

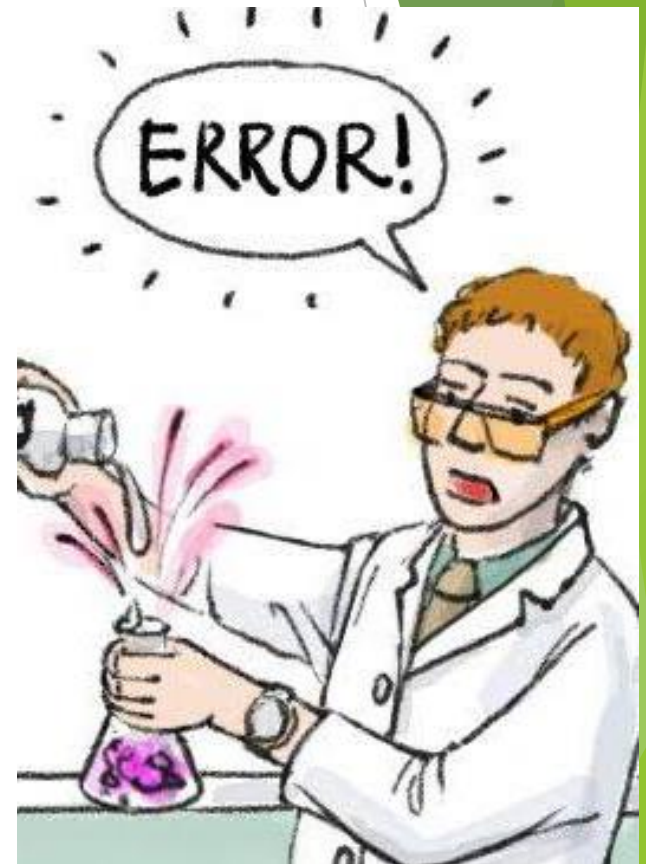
QUALITY ASSURANCE AND MANAGEMENT OF MEDICAL LABORATORY

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INTRODUCTION

- ▶ Medical Laboratory -Testing on specimens to aid in diagnosis, treatment, and prevention.
- ▶ Quality assurance - activities aimed at achieving that required standard.
- ▶ Aim - accuracy, reliability, and timeliness of test results.





AIM of the project

- ▶ AIM:- the main objective of my project is to study the importance of implementing a good quality management system in medical laboratory.
- ▶ A laboratory in simple terms is a unit where human blood fluids and tissues are examined to give out an appropriate and accurate diagnosis. all laboratories have one common goal which is to provide reliable , timely and accurate results. Now how is it ensured ? there are certain steps and procedures followed in a laboratory that make sure that the expected goal is met and hence these steps are cumulatively known as quality assurance.



Organization



Customer Focus



Facilities and Safety



Personnel



Purchasing and Inventory



Equipment



Process Management



Documents and Records



Information Management



Nonconforming Event
Management



Assessments



Continual Improvement

METHODOLOGY

- ▶ DATA SOURCES – Secondary data from websites, handbooks and research papers
- ▶ QMS01 MODEL - compliant with ISO requirements and has been established by CLSI1.
- ▶ The QMS -01 established by the clinical and laboratory standards institute (CLSI) because it uses 12 different quality systems to collectively form a result oriented quality management system with is compliant with the international organisation for standardisation (ISO).

AREA OF STUDY

Quality management system has 2 facets one is:-

- Quality assurance:- that is all the steps taken in a laboratory to make sure the desired or expected quality will be achieved
- Quality control :-which is a part of the quality assurance process pointing to the steps taken to actually fulfil the quality which is expected.
- For eg : quality control ensures that a test conducted on a sample will have accurate results.
- Whereas quality assurance Ensures the samples are collected from the right patient , delivered the right results to the right patient at the right time.



PATH OF WORKFLOW

The ISO divided the laboratory process into 3 phases:-

- Pre-analytical phase including :-

1. sample collection
2. sample identification
3. sample transport

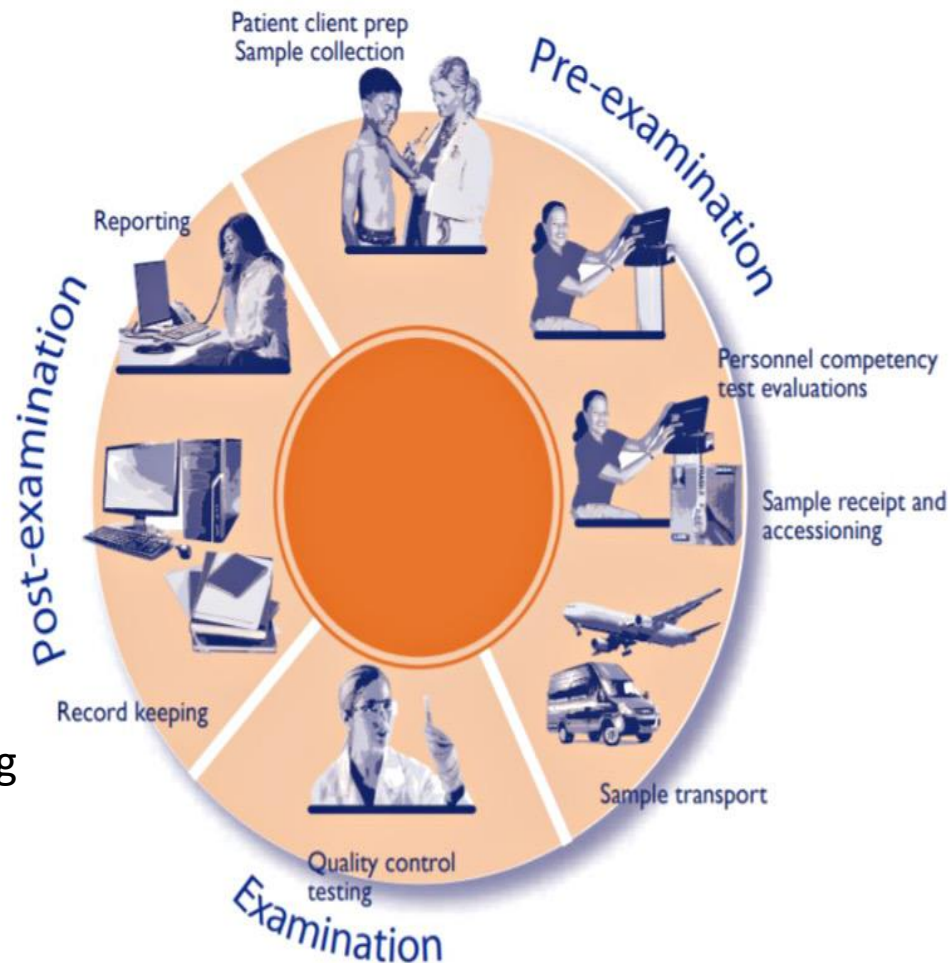
- Analytical phase :-

sample is evaluated and the tests are performed on the collected sample generating results.

- Post-analytical phase:-

The reports are prepared and the interpretations are drafted and the report is delivered to the patient.

These 3 phases are collectively known as path of workflow. Studying this path of workflow is important before implementing any quality management system.





► The model for the following 12 essentials is from the Clinical and Laboratory Standards Institute (CLSI) and [ISO 15189](#).

► 1. Organization

The laboratory needs to be organized around a formal quality management system that supports consistent procedures. The management team and quality unit play an integral role in a quality-driven culture, along with structures for monitoring ongoing quality.

► 2. Personnel

Capable staff members are the single most important asset to a laboratory. Training, motivation, and engagement are key parts of the quality management system.

► 3. Equipment

Every piece of equipment used in the laboratory must be maintained to operate safely.

► 4. Purchasing and Inventory

Properly managing the supply chain is critical to ensure that raw inputs and other supplies are consistently high-quality. Inventory activities should verify that materials and supplies are stored in a way that protects integrity.

► 6. Information Management

The laboratory produces many forms of information, including QC test results, maintenance reports, and other data. This data needs to be managed in a way that ensures all information is accurate, secure, confidential, and accessible to individuals with the right privileges, such as lab managers and leadership.

► 7. Documents and Records

Documents are a similar concept to information management, and there's a significant overlap between these categories. One of the most essential lab documents is standard operating procedures (SOPs) to create a standard for each process. Documents need to be available at the point of work, maintained, accurate, and secure.

► 8. Occurrence Management

An "occurrence" is any error or non-conformance. A **QMS software** can help you detect these issues and facilitate investigations to discover the root cause and prevent reoccurrence.

► 9. Assessment

Assessment involves comparing laboratory performance to internal standards for quality or external data sets, such as industry benchmarks. Assessments include the activities of lab or QC managers, internal auditors, or external inspectors.

► 10. Process Improvement

A quality management system should support continuous process improvement of laboratory processes. Components of the QMS which support improvement can include QC and CAPA (occurrence management).

► 11. Customer Service

Customer service is the goal of a laboratory. A laboratory's QMS should support operations that consistently provide a positive customer experience through the production of consistently high-quality products or other missions. The laboratory needs to understand the customers and their needs and use customer feedback for improvement.

► 12. Facilities and Safety

Laboratories need a comprehensive set of procedures and standards to ensure a safe, secure, and clean environment. This includes physically securing the lab, containment procedures for hazards, worker safety, and ergonomics.

FINDINGS

- ▶ Reduce and eliminate errors.

a suitably implemented quality management system reduces, almost eliminates the errors.

- ▶ Meeting customer expectations.

Once these errors are eliminated the reports generated are accurate and reliable leading to greater customer satisfaction

- ▶ Effective and efficient operations.

As soon as the errors persisting is eliminated there is a smooth smooth and efficient operations in the laboratory

- ▶ Achieve and maintain accreditation.

To achieve and maintain accreditation unwanted errors should be reduced.



RECOMMENDATIONS

- ▶ Research on levels of pre-analytical, analytical, and post analytical errors.

Study should be conducted on the percentage of pre and post analytic errors since most of the quality work is implemented during the analytical phase of the process.

- ▶ Six sigma for data entry errors.

Manual data entry is prone to human error and hence studies should be conducted to analyze the benefit a six sigma model would have on data entry error.

- ▶ Automation of pre-analytical phase.

A study to learn the impact of automation during the pre analytic phase leads to reduction of errors.



CONCLUSION

- ▶ Detecting and preventing errors.
- ▶ Patient protection and care.
- ▶ Accurate Clinical decision making.
- ▶ Appropriate treatment.

A good quality management system when appropriately implemented in a medical or clinical laboratory not only leads to prevention and elimination of errors but also ensures the patients are correctly diagnosed and receive appropriate treatment and care.

The results of effective internal control will improve the degree of health safety, satisfaction and protection and satisfaction of the patient.

Providing and ensuring quality in medical laboratory is not only important for the business but also equally for humanity because as a health care professional our motto should always be “patient first”.



E-HEALTH:-More than just a electronic record

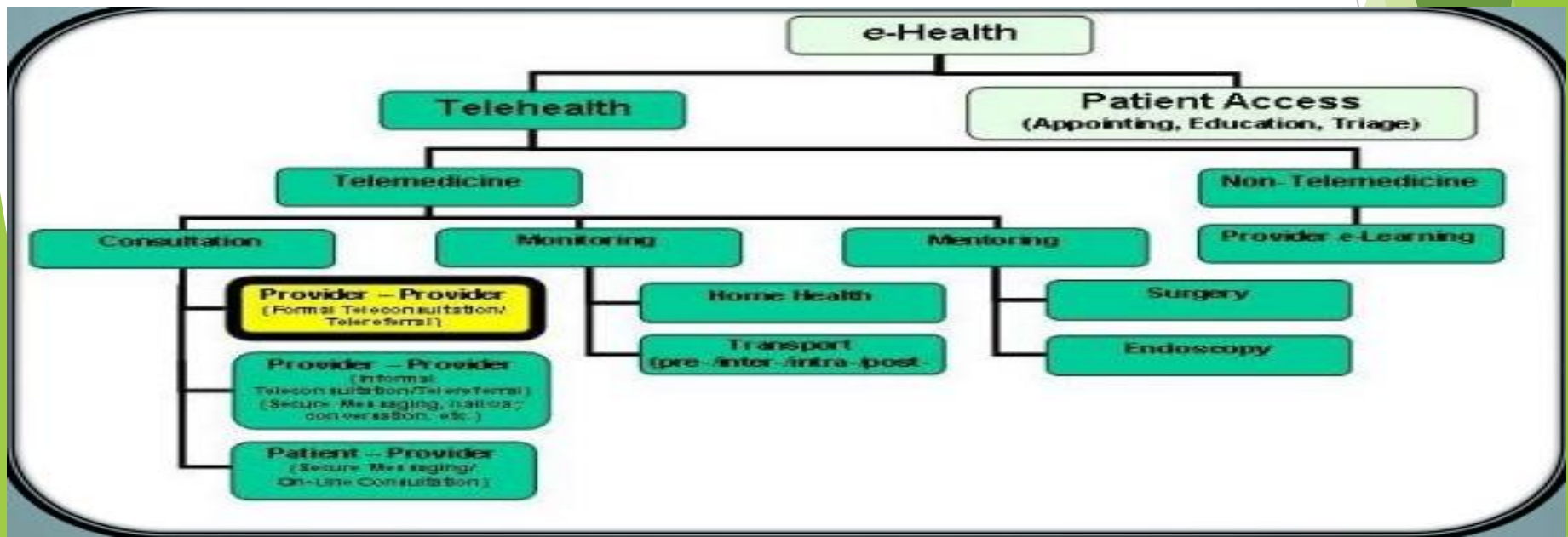
- ▶ What is E-health?
- ▶ It is a application based technology in the healthcare industry to improve :-
 - ❖ Accessibility
 - ❖ Efficiency
 - ❖ Effectiveness
 - ❖ Quality of treatment

Utilized by healthcare organizations, practioners, patients, and consumers to improve the health of patients.



A model of eHealth

- ▶ The model of eHealth is used to support and to conceptualize how eHealth impacts on practice, teaching, and research.
- ▶ Three domains in model include :-
 - ❖ Health in the hands of consumer
 - ❖ Telehealth
 - ❖ Data records in quantified self



An illustration of a hand holding a smartphone. The screen displays a heart icon with an ECG line, a dumbbell, a clipboard with a checklist, and a pill bottle. The background is a vibrant red and green geometric pattern.

Health in our hands

- ▶ Health in the hands of consumer includes the growing use of wearable devices, apps and social media to monitor and report the health and wellness.
- ▶ For eg :- Fitbit , Apple watch(app as well as wearable device to monitor the health)

m-Health

It includes the use of mobile devices in collecting aggregate and patient level data.

Telehealth

- ▶ There are many terms for technology to enhance communication in healthcare it includes :- telemedicine, telehealth , mobile health, teleconferencing and video conferencing
- ▶ The delivery and facilitation of health and health-related services including medical care, provider and patient education, health information services, and self care via telecommunications and digital communication technologies
- ▶ Telemedicine is impact of new technologies on how health professionals communicate with patient, traditionally it is referred to as telehealth it involves real time video conferencing or streaming btw patient and doctor.



Data quantified self

- ▶ Data records in quantified self this includes how data is stored in traditional medical records through devices and apps.
- ▶ Digitizing paper records is clearly beneficial as it enables a patients medical history to be tracked over time.
- ▶ To alert patients for routine follow up consultations , to monitor patients vital signs.
- ▶ To improve the quality of care the aggregate medical records can be used to provide regular downstream information on individual team or organization performance.



Advantages of e-Health

- ▶ Improves communication among healthcare stakeholders.
- ▶ Facilitate better decision support.
- ▶ Reduce medical errors.
- ▶ Enhance reporting capabilities .
- ▶ Encourage disease prevention and wellness.



e-Health challenges



- ▶ The main areas of e-Health challenges are :-
 - ❖ Information (inaccurate and incomplete)
 - ❖ Human resources (inadequate)
 - ❖ Infrastructure
 - ❖ Quality and security of data
 - ❖ Financial and legal issues
 - ❖ Authenticity

REFERENCE

- ▶ https://www.cartercenter.org/resources/pdfs/health/ephti/library/lecture_notes/med_lab_tech_students/ln_hlth_lab_mgmnt_final.pdf
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