Original Article

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Pathology Section

Quality in Surgical Pathology- A Story of Continuous Improvement Over Seven Years at Rural Teaching Hospital in Western India

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ABSTRACT

Introduction: Quality assurance in histopathology is a long sought phenomenon with a limited objectiveness and well defined quality parameters. We tried to design, implement and monitor a Quality Improvement Plan of histopathology with target based approach and required interventions.

Aim: To establish and implement Quality Improvement Plan in histopathology, to identify various error rates, their reduction strategies and to assess scope for improvement in histopathology services.

Materials and Methods: Various defined parameters of pre-analytical, analytical and post-analytical phases of quality were implemented and monitored with necessary corrective and preventive actions to improve the outcome over a period of seven years.

Results: The study included 24,266 samples. Pre-analytical indicators showed improvement over a period of time with good performance in area of specimen fixation, specimen delivery, and completeness of requisition form and slide quality. The analytical phase showed continuous improvement in various correlations and error rates. A discordance rate of 1.09% was found in histopathology-frozen section correlation and 6.6% for histopathology-cytology correlation. Histopathology-IHC correlation rate was 87.1% and 0.2% cases showed discordance in internal peer review. Incomplete reports were found in 0.024%. In post-analytical phase, the total amended reports were 0.25%. A 96.8% of all critical alerts were intimated to clinicians. The Turn Around Time (TAT) outliers were 0.78%. External Quality Assurance Scheme (EQAS) performance was 76.3% and 97.7% for pre-analytical and analytical phase respectively.

Conclusion: The effective quality improvement plan for surgical pathology can be successfully implemented at rural teaching hospital by designing a plan and executing it with continuous monitoring and necessary intervention.

Keywords: External quality assurance scheme, Immunohistochemistry, Quality improvement plan, Turn around time

INTRODUCTION

Over the last few decades, there has been an increasing emphasis on the quality of healthcare. Surgical pathology plays a key role in patient management, therefore, its quality needs to be maintained. It is error prone due to its multifaceted nature. According to Nakhleh R [1], multiple factors at different levels of process contribute to errors in surgical pathology. Appropriateness in laboratory medicine can be assessed and improved through the governance of the entire testing process. The process initiates with test selction followed by pre-, intra- and post-analytical procedures and finally by concluding on correct interpretation using laboratory information. Therefore quality assurance and improvement plans in surgical pathology should be framed to reduce these errors. The Association of Directors of Anatomic and Surgical Pathology (ADASP) [2] had first published the recommendations for quality assurance and quality control in 1991. The quality improvement plan might be evolved bearing in mind the quality indicators which the laboratory identifies, setting thresholds and identifying established benchmarks for each parameter. These indicators then should be monitored on a regular basis in the context of the goals or thresholds set. Quality improvement plan includes not only taking corrective action, if laboratory falls below agreed standard, but also setting new and higher standards once the original targets have been achieved. Continuous Quality Improvement (CQI) is used to approach, evaluate and identify opportunities to improve quality before problems occur through evaluation of all systems/processes in the laboratory [3]. The aim of this study was to develop a quality improvement plan and assess its implementation by finding various error rates and their reduction strategies as well as identifying the scope for improvement for the histopathology laboratory.

MATERIALS AND METHODS

This is an observational and interventional study carried out at histopathology section of Central Diagnostic Laboratory (CDL), a rural based teaching hospital in central Gujarat, India. The CDL is accredited by National Accreditation Board for Testing and Calibration of Laboratories (NABL). The study was carried out from January 2012 to December 2018.

Inclusion criteria: All the specimens received and reported at histopathology section, were included. The specimens received from outside hospitals were excluded.

The study included various quality indicators and focused on prevailing and additional indicators to assess quality. Daily documentation of these indicators was done and then discussed and evaluated on a monthly basis in the laboratory services meeting. As a part of CQI the target for each indicator was set according to previous year's performance. If a target was achieved then it was re-set to higher level. CQI was assessed with the help of analytical studies and regular audit. The data was analysed by simple statistics with the help of Microsoft Excel software 2007. Corrective action for any deviation was taken whenever required. The study was conducted after formal approval from institutional ethical committee. Following indicators were included in study from pre-analytic, analytic and post-analytic phases.

Pre-analytical Phase

Specimen fixation: Volume of fixative in all received specimens was assessed for adequacy and documented daily. It should be at least ten to twenty times of that of volume of tissue [4].

Specimen delivery: Each specimen of histopathology was checked for proper delivery by technician for proper container (Open or leaky container was considered improper) and proper fixative (10% formal saline).

Completeness of requisition form: All requisition forms were checked for adequacy of clinical history including name and hospital number of patient, age, sex, date and time of collection, name of referring clinician, clinical history, provisional clinical diagnosis, radiological findings, concerned other laboratory findings and previous histology and/or cytology findings.

Block and slide labelling errors: Blocks and slides were labelled manually by laboratory assistant or technician. Any labelling error was documented with reason and step at which the error occurred. It was followed by appropriate corrective action.

Slide quality: All slides were stained with Haematoxylin and Eosin (H&E) stain. A control slide was put everyday to check for staining and section quality by reporting pathologist. After approval from pathologist, test slides were stained. For control, the tissue which has good mixture of haematoxyphilic and eosinophilic material was selected (e.g., from fibroadenoma). The poor quality slides were marked and given back for restaining with documentation.

Frequency of repeat slide: Frequency of repeat slides was noted. The repeat slide category includes two reasons, re-cut and re-stains. The re-cut included the deeper cut, thinner cut, reorientation, block reprocess due to poor section quality and extraneous tissue present in the slide.

Analytical Phase

Parameters in analytical phase were analysed to determine the diagnostic accuracy.

Frozen section-permanent section correlation: All the frozen section diagnoses were compared with final histopathological diagnoses. Any discordance was documented and informed to clinician as a critical alert. When the diagnosis could not be given or remain inconclusive at the time of frozen section then it was called deferred diagnosis.

Histology-cytology correlation: Histology-cytology correlation entails the concomitant review of cytologic and histologic specimens that were obtained within narrow time frame from the same site in a given patient. Concordance or discordance was documented.

Histology-Immunohistochemistry (IHC) correlation: The slide and block was sent to outside laboratory (which is NABL Accredited and having a Memorandum of Understanding (MOU) with our institute) for immunohistochemistry as per request by clinician. Any discrepancy between immunohistochemistry diagnosis and routine histopathological diagnosis was noted.

Peer review error rate: For peer review, one random case from histopathology is selected every working day by a resident doctor. Peer review was done by the professor other than reporting pathologist of that case. It is done on the next day of original reporting day with daily documentation. In case of any major or clinically significant discrepancy affecting patient's treatment or prognosis, the report is revised and amended report is released.

Incomplete report: 10% of randomly selected reports were checked for completeness daily. Grossing and reporting was done according to standard guidelines and textbook. Pre-defined formats were used for grossing and reporting of resection specimens. All incomplete report noted by clinician or random check was completed, amended and documented.

Post-analytical Phase

Transcription error: Gross and microscopic findings of reports is first written on the paper manually then transcribed to computer by transcriptionist to take print out. All reports were verified by pathologist before signing out. All transcriptional mistake picked during 10% random check by pathologist or clinician's check, was corrected documented.

Report delivery error: Delivery of reports was done to wards or OPDs from where specimen received. The deliveries of all the reports were recorded in a report dispatch register by signing on receiving.

Amended reports: When any report has to be revised because of change in original report, it is called amended report. The number and reason of amended reports were noted.

Intimation of critical alerts: The list of critical alert was made according to various published guidelines for histopathology [5]. The critical report was informed to the clinician telephonically by resident and documented on the same day.

Turnaround Time (TAT): TAT for each category (Large biopsy-5 days, Medium biopsy-4 days, Small biopsy-3 days) of specimen was defined. It was calculated from the time of receiving of the specimen to the time of online release of report. TAT was calculated by Laboratory Information System (LIS) software automatically. The cases where TAT was exceeded were analysed.

RESULTS

During the study period, a total 24,266 surgical pathology samples were received. The quality performances are depicted in the [Table/Fig-1-4].

Pre-analytical Phase

Specimen fixation, volume adequacy and proper specimen delivery were found better with every year of performance. Inadequate volume and open container were mainly found in very large specimen, but after receiving at laboratory the specimen is transferred to another container with adequate formalin. The completeness of requisition form improved down the line because of integration of Laboratory Information System (LIS) with Clinical Information System (CIS), so it became easy to access the clinical and radiological findings online. Block and slide labelling errors were monitored vigilantly and over all less than 0.5% mislabelling happened but none of them caused reporting error, all were random human error and identified during microscopy. The quality of sections and staining were also monitored daily and necessary improvements were introduced in terms of timely and adequate fixation and proper processing of tissue, daily maintenance of tissue processor, embedding station, microtome (their maintenance log were maintained) and preparation of stains as per SOPs with necessary modifications, if required. This is reflected in the improving trends of slide quality over the years. The total repeat slides were 1.25% of all submitted slides and the various reasons for repeat slide were deeper cut (56.3%), thinner cut (10.4%), section reorient (18.3%), section reprocess (12.5%) and floater or extraneous tissue present (2.5%). Few of them were unavoidable, as some times deeper cuts or thin cuts were required to look for invasion and proper morphology but still we tried to keep it minimal with reasons being recorded and discussed [Table/Fig-1].

Analytical Phase

Frozen section: Permanent section correlation was almost cent percent except for three cases. The discordant cases were

Quality indicator		2012		2013		2014		2015		2016		2017		2018	
		T	P	T	P	T	P	T	P	T	P	T	P	T	P
Specimen with adequate fixative		95	97.5	97	98.2	98	98.5	98	99	99	99.2	99	98.5	99	99.1
Specimen delivery	Specimen with open/damaged container	<5	6.26	<5	1.91	<3	2.5	<3	2	<2	1.7	<2	1.2	<2	0.8
	Improper fixative/normal saline		0.09		0.06		0.02		0.09		0.09		0.06		0.05
Completeness of requisition forms		80	62.5	80	75.5	80	79.6	85	92	90	99.5	95	98.5	98	99.1
Block and slide labeling error		0	0.19	0	0.08	0	0	0	0	0	0.052	0	0.021	0	0.042
Slide quality	Poor quality stain	<5	7.9	<5	7.8	<5	4.5	<4	2	<4	1.5	<2	2.3	<2	1.1
	Poor quality section	<5	5.6	<5	5.4	<5	2.1	<4	0.8	<4	1.1	<2	0.5	<2	0.2
Frequency of repeat slides		<3	1.02	<3	1.35	<2	1.1	<2	1	<2	1	<2	2	<2	1.3

[Table/Fig-1]: Pre-analytical quality performance.
T: Target in %; P: Performance in %

Quality indicator		2012		2013		2014		2015		2016		2017		2018	
		T	P	T	P	T	P	T	P	T	P	T	P	T	P
Frozen section permanent section correlation	Correlation %	100	100	100	96.4	100	100	100	100	100	100	100	99.3	100	100
	Total frozen		50		57		63		96		182		154		143
Histopathology-Cytology correlation	Correlation %	100	90.4	100	88.9	100	91.9	100	97.1	100	99.3	100	92.3	100	93.3
	Total cases for correlation		73		36		62		69		58		78		75
Histopathology-IHC correlation	Correlation %	100	68.2	100	82.3	100	90	100	91.6	100	90.4	100	88.75	100	85.8
	Total IHC Cases		22		17		30		48		52		80		99
Peer review error rate	Error rate %	0	0.34	0	0.33	0	0	0	0	0	0	0	0	0	0.67
	Total peer reviewed cases		292		296		298		297		298		297		298
Incomplete report		0	0.07	0	0	0	0	0	0	0	0.025	0	0.023	0	0.04

[Table/Fig-2]: Analytical quality performance.
T: Target in %; P: Performance in %

Quality indicator		2012		2013		2014		2015		2016		2017		2018	
		T	P	T	P	T	P	T	P	T	P	T	P	T	P
Transcription error		0	0	0	0	0	0	0	0.03	0	0	0	0	0	0.02
Report delivery error		0	0	0	0	0	0	0	0	0	0	0	0	NA	NA
Amended reports		<2	0.37	<2	0.15	<2	0.18	<2	0.35	<1	0.27	<1	0.21	<1	0.22
Intimation of critical alert	% intimated	95	90.3	95	96	95	96.2	97	98.5	97	99.2	98	99.9	98	97.6
	Total critical alerts raised		273		251		301		409		440		493		519

[Table/Fig-3]: Post-analytical quality performance.
T: Target in %; P: Performance in %; NA: Not applicable

Quality indicator			2012		2013		2014		2015		2016		2017		2018	
			T	P	T	P	T	P	T	P	T	P	T	P	T	P
TAT outlier (%)	Total outlier (%)		2	0.6	1	1	1	0.4	1	1	1	0.89	1	0.68	1	0.84
	Total outlier (n)			16		26		11		31		35		29		42
	Total number of reported cases		2701		2593		2683		3104		3932		4270		4983	
	Total small biopsies (n)	Outliers (%)	1551	0.2	1650	0.42	1752	0.17	2011	0.5	2684	0.37	2974	0.17	3491	0.2
		Outliers (n)		5		7		3		10		10		5		7
	Total medium biopsies (n)	Outliers (%)	940	0.4	726	1.1	713	0.14	803	1.12	863	00	891	00	930	0.21
		Outliers (n)		2		8		1		9						2
	Total large biopsies/ Radical resections (n)	Outliers (%)	210	4.2	217	5.07	218	3.2	290	4.13	385	6.5	405	5.9	562	5.9
		Outliers (n)		9		11		7		12		25		24		33

[Table/Fig-4]: Turn around time performance.
T: Target in %; P: Performance in %

informed as critical alert. The indication for frozen section was to assess the surgical margins (88%), metastatic nodal status (3.5%) and to know the primary diagnosis (8.5%). A steady increment was found in the histo-cytology correlation. However, in the last two years, discordance was noted in the four cases of intracystic and small papillary carcinoma of thyroid reported as benign thyroid lesions on cytology. Regarding Histo-IHC correlation, changing trends were seen; initially discordances were high due to limited experience of reporting but in later years it showed better performance due to increasing number of cases and stringent departmental review on little suspicion of diagnosis. All the discordant cases were discussed at departmental level for education and preventive action purpose. Histopathology-clinical correlation was started in 2016 to know the matches between clinician's provisional diagnoses and final histopathological diagnoses. Performance target was not set for this parameter but it is included due to requirement from NABL. Total 4 cases (0.2%) were revised due to peer review error in whole study period. A total six incomplete reports were identified during entire study period [Table/Fig-2].

Post-analytical Phase

Two cases of transcriptional error were noted in total study duration. No report delivery error was found. Reports of total 61 cases were amended due to various reasons like change in diagnosis after departmental review after clinician's request (commonest, 23 cases), change in diagnosis after submitting additional section or special stain (11 cases), peer review discordance (4 cases), typographical error (10 cases), incomplete report (6 cases) and incorrect requisition form (7 cases). More than 95% of the critical alerts were informed with more or less increasing trends [Table/Fig-3].

Turnround Time (TAT)

Total 190 cases (0.78%) were TAT outliers out of 24,266 total reported cases. Highest TAT outlier was found in large biopsies with 121 (5.3%) outlier cases among total 2287 large biopsies submitted. Various causes of delay include decalcification (30%), extra sections or reprocessing (20%), departmental review (23.3%), machine breakdown (16.6%) and special stain (3%). TAT outliers are 0.37% and 0.3% for medium and small biopsies respectively. Target was well achieved and performance was found consistently good due to data monitoring and adherence to reporting protocol. It was achieved TAT outlier rate below one percent even work was doubled in last seven years [Table/Fig-4].

DISCUSSION

Pre-analytical phase: A total 1.43% (347) specimen was received with inadequate volume of fixative. This study shows 2.34% (568) cases of improper container and 0.066% (16) cases of improper fixative among all received specimens. The trends were improved over the years and this could become possible by continuous training and education of nurses and clinical residents regarding significance and way of fixation and also better availability of fixative. Incomplete requisition form was found in 15.3% cases in our study, while study of Burton JL and Stephenson TJ, show 6.1% such cases [6]. Inadequate clinical history has been shown to affect the accuracy and completeness of pathology reports [7,8]. Failure to provide the requested and relevant information prevents the pathologist from assessing the appropriateness of the investigation as well as also causes increased cost upon laboratory and patient and faulty patient management. Improving clinical information in surgical pathology is likely to come from improvement in information technology [9,10]. One of the principal advancement that many institutions have already adopted is the introduction of the electronic medical record. The present study also experienced drastic reduction in incomplete requisition form after 2016 due to adoption of electronic clinical information system. This electronic computer based record keeping and a merged LIS and CIS caused overall improvement of many quality indicators and also gave a beautiful bi-product, "the paper saving". Block and slide labelling error were seen in 0.05% (12) cases. Layfield LJ and Anderson GM, found 0.06% and 0.03% slide and block labelling error respectively [11]. In all cases the error was corrected before the issue of report. The poor quality stain and sections were found in 3.87% and 2.24% slides respectively among total submitted slides. In majority of times the reason for poor quality stain and section was lack of trained manpower. Use of standard chemical reagents for tissue processing, periodic change of reagents, daily monitoring of temperature of paraffin wax and water bath lead to optimal tissue processing, which is an important prerequisite for good sectioning [12]. Use of standard material for staining and daily use of control for H&E stain was another factor to keep check on quality of staining. It was also monitored the number of repeat slides to keep a check on unnecessary wastage of consumables. The target to reduce repeat slides below 2% was set and achieved.

Analytical Phase

A total 1.09% (3 cases) was discordant in histo-frozen correlation, one was from parotid gland and two were of brain tumours. The commonest site of frozen section was oral cavity for margin status in wide excisions and radical neck dissections. According to Shrestha S et al., the diagnostic discrepancy in frozen section is mainly due to interpretative error, sampling error, technical artifacts and partly due to lack of communication between departments [13]. Discrepancies are also different according to tissue sites. Geramizadeh B et al., observed 3.3% discordant cases with CNS being the most common submitted site [14]. Few precautions can avoid discrepancy including proper inspection of gross specimen with careful and selective sampling and good communication with surgeon. In the present study of the total 451 cases of cytology with histology follow-up, 30 (6.6%) cases showed discrepancy. The most common site for discrepancy was found in lymph node (11 cases) followed by thyroid (6 cases) and salivary gland (4 cases). Monitoring of cytology-histology correlation is an important internal quality assurance activity for cytology which permits an improvement in diagnostic accuracy and reproducibility. Raab SS et al., found highest rate of discrepancies in urinary bladder followed by breast cytology [15]. The histopathology-IHC correlation rate was 87.1% and it improved over the years slowly, with increasing number of IHC cases. The most common site for IHC correlation was lymph node. The majority discordances were due to known pitfalls and limitations of H&E stained sections. Peer review is the best method to determine diagnostic accuracy. In the current study out of total 2075 peer reviewed cases, 0.2% (4) cases were discordants and all were revised. A study conducted by Renshaw AA and Gould EW, stated that the disagreement by peer review was 4.8% and 6.9% respectively for review by one or more than one pathologists [16]. In present study percentage of total disagreement was low as compared to other studies because of uniform pattern of reporting followed and a system of reporting by a group of three pathologists. In the present study incomplete histopathology report was found in 0.024% cases. Branstone LK et al., showed that computerised pre-defined forms improve the completeness of reporting [17].

Post-analytical Phase

Total 0.008% (two cases) transcription errors were identified in whole study. This low rate is attributed to double check of transcribed report in pre-release report as well as final report and signing out of report by three pathologists. No delivery error was found in entire study period. Due to zero error and online availability of report in LIS, Monitoring of this parameter was stopped from 2018. The total amended reports were 0.25% (61). Renshaw AA and Gould EW, shows 0.8% amendment rate [18]. The total 96.8% of total raised critical alerts (2686) were intimated to clinicians.

TAT: Clinicians depend on fast TAT to achieve early diagnosis, treatment and patient discharge. For better or worse, TATs also influence the perception of the laboratory in the community of health care providers. Using such a software based calculation approach also could help pathologists to identify the factors adversely affecting TAT. Patel S et al., found various common reasons for exceeding TAT are diagnosis of malignancy (including staging), consultation with other pathologists, having had a frozen section and use of immunohistochemical stains [19].

LIMITATION

While all the samples over 7 years have been included, the completeness of reports has been a sampling exercise of 10% cases. Additionally, indicators like performance in EQAS have not been discussed in this paper.

CONCLUSION

The observations made from the current study showed the performance of quality indicators were improved or remained within assigned targets.

Quality improvement plan in surgical pathology is an effective tool for ensuring continuous quality improvement by the use of quality indicators, which helps to quantify the quality. Monitoring of quality indicators also ensures early detection of errors and thereby effective and timely intervention of corrective and preventive action. Error exposure strategy by utilising histology-cytology correlation, histology-frozen section correlation, internal peer review are important tools for promoting a culture of patient safety and integrated quality that inspires individuals to learn from previous mistakes.

Documented the root cause, analysis of any diagnostic discrepancy and synoptic reporting is recommended to reduce the reporting error and incomplete reports. To make and implement a functionally successful quality improvement plan, individual and collective training, well-defined goals and implemented accountabilities with effective supervision are required.

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