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Analysis Of Key Performance Quality Indicators In Histopathology Laboratory

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Abstract

Background

Quality Indicators (QI) are the variables defined by Quality Management System (QMS) in a laboratory to assess and monitor the quality of results generated. Monitoring of quality in histopathology is a cycle from reception of the specimen till the report generation. A regular & periodic review of these quality variables is mandatory to improve the quality of reporting which helps in patient care.

Aims & Objectives:

To evaluate the quality parameters & their role in improving the quality in histopathology laboratory.

Materials And Methods:

This was a cross-sectional study conducted in histopathology laboratory of a tertiary care hospital from January 2018 to December2021. Quality indicators were identified and recorded daily. These Records & registers were checked for the errors which can affect the quality of the reporting, documented and analysis was done.

Results:

The study revealed that number of specimen not sent in formalin were 0.05%,0.02%,0.02% &0.018 % in 2018,2019,2020 & 2021 respectively. Performance of External quality assurance (EQAS) programme was satisfactory in 22 of 23 cycles during study period. The number of reports with delay in turnaround time (TAT) was within the defined cut off percentage. A total of 106 non conformities (NC) were identified out of which majority belonged to preexamination phase and the predominant NC identified was thick sections.

Conclusion:

Timely review of Quality Indicators helps in identifying glitches in the Laboratory so that appropriate actions can be undertaken accordingly which helps in improving the quality in histopathology.

Keywords: Quality assurance, Turnaround time, Non conformities

Introduction

Quality is defined as the degree to which healthcare services seek to facilitate accurate patient outcomes and are compatible with existing clinical practice. [1] Quality in pathology and clinical medicine is the process of measuring efficiency at all levels of the laboratory test cycle which includes pre examination, examination and post examination processes to which healthcare services strive to provide accurate desired outcomes for patients and are consistent with current professional knowledge. [1]. In laboratory medicine Quality assessment is very important and is an essential requirement to ensure accuracy and precision of test results.

Quality analysis is well established and practiced with respect to Haematology, Biochemistry & Clinical pathology where numerical data is obtained. However implementation of quality in histopathology

laboratory is different due to many factors like cumbersome processing, subjectivity of reports, interpretations, lack of numerical values and clinical judgments. [2]

A quality indicator is defined as an objective measure evaluating critical health care domains as defined by the Institute of Medicine (IOM) which includes patient safety, effectiveness, equity, patient centeredness, timeliness & efficiency. [2] Quality indicator acts like a tool which enables to check the performance of the laboratory. Any potential quality indicator should fulfil the 2 criteria's: 1. It must be an indicator of laboratory functioning. 2. It must serve as indicator health care domain. [3]

To ensure the quality performance every diagnostic pathology laboratory should have adequate laboratory staffing, equipment and space so that the pathologists have good technical support & sufficient time to provide a good quality of report for patient care. [1] Therefore it is mandatory to have quality assessment for all the procedures from the laboratory & to be done constantly, so that report generated will be reliable & accurate. In the laboratory test cycle the preexamination phase acts as the critical step since it influences the subsequent steps.

Laboratory accreditation for the clinical laboratories have become common recently with the emergence of National accreditation board of laboratories (NABL) which gives the certification for the laboratory by focusing on the standards & quality. Hence quality indicators help in maintaining the standards of the laboratory & also in good patient care. There are limited studies on quality assessment in histopathology laboratory. Thus present study was initiated to assess the quality parameters in all the phases in a histopathology laboratory.

Materials And Methods

This study was a retrospective from January 2018 to December 2021 conducted in histopathology laboratory at a tertiary care centre after obtaining ethical clearance from institutional ethics committee.

Quality indicators were retrieved from the registers, records and files and the errors identified were noted. The parameters studied are as follows:

1. Sample identification
2. Specimen in appropriate fixative
3. Lost specimen
4. Daily quality control
5. Daily Non conformities
6. Daily TAT monitoring
7. External quality control

All the parameters were analysed and wherever necessary percentage, graphs, bar diagram & pie chart were used for the result analysis.

1) Sample identification: Patient requisition form with unique identification number was checked with the manually labelled specimen containers. Any errors & discrepancy were checked for & resolved.
2) Specimen in appropriate fixative: Universally used fixative is 10% formalin to fix the specimen in histopathology laboratory. Registers were checked for the number of specimens not sent in formalin. Policy of the laboratory is immediately after receiving the specimen it should be checked whether the specimen is sent in formalin or not & also the proper proportion of formalin is added to the specimen container. If specimen is not sent in formalin immediately it was added.
3) Lost specimen: Files were checked for any lost specimen during study period.
4) Daily Internal Quality Control (IQC): As quality documentation the internal quality control performance with respect to haematoxylin & Eosin (H&E) staining slides were assessed & scored daily.
5) Daily Non Conformities (NC): Anything that deviates from normal and has a potential effect on patient care is defined as non-conformity. Registers were maintained for the daily monitoring of NC's.
6) Daily Turn Around Time (TAT) monitoring: Record was maintained with number of cases with delay in reporting.
7) External quality Assurance (EQAS) performance: The laboratory had been enrolled for EQAS programme for histopathology with another NABL accreditated laboratory. In this a tissue will be sent in 10% formalin from the nodal quality control centre & it will be

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processed, sectioned and stained. The same slide will be sent back to the nodal centre for evaluation of the quality of processing & staining.

All the parameters were analysed and statistical analysis was done using percentage, bar diagram and pie chart wherever necessary.

Results

A total of 11,520 tissue samples were processed in histopathology test in histopathology laboratory between January 2018 to December 2021. Histopathology lab in the present study has been accredited by National board for Testing & Calibration Laboratories (NABL) since 2017. All the quality indicators mentioned were documented & analysed.

Sample rejection: As per the NABL policy no specimens were rejected and in case of any discrepancy it was rectified by contacting the operating surgeon.

Specimen identification: After receiving the specimen check was made regarding identification of the specimen with the patient details on the request form and submission of the specimen in the appropriate fixative. (Table 1)

Specimen not sent in fixative: 10 % formalin is the routinely used fixative. The specimen which was not sent in formalin was identified and immediately 10% formalin was added. Root cause analysis was found to be due to high attrition of the operation theatre (OT) staff & recruitment of the new staff. To reduce the incidence of specimen not sent in formalin regular training was given to the newly recruited OT staff.(Table 1)

Lost specimen: No loss of specimen during the study period

Internal quality control performance (IQC): As a daily quality check paraffin block were selected randomly and assessed for fixation, tissue processing, embedding .The same block sections were cut and H & E stain was done. Scoring was be given for all these parameters (Score1=unsatisfactory, score 2=poor, score 3=average, score 4=good and score 5=excellent). Anything <3 score action to be taken. But in this study overall score analysis showed average & good.

Daily Non conformities (NC's): Anything that deviates from normal & affects the patient care are called non-conformities. Following were the NC's identified during the study period & troubleshooting with root cause analysis & CAPA was undertaken depending on the type of NC. (Figure 1)

Delay in TAT: Laboratory defined the TAT for small biopsy has 3 days and for large specimens it was 7 days. The cut off percentage defined for out of TAT was 7%. Analysis of the TAT record showed the percentage of cases with delay in TAT was within defined percentage. The most common cause for delay in TAT was observed in preexamination phase which was regrossing followed by inadequate fixation, processing problems and reembedding.

External quality assurance program (EQAS) performance: Enrolled for RML EQAS with 6 cycles/year. One cycle was not sent in 2020 due to COVID-19 pandemic. Analysis of the records of EQAS showed satisfactory in 22 cycles out of 23 cycles in 4 years. One cycle showed errors related to staining. It was recorded and CAPA was taken by increasing the staining time of hematoxylin. (Fig: 2-5).

Table 1: Results of assessment of Specimen collection

Year	Specimen not sent in formalin	Specimen wrongly labeled	Corrective and preventive action taken CAPA
2018	10	5	Informed the in Charge clinician & educated the residents
2019	7	3	
2020	7	3	

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2021	6	2	

Figure 1: Non conformities identified

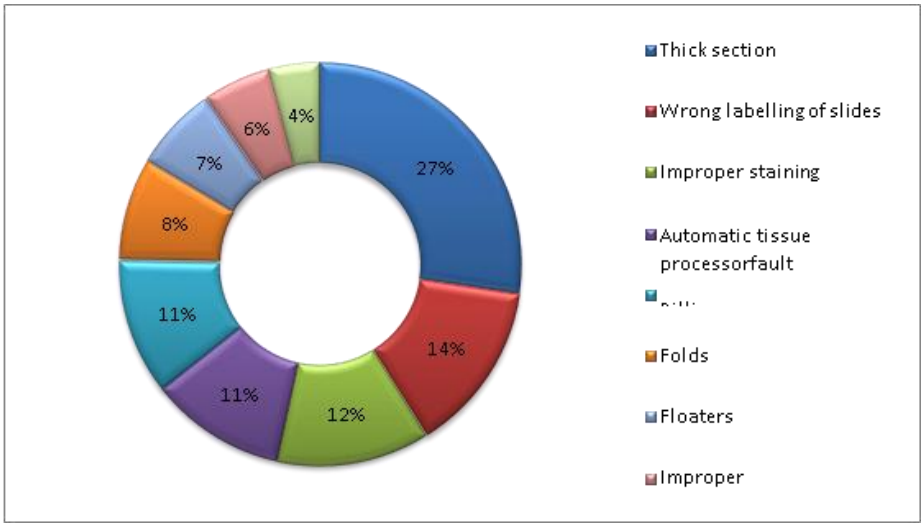

Table 2: Non conformities with RCA & CAPA

SL.NO	Type of Non conformity	Root cause analysis(RCA)	Corrective and preventive action(CAPA)
1.	Thick section	Faulty microtome mechanism	Lubrication, tighten blade & block
2.	Wrong labeling of slides	Human error	All technicians were educated to check the label twice before issuing the slides for reporting
3.	Improper staining	Defect in blueing	Standardize the procedure & proper blueing
4.	Automatic tissue processor fault	Technical fault	Manual processing was done and service engineer was called to resolve the issue.
5.	Billing error	Fault of billing section	Educated the billing section staff
6.	Folds	Dull blade edge	Change of blade

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7.	Floaters	Inadequate washing of the knife after grossing & fault of technician not changed the water in water bath	Residents and technicians were educated about this
8.	Improper impregnation	Technical fault of automatic tissue processor	Service engineer was called for service for rectification.
9.	Improper deparaffinization	Incomplete drying or leaving the sections for long time in xylene	Training was given for proper drying of the

Figure 2: EQA analysis –2018

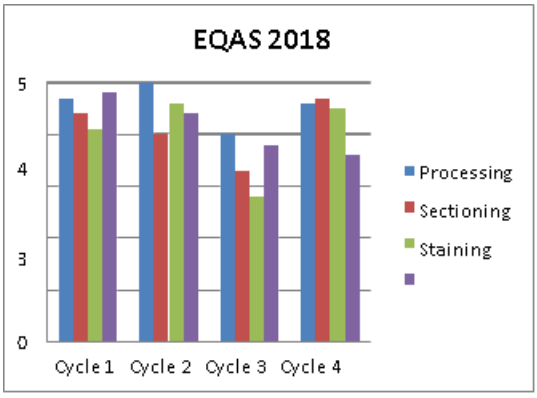


Figure 3: EQA analysis-2019

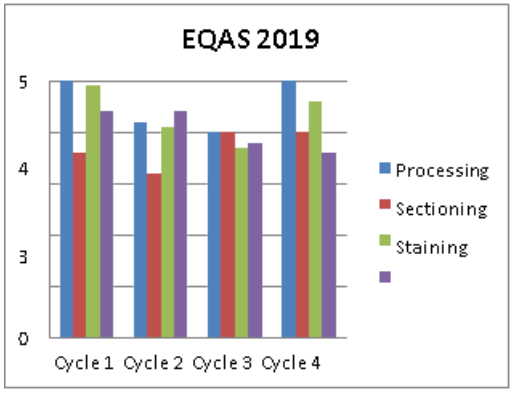


Figure 4: EQA analysis-2020

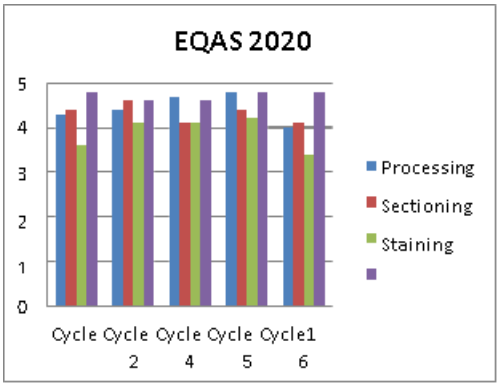
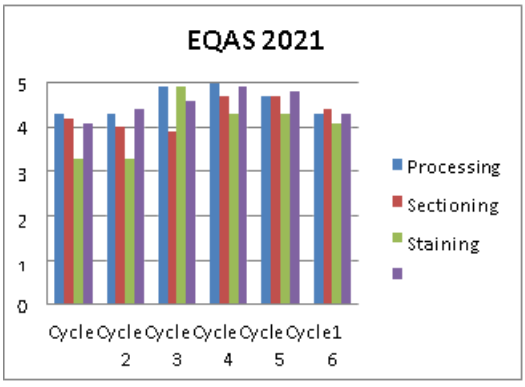


Figure 5: EQA analysis-2021



Discussion:

Histopathology is the study of diseases by analysing and interpreting the cells & tissues obtained from a patient at surgery or autopsy to reach an accurate diagnosis**.** Histopathology reports should be accurate & timely since it directly influences on the treatment of choice & patient outcome. [1] The accurate histopathological diagnosis depends on a well processed good quality sections without any artifacts.

For a histotechnician, quality means good quality of sections, for a pathologist, quality means accuracy of diagnosis & for a clinician, quality means whether he

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received all the desired information or not. Hence in laboratory Quality is defined as accurate, timely and complete reports. [4]

A good quality section is the initial point for an accurate histopathology report. All the processes involved in generating the section are grouped under the preexamination phase. The examination phase is concerned with the interpretation of the slide & making accurate diagnosis. The post examination phase deals with the generation of report dispatch of report, storage/disposal of samples, retention of slide/blocks & request forms.

A study done by Meier et al., revealed that the incidence of wrong identification & defective specimens ranged from 27% to 38% & 4% to 10%. Laboratory errors showed reported frequency of 0.012%-0.6% in all test results. In a study by Plebani among a total of 40,490 analyses, 189 laboratory mistakes were identified contributing a relative frequency of 0.47%. The distribution of errors was as follows: preexamination 68.2%, examination 13.3% and post examination 18.5%. [5] It is observed that in all the studies significant errors are most common in preexamination phase so effective measures should be taken in quality control during this phase of tissue processing.

The first step in preexamination phase is patient & specimen identification which is the most essential. In case of any discrimination immediate communication with the concerned staff will resolve the problem. In this study very minimal error was found with respect to wrong labelling which was identified & immediately RCA done & CAPA was taken.

As a universal policy there is no sample rejection in histopathology since rebiopsy cannot be taken. Hence all the biopsies should be accepted and in any instance of discrepancies clinician should be contacted and rectified. One of the accreditation bodies (NABL) also mentions in their guidelines "Histopathology specimens should not be rejected on grounds of poor specimen integrity. They should be accessioned & remarks be incorporated in the gross, microscopic descriptions and diagnostic interpretation as appropriate. In the case of specimen mislabelling or issues in specimen identification and traceability, the specimen shall not be accepted for testing without reconciling all issues. In the intervening period, the specimen shall not be discarded. Appropriate temporary labelling and if necessary, processing of the specimen may also be undertaken" [6].

Another important element in preexamination phase is incidence of lost specimen. In the present study there were no lost specimens. This showed the thorough system of specimen transfer from operation theatre to histopathology lab.

The critical step in preexamination phase is the fixation of specimen in proper fixative for adequate time. Improper fixation results in poor morphology of the cells due to autolytic changes which can interfere in histopathological diagnosis and inadequate report due to this the clinician may be put into dilemma with regards to further treatment. In our study few of the specimens were sent in saline instead of 10% buffered formalin. These specimens were identified and immediately formalin was added.

Daily internal quality control (IQC) is mandatory for the quality assessment and as an improvement step. This quality check ensures sectioning and staining quality. In the present study one random tissue block was selected and sections were cut and stained with routine Haematoxylin & Eosin staining before the routine batch of slides were submitted for reporting. The IQC slide was assessed by giving the scores. The same was documented. A laboratory with good internal quality control is the hallmark of the proper functioning lab. Under processed tissue, faulty sectioning & improper staining results in unnecessary delay in reporting.

Adhering to strict criteria for chemical change in the tissue processor, total number of blocks to be cut with each blade & following proper staining procedure might help in bringing good quality sections. In the laboratory in present study chemicals in the tissue processer were changed after 150 blocks.

The laboratory participated in the EQAS programme. In this part tissue was received in 10% formalin. The same was sectioned and stained which was sent back to the nodal centre and it was assessed and scoring was given. Performance in external quality control programme is the important quality indicator for the laboratory for the quality improvement & assessment. Enrolling in the EQAS programme helps as a quality check & also in evaluating & assessing the quality of our self.

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TAT is the measure of the number of tests that do not meet a reporting deadline. There are no guidelines available for determination of ideal TAT goals. Monitoring of TAT is critically important and all the reports should be dispatched within the defined timeline. [3] In the present study the causes for delay in TAT was mainly due to preexamination phase problems. Root cause analysis of the problems were identified and certain amendments were made in the standard operating procedures which helped in improving TAT e.g., mentioning suitable special stains as per the differential diagnosis on the requisition form at the time of grossing wherever possible. In addition grossing discussion, seminars and other teaching sessions were conducted for the residents. This helped in reducing the grossing errors. Zuk JA et al., observed that 1/5th of the requests forms had incomplete/absent clinical details which led to wastage of time. [7]

Daily filling of NC register is very important & the aim of it to investigate the irregularities that can occur so that timely corrective and preventive actions can be undertaken after thorough root cause analysis (i.e., Risk Management). [5] Technical staff, residents and the reporting pathologists should know where all non-conformities can occur so that accordingly CAPA can be undertaken for the rectification. Layfield LJ et al. reported that most of the mislabelling errors occur as the most common NC which occurred during grossing. [8] On the other hand, Nakhleh RE et al. reported in a multi-institutional study that the mislabelling errors occurred mostly while tissue cutting (30.4%) followed by labelling the blocks (21.7%), pre-accessional stage (20.9%), and accession (12.4%) and during grossing (10.2%). [9] In current study, thick sections were common & it was resolved by regular training of technicians regarding section cutting. The wrong labelling of slides was the second most common error. Presence of floaters can interfere in the reporting & leads to erroneous diagnosis. [10]

Laboratory should have the process of conducting internal audits as per the NABL ISO 15189: 2012 standards and it in turn improves the quality of the lab. Each individual working in the section should raise NC's for better performance of the laboratory and should keep in mind that "it is not fault finding but it is fact finding". A designated Pathologist/section in charge of the laboratory should review quality parameters at decided intervals. Frequent conduct of such internal audits will be helpful for the NABL assessment of the laboratory.

Conclusion

Analysis of quality indicators helps in minimising the error rate in laboratory. In all the three phases errors should be identified ,documented and the correction of these errors with proper RCA and CAPA can be the key tool for improving the standards of the quality of In histopathology laboratory which in turn helps in the ameliorating the quality of health care delivery system.

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