

Quality Standards of Histopathology Laboratory and Work Facilities in a Developed Country

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Abstract

Background: Quality in pathology and clinical medicine is the process of measuring efficiency at all levels of the laboratory test cycle, including pre-analytical, analytic, and post-analytical processes, to facilitate outstanding findings in medical treatment. Quality can develop productivity and production in the laboratory resulting in improved patient care and outcomes. **Aim of the study:** This paper aimed to overview the standards of quality of histopathology laboratory and work facilities in developed countries. **Conclusion:** Quality evaluation, processing, and monitoring of establishment, procedures, and activities of histopathology laboratory are essential to function effectively and safely. Guaranteeing the safety of operational personnel as well as setting is also highly significant. Quality standards of histopathology laboratory and work facilities are a must and all the standards must be applied to function effectively. A Quality Committee should be established within each histopathology laboratory to ensure routine review of quality data and to initiate improvements where required.

Keywords: quality, histopathology lab, quality in labs in developed countries, quality standards in histopathology lab

INTRODUCTION

Histopathology is the science of analyzing and interpreting the cells and tissues obtained from a patient at surgery or autopsy to reach an accurate diagnosis through working in clinical groups that care for patients. ^[1]. Pathology results must be as accurate as possible as it has a direct influence on treatment choice and health outcomes of the patient ^[2]. Quality is defined as the degree to which healthcare services seek to facilitate accurate patient outcomes and are compatible with existing clinical expertise. Quality in pathology and clinical medicine is the process of measuring efficiency at all levels of the laboratory test cycle, including pre-analytical, analytic, and post-analytical processes, to facilitate outstanding findings in medical treatment ^[1]. Quality can develop productivity and production in the laboratory resulting in improved patient care and outcomes ^[3].

Quality does not happen spontaneously. A quality management framework must be established to promote coordinated management and quality control practices ^[3, 4]. The main vein of the quality management system is determined by a method called a quality assessment. To ensure consistency during laboratory activities and to obtain correct, consistent, and timely pathology outcomes, all critical quality systems must be handled ^[5].

A diagnostic pathology service requires appropriate laboratory staffing, space, equipment, and consumable funding so that pathologists have sufficient time and technical support to provide a good quality of report for patient care.

Aspects of this are considered as part of laboratory accreditation ^[6].

Accreditation for clinical laboratories became common recently with the emergence of international laboratory standards. Several guidelines for laboratories have been developed to regulate laboratory test procedures and maintain their quality ^[7]. Accreditation Co-operation, the Inter-American Accreditation Cooperation, and the International Laboratory Accreditation Co-operation), tests performed by accredited laboratories are recognized by signatories across country boundaries ^[8].

The cooperation of the WHO, governments, and national professional bodies has been crucial in the global paradigm shift in laboratory testing toward quality and international standardization ^[9].

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Study objectives:

This paper aimed to overview the standards of quality of histopathology laboratory and work facilities in developed countries.

METHODOLOGY:

A narrative review was carried out, including PubMed, Google Scholar, and EBSCO using the following terms in different combinations: standards, quality, histopathology laboratory, work facilities, developed countries. We included all full texts about our subject. The authors extracted the data, and then the author's names, year and region of publication, the study type, period of study, and the result were reported.

Regarding statistical analysis, No software has been utilized to analyze the data. The data were reviewed by the group members to determine the initial findings, and the modalities of performing the surgical procedure. Double revision of each member's outcomes was applied to ensure the validity and minimize the mistakes.

Definition of Quality

The quality is obtained when the least value of the specified quality standard is encountered. Quality is a much more complex term than it seems. Definitions are frequently insufficient in serving a quality proficient comprehend the concept. Quality is the specified performance scale^[10]. There are quite a lot of customs to define quality as a standard of perfection, conformity with standards, the entirety of characteristics that suit the needs, fitness for use, fitness for function, defect-free and delightful clients. This system originates with reliable and routine checks that recognize and address omissions and errors, protecting the integrity, completeness, and precision of data, though also recording all quality control accomplishments^[11].

Quality of care has been a developing concept ever since its first appearance. Despite the variation in literature, the WHO holds the definition of Quality of care as "the extent to which health care services provided to individuals and patient populations improve desired health outcomes. To achieve this, health care must be safe, effective, timely, efficient, equitable, and people-centered." The variation in definition happens to also occur regionally. In a study conducted in 2013 to assess the agreement and disagreement on Health Care Quality Concepts Among Academic Health Professionals within Saudi Arabia, it appears that there's quite a variation in definition even within superficially similar groups^[12].

The current status of quality of care in Saudi Arabia varies regionally and there is no enough data to precisely describe it around the kingdom^[13], however, in several studies, it has been established that there is still a great need for improvement and barriers to break^[14]. According to a systematic review published in 2014, the barriers to high-quality healthcare can be classified into patient factors and

provider's factors. The patients include health literacy, access to care, and culture. The providers include medical care, workload, culture, and job satisfaction^[15-19].

As evident, there are many key role players to achieve a better quality of care; a major one of which is healthcare providers^[20], and hence, assessment of their current knowledge is vital to the delivery of high-quality service.

Quality assurance:

Quality assurance (QA) is a comprehensive concept that emphasizes the whole quality system including providers and eventual consumers of the creation or service. It comprises all activities intended to yield products and services of suitable quality. Statistical investigation of quality control offers the information for quality assurance actions wherever correspondence of errors, objections, disappointments, or other unpredicted consequences are assessed in contradiction of the laboratory expectations^[21].

Quality control

Quality control (QC) has a tighter emphasis than quality assurance. Quality control focuses on the procedure of making the invention or service with the concentrating on eradicating difficulties that might result in imperfections. It delivers routine and reliable checks to recognize, address errors and oversights confirm data integrity, accuracy, and comprehensiveness, and also registers all quality control actions^[21].

Quality management

Quality management is the whole of roles encountered in the determination and accomplishment of quality (comprises quality assurance and quality control). This assists in triumph a culture of a leader determined and employees' incentive for unremitting quality enhancement in all repetitive activities^[22].

Reliability

Reliability is the likelihood an element will function appropriately when required, for the essential period, in the indicated environment. An all-incorporating meaning for reliability is 'the chance of accomplishment. With accomplishment defined by whatsoever degree, you desire to use that tells you when success is attained^[22].

Current status of healthcare quality in Saudi Arabia:

A systematic review was conducted in 2005 to assess the current status of the quality of primary health care provided in Saudi Arabia. The quality was evaluated in terms of both access and effectiveness of provided care; either clinical or interpersonal.

Good access and effective care were found in certain services including immunization, maternal health care, and control of epidemic diseases. ON the other hand, poor access and

effectiveness were found in chronic disease management programs, prescribing patterns, health education, referral patterns, and some aspects of interpersonal care including those caused by language barriers.

Also, it was found that multiple factors played a vital role in the delivery of high-quality care. These included factors related to management and organization, evidence-based practice, professional development, use of referrals to secondary care, and organizational culture [23].

In another systematic review conducted to assess the quality of healthcare provided in Saudi Arabia, it becomes evident that the quality of healthcare in Saudi Arabia has evolved over years. Yet, many challenges are faced with the achievement of high-quality care, of which we count the rapid increase in the number of the population associated with an increase of both needs and demands of the population. According to the study, Factors affecting the quality of healthcare can be classified into patient factors including health literacy, access to care, and culture, and providers' factors like medical care, workload, culture, and job satisfaction [15].

A third systematic review discussing the quality of care in university hospitals in Saudi Arabia reveals a need to improve the quality of healthcare delivery, specifically in areas of patient safety, clinical effectiveness, and patient-centredness. The review suggests that better leadership is needed alongside with establishment of a culture of safety and enhancement of verbal communication between health care providers and patients [14].

Accreditation and quality

A cross-sectional study was carried out at one accredited and another nonaccredited hospital in Al-Khobar city, Saudi Arabia using a questionnaire filled by nurses to assess the quality of care in both hospitals. As perceived by the nurses, accredited hospitals perform better in terms of quality in comparison to non-accredited hospitals, and hence the study suggests the usage of accreditation as a means to enhance the quality of care provided by facilities [24].

Patient safety culture

A survey study was distributed to 13 general hospitals in Riyadh city, Saudi Arabia including 223 health professionals to assess patient safety culture in these hospitals. Overall Patient Safety Grade was rated as excellent or very good by 60%, acceptable by 33%, and failing or poor by 7%. The study suggests that better improvement is needed in terms of under-reporting of events, non-punitive response to error, staffing, teamwork across hospital units. It also highlights the vitality of good leadership for patient safety initiatives to work [25].

A systematic review and meta-analysis were done to assess the culture of patient safety in studies that employed the hospital survey on patient safety culture (HSOPS) in hospitals around the world. 59 studies with 755,415 practitioners

surveyed were included in the review. In the results, the culture of culpability appears to be the main weakness across studies [26].

Attitude and practice towards clinical practice guidelines (CPGs)

A cross-sectional study was conducted on 2225 healthcare professionals working at King Khalid University Hospital in Saudi Arabia to estimate the Attitude and practice of the health care professionals towards the clinical practice guidelines. The majority of respondents (96%) agreed on the effectiveness of compliance to CPGs in enhancing the quality of service provided to patients. The degree of compliance to CPGs was greater in nurses than in doctors, and it positively correlates with the years of experience of the provider [27].

Perception of healthcare providers about the quality of care

In a study aimed to assess the Culture of quality in infection prevention (CQIP) of a hospital in Saudi Arabia as perceived by health care workers, the study focused on four dimensions to assess; psychological safety, prioritization of quality, supportive work environment, and improvement orientation. The lowest grade of all turned out to be a “supportive work environment” which suggests a special concern be given to it. The results varied depending on Gender, nationality, highest education, and job title [28].

Another cross-sectional study was conducted on 80 healthcare providers working at the palliative department of a tertiary hospital in Riyadh, Saudi Arabia, to estimate the quality of palliative care from the perspective of healthcare professionals. Participants' mean rate of agreement on the quality of palliative care services provided was 4.62 out of 5 which indicates that the majority agree that they and their colleagues provide high-quality palliative care [29].

A cross-sectional qualitative study was conducted in the outpatient department in Mwananyamala Hospital in Dar es Salaam, Tanzania to assess health care workers' perceptions about the quality of health care. The results identified multiple factors contributing to healthcare quality. Factors were classified into intrinsic and extrinsic factors; extrinsic factors included poor physical infrastructure, unavailability of medical equipment, and/or essential drugs, and poor staffing levels. Intrinsic factors mentioned were the motivation for health care workers and workplace training [30]. A questionnaire-based cross-sectional study conducted in Poland to analyze healthcare providers' perspectives in terms of nine core dimensions of the Polish Primary Care system: Economic conditions, Workforce, Accessibility, Comprehensiveness, Continuity, Coordination, Quality of Care, Efficiency, and Equity. The results came negative in the major part; with the accessibility of care evaluated the best dimension and economic conditions coming as the most negative. This reflects the urgent need for a multisectoral reform in PC in Poland [31].

Secondary data analysis of two qualitative studies examining parents' and healthcare professionals' perceptions of caring came with the acronym 'PITSTOP' in referring to the seven themes important to both parents and healthcare providers in their perception of quality care. The seven themes are patient-centered care, interprofessional collaboration, team communication, safety and security, trusting relationships, optimal outcomes, and positive patient experiences [32].

Quality meaning to the pathologist

To the pathologist, quality means accurate, on-time, and comprehensive reports. To the entreating physician, quality means on-time reports valuable in the managing of patients. To the patient, quality means receiving on-time medicinal management at the shortest conceivable period.

Importance of Total Quality Management (TQM) in Histopathology Lab

Histology laboratories come with many distinguishing characteristics that can only be understood through equaling the laboratories with other extents of therapeutic laboratories. It is well prominent that quality control checks in histopathology laboratories comprise precise documentation of patients, fixation, appropriate processing, proper procedures for embedding, objectionable artifacts, microtomy, as well as assessments of controls, therefore, to control how proper or accurate protected histochemical techniques and distinct stains are [33]. To work effectively and securely, all the techniques and accomplishments of the histopathology laboratory should be appraised and monitored precisely. In a histopathology laboratory, the perception of quality control is appropriate to pre-analytical, analytical, and post-analytical undertakings. Confirming the security of the employed person as well as surroundings is also extremely significant [34].

Safety concerns that may come about in a histopathology lab are principally those interrelated to theoretically dangerous chemicals, biohazardous constituents, accidents accompanying the equipment and musical arrangement employed, and general hazards from electrical and fire exposures [33]. Quality control in histopathology laboratories diminishes the opportunity for the existence of hazards and accidents. Also, quality control in histopathology labs improves its competitiveness and creates better-quality workplace environments.

Objectives of Quality Control in Histopathology Laboratory:

The quality control program is premeditated to monitor all constituents of laboratory processes, taking account of specimen assortment and dealing out test procedures, and recording of test results. Additionally, this program is not merely used to monitor test outcomes, nonetheless, it correspondingly monitors types of equipment, substances used in testing, employees and delivered

1. To confirm quality services that assures patient's gratification
2. To create extraordinary quality subdivisions in the interior and amongst laboratories
3. To create precise, timely, and comprehensive reports
4. To diminish turnaround time
5. To support ethics and professionalism
6. To develop better-quality performance
7. To develop continuous training as well as a professional improvement [3]

Quality Framework in Histopathology Lab:

Figure (1) illustrates the the key quality framework defined by the World Health Organization, 2005. As it is clear from the figure, the key quality framework defined by the World Health Organization in 2005 is an organization, customer focus, facilities and safety, personnel, purchasing and inventory, equipment, process management, documents and records, information management, nonconforming event management, assessments, and continual improvement [35].

Pathology lab needs proper capacity and ventilation, electrical, light, water, sanitation, storage, safety, and communication equipment. Wastes of the lab from pathology processes are the greatest risk to the environment. It is essential to handle these wastes properly, protecting water and adequate disposal [36].

Laboratory staffs need to be trained and made aware of the possible risks and the proper handling of such products. A written protocol for safe handling, including the cleanup of formalin spills, should be in operation for the pathology laboratory [37]. It is necessary to choose the most suitable laboratory equipment. Criteria for choosing laboratory instruments should be considered. The choice of equipment to be manual, semi-automatic, or fully automated depends on the number of experiments and the resources available to the laboratory [38]. The machinery is therefore depreciated yearly and will inevitably have to be upgraded [39].

It is also necessary to retain a sufficient number of trained personnel to provide timely and reliable pathology services. Educating and preparing greater numbers is of vital importance in developing a viable pathology network. Pathologists are professionally trained physicians who have obtained postgraduate education and experience in pathology [40]. It is necessary to ensure qualifications via adequate preparation, training, and professional development, as laid out in the country's national standards [41].

A laboratory information system is valuable in the management of results and other pertinent information regarding patients and their samples. Recently, the focus has evolved into the aspects of digital histopathology and genomics, and issues about patients' access to data, and a lot more [6].



Figure 1: key quality framework defined by WHO 2005

Quality Phases in Histopathology Lab:

Planning and implementation a quality control and assurance plan in histopathology be duty-bound to emphasize three fundamentals: pre-analytical stage, the analytical stage, and the post-analytical stage^[42].

The pre-analytical stage:

Understanding the activities of specimen collection, transportation to histopathology laboratory, receiving by laboratory personnel, and groundwork for the consequent dealing out. Completely histological techniques and processes which are convoluted to get ready a respectable section originate underneath the pre-analytical stage. Several studies designate that most errors in the laboratory are interconnected to the pre-analytical stage^[43].

Approval Form and Registration: Manually categorized specimen vessels carrying exceptional identification digit received at the reception hostage to the fortune of histopathology corresponding to requisition formula intended for patient identification. This standard operating procedure (SOP) had better be written in unpretentious language that can be understood by everybody^[44]. The SOP should be existing at the workplace and altogether procedural employees should be conscious of its subjects. If the correct investigative material is mislaid at this stage, the ultimate preparation of the slide and henceforth the microscopic reading of the identical result into deprived diagnosis and an inappropriate managing of the case^[45].

Referral form:

It would be valuable for the laboratory to enterprise its peculiar "**referral form**" for histopathology and immunohistochemistry and mark it accessible to all regions of sample assemblage^[46]. This form should afford interplanetary intended for recording the pertinent clinical information. It might be beneficial to introduce check

rectangles for well clinician obedience. Discussion with the clinician around the significance of appropriately completed formulae might be desirable. A not accurately labeled specimen must not be conventional and must not be received. Every single specimen necessity is appropriately recognized and necessary to be recorded in the department by allocating an irreplaceable ID number^[47].

The specimen in suitable fixative:

Fixation of the tissues is pretentious by different influences comprising the size of the container and nature of the specific specimen. The strategy of this lab was to be sure of the availability of suitable fixative by the specialist at reception hostage. A respectable fixative certificates preservation of all ingredients of the tissue. A furthestmost appropriate fixative must be designated as apiece the nature of the tissue under examinations^[48].

Attention must be taken to perceive the accurate timings for the procedures of dehydration, clearance, impregnation subsequently after the fixation of the tissue specimens to achieve the accurate morphology and intactness of the tissue ingredients. Several determining influences of the tissue dispensation are the suitable temperature situation, campaigning of specimens, viscidness of the reagents, and conservation of precise vacuum of the processor^[49]. To permit dependable reporting it is indispensable that the staining techniques must also be dependable.

Factors affecting staining procedures:

Several influences affecting the staining procedures which essential to be monitored are; modification of product and supplier of the stains (hematoxylin and eosin stains used in routine), consistency in pH, the oldness of the stain in addition to the degree of its convention. Natures of fixatives, treating schedules, segment thinness, standardization, and conservation of the apparatus are significant variables that may influence the staining physiognomies^[50, 51].

Analytical Phase:

Analytical features in histopathology are not informal assumed the prejudice of the reports. Error recognition and prevention in histopathology has been transcribed about very frequently^[52]. The analytical phase comprises the procedure of understanding and interpreting the histology stained slides underneath the microscope. considering balance, knives of dissimilar sizes, scissors, needle inquiries, thread, blade, ruler, board, sieve, etc must be completely accessible. The laboratory technologists and pathologists prerequisite must guarantee quality patient carefulness by constructing precise case identification^[53].

Positive and negative controls are essential continuously to be encompassed in every consignment of the recording of slides. It is fine recognized that the analytical phase of histopathology is complex and difficult owing to individual judgment and biases. Intradepartmental discussions, comparison with other reports (frozen, cytology, or

histopathology), blinded random case appraisal, exterior discussions and evaluation by professionals are particular step which could be taken to advance the quality [54]. Pieces of equipment must be reserved warm through the chief power foundation for optimal performance. Refrigerators and freezers to be reserved for reservation of reagents and apprehensive melting and re-freezing. Lastly, in attendance must be periodic spring-cleaning in addition to lubrication of equipment [55].

Post-analytical Phase:

Post-analytical characteristics are significantly prejudiced by the accurateness and comprehensiveness of the reports. Preparation and communication of histopathology reports are considered one of the items of the post-analytical phase. It as well encompasses the storing/discarding of samples, slides, and blocks and appropriate preservation of examination results [56].

Monitoring of TAT is of vigorous importance, as well as laboratories must struggle to accomplish the goal line of authorization of the majority of cases within 48 hours of receiving the specimen. Clinician contentment may also be reliant on anticipations of a clinician from the laboratory. Consequently, in addition to management and monitoring completely the fundamentals of quality, the pathologist necessity likewise accomplish the clinician prospects and make unquestionable that they are realistic [57].

Quality and Safety of Lab:

All laboratories must register in a safety program which must originate with the appreciation and empathy of the threats, shadowed by the implementation of safety guidelines and rules [58]. Risk controlling pertains not just to individual wellbeing and safety in the conservative logic, but correspondingly to environmental well-being and care. Poisonous materials as cyanides and heavy metal salts are accomplished of producing death by ingestion, skin interaction, or inhalation at definite quantified concentrations [59].

It is fine approved that nearly every additional material utilized in histopathology labs is poisonous and dangerous to whichever manipulator particularly when handled improperly. The hazards accompanying the dangerous chemicals could be controlled by obtaining adequate information of the possessions of these substances and protecting equipment and availability of the protective procedures [60]. Approximately all the chemicals could be irritants, assumed adequate exposure to tissue and can lead to rescindable inflammation particularly to the eyes, skin, and respirational passageways. Chemicals producing particular impairment to specific structural or physiological systems are supposed to possess target organ influence [61]. Explosive chemicals are infrequent in histopathology, the chief example being picric acid. Stored chemicals must be scrutinized

periodically intended for replacement, deterioration, and container truthfulness [62].

Even on behalf of materials that possess no acknowledged substantial threat, exposure had better be decreased. Purchase hazardous reagents in plastic or plastic-covered glass flasks. Exceptional storage requirements are necessarily used for acids, flammables, radioactive isotopes, and dangerous chemicals in unpackaged containers. It is greatest to evade flammable solutions that have volatile nature besides to very low flash point or purchase only the necessary quantity and do not attempt to stockpile any remains [63].

Recognize chemicals that could be disposed of safely in ordinary garbage baskets or sewage disposal systems and the other chemicals necessity be recycled or reduced as soon as conceivable, or positioned in suitable containers to be handpicked up by safety service station [64].

Laboratory equipment and appliances which stand electrically powered could pretense an electrical hazard, in addition to mechanical and other possible hazards. Electrical equipment must be checked every twelve months for grounding and current leakage and outflow [65]. The amalgamation of sufficient precautions and protections is compulsory if flammable solvents of the solid materials must be used through the centrifuge. The overall regulation concerning the safe procedure of the different instruments and even collective laboratory equipment is that the operator essentially is guided using the information in the technical manuals in addition to experienced personnel [66].

CONCLUSION:

Quality evaluation, processing, and monitoring of establishment, procedures, and activities of histopathology laboratory are essential to function effectively and safely. Guaranteeing the safety of operational personnel as well as setting is also highly significant. Quality standards of histopathology laboratory and work facilities are a must and all the standards must be applied to function effectively. A Quality Committee should be established within each histopathology laboratory to ensure routine review of quality data and to initiate improvements where required. Also, the development and implementation of guidelines for the routine measurement and review of quality indicator data for Histopathology Laboratories are needed.

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