the patient, the clinician or other institution, it is recommended that the diagnosis as listed in the final report be compared with that made at the outside institution.

An acceptable threshold for clinically significant disagreement is 2%, as applied to those cases in which it is decided that the correct interpretation is that from the outside institution.

G. Surgical Pathology Turnaround Times:

The followings are acceptable turnaround times for surgical pathology reports, as measured in working days from the time the specimen is accessioned in the laboratory to the time the verbal report is available or the final report is signed.

Cytology 1 - 2 days

Biopsies 2 - 3 ,,

Surgicals 2 – 3,,

Extra time should be allowed for the following procedures, to be measured in days from the time the procedure is initiated or ordered and independently from each other:

Overnight fixation	**1day**
Decalcification	**1 ,,**
Re-submission	**1-2 ,,**
Re-cuts	**1 ,,**
Immunocytochemistry	**1-2 ,,**
Electron microscopy	**2-3,,**
Intradepartmental consultation	**1,,**

I. Specimen Adequacy:

It is recommended that the adequacy of submission of specimens to the laboratory be monitored in terms of fixation, safety requirements, and proper identification.

J. Lost Specimen:

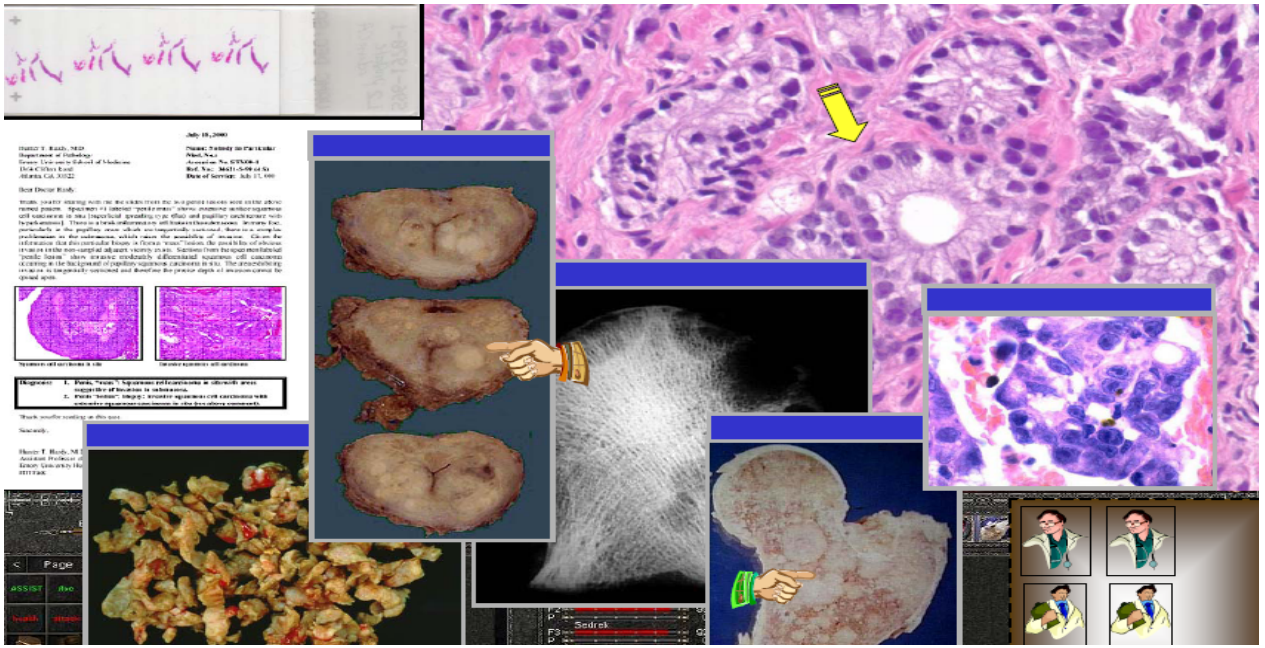
This is defined as the irreversible loss of a surgical pathology specimen that has occurred after the case has delivered to the laboratory and that prevents an adequate pathologic examination of that specimen. The Association estimates that an acceptable threshold for lost specimens is one in 3,000 cases.

K. Histology QC:

It is recommended that the QC related to the histology lab include:

1. Record of time of delivery of slides
2. Evaluation of slide quality as performed by the pathologist
3. Evaluation of tissue adequacy as performed by the histo-technologist

Standardization of Surgical Pathology Reports



Standardization of Surgical Pathology Reports

Demographic And Specific Information

Gross Description

Microscopic Description And Comment Section

Intraoperative Consultation

Final Diagnosis

General Considerations

A.Demographic And Specific Information:

1. Placing all demographic information in the top portion of the report including: patient's name, location, gender, age and/or date of birth, and race.

2. The requesting physician's name, the attending physician's name (if different from the requesting physician), and the medical record or unit number.

3. Printing the name, address, telephone number, and FAX number of the laboratory at the top of the surgical pathology report.

Demographic And Specific Information (cont.):

4. Placing the surgical pathology number in the top portion of the report on every page.

5. Summary of the relevant clinical history as part of every surgical pathology report.

6. Including a separate "specimens submitted" section in every report in which each separately identified tissue submitted for individual examination and diagnosis is clearly identified and listed as a separate specimen.

Standardized Surgical Pathology Report Demographic And Specific Information

REFERRING PHYSICIAN/HOSPITAL	PATIENT INFORMATION			
Dr._____	Last name		First	
	Address			
Phone:				
Fax:	Age	Sex	D.O.B	Date of Surgery
↓ Copies to ↑	Phone		SS#	

PATIENT BILLING ☐ INSURANCE BILLING ☐ CLIENT BILLING ☐

Specimen Site	Clinical Description / Impression
1	
2	
3	
4	

B. Gross Description:

1. Surgical pathology report must include an adequate gross description of specimens.

2. Each separately identified tissue specimen submitted for individual examination and diagnosis should have its own gross description.

3. Whether "part" or "all" of the specimen has been submitted for microscopic examination should always be recorded in the gross description.

Gross Description (cont.):

4. Identifying each block with a unique number or letter. Giving multiple blocks the same identification number of letter is discouraged.

5. A summary listing the sites from which each identified block is taken should be placed at the end of the gross description.

6. Complex specimens need further identification by drawings, photographs, xerographs, etc.; but these illustrative records should not replace the block identification summary recommended above.

Gross Description (cont.):

7. Recording in the gross description the fact that margins are inked or labelled with threads.

8. Recording the distribution of tissue for special studies in the gross description.

9. Including in the pathology report, when slides or blocks or tissues are received from another laboratory, the numbers of the slides and blocks, the referring hospital's identification numbers or letters, and the referring hospital's demographic data.

C. Microscopic Description And Comment Section:

Microscopic description is defined as a description of the cytologic features and the architectural arrangement of the cells in a histologic section.

A comment refers to all other relevant information.

It is optional to place microscopic descriptions and comments in separate sections or to combine them.

Microscopic Description And Comment Section (cont.):

1. Recording microscopic features whenever the responsible pathologist deems it appropriate, but a microscopic description need not be a part of every report.

2. Placing comments into the report whenever the responsible pathologist considers they are indicated, but a comment need not be written for every case.

3. Designating that "special" stains have been performed, listing each stain and the results of the staining in the microscopic or comment section.

Microscopic Description And Comment Section (cont.):

4. Listing, when immunohistochemical stains have been performed, each antibody tested and the results of the staining in the microscope or comment section, in a separate immunohistochemical report, or both.

5. Grading all tumors for which grading has been shown to be a significant prognostic variable. When a grade is given, the grading criteria or scheme should be recorded in a comment or in the diagnosis line unless the grading scheme is standard and well understood by all clinicians.

Microscopic Description And Comment Section (cont.):

6. Using a "checklist" for recording information needed for patient treatment and prognosis.

Whether each item on the checklist is positive or negative should be made.

The checklist includes for example: grade, depth of invasion, presence or absence of vascular invasion, size of the tumor and type of tumor. It is often different for different types of resection specimens.

Microscopic Description And Comment Section (cont.):

7. The condition of resection margins should be recorded if clinically indicated.

8. All information needed to formulate the pathologic stage of a cancer must be present in the report, but this information need not be recorded by a number of letter per se. If a stage number or letter is recorded, then the system used should be specified.

D. Intraoperative Consultation:

It is recommended that the intraoperative consultation report be incorporated exactly into the final report.

The persons responsible for the intraoperative report should be identified.

If there is a discrepancy between the intraoperative diagnosis and the final diagnosis, this discrepancy should be recorded and discussed in a comment.

E. Final Diagnosis:

1. Specifying the organ, site, and procedure as well as the diagnosis in the diagnosis section.

2. Standardizing the format of diagnoses within each pathology department.

3. Setting off anatomic diagnoses so that they can be quickly and easily identified.

4. Listing each separately identified tissue submitted for individual examination and diagnosis in the diagnosis section along with the anatomic diagnosis for that specimen.

F. General Considerations:

1. Doing a search for prior histologic and cytologic accession numbers for each case and recording important prior specimen numbers in the current surgical pathology report.

2. Incorporating the results of special studies such as electron microscopy, immunohistochemistry, flow cytometry, receptor status, data, etc., into the surgical pathology report whenever possible.

General Considerations (cont.):

3. Recording in the pathology report procedures other than routine handling of tissue, such as gross photography, decalcification, specimen x-ray and freezing of samples.

4. Documenting intradepartmental consultations in the surgical pathology report by having the consultant cosign the report.

5. Noting when external consultation is initiated by the pathologist. When the consultant's report is received, a supplemental report containing the consultant's interpretation should be issued.

General Considerations (cont.):

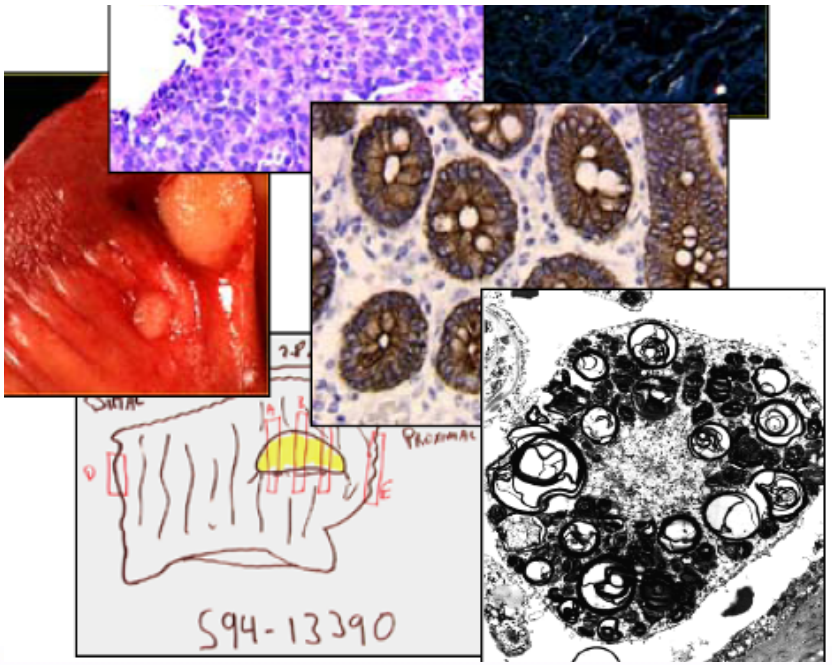
6. Citing references in the surgical pathology report when significant.

7. Suggestions for additional studies or procedures in the surgical pathology report if the pathologist thinks they will contribute to the case.

8. Note clearly when an amended report is issued. Changes that have been made in the report should be specified if the new report is a complete one.

9. Including the date the specimen was received and the date of the final report in all surgical pathology reports.

Incorporation of IHC Results into a Pathology Report



1. Immunostaining results should always be reported, regardless of perceived significance.

2. Ideally such information should be included in the original main report (surgical, cytology, or autopsy); however, due to time constraints, it may be necessary to report immunostaining separately. When the latter method of reporting is used, it is essential that the initial report state that such studies are awaiting, and likewise, it is essential that the separate report refer to or even include the original report.

3. A differential diagnosis justifying immuno-staining methods should be provided in the report. Reference to differential diagnosis may be very brief or general, for example, "anaplastic large-cell neoplasm of uncertain differentiation" or "epithelial versus lymphoid nature."

4. The nature of the studied sample, e.g-, paraffin sections, frozen sections, aspiration biopsy smears, cellular imprints, cytocentrifuge preparations, should be mentioned.

5. The immuno-reagents used should be specifically described, e.g., "HMB-45" rather than simply "melanoma-related antigen."

6. Results of the staining for each antibody should be reported in detail sufficient to justify the interpretation, e.g., positive or negative, intensity of staining, percentage of stained cells, cellular patterns of staining or localization of some stain reactivity to certain cellular compartments.

7. Detailed technical information regarding the immuno-staining procedures, including fixation, enhancing methods such as enzyme predigestion, etc., need not be included in the diagnostic report but should be available in permanent laboratory records.

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Thank You!