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Recommendations For The Application And Followup Of Quality Controls In Medical Laboratories

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Abstract

Important technological advances in data processing and result distribution center users' attention on the benefits gained from laboratory results. Many trends converge to implement and automate laboratory systems contributing to positive results. However, for this scenario to be realistic in the clinical scope and guarantee good results reliability, effective quality management in laboratory activity is necessary. One of the basic procedures to guarantee that results obtained in medical laboratories are of sound quality refers to the implementation and regular application of a set of quality control tests. This procedure makes it possible to monitor the quality of the results and the laboratory performance through the use of commercial control materials produced under strict parameters and normative requirements, demonstrating a characteristic behavior in a determined situation. The systematic application of these tests furnishes support to health professionals' confidence in the results provided, guaranteeing the quality of the results. There are multiple factors affecting the clinical-technical role within the attained quality limits. Thus, besides participating in external quality control programs, auditing the whole process should be given prime importance. Data generated by the application of control materials are an outstanding source of information about the performance of the methods at the laboratory level.

Keywords: medical laboratory, quality management.

1. Introduction

Important technological advances in data processing and result distribution center users' attention on the benefits gained from laboratory results. Many trends converge to implement and automate laboratory systems contributing to positive results. However, for this scenario to be realistic in the clinical scope and guarantee good results reliability, effective quality management in laboratory activity is necessary. One of the basic procedures to guarantee that results obtained in medical laboratories are of sound quality refers to the implementation and regular application of a set of quality control tests. This procedure makes it possible to monitor the quality of the results and the laboratory performance through the use of commercial control materials produced under strict parameters and normative requirements, demonstrating a characteristic behavior in a determined situation. The systematic application of these tests furnishes support to health professionals' confidence in the results provided, guaranteeing the quality of the results. There are multiple factors affecting the clinical-technical role within the attained quality limits. Thus, besides participating in external quality control programs, auditing the whole process should be given prime importance. Data generated by the application of control materials are an outstanding source of information about the performance of the methods at the laboratory level.

Methods

Standardized channels are essential in medical laboratories to ensure quality results. Recommendations for their implementation and follow-up are proposed based on International Standard 15189. These

recommendations include addressing technical requirements, controlling documents and using standardized methodologies, managing non-conformities, and applying corrective measures. Personal competence and facility control are also important. Personnel must pass theoretical or practical tests to demonstrate their knowledge. Accreditation by internationally ratified organizations is necessary for certain tests.

Conclusion

In conclusion, the fulfillment of quality control facilities in medical laboratories is an unfailing necessity. Apart from the substantiation of the precision and exactitude of results, adherence to the quality of control test performance could possibly be the cause of faults and the need for full system realignment or even substitution of reagents or equipment, thus preventing the creation of unnecessary costs for any laboratory. The establishment of a meticulous control plan, particularly for clinical laboratories coping with a heavy workflow, that constantly deals with practical issues and evaluates the entire performance capacity of the analytical systems is an unavoidable condition. The uniform integration of such through permanent insight from all levels of staff is essential to provide managers with a worthy tool for management and decision-making. Apart from the apparent quality improvements, a cooperative quality control planned effort could provide adequate information about the applicability of any system for a given matrix of clinical importance concerning system preciseness and trueness, as well as any interfering factors' potential existence that restricts determination accuracy. However, the reality of most medical laboratories faces limitations related to the conditions existing for compromised research, leading to inadequate procedures being more often found. The major drawbacks of quality control testing in medical laboratories could be primarily affected by both technical-commercial and designer-related equipment issues. Other situations, such as the calibration process, procedures, patient sample matrix, and required reagent property constraints, may also frequently evolve and necessitate the establishment of specification boundaries with practical real-life conditions that should bear the force of obligation and must be integrated into the quality control programs for laboratory performance evaluation.

2. Importance of Quality Controls in Medical Laboratories

The correct medical decision is based on the quality of the examination that led to it, i.e., the choice of the laboratory test to be performed, the application of the sample collection and preparation techniques established for this examination, the practice of the best detection methods, the error-free execution of the laboratory test, and the result validation interpretation to the clinical framework of the individual. The importance of minimizing the number of errors inherent to the laboratory test begins with an understanding of its influence on various factors related to the healthcare system, the patient, and public health. Its potential for providing the correct result for the tested parameter is denominated accuracy. In the laboratory test, the term application accuracy refers to the choice of appropriate patient preparation methods, sample type, storage and preservation conditions, and test and result validation, while performance accuracy reflects the precision of error-free tests and test results.

The performance quality control programs, beyond the legislation, involved the establishment of performance quality indicators, which have the characteristic of being easily measured, quantifiable, and reproducible in routine work. Among the various performance quality indicators, we included the control of technical procedures by the establishment of basic accuracy and precision components, known as control tests, relating to the needs of using a laboratory test. These allow monitoring the application of all technical requirements for laboratory examination, such as the practice of accurate patient preparation methods for patient examination, sample type choice, storage and preservation conditions; sample collection methods; acceptable sample preparation, sample transport, and processing conditions; errorfree test practice; and the right previously defined batch methodology. Even so, our experience has shown that the use of clinical laboratory test support models by technicians, operators, and other healthcare professionals during test performance, both in medical practice and in pre- and post-analytical phases, could compromise the reliability of the basic quality control process outcome and the quality of obtained test results.

3. Regulatory Framework for Quality Control in Medical Laboratories

Quality control is the reliability and accuracy achieved on a regular basis when carrying out the analyses laboratories are accredited to perform for their services. Quality control is an essential activity in any laboratory providing diagnostic services. Therefore, quality control is a fundamental criterion for ensuring that laboratories adhere to standardized operational protocols, and the results issued are reliable. The use of quality control measures assists in checking the accuracy and reliability of a medical laboratory's results. The level of compliance with regulatory requirements demands quality controls as part of these operations. Additionally, the reporting of laboratory results is critically important to the decision-making process during diagnosis.

In the regulatory framework for quality control in medical laboratories, several governing bodies provide the medical laboratory practice regulations, education, and closure policies. National and international regulatory bodies promulgate various laws and regulations that dictate the operational standards. The basis of these regulations is the international medical laboratory operational standards suggested by the International Organization for Standardization. The regulatory criteria for medical laboratories include licensing, technical certifications, exploratory audits, follow-up audits, and complaints examination systems for continued laboratory support and efficacy.

4. Types of Quality Controls

In response to internal or external quality control, the laboratory channel, depending on the particular differences in its protocol, of course, without negative consequences on the results of patients and research staff. The initial vocation of quality control in laboratories was the evaluation of analytical performance to indirectly evaluate the ability of the laboratory test correctly. Since then, other types of quality controls have been developed in the laboratories. It is important to distinguish the three types of quality and their specific actions. They are: Internal Quality Control - Ensures that the system of control, in particular through the measurement of raw quality, uses the principle of continuous improvement. It allows the implementation and maintenance of a continuous improvement quality control system. The definitive decision point is to validate the analytical method used by the laboratory. Its results should be compared to the types of other quality control. The data and their specific selection are an integral part of the quality of the laboratory. External Quality Control - These are performed through a neutral organization's own criteria. This provides the laboratory a unique opportunity to measure its implementation quality and to compare it with those of other laboratories both locally and internationally. Its results should be compared to the types of other quality control. The data and their specific selection are an integral part of the quality of the laboratory.

5. Pre-Analytical Quality Controls

Within the pre-analytical phase, the variables under full control of the laboratory are small. To monitor the performance of these few things, a laboratory may use relatively simple data: the volume of specimens, the type of specimen, and the frequency of repeated blood collection. By keeping track of these parameters, the laboratory begins to understand the dimension and volume of different parts of the pre-analytical workflow that affect the analytical phase. The laboratory can identify spaces for improvement and allocate resources to prevent errors of a pre-analytical nature. The pre-analytical phase is as important as the analytical phase of in vitro diagnostics in a medical laboratory. Errors in the pre-analytical phase account for a significant percentage of the errors in the analytical phase. Only a portion of laboratories have the resources to establish and follow up on the pre-analytical variables to a sufficient extent today. This situation is possible despite the fact that the information about pre-analytical errors is easy to collect and use. The modest abilities developed to prevent errors in the pre-analytical phase result, among other things, from the limitations of the informatic systems that support laboratory tests. These systems have developed with the primary aim of optimizing the elaboration of the tests and do not leave ample space for the monitoring of other pre-analytical variables. The pre-analytical quality control is sometimes considered information that only suits organizations that have computerized health systems to monitor the pre-analytical phase. (Rodziewicz et al.2022)(Kang et al.2021)

6. Analytical Quality Controls

Analytical quality controls are employed to measure the precision and accuracy of an analytical method and to verify the presence of systematic errors and drifts in patient measurement sequences. The precision of the measurement is determined by the intra- and inter-assay coefficients of variation. The accuracy of the analytical method is estimated by its mean recovery or measured bias. Both of these characteristics are usually determined in linearity-check studies and are given in the datasheet provided by the manufacturer of the analytical system. They generally refer to the determination of a set of samples with a matrix equivalent to that in which the method will be used. Ensuring that the method uses the most appropriate quality controls in the clinical setting is always problematic.

Assuming that the inter- and intra-assay precision of the method is acceptable, a normalization check can be made. The usual procedure is to join as many of the maximum available normal level samples in replicates and perform assaying and verifying the acceptability of the precision and mean accuracy for each level. This normalization check is carried out after acceptance or installation of a new method with new lots of reagents, or when control values do not match the behavior of the system in the laboratory. This is essential to establish a normal range area where it is expected that 95% of the normal samples to be run will be concentrated. For this reason, the more levels of normal and pathological samples assayed, the more accurate the system is expected to be. For clinical laboratories, it is recommended to have at least 10 determinations per level performed on three different days. The persistence of the drift can be assessed by comparing the average of all three levels and/or the mean of the patient results. Only if the checks repeatably indicate values within the reference range should assays of the patient samples be started. Any readjustment of patient results retroactively should be communicated to the users.

7. Post-Analytical Quality Controls

7. Post-analytical Quality Controls. Post-analytical errors are a significant cause of the main adverse effects in patients. It is a waste of time and financial resources and produces stress and discomfort for the patient. Post-analytical quality control strategies include tools for improving patient and sample identification, monitoring test utilization, and providing clinical decision support using information technology. Before losing any sample in the analysis, we should check the identification data with the contact information in the laboratory to clarify mistakes. By implementing good procedures with staff education, clear rules, and effective technology applications, we can verify the data in the first three steps of the testing before beginning the sample analysis. It is recommended to perform all specific tests and analyses on a second laboratory sample before the patient leaves the collection office to detect and preserve quality information (gender, identification number, age, health insurance, pre-analytical conditions, comments, hours, technician names, collection room, conditions, sample transportation, arrival time, and accommodation errors).

8. Internal Quality Controls

Internal Quality Controls (IQC) are a part of the set of measures that are applied to ensure one lab's work and are essential for the laboratory quality management system. IQC rules must be previously defined and publicized, mainly through Standard Operating Procedures (SOPs), to guide the personnel that conducts tests daily. Neither too tight limits nor very wide ones may be used. Limits hardly reflect the laboratory's reality of results generated through a greater number of samples and a longer time interval, so it is recommended they be adjusted based on internal laboratory studies. The internal laboratory evaluation of these services should consider the quality goals that laboratories want to reach, evaluating how the most significant factors may individually or together affect these results.

Traceability, uncertainty of measurement, and the uncertainty of calibration must also be considered and controlled. When they are used in all recommendations for the application of quality controls in medical laboratories, they are technically able to generate reliable results. With this security, professionals' and the client's confidence levels increase. They, in the same way as Standard Operating Procedures (SOPs), are a paper trail that may prevent legal problems stemming from the quality of our laboratory results, as long as measures are taken to avoid the occurrence of undesirable events. With all of this working properly, requirements of many international standards may easily be met. Therefore,

more and more laboratories invest in cost-cutting among all technicians, both in terms of the period during which the analytical system is operating and in the provision of human support, mainly because such analyses are realizable.

9. External Quality Controls

This control is focused on the laboratory in a global manner. The clinical laboratory participates in national and international quality control programs with the objective of obtaining periodic control, while internal control allows for continuous control of the entire analytical process. This allows us to know the quality of the performance of the laboratory compared with that of other laboratories. These programs are carried out by specialized companies that can compare the results they receive for the same serum among different laboratories and with the reference quantification methods. They can reproduce the process of the routine laboratory, including those where certified methods are not being used. The distribution of the results is made in such an individual manner that the control values can only be known if the laboratory that has carried out the analysis has made an error. The laboratory compares its results with those of the entire group in which it is included, and it can carry out a periodic and individual study to detect the capacity to correctly classify the data and return a true result. (Babyar, 2020)(Nielsen et al.2021)

The programs are carried out in phases and include individualized reports with general information on each phase, data for evaluating the performance of the participating laboratories, and, in the case of a negative result, the correct value. The member laboratories classify their results and return them to the headquarters. Periodic evaluations are available and are expressed in a graphic manner by means of a pair of scatter diagrams in which some of the participants return the assessing error. The laboratory has not only to decide its speed but also to use the hired results properly. Unlike what occurs with the classic problems of control, the results obtained in external quality controls have to be considered as true, with an error associated with the individual parameters of the laboratory. A sample that cannot be analyzed correctly will have little or no diagnostic value. The same will occur if an excessive delay occurs in the laboratory's results in comparison with those at the control center. All clinical laboratories should participate in an external quality control program and should use the means at their disposal to be able to compare their results with the group to control the entire analytical process. The cost and loss of independence have to be accepted by the clinical laboratory.

10. Frequency and Timing of Quality Controls

There are some ways to determine the occurrence of quality control on the analyzed parameter of a clinical laboratory, and the decision depends on the specific features of the analyzed parameter or technique or after a risk analysis. There are some organizations and associations that set recommendations about the frequency of quality control, which range between 1 to 8 levels of control per day of work for parameters like glucose, creatinine, potassium, urea, amylase, ALT, gamma GT, inorganic phosphorus, iron, calcium, triglycerides, sodium, total protein, cholesterol, albumin, bilirubin, LDH, aldolase, transaminases, and glycated hemoglobin. The frequency of quality control should be established based on basic statistical principles, biological considerations, analysis of the risk, uncertainty, cost, technical and productive implications, and the number of patient results that are generated, as well as the hazards involved. A major factor that influences the functionality of the quality control system in a medical laboratory is the number of replicates for each control level, the number of runs of controls per day, and its frequency and timing in the working day. These recommendations do not take into account the resolution and uncertainties of the measurement method.

11. Documentation and Record-Keeping

There should be a detailed intendance and record-keeping of the internal and external EQA schemes and any deviations and follow-up actions taken. The laboratory should have procedures to maintain records, including the original records of observations, as well as verification of observations recorded during operation, maintenance, and monitoring activities. Records should be kept legible, identifiable, and traceable to calibration or instrument status. These procedures should be written in a laboratory manual or at least made available to the personnel involved in their daily activities. The laboratory must ensure that current procedures are accessible to all personnel in the laboratory.

Laboratory records must accurately reflect the details of each test performed and be kept for a sufficient time to allow determination of whether the results of the tests were consistent with the required quality control. The laboratory is responsible for maintaining documentation. Each laboratory should have a system to archive documents based on their importance, use, and the time required for conservation, destruction, or storage. Guidelines on the archiving of documents are important for traceability and are presented in specific regulations. The laboratory must ensure that the disposal process is clearly defined, identified, and controlled. The destruction of related records may be authorized or required depending on institutional requirements, professional scientific integrity, and confidentiality.

12. Responsibilities of Laboratory Staff

Laboratory managers should oversee quality management system implementation and work/employee harmony within the laboratory. Implementation of a quality management system is a practically long-lasting process. At the start-up stage, managers and staff may experience several problems and even resistance; however, after a certain period, all personnel and managers inside the laboratory will realize the reasons, needs, targets, advantages, and other features of the quality management system altogether and clearly. A multidisciplinary team should be organized within the scope of developing, implementing, and providing continuous improvement of all laboratory activities required by the quality management system. Members of this team should be individuals who are at an appropriate level for initiating change. The laboratory should provide job training internally and externally. In order to implement a quality system and to obtain necessary data, the personnel should be trained according to their job functions; their performance should be evaluated. Laboratory personnel should be motivated with a sensitivity to quality and other information about the quality system. Laboratory personnel should know customer needs and monitoring standards, requirements of accreditation, the laboratory's mission, vision, and objectives. Laboratory personnel should be evaluated at specific intervals, and performance reports should be shared. Staff satisfaction and responsibilities should be evaluated and recorded regularly. The effectiveness of the training shall be evaluated through the laboratory training records.

13. Training and Education in Quality Control

Theoretical courses in quality control are usually included in the curricula of undergraduate courses in such areas as clinical biochemistry. It is highly desirable that human resources in medical laboratories should be properly informed about quality control, especially those involved with the different stages or levels of this process. Both undergraduate and postgraduate students should be made aware of possible operational problems, inherent pitfalls, and limitations of each device used for implementing or following the application of quality control, together with the potential errors arising from frequently used, properly established but unreliable rules and approaches developed for medical laboratory quality control. Also, there should be emphasis on the fact that, as in any other evaluation process, objectives require sound ethical considerations.

Exposure to operational or peripheral activities such as evaluation and validation of new procedures should be stimulated, including reading and reflection. It is difficult to create programs to transform theory into practice. This usually only occurs where training facilities exist, such as by cooperation with reference laboratories equipped with a state-of-the-art quality management structure. Participants should consider supporting these activities, also in order to extend cooperation and mutual growth, aiming at pre- and post-analytical procedures that are often left out of incipient training, with potentially serious consequences for the quality of the obtained information. Although these topics will not be discussed in detail, their relevance must be underscored.

14. Troubleshooting Quality Control Failures

Appendix Troubleshooting Quality Control Failures

QC Failure

Trend to increase values or concentration.

Check of calibrator values in order to avoid growth due to evaporation.

Change of values for DUT because of serum conversion.

Cutting the tip on the stopper to avoid turbidity or repeat a dilution of a sample by recollecting the glass of hemolyzed samples. Trough to decreases in values or concentration.

Increase values of a calibrator which absolute concentration is already critical. The low value may be considered as a new lower value.

If the high values of a calibrator cannot increase more than a reference point, additional samples with a lower value of DUT must be run.

Alarm due to a decrease in the barometric pressure of a sample storage unit, alerting to increased evaporation of the sample.

Instability of the machine.

Literal decrease indicating a failure in reconstitution of the packaging.

Change in a critical point or algorithm indicating an incident in the method.

Shift of the trend bar (day to day and cumulative) manifesting a change of the sample management system.

Suspicious increase in the number of tempered samples.

Consumable trouble.

Artifact due to crystals. Rotor cleaning can restore the situation.

Delocalized alarm and spurious values. This is caused by a failure of the sample needle with increasing gaps to the tip, coupled with a processing speed of analysis exceeding the recommendations.

Latent artifact after the dialysis kit change inducing large carry-over problems.

Misalignment of elastomeric droppers in a spot sample at the exact moment of the action of the mechanical arm.

False alarm.

Dilution failure increased by the high content of IgM.

Dilutional integrity showing negative shifts of both points.

Falsely elevated signals induced by insufficient washing.

The dilutors did not work.

Sampling irregularities.

Positive drift secondary to a hemolyzed increase of the sample, which must be recollected.

Randomly increased positive values with no real evidence of scattering, which must be confirmed by a new sampling and recollection.

Trend of artefactual toxic levels secondary to contamination.

Falsely elevated analytical signals due to misidentified carryover substance.

Calibration incident.

Positive drift of high negative results that was formed since the corresponding purging.

Flattening of the adjustment curve showing a low concentration. The problem had already been detected by leakage at the previous purging.

Inaccurate values in one analytical sample box after recalibration of the analyzer from a critical calibration point.

Random signs of an out of date calibrator.

Data processing anomalies.

Smear-like increase in the values of each calibrator box with indications of a latent decision effect.

Positive shifts due to internal instrument pressure losses. The MEMAs, which are in the yellow range, are the first ones to be affected.

Clusters of positive shifts for the measurement of specific proteins indicating loading incidents on the corresponding membrane.

Context of the reagent service refusal to properly perform the values.

Mixer incident. Random diluted and non-diluted plasmas were run, obtaining very similar signals. However, only the plasma with a double measured concentration possessed a reliable value.

The unusual sample. A sample with a jammed pipette was taken over the plate, and it was necessary to add a sufficient volume in a vial for a proper sample reprocessing as a new analytical CPU.

15. Utilization of Quality Control Data

The basic aim of quality control data is data quality to maintain the quality of both measurement processes and clinical laboratory tests. The ability to produce accurate, reliable, and cost-effective data by the measurement process can only be guaranteed by its regular management. Control charts are the most crucial instruments that help to detect errors related to the measurement process and to interpret their sources. The wide application of the C.V. and biases to the laboratory tests as a practical tool has resulted in minimum numbers of analytical significant differences related to the risk level between the measurement processes. It fails to sufficiently and separately ascertain the variation caused by both the control materials and the requirements of clinical tests, determining the minimal acceptance of the quality controls.

The frequency of program scores and the minimal acceptance limits showing a significant increase or decrease are in the classification of the C.V. and biases are the same, which is contradictory to the fundamentally opposite meanings of the negative and positive shifts. These relationships can be formulated by determining unique acceptance limits for each quality level in control chart rules, which can be used to detect positive and negative shifts at a level corresponding to the medical diagnostic needs. The practical implications of using preferred control procedures that take these differences into account are presented as a developmental tool.

16. Continuous Quality Improvement

16.1. Introduction Analyzing control processes and results provides the basis for continuous quality improvement. This section discusses the basic principles that are important in the evaluation of control data and various techniques that can be used for statistical analysis of control data. The aim is to assist laboratories in setting up a CPV that suits the laboratory's own equipment and circumstances and provides optimal process control. Control results can only provide information about analytical variability if the control materials are used in accordance with the manufacturer's instructions for use. Additionally, control materials must have the desired characteristics and the kit must be stable. Control results alone are not sufficient to improve the quality of analytical processes. It is necessary to gain insight into the causes of variations and to know how the effectiveness of improvement interventions can be evaluated. Control processes must be equipped to signal perturbations or shifts in the analytical process and must be capable of separating common source variability from special causes. The use of a quality control chart will give a picture of common variability and enable the laboratory to determine whether a newly appearing error may be ascribed to the common source or whether it is the result of a special cause. The chart shows when a group of data points exceeds two expressive values in succession. Such a situation means that the process has to be interrupted. Disadvantages of these charts are that they signal late, making it difficult to subsequently determine when in time the reason for the rejection occurred. (Pustejovsky & Tipton, 2022)(Heumos et al.2023)(Paul & Barari, 2022)

17. Emerging Technologies in Quality Control

The rapid evolution of instrumentation in the clinical laboratory has led to a widening gap between the conventional approach to quality control systems and the data produced by some of these instruments. In addition, the new regulatory systems face resistance to change, and applications are generated at a greater pace than that of the updating of laws on quality assurance or standardization bodies. The transition of private and public healthcare systems, with the need for increasingly sophisticated equipment, points to the necessity of a quality monitoring system capable of evaluating the compatibility of results, in addition to ruling out the performance of the method. New technologies emerge so that materials that mimic the matrix and its chemistry, or microparticles that behave like patients, can be inserted into routine runs. These particles contain reagents and exhibit a wide range of interacting behaviors with the analyzers, such as when the sample material is brand new or deteriorated.

The report can be prepared for all pre-analytical, analytical, and post-analytical phases of the laboratory, and the inclusion in the run can be managed to stimulate the usual laboratory processes, for the registration of procedures, for education, and preparation for surveys of the competence of the management of the demand for laboratory tests of international quality assurance societies. It can provide qualitative and quantitative analysis of matrix material samples, as well as simulate the patient's movement within the laboratory. Since reagents are usually used by the same analyzer but manufactured by different manufacturers, the emergence of participation in different samples is necessary. Their selection is essential to make the participation of all those who work in the area technically feasible. The drawback of simulating interactions is limited to a few microorganisms and the simultaneity of biochemical agents. Therefore, they do not solve all the quality control issues that need to be addressed for the increasing demands of advanced analytical methods implemented in daily routine assistance. (Dugad et al.2022)(Plebani, 2024)(Gajjar et al.2024)

18. Global Harmonization of Quality Control Practices

Global harmonization of quality control procedures remains an attainable and desirable goal. The application of locally derived estimates is an expensive, resourcedemanding, and round-the-clock activity in medical laboratories. This time-honored approach places an inordinate burden on laboratory resources, particularly in times of staff shortages, budget restrictions, or competing activities. Master procedures can and should be used within the country to derive local estimates of precision, bias, and total analytical error. However, if Standard Reference Materials are not available, the global approach must be used.

The laboratory shall use quality control procedures that monitor the precision and accuracy of the tests that are performed. It is a well-acknowledged fact that the costs associated with the application of quality control techniques should not exceed the benefits. If we continue to utilize the traditional, empirical, unhygienic, and inefficient processes, there is a considerable potential for catastrophic influenza outbreaks. The current quality control procedures employed to monitor and evaluate the precision and accuracy of analytic data need to be seriously reviewed. It is time that we moved towards the global use of fewer local quality control materials and study a larger number of replicates. Only in this way can we provide additional restrictions on test performance. Failure to embrace these new tools and to relinquish the banal practices reduces laboratory medicine to a dark, dangerous, and despotic place.

19. Challenges and Solutions in Quality Control Implementation

In the struggle to improve patient care, laboratorians often face a variety of highestpriority problems: essentiality, the necessity to obtain the core vitamins and tests in extreme life-and-death situations; comprehensiveness, the pressure to provide analyses for thousands of potential diagnoses using a single sample; and urgency, the need to provide the information rapidly and accurately. The success of all laboratorians, including medical laboratories, in addressing these challenges and providing test values of unquestioned acceptability is dependent primarily upon the continuous maintenance of high quality at all levels of laboratorian error, from the physical to the interpretive. Laboratories with a well-developed quality assurance program find it easier to recruit and retain the most talented professionals and technicians.

An effective quality assurance program should be perceived as an integral part of the business process. As such, it should require the commitment and participation of individuals with a variety of skills and areas of expertise. Leadership should provide an atmosphere conducive to the active participation of all laboratorians. All laboratorians should formally evaluate their activities on a regular basis and continuously evaluate them informally. The program should set some directions for laboratorian education and in return should signal what education is most urgently needed.

20. Case Studies and Best Practices

Case studies of continuous optimization in any sector, however different it may be, from model simulation, agricultural production systems, and the flexibility budget, imply managing levels, optimal acquisition models, and variation in inventory.

Economic complexity reduces EQ to a more concrete and manageable concept of management decision-making, recognizing its nature, heritage, and functioning. Its application gives validity to its use in a process of continuous improvement of quality in health care. The gate model for a laboratory.

It is hard to choose which are the best practices; yet, the Brazilian experience, collaboratively with international specialists, within the reach of both the public and private sectors, transformed the health system into one of the most complex laboratories of management practices for health care in the world. Its laboratory is unique and reflects the socioeconomic characteristics of the Brazilian population, as well as various forms of their social behavior. One of the facets of its scientific work, anchored in public management, is the vast number of theses, dissertations, and articles on quality published in the last 15 years, without probably similar work in other countries. Public administration has always been a subject of the diligence of the administrators of the health care system, formed either in management courses or from the necessary assimilation of concepts and practices.

21. Conclusion and Future Directions

In conclusion, many of the difficulties that occur in laboratories can be ameliorated through appropriate application of laboratory quality concepts. For this reason, there exists a clear need to inculcate these concepts at all levels where they are applied, from regulatory agencies down to the smallest private laboratory, including those government agencies charged with establishing laboratory testing standards. It is for these reasons that the Latin American EQAS has established its regional quality tracts for external controls by employing certified materials for this purpose. The laboratory quality control evaluation and discussion can include the laboratory management if they so request, since the inclusion of quality controls in these schemes enables them to evaluate the laboratory performance, especially with respect to the other participants, who are important indicators of the reliability of the laboratory results.

In addition, the LATAM EQAS organizes regular workshops about all parts of laboratory quality, such as these recommendations for the use and follow-up of laboratory quality controls. The results have shown an improved understanding among laboratory directors of the benefits of applying these quality concepts and regulations in relation to patient care and laboratory results. However, laboratory management, the diagnostic industry, the medical community, and regulators all have a part to play in understanding how the practical benefits can accrue to the medical laboratory. There is a need for laboratory management to accept accountability for patient outcomes related to the quality of laboratory services.

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