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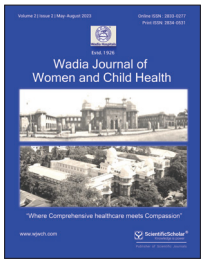

Original Article

Audit in surgical histopathology at Wadia hospitals - Study of pre-analytical, analytical, and post-analytical phase

Leena Milind Patwardhan[1], Sunita Sharma[1]

[1]Department of Histopathology, Bai Jerbai Wadia Hospital for Children, Mumbai, Maharashtra, India.

***Corresponding author:**
Leena Milind Patwardhan,
Department of Histopathology,
Bai Jerbai Wadia Hospital
for Children, Mumbai,
Maharashtra, India.

leenapatwardhan68@gmail.com

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ABSTRACT

Objectives: This audit of surgical histopathology aims to verify conformance to required processes, assess their implementation, and define the targets of quality control with appropriate changes in the existing system by evaluating pre-analytical, analytical, and post-analytical phases of histopathology.

Material and Methods: This study was an observational retrospective study done over a year, from March 15, 2022 to February 28, 2023. Small biopsies, large organ resections, and second opinion samples like paraffin blocks or slides received in the surgical histopathology department were categorized as I, II and III respectively. Samples were also segregated as per the department it was received from, namely, gastroenterology, neurology, pulmonology, nephrology, orthopedics, gynepathology, and others. Manual audit was done as a pre-analytical phase including adequacy of clinical information and grossing adequacy, analytical phase to study the turn around time (TAT) and tissue section quality, and the post-analytical phase in the form of report verification, approval and dispatch, and amendment if any, were studied.

Results: During this audit period, 1752 surgical histopathology samples were received of which 80% were small biopsies (category I), 19.6% were large organ resection samples (category II) and 0.4% samples were received for second opinion (category III). General pediatrics (n = 798) and Gynepathology (n = 569) were the main departments from which the samples were received. Incomplete request forms, errors in sample fixation, wrong payment/barcode were some of the pre-analytical errors. Training of staff on one to one basis was done. In the analytical phase errors such as nicks, folds or air bubbles in the mounted sample were seen. Histotechnical staff were retrained to reduce errors. In the post analytical phase, the turnaround time was achieved as per the hospital quality process indicator, feedback from cases on second opinion was received only in 25% of samples.

Conclusions: In this surgical histopathology audit of 1752 samples, quality indicators were achieved as per external quality assurance system (EQAS). Remedial actions were carried out to prevent errors.

Keywords: Audit, Quality, Surgical histopathology, Turnaround time

INTRODUCTION

Surgical histopathology deals with gross and microscopic analysis of tissues. Integrated quality maintenance is essential at pre-analytical, analytical, and post-analytical steps. Audit compares current practices against standard criteria as laid down by External Quality Assurance Scheme (EQAS) and suggests steps for improvement. Currently the Histopathology services at B.J. Wadia Hospital has been graded very good as per the EQAS.

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This study was undertaken to audit the pre-analytical, analytical, and post-analytical phases of surgical histopathology samples received from Bai Jerbai Wadia Hospital for Children (BJWHC) and Nowrosjee Wadia Maternity Hospital (NWMH). This study also aims to find out alignment to EQAS indicators.

MATERIAL AND METHODS

This is a retrospective study of all specimens that were sent to the histopathology laboratory of Bai Jerbai Wadia Hospital for Children (BJWHC) from March 15, 2022 to February 28, 2023. This histopathology laboratory renders services to both the BJWHC and NWMH hospitals of the organization. These specimens were fixed in 10% formalin, processed on an automatic processor, embedded in paraffin, and stained with hematoxylin and eosin. Tissues that required special stains and additional processing were also included in the study.

Tissues were grouped as follows: Category I (small biopsies), Category II (large specimens), and Category III (slides and blocks for second opinion).

Following logs in the histopathology department were studied,[1]

- Arrival/accessioning, the nature, and type of tissue
- The date of surgical cut up (grossing)
- Duration of tissue processing/handling in the laboratory
- Duration of handling of the slides by the technologists and the consultant pathologist, histological diagnosis
- Duration of typing and verification of results.

Information from these logs were later entered into an excel sheet and analyzed. Simple results were calculated. Major limitations of this study include the lack of IHC which when done may increase the TAT. As our patients come from all over the country, compliance was many times poor and so the survey was not able to elicit an effect of histopathological diagnosis on their management. This audit was approved by the institutional ethics committee and quality committee review board of the hospital.

Table 1: Category wise samples received.

Category I (small<1 cm)	80% (1402)
Category II (big specimens, more than 1 cm)	19.6% (344)
Category III (slides/blocks for second opinion)	0.4% (6)

Table 2: Department wise samples received.

Department	Number of cases
General paediatrics	798
Gastroenterology	136
Neurology	42
Pulmonary medicine	32
Oncology	18
Nephrology	09
Orthopaedics	40
Obstetrics	108
Gynaecology (Biopsies and specimens)	569

Table 3: Pre analytical phase errors.

Details of request forms (clinical history, lab investigations, referring doctors details)	6.0% (106)
Fixation process (adequacy of formalin)	0.3% (7)
Transport to the testing laboratory department (large specimen sent in a disproportionately small container)	0.2% (5)
Wrong payment or bar code	1.2% (17)

RESULTS

In this audit of 1752 samples, 1402 (80%) samples were small biopsy specimens and 344 (19.6%) samples were big samples [Table 1].

The various departments from where the samples were received is shown in Table 2.

Table 4: Analytical phase errors.

Fixation quality	0.02% (1)
Processing-re-embedding	0.0 (0)
Re-cuts	0.3% (4)
Re-staining (special stains-1151 and routine hematoxylin and eosin staining-3095)	0.06% (1)
Section quality-air bubbles, nicks, folds in the sections, etc.	0.9% (12)

Table 5: Post analytical phase observations.

TAT	On time: 99.7% (1746)	Exceeded the TAT: 0.3% (5)
Typing errors	00%	
Reports	Collected: 79% (1384)	Not collected: 21% (367)
Amendment of reports	0.06% (1)	
Second opinion obtained from clinicians of our reports	1.9% (33)	
Feedback given to us of those above mentioned second opinion reports	0.48% (8) Feedback given to us	1.41% (24) No feedback given to us about the second opinion
Comparison of the reports, wherein feedback was given	100% concordant to our reports; wherein feedback was given, that is in 7 reports	

TAT: Turnaround time

Table 6: Various errors found and Corrective and Preventive Actions (CAPA) taken.

Errors	Corrective Action	Preventive action
Details of request forms (clinical history, laboratory investigations, and referring doctors' details) not complete in 6% samples.	Forms were sent back and the referring resident doctors were made to enter necessary details.	Importance of the exact details in facilitation of the reports were explained.
Tissue received without fixative in 0.3% samples.	Details of tracking of the sample from the OT to the laboratory were obtained and an incident report was made with reason explaining why formalin was not added.	Purpose of making an incident report was explained to the OT staff and clinicians; as it helps in documentation and quality improvement.
Transport to the testing laboratory department (Large specimen sent in a disproportionately small container) in 0.2% samples.	Sample was immediately transferred to the larger, appropriate container and adequate (in the ratio of 0:1 proportion) formalin was added for good fixation of specimens.	The concerned OT and ward staff were explained the importance of adequate formalin for fixation and further processing of tissue for examination.
Wrong payment or bar code in 1.2% samples.	The request form was sent back to the cash counter for correction	Training session was conducted with the cash counter staff and they were explained the importance of correct code for generation of reports.
Tissue fixation, processing, and staining errors in 0.35% samples.	Re-embedding, restaining, and remounting were done wherever needed.	Histotechnical staff was explained the importance and trained to reduce these errors.

Each tissue was audited for the following quality indicators.

Pre-analytical phase

In this the criteria audited included adequacy of clinical information and grossing adequacy, way of transport to the laboratory and bar code generation.

The various observations found are shown in Table 3.

The areas considered and the errors found are tabulated [Table 3].

Analytical phase

Once the specimen arrives in the histopathology section, the specimen is examined at the tissue processing unit and work station for grossing of specimens (ISTOS®) with good monitoring over formalin vapors in the air.

Grossing of various specimens is conducted by strictly adhering to the techniques described in the grossing manual of surgical specimen by Tata Memorial Hospital. A latest copy of the same manual is kept at the grossing station for quick reference.

Following microscopic examination, reports are formulated by adhering to the guidelines in various system-wise datasets and World Health Organization (WHO) manuals.

Various errors found in this analytical phase of the audit are shown in Table 4.

Post-analytical

The various factors like turnaround time of report, amendment of reports, feedback received from second opinion reports and others were analyzed.

The errors and inferences are shown in Table 5.

Corrective And Preventive Actions (CAPA) taken for various errors and deviations from protocol/process is shown in Table 6.

DISCUSSION

The present audit of surgical histopathology covered 25% of annual workload. Major limitations of this study include the lack of IHC which when done may increase the TAT.

Following inferences are drawn.

Pre-analytical phase

- 7.4% of requisition forms showed the maximum inadequate demographic data and clinical investigations and inadequate clinical history. Possibly in these cases clerical work was delegated to the junior most staff. The clinicians were intimated to write exact details along with the contact details of the referring doctor on the requisition paper.
- Tissue received without fixative in only 0.3%[2-4]
- In our study, it was found that lymph node biopsies were divided into formalin for histopathology examination and saline container for microbiology examination; however, a larger fragment was put in the saline container and a small fragment was put in the formalin container. Clinicians can be counseled to change this proportion and put in the bigger fragment in formalin container
- In 0.3% cases, larger specimens were sent in a small container, not allowing enough formalin for fixation. Such specimens were immediately transferred to the

bigger containers and kept for fixation after addition of fresh formalin
- About 1.2% cases had the wrong barcode selected. Personal "one on one" training was conducted with the clerical staff in this regard.

Analytical phase

Errors such as air bubbles, nicks, and fold were observed in few of the sections provided for examination. The histotechnical staff was trained to reduce these errors. However, as there are multiple levels of the section on one slide, no actual corrective action was required.

Post-analytical

- Most of the samples were reported in the stipulated time, for example,
  Small biopsies - 4 days
  Large specimens - 6–7 days
  Specimens where decalcification is required - 10 days
- 1.9% of the cases were sent for second opinion to outside sources with our knowledge out of which 25% of the cases, feedback with the report of second opinion was provided to the laboratory which had 100% concurrence.
- Clinicians were explained the benefits of the feedback and requested to give us the feedback of the reports of second opinion for knowledge enhancement and betterment of histopathology reporting.

CONCLUSION

Despite training there are still some errors in filling the histopathology request forms, selection of bar codes, delay in sending samples from OT or wards. This can be avoided by systemic regular induction training for newly joined doctors and frequent refresher training at regular intervals for completeness of information.

Electronic medical records – futuristic dimensions can help avoid these errors in manual information sharing. After communicating with the clinicians about the importance of the feedback (particularly in cases where a second opinion was sought); there is regular feedback from the clinician side.

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Declaration of patient consent

Patient's consent not required as patients identity is not disclosed or compromised.

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Conflicts of interest

There are no conflicts of interest.

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