

**Short Communication****To prevent error is sign of triumph: Quality control in surgical pathology**Rateesh Sareen^{1*}, Anurag Govil², G N Gupta¹¹Dept. of Pathology, Santokba Durlabhji Memorial Hospital & Research Centre, Jaipur, Rajasthan, India²Dept. of Gastroenterology, Santokba Durlabhji Memorial Hospital & Research Centre, Jaipur, Rajasthan, India**ARTICLE INFO***Article history:*

Received 15-09-2020

Accepted 30-09-2020

Available online 20-10-2020

Keywords:

Histopathology

Quality control

Laboratory

ABSTRACT

The measurement of quality matrix has become increasingly important in current health care environment. Quality management system have been recommended by accreditation bodies to reduce errors in surgical pathology but there is strong need of standardization so that errors are kept to minimal thereby improved patient care. The histopathology report influences patient treatment decisions and therefore a good histopathology report should be reliable, timely, addressing to clinician demand. Any error has lethal consequences for patients. The paper gives a lucid review of quality control in histopathology.

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1. Introduction

The concept of quality control is an established, recognized aspect of laboratory medicine with deep roots in hematology and biochemistry which have quantitative data.¹ It is relatively new in histopathology where the reports contain interpretation, clinical judgment and explanations. Anatomic pathology by virtue of its complex nature and manual interventions is highly prone for errors and the descriptive nature of reports with subjectivity makes quality control in histopathology a daunting task. There are studies in literature to suggest that anatomic pathology errors have grave consequences on patient prognosis as illustrated by National Academy institute of Medicine, USA.² Surgical pathology is now armed with Immunohistochemistry and molecular techniques. A good pathology report is one that is reliable, timely and address to clinician demand. Any error has lethal consequences for patients and therefore all quality control measures are targeted to strengthen histopathology in order to deliver an accurate complete and timely report.

The joint commission on accreditation of health care organization issued patient safety goals³ including patient identification and communication which apply

to histopathology as well. Quality management system should be in place for each laboratory to ensure quality performance. It covers quality assurance, continuous quality improvement and quality control as key ingredients.⁴

The quality control in histopathology like other disciplines of pathology involve three phases: Pre analytical, Analytical & Post analytical phase.

2. Pre analytical phase (Table 1)

The pre analytical phase encompasses all processes that are involved up to submission of stained slides for microscopic examination by pathologist. It is show in many literature studies that this phase of testing harbors majority of errors,⁵ the frequency varying from 53.3%⁶ to 92.9%.⁷ In a study by Shaline Rao et al on 18,626 tissue sections over 34 month period it was found that out of 113 errors 92.9% errors belonged to pre analytical phase with the most common error been wrong labeling of slide.⁷ The errors in pre analytical phase can seriously jeopardize quality of histopathology report.⁸

The critical element in pre analytical phase is:⁹

1. Specimen fixation
2. Specimen delivery

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3. Specimen identification
4. Patient identification
5. Adequacy of clinical history
6. Accessioning errors

Every laboratory should have a standard operating procedure (SOP) for accession, identification, rejection, processing of tissue samples and whenever possible must be documented, displayed in laboratory and brought in acquaintance of all staff members, this shall prevent occurrence of errors.^{1,4,10}

2.1. Sample collection & accessioning

Each laboratory should have clear written guidelines for sample acceptance, repetition and accession. The laboratory should ensure that the biopsy material received should be in appropriate container and fixative as well as in quantity. There should be a predesigned referral form which should be available to all at point of specimen collection. The self designed 'referral form' helps in reducing errors like wrong identification of anatomic location or laterality (right vs. left) as well as wrong identification of patient.¹¹ Once the laboratory receives the biopsy examination request, adequate check mechanism for appropriate sample in fixative, relevant clinical history, radiological findings if available, demographic details of patient, assignment of unique laboratory identifier (bar code label, auto labeling system or tissue Tek system), entry of specimen in log book and sample accession formalities must be done as early as possible. Inadequate clinical and imaging information leads to delay in delivery of reliable histopathology report as emphasized in study by Nakhleh et al.¹²

2.2. Grossing

Systematic gross description, an elaborate dissection (especially for large specimens with lymph nodes) is crucial for correct diagnosis. The specimen needs to be carefully handled, adequately and properly grossed as these pre analytical steps once neglected could compromise reporting and could not be further rectified resulting in inadequate diagnosis.¹¹

2.3. Tissue processing and embedding

The instruments and equipments used in histopathology should be of sufficient quality with periodic calibration. It is crucial for laboratory to give adequate sufficient time for processing ensuring completeness and not rushing with the steps as inadequately processed specimen will not fetch optimal results. Under fixation and over fixation both leads to compromised quality, simultaneously prolonged contact with reagents should be avoided. The changing of chemicals used in processing should be planned through. This could only be achieved if the number of tissue

passed everyday is recorded and a compulsory change of chemicals is initiated once a pre determined limit is reached. Each and every step of changing chemicals for Deparaffinization, staining, dehydration and clearing should be done in above mentioned steps. Paraffin bath, water bath and slide warming table used should be of standard quality with periodic calibration and daily temperature recording.

Good microtome⁶ is the key for section cutting which should undergo periodic calibration and servicing. The problem of inconsistency in section thickness can be overcome by using disposable knife.

2.4. Staining

Laboratory should use standardized staining protocols for routine and special stains. It is extremely essential to use positive and negative controls in Immunohistochemistry. For routine Hematoxylin and eosin staining the control slide should have tissue having both hematoxyphilic and eosinophilic affinity like cervix or fibroadenoma¹¹. The standard practice is to cut multiple sections and keep them for later use as it removes any variations related to type of tissue. It is recommended to first stain the control slide and later the entire batch, with documentation of control slide characteristics like staining quality. In the same fashion known positive and negative control slides are to be employed in Immunohistochemistry.

2.5. Mounting & Labeling

Mounting should be done using good quality chemicals (DPX) and the label affixed should be of appropriate size so that it neither projects beyond the slide nor covers the tissue section. The numbering on the slide should be legible. As far as possible the use of bar code is beneficial as it prevents misidentification errors and one may incorporate details like name of patient, name of laboratory, date and unique identifier by laboratory.^{7,9}

Table 1: Preanalytical phase

Patient misidentification
Specimen identification
Collection and fixation of specimens
Clinical history
Transport
Accessioning

3. Analytical phase (Table 2)

In analytical phase the pathologist is the sole pilot, with their knowledge, judgmental abilities, experience and conscious mind strive to provide a good accurate diagnosis. This phase is prone for errors due to subjective nature of reports and interpretation.^{13,14} The literature studies have shown lack of consensus among pathologists for range

of specimen types varying from 4%¹⁵ to 42.1%,⁶ even the same pathologist can produce different report when examining same specimen on different occasion.^{16–18} There could be other potential sources of errors in analytical phase. In a study by Troxel et al¹⁹ the most common error was missing out malignancy i.e. False negative report was in a range of 63% of all errors. Wrong grading, misclassification, assessment of margin and base, vascular or perineural invasion²⁰ are potential areas that frequently produce erroneous reports as evidenced in literature studies.^{21,22}

The levels of errors in diagnostic laboratory can be monitored by audit.²³ Audit helps us to assess turnaround time, staining quality and overall workload. The American Association of Directors of Anatomic and Surgical Pathology recommended different types of audits.²⁴ like: review of cases by colleagues (intradepartmental consultation), re reporting of random samples (random case reviews), case selection on clinical basis to ensure consistency in diagnosis and reporting (clinical indicator audit), review of cases (clinic pathological meetings), inter institutional review, surgical pathology turnaround time, specimen adequacy audit, lost specimens audit and accreditation with participation in external quality assessment schemes.

For resource limited countries and where laboratory is run by single pathologist it is recommended to go for random blinded review of reported cases, external consultation, expert review and active participation in continued medical education programs. In a study by Lind et al,²⁵ the errors were classified into two types. The first type were oversight error 57% were pathologist missed significant pathology and misinterpretation errors 43.7% were pathological changes were incorrectly interpreted. Similar study from Southampton by Ramsay et al²⁶ classified oversight and interpretation errors and concluded that these errors were more frequent in occurrence where large batches of surgical specimens were reported. Peer review and inter departmental clinic pathological meeting are useful for minimizing analytical errors.^{27,28}

Last but not the least is the issue of timely diagnosis referred as turnaround time i.e. the time passing from receiving the surgical specimen in pathology laboratory and releasing the final report.²⁹ The college of American college of Pathologists suggested that 90% of surgical pathology reports must be released in 2-3 days.³⁰ It was also advised that each pathological laboratory must establish its routine specimen reporting turnaround time. Volmar et al³¹ in their study found that larger specimens require higher time for reporting in comparison to smaller biopsies and for cases involving cancer specimens.

Table 2: Analytical phase

Diagnostic accuracy
Interpretation of morphological findings
Use of standardized terminology
Clinical correlation
Confirmatory tests
Secondary review
Intra operative frozen concordance with routine histopathology
Quality of histology section
Loss of specimen in processing
Labeling of block and slide
Turnaround time
Audit
Turnaround time
External quality assessment scheme

4. Post analytical phase (Table 3)

The post analytical phase involves activities following analytical phase and include preparation and delivery of reports, storage of reported specimen for specified retention period as per local guidelines and safe disposal of specimen thereafter.³² Some common errors of this phase include reports with wrong validation data, delayed turnaround time, wrong/ missing information unrelated to pathological report and typing errors.³³ If the facilities are available every effort should be made to store blocks and slides for indefinite period of time.³⁴ The retention period for specimen is a matter of debate and there is need for consensual national guidelines for uniformity across the country.^{1,35}

Finally as the interpreting comment is not always consistent among histopathologists a highly structured reporting approach is generally adopted taking into account a note on: demographic information, gross description, microscopic description, intra operative consultation (if present), final diagnosis and general considerations with advice if any.

Table 3: Post Analytical phase

Proof reading
Report completion
Report delivery
Communication of critical results
Communication of ancillary findings

5. Conclusion

The histopathology report influences majority of patient treatment decisions and therefore plays vital role in patient care. Quality is not an overnight success it is rather continual improvement and developing a habit of doing things accurately, in a timely manner. Every laboratory should establish quality system in histopathology to enhance

quality of histopathology reports at par with international standards so that best patient care with minimal errors is delivered.

6. Conflict of Interest

None.

7. Sources of Funding

None.

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Cite this article: Sareen R, Govil A, Gupta GN. **To prevent error is sign of triumph: Quality control in surgical pathology.** *IP Arch Cytol Histopathology Res* 2020;5(3):262-265.