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REVIEW ARTICLE

RISK-BASED QUALITY CONTROL IN THE SURGICAL PATHOLOGY LABORATORY; BRIEF REVIEW AND DEVELOPMENT OF AN INDIVIDUALIZED QUALITY CONTROL PLAN

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Abstract: One of the most important tools for reducing or preventing diagnostic errors in the surgical pathology laboratory is the establishment of a quality management system. Risk analysis and quality assurance are important components to ensure the sustainability of the quality management system. Quality assurance ensures the integrity of program design and includes interrelated activities quality control and quality monitoring-evaluation programs. Risk-based thinking is expressed as the planning of risks and how they should be managed by determining the possible dangers and risks in achieving the determined goals and objectives, using the available information systematically. Laboratories must identify and carry out a large number of interrelated activities to maintain their functions effectively. To achieve its goals, it must demonstrate the ability to measure and evaluate process performance, as well as to demonstrate the effectiveness of past decisions, along with improving operational effectiveness and efficiency. With a successful quality management process, the reliability of laboratory results can be increased. In this study, our objective was to develop a roadmap for the detection, monitoring and minimization of diagnostic errors in the surgical pathology laboratory, in line with the views of international regulatory organizations, to develop a quality plan based on risk management that covers the entire analytical cycle. It is not possible to discuss the quality control of laboratories without accepting the possibility of error in surgical pathology. Investing in continuing medical education and patient safety, as well as the training of new pathologists with a critical view to reducing errors is an imperative way to improve the practice of pathology.

KEYWORDS: Quality Control Plan, Risk Management, Quality Monitoring

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INTRODUCTION:

The main purpose of the quality management system in surgical pathology (SP) is to play a role in the delivery of laboratory services as a tool to reduce and prevent errors. With a successful quality management process, the reliability of laboratory results of the laboratory can be increased. Quality assurance (QA) and risk management are part of quality management. Quality control (QC) and Quality assessment are subcomponents of the quality assurance program. QC focuses on meeting quality requirements, while quality assurance focuses on providing confidence that quality requirements are met. Using QC applications, a laboratory can find and correct flaws in laboratory analytical processes before potentially incorrect patient results are disclosed.[1] The existence of studies focused on improving the quality of SP and cytology in the last 20 years is promising. [2-16] However, it is not possible to say that it is sufficient. Investing in continuing medical education, patient safety, and training of new pathologists with a critical view of reducing errors is an essential way to raise awareness to improve pathology practice. [17]

QC was first described by Shewhart, an industrial statistician and physicist, as a system designed to verify and maintain the desired level of quality in a test or analytical process. Walter Shewhart was instrumental in promoting and developing "process control" in 1924. It was also called the "Father of Modern Quality Control" and was also recognized as the founder of the "Shewhart cycle".[18,19]

Efforts to improve patient care in pathology were initiated by the "American College of Pathologists" (CAP), which was founded as a national organization in Chicago in 1946. Since its inception, the organization that promotes pathology and laboratory science practices and excellence in patient care has become one of the leading organizations in the world. In 1950, Levey and Jennings introduced QC in clinical pathology laboratories.[20] Clinical Laboratory Act Improvement (CLIA) studies began in the 1960s with the emergence of problems in cytology laboratories that evaluated PAP smears. In 1967, CLIA became law and the first laboratory arrangements were born. The final CLIA regulations were published in 1992. These arrangements offer the opportunity to adopt a flexible laboratory-specific Quality Control Plan (QCP). [21 and 22] In the early 1990s, a national laboratory accreditation plan (CPA) was developed in collaboration with the British government and four professional organizations (Royal College of Pathologists, Clinical Pathologists Association, Clinical Biochemists Association, Institute of Medical Laboratory Sciences). [23] CPA accreditation focuses on evaluating processes within the laboratory but does not adequately cover relationships between patients, clinicians and laboratories [24]. The standards developed by CPA will then form the basis of an international standard for medical laboratories.

The International Organization for Standardization (ISO) has published the ISO/IEC 17025:1999 standard, which defines the general requirements for the competence of test and calibration laboratories, and the ISOIEC 15189:2003 standard regarding the quality and competence of medical laboratories. ISO 15189 is a standard that offers a comprehensive structure for laboratory operations. Continuous improvement is a permanent goal of ISO 15189 quality management. Labs, where this standard is applied, create as few fault-based systems as possible, capture errors before problems, reduce errors, and create opportunities to improve at all times. Since they affect patient safety, the laboratory should evaluate the working processes and the impact of potential failures on the results of the review and document the decisions and actions taken to reduce or eliminate the identified risks. [25, 26] (Figure 1)

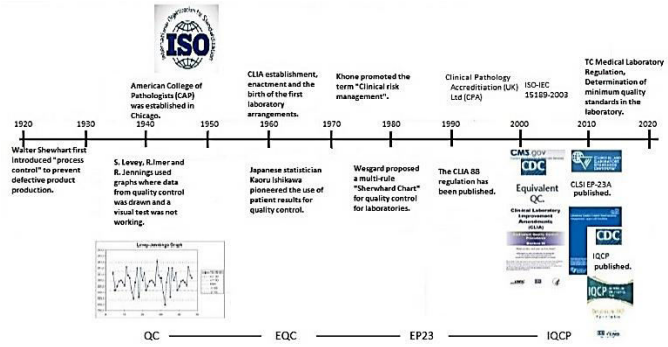

Figure 1: The process of QC's development over time.

The CLSI publication (CLSI EP23-A) contains the analysis of all process steps to see where errors can occur and which actions can prevent or reduce the risk of these errors occurring. The U.S. Department of Health and Human Services (CDC) has created an individualized QCP application workbook for use in

clinical laboratories (outside pathology) by this guide. [27]

İn this study, it was aimed to create a risk management-based quality plan for the detection, monitoring, and minimization of diagnostic errors in the SP laboratory. Care was taken to ensure that this plan covers the entire test cycle and, most importantly, is compatible with the views of international regulatory agencies.

For this purpose; The literature on reducing diagnostic errors, quality control, and risk management in the pathology laboratory was reviewed. The information collected was combined with the opinions and recommendations of international regulatory agencies. Opinions from laboratory personnel about technical processes and laboratory errors were received. After synthesizing all of the data, a quality plan and quality monitoring plan were created in the SP laboratory based on risk management covering the entire test cycle.

Some concepts need to be explained to ensure the dominance of the subject.

Diagnostic error: The National Academies of Sciences, Engineering, and Medicine defined diagnostic error as the failure to establish an accurate and timely explanation of the patient's health problem or communicate that explanation to the patient. [28]

Quality: WHO defines laboratory quality as the precision, reliability and timing of the reported test results. [1] In this context, the definition of quality refers to the product produced or the service provided. In terms of surgical pathology, it is to provide the highest efficiency in patient care by producing an accurate, precise, timely and complete report. [29]

Quality assurance is defined as all the planned and systematic actions required to provide sufficient confidence that a product, service, or result will meet the given requirements for quality and be fit for use. The Quality Assurance program is defined as the sum of activities that aims to achieve this standard (ISO, 1994). The components of a QA program are generally defined at three levels: 1). Strategic or organizational level; It deals with the quality policy, goals, and management. Generally, the resulting product is the Quality Handbook. 2). Tactical or functional level; dealing with general practices such as training, facilities, and QA operations. 3). Operational level; Standard Operating Procedures (SOP) worksheets and dealing with other aspects of daily operations. [30 and 31] The assessment program and the quality control program are operational subcomponents of the quality assurance program.

Quality assessment is a tool used to examine laboratory performance, analyze the extent to which the measurements obtained from the collected data meets predetermined standards or compare with the performance of other laboratories.[1] Accordingly, improvement activities are initiated and then quality is reassessed. This step-by-step process turns quality assurance into a dynamic activity in which criteria and standards are constantly revised to improve service quality.

Quality control consists of two elements: internal quality control (IQC) and external quality control (EQC). IQC consists of operational techniques used by laboratory personnel to continuously evaluate the quality of the results of analytical procedures. EQC or inter-laboratory comparison is done periodically and checked by the laboratory responsible for the monitoring system. QC focuses on individual methods; it is a routine technical evaluation system where measurement and control are performed while increasing the quality of the product. [32] It is a result/product-oriented activity.

In the ISO 17011: 2017 standard, **the risk** is defined as a situation or event that may prevent an organization from achieving its organizational goals and objectives and fulfilling its basic activities, or cause unexpected damages**.** [33]

Risk analysis is defined as the systematic use of available information to identify hazards and estimate the risk (ISO 14971). [34]

Risk-based thinking: Preventive activities that are part of strategic and operational planning. It is what we all do in our subconscious to get the best results automatically and often. Risk-based thinking ensures that it is evaluated from the beginning until it eliminates risk. A health system should be considered a complex system with various variables (the complexity of processes, the specificity of individual patients, and the participation of different professionals). Therefore, an error or event risk is always present. Anatomical Pathology can be cited as

an example of a complex system where errors can be seen at different stages of the diagnostic process. [35]

Risk Assessment; It is a way of identifying and evaluating potential problems or errors that may occur during the testing process. In the ISO 9001 standard, the concept of preventive action is expressed in the use of risk-based thinking in setting the requirement of the quality management system requirements. [36]

Risk management is a system that determines to what extent risks should be managed to achieve goals and objectives determined and aims to ensure that this process takes place as planned. Risk management; can be carried out as 1) a project triggered by an event or finding, 2) as a project (proactive) to assess potential weaknesses in reviewed or complex processes, or 3) as a continuous evaluation and monitoring activity (reactive) daily events. [37]

Risk management process in its simplest form;

- Analysis of the laboratory process (process mapping and determination of risk points) to identify organization-specific risks.

- Assessing how likely and to what importance these risks are (risk score evaluation).

- Determination of how important risks can be reduced that may change the process (determination of risk control measures, determination of indicators or monitors to monitor whether the control plan is working).

- It includes making decisions on what should be done for these risks and monitoring and evaluating the measures taken by implementing these decisions (monitoring of risks).

Scenario: A risk-based QCP is required to meet the CLIA requirements and ISO 15189 expectations in a comprehensive Surgical Pathology and Cytopathology Laboratory that provides corporate service.

First, a risk assessment is expected regarding the routine histology and cytology laboratory process. At the beginning of the study;

1. When starting the risk analysis, it is necessary to review records such as laboratory procedures, manufacturer's instructions, historical quality control results, calibration data, PT results, regulations, and complaint records. This information will be used to think about "What could go wrong" during the entire testing process.

2. To raise awareness of the central role of laboratory workers in the risk management process, targeted training should be provided. A risk assessment and evaluation group of employees should be created.

3. The process map is a planning and management tool that visually defines the workflow. The preanalytical, analytical and post-analytical phases of the testing process should be reviewed, and workflow charts should be created. To detect potential failures and errors on the map, each stage can be divided into steps and control and decision points can be created. (Figure 2)

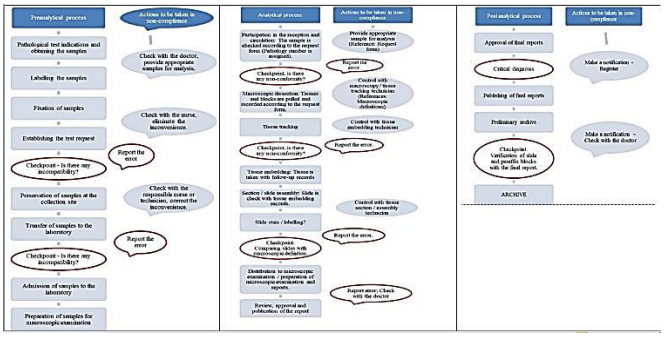

Figure 2: Surgical pathology laboratory processes and process control points

The testing cycle in surgical pathology and cytology consists of preanalytical, analytical and post-analytic processes, similar to the test cycle of other laboratory tests. The preanalytical process begins with the emergence of pathological testing needs after clinical evaluation, consisting of test demand creation, sample collection, sample labelling, transport to the laboratory and laboratory delivery, and preparation for the analytical process of the sample. The post-analytical process begins with the creation of the result report and ends with the delivery of the report to the clinic. In surgical pathology, the analytical process begins with the macroscopic identification of samples, dissection, and sampling. It usually covers the interpretation of slides obtained as a result of multiple experimental struts. In interpretation, it contains the pathologist's natural reasoning. However, unlike clinical pathology, the analytical process in surgical pathology is significantly different and more

subjective, unlike other phases of the test cycle. Many factors contribute to an accurate diagnosis, including the knowledge and experience of the pathologist, clinical correlation, standardized diagnostic criteria and taxonomy, confirmation assistive studies and secondary examination of cases when appropriate.

What needs to be known when dealing with laboratory pre-analytic process errors is that you do not have a magic hand to solve all problems. A serious solution can be considered in the form of eliminating all of these processes that are more vulnerable to errors and uncertainty. However, this is not practically possible, because close to all of the pre-analytical activities required to obtain appropriate samples are not directly within the domain of pathology laboratory management. The laboratory responsibility for pathology is limited to counselling and training activities. Therefore, regulations related to the preanalytical process can take a long time and can be worn.

4. With a proactive approach, potential failures and possible errors must be determined through brainstorming along with those working in the testing process. With a reactive approach before starting risk analysis, it can contribute over several months to the collection and analysis of log records of errors in the laboratory. (Table 1)

5. Risk refers to a combination of the probability of error and the severity of the error (ISO14971). It is necessary to assess the possible frequency of the risks you detect and the levels of impact of the risk. To do this, you can assign one point to each risk through the risk matrix and determine the degree of admissibility. (Table 2)

6. The first and most important thing to succeed in this process is the initiation of process analysis and root cause analysis. Root cause analysis is effective in risk management and easy to use. It is an important step to identify and prevent errors caused by multiple causes. Also, for time, resources, or other reasons, it is not possible to pay the same attention to all of the risks identified. For maximum hazard reasons, it is essential to identify opportunities that offer maximum benefit and pay more attention to them.

Try to determine the possible errors, causes, and areas where errors have developed during the test process so that you can apply the 'fishbone' diagram for this purpose. [42] (Figure 3)

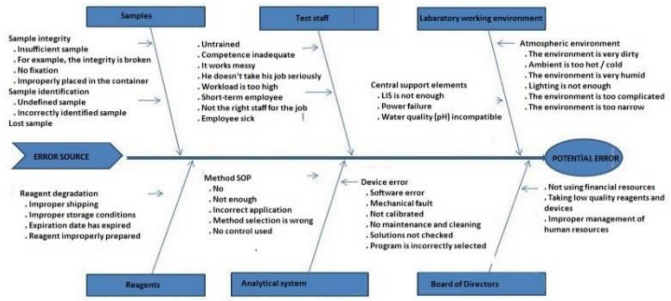

Figure 3: Fishbone Chart example.

The diagram will support you on the following topics;
- Allows a team to explore possible causes, fundamental causes, and possible solutions to a problem.
- Visually represents the causes, root causes, and possible solutions to a problem
- Help identify ideas for change and develop an improvement plan.
- Allows the team to focus on the content of the problem, not history or different personal interests.
This assessment essentially requires you to consider an assessment that includes at least the following five components when evaluating potential error sources in your testing process.
• Samples • Analysis system • Reagents • Laboratory environment • Test staff

7- What possible corrective measures may be for detectability, elimination, or reduction of identified causes during the process are discussed. All evaluation results are collected on the Risk assessment worksheet. (Table 3)

Finally, check and create checkpoints to determine whether your existing applications are sufficient to detect error sources or failures in the test system.

Table1, Possible errors in the total testing process of the histopathology laboratory

Pre-analytical process	Analytical process	Post-analytical process
. **Sampling errors** Insufficient sample Damaged sample Wrong anatomical region Test request errors No test requests Examples of worksheets incorrectly added Inadequate patient identification Inadequate sample identification Inadequate clinical history The mismatch between the request form and the test request Missing sample request Missing or mislabeled claim form **. Conservation/fixation of samples** No tissue was placed in a sample cup The sample was taken inappropriately No fixation / insufficient Wrong fixation type . **Labelling of samples** Number of samples inconsistent with the request form Untagged examples Labels without adequate identification Missing or mislabeled samples Inconsistency between test request form and samples Damaged, unidentified labels No proper biosecurity marks . **Sample transport** Delayed transport Broken, damaged samples Samples sent at inappropriate ambient temperature . **Acceptance of samples and data entry** Undelivered / lost samples Samples accepted without conformity check (request form-sample) Samples assigned wrong number and request form Sample and request form with different laboratory numbers Inappropriate sample storage that allows cross-contamination Samples were taken without creating enough records **. Incorrectly entered data in LIS**	**. Macroscopic examination/sampling lines** Request form and sample match not performed Macroscopic identification errors Error checking the request Sample loss Cross-contamination Insufficient sampling Incorrect/insufficient numbering of cassettes Tissue loss during dissection Samples not suitable for tissue processing Foreign tissues in the sample Samples not decalcified Examples of inadequate fixation **. Tissue tracking** The tissue has not been detected sufficiently before processing The reagents of the tissue processor are contaminated Tissue processing reagents loaded in the wrong order The tissue processing program is not finished Error in reagent replacement The program is incorrectly selected Overloaded cassette Loss of tissue during the procedure **. Embedding texture** Sample loss Cross-contamination Wrong paraffin selection Poorly positioned examples Incomplete waxing Cooling failure and other equipment failures **. Cross-section** Sample loss/end Incorrect slide number Cross-contamination Thickness selection error Damaged tissue sections Insufficient sections Error in defining the block to be cut **. Slide staining and mounting** Inadequate deparaffinization Reagents in the wrong order Reagent run out / decrease Reduced reagent performance Wrong staining method Separation of sections from slide Slide breakage Improper use of colouring solutions Cross-contamination Montage error Mislabeling of slides No quality control **. Microscopic examination and interpretation** Interpretation errors (False positive, false negative and incorrect classifications) Identification errors Report-related errors Delayed results **. Review of results and report approval** Interpretation errors Transcription errors Delayed results	. Reports not reported in time . The reports do not contain enough information . The report contains transcription errors . Revised but not notified . LIS errors . Archiving errors . Delivery errors . Clinician satisfaction and/or complaints . Verification errors: Diagnostic finding correlation with ancillary studies (IHC, EM, FISH) . Phrozen diagnosis - compliance with the final pathological diagnosis . Insufficient PT results . Insufficient LAC mismatches

Table2, Error score classification and risk matrixA

Probability level:			
	Common terms	Explanation	
5	Too often	Everyday	
4	Usually often	Once a month	
3	Sometimes	Once a year	
2	Remote possibility	Every few years	
1	Out of possibility	Laboratory activity once in a life	
Severity/effect level:			
	Common terms	Explanation	Impact description
5	Unacceptable	Misdiagnosis could result in an error causing patient death. It is against legal regulations. Employee safety endangers.	Misdiagnosis could result in an error that caused the patient's death. It is against legal regulations. Employee safety endangers.
4	Critical serious error	The diagnostic error can cause permanent damage or life-threatening deterioration. Sample loss (samples that cannot be repeated and samples that require invasive intervention for repetition). The device cannot be operated or operates at a very low-performance level	The diagnostic error can cause permanent damage or life-threatening deterioration.
3	Serious mistake	Diagnostic errors or delayed results may cause professional injury or damage to patient care. Sample losses (samples that can be repeated using non-invasive methods). The device can be operated but the degree of perfection is low. Reagent without performance verification.	Diagnostic errors or delayed results may cause professional injury or damage to patient care. Sample losses. (With non-invasive methods repeatable examples).
2	Minor error	Diagnostic errors that cause temporary discomfort that does not require professional medical intervention. Errors cause process repetitions, difficulties in interpretation and prolonged results in	Diagnostic errors that cause temporary discomfort that does not require professional medical attention.
1	Insignificant	Errors that cause temporary discomfort result in short process repetition.	Errors can cause temporary discomfort.

follow-up form must be created to see if the corrective-preventive activities envisaged in the process have been carried out or to detect unforeseen errors. Information collected as a result of follow-up with the appropriate intermediates will be analysed and used for improvement purposes.

The outcome of the risk assessment process is the creation of a quality control plan. It is not possible to monitor and analyse all the identified errors. For maximum hazards, it should be essential to identify opportunities that offer maximum benefit and pay more attention to them.

Creation of quality control plan:

There are some conditions to consider in the development of QCP. It should ensure instant detection of errors in the test system due to adverse environmental conditions and employee performance. It should also monitor the accuracy and precision of the assay performance that may be affected by changes over time (worker performance, sample, test system, reagents and variables in the work environment).

The QCP should be developed with a risk assessment to include the following:

- Equipment and equipment maintenance,
- Internal controls (additional examinations such as histochemistry and immunohistochemistry)
- Personnel training and qualification assessment,
- Device calibration, etc.

In addition to all this, for the creation of a full QCP:

- The type and frequency of the QC activity should be determined.
- The admissibility criteria of the QC results must be determined.
- The laboratory is expected to perform QC activities for the automated instrument and some reagents (antibodies) as specified in the manufacturer's instructions.

In this context, the lab-specific QCP worksheet can be created as follows. (Table 4) However, the quality control parameters are not limited to these. Each laboratory is free to set specific parameters according to the scope and conditions of service.

Table 3: Risk assessment worksheet

Risk assessment components	What could be a potential error? What can go wrong?	What could be the result of the potential error?	Potential causes	Risk assessment of the error				Specify how to reduce possible errors. - Internal controls - Operations by the laboratory - Assurances in the test system or laboratory applications
				RIL	ROF	D	AE	
Staff	Patient identification / labeling errors.	Pathology reports produced on behalf of different patients can lead to inadequate treatment, unnecessary limb / organ loss or even death of the patient.	Technician error, environment, defective rules, policies or procedures.	5	4	N/ Y	N	All employees are trained in the use of unique elements that define the patient. He is warned to check the label at least twice and his importance is emphasized. Control mechanisms are increased. Related policies and procedures are reviewed.
Environment	Gross inspection room ventilation failure	It directly affects employee safety.	Ventilation filter obstruction, technical failure.	5	3	Y/ N	N	Regular maintenance service and ambient chemical level are measured.
Staff Instruments Reagents Environment SOP	Slide quality defect (cross section, paint, assembly,)	The quality of the slides is the main factor for accurate diagnosis. In some cases, inadequate cutting, staining, or coating of slides may completely obscure the diagnosis.	Staff failure, environment, reagents, equipment failure, and finally defective procedures / instructions.	3	4	Y	N	Laboratory technicians are trained, root cause analysis is started, reagents, working environment and SOP are reviewed.
Staff	Interpretation errors: False negative results False positive results Reports that do not contain sufficient information in terms of disease management	Diagnosis and treatment can lead to consequences that cannot be repaired as a result of delay (especially in tumor). It results in moral and material losses. Unnecessary treatment can cause surgical intervention or loss of organs and limbs. It results in material and moral losses. It prevents the effective treatment and management of the disease. Inadequate treatment, prolonged treatment procedure can cause material and moral losses.	Inadequate experience and competence of the pathologist. Failure to apply diagnostic taxonomy. Technical defects in sample processing. Lack of evidence-based, supportive additional diagnostic tools.	5	3	Y	N	To increase pathology training and competence; In-house training programs, inclusion in national / international training programs and ensuring their participation in PT programs. Participation in LAK programs is ensured. A prospective / retrospective control is created. Laboratory internal quality control program (IQCP) is reviewed and revised if necessary. Evidence-based, supportive diagnostic tools are developed.

RIL: Risk impact level, ROF: Risk occurrence frequency, D: Detectability, AE: Acceptability of error, Y: Yes, N: No
Other possible sources of error that should be evaluated include (but are not limited to) the following.

. Tissue not fixed - Bad tissue processing - Automatic tissue processor malfunction - Reports that do not contain sufficient information in terms of inability to

Table 4: Individual Quality Control Plan (QCP) Worksheet.

	Parameter	Purpose	Method	Frequency of control	Admissibility criteria	Corrective / preventive actions
PRE ANALITIC PROCESS	Patient identification errors.	Ensuring patient safety (Right patient-right example).	In the sampling units, in the collection areas and in the laboratory acceptance unit, the sample management procedure is inspected according to the acceptance criteria of the samples. The nonconformity notification form is prepared, notified and the error identification information is recorded on the registration form.	Each case (twice if possible) is checked.	Laboratory sample management procedure and acceptance criteria must be met. Each request form should be traceable to the patient concerned.	When a patient identification error is detected, the clinician is informed by filling in the nonconformity notification form and contacting the unit requesting the test, and the case is rejected and returned for correct labelling. Error cookies are saved in the registration form. The case that has been corrected and approved by the clinic doctor is accepted.
ANALYTICAL PROCESS	Slide quality defect (cross section, paint and assembly error).	Improving diagnostic accuracy.	In the slide quality control, it is essential to use reference tissue (tissue samples previously selected from the tissues where the suitability of each stage of the tissue procedures have been confirmed). At least 10 (ten) slides selected from the slides to be stained that day accompanied by reference tissue / s at the beginning of the day [preferably belonging to different tissues (fat, bone, fibrous, bloody etc.)] are painted and assembled with HE method. The slides are first by the technician in charge in the process and then by the technician / technician responsible; Tissue integrity Section thickness and - It is checked with the naked eye and under a microscope for its staining characteristics (minor / excess / other non-suitable staining). After routine staining / assembly, all slides are reviewed with the naked eye for tissue integrity and mounting defect. During the microscopic examination of the slides, all the above features are taken into consideration. The nonconformities detected are recorded with the notification form.	Slide quality control processes are actively evaluated every day, at the start and duration of the process.	The staining characteristics of the reference tissues should be fit for purpose. Each slide should be prepared purposefully and should show staining characteristics.	When nonconformity is detected; First of all, together with the technician-technician responsible for the process, together with the physician responsible for the unit, it quickly searches the source of the error (root-cause analysis) and ensures that the necessary actions are taken to correct the error. Reagents, devices and working environment properties are reviewed. Employee defect is evaluated in the implementation of the application procedure. The necessary corrective action is quickly put into action and according to the reason identified as a preventive measure, technician training, device maintenance, changing reagents, etc. actions are planned.
	Interpretation errors: - Diagnostics mismatches - False negative results - False positive results - Results that do not contain sufficient information in terms of inability to classify or manage disease	Diagnostic accuracy and improved patient care.	Controls are made on the basis of secondary review of cases. These reviews include: (1) Examination of 10% of cytology cases, (2) Review of tumorous cases by a second pathologist before publication, (3) Retrospective review of 1-10% of the cases with a random selection, (4) Frozen result-histopathological diagnosis comparison, (5) Case study for multi-disciplinary conferences, (6) Monitoring of internal cases sent out for examination, (7) Cytology-histology correlation control, (8) Case study at the consensus conference, (9) Participation in inter laboratory comparison, (10) Participation in proficiency tests, The detected nonconformities and correction activities are recorded.	(1) Every day in cases scanned by technicians (2) All neoplasia cases are reviewed by a second pathologist before publication, (3) Every 3 months (4) In every frozen case (5) After every meeting (6) Once a month (7) Once a month (8) Once a month (9) Once a year (10) Once a year	Interpretation errors in diagnostic results should be consistent with studies published in national and international literature.	Root cause analysis is performed for detected incompatibilities. The subject is put on the agenda at the management review meeting and necessary preventive measures are provided.
	Quality control errors.	Improving diagnostic accuracy.	histochemical immune histochemical and immune fluorescent staining results added to morphological evaluation; Positive and negative controls of internal / external control tissues are primarily by technically responsible technician, -Quality control sample used, -Use the appropriate control sample, In the control sample, it is evaluated in terms of the presence / severity of the staining. Internal quality control is recorded with a daily follow-up schedule. When non-compliance is detected, the non-compliance is recorded on the registration / notification form. Quality control materials are selected from tissues whose suitability for the purpose has been validated in a laboratory environment.	Quality control of each histochemical, immune histochemical and immune fluorescently painted slide is performed.	The staining feature (positive / negative) in the quality control sample on the slide should be suitable for the purpose.	In case of inappropriate painting in the quality control sample; - All processes are repeated due to the possibility of incorrect application in the process steps in the staining procedure. -Standard painting procedure is compared with the recommendations of the manufacturer, the differences are eliminated and the process is repeated -The reagents expire dates are checked. - Temperature controls of the area where reagents are stored are controlled - If necessary, used reagents are changed and the process is repeated. Technician training is repeated - In the quality control material, the test result in which proper painting cannot be achieved is not taken into consideration.
POSTANALİTİK SÜREÇ	Delayed results.	Improving patient care by ensuring timely return of test results.	It is monitored through LIS. The target processing time is predefined at each stage of laboratory processes. In determining the target processing times, the times defined in international guides are targeted. From the moment the test request is created, the employee with the colour change in the case record is warned on the LIS within the time limit defined in each process. The reason for the delay of the case is recorded. At the end of each month, the LIS breakdown of cases that exceed the targeted processing times are taken and analysed. Non-compliance situations are recorded.	Each patient whose pathology test request is created and registered and approved by LIS is followed up. Transaction timeouts are analysed every month.	Total turnaround times: - Cytological cases: 3 (three) working days - In biopsy cases: 7 (seven) working days -Radical operations: 10 (ten) working days - In special cases (bone tissues, fatty tissues, cases with additional examination, etc.),	In cases where a transaction delay warning / notification was received; -The phenomenon is given priority. - The patient / clinician is informed about the delay in the conclusion of the test. -If necessary, the causes of delay are evaluated by laboratory management and preventive measures are taken for the cause.

					these periods are added to 2-4 days.	
	Transcription errors.	Ensuring complete and accurate reporting of results, improving patient care. Increasing trust in the laboratory.	Reported test results are checked in two stages. -It is checked by the pathologist who evaluated the case before its publication for the accuracy of the information in the report and for typographical errors. - After the reports are published, they are checked periodically (at least once a month) by random sampling, not less than 5% of the produced reports. The detected nonconformities and correction activities are recorded.	- Each result report produced in the laboratory is checked and approved before it is published. -Periodic check is done at least once a month. If necessary, the time is shortened.	- There should be no spelling mistakes that could affect patient care.	Before the result is published, after the detected errors are corrected by the responsible pathologist, approval is given for publishing the report. In nonconformity detected in periodic controls; - In spelling mistakes that do not affect patient care, a revision is made on the main report, the revised report is published again and the relevant patient / clinic doctor is informed. In case of non-compliance, which may affect patient care, the pathologist who prepared the final report is informed. Urgent necessary corrections are provided in the report and explanatory information is given to the patient / clinician about the change of report. The last revised report is published. Old reports are withdrawn / activated and stored. The subject is discussed in laboratory review meetings, preventive measures (workload reduction, software support etc.) are taken for the cause of errors.

Examples of other parameters (including but not limited to) to be included in the quality control plan:
. Ventilation defect / chemical gas analysis in working environment
. Personnel competence
. Storage of reagents
. Device calibration
. Insufficient clinical information
. Missing sample / no sample in container
. Undetected / unprotected tissues
. Sampling errors: Insufficient samples that do not allow / limit analysis
. Bad tissue tracking
. Mislabeling of slides
. Faults / deficiencies in macroscopic examination
. Results that do not contain sufficient information in terms of inability to classify or manage disease
. Lost result reports / slide / block.
. Synoptic reporting errors

A QCP is not complete without regular quality reviews. Laboratories must verify that the QCP that is commissioned is working to check for errors. If an error or failure occurs, the lab must take appropriate corrective measures, investigate the cause, and assess whether changes to the QCP should be made.

The quality assessment plan should include a review of the effectiveness of the corrective actions taken to resolve the detected issues (Table 5). When the lab detects an error in the test process, it should conduct a study to determine the cause of the error and its impact on patient care. Research should include corrective actions for all patient outcomes affected by test process failure and should also certify the effectiveness of corrective activities. The laboratory should implement the necessary fixes and related corrective actions to resolve the error and reduce the risk of future recurrence. If necessary, the laboratory should update the risk assessment with new information and change the QCP as needed.

From a quality assurance perspective, the development of comparable evidence-based measurements should be based. All these assessments must be documented as part of the QA program.

Table 5: Quality assessment worksheet

Laboratory Name: PATHOLOGY LABORATORY
Test System Name: HISTOPATOLOGY & CYTOLOGY

QA Activity	Targeted process	Tracking frequency / period	QM Rating scale (Established policy / procedure)	Corrective action
Timeliness in pathology (Follow-up times)	Analytical	Six months	Total turnover time for surgical biopsies; -1, 2, .. 10% of those who complete the day Total turnover time for cytology cases; - 1, 2, .. 7% of the completed on the 7th day For biopsy types; Small biopsies (1-7 days) -GI endoscopic b. (1-7 days) Cancer resections (3-10 days) Other biopsies (3-10 days) -Non gyn. cytology -FNA (3-7 days) Non-gyn. cytology –exfoliative (3-7 days) % Of those completed in gyn. cytology (3-7 days).	In case of non-compliance, the causes are determined according to the root cause analysis. The issue is discussed in the top management agenda and an arrangement is made for the reason.
Monitoring the results of Laboratory EQC / LAC (External quality assessments)	Analytical	Once a year	The list of external quality assessment plans prepared should be implemented.	In case of nonconformity, the reasons are determined according to the root cause analysis. The issue is discussed in the top management agenda and a regulation is made for the cause.
Insufficient sampling (CLIA-88)	Pre-analytic	Three months	Total number of non-conformities (expressed as% of total cases), Target: 0.5-2.0% (Canada)	In case of nonconformity, the reasons are determined according to the root cause analysis. The issue is discussed with the relevant units and, if necessary, discussed in the top management agenda and a regulation is made for the cause.
10% prospective screening of negative PAP tests. (CLIA A-88)	Analytical	Three months	False negative test count rate: Number of positive results detected in secondary screening x 100 Sufficient number of secondary tests scanned Target: 2.1% (STEC / INCA)	//
Numbers of GYN diagnostic categories	Post analytics	Once a year	Number of ASC-US and ASVC-H reported during the year x 100.	//

containing the ASCUS / SIL ratio. (CAP)			Total number of LSIL and HSIL tests. Target: 0.4-5.1 (CAP)	
Standardized user satisfaction survey evaluation.	Post analytics	Once a year	Number of satisfaction notices in the survey (expressed as a percentage of the total number of respondents).	In case of nonconformity, the reasons are determined according to the root cause analysis. The issue is discussed in the top management agenda and a regulation is made for the cause.
Competence / proficiency tests (PT) (CLIA, CAP).	Analytical	Once a year	The results of the competence / competence assessment body are taken as basis.	In case of nonconformity, the reasons are determined according to the root cause analysis. The issue is discussed in the top management agenda and a regulation is made for the cause.

Laboratory director:
Signature: Date:

DISCUSSION:

Demonstrating that laboratories are competently operating and producing valid results provides confidence in their work both nationally and worldwide.

Pathology laboratories are a vital part of patient safety. Each laboratory staff member should be aware of their role in identifying, managing, and reducing adverse events that may affect patients. Patient safety in pathology is not only about standards, corrective and preventive action, and event reporting, but these are valuable and important. It is also often about asking why things are reasonably good and what we can learn from them. While rules and regulations are required for an experimental study to work as planned, control of no violations or non-compliance and monitoring performance variability are vital to system security.

There are also important publications on pathology that draw attention to the need to focus more on the quality of diagnosis. In 2000, the American Medical Institute's report "To Err is Human" estimated that at least 44,000, and perhaps as many as 98,000, Americans die in hospitals each year due to medical errors. The report points out that the problem is not bad people in the health service, but working in bad systems where good people need to be made safer. [38] Since then, international regulatory agencies have focused strongly on patient safety.

A 2016 article by Johns Hopkins, after analyzing the scientific literature on medical errors, states that medical errors can result in 250,000 deaths per year, with medical errors being the third most common cause of death in the United States. [39]

The CAP Laboratory Quality Center reviewed more than 100 published studies on diagnostic inconsistency in an 18-month meta-study on interpretive diagnostic error reduction in SP and cytology. For SP, the median discrepancy was 18.3%, and the major discrepancy rate was 6.3%, in cytology the median inconsistency was 24.8%, and the major discrepancy rate was 4.3%. [40] In this study, it was emphasized that new-generation quality tools should be applied if a significant improvement is desired in reducing diagnostic inconsistencies.

The report, 'Improving Diagnosis in Health Services', published in 2015, stated that improving the diagnostic process is not only a goal but also a necessity for moral, professional and public health.[41]

The difference between pathological procedures from other clinical procedures is that each process contains multiple experimental activities and the results of the examination are qualitative or semi-quantitative. However, it is important to show that the results of these examinations are also accurate before they are reported. In many of these tests, QC is not as easy as it is in quantitative tests. Therefore, in addition to traditional QC methods, other processes within the quality system must be carried out carefully. [42]

The scope of a QCP is considered an all-inclusive approach to ensure the quality of the entire testing process. To ensure that QC procedures are equivalent to CLIA regulations and are appropriate for your laboratory, the test system, test environment, and test staff foresee the establishment and documentation of a suitable QC. [21-22]

Although the CDC-published QCP preparation guide has indicated its applicability to clinical laboratories, we consider the applicability of this guide to pathology and cytology laboratories. For this reason, this guideline document was taken as the basis of our study. It was aimed to develop a worksheet that can be modified as required, is sustainable, evaluates your current quality activities, and serves as your QCP document when completed. This study is an exemplary format that can be used to approach or document the outlined information. Each laboratory can develop a format that meets its needs.

As a result; The taboo around a diagnostic error in pathology must be broken. It is not possible to discuss the quality checks of laboratories without accepting

the possibility of errors. Investing in continuous medical training, and patient safety, as well as training new pathologists and laboratory workers with a critical perspective on reducing errors, is a mandatory way to improve pathology practice. Working with accreditation agencies in which internationally accepted business rules are defined contributes significantly to the targeted path.

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