IJPPR
INTERNATIONAL JOURNAL OF PHARMACY & PHARMACEUTICAL RESEARCH
An official Publication of Human Journals
ISSN 2349-7203
HUMAN

Human Journals
Review Article
January 2021 Vol.:20, Issue:2

Quality Management in Histopathology Lab

IJPPR
INTERNATIONAL JOURNAL OF PHARMACY & PHARMACEUTICAL RESEARCH
An official Publication of Human Journals
ISSN 2349-7203
HUMAN

Sheeba Ali*[1], Puja Bansal[2], Deepak Bhargava[3]

[1]Assistant Professor, School of Dental sciences, Sharda University, Greater Noida. India.

[2]Professor, School of Dental Sciences, Sharda University, Greater Noida. India.

[3]Professor & Head, School of Dental Sciences, Sharda University, Greater Noida. India.

Submitted: 10 December 2020
Revised: 30 December 2020
Accepted: 20 January 2021

Keywords: quality, histopathology, assurance, management

ABSTRACT

The fundamental aim of quality management is to improve patient safety and enhanced patient care with timely, accurate and complete pathology diagnosis and reports. Management policy should ensure that standard facilities are available before any laboratory work is commenced. In practice, anything that restricts the efficient running of the laboratory would be a cause for concern and should lead to noncompliance with the quality assurance system. Present article discusses quality management system which can ensure quality performance in histopathology laboratory.

HUMAN JOURNALS
www.ijppr.humanjournals.com

INTRODUCTION

Management is an important aspect of the day-to-day life of the histopathology laboratory particularly since the emergence of accreditation. The accreditation standards include management as part of the evaluation and it is necessary that the laboratory worker is familiar with the processes involved.[1]The National Academics Institute of Medicine (IOM) in the U.S.A. estimates that approximately 44,000 to 98,000 deaths occur annually in that country alone due to medical errors. This has prompted joint commission on accreditation of healthcare organization to issue patient safety goals that include patient identification and effective communication among caregivers in addition to many others. These goals also apply to the field of histopathology.[2] The National Accreditation Board for Testing and Calibration Laboratories (NABL) has been providing accreditation services to medical laboratories since 1998 and is currently following ISO 15189; 2012 standards.[3]

Most results emanating from most Indian institutional laboratories lack consistency and accuracy with the fact that sensitivity and specificity are highly compromised. Prolonged laboratory reports would have lost its value before the attending clinician who may have treated his patient empirically. Reagents that are not properly stored or that have expired, produce many highly compromised false positive and false negative results.[4]

For every practicing surgical pathologist, improvement of diagnostic accuracy is an important objective. Several retrospective and prospective methods are available that are important in the attainment of this objective. Organizations such as the College of American Pathologists (CAP) have published quality assurance (QA)/quality control (QC) programs to ensure not just diagnostic accuracy but also completeness and timeliness of all surgical pathology reports.[5] Current regulations require that departments of pathology have a structured and active program of quality assurance and quality improvement with the goals of enhancing patient safety, minimizing error, ensuring timely delivery of reports and monitoring physician competence.[6]

This article is intended to raise concern on how feasible histopathology laboratories in India would be able to achieve efficient quality control and produce standard results.

QUALITY MANAGEMENT

Quality is the degree to which healthcare services strive to provide accurate desired outcomes for patients and are consistent with current professional knowledge. As pathology is pivotal to health care, deterioration in the quality of pathology services can compromise patient care and lead to adverse health events.[7]

Thomas Berry once said ‘‘Total quality management is a journey, not a destination.’’.[8] If any journey begins with a single step, then the journey toward total quality management must begin with an understanding of the relationship between laboratory quality activities that should be designed and supported by laboratory management and the technical activities that produce laboratory results for patient care.[9]

ISO 9000 defines quality management as “coordinated activities to direct and control an organization with regard to quality”. This is intimately related to the definition of a quality system— “organizational structure, resources, processes and procedures needed to implement quality management”.[10]

Whether considering proficiency testing, accreditation or legislation, peer-review is the key to success. All three approaches towards establishment of quality in pathology laboratories require reference to National guidelines. Six Professional Practice Guidelines that should be developed are (1) retention of pathology records and materials, (2) minimum qualification, training and experience of professional personnel working in a pathology laboratory, (3) laboratory construction and design, (4) maintenance and operation of equipment in a pathology laboratory, (5) safe laboratory practice, and (6) sample management.[11]

To ensure quality performance, every laboratory should have some form of quality management system. Quality assurance, continuing quality improvement and quality control are integral component of a required ‘quality system’.[7]

Quality Control (QC)

This system checks that the work process is functioning properly. QC evaluation includes accurate patient identification, fixation, adequate processing, appropriate embedding techniques, acceptable microtomy, unacceptable artifacts, and inspection of controls to determine correctness of special staining and immunohistochemistry methods. It is the

responsibility of higher-level pathologist to perform the final QC examination as they 'read' the slide. Errors/problems reported by pathologists and others should be included as part of the laboratory QC data collection.[1]

Quality Assurance (QA)

Quality assurance in histopathology lab is defined as a program for systematic monitoring and evaluation of the various aspects of the laboratory service to ensure that quality standards are being met.[6]It includes a planned system of review procedures conducted by personnel not directly involved in the laboratory process. Statistical analysis of quality control provides the data for quality assurance activities where correlation of errors, complaints, failures or other unexpected results are evaluated against the laboratory expectations. Participation in external programs also contributes valuable information.[7]

Quality assurance achieves these objectives by establishing protocols and quality criteria for all aspects of laboratory work, and provide a framework within which internal quality assurance (IQA) and external quality assurance (EQA) programmers' can be effective.[12]

Although EQA is fundamental to quantitative pathology such as clinical chemistry and hematology, there were initial concerns about the value and design of EQA schemes in interpretive histopathology. The Oral Pathology EQA Scheme developed from the Oral Pathology slide club and began operating as a pilot scheme in 1993 in UK.[13] In 1999, Quality System Essentials were introduced to laboratory practice by the National Committee for Clinical Laboratory Standards (now Clinical Laboratory Standards Institute [CLSI]).[14]

Such programs are expensive or not easily available in India. The Indian College of Pathology in collaboration with the Association of Pathologists of North America (AIPNA) has initiated a program. The Inter-Laboratory Quality Assessment program for Histopathology (ILQA-HP) was launched in the year 2006 as part of the activities of parent organization ILQA-Bangalore. The program was started with objective of providing external quality assessment in histopathology to NABL accredited laboratories in India, with the long-term goal of including non-accredited laboratories into the program.[2]

Quality in a laboratory is dependent on a host of structural and personnel factors. A Quality Committee should be established within each histopathology laboratory to ensure routine review of quality data and to initiate improvements where required. It is critical that well

established procedures and systems are in place for the reporting, evaluation and root cause analysis of errors.[15]

Components of Quality Assurance

1. Organization of histopathology lab: Workflow should be smooth without too much cris-cross traffic (Figure 1). Access to rooms where manipulation or analysis of samples takes place or where hazardous chemicals or other materials are stored must be restricted to authorized persons only. Restriction of access may be accomplished using signs on doors. Sample accession area should be manned by well trained personnel. Use of computers with local networking and bar codes has its own advantages.[10,12, 16]

Grossing station should be well ventilated with adequate lightening and have proper facilities to "exhaust" the formalin vapor. This area should be towards one end of the histopathology lab, close to open window spaces. It is preferable to partition this area of activity. Pre-fabricated grossing stations are available that have in built facility for running water supply, fume exhaust, photography and computer recording of gross specimen. [16]

Tissue processing, microtomy, and staining areas should have adequate space to accommodate all the steps involved and must be equipped with good quality of needed instruments and materials.[17]

Physical Aspects of lab

The laboratory must be designed to ensure proper ventilation throughout, with an active ventilation system, and adequate space for circulation of persons and laboratory carts and trolleys. Rooms should have a high ceiling to ensure proper ventilation. Walls and ceilings should be painted with washable, glossy paint or coated with a material suitable for cleaning and disinfection. The floor must also be easy to clean and disinfect and have no edges between the walls and floor.[18]Ceramic tiles are good materials to use for benchtops, as they are resistant to deterioration from harsh disinfectants and aggressive cleaning products. Wood is not easy to clean/ disinfect and deteriorates over time, moreover it also harbors growth of contaminants. The disadvantage of using steel that it will rust when washed with chlorine. Benchtops should be at the proper heights based on the guidelines suggested by the National Institute of Occupational Safety and Health (NIOSH). Cleaning and disinfection of laboratory

areas should be recorded, including the date and name of the person performing the maintenance.[19,20]

2. **Comprehensive managements of documents**: Documents should clearly define communications channel and a clear reporting structure. The documents should also identify the records that should be kept of routine operations, such as equipment calibration and maintenance. Such documentation should be brought together as a single "Quality Manual" which can act as a reference text for the whole quality assurance programme.[12]

3. Training: It is important that all staff members should be adequately trained for the task they have to perform. Criteria for correct levels of training or competence for particular procedures, and job roles, are often specified by national and international agencies and in some cases, by professional associations.[21]

4. Standard Operating Procedures (SOP): They are the documents describing in detail every procedure conducted by the laboratory. This includes sampling, transportation, analysis, use of equipment, quality control, calibration, production of reports, etc. They are the laboratory's internal reference manual for the particular procedure, for that reason, SOPs must document every relevant step in the procedure. Thus, anyone of the appropriate training grade should be able to apply the procedure when following the SOP. In addition, the SOP must cross reference and, where necessary, expand any other SOPs which are related to it.[22]

5. **Equipment maintenance and calibration:** All equipment must be maintained on a regular basis, consistent with the documented criteria of the laboratory and normally accepted codes of practice. The laboratory must apply standards which are well within the limits normally established and recommended for the care of the particular piece of equipment. This should be checked by the quality assurance officer, and be corrected if inappropriate. [10, 12]

These principles apply to general laboratory equipment such as glassware as well as to sophisticated analytical instruments. Frequent checks on the reliability of equipment must also be performed. This includes calibration checks on all relevant equipment, such as balances, pipettes, etc.[10, 12]

6. **Patient safety and error reduction:** Patient safety is defined as freedom from accidental injury in the delivery of health care. Joint Commission on Accreditation of Healthcare Organization (JCAHO) and the College of American Pathologists (CAP) had declared that

patient and specimen identification are primary patient safety goals, gives pathology the legitimacy and the muscle to strictly enforce prescribed labeling standards (Table 1). Factors that can contributes to the errors in surgical pathology are variable input, complexity, inconsistency, human intervention, time constraints and inflexible hierarchical.[23]

The quality of the work a laboratory produces is only as good as the quality of the samples it uses for testing. The laboratory must be proactive in ensuring that the samples it receives meet all of the requirements for producing accurate test results.[10]

The gravest errors in specimen identification occur at the receiving area. A complete requisition form must accompany each specimen including patient's full name, hospital identification number, and birth date along with clinician name. The clinical history provided must be accurate and complete in order for the pathologist to come to an appropriate diagnosis. If the patient has an infectious disease (i.e., HIV, Hepatitis B or C, tuberculosis) should be indicated on the form.[24,25]

Inadequate clinical information has also been the underlying cause of malpractice claims brought against pathologists. Troxel and Sabella documented that failure to obtain all relevant information contributed to one fifth of the diagnostic errors. McBroom and Ramsay noted that clinical information affected 7.5% of surgical pathology reports that were amended during review of cases for clinicopathologic conferences.[26]

Table No. 1: Patient Safety Goals[23]

JCAHO 2007 Laboratory National Patient Safety Goals	
Goal 1	Improve accuracy of patient identification
Goal 2	Improve the effectiveness of communication among caregivers
Goal 7	Reduce the risk of health care-associated infection
Goal 13	Encourage the patient's active involvement in their own care as a patient safety strategy
CAP Laboratory Patient Safety Goals (April 2006)	
Goal 1	Improve patient and sample identification
Goal 2	Improve the verification and communication of life threatening or life-altering information
Goal 3	Improve the identification, communication, and correction of errors
Goal 4	Improve integration and coordination of laboratory patient safety role within health care organizations and operations.

JCAHO indicates Joint Commission on Accreditation of Healthcare Organizations; CAP, College of American Pathologists.

CONTINUING QUALITY IMPROVEMENT

This system is used to approach, evaluate and identify opportunities to improve quality before problems occur through evaluation of all systems/processes in the laboratory. The goal is to improve potential care and safety through recognition of potential problems/errors before they can occur. .[27, 28]Figure **2** shows the plan that can be adapted for continuing quality improvement.

CONCLUSION

This document sets out description of procedures/ requirements to ensure that a product or service meets its purpose and consistency performs to its intended use.

THE FUTURE

Pathology and laboratory medicine are rapidly changing field where new technology and scientific advances are introduced into medical practice. Any approach to control the pathology laboratories (whether proficiency testing, accreditation or legislation) has to allow

for evolution of technology and scientific concepts, without compromising minimal standards and without losing sight of the patient care and ethical responsibilities of the laboratory.

REFERENCES:

1. Bancroft JD, Gamble M. Theory and Practice of Histological Techniques. 6th ed. London: Churchill Livingstone; 2008
2. Iyengar JN. Quality control in the histopathology laboratory: An overview with stress on the need for a structured national external quality assessment scheme. IJ M. 2009;52(1):1-5.
3. National Accreditation Board for Testing and Calibration Laboratories (NABL). Doc. No: NABL 112. Specific Criteria for Accreditation of Medical Laboratories Issue No: 04 Issue Date: 11-Feb-2019 Amend No: 01 Amend Date: - 26-Apr-2019 Page No: 7 of 100.
4. Forae GD. Quality Assurance for African Laboratories: How Soon can this be Accomplished?. N Am J Med Sci. Mar 2014;6(3):155–157.
5. Khurshid A, Ahmed Z, Qureshi A. In house daily consensus conference: An important quality/quality assurance activity- Experience at a major referral center. Indian J Pathol Microbiol. 2009;52:325-7.
6. Yoon HK, Diwa MH, Lee YS, Kim G, Song SY, Lee KB, et al. How overworked are pathologists? An assessment of cases for histopathology and cytopathology services. Basic and Applied Pathology. 2009;2(4):111–117.
7. Adyanthaya S, Jose M. Quality and safety aspects in histopathology laboratory. J Oral Maxillofac Pathol. 2013;17(3):402–407.
8. Berry T. Managing the total quality transformation. New York: McGraw-Hill; 1990. 223p
9. Berte LM. Laboratory Quality Management: A Roadmap. Clin Lab Med. 2007: 771–790.
10. WHO Library Cataloguing-in-Publication Data. Laboratory quality management system: Handbook. World Health Organization 2011. Available at www.who.net
11. Lai-Meng LOOI. The Pathology Laboratory Act 2007 explained. Malaysian J Pathol 2008;30(1):1-10.
12. Bartram J, Balance R. Water Quality Monitoring - A Practical Guide to the Design and Implementation of Freshwater Quality Studies and Monitoring Programmes. Published on behalf of UNESCO & WHO by E & FN Spon. London (UK).1996. Ch 9- Analytical Quality Assurance. ISBN 0 419 22320 7.
13. Woolgar JA. The national head and neck histopathology external quality assurance scheme: evolution, design, and analysis of 11 circulations from 1999 to 2005. J Clin Pathol 2006;59:482-488.
14. Sergi C, Mikuz G. External quality assurance as a revalidation method for pathologists in pediatric histopathology: Comparison of four international programs. BMC Clinical Pathology. 2008; 8**:**11
15. Guidelines for the Implementation of a National QA Programme in Histopathology: Faculty of Pathology, Royal College of Physicians of Ireland. 2009. Available at www.rcpi.ie/content/docs/000001/312_5_media.pdf.
16. Handbook of quality assuarance in laboratory medicine. Shubhangi Tambweker. BI publications Pvt Ltd. New Delhi. 2009. ISBN 817225315X, 9788172253158.
17. Sathyakumar M, Premkumar J, Magesh TK, Martin Y, Thirumlaisamy E. Tissue processing of oral biopsy specimens: An adjunct to diagnosis. Journal of Cranio-Maxillary Diseases.2013;2(1):38-45.
18. Laboratory Quality Management System (LQMS) training toolkit. Facilities and Safety. Module 2. Content Sheet. Available at www.who.int/ihr/training/laboratory _quality/facilities/en.
19. Sundaragiri KS, Shrivastava S, Sankhla B, Bhargava A. Ergonomics in an oral pathology laboratory: Back to basics in microscopy. 2014;18(4):103-11.
20. Edwards FP, Campbell AR. Removal of formaldehyde and xylene fumes from histopathology laboratories: a functional approach to the-design of extraction systems. J Clin Pathol. 1984;37:401-408.
21. Edwards FP, Campbell AR. Removal of formaldehyde and xylene fumes from histopathology laboratories: a functional approach to the-design of extraction systems. J Clin Pathol. 1984;37:401-408.
22. Colligon I, Rosa M. GLP SOPs for Equipment Calibration and Maintenance. Part 4: Logistics of SOP Writing. Qual Assur J. 2007;11:60–63.
23. Dimenstein IB. Root Cause Analysis of Specimen Misidentification in Surgical Pathology Accession and Grossing. Lab Medicine. 2008;39:497-502.

24. Specimen Submission Guidelines. University of Colorado Denver, Anatomic Pathology, Anschutz Inpatient Pavilion, Aurora. Gross Room Manual 2011-2012. Available at www.ucdenver.edu/.../Pathology/.../Specimen SubmissionGuidelines.pdf
25. Nakhleh RE, Gephardt G, Zarbo RJ. Necessity of Clinical Information in Surgical Pathology. Arch Pathol Lab Med.1999 Jul;123(7):615-9.
26. Laboratory Quality Control Based on Risk Management; Proposed Guideline. CLSI document EP23-P. Wayne, PA: Clinical and Laboratory Standards Institute; 2011. Available at shop.clsi.org/site/Sample_pdf/EP23A_sample.pdf.
27. Laboratory Quality Control Based on Risk Management; Proposed Guideline. CLSI document EP23-P. Wayne, PA: Clinical and Laboratory Standards Institute; 2011. Available at shop.clsi.org/site/Sample_pdf/EP23A_sample.pdf.

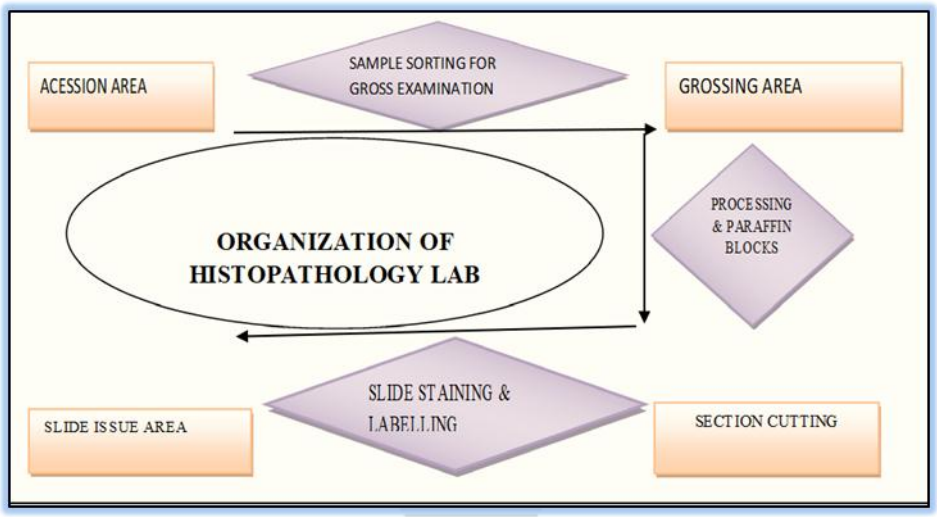

Figure No. 1: Organization of a histopathology lab[16]

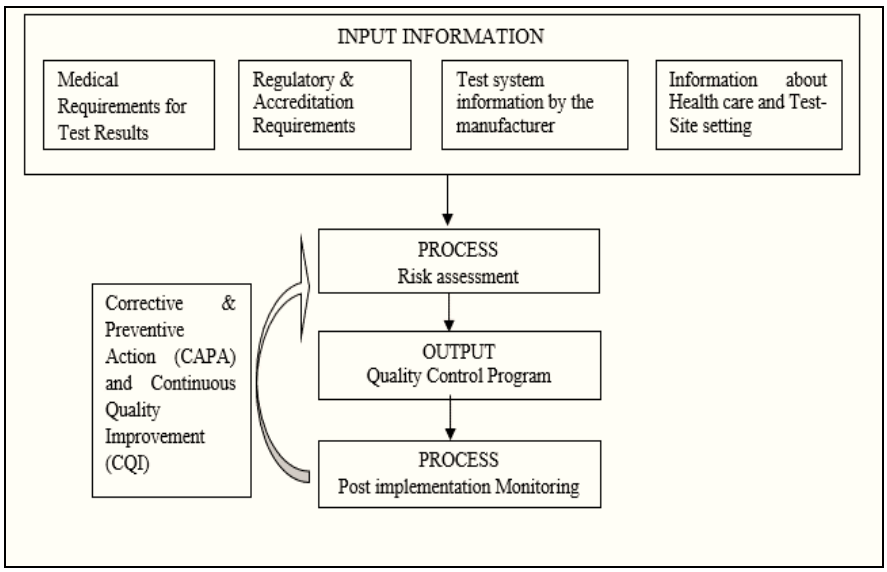

Figure No. 2: Process to develop and continually improve a quality control plan[28]