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Review Article

Quality Assurance in Histopathology Laboratories

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Abstract

Achieving and maintaining quality is of utmost importance in laboratory operations for the best possible patient care. The concepts of quality control and related quality procedures and programs are relatively new and less well understood in histopathology laboratories than in other sections of clinical laboratories, particularly in developing countries. This is because the main product from these laboratories consists of descriptive, opinion-based reports rather than numerical reports as in other fields of laboratory medicine, and most of the work is still manual and involves multiple steps. The scope and extent of quality schemes in histopathology laboratories are very broad and complex, requiring coordinated and concerted efforts on the part of all stakeholders to achieve and maintain quality services in these laboratories. There is a need to create awareness among the pathologist community and other healthcare members about the necessity of quality assurance and improvement schemes in these laboratories to achieve optimal patient care.

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Introduction

Before discussing the concepts, measures, and actions of quality control (QC) in histopathology laboratories, it is befitting to reiterate the old dictum "To err is human," which is a fact of life. Errors are associated with almost all activities of human life. Healthcare and the medical field are not immune to this phenomenon. Medical errors result in the death of approximately 98,000 people per year in the USA alone.[1–3] Errors also occur in laboratory tests. This is because laboratory functioning is a complex process incorporating multiple components. Laboratory errors incur loss of time, personnel effort, and patient outcomes.[4–8] The objective of various quality plans, measures, and actions is to reduce the error rate to the minimum possible. An acceptable significant error rate in surgical pathology is 0.5–1% (false positives, false negatives, and misclassifications).[9–12]

Histopathology tests are considered the final, definitive, and often the gold standard in the diagnosis of many diseases. Thus, the generation of accurate and reliable reports is crucial for quality patient care. QC and quality assurance (QA) programs are imperative in achieving this goal. The concepts of QC and related quality procedures and activities are relatively new and less well understood in histopathology laboratories than in other sections of clinical laboratories.[10,13,14] One of the main reasons for this is the intrinsic multistep, complex, and often manual nature of work in histopathology laboratories. Histopathology reporting is still predominantly subjective, interpretative, and opinion-based; therefore, it is associated with little homogeneity in reporting across the world. The reporting patterns vary greatly from one pathologist to another and from one center to another. Moreover, newer techniques and investigations, e.g., immunohistochemistry (IHC), morphometry, fluorescence *in situ* hybridization (FISH), and molecular tests, are being conducted on tissue biopsies regularly, and their integration with light microscopic data is increasingly being used. For all of the above reasons, it is difficult to assess and implement the usual QC methods in these fields.[15–17] This narrative review aims to provide a brief overview of the importance and role of QC methods in achieving and maintaining quality service by histopathology laboratories to optimize patient care. Due to the scope of this review, it will not be possible to describe every aspect of QC methodology in detail. Since cytopathology laboratories have some unique considerations, this review will be restricted to discussion of QC methods in histopathology laboratories only. This review will help to increase awareness of these methods among histopathologists and other concerned stakeholders so that best practices are followed in histopathology laboratories.

The concept of quality has its origins in the manufacturing industry. From there, it has been borrowed from other fields including clinical laboratories. In the manufacturing industry, the manufacturer uses raw materials produces the final product from them and then delivers it to the clients. The final product is continually checked to uphold a particular standard or compliance with a specification. If there is any fault, the company instantaneously rectifies it and also takes measures to prevent such faults in the future. The work of the histopathology laboratory is similar to the manufacturing industry. In the histopathology laboratory, one receives the tissue sample (raw material), processes the sample, prepares stained sections on glass slides for the study and interpretation by the pathologist, and finally the findings are reported in a descriptive report (the product). This process is analogous to the industrial workflow. Rigorous maintenance of the quality or standard is required for a quality laboratory

Keywords: Quality control; Quality assurance; Histopathology; Laboratory.
Abbreviations: EQA, external quality assessment; FISH, fluorescence *in situ* hybridization; IHC, immunohistochemistry; QA, quality assurance; QC, quality control; QA&I, quality assurance and improvement; TAT, turnaround time; TQM, total quality management.
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service/product.[18–22]

Many terms/concepts centering around the concept of quality, such as total quality management (TQM), QA, QC, etc., are used. Achievement and maintenance quality are the central themes and goals of all of these terms. It is well-known what is meant by quality, but the term itself is not easy to define. In the simplest words, quality means the product/service should be error-free. In histopathology, the meaning of quality differs for different professionals/stakeholders. Quality in histopathology is best defined as the generation of timely, accurate, and complete reports. The achievement of quality is not "a one-man job;" instead, the whole organization needs to be involved to succeed in this objective. It requires considerable investment in the basic infrastructure and in the staff who perform surgical pathology tasks in addition to stringent control of the testing processes.[23–26]

The term QC means the sum or aggregate of all operational techniques and processes needed to identify, decrease, and rectify deficits in the analytical process to uphold a chosen set level of quality in the laboratory test or process. It encompasses real-time measures taken to ensure that the quality of the product meets the specifications. It is the most fundamental component of all quality plans. QC aims to achieve, implement, and maintain the quality of a product. Thus, QC is the sum of all techniques, tools, and methods used to control the final quality of the product. It is an operational and continuous process. It typically covers the analytical phase vs. QA. QA is the exercise of evaluating the performance in all phases of the laboratory testing cycle including the pre-analytical, analytical, and post-analytical phases to ensure best outcomes in patient care. Compared to QC, QA is a conceptual plan or program. QC is an integral component of QA. Quality improvement is the exercise of constantly evaluating and amending performance using statistically and scientifically recognized techniques. QA and improvement (QA&I) work best when woven into the systems of histopathology with well-informed, well-trained, and well-educated staff. TQM is the overall process of achieving, maintaining, and continually improving quality in any setup. It involves many essential components ranging from management to materials/equipment to work processes.[9,10,14,19–25] The above quality concepts differ from each other in terms of the degree of process and organizational involvement, which is overall and maximal in TQM (Fig. 1).

Quality indicators or quality monitors are objective measurable quality standards that monitor, identify, and evaluate performance issues throughout the crucial aspects of the pre-analytical, analytical, and post-analytical phases to ensure the best health outcomes.[26]

Objectives of quality schemes in histopathology laboratories

The main aims of various quality schemes in histopathology are as follows: (1) to produce an accurate and complete test report for the patients/clinicians, whose satisfaction is also an important element of QC; (2) to generate and deliver the report in a minimum amount of time; (3) to maintain ethical and professional standards; and (4) to provide constant education and training to the laboratory staff.

A QA&I plan is simply a minor component for achieving and maintaining quality services in a laboratory. Quality in a laboratory depends on a multitude of organizational and personnel elements that are indispensable, irrespective of the QA&I plan. Better still, the QA&I plan must be woven into all of the other elements of the laboratory to attain the best possible outcomes.[9,10,14,21–25]

Fig. 1. Schematic diagram of different laboratory quality plans/programs and their relationship with each other. Note that there is overlap among all three components as signified by the confluence of all circles at the upper part of the diagram.

Phases of the testing cycle and quality schemes in histopathology laboratories

For the sake of convenience, the testing cycle in all laboratory fields, including histopathology, is often divided into three phases (Fig. 2). However, there is significant overlap among these phases. In fact, the processes themselves and the elements of QC and QA, which control these phases, are continuous. The phases are the pre-analytical phase, the analytical phase, and the post-analytical phase. Two additional parameters of the testing process that are also important from the quality point of view of the laboratory results include the turnaround time (TAT) and clinician/patient satisfaction/complaints. A final element of quality, particularly in the manufacturing industry, is the price or cost of the product, which is relevant for private laboratories.

Pre-analytical phase

The pre-analytical phase is the most important aspect of the testing cycle in histopathology/cytology laboratories and, thus, the QA and QC check system. If something goes wrong during this phase, all subsequent steps will be affected. Among these, accurate patient/sample identification is the most critical activity.

The pre-analytical phase is the most vital step in the histopathology laboratory from the point of view of the occurrence of errors. A vast majority of errors (70–80%) occur during this phase for various reasons. The principal reason is that several steps/elements are involved. Importantly, many personnel other than laboratory staff are also involved in this phase. Consequently, major improvement in this phase necessitates acceptance of this objective across an organization with a significant awareness and educational program. QA and TQM plans cover these aspects of the testing cycle.[27,28] The QA monitors commonly used for assessing the performances in this phase are presented in Table 1.

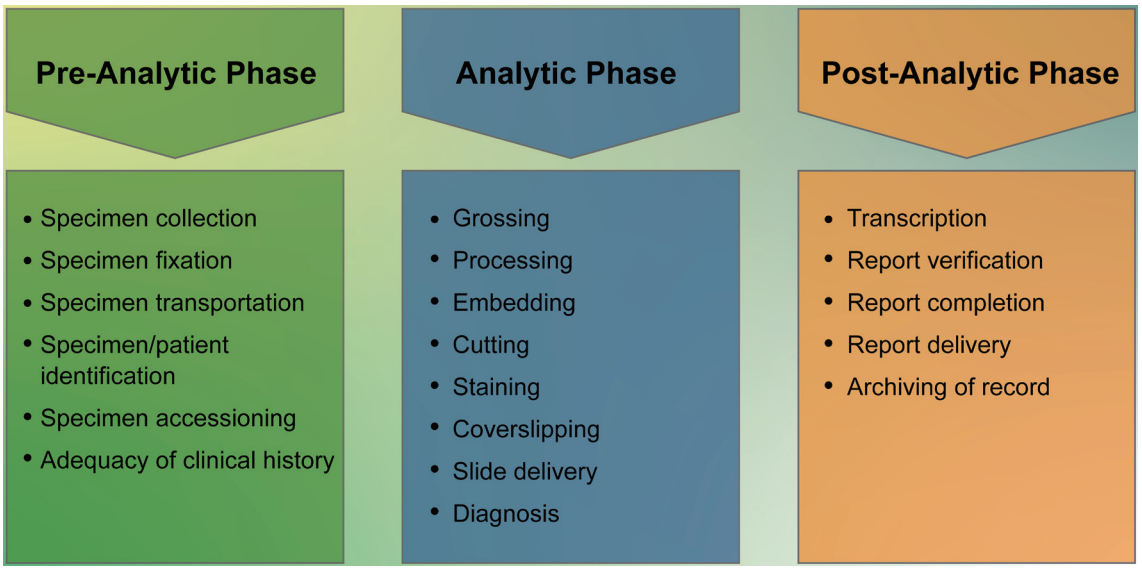

Fig. 2. Schematic diagram of different phases of the laboratory testing cycle and their components in a histopathology laboratory. In practice, it is a continuous process.

Analytical phase

There is some controversy regarding the scope and components of the analytical phase in the histopathology laboratory. According to some, this phase commences with the gross examination of the sample and ends with the rendering of a diagnosis. Others restrict the definition of this phase to the diagnostic process only. According to the former view, many components, both technical (microtechniques) and interpretational (pathologist) are involved.[27,28] The technical steps include grossing, processing, embedding, cutting, staining, etc., as shown in Figure 2 and Table 2.

However, the most critical step is that of diagnosis itself, which is made by the pathologists/consultants.[29] The accuracy of the ultimate diagnosis critically depends on the effective execution of all of the previously listed successive steps. There are no formal gold standard methods/calibrators/controls as in other fields of laboratory medicine. In the absence of the best methods, peer review is the most vital measure of quality with regard to the accuracy of the report and ultimately patient care.[29–35] A variety of peer review methods have been utilized to achieve the objective of quality reporting (Table 3). Some of these are prospective and others are retrospective in nature. However, no single method has been shown to be better than others in detecting errors. A combination of both prospective and retrospective methods is effective for reducing error rates.

The prospective methods are applied before the verification of the report and are the only processes that can prevent the occurrence of errors. The most important prospective methods comprise intradepartmental or interdepartmental consultation before rendering the final diagnosis.

The retrospective methods are used after the primary reporting is done and delivered to the concerned stakeholders. The objective of these is to identify errors, assess the causes of errors, and formulate plans to prevent the future occurrence of such errors. A comprehensive account of these methods is outside the scope of this review.

A number of different QA&I monitors are used to evaluate the quality of the analytical phase of testing. These are shown in Table 4. In addition, it is recommended that the QC related to the histopathology laboratory should include the following: (1) Record of the time of delivery of the tissue slides; (2) evaluation of the slide quality by the pathologist; and (3) evaluation of tissue adequacy by the histotechnologist.

Post-analytical phase

The post-analytical phase is also important for achieving quality histopathology products and includes the following activities: (1) completeness of reporting; (2) transcription/report correction; (3) verification/validation of the report; (4) diagnostic finding correlation with ancillary studies (IHC, electron microscopy, FISH); and (5) report delivery.

Table 1. Quality assurance monitors commonly used for the pre-analytical phase in the histopathology laboratory

Quality assurance monitors
Labeling errors
Accessioning errors
Adequacy of clinical history
Lost specimens

Table 2. Different steps in the analytical phase of the testing cycle in the histopathology laboratory

Steps
Grossing
Processing
Embedding
Cutting/microtomy
Staining
Coverslipping
Assortment/distribution of cases to pathologists
Examination/interpretation of slides by pathologists
Rendering diagnosis, writing report

Table 3. Different methods of peer review for quality monitoring in histopathology reporting

Method	Description
Prospective	Second pathologist review before sign-out
Retrospective	Review of a randomly selected number/percentage of cases
	Focused internal review of the specific organ system or malignancy type (for example, breast cancer)
	Intra- and interdepartmental conferences (e.g., tumor boards)
	Intradepartmental quality assurance conference
	Frozen section/permanent section correlation
	Cytology/surgical pathology correlation
	Review of previous pathology material in repeat biopsies
	Intradepartmental review of material before release to other institutions
	Review of outside diagnosis of in-house cases
	Clinical indicators
	Pathology turnaround times

The key elements in the post-analytical phase are accurate transcription, comprehensive reporting, report verification, and proper and timely delivery of the report (Fig. 2). Recently, there has been a lot of emphasis on complete reporting, particularly in cancer reporting. The use of summary checklists has resulted in the generation of more complete reports with ultimately better patient care.[35,36–39]

The QA monitors commonly used for checking the performance in the post-analytical phase in histopathology are shown in Table 5.

TAT

TAT is an important element of quality and usually implies all aspects of the laboratory testing cycle. It may be split into smaller constituents for analysis, but the total TAT is the only parameter by which the customer/clinician will evaluate the performance of the laboratory. TATs vary depending on the nature and size of the specimen and the type of test required. For example, for frozen sections, the TAT is minutes; while for bone specimens and final autopsy reports, it may take weeks.[40–42]

The acceptable TAT for histopathology reports, as calculated in working days from the time the sample is accessioned in the laboratory to the time the oral report is conveyed or the final report is issued, is 2–3 days for small biopsies as well as surgical specimens. Additional time should be acceptable for the following processes, to be measured in days from the time the process is initiated or ordered and separately from each other: overnight fixation, 1 day; decalcification, 2 days; recuts, 1 day; resubmission, 1–2 days; immunohistochemistry, 1–2 days; electron microscopy, 4–5 days; and intradepartmental consultation, 1 day.

Clinician or customer satisfaction

Clinician or customer satisfaction is undoubtedly one of the most vital parameters of quality because it provides the understanding of the clinicians' or customers' perceptions and expectations from the laboratory. It is important for pathologists to create awareness among clinicians regarding realistic expectations from the laboratory. Feedback from the clinicians may help to identify their perceptions about the laboratory quality and what they expect from the laboratory. This will help pathologists in educating clinicians regarding the realistic output of the laboratory. Customer satisfaction

Table 4. QA&I monitors for the analytical phase of histopathology laboratory testing

QA&I	Examples
Histopathology and gross room monitors	Block labeling errors; Slide labeling errors; Quality of histologic sections; Specimens lost in processing
Histopathology TAT	
IHC monitors	TAT of immunohistochemistry; Frequency and causes of repeat IHC staining; Integration of IHC results with morphologic features; Annual review of antibody supply and frequency of use; Participation in external proficiency testing should be considered particularly for tests that directly impact patient therapy such as HER2/neu immunostaining
Other ancillary study monitors	Monitors for FISH, electron microscopy, and other molecular tests
Frozen section: permanent section concordance	
Final diagnosis	
Peer review error rate	

FISH, fluorescence *in situ* hybridization; QA&I, quality assurance and improvement; HER2/neu, human epidermal growth factor receptor 2; IHC, immunohistochemistry; TAT, turnaround time.

Table 5. Quality assurance monitors commonly used for the post-analytical phase in histopathology

Quality assurance monitors
Transcription errors
Verification errors
Report delivery errors
Incomplete reports

surveys are often conducted at variable intervals to gauge this indicator.[43]

Incorporation of IHC findings into the pathology report

The IHC results for all markers tested should be listed in the report, regardless of supposed implications. Preferably, such information should be incorporated in the original main report (surgical or autopsy); however, due to time limitations, it may be indispensable to report immunostaining results separately as, for example, an addendum. When the latter method of reporting is used, it is important that the preliminary report states that such studies are pending; likewise, it is essential that the separate report should make a reference to or even include the original report. A differential diagnosis justifying the immunostaining methods should be provided in the report. The differential list may be very brief or broad, for example, "anaplastic large-cell neoplasm of uncertain differentiation" or "epithelial versus lymphoid nature." The nature of the investigated sample, e.g., frozen sections, paraffin sections, or aspiration biopsy smears, should be stated. The IHC reagents used should be explicitly stated, e.g., "HMB-45" instead of simply "melanoma-related antigen." The results of the staining for each reagent antibody should be stated in sufficient detail to rationalize the interpretation, e.g., negative or positive, percentage of stained cells, the intensity of staining, patterns of staining, or localization of some antibody reactivity to certain cellular parts. Full technical information concerning the IHC staining methods, including fixation and augmentation methods such as enzyme predigestion, etc., do not need to be incorporated in the diagnostic report but should be obtainable in permanent laboratory records. However, some laboratories do report such information. Similarly, other ancillary technique results (e.g., FISH results) should be incorporated in the final report as per relevant/current guidelines/protocols.[44–49]

External quality assessment schemes

In addition to stringent QC protocols, diagnostic standards in histopathology laboratories are upheld and improved by participation in the following activities: external quality assessment (EQA) schemes, clinical audits, continuing medical education, clinicopathological case review meetings, and laboratory accreditations. The above processes are closely interrelated; for example, feedback from EQA schemes provides opportunities for continuing medical education, and participation in pertinent EQA schemes permits compliance with the accreditation standards.[50–53]

The principal objective of EQA in the histopathology field is education. The educational value is attained not only from the content but also from individual feedback, which allows individual contributors to recognize and rectify problems in their individual performance. Regarding EQA, several general and specialist programs have been developed during the last few decades throughout the world, more so in developed countries. Participation is mostly optional, except for some schemes linked to cervical and breast cancer screening in some countries, and the focus is on education and improvement of laboratory services.[50–53]

Conclusion

In conclusion, the scope and extent of quality schemes are very broad and complex. Therefore, they require coordinated and concerted efforts on the part of all stakeholders to achieve and maintain quality services in histopathology laboratories, particularly in developing countries. In particular, there is a need to create awareness among the pathologist community and other relevant healthcare members about the necessity of QA&I schemes in these laboratories in order to achieve optimal patient care.

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Conflict of interest

The author has no conflicts of interest related to this publication.

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