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INNOVATIVE APPROACHES TO QUALITY MANAGEMENT IN CLINICAL LABORATORIES

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Abstract:

This abstract explores the latest innovative approaches and strategies employed in clinical laboratories to enhance quality management. It is based on Effective laboratory quality management, meticulous documentation, comprehensive training, and rigorous process control are pivotal in ensuring the accuracy, consistency, and reliability of experimental results. The core elements collectively underpin the foundation of a well-functioning laboratory, fostering trust in research outcomes and adherence to regulatory standards. Adherence to Good Clinical Laboratory Practices (GCLP) is paramount for scientific rigor. The integration of rigorous risk assessment processes, diligent error monitoring, and systematic internal audits is fundamental to maintaining the integrity of research, preventing errors, and enhancing the overall quality assurance framework within laboratories. By examining these innovative approaches, the review aims to provide valuable insights into the evolving landscape of quality management in clinical laboratories, ultimately contributing to better patient outcomes and healthcare system efficiency.

Key words: *Laboratory Quality Management, Good Laboratory Practices, Risk Assessment, Internal Audit*

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INTRODUCTION:

Clinical laboratories play a pivotal role in all disease control and prevention programs by providing punctual and precise information for patient management and health monitoring. Clinical laboratories specifically, provide accurate diagnosis of present, recent or past infections for proper case supervision.[1] Though laboratories form the backbone of health systems, providing health care workers with critical test findings for numerous lethal diseases.

Internal quality control, external quality assessment and recently external quality assurance of the analytical procedure are renowned and extensively utilized procedures in laboratory medicine.[2-4] Regarding the extra-analytical processes, the Clinical Laboratory Improvement Amendments (CLIA) have stated that quality management programs should include comprehensive assessment of each stage comprising the ‘‘total testing process’’.[5] Moreover, the Joint Commission on Accreditation of Healthcare Organizations (JACHO) has recommended that external comparisons with other laboratories should be performed to evaluate individual laboratory performance and to begin activity for improvement. This method is known as benchmarking.[6] Benchmarking systems controls performance of all the processes by evaluating the results formed with those of the leading laboratories.[7]

Clinical laboratories have well established the need to serve their customers with an updated, reliable information resource about their diagnostic testing services.[8-9] Traditionally, this was achieved by using printed materials that laboratories have faced a challenge to keep up-to-date owing to the ever changing nature of laboratory policies, test offerings, specimen requirements, and standard ranges. An online laboratory manual has been shown to be a useful means for storing and universally sharing the latest laboratory information and can assist as a user-centric platform for clinician inquiries to the laboratory.[10-12]

In order to meet international standards, the laboratory worked to adhere to the requirement of NIS ISO 9001:2000 and has actually transformed to the ISO 9001:2008 standard, making it the first diagnostic laboratory to be so certified in Nigeria. The major difference between the two standards is that the ISO 9001:2008 standard has a wider perspective and application of its requirements. Because ISO 15890 requirements are more related to diagnostic laboratories, the HVL has applied for the WHO accreditation scheme through the efforts of the President’s Emergency Plan for AIDS Relief (PEPFAR), which uses this standard.

Similarly, the laboratory found it essential to adopt a quality policy which drives its vision as well as to initiate a Top Management Committee, in line with the ISO requirement, which supports as the Management Advisory Committee to the laboratory.

LABORATORY QUALITY MANAGEMENT:

Laboratory Quality Management is crucial for ensuring accurate and reliable results in scientific research and healthcare settings. It encompasses a set of principles and practices aimed at maintaining high standards. This includes robust documentation of procedures, calibration of equipment, and regular proficiency testing.[13] Quality control measures, such as daily checks and validation protocols, are essential to identify and rectify errors promptly. Accreditation and compliance with international standards, like ISO 17025, are common in reputable labs. Continuous improvement through data analysis and staff training is integral to maintaining and enhancing quality. Overall, effective Laboratory Quality Management is fundamental for trustworthy scientific outcomes and patient care.

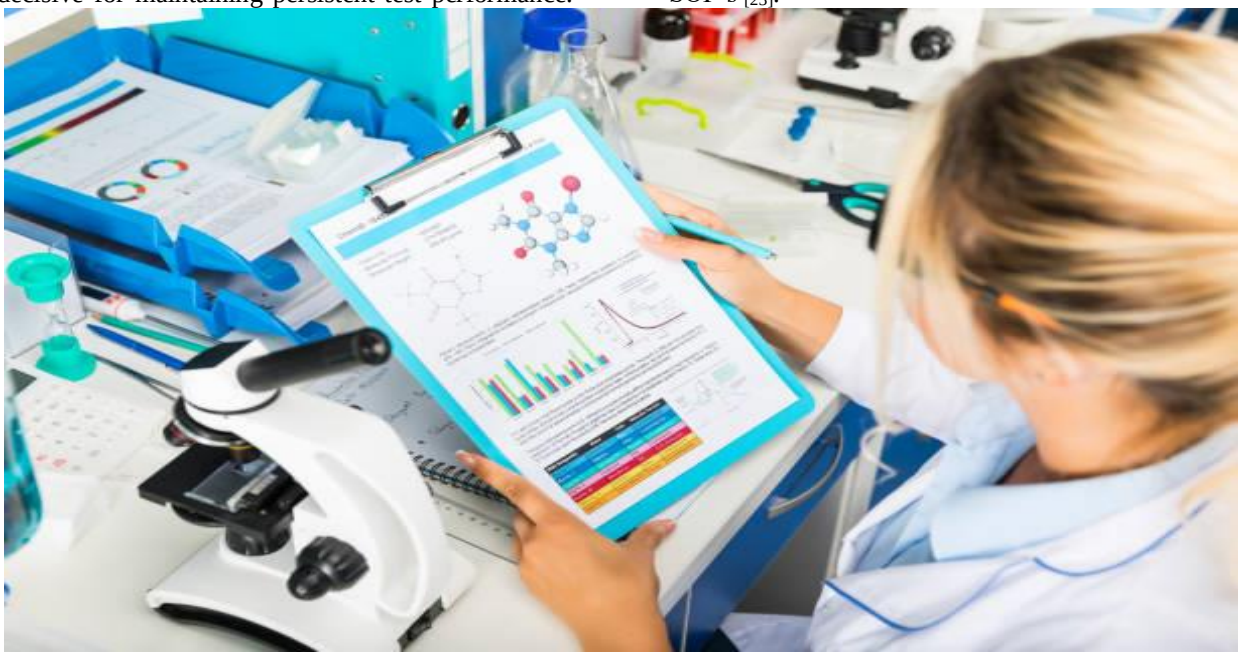
TQM places emphasis on integrating all organizational efforts towards quality enhancement, development, and maintenance to achieve complete customer satisfaction at all economic levels. It not only elevates the quality of work but also enhances employee satisfaction by encouraging participation and involvement, consequently improving the organization's image. TQM fosters a participative culture where every employee can directly engage in matters related to their work and decisions affecting their tasks. This is often facilitated through voluntary quality circles and quality improvement teams.[14]
Quality system management includes: Documentation, process control, training.

DOCUMETATION:

This includes standard operating procedures (SOP s), policies, procedures, forms and templates. They provide instructions for various chores starting at sample collection to reporting, encompassing safety protocols and guidelines for acquiring substances. It's important to assure that these documents are attainable to everyone while sustaining strict control. This ensures the entire laboratory sticks to a uniform and steady process. A testing laboratory must have the pursuing documents stored in the laboratory or readily accessible for authorized personnel: Organizational, departmental, and personnel policies which address such topics as orientation, training,

ongoing education mandates, performances, analysis, benefits, discipline, dress codes, holidays, security, communication, dismissal, and attendance[15-17]; employment outlines that define qualifications and assigning responsibilities for all laboratory positions[16-18]; personnel files that document each employee's accomplishing, training, and competency assessments as they correlate to job performance[19]; and the organizational chart that depict the structured reporting and communication relationships that exist among personnel and management and between the main laboratory unit and satellite units[20].

SOP: Standard operating procedures (SOP's) are decisive for maintaining persistent test performance. The laboratory must compose SOP's for all laboratory work to guarantee the consistency, quality, and rectitude of the generated data. Current SOP s must be readily available in the work areas and attainable to testing person [21]. The laboratory must write these SOP's in a demeanor and language that is suitable to the lab workers performing the protocols. SOP's should also be written in a standard format, such as the format recommended by the Clinical and Laboratory Standards Institute (CLSI) [22]. All research associates must document and preserve verification that they have scrutinized and understood all related SOP's so that there is evidence that all personnel are educated of appropriate laboratory SOP's [23].



Documentation process

PROCESS CONTROL:

Control of the laboratory's pre-processing, analysis, and post-processing work processes is very important to the quality of the laboratory test results. Such process control starts with recognizing and documenting the laboratory's many job tasks. A brief guide of laboratory processes with examples is available [24]. Use of properly constructed process flowcharts effectively identifies the activities for which procedures are needed for the laboratory staff to perform their assigned job tasks. Such process analysis accelerates the writing of individual procedure documents. Together, the process and procedure documents conveniently form the basis of the technical guides [25]. Before any process is executed in the live environment, the process needs to be confirmed as meeting its desired result. Verification consists of creating a plan that allows the technical personnel to challenge the process as initially developed, document the results, and determine if the pre defined standards set for the process have been met and whether the needs of the customers in the process have been fulfilled. In processes where laboratory testing is executed, test method authentication is also required. Also, the laboratory must verify that the manufacturer's stated requirements are being met with the laboratory's own processes, equipment, personnel, and materials. Several guidelines are available to support laboratories in such authentication of test methods [26-33]. Quality control programs are a means of regulating patient testing processes at the laboratory scale. Laboratories must meet the specified standards for quality control of test methods; both the minimum required quality control[34] and any manufacturer's criteria must be followed. The use of statistical

methods provides a visual means to understand quality control data so that swift reaction can be taken when procedural issues are detected.[35]

TRAINING EDUCATION AND ASSESSMENTS:

The laboratory director must designate staff that has principal accountability for the examiner and accommodate as the single point-of-contact for record management, employee development and acquaintance with GCLP. All laboratory personnel must receive specific task oriented training and ongoing professional development to perform all works assigned so that they understand and adequately perform the necessary functions [36-37]. Additionally, skills evaluation must be performed every six months during the first year of occupation, and annually thereafter. Annual evaluations for the employee's total performance of job responsibilities, duties, and tasks as specified in the job description must be given to all laboratory workers. The laboratory must employ a sufficient quantity of skilled professionals to perform all of the functions connected with the volume and of duties and testing performed within the laboratory [38-39].

Training program

All laboratory staff signatures, initials, or codes used as personnel markers on any laboratory documentation must be linked to a directory. This laboratory's recorded inventory should be a "controlled or traceable version" document that must be modified if changes happen in the laboratory. Signature logs should be recorded so that those individuals who carried out trial testing throughout the trial span are recognizable.

STANDARDS AND RESPONSIBILITIES:

The International Organization for Standardization (ISO) is a global body that sets standards, established in 1947, headquartered in Geneva, Switzerland, and operating in 164 countries. It promotes international standards for various industries. ISO15189 is now the global standard for quality management systems in laboratory medicine, accepted in many countries, including Europe. In the United States, CAP has introduced CAP15189 based on ISO15189.

According to ISO15189:2012 (and CAP and CLIA regulations), Section 4.1.1.4 mandates that a board-certified and qualified laboratory director must have ultimate responsibility for the laboratory's overall operation. This director must possess the necessary competence, authority, and resources to meet this international standard, with full accountability in case of any issues.

In contrast, responsibilities for medical devices follow ISO13485, which outlines requirements for medical device manufacturers' management systems. While ISO13485 certification doesn't satisfy FDA or foreign regulatory requirements, it aligns an organization's management system with the FDA's Quality System Regulation and other global regulations. ISO13485:2016, Section 5, requires upper management, often the CEO or COO, to be directly involved in setting quality policies, providing support, and overseeing the Quality Management System. ISO 13485 does not require a qualified medical professional to be involved with the devices. Consequently, it presents a distinct perspective on liability in medical device deployment, aligning with FDA regulations.

GOOD CLINICAL LABORATORY PRACTICES:

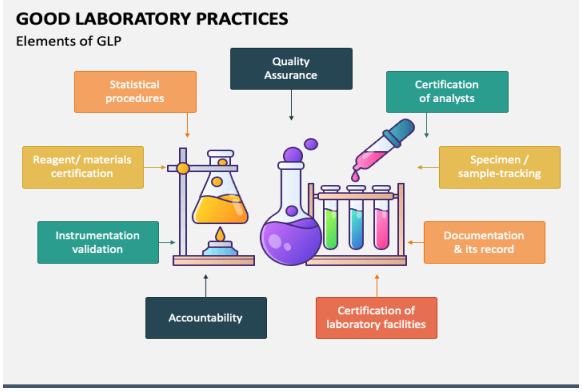
Good Clinical Laboratory Practice represents a set of principles that provide a framework within which laboratory studies are planned, performed, monitored, recorded, reported, and archive. The primary purpose of GCLP is to assure uniformity, consistency, and dependability of safety tests (nonclinical) for pharmaceuticals, agrochemicals, aroma and color food/feed additives, cosmetics, detergents, novel foods, nutritional supplements for farm animals, and other chemicals [40]. These safety tests are used to generate data on diverse parameters from physicochemical properties to toxicity (nonclinical) for use of regulatory authorities for the purpose of make risk assessments. Establishment of GCLP is compulsory to assess safety or toxicity of products planned to undergo clinical trials [41].

Compliance with GCLP demands that:

1. The tests should be performed by qualified personnel.
2. Each study should have a Study Director responsible for the overall execution of the tests.
3. The laboratory study and the accompanying with data should be audited by a Quality Assurance Unit.

4. All laboratory activities must be carried out in accordance with written and filed management approved Standard Operating Procedures (SOPs). SOPs must encompass policies, administration, equipment operation, technical operation, and analytical methods.

5. The equipment must be maintained, calibrated, and must be designed to fulfill analytical requirements.
Compliance with GCLP has aided to harmonize test methods across nations, facilitating generation of mutually acceptable data, thus avoiding duplication of tests, and conserving time and resources.



GOOD LABORATORY PRACTICES

RISK ASSESSMENT:

No laboratory test or process is without risk. Moreover, because the laboratory testing process involves abundant steps, the number of potential mistakes can be large. It is therefore important to evaluate and prioritize risks and as certain what level of risk is adequate in the clinical laboratory. Failure Mode and Effect Analysis (FMEA) is executed to identify weaknesses, evaluate the probability and seriousness of harm that could arise from errors in weak steps of the testing process, and depict controls to detect and prevent such errors. This is best done through process mapping [42]. Each stage of testing is investigated to identify possible failure points and control processes that can be enacted to detect and prevent errors. All constituents of the measuring system, initiating with the patient sample, reagents, environmental conditions that could impact the analyzer, the analyzer itself, and the testing personnel, are assessed in the examination of possible failures.

A prediction of the happening of these failures, whether habitual, occasional or remote, as well as the probability of harm arising from each failure is determined. The mixture of frequency and severity of harm permits the laboratory to estimate the vitality or risk of the error. Criticality allows the laboratory to manage high risk failure ways first and determine the clinical acceptability of low risk events [43]. For example, a grossly hemolytic sample can lead to an elevated potassium level. If hemolytic is not recognized in the patient's medical record, the clinician could misjudge the elevated potassium leading to patient harm from improper treatment. Errors that involve incorrect or delayed patient results that impact medical decisions are generally considered more severe than errors that lead to no change or confirmatory follow up prior to patient treatment. The degree of harm is defined using a semi quantitative scale of serious levels, ranging from negligible harm causing disruption or temporary discomfort, to critical or catastrophic harm causing permanent disability or patients death.

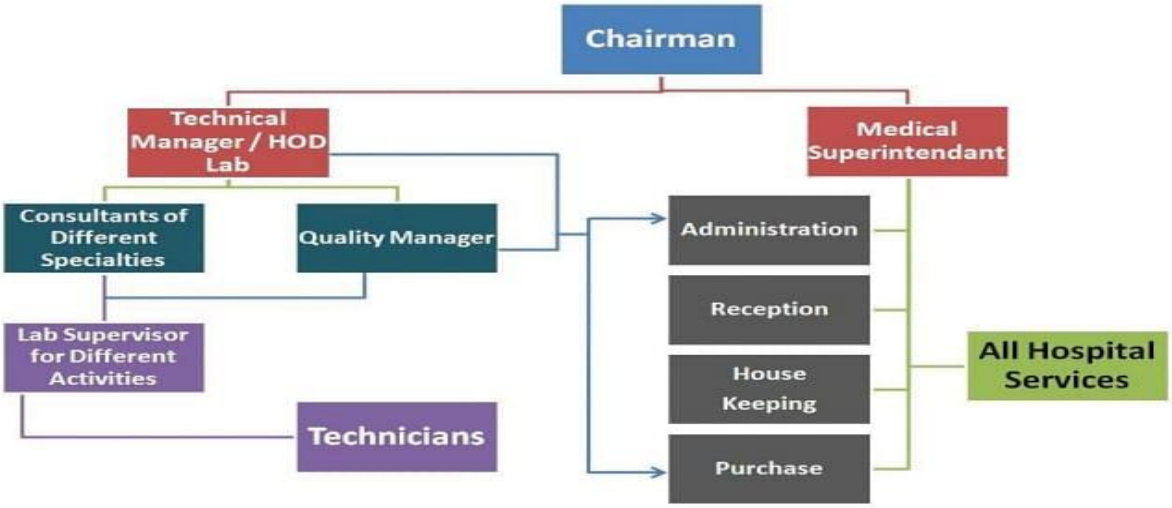
ERRORS:

Any failure in the processes founded into the laboratory can lead to consequences in patients, being a vital component in relation to patient safety [44]. That is why we have to monitor these defeats and execute enhancement strategies to reduce them [45]. Nowadays, it is seen an inclination to move from the culture of error identification to the risk mitigation in all quality systems of clinical laboratories [46]. In the literature, authors believe that the study of the impact of risks must be made in functional, tactics and support processes. There are studies showing these processes by designing indicators, such as related to the expertise of experts, customer service[47] or indicators associated with strategic aid processes or functional and support processes[48-49] or operational and support processes[50]. It must be overwhelmed, however, that most publications are focused on the daily procedures[51-54] or pre analytical and post analytical[55-56] or exclusively pre analytical[57-58].This series of quality indicators explained in those studies, as well as patient safety concerns, come to fulfill the requirement to adhere with the strategic lines that are being outlined in the health sector, related to the propagation of the safety-oriented culture and the execution of improvement plans to increase secure protocols in this environment.

INTERNAL AUDIT AND MANAGEMENT REVIEW:

Management Review Meetings (MRMs) are conducted by the Quality Manager (QM) in the presence of the Technical Manager, Chairman, and relevant Consultants from various specialties. Detailed minutes of these meetings must be documented.

Internal audits are to be carried out annually for each specialty, led by internal auditors from a different department. All non-compliances discovered during these audits, along with the corresponding corrective actions taken, should be documented. Additionally, the laboratory is required to maintain a photocopy of the auditor's certificate issued by a recognized agency conducting internal audit programs. A minimum of one internal audit report must be submitted.



Depicting example of an organizational chart

A quality system audit is a comprehensive evaluation process that assesses an organization's adherence to established quality standards and procedures. It involves:

1. Examination of documented quality policies and procedures.
2. Verification of compliance with industry-specific regulations.
3. Assessment of process efficiency and effectiveness.
4. Evaluation of quality control measures and their implementation.
5. Identification of non-conformities and areas for improvement.
6. Review of corrective and preventive action plans.
7. Assessment of employee training and competence.
8. Examination of equipment and resource adequacy.
9. Validation of product or service quality through sampling and testing.
10. Reporting findings and recommendations to ensure continuous improvement.

Every laboratory should have a thorough assessment of the operating and take corrective measures. The audit process could be internal audit, external audit or accreditation. The introduction of new test also should be audited to know if these new tests are really useful for the patient and also clinician. Every laboratory should have a critical review of the operating and obtain corrective measures. The audit process could be internal audit, external audit or accreditation.

CONCLUSION:

In conclusion, the complex network of laboratory quality management, documentation, rigorous training, and systematic processes, guided by standards like Good Clinical Laboratory Practices, forms the foundation of robust scientific methodology. Through meticulous risk assessment and vigilant internal audits, we not only protect against errors but also continually improve our methodology. This comprehensive approach ensures the highest level of data integrity, compliance with established standards, and facilitates the way for advancements in research, strengthening the cornerstone of scientific progress. As we advance, the relentless pursuit of excellence and an unwavering dedication to quality assurance continue to be of utmost importance in our collective quest for discovery.

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