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QUALITY DETERMINANTS FOR MEDICAL HISTOLOGY LABORATORY

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Abstract: Unlike other fields of laboratory medicine, the concept of quality control and quality assurance is relatively less applied and experienced for histological testing. This conceptual review article is an attempt in the direction to observe best practices in a histology or histopathology laboratory. These best practices have been observed and experienced by us over a long period while working in a histology laboratory. Quality control and quality assurance involved at every step of the histological testing right from the specimen collection up to issuing of the final report will help to achieve quality outcomes in a comprehensive manner which ultimately will contribute towards achieving of a culture of total quality management in a hospital or any healthcare organization.

Keywords: Quality; pre-analytical; analytical; post-analytical; histological; total quality management

INTRODUCTION:

The discipline of Histology in the Department of Anatomy or the section of Histopathology under Laboratory Medicine deals with the scientific study of cells & tissues and related diseases. The study involves microscopy to look at cells and tissues present in the specimens which have been carefully prepared by undergoing procedures called histological techniques. The concept of quality assurance and quality control is relatively new to these sections unlike other parts of Laboratory Medicine.

It is basically due to inherent characteristics of histology specimens and their studies including lack of numerical data, subjective assessment of histological and pathological slides, descriptive reports, lack of standardized pattern of reporting and individual bias and judgement while interpreting the slides under the microscope.[1] In cases of histological processing which are done manually, most of the variables depend upon the individual operator's ability and training which in turn influence the final findings.

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The term 'Quality' carries different meaning to different individuals. If we talk about the use of the term in histology section; to a medical laboratory scientist, quality means preparation of good sections and slides which are free from artifacts, air bubbles, well differentiated and staining of highest quality which makes all the constituents of the tissue well understood. For the pathologist, quality means accurate diagnosis and complete reporting of the tissue under investigations. At the same time, for a clinician or a physician, the term quality means timely report which helps in right management of the patient and for the patients themselves, quality carries the meaning of quick diagnosis and timely treatment at the least possible cost.[2]

QUALITY AND RELATED TERMS

Quality: As defined by ISO, quality is defined as "the totality of features and characteristics of a product or service that bears its ability to satisfy stated or implied needs."[3]

Quality Control (QC): A system which verifies a desired level of quality in an individual procedure or a testing method/technique is called a quality control system.

Under the quality control system, all technical activitieswhich are carried out in routine are aimed at maintaining the accuracy and precision. The procedures are carried out in such a way that consistencies in the procedural steps is maintained avoiding all possible errors.[4] This also ensures documentation of all quality control activities.

Quality Assurance (QA): As defined by the College of American Pathologists, quality assurance is a method of systematic monitoring the results of quality control and practices to ensure that all the activities are carried out in a manner to impart excellent healthcare services. QA is functioning on the principal of detection, control and prevention of errors at every stage of patient care which eventually enhance the clinician's ability to provide most appropriate care for the patient. The process of QA also involves subsequent statistical analysis of data derived from quality control documentation.[5]

Total Quality Management (TQM): It is a management system which is based on the principles of quality control and quality assurance in such a way that every member of the organization from top to bottom is committed towards maintaining high quality standards in every aspect of the organizational activities. This helps to prevail a culture of leader driven and employees' motivation for continuous quality improvement in all routine activities.[6]

Quality Management System (QMS): Under QMS,the organization is following a set pattern of policies and procedures for every activity of the organization. This helps to achieve the ability of the organization to meet the clients' requirements. [7]

ISO 9001 Quality Management System is world-wide applied system in healthcare. This system decides quality policies and guidelines for healthcare organizations. It provides a vision, mission to the organization and also provides various tools which help in benchmarking. The guidelines are kept in such a way that give attention to patient needs and respect and also protects the interests of all stakeholders including payers, suppliers, staff and regulators. This eventually help to achieve standardized procedures and activities, increased efficiency, low operating cost and the staff satisfaction.[8]

Quality Standards: Quality standards are stated as a description of a procedure or an activity with a measurable levels of performance against a decided target for achievement. Quality standards are designed in such a way that these are measurable i.e., quantitative with some set criteria which are reliable, valid and feasible too.[9]

Quality Healthcare Services; Need of the hour:

It has become an important policy issue to maintain quality healthcare both at the national and international level. Various studies in this direction has shown that the transparency issues of healthcare quality have become an important aspect in clinical governance even in the public hospitals. Keeping this aspect into considerations, AHRQ (Agency for Healthcare Research and Quality) and National Quality Forum have been developed in USA for developing and promoting quality measures.[10]

1. A review of literature shows that implementation of quality management system in the organization helped to achieve many benefits. An implementation of ISO 9000 quality management system at Red Cross Hospital in Beverwijk, Netherlands reported various benefits in the organization. A focus on the patients' needs and expectations were reestablished. All processes were accurately identified and were subjected to continuous improvement. The documentations and records were strengthened and a highest level of patient safety was observed.[11]

OBSERVATIONS

This article has been conceived by observing and practicing of the tissue processing techniques in the histology laboratory for more than twenty years. These quality determinants can provide a handy solution to the operators and researchers to maintain and run the histology services of their departments in an efficient and effective manner.

Traditionally the histological testing right from collection of specimen up to the final reporting involve mainly 3 phases of pre-analytical, analytical and post analytical phases.

A. Preanalytical phase:

The pre-analytical phase comprises the activities of specimen collection, its transport to histology laboratory, receiving by laboratory staff and its preparation for the subsequent processing. All histological techniques and procedures which are involved to prepare a good section comes under the pre-analytical phase. Various determinants of pre-analytical phase for histological testing are mentioned below:

1. Proper Selection of Tissue under Study:

To obtain the correct tissue contents under investigations, it is essential that a systematic gross description, selection and dissection of the desired tissue material must reproduce a precise sampling. If the right diagnostic material is lost at this stage, the final preparation of the slide and hence the microscopic study of the same will result into poor diagnosis and hence an improper management of the patient.

2. Proper Request Form:

Each request form must accompany with the details of patient identification data, name of the requesting clinician, date of specimen collection, date of arrival of specimen in the laboratory, type of sample with its anatomical site of origin and other relevant clinical details. Each received specimen must be assigned a laboratory ID number.

As stated by Sharif and colleagues the first contact of the clinician with the department of histopathology is through the request form, so it is the primary responsibility of the clinician to provide correct information of the patient's specimen to the pathologist so that the correct patient management can be ensured. [12]

A literature review also manifests that providing a correct **c**linical history is very important to provide an accurate and complete pathological report. An adequately filled request form by the clinician is an essential tool to provide essential information to the pathologist. This also influences the overall turnaround time (otherwise, additional time would be spent in asking the clinician for the required information). Availability of patient's information facilitates the histologist to narrow down the differential diagnosis. Inadequate clinical details of the patients on the request forms resulted into contrasting results in these studies. [13]

3. Registration and lab ID Number:

A specimen which is not properly labelled should not be received. Every specimen must be properly identified and must be registered in the department by assigning a unique ID number.

4. Proper Fixation:

Fixation of the tissues is affected by various factors including the size of the container and nature of the individual specimen. To preserve the correct morphology of the tissue, it is essential that the size and shape of the container

must be adequate so that there is sufficiently free space.

It is very important that a most suitable fixative should be selected as per the nature of the tissue under investigations. A good fixative permits preservation of all constituents of the tissue. An ideal fixative of a specific specimen is the one which is most compatible with further chemical treatment undergoing subsequent stages of the processing. It permits storage for long period and allow generation of good sections during microtomy and subsequent staining procedures. At the same time, selection of a good fixative also accounts for its cost-effectiveness. Various determinants of adequate fixation procedures are its pH, duration of fixation, size of the specimens, temperature and the ionic concentration of all the constituents of fixative.[14]

Proper Processing of Tissue Specimens:

Care should be taken to observe the correct timings for the processes of dehydration, clearing, impregnation after the fixation of the tissue specimens to obtain the correct morphology and intactness of the tissue materials. Various determinants of the tissue processing are the appropriate temperature setting, agitation of specimens, viscosity of the reagents and maintenance of correct vacuum of the processor.

An appropriate embedding media must be selected according to the nature of the tissue and the need of demonstrating specific tissue constituents. A correct orientation of the tissues at the time of embedding of the tissue is necessary to obtain the proper morphology of the specimen. If the orientation of the tissue is not properly laid, there is the possibility of missing the diagnostic tissue elements during microscopy (under the analytic phase of the histology testing).

To obtain good quality of the tissue sections, the microtome should be of good quality and serviced regularly. To obtain correct section thickness, it is essential that the periodic calibration of the micrometer should be ensured. The use of disposable blades is recommended instead of knives since the later require efforts and time for maintaining its sharpness, which turns out to be a costly affair. [15]

5. **Quality Staining Procedures:**

To allow a consistent reporting it is essential that the staining procedures should also be consistent. Consistency is well maintained in automated staining procedures by adjusting the predetermined timings at each step. Various factors affecting the staining techniques which need to be monitored are: change of brand and supplier of the stains (hematoxylin and eosin stains used in routine), difference in pH, age of the stain and degree of its usage. Running of control slides with every batch and standardization of timings is highly essential to maintain the quality of staining steps. Types of fixatives, processing schedules, section thickness, calibration and maintenance of the

equipment are also important variables which may affect the staining characteristics.

Last but not the least, the label affixed on the stained histology slide should be of an appropriate size so that it does not project beyond the slide or cover the tissue sections. It should be legible sufficiently and ideally should carry the name of the laboratory also.

B. Analytical Phase:

The analytical part concerns with the interpretation of the slide to make an accurate diagnosis.

Accurate histological diagnosis depends upon an accurate processing and interpretation of histological specimens. This further depends upon appropriate macroscopic and microscopic description, interpretation of microscopic findings and correlation with the clinical findings.

The analytical phase includes the process of reading and interpreting the histology stained slides under the microscope. It is important that the laboratory technologists and pathologists must ensure quality patient care by producing accurate diagnosis. They should also strive for new knowledge and practices in the field to ensure continuous improvements. Positive and negative controls must always be included in every batch of reporting of slides. It is well known that analytical phase of histology is not easy due to subjective judgement and biasness. However, intradepartmental discussions, benchmarking with other laboratories and blinded random case reviews are some of the methods which can ensure quality control of histology reporting. [16]

C. **Post-analytical Phase:**

Preparation and transmission of histopathology reports come under the post-analytical phase. This phase also involves the storage/disposal of samples, slides and blocks and proper retention of test results. Proper measures should be taken to allow minimum TAT (Turnaround time) of histological testing and reporting of results.

Post-analytical aspects are greatly influenced by accuracy and completeness of the reports. On the basis of the same, the clinicians are in the position to start a correct management of pathological conditions. Joint Commission on Accreditation of Health Care Organizations (JCAHO, USA) and the College of American Pathologists recommend that tissue blocks and slides must be retained for at least ten years. As per the recommendations of Royal College of Pathologists, UK, histology blocks must be preserved permanently, slides and smears for 10 years and wet tissue for at least 4 weeks after dispatch of the report. In general, a period of 10–20 years is considered as a lower limit guideline for retention. In India, most of the institutions are preserving slides and blocks for 10 years and for cancer referral centers the retention period is up to 25 years.[17]

Other Factors and Practices which enhance the Quality Services of the Laboratory:

1. **Qualified personnel:** All staff must be qualified and professionally competent to carry out their assigned roles and responsibilities. Training and competency records should be retained and maintained in the department at all times for quick reference.
2. **Availability of Standard Operating Procedures:** Based on national and international standards, all stages of the histological testing must be documented in the form of standard operating procedures (SOPs) including purpose and aim of procedure, requirement of various items to run the procedures, technique of carrying out the procedures, warning and precautions including the safety and quality aspects. It should be written in a simple language which is understandable to all. It is highly desirable that every laboratory must maintain its technical manual.
3. **Controls:** Known specimens including positive and negative controls and calibrators enhance the confidence levels of the testing methods. Internal quality assurance practices must be observed in daily practices. Performance evaluations, periodical audit of microscopic findings, random review of slides (by the same or different pathologist) and intra-departmental consultations are the methods to maintain the internal quality control in histology laboratory.
4. **Availability of well-maintained Equipment and Material Supply:** Reliable equipment is the backbone of histological testing. Proper calibration and safety inspections are the basic essentials to keep the medical devices reliable in the histology department. An availability of adequate HVAC (humidity, ventilation and air conditioning) in the histology laboratory will optimize the working conditions. Paraffin wax baths and embedding stations must be maintained at required temperature before starting the procedures. Refrigerators and freezers must be maintained well for the preservation of reagents and solutions.However, these must be brought to room temperature before starting the testing procedures. In addition, all the equipment must be well maintained by carrying out planned (scheduled) preventive maintenance. Periodic cleaning and lubrication are essential for proper upkeep of the equipment.

Care should be taken not to induce tissue artifacts due to improper processing, sectioning, staining and mounting. The artifacts can be minimized by selecting chemicals of good quality. The samples of chemicals including alcohol for dehydration, xylene or toluene for clearing, paraffin wax for impregnation & embedding and mounting media for final preservation of slides must be tested for their technical specifications and desired qualities before purchasing the bulk quantity. It will also ensure the quality results and at the same time

the supply must be economical also to provide patient services at the least cost.

5. **Screening of Slides:** Before sending the slides for the reporting, it is a good practice that these must be screened both macroscopically and microscopically by the histoscientists/laboratory technologists.

6. **Blocks and Slides Archive:** All laboratories must maintain the proper records of all the slides and blocks in proper cabinets (preferably stainless steel). It must ensure pest-free environment and if required, the structures must be given pesticide treatment periodically. A systematic method of issue and filing must be put in place for easy retrieval of tissue blocks and slides.

7. **Proper Storage Conditions:** The conditions of storage are equally important. Museum specimens and left-over gross specimens are stored in 10% neutral buffered formalin, (20-30 times the volume of the specimen). Neutral buffered formalin maintains the solution at neutral or slightly alkaline pH and is advantageous to counter the degradation of formalin into paraformaldehyde on prolonged storage.

   Paraffin blocks and slides should be stored at room temperature only, preferably in humidity-free conditions with adequate pest control measures. Stained slides should also be kept away from direct light to preserve staining characteristics for a longer duration. In case unstained slides are required to be stored (for immunohistochemistry and molecular testing etc.), it is recommended that they are kept in absolutely dry conditions to prevent hydrolysis and proper preservation of proteins.

8. **Tissue Bank:** Positive blocks and special cases must be kept in a refrigerated apartment to promote research and educational advancements.

9. **Continuous Development Program:** Seminars and updates must be carried out on regular basis to maintain the quality functioning of all professionals.

10. **Maintenance of Proper Inventory:** An adequate and timely supply of materials, chemicals, reagents and equipment with accessories are the prerequisite to maintain the quality services of histology laboratory.

11. **Quality Assurance Program:** A standard histology laboratory must establish both internal and external quality assurance policies. Participation in the quality assurance program helps to measure the current performance of the laboratory by comparing it with the established goals and standards. Good laboratory practices are eventually aiming at continuous quality improvement.

12. **Information/ Communication Technology:** An implementation of information technology reduces the reporting errors, reduces turnaround time and improving the performance and efficiency of services. Bar code readers must be utilized for proper identification of the tissue specimens. On the other hand, unidentified

specimens will result in delays of results and unnecessary workload and disturbing the routine working of the laboratory.

13. **Health and Safety Compliance:** A standard histology laboratory must be compliant with national, legal and statutory health and safety requirements. Proper disposal procedures of the tissue specimens must be carried out in compliance with Biomedical Waste Management and Handling Rules, of Government of India to ensure that the waste generated in the laboratory is handled and disposed in such a way that it does not produce any adverse effect to the environment including human and animal health. This must also apply to other hazardous chemicals including chemical wastes. [18]

DISCUSSION:

Modern oncology stands on the reliable diagnostic feedback through histological investigations and techniques. Other than oncology, histology also plays a major role in the treatment of many other types of disease. Errors in the histology reports can critically affect patient care and may result into a subject of media concern, which adversely affects the reputation of the healthcare institutes. This article considers how maintenance of quality aspects in histopathology laboratory can provide information about errors and inconsistencies in the diagnosis of various types of surgical specimens. It is crucial to maintain and enhance quality of laboratory in line with national and international standards which also plays a vital role in patient safety. The journey towards total quality management should start with the decision to take the right sample, handled in the right manner and end with the timely and an accurate treatment for the patient based on the correct interpretation of the laboratory result.

CONCLUSION:

Promotion of quality management practices should be the primary objective of every medical histology laboratory to promote quality patient services. Sincere efforts put on the part of administration and laboratory staff can ensure that in routine procedures, errors do not creep in due to inadequacies in operations and the process of quality control is in place to avoid human errors including technical errors during pre-analytical phase and transcription errors during analytical and post analytical phases of histology testing. The practices of Total Quality Management by adopting the techniques of Quality Control and Quality Assurance must be put into practice in the area of histology laboratory also to achieve the most desired health outcomes.

Conflict of Interest:The authors declare that there are no areas of conflicting interest.

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