REVIEW ARTICLE

Quality and safety aspects in histopathology laboratory

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ABSTRACT

Histopathology is an art of analyzing and interpreting the shapes, sizes and architectural patterns of cells and tissues within a given specific clinical background and a science by which the image is placed in the context of knowledge of pathobiology, to arrive at an accurate diagnosis. To function effectively and safely, all the procedures and activities of histopathology laboratory should be evaluated and monitored accurately. In histopathology laboratory, the concept of quality control is applicable to pre-analytical, analytical and post-analytical activities. Ensuring safety of working personnel as well as environment is also highly important. Safety issues that may come up in a histopathology lab are primarily those related to potentially hazardous chemicals, biohazardous materials, accidents linked to the equipment and instrumentation employed and general risks from electrical and fire hazards. This article discusses quality management system which can ensure quality performance in histopathology laboratory. The hazards in pathology laboratories and practical safety measures aimed at controlling the dangers are also discussed with the objective of promoting safety consciousness and the practice of laboratory safety.

Key words: Histopathology, quality, safety

INTRODUCTION

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.[1] Quality analysis are well-established in the departments such as clinical biochemistry and hematology where numerical data is obtained compared to histopathology laboratory where reports contain interpretations, explanations, evaluations of probability and clinical judgments. Assessment and implementation of quality control in histopathology is not easy as its output is wholly qualitative rather than quantitative.[2] An integrated coordination between technical and managerial activities along with highly skilled pathologist is essential for the continuous, unimpeded realization of high quality, error-free, efficient and effective laboratory operations.[3]

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Equally important is safety, which is defined as "freedom from accidental injury". Healthcare system should be safer at all levels to prevent errors.[1] The hazards that workers in pathology laboratories face include specific risks from toxic chemicals which are used in investigative procedures, pathogenic microorganisms in patient's samples and general risks from mechanical, electrical and fire hazards. The danger can be aggravated by ignorance of the hazards, lack of knowledge on safety measures and inadequate safety measures adopted by laboratories.[4] Safety consciousness and safe laboratory practices are therefore of primary importance for the protection of laboratory workers against injury and infection and the prevention of damage to property.

To ensure quality and safety in histopathology laboratory, it is imperative that there be a clear understanding of quality and safety control program and implementation of the same. Therefore, in this article we are making an attempt to describe the steps involved in producing a quality histopathology report and safety measures for minimizing the risk in histopathology laboratory.

LABORATORY QUALITY MANAGEMENT SYSTEM

To ensure the quality performance, every laboratory should have some form of quality management system for all the procedures performed under its scope of activity. Quality assurance, continuing quality improvement and quality control are integral component of a required 'quality system'.[5]

Quality control

Quality control is a system of routine technical activities, to measure and control the quality of the inventory as it is being developed. It provides routine and consistent checks to identify, address errors and omissions, ensures data integrity, correctness and completeness and also records all quality control activities.[6] The quality control checks in a histopathology lab will include accurate patient identification, fixation, adequate processing, appropriate embedding techniques, microtomy, unacceptable artifacts and inspection of controls to determine correctness of special stains and immunohistochemical methods.[5] It is the responsibility of the pathologist to perform the final quality control examination as they read the slide and determine whether the slide is adequate for the diagnostic interpretation.

Quality assurance

It includes a planned system of review procedures conducted by personnel not directly involved in the laboratory process.[6] 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 for a quality assurance program. Organized external quality assessment programs are available in other countries [College of American Pathologists (CAP), United Kingdom National External Quality Assessment Service (UK NEQAS)]. There are two distinct systems that can be used to deliver quality assurance such as selective system where stained preparations from departmental archival records are used to assess the quality of staining or distributive system in which participating laboratories are asked to stain sections that have been submitted by the scheme organizer.[2,5,7,8]

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.[5]

Quality control and assurance plan for histopathology lab

Designing a quality control and assurance plan in histopathology should focus on three elements: (1) pre-analytical phase, (2) the analytical phase and (3) the post-analytical phase[2] as defects may occur at any of these phases, resulting in an erroneous diagnosis.

Pre-analytical aspects

It includes sample collection, transport, accession and tissue processing and submission of the slide for reporting. Studies have indicated that errors related to pre-analytical phase can endanger quality of histopathology report.[9,10] The accuracy of the final diagnosis is a measure of the effectiveness of many elements including specimen collection, gross dissection and section, tissue processing, embedding, sectioning and staining. Patient or specimen identification is one of the most important aspects and it begins with specimen labeling and accessioning.[11,12]

Other critical element is adequate clinical history and has been shown to affect the accuracy and completeness of pathology reports.[13,14] Endorse definitive laboratory specimen rejection policies to prevent further processing of and interpretation of specimens with potential demographic mismatches or pertinent clinical information. Standard operating procedure for sample accession, identification, rejection of the sample and all steps of tissue processing must be documented and displayed in laboratory and the technical staff should be aware of its contents.[2,5,12]

Precise and systematic gross description, dissection and selection of sections for microscopic study are crucial parts of the pathologic examination and often cannot be remedied if omitted or done poorly at the time of the initial work up.[15] The stages of fixation, dehydration and clearing must be of sufficient length to ensure completeness.[5,12,16]

All the equipment and instruments used in the laboratory should be of standard quality and calibrated at periodic intervals. Disposable blades can provide a sharp cutting edge from which flawless 2-4 μm sections can be cut with ease. The microscope and its parts should be serviced regularly to help in imparting an accurate diagnosis.[5,12]

In case of frozen section, it is critical that the pathologist communicates effectively with clinicians to verify clinical history, appearance and exactly what information the surgeon wants. Even though overall diagnostic accuracy of frozen section ranges from 89% to 98% in various studies, frozen artifact can produce inferior slides for microscopic examination and sampling errors can result from the heterogeneity of a tumor.[17-20] Checklists to ensure quality control during pre-analytical phase has been provided in Table 1.

Analytic aspects

The analytical phase is related to slide reading along with relevant data and preparation of report.[2] Pathologist must have judgment, be conscious of the patient's welfare and should always strive to provide accurate diagnosis. He/she must constantly seek out new knowledge and adopt new practices as they become available.

Assessment of analytical aspects in histopathology is not easy because of the subjectivity of the reports. Error detection and avoidance in histopathology has been discussed by many authors.[21-23] Intradepartmental

discussions, comparison with other reports (frozen, cytology, or histopathology), blinded random case review, external consultations and review by experts are some of the steps which can be taken to improve the quality. Complete reporting in pathology has been given sufficient attention in recent times particularly in oncology, where many protocols are dependent on the pathological staging of tumors.[24-27]

Post-analytical aspects

Post-analytical phase involves the activities that follow the analytical phase including preparation and delivery of the report, archiving of request form and report, storage of the reported specimen for set retention period and safe disposal of specimen thereafter.[3] All slides and paraffin blocks should be stored indefinitely if facilities are available as these are of permanent nature and can be evaluated on need.[15] Laboratories should attempt to achieve the goal of signing out majority of cases in shortest time possible as turnaround time is one of the measures by which the clinician or patient will judge the laboratory.[28] The retention period for specimens has always been a subject of debate and national guidelines for this are warranted.[2,29]

Table 1: Checklists to ensure quality control during pre-analytical phase

Sample collection
Biopsy
Appropriate procedure with adequate size and depth of the tissue
Specimen from representative area
Fixation
Immediate primary fixation
Suitable fixative in adequate quantity
Referral form
Adequate clinical history
Pre designed referral form should be made available to all points of specimen collection
Accession by laboratory
Entering details into a log book
Assigning a unique laboratory number (use of tissue Tek system, selfadhesive bar code label, automated prelabeling systems)
Gross analysis
Precise and systematic gross description
Adequate sampling
Careful handling of specimen
Tissue processing and embedding
Sufficient time to ensure completeness
Avoid prolonged contact with the reagents of tissue processing
Planned changing of chemicals used for processing based on the number of tissues passed through
Recording the temperature of paraffin wax bath, water floatation bath and slide warming table daily
Cutting of sections
Replacing microtome knives by disposable blades
Servicing and periodic calibration of the microtome
Staining of slides, mounting and labelling
Standardized staining protocols for routine and special stains
Use of positive and negative control in histochemical staining
Equipments
Equipments and instruments used in the laboratory should be of standard quality
Equipments and instruments should be calibrated at periodic intervals
The microscope and its parts should be serviced regularly
Submission for reporting

Clinician satisfaction may also be dependent on expectations of a clinician from the laboratory. Therefore, in addition to managing and monitoring all the elements of quality, the pathologist must also manage clinician expectations and make sure that they are realistic.[30,31]

Safety control

All laboratories should enroll in a safety program which should begin with the recognition and understanding of the hazards, followed by implementation of safety rules and regulations. Risk management pertains not just to personal health and safety in the conventional sense, but also to environmental health and safety. Deficiencies have been reported in the knowledge, attitudes and practice of laboratory safety by laboratory personnel.[32]

Hazards associated with chemicals

A wide range of chemicals which are potentially dangerous are employed in pathology laboratories.[33] The risks associated with hazardous chemicals may be controlled by having adequate knowledge of the properties of these substances and protective equipment and preventive measures available.

Health hazard effects of chemicals

Nearly all the chemicals can be irritants, given sufficient exposure to tissue and can cause reversible inflammation specially eyes, skin and respiratory passages. The alkaline substances, strong acids, dehydrating and oxidizing agents are particularly corrosive and can damage or destroy living tissues. Chemicals that are sensitizers cause allergic reactions in a substantial proportion of exposed subjects. Sensitization may occur at work because of the high exposure level, formaldehyde being a prime example.[5,34,35] Chemicals including chloroform, chromic acid, dioxane, formaldehyde, nickel chloride and potassium dichromate and dyes such as auramine O, basic fuchsin and Congo red are carcinogenic.[5,34,36]

Toxic materials are capable of causing death by ingestion, skin contact, or inhalation at certain specified concentrations. Among the more familiar toxic substances are the cyanides and heavy metal salts which cause acute or chronic poisoning.

Mercury, lead, arsenic and a number of organic substances are cumulative poisons and are injurious to health on long exposure. Methanol is toxic; chromic acid, osmium tetroxide and uranyl nitrate are highly toxic. Chemicals causing specific harm to select anatomical or physiological systems are said to have target organ effects. Their effects are not immediately evident, but are cumulative and frequently irreversible. Xylene and toluene have neurotoxic effects and benzene can affect blood.[4,5,34,36]

Physical risks of chemicals/risk from fire and explosion

Many of the commonly-used organic solvents like diethyl ether, ethyl alcohol, methyl alcohol and acetone have flash points below 21°C and are highly flammable. Some have very low ignition temperatures and can even be ignited on contact with surfaces below red heat. Explosive chemicals are rare in histology, the primary example being picric acid. Certain silver solutions may become explosive upon aging and they should never be stored after use. Oxidizers can initiate or promote combustion in other materials and may present a serious fire risk when in contact with suitable substances. Sodium iodate, mercuric oxide and chromic acid are some of the examples for oxidizers.[4,5,34,35]

Safety measures while handling hazardous chemicals

Even for substances with no known significant hazard, exposure should be minimized. Unless known otherwise, assume that any mixture will be more toxic than its most toxic component and all substances of unknown toxicity are hazardous. The permissible exposure limits (PEL) of the Occupational Safety and Health Administration (OSHA) should be observed.[4,37]

Avoid storing or handling food or beverages in storage areas, refrigerators, glassware or utensils which are used for laboratory operations.[4,37] The masks should be used when contamination is below the permissible exposure limit of hazardous materials. When contamination exceeds permissible levels, respirators should be used. The dust particle mask (yellow) should be used when weighing out powders and the charcoal mask protects against organic solvent fumes. Sleeves are disposable garments worn to protect the arms from contact with biohazards and chemicals.[33,37-39]

Containers of chemicals should be labeled with certain basic information: chemical name, manufacturer's name and address, storing and handling instructions, date of receipt and opening, date purchased, expiration date, hazard warnings and safety precautions.[4]

Stored chemicals should be examined periodically for replacement, deterioration and container integrity. Whenever possible, buy dangerous reagents in plastic or plastic coated glass bottles. Special storage provisions are warranted for acids, flammables, radioactive isotopes and hazardous chemicals in bulk containers. It is best to avoid flammable liquids with volatile nature and very low flash point or buy only the required quantity and do not try to store any leftovers.[5,34,37]

In the laboratory, storage on bench tops, open shelves and in hoods is inadvisable. Exposure to heat or direct sunlight should be avoided. Periodic inventories should be conducted, with unneeded items being properly disposed of or returned to the storeroom. Upon receipt and the opening of a chemical, the container must be dated.[34,37]

Identify chemicals that can be disposed of safely in normal trash or sewer systems and other chemicals must be recycled or reduced when possible, or placed in appropriate containers to be picked up by safety services. Reducing toxics use by substitution and minimization, coupled with recycling, could lead to low quantities of waste to be hauled away.[37,39] Biohazardous waste should be incinerated onsite or hauled away. Potentially infectious waste ought to be segregated from chemical or non-regulated waste.[5,37]

Risks occurring due to equipment can be minimized by proper installation, care and personnel training. Electrical shock can be minimized by properly polarizing and grounding all the outlets. Refrigerators and freezers must never be used to store highly flammable chemicals. Mechanical injuries due to hot surfaces of instruments can be avoided by adapting safety measures. Broken glass particles and disposable microtome blades should be disposed in special 'sharp' containers. Microtomes and cryostats must be cleaned after the removal of blades.[5] Basic principles to be followed to minimize the exposure to chemicals and also to prevent accidents related to chemicals are provided in Table 2.

HAZARDS ASSOCIATED TO PATHOGENIC MICRO-ORGANISMS

The first and most obvious source of biological risk is with fresh tissue and body fluids: grossing carries the highest risk of all histological activities. Fixed specimens have a much-reduced risk because nearly all infectious agents are readily deactivated by histological fixation.[5] The potential routes through which laboratories workers can get exposed to biohazards are inhalation of aerosols, contact with non-intact skin and contact with mucous membranes. Exposure can occur in the course of receiving, processing and disposal of these material.[4] Many have discussed on the biohazards in laboratories.[38,40-42]

HAZARDS ASSOCIATED WITH LABORATORY EQUIPMENT AND INSTRUMENTATION

Laboratory equipment and appliances that are electrically powered can pose an electrical problem, besides mechanical and

Table 2: Safety measures while handling hazardous chemicals

General principles
Minimize all chemical exposures by taking precautions
If possible substitute less toxic materials
E.g.: xylene substitutes (aliphatic hydrocarbon clearants) instead of xylene
Technical staffs should have information on proper handling, storage,
and disposal of chemicals
Only authorized personnel are allowed in the laboratory
Personal hygiene practices
No eating, smoking, drinking, gum chewing or applications of cosmetics in prohibited areas
Confine long hair and avoid loose clothing
Avoid open toed shoes, sandals and footwear with holes on the top
Avoid mouth pipetting chemicals or infectious materials
Personal protective apparel
Personal protective equipments like aprons, goggles, gloves and respirator should be used accordingly
Simple disposable plastic aprons are preferred
Lab coats must be completely buttoned/snapped
Selection of appropriate type (latex, nitrile, butyl rubber and neoprene) of glove for each circumstance
Wearing safety goggles/glasses
Labels
Work areas must display warning signs of fire hazards and various hazardous materials
Display hazard warning symbols on the labels of chemical containers
Containers of chemicals should be labeled with basic information
Ventilation
Separate systems of ventilation for general air circulation and for removal of hazardous fumes
Use the hood when working on toxic chemical vapors or dust
Confirm and document adequate hood performance before use
First aid
All laboratory personnel should possess knowledge of basic first aid
On ingestion of chemicals, the first aid will depend on the nature of the chemical ingested
Provision for emergency eye wash station
Immediate removal of contaminated clothing
Storage of hazardous chemicals
Special storage provisions for acids, flammables, radioactive isotopes and hazardous chemicals
Stockrooms and storerooms should be ventilated and segregated in a well-identified area
Spills and containment
Take action depending on the nature of the hazard and the volume of the spill
Laboratory should possess protective equipment needed
Waste disposal and recycling
Care has to be taken for proper disposal of toxic and biohazardous substances
Reduce the use of toxic substances by minimizing the use and/or substitution with less/nontoxic substances
Recycling of chemicals is recommended wherever possible

other possible hazards. Three-to-two plug conversion adapters and extension cords are prohibited. Electrical equipment should be checked annually for grounding and current leakage. Malfunctioning equipment should be taken out of service immediately and reported to supervision.[43] The incorporation of sufficient safeguards is necessary if flammable solvents are to be used with the centrifuge. A suitable exhaust connection is required to prevent the build-up of dangerous levels of flammable gases and hazardous vapors and fumes emerging from the flame unit. The autoclave can pose hazards arising from heat, steam and pressure. The general rule for safe operation of the different instruments and even common laboratory equipment is that the operator must be guided by information in the technical manuals and by experienced persons.[4]

CONCLUSION

It is crucial to maintain and enhance quality of laboratory in line with international standards, as histopathology report influences the majority of patient treatment decisions and plays a vital role in patient safety. The journey towards quality should start with the decision to take the right sample, handled in the right manner and end with the timely implementation of the accurate treatment for the patient based on the correct interpretation of the laboratory result. Promotion of health and safety of patient, laboratory personnel and environment should be the primary objective in quality and safety control programs adopted by the histopathology laboratories.

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