Original Article

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Auditing Histopathology Processes to Augment Reporting Quality: An Objective Analysis in a Tertiary Care Neuropathology Laboratory

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ABSTRACT

Background: Laboratory audits are an integral component of the continuous quality improvement process and one of the key elements of quality control in the laboratories. These audits are primarily concerned with the everyday aspects of laboratory services and are a means of providing feedback to the users of the laboratory and its staff. These audits measure the performance of laboratory services against established standards that are evidence based and established by the audit team itself. This original study was initiated with an objective to audit all those histopathology processes that are involved in the generation of a quality histopathology report. The purpose was to detect the gaps which in turn maybe used to reduce and avoid errors in the processes, thus improvising the quality assurance practices of the histopathology laboratory.

Materials and Methods: In this retrospective cross- sectional study, total twenty standards were audited, including the clinical details, the pre-analytical, analytical and post-analytical laboratory processes.

Results: Overall, out of the 20 standards audited it was found that in the first audit, full compliance was observed in 10 standards, whereas the re-audit showed full compliance in 11 standards. Undoubtedly the compliance showed an improving trend in the re-audit.

Conclusion: such laboratory-based audits not only form an integral component of the quality assurance programs but definitely add on to the quality of patient care, as the reports generated by the histopathology laboratories do help the treating team in deciding or modifying the treatment plan in central nervous system and spinal tumours.

Keywords: *Laboratory Audit, Histopathology, Quality Improvement Process*

Introduction

The concept of quality control as in most other disciplines of laboratory medicine is equally important in the histopathology laboratory. Certain factors like the lack of objective numerical data, descriptive nature of reports, subjectivity, individual judgment and bias, non-uniformity of reporting patterns may make assessment and implementation of quality control more difficult in histopathology. However, advanced methods like immunohistochemistry, morphometry and molecular techniques do add an element of objectivity to the traditional slide interpretation.

As in any other laboratory, quality control in histopathology is traditionally applicable to three phases: the pre-analytical phase, the analytical phase and the post-analytical phase. [1] The pre-analytical phase is related to sample collection, transport, accession and processing. The analytical phase is related to actually carrying out the test (manual/automated) and the activities that follow (transmission of results, storage/disposal of samples, and maintenance of test data) comprise the post-analytical part.

Objectives

This original study was initiated with an objective to audit all those histopathology processes that are involved in the generation of a quality histopathology report. The purpose was to detect the gaps which in turn maybe used to reduce and avoid errors in the processes, thus improvising the quality assurance practices of the histopathology laboratory.

Materials and Methods

This audit study was conducted in the department of Pathology in a tertiary care super speciality hospital of East Delhi, India. Requisition forms filled by the Neurosurgery department, histopathology reports issued by the Pathology department and the records maintained

in the Pathology department for the last three years of all the Central Nervous System (CNS) and spinal tumours were included in this audit study. Forms excluded from the study were histopathology requisitions other than CNS and spinal tumours. Overall certain standards were defined by the audit team, these standards included all the three phases of a histopathology laboratory procedure, the pre-analytical phase (sample labelling details, sample fixation details, sample receiving details, contact details) the analytical phase (grossing details, tissue processing (details including TAT), sectioning details(details including TAT), staining details (details including TAT) and the post-analytical phase (report for completeness, report for any transcription error, TAT details, any recall/amendment of reports, disposal of specimens). In addition, the requisition forms received with the histopathology samples were also audited for patient demographics, localization of tumour, adequacy of clinical history, adequacy of radiological details and for complete intraoperative details [Box 1]. Overall, 20 standards were defined and compared with the standard protocol for any deviation. All the deviations were shared with the concerned clinical and laboratory staff and it was decided to have a re-audit after three months. A re-audit was conducted, requisition forms, histopathology reports issued and the records maintained in the Pathology department for the last three months of all the CNS and spinal tumours were re-audited. Data generated from the audit and re-audit was analysed by SPSS 18.0, frequency and percentage were calculated.

This retrospective study was carried out on archival material. Patient confidentiality was protected. As per the policy of the Institutional Ethics Committee, such projects are exempt from ethical review.

Results

In the first audit a total of 331 requisition forms filled by the Neurosurgery department, histopathology reports issued by the Pathology department and the log books maintained in the Pathology department were audited. These 331 cases were from two superspeciality government hospitals, Institute of Human Behaviour and Allied Sciences and Guru Teg Bahadur Hospital in East Delhi, India. In this audit, it was found that regarding the clinical details in all 331/331 cases absolute compliance (100%) was found for name, age and gender filled in the histopathology requisition forms. Details of site of the lesions were filled in 329/331 cases (99.39%), while in 02 cases ((0.61%) the details were not filled. Complete radiological findings were available in 284/331 cases (85.80%), partially complete details were available in 40/331 cases (12.09%) while in 7/331 cases (2.11%) the details were not available at all. Detailed complete clinical findings were available in 152/331 cases (45.92%), in 161 cases (48.64%) the details were partially complete, as duration of the clinical findings was missing in all these cases and in 18/331 case (5.44%) the clinical details were not available at all. The column for intra operative details was completely filled in 204/331 cases (61.63%), partially filled in 30/331 cases (9.06%) while in 97/331 cases (29.31%) the details were not available. [Table 1].

Regarding the pre analytical phase standards, sample labelling details were complete in all 331/331 cases (100%). As per the records, in 330/331 cases (99.70%), samples were received in correct and adequate quantity of fixative but a single case (0.30%) was received without any fixative as per the records. Sample receiving details and contact details were complete in all 331/331 cases (100%) [Table 1].

Regarding the analytical phase standards, complete gross details were available in 324/331 cases (97.89%) and were partially complete in 7/91 cases (2.11%). TAT for tissue processing, sectioning and staining was well maintained in 325/331 cases (98.19%) whereas in 6/331 cases (1.81%) it was violated, although the reasons for TAT violation were documented as found in the records. [Table1]

Coming to the post analytical standards, the histopathology reports were found to be complete in all aspects, without any transcription error in all 331/331 cases (100%).Turnaround time for the release of the report was well maintained in 313/331 cases (94.56%) whereas in 18/331 cases (5.44%) TAT was violated for reasons well documented in the records. None of the histopathology reports required any amendment or recall. All the 331/331 (100%) samples were disposed of as per the existing standard operating procedure (SOP) of the department and it was well documented. [Table 1]

After completing this audit, the results were discussed amongst the histopathologists, their technical staff, the neurosurgeons, their residents and the nursing staff. The feedback was shared and with consensus it was decided that a similar audit shall be conducted after three months.

After 3 months the re-audit results showed that regarding the clinical details, considering the name, age, gender it was complete in all 52/52 cases (100%). Details of the site of the lesions were filled in 51/52 cases (98.08%), while in a single case (1.92%) the details of site were found missing. Complete radiological findings were available in 50/52 cases (96.15%), whereas in 2/52 cases (3.85%) the radiological findings were not filled. Detailed clinical findings were available in 30/52 cases (57.70%), again in 21/52 cases (40.38%) the clinical findings were

partially complete as the duration of the clinical findings was not mentioned, whereas in a single case (1.92%) the clinical findings were found missing. The column for intra operative details was complete in 43/52 cases (82.69%) and in 09/52 cases (17.31%) the intraoperative details were not complete. [Table 2]

Coming to the pre analytical phase standards, sample labelling, sample fixation and contact details were complete in all 52/52 cases (100%). However, details of sample receiving were complete in 48/52 cases (92.31%) and were found to be missing in 04/52 (7.69%) cases. [Table 2]

Regarding analytical phase standards, complete gross details were available in all 52/52 cases (100%). TAT for tissue processing, tissue sectioning and tissue staining was well maintained in 48/52 cases (92.31%), whereas in 04/52 cases (7.69%) TAT was found violated for some technical issues mentioned in the records. [Table 2]

As far as post analytical standards are concerned, the histopathology reports were found to be complete in all aspects, without any transcription error in all 52/52 cases (100%). Turnaround time for the release of the report was well maintained in all 52/52 cases (100%). None of the histopathology reports required any amendment or recall. All the 52/52 (100%) samples were disposed of as per the existing standard operating procedure (SOP) of the department and it was well documented. [Table 2]

Overall, out of the 20 standards audited it was found that in the first audit, full compliance was observed in 10 standards, whereas the re-audit showed full compliance in 11 standards [Table 3] **[Figure 1-4]**.

Table 1: Table showing the audit findings for the defined standards including the clinical details, pre analytical, analytical and post analytical details (n=331).

Audit standards	Compliance	Partial compliance	Non compliance
Clinical details			
Name	331 (100%)	-	-
Age	331 (100%)	-	-
Gender	331 (100%)	-	-
Site	329 (99.39%)	-	02 (0.61%)
Radiology findings	284 (85.80%)	40 (12.09%)	7 (2.11%)
Clinical finings	152 (45.92%)	161 (48.64%)	18 (5.44%)
Intraoperative details	204 (61.63%)	30 (9.06%)	97 (29.31%)
Pre analytical			
Sample labelling details	331 (100%)	-	-
Sample fixation details	330 (99.70%)	-	01(0.30%)
Sample receiving details	331 (100%)	-	-
Contact details	331 (100%)	-	-
Analytical			
Gross details	324 (97.89%)	7 (2.11%)	-
Tissue processing/ sectioning/staining (Details including TAT)	325 (98.19%)	-	06 (1.81%)
Post analytical			
Report for completeness	331 (100%)	-	-
Report for any transcription error	331 (100%)	-	-
TAT	313 (94.56%)	-	18 (5.44%)
Recall/amendment of report	331 (100%)	-	-
Disposal of specimens	331 (100%)	-	-

Table 2: Table showing the re-audit findings for the defined standards including the clinical details, pre analytical, analytical and post analytical details (n=52).

Audit standards	Compliance	Partial compliance	Non compliance
Clinical details			
Name	52 (100%)	-	-
Age	52 (100%)	-	-
Gender	52 (100%)	-	-
Site	51 (98.08%))	-	01 (1.92%)
Radiology findings	50 (96.15%)	-	02 (3.85%)
Clinical finings	30 (57.70%)	21 (40.38%)	01(1.92%)
Intraoperative details	43 (82.69%)	09 (17.31%)	-
Pre analytical			
Sample labelling details	52 (100%)	-	-
Sample fixation details	52 (100%)	-	-
Sample receiving details	48 (92.31%)	-	04 (7.69%)
Contact details	52 (100%)	-	-
Analytical			
Gross details	52 (100%)	-	-
Tissue processing/ sectioning/staining (Details including TAT)	48 (92.31%)	-	04 (7.69%)
Post analytical			
Report for completeness	52 (100%)	-	-
Report for any transcription error	52 (100%)	-	-
TAT	52 (100%)	-	-
Recall/amendment of report	52 (100%)	-	-
Disposal of specimens	52 (100%)	-	-

Table 3: Table providing an overview of the defined standards, the expected outcome with the compliance observed.

Defined Standards	Expected outcome (in %)	Compliance (in %) after 1st audit	Compliance (in %) after re-audit
Name	100%	100%	100%
Age	100%	100%	100%
Gender	100%	100%	100%
Localization	100%	99.4%	98.1%
Radiology findings	100%	85.8%	96.2%
Clinical findings	100%	45.9%	59.6%
Intra-operative details	100%	61.6%	82.7%
Sample labelling details	100%	100%	100%
Sample fixation details	100%	99.7%	100%
Sample receiving details	100%	100%	92.3%
Contact details	100%	100%	100%
Grossing details	100%	97.9%	100%
Tissue processing/ tissue sectioning/ tissue staining (details including TAT)	100%	98.2%	92.3%
Report for completeness	100%	100%	100%
Report for any transcription error	100%	100%	100%
TAT	100%	94.6%	100%
Recall/ amendment of reports	100%	100%	100%
Disposal of specimens	100%	100%	100%

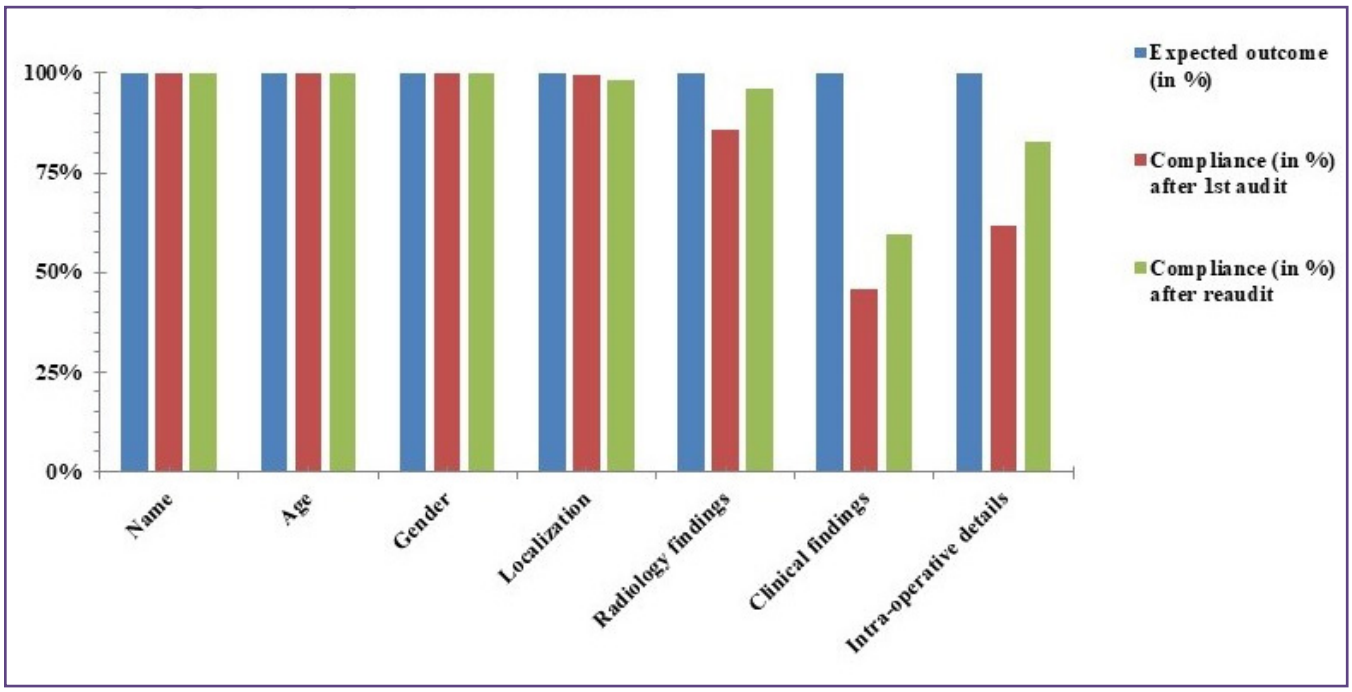

Fig. 1a: Bar graph showing the compliance for the clinical details.

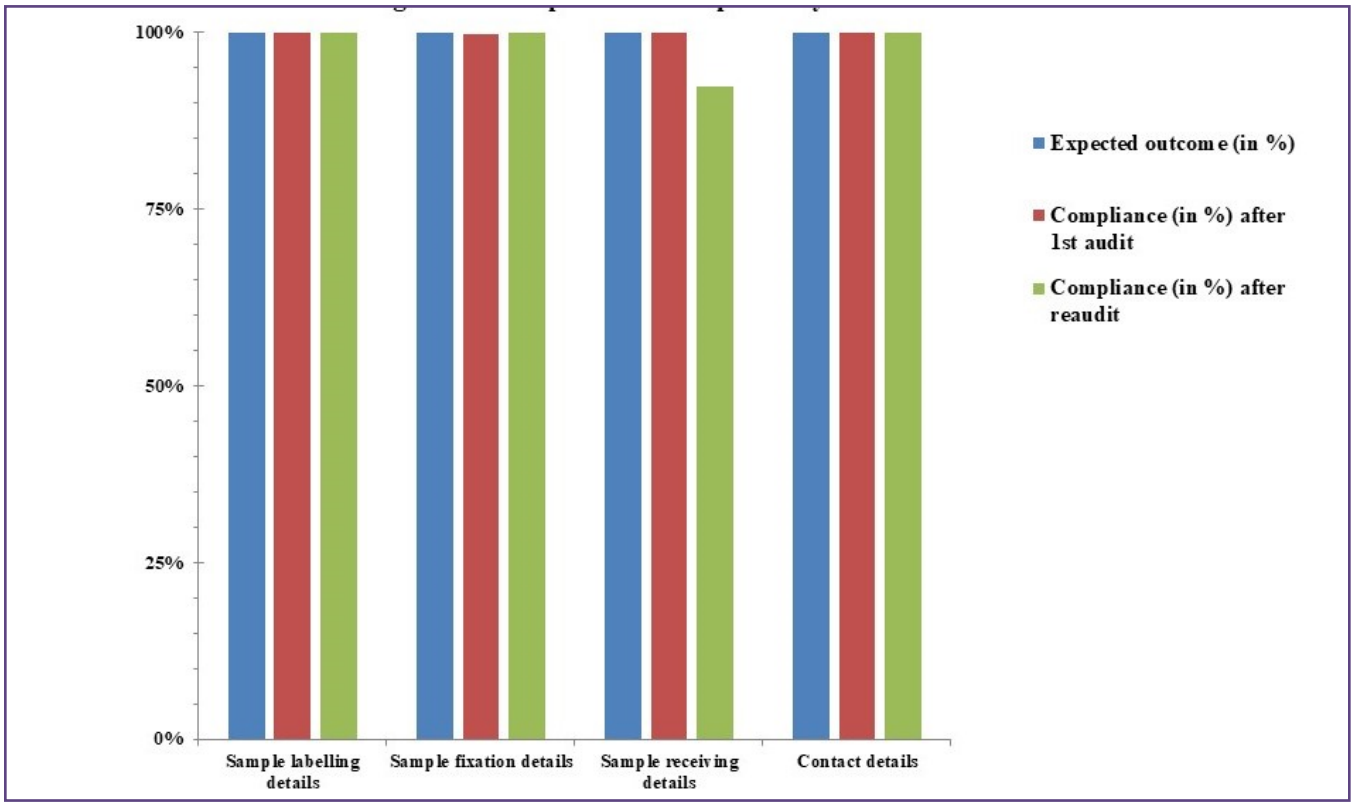

Fig. 1b: Bar graph showing the compliance for the pre-analytical details

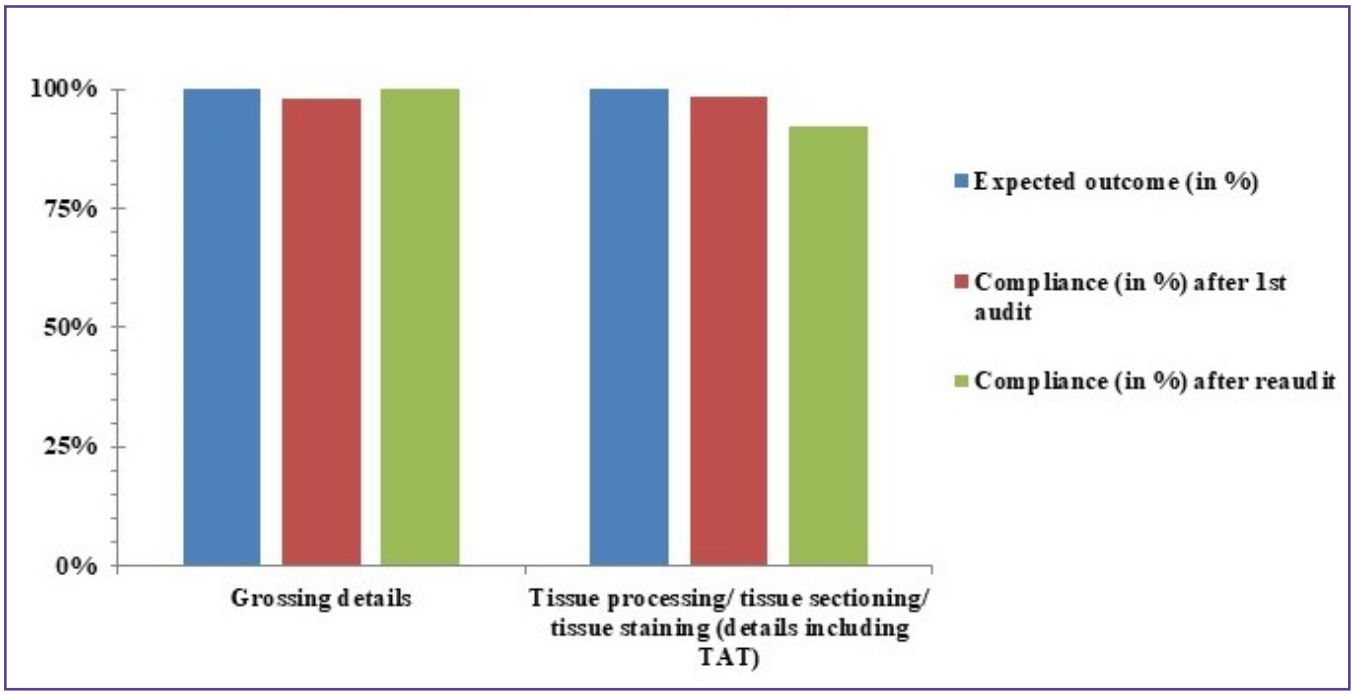

Fig. 1c: Bar graph showing the compliance for the analytical details.

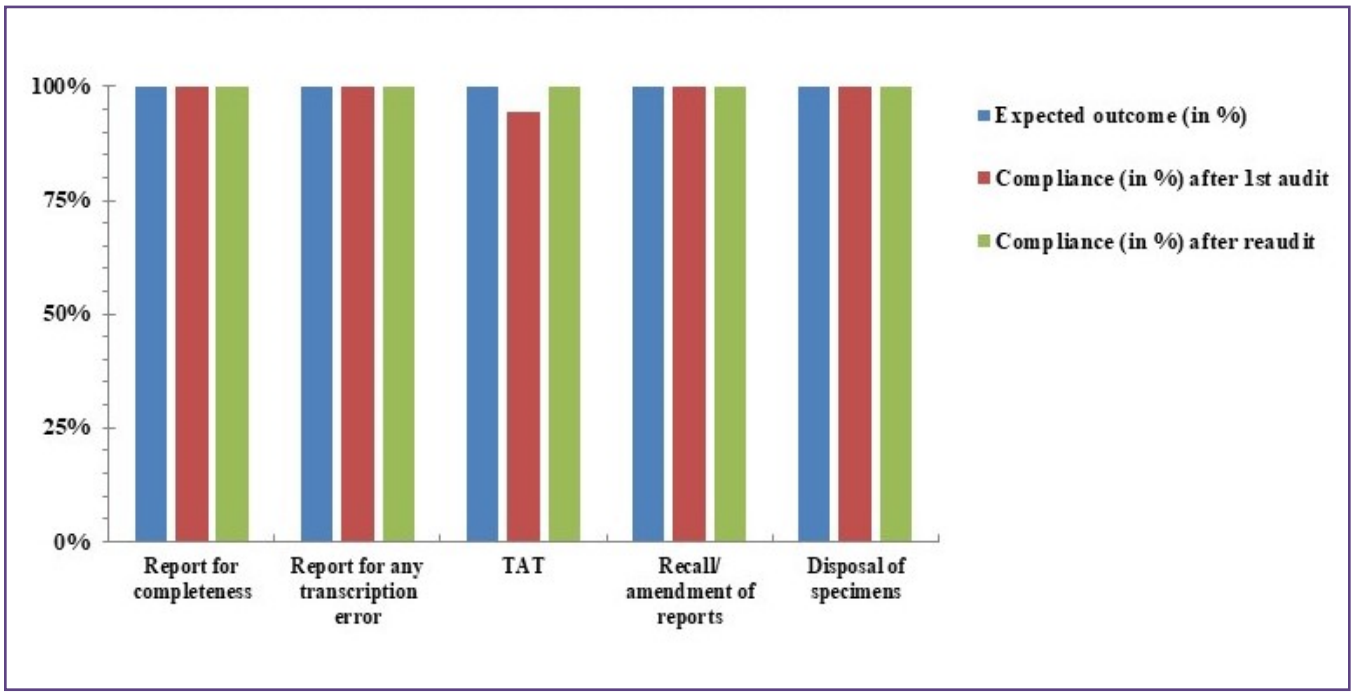

Fig. 1d: Bar graph showing the compliance for the post-analytical details.

Box 1: Standards formulated by the audit team

CLINICAL DETAILS
Name
Age
Gender
Localization
Radiology findings
Clinical findings
Intra-operative details

PRE-ANALYTICAL
Sample labelling details
Sample fixation details
Sample receiving details
Contact details

ANALYTICAL
Grossing details
Tissue processing (Details including TAT)
Sectioning details (Details including TAT)
Staining details (Details including TAT)

POST- ANALYTICAL
Report for completeness
Report for any transcription error
TAT details
Recall/amendment of report
Disposal of specimens

Discussion

Audits are always a part of the continuous quality improvement process and one of the key elements of quality assurance programs. Laboratory-based audits are concerned primarily with the everyday aspects of laboratory services and are a means of providing feedback to the users of the laboratory and its staff. They involve measuring the performance of laboratory services against established standards. If necessary, changes are implemented and then a re-audit is performed after a certain time period to ensure that the changes have been implemented and maintained. [2]

Areas of audit in a histopathology laboratory usually include the pre-analytical, analytical and post-analytical phases. In the laboratory, all the processes involved in providing a tissue section/slide are grouped under the pre-analytical phase. Recently some laboratories have started including aspects like patient satisfaction with the sample collection process, professional staff satisfaction with arrangements made by the laboratory towards sample collection in the pre-analytical phase. The analytical phase is all about the interpretation of the slides, and reaching to an accurate diagnosis. The post-analytical phase involves the report generation without transcription error within the defined turnaround time, report transmission/dispatch to the right person(s), proper storage/ retention of slides, blocks, test results, storage/disposal of samples. [3]

Over the years, it has been observed and reported, that majority of errors in any laboratory, including the histopathology laboratory usually relate to the pre-analytical phase. [4]To start with, in any histopathology laboratory, the process starts by receiving the tissue sample in an appropriate fixative accompanied by a properly filled histopathology requisition form. Adequate primary fixation and the choice of fixatives for specific histopathology investigations is of utmost importance and so is the requisition form. In general, it is always preferable and advisable for the laboratory to design its own "requisition form" for histopathology/ immunohistochemistry and make it available to all areas of sample collection. An ideal requisition form should provide space for entry of the relevant clinical, radiological and intraoperative details. It has to be followed by a correct patient identification by a unique identification number (traceable from the time of specimen receiving until its disposal). Other errors in the pre-analytical phase maybe any misplaced/lost specimens, inadequate quantity of the fixative, erroneous measurements during grossing, extraneous tissue (floaters), improper sections/inadequate serials, poor staining and mounting quality.

It is worthy discussing that almost all these pre-analytical phase errors are common but avoidable. In order to minimize the errors, it should be ensured in the laboratory

that documented instructions containing relevant information are made available at all points of specimen collection and the staff is well aware of this information.

Regarding the analytical phase, unlike in other disciplines of laboratory medicine, assessment of analytical aspects in histopathology is not so easy because of the subjectivity of the reports, still the errors in this phase may be minimized by conducting frequent internal audits including intra-departmental consultation (review of selected cases by colleagues), random case review/ blinded re-reporting of random cases to check the precision (when reviewed by the same pathologist who had reported previously) and accuracy (when reviewed by another pathologist).

Errors of the post-analytical phase like violation of TAT, reports with transcription errors, report transmission/ dispatch to the wrong person(s), improper storage/disposal of samples, slides/ blocks/test results maybe always minimized by continuous monitoring and conducting frequent internal audits in the laboratory.

This laboratory audit conducted by us helped us in assessing, monitoring and evaluating our histopathology services. In this audit we analysed the performance of the histopathologists, laboratory technicians, residents involved in typing the reports and the clinical team filling the histopathology requisition forms.

In this study, a major partial compliance/ non-compliance observed was the incomplete or missing clinical, radiological and intra-operative details in the requisition forms. This issue was discussed amongst the histopathologists, their technical staff, the neurosurgeons, their residents and the nursing staff. The importance of knowing the age of the patient, the site of the lesion along with any particular radiological features, clinical signs/symptoms and any characteristic intraoperative findings was shared with the neurosurgeons. It was also discussed that microscopic findings corroborated with this information definitely helps in reaching to an accurate histopathological diagnosis in CNS and spinal tumours. The unfilled or partially filled requisition forms not only reflects a wrong practice but also wastes the time of technical staff and the reporting histopathologists engaged in extracting the data from the treating clinician/team. However, from the clinician's perspective it was felt that to insert relevant check boxes in the requisition form rather than the descriptive columns may be a better alternate as it may be a time saving option in overworked public hospitals.

The audit also allowed us to identify the strengths of our histopathology laboratory like the parameters of the analytical phase including the grossing details, tissue processing details, sectioning details, staining details (all including TAT) which showed remarkable results. Similarly in the post analytical phase no gaps were identified in the reports for completeness, there were no transcription errors in any of the reports audited,turnaround time for reporting was well maintained, there was no evidence of recall/ amendment of reports reflecting an effective internal quality assurance in place, storage of tissue, blocks, retention of records and disposal of specimens all was found as per the standard operating procedures (SOPs) of the laboratory.

After completing the audit, complete results were shared with all the stakeholders and a written communication stating the need for improvement was also sent to the concerned neurosurgeons. After three months a re-audit was conducted and it showed marked improvement especially in terms of properly filled histopathology requisition forms. Thus, this study re-established that an open communication with the treating team about the importance of properly filled requisition forms is definitely effective and must to do. [5]In case whenever clinical data is not provided, the laboratory should take the initiative to extract relevant data from the treating clinician/team.

As per the existing standards, this audit fulfilled the major principles of the process of effective audit as it was relevant, objective, quantified and repeatable with identification of gaps requiring improvement. It also provided a method for reassessment of performance once appropriate corrective/ preventive actions (CAPA) have been implemented. As with all valid audit systems, this final step of reassessment is of utmost importance, resulting in the "closing of the audit feedback loop". [6, 7]

Conclusion

Continuous quality improvement of laboratory services requires the objective measurement of people, practices and organizations against valid and explicit standards in order to identify and implement appropriate changes. It may be concluded that such laboratory-based audits not only form an integral component of the quality assurance programs but definitely add on to the quality of patient care as the reports generated by the histopathology laboratories do help the neurosurgeons in deciding or modifying the treatment plan in case of CNS and spinal tumours. As an ongoing process, it is advisable to have series of smaller audit compared to one large audit so that any non-compliance discovered in the course of auditing may get corrected immediately.

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Competing interests
None declared

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