INTERNATIONAL RESEARCHERS

AN EXPERT VIEW ON QUALITY CONTROL IN MEDICAL LABORATORY- A BRIEF STUDY

Dr. Md. Kamal Hussain, PhD

Volume No 1 Issue No.2 June 2012

www.iresearcher.org

ISSN 227-7471

THE INTERNATIONAL RESEARCH JOURNAL "INTERNATIONAL RESEACHERS"

www.iresearcher.org

INTERNATIONAL RESEARCHERS is peer-reviewed, supported by rigorous processes of criterion-referenced article ranking and qualitative commentary, ensuring that only intellectual work of the greatest substance and highest significance is published.

AN EXPERT VIEW ON QUALITY CONTROL IN MEDICAL LABORATORY- A BRIEF STUDY

Dr. Md. Kamal Hussain, PhD

Horizon Healthcare

(KINGDOM OF SAUDI ARABIA)

Emails: drkamalhussain@gmail.com

ABSTRACTS

The medical laboratory is a place where blood, body fluids and other biological Specimens are tested, analyzed, or evaluated. The observation may be macroscopic or microscopic. The tests may be performed manually or using specialized instruments. Precise measurements are made and the result are calculated and interpreted. Because of this, laboratory workers must have the skills necessary to perform variety of tasks. Laboratory testing is an integral part of modern medical practice, and laboratory medicine confronts the same challenges of quality, cost, and access as the larger health care system. Quality is paramount in a medical laboratory setting & Safety is a topic that should be foremost in the thoughts and actions of all health care providers, both employees and employers. The goal of medical laboratory health care workers should provide quality patient care in an environment that is safe for both workers and patients.

Keywords: Quality Management, Quality Control, Laboratory Quality Assurance, Medical Laboratory Quality

1. INTRODUCTION

Quality assurance in clinical laboratories is such an important issue because laboratory results are used to aid in diagnosing, prescribing treatment and monitoring the progress of patient. Laboratory result must be reliable and laboratory quality control procedures and result must be documented. Laboratory workers have the ethical and legal responsibility to ensure the work performed in the laboratory is of the highest quality. This can be guaranteed by adherence to a comprehensive quality assurance program. Medical laboratory services are essential in the diagnosis and assessment of the health of patients. Their services encompass arrangements for requisition, patient preparation, patient identification, collection of samples, transportation, storage, processing and examination of clinical samples, together with subsequent result validation, interpretation, reporting and advice. Medical laboratory services should therefore meet the needs of all patients, clinical personnel responsible for patient care and any other interested parties. The laboratory's aim is not only to provide accurate results, but to do on the right patient within a

meaningful timeframe as regards clinical management, using appropriate laboratory procedures and with a respect for ethics, confidentiality and the safety of the patient.

2. QUALITY MANAGMENET/ CONTROL IN MEDICAL LABORATORY

Quality management/ control are an essential part of every laboratory daily operations. It is often thought to be applicable only to testing procedures. A program of quality management or quality assurance should be in place to ensure quality throughout the total testing process, from ordering the test to entering the result on the patient chart. Processing the samples in the lab, the test procedures, and procedural control are parts of quality control. Quality Management is an enabler of quality and a core component of good clinical management; it is patient-focused, impartial, objective, and operates within a peer review model. It provides many benefits such as those detailed below. The need to drive up the quality of care for patients, whilst delivering efficiency and productivity, is a key principle for regulators of healthcare services. Quality Management & Accreditation can be used as a tool to support the commissioning or specification of medical laboratory services that are technically competent, safe and reliable, and that continually improve the experience for patients by: a). providing an independent assurance of quality and safety that supports world-class decisions on how to deliver better care and value for patients; b). providing a mechanism for measuring quality improvement; c).supporting consistency in the quality of care; and encouraging innovation.

3. QUALITY ASSURANCE ACTIVITIES IN MEDICAL LABORATORY

From the moment a test is ordered, attention to detail becomes an issue critical to the quality of lab results. The strict quality assurance programs and quality controls procedures that guide the work of the clinical laboratory, from the first handling of test specimen and paperwork to the reporting of results to your health care provider (Fig.1). To make it easier to see all the points where quality is monitored and the areas where the quality of inputs is important- we have divided the tasks into three main phases.

3.1. PRE-ANALYTICAL ACTIVITIES

What will happen when the test is ordered and the sample is collected. This question will be arise, where quality originates from the moment of test is ordered, quality becomes an issue critical to the outcome. Quality assurance procedures extend to the following areas: a). Test ordering process b).Specimen collection procedures, c). Transport to the lab, d).Specimen handling and storage, e).Completeness of patient information. Automated ordering systems are increasingly used to minimize errors in sample collection and test request. Well-organized computer screens allow health care provider to quickly input test order themselves, minimizing the chance for misunderstanding and error. Important: a patient who does not follow preparation instruction or provides insufficient information to the health care providers undermines the entire quality assurance effort for a specific test.

3.2. ANALYTICAL ACTIVITIES

What happens in the lab where the test is conducted? This question to be seen in this phase. In the lab where the specimen in analyzed, quality assurance procedures guide and monitor all related activities, including the following: a). Instrument maintenance and operation b). Test regents, c).Supplies, d) Personnel, e).Actual test performance, and f).Other aspects of lab activity. Where procedures can be conducted, human error can be minimized. Many test method use automated analyzers. Most instruments have internal computer systems to detect malfunctions. Also in some labs, external computer systems bring extremely abnormal result to the operator's attention.

3.3. POST ANALYTICAL ACTIVITIES

What happens between the time test is run and the result are reported. As test result are made available to the health care provider, work quality continues to be monitored in areas such as the following: a). Report sent to appropriate party, b).Timely reporting of data, c).Reference ranges included, d).Immediate notifications. Where procedures can be automated, errors in reporting can be minimized. Most lab results are collected and managed by a computer system capable of sending electronic reports to the health care provider.

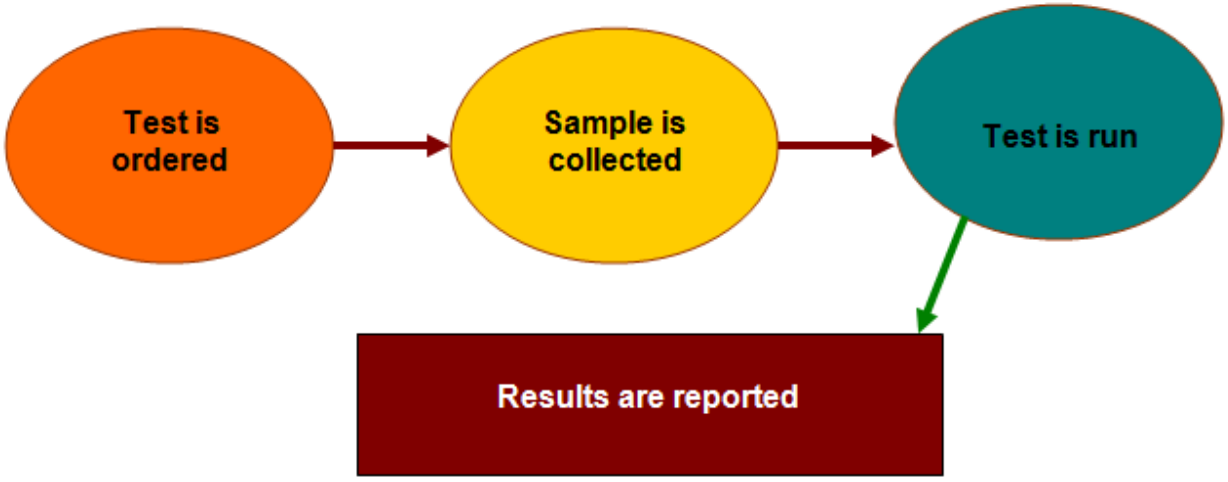

Fig.1. Quality assurance activities in medical laboratory

4. THE ROLE OF TESTING: EVALUATING TEST DATA IN A CLINICAL CONTEXT

The health care providers are expected to evaluate all of the relevant finding-test data plus information from other sources- before setting on a diagnosis and developing a treatment plan. Careful evaluation and consideration of test finding increases the reliability of a diagnosis and reduces the chance of medical errors. As the diagram shows (Fig.2), data from medical tests are part of the information set that needs to be considered when a health care provider makes a diagnosis. A retest or other test to confirm the findings may be appropriate.

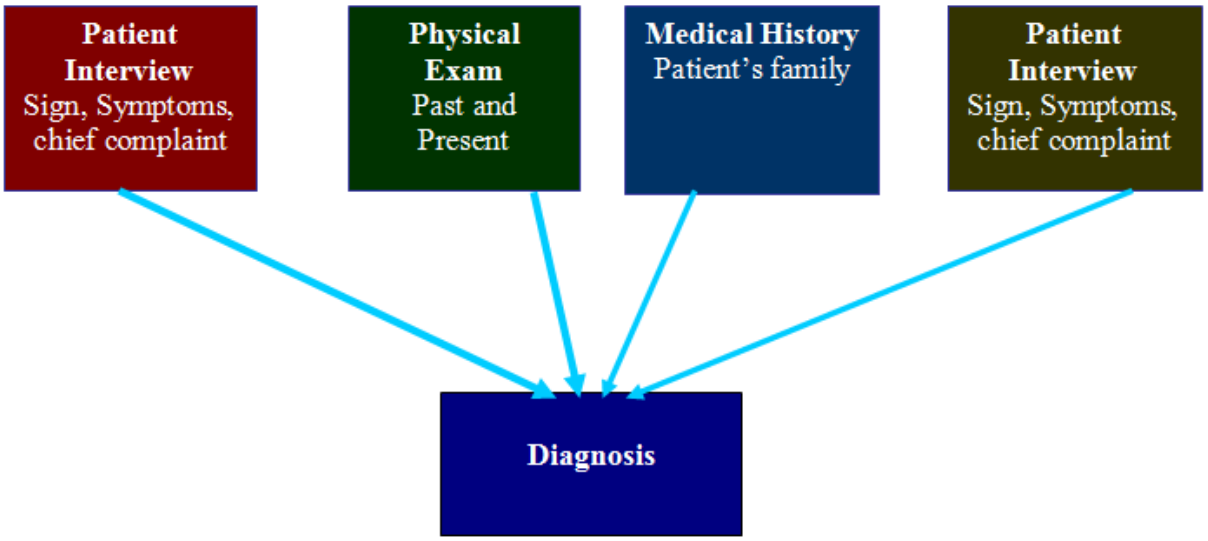

Fig.2. Information Sources critical to the Diagnostic Process

5. ACCREDITATION AND QUALITY MANAGEMENT SYSTEM

Accreditation of health laboratories is the process by which an independent and authorized agency accredits the quality system and competence of a laboratory on the basis of certain pre-defined standards. Accreditation is done at regular intervals to ensure maintenance of standards and reliability of results generated to support clinical and public health activities by the laboratories. The accreditation process requires: a). Identification of an authoritative body b). Adoption of standards, and c). Institution of a mechanism of assessment of laboratories to certify their compliance with standards.

5.1. BENEFITS OF A QUALITY MANAGEMENT SYSTEM & ACCREDITATION

a) Facilitates the implementation and maintenance of an effective quality system
b) Gives confidence to users in availing the services
c) Gives confidence to the laboratory for the results generated
d) Provides national/international recognition of technical competence
e) Helps in defending laboratories while dealing with legal disputes pertaining to laboratory results
f) Reduces the operating costs of the laboratories by getting results right the first time and every time
g) Helps private sector laboratories to attract more business
h) Helps in national and international acceptance of results
i) Meets purchase or regulatory specifications
j) Increases competitiveness and market share.

6. QUALITY SYSTEM

A well-defined quality system is a must for ensuring quality. It is a part of overall quality management which aims at ensuring the consistency, reproducibility, traceability and reliability of the products or services. A quality system is defined as the organizational structure and resources needed to implement quality requirements. The International Organization for Standardization (ISO) defines a quality system as the organizational structure, responsibilities, procedures and resources needed for implementing quality management. A quality system has the following five key elements: a).Organizational management and structure b).Quality standards, c).Documentation, d).Training, e). Assessment

6.1. ORGANIZATIONAL MANAGEMENT AND STRUCTURE

The overall responsibility for the design, implementation, maintenance and improvement in the quality system rests with the laboratory management. Quality is the responsibility of all staff members of the organization.

6.2. QUALITY STANDARDS

Quality standards are an integral part of the quality system. These aim at ensuring safety and consistency. They need to be followed to meet regulatory requirements as well as to monitor functioning of the laboratory.

6.3. DOCUMENTATION

A document is a record of any information or instructions including policy statements, quality manuals, procedures, specifications, calibration tables, reports, job description, documents of external origin such as regulations, standards and examination procedures, etc. Documents may be stored either as hard copy or electronically.

6.4. TRAINING

The quality system is only as good as the staff who actually works with it. No matter how good the quality system is on paper, if theory cannot be translated into practice, quality cannot be achieved. Training must also include an understanding of why quality is important. Training should be competency-based and must be followed by post-training support.

6.5. ASSESSMENT

The laboratory management shall develop and implement quality indicators to systematically monitor and evaluate the laboratory's contribution to patient care. When the programme identifies opportunities for improvement within the system, the laboratory management shall take appropriate steps to address them. Error management shall be vigorously implemented.

7. MEDICAL LABORATORY SAFETY

Safety is a topic that should be foremost in the thoughts and actions of all health care providers, both employees and employers. The goal of health care workers should be provide quality patient care in an environment that is safe for both workers and patients. Safety has become not just a humanitarian issue, but also a legal necessity.

7.1 PHYSICAL AND CHEMICAL HAZARDS

Physical hazardous are present in ordinary equipment or surrounding. Electrical equipment, open flames, laboratory instruments. Electricity: one of the major sources of physical hazard. All equipment must be properly grounded, all electrical cords are plugs must be kept in good repair, with no frayed cords or exposed wires. Extension cords present several safety hazards and should not be used except in an emergency. Fire is another potential danger in the workplace. Examples of fire safety signs: a). Extinguishers for different kinds of fires, b). Fire extinguisher locator, c). Flammable liquids warning, d). fire escape route. Glassware is a routine item in most laboratories, but it can cause injuries. Only glassware that is free of chips and cracks should be used. Damaged glassware is weakened and may break, resulting in injury. Broken glass should be cleaned up with a brush and dustpan, not with bare hands. Wherever possible, Plastic ware should replace glass containers in the laboratory. Chemicals Hazards present a variety of hazards. Chemical may be flammable, toxic, caustic, corrosive, carcinogenic, or mutagenic. Occasionally, laboratories procedures use radioisotopes that present that hazard of potential exposure to radioactivity. "Chemicals must be labeled with hazard information" Examples of hazard information on chemical labels: corrosive materials, toxic chemicals, flammable solvents, cancer hazard.

7.1.0. SAFE STORAGE OF CHEMICALS

Flammable liquids, concentrated acids, and concentrated bases should be stored in proper containers in safe places. Special cabinet are available for safe storage of different types of hazardous chemicals. Personal items, such as purses, should not be kept in the storage space, as they my cause a container to be overturned. Manufacturers color-coding of chemical container labels to indicate proper storage makes this task easier.

7.1.1. DISPOSAL OF CHEMICAL WASTES

All chemicals and reagents should be disposed of properly and according to regulations. It is very important that the laboratory supervisor or instructor provides explicit instructions for disposal.

7.2. BIOLOGICAL HAZARDS

Safety in the clinical lab used to involve avoiding acid splashes onto the skin or into the eyes and avoiding fire hazards or the breathing of toxic fumes. However, with the appearance of HIV and AIDS, along with the recent increase in Hepatitis B and Hepatitis C infections, health care workers must be especially cautious of biological hazards as well.

7.2.1. STANDARDS PRECAUTIONS

Standards Precautions are a set of guidelines for health care workers developed by CDC in 1996 as an extension of OSHA Blood Borne Pathogens (BBP) standard. The use of Standards Precautions intensifies safety practices requiring that every patient and every body fluid be regarded as potentially infected with blood borne pathogens. Standards Precautions for infection control:

- √ Wash hands (plain soap):- wash after touching blood, body fluids, secretions, excretions, and contaminated items. Wash immediately after gloves are removed and between patients contacts. Avoid transfer of microorganisms to other patients or environments.
- √ Wear gloves: - Wear when touching blood, body fluids, secretions, excretions, and contaminated items. Put on clean gloves just before touching mucous membranes and no intact skin. Change gloves between tasks and procedures on the same patient after connect with material that ma contain high concentrations of microorganisms. Remove gloves promptly after use, before touching non contaminated items and environmental surface, and before going to another patient, and wash hands immediately to avoid transfer of microorganisms to other patient or environments.
- √ Wear mask and eye protection:- protects mucous membranes of the eyes, nose and mouth during procedures and patient care activities that are likely to generate splashes or sprays of blood , body fluids, secretions, or excretions.
- √ Wear gown: - protect skin and prevent soiling of clothing during procedures.
- √ Patient care equipment.
- √ Environmental control: - follow hospital procedures for routine care and disinfection of environmental surface, beds, bedside equipment and other frequently touched surface.
- √ Never recap used needles using both hands.
- √ Patient placement: - use a private room for patient who contaminated the environment or who does not assist in maintaining appropriate hygiene or environmental control. Consult infection control if a private room in not available.

8. QUICK OVERVIEW OF CONTINUOUS LABORATORY QUALITY MANAGEMENT (Fig.3.)

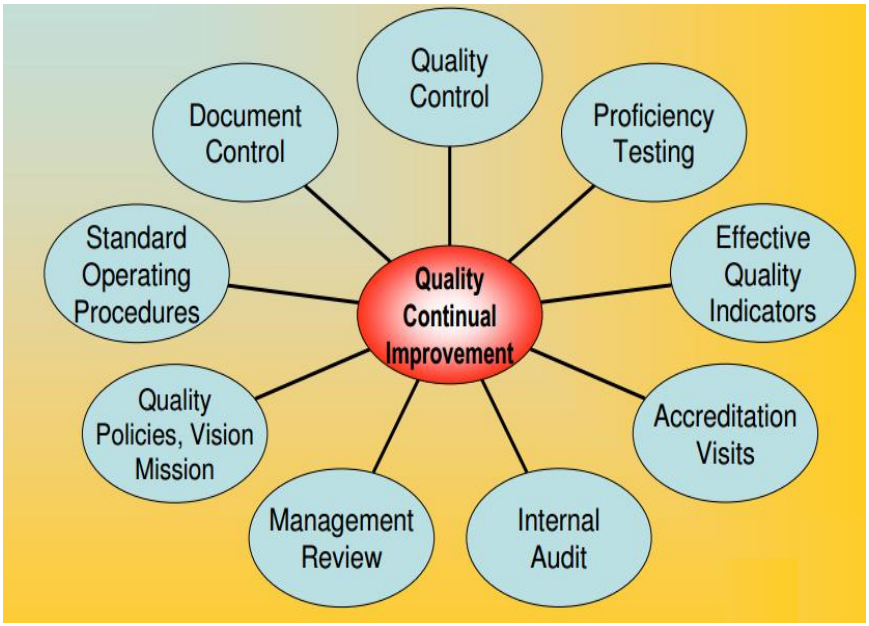

Fig.3. **Continuous Laboratory Quality Management**

9. GENERAL LABORATORY RULES DESPITE CERTAIN SAFETY HAZARDS

The clinical laboratory can be safe work environment. Each worker must be responsible, use safe work habits, and observe and follow all safety rules which is given below:

- √ Refrain from horseplay
- √ Do not eat, drink, chew-gum, or apply cosmetics in the work area.
- √ Wear a laboratory apron, or buttoned laboratory coat, and closed- toe shoes.
- √ Pin long hair up to prevent contact with chemicals, equipment, or flames.
- √ Do not wear chains, bracelets, rings, or other loose jewelry.
- √ Use gloves when handling hazardous chemical and biological specimens.
- √ Clean and disinfect the work area before and after laboratory procedures and at any other time as appropriate.
- √ Wash hands before and after any lab procedures, after removing gloves, and at any other time as appropriate.
- √ Wear safety glasses, goggles when working with strong chemicals and whenever splashes are possible.
- √ Wipe up spills promptly, using the appropriate procedure for the type of spill.
- √ Use an appropriate mask or respirator when working with chemicals or other materials that give off dust or fumes.
- √ Follow manufacturer's instructions for opening for operating all equipment. Handle all equipment with care and store properly.
- √ Report any broken or frayed electrical cords, exposed electrical wires, or damage to equipment.
- √ Do not use bare hands to pick up broken glass. Use a broom or brush and a dustpan. Discard into special containers for broken glass.
- √ Do not allow visitors into the work area of the lab unless they are properly attired and have been instructed in patient confidentiality issues and safety precautions.
- √ Report any accident immediately to supervisors.

10. CONCLUSION

The influence of laboratory medicine on the quality and cost of health care as a whole is much greater because laboratory test results influence the majority of patient care decisions. Thus, practices that reduce laboratory-related error rates or optimize use of laboratory testing can have a substantial effect on patient safety, clinical decision making about treatments and interventions, health outcomes, and costs. Quality Management can systematically assess & improve important functions & work process & their outcomes of Medical Laboratory. In the last two decades, the initiative for quality management & quality improvement in medical laboratory has been recognized predominantly by the requirement of healthcare providers & public at large. It is really very important to all the healthcare providers to maintain the basic quality management system within the laboratory as this cost the patient life & death as well as staff safety & satisfaction. The outcome of good quality management can increase the level of the patient safety & patient satisfaction as well as the staff safety & satisfaction. Medical Laboratory deals with blood, body fluids and other biological Specimens & carries various chemical & hazardous waste & risk. It is recommended to all medical Laboratory services provider to apply the universal precaution to assure the clean & healthy environment. "Quality is based on patient satisfaction" The principles and the statistics involved in Quality Assurance can be become quite complicated. However, the terminology and less complicated applications must be understood and used by all lab workers who perform tests.

REFRENCES

1. Comprehensive Accreditation Manual for Pathology and Laboratory Services. Okbrook Terrace, Join Commission on Accreditation of Healthcare Organization; 1998
2. Guidelines on Establishment of Accreditation of Health Laboratories, Dr Panadda Silva; WHO Collaborating Centre on Strengthening Quality System in Health Laboratories, Department of Medical Sciences, Ministry of Public Health, Nonthaburi, Thailand ; 2007
3. ISO 10011:1993. Guidelines for auditing quality systems.
4. ILAC G3:1994. Guidelines for training courses for assessors.
5. ISO EN 15189:2003. Medical laboratories – particular requirements for quality and competence.
6. Jansen RT, Blaton V, Burnett D, Huisman W, Queralto JM, Zerah S, et al. (1997) Essential criteria for quality systems in medical laboratories. Eur J Clin Chem Clin Biochem 1997; 37:121–32
7. Plebani M (2001). Role of inspectors in external review mechanisms: criteria for selection, training and appraisal. Clin Chim Acta 2001;309:147–54.