Analysis of quality assurance: a novel step in fixing the turn-around time of surgical pathology reports as a part of quality management system

Anandraj Vaithy. K[1,*], Shanmugasamy K.[2], Garima Anandhani[3], Dhananjay S. Kotasthane[4]

[1,3]Assistant Professor, [2]Associate Professor, [4]Professor & HOD, Dept. of Pathology, Mahatma Gandhi Medical College and Research Institute, SBV University, Puducherry

***Corresponding Author:**
Email: kanandrv@gmail.com

Abstract

Introduction: Lab investigations are essential in patient and quality management system. The essential aspect of quality which goes often overlooked is turnaround time (TAT), a key performance indicator of laboratory. Most laboratories put undue stress on only reliability, but nowadays the clinician is more inclined towards getting the result done in a shorter time. Analyzing outliers in TAT in a lab gives insight of causes delay and the areas need improvement. Laboratories in developing countries are yet to use TAT and analyze them for laboratory improvement.

Methodology/strategy: Analysis was conducted for a period of four months on Histopathology specimens. The initial step was to trace the flow process. Laboratory improvement strategy was developed by designing a time log sheet attached to all histopathology request forms at the time of receiving specimens. All the data including and all sub process in the flow path were documented and an attempt was made for corresponding remedial measures

Results: Root cause analysis revealed that the processes of slide allocation and delivery to pathologists, report editing by transcriptionists, report verification by pathologists are the sub-processes where most delays occur and set to be a target area for our improvement and subsequent remedial actions were drafted to ensure quality assurance

Conclusions: The study re-emphasized the fact that small and simple change can lead to huge improvements in surgical pathology laboratory TAT and not necessarily complex changes. It also helps in mapping out the workflow process using time log sheet, had led to process and systems improvement by Focusing and fixing sub processes which showed that 94% of all histopathology cases being reported within the standard TAT.

Keywords: Quality assurance, Surgical Pathology. Time Log sheet, Turn Around Time.

Introduction

Laboratory analysis of samples and services have an vital role in the of health care and in utilization of quality delivery.(1) A good quality assurance is a marker for effective laboratory work –up.(2) Assessing the quality assurance of laboratory services using quality indicators or performance measures requires a systematic approach and feasibility for collecting and analyzing data. A comprehensive approach would address all stages of the laboratory total testing process.(1,2)

The Institute of Medicine (IOM) defines the quality of laboratory care as "the degree to which health care services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.(3) An "Quality indicator" is a tool that enables the user to quantify the quality of a selected aspect of care by comparing it with specific parameters.(3,4)

A quality indicator is termed as an objective measure that evaluates and analyses the critical health care domains as defined by the IOM which also includes patient care & safety, efficiency, equity, patient-centeredness, time-bounding and customer satisfaction.(3) Quality assurance includes various domains in intra-laboratory phases with hierarchical parameters and protocol. Both the domains are covered under a broad entity called as "Turn Around Time" (TAT). Turn -around time plays a crucial role in laboratory work up which is often termed as "Gold Standard" indicator of Laboratory efficiency.(4,5) TAT is universally followed in all the diagnostic laboratory up as a mandate.(5) TAT in Pathological laboratory especially surgical pathology laboratory is of utmost importance in both Clinician's and as well Patient's point of view.(4) Turnaround time is a major quality indicator for clinical hematology and surgical pathology laboratories. Several Constitutional bodies like College of American Pathologist (CAP), National Accreditation Board for Laboratories (NABL) are formed to define TAT & its variables.(5,6) According to the College of American Pathologists (CAP), most of the routine diagnostic cases should have a turnaround time of two days or less for the surgical pathology report.(6) In precise, TAT is defined as the time period from day of receipt of sample to the day of dispatch of report.(7)

Quality assurance includes various domains at intra-laboratory phases and hierarchal protocol system.(7) TAT has 3 broad phases which includes

A. Pre Analytic phase
B. Analytic phase
C. Post Analytic phase

Pre analytical phase: All processes involved from receipt of sample upto submission of stained slides to pathologist for analysis. It involves mobilization of samples involving clerical and technical staff.

Analytical phase: Involves interpretation and finalizing a report with sole involvement of Pathologists.

Post analytical phase: Involves report generation and report dispatch until it reaches the Patient and referred Clinician.

Increase in TAT alleviates the anxiety of the patients' stress. Timely anatomical pathology reports are one of the most important tools physicians use to adequately manage the quality and safety of patient care.[7,8] Hence, verifying pathology reports in an appropriate time frame helps health care practitioners with diagnosing patients in a timely fashion, which will lead to an effective treatment plan.[8]

Extensive Research analysis proved shows that a delayed turnaround time raises morbidity and mortality rates considerably.[9] Most pathology departments in histopathology section worldwide follow the standards of the International organizational bodies like The Joint Commission (TJC), CAP, National Accreditation Board for Laboratories [NABL] warranting precise evaluation and reporting of specimens for patient management plans.[9,10]

Researchers had postulated that to establish proper TAT requires month to years and more importantly to sustain the established TAT required in skillful effort in conjunction with knowledge.[10,11]

Accuracy of reporting and delivering timely complete reports plays a major quality indicators in surgical pathology.[11] Several unexplained factors had been round off causing delay in TAT. In a Surgical Pathology laboratory, pathologists has the key role in all the 3 phases of the TAT and on tops it Patient's anxious has a great impact on TAT. However Unlike Hematological Laboratory which has EQAS programmer for checking TAT and quality assurance, there are only few standard methods available to have a quality check on TAT in Surgical Pathology Laboratory.[11,12]

Thus in the present analytic study, we decided to employ quality improvement methods and tools to identify the cause for delay and to maintain the turnaround time of surgical pathology laboratory reports, and meet the CAP standard approved turnaround time meeting Clinician and Patient's satisfaction

Aims & Objectives

1. A novel aim for quality improvement in Turnaround time in surgical pathology reporting for a period of 4 months [Quarterly period].
2. To assess the efficacy of attaching Log sheet in the request form and thereby verifying TAT in step by step process
3. To draft a remedial action based on the analysis for the identified cause for prolonged TAT.

Material & Methodology

The study was conducted in Dept. of Pathology-Histopathology section in Puducherry, for period of 4 months duration as a quarterly evaluation. TAT was determined as per the standard definition [1].

A separate log sheet was attached to the routine histopathology request form sent by the clinician. It included all the terms of TAT as defined and entry was noted in the corresponding column at each and every step of the TAT phases. We started by attaching a time log sheet to all surgical pathology request forms. The time for each sample processing stage was documented by medical technologists and administration assistants until the slides reached the pathologist's office. Then the pathologist took over to document the time spent in the main process until verification. Transcriptionists then entered all data into an Excel worksheet and calculated the turnaround time.

Results & Observation

During the period of study, overall of 342 cases were analyzed in the histopathological sections. Step by step protocol was documented as described in the following table.

Table 1: Transfer of samples from Surgery theatre to Histopathology Section

Transport of Samples to Laboratory	Number of Cases
Samples received on date of surgery	212
Samples received 1 day after surgery	80
Samples received 2days after surgery	21
Samples received 3 days & more than 3days Post surgery	29

Table 2: Processing of the samples in TAT protocol phases

Phases	Days From Reveiving Sample	Procedures
Pre-Analytical	Working day 1 to 2	Sample receiving, labeling, tissue processing &slide put up to the Pathologist
Analytical	Working day 3	Interpretation and finalization of reports
Post–Analytical	Working day 4	Typing, proof reading and dispatch of results

Table 3: Number of cases dispatched within TAT & prolonged TAT

Time period for Reports dispatch	Cases in Number & %	Reasons for delay
Routine 3days	222 (64.3%)	Normal TAT as per NABL &CAP protocol
In 3 to 4 days	49 (14.2%)	Additional clinical details, intra departmental consultation and work up.
Within 5 days	29 (8.4%)	Kept for fixation, collecting Clinical details, intra departmental consultation by professors.
More than 5 days	11 (3.18%)	Special stains, Re-grossing, thinner/ deeper sections.
More than 10 days	18 (5.2%)	Decalcification for bone specimens, special stains, Re-grossing.

Discussions

Quality assurance is the backbone for effective running up of any laboratory.[2] Histopathologists have a great role behind the screens in delivering diagnosis to the Clinician based on which the further plan of management is carried over.[2,3] The observations from the data showed about 65% of cases were dispatched well within time frame and a quarter (24%) of surgical pathology cases were reported beyond the two day turnaround time as recommended by statutory bodies.[4]

The Laboratory Medicine specialists the Pathologist works consistently to meet the Clinicians requirements.[5] Previously many Scholars have postulated many models to analyze TAT in Surgical Pathology Laboratory.[6,7,8] The turnaround time (TAT) for a histopathology laboratory test can be an important measure of how well the laboratory is meeting the needs of its patients.[9] Previous studies have shown many factors influencing to the TAT for reporting which includes-[9,10]

a) selecting and ordering the test
b) collecting the specimen and delivering it to the laboratory
c) accessing the specimen and delivering the specimen within the laboratory
d) reporting and finalizing results & communicating to the clinician.

In the similar regard, the present study applied the method of attaching "log sheet" to the Clinician's request form and thereby curbing the delay in TAT. The following table clearly depicts the factors affecting effective TAT and the subsequent remedial actions to be taken in their Correspondence.

Table 4: Factors affecting effective TAT and proposed remedial measures

Phases	Factors Affecting	Remedial Measures Warranted
Pre-Analytic Phase	Autolyzed specimen Erroneous labeling of specimen bottles in Theatres	Proper supervision and labeling at clerical and technical domain
Analytic Phase	A. Incomplete investigation forms basic details like Unit/ ward not mentioned. Clinical history, investigations (X-ray, imaging studies), type of surgery, reference to earlier reports, not mentioning the side and site of biopsy	Proper filling up of forms by clinical dept. Name and Contact number of concerned Clinician.
	B. Scientific reasons for delay Additional tissue bits, Deeper sections Thinner sections, Special stains are needed in few cases for finalizing reports	When re-bits are taken, sample goes again into pre-analytic phase.
Post–Analytic Phase	A. Hospital and referring Clinician identity was not mentioned in the investigation forms; hence reports couldn't get dispatched at correct places.	Proper entry of details
	B. Reports getting lost /misplaced	Preparing of Backup database of the results
	C. Reports held up for non -payment/ Miscellaneous reasons	Informing reports to the clinicians over telephonic conversation

Various models are applied and analyzed to assess performance and efficiency in the steps taken to ensure proper TAT. However most of the study results portraits only the reasons for the delay in TAT and very sparse articles suggest the remedial measures to be implemented. The unique feature of the present study is that it identifies the unexplained reasons and hindering factors at various levels in maintaining effective TAT

and also suggests the appropriate measures as precautionary corrective measures, thereby adhering to the standardized norms.

Conclusion

Quality assurance in the form of Turn Around Time plays a vital role in effective running of successful histopathology laboratory. Proper TAT helps timey treatment and also alleviates the patient's anxiety. Attaching a well framed log sheet to the histopathology request form significantly reduces the delay in TAT and also aids in drafting future remedial plans. Also it is evident from the present study that instead of complex changes, small and simple changes can guide to huge improvements as quality assurance is concerned.

References

1. Nakhleh RE. Fitzgibbons PL. Quality Management in Anatomic Pathology: Promoting Patient Safety Through Systems Improvement and Error Reduction. Northfield (IL): The College of American Pathologists, 2005;(2):1-4.
2. Howanitz JH. Howanitz PJ. Timeliness as a quality attribute and strategy. Am J Clin Pathol. 2001;116:311-15.
3. Novis DA. Walsh. Continuous monitoring of Stat and Routine outlier turnaround times. Two College of American Pathologists Q-tracks monitoring in 291 hospitals. Arch Pathol Lab Med. 2004;128:621-26.
4. Steindel SJ. Novis DA. Using outlier events to monitor test turnaround times. A College of American Pathologists Q-probes study in 496 laboratories. Arch Pathol Lab Med. 1999;123:607-14.
5. Vollmer RT. Analysis of turnaround times in pathology. An approach using failure time analysis. Am J Clin Pathol. 2006;126:215-20.
6. Patel S. Smith JB. Kurbatova E. Guarner J. Factors that impact turnaround time of surgical pathology specimens in an academic institution. Hum J Pathol. 2012;43(9):1501-5.
7. Jerjes W. Upile T. Radhi H. Delay in pathological tissue processing time vs. mortality in oral cancer: Short communication. J Head Neck Oncol. 2012;2:4:14.
8. Nakhleh RE. What is quality in surgical pathology? J Clin Pathol 2006;59(7):669-72.
9. Novis DA. Zarbo RJ. Saladino AJ. Inter-Institutional comparison of surgical biopsy diagnosis turnaround time: a College of American Pathologists Q-Probes study of 5384 surgical biopsies in 157 small hospitals. Arch Pathol Lab Med 1998;122(11):951-6.
10. Nakhleh RE. Souers R. Ruby SG. Physician satisfaction with surgical pathology reports: a 2-year College of American Pathologists Q-Tracks Study. Arch Pathol Lab Med 2008;132(11):1719-22.
11. Röcken C. Manke H. Accreditation in pathology. Systematic presentation and documentation of activities in pathology. J. Pathologe 2010;31(4):268-78.
12. Bekeris LG. Tworek JA. Walsh MK. Trends in blood culture contamination: a College of American Pathologists Q-Tracks study of 356 institutions. Arch Pathol Lab Med. 2005;129:1222-25.