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**MBA HOSPITAL AND HEALTH MANAGEMENT**

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# TOPIC :- QUALITY ASSURANCE AND MANAGEMENT OF LABORATORY IN A HOSPITAL SETTING

THE UNIVERSITY OF SYDNEY

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It was an invaluable lesson and one I will cherish throughout my life.

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# ACRONYMS

**BBP** Blood Bore Pathogens

**CDC** Centres for Disease Control and Prevention (United States of America)

**CLSI** Clinical and Laboratory Standards Institute (Wayne, Pennsylvania, United States of America), uses a consensus process to develop standards

**CLSI GP26-A3** Application of a quality management system model for laboratory services (quality document)

**CLSI HS1** A quality management system model for health care (quality document)

**DNA** deoxyribonucleic acid

**GQC** Global Quality Control

**HIV** human immunodeficiency virus

**ISO** International Organization for Standardization

**MSDS** material safety data sheet

**NCCLS** National Committee for Clinical Laboratory Standards

**PPE** personal protection equipment

**QC** quality control

**SARS** serious acute respiratory syndrome

**WHO** World Health Organization

# ABSTRACT

The health laboratory is a facility for the testing, testing or evaluation of blood, bodily fluids and other biological specimens. It can be observed either macroscopically or microscopically. Experiments might be conducted physically or with advanced equipment. Accurate observations and calculation and interpretation of the results was carried out. Laboratory staff would also have the expertise to undertake a number of activities. Laboratory tests are an important part of current physician practice and laboratory medicine faces the same problems as the wider health care environment in terms of efficiency, expense and availability. Quality is of prime importance in a diagnostic laboratory Safety is a subject that can take precedence across both health care professionals, staff and employers' thoughts and behaviors. The goal of healthcare staff in the medical laboratory personnel and clients should be able to receive consistent patient care in a healthy environment.



***Keywords***: Quality Assurance, Management, Laboratories, Hospital

# I – OBSERVATIONAL LEARNING

## CHAPTER 1: INTRODUCTION

## 1.1 THE IMPORTANCE OF LABORATORY QUALITY

As precision, durability and timeliness of published samples, laboratory consistency may be defied. The laboratory reports shall be as exact as practicable, all elements of the work must be consistent and clinical and public health documentation needs to be prompt.

There is often a degree of lack of accuracy when producing calculations. Given the shortcomings of our systems integration, the task is to reduce the degree of inaccuracy as far as possible. An reliability standard of 99 percent can seem reasonable at a glance, but a 1 percent mistake in a framework where several incidents, such as laboratory research, occur may become very extensive.

Clinical and public health settings use the tests to determine health effects, and the quality of the testing and reports are critical to the success of the tests. Incorrect findings may have major effects, including:

Continuing needless care

— problems with treatment

— inability to provide the right treatment

— uncertainty in the accurate evaluation with further and unwanted medical tests.

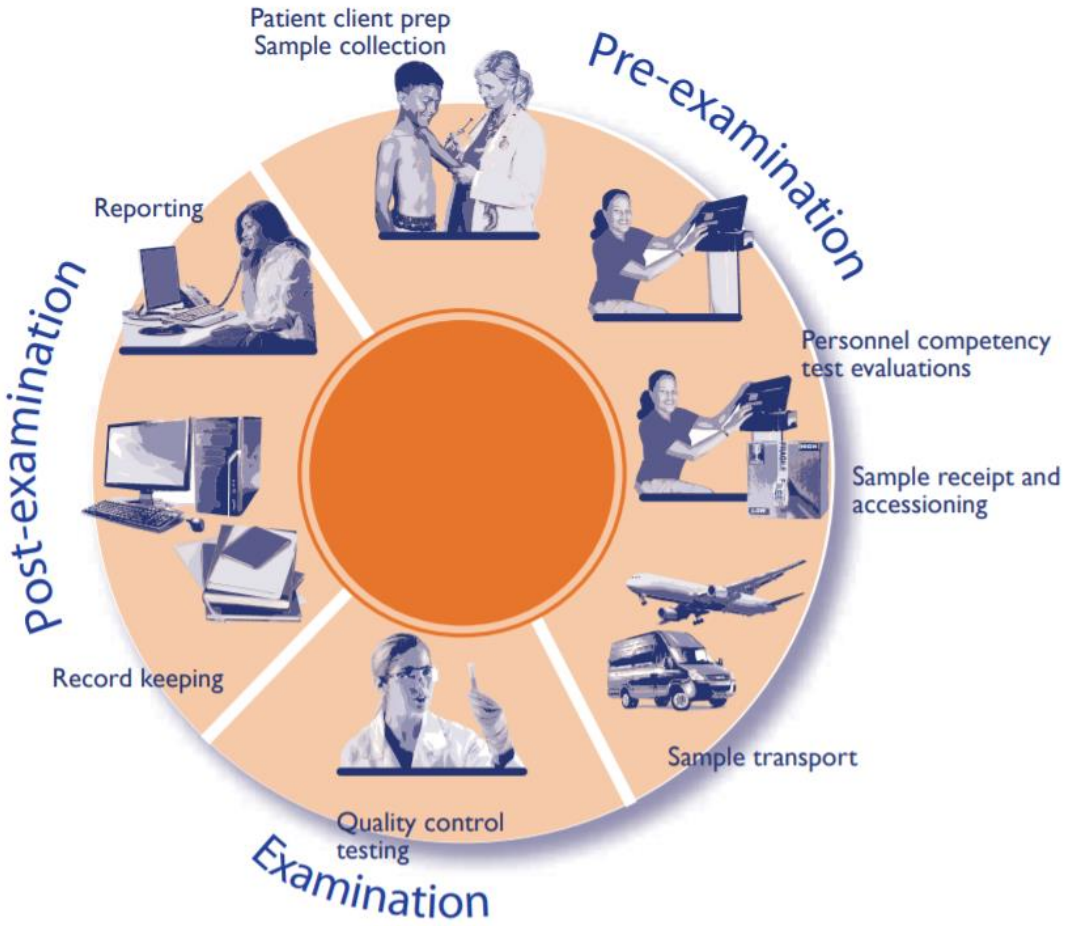
These effects lead to higher time and staff costs and sometimes bad patient results.

To attain the maximum degree of precision and efficiency, both methods and procedures must be performed best in the laboratory. The laboratory is a complicated structure of numerous phases and numerous individuals. The sophistication of the method includes the proper execution of multiple systems as well as procedures. System design for quality management examines the whole process, is however very critical for achieving good laboratory results.

## 1.2 THE QUALITY MANAGEMENT SYSTEM

As defined by the Institute of Clinical and Laboratory Standards (CLSI) and the International Organization for Standardization (ISO), a quality management scheme is "coordinated practices that ensure a quality enterprise.". Both organisations' standards are respected throughout the world and will be discussed later in this manual.

In a quality control scheme, quality assurance must be approached in all areas of laboratory operations, namely operational layout, practices and systems.

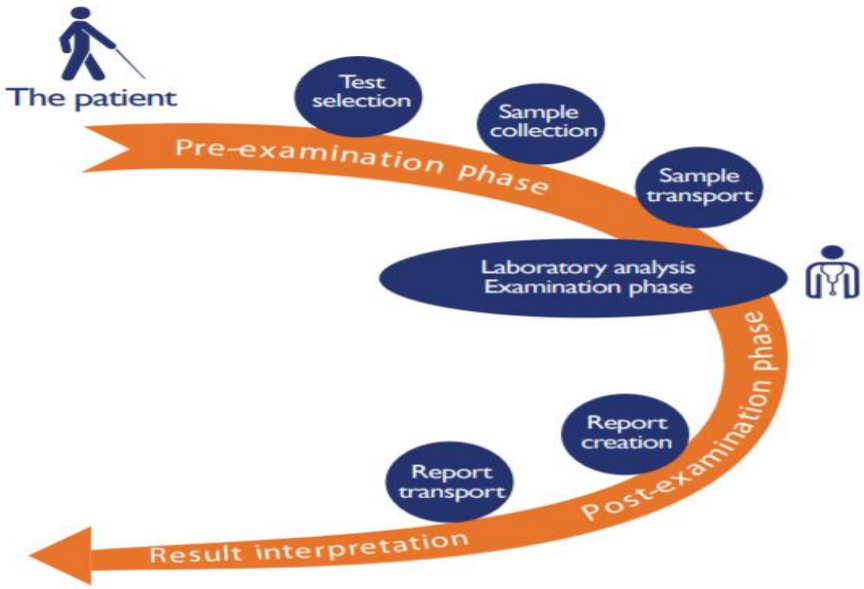



There are several steps in the laboratories, and each must be done properly to ensure the precision and durability of the examination. An mistake will lead to bad laboratory results in any section of the cycle. A system of correcting defects at each test point is required to ensure accuracy.

ISO guidelines group laboratory procedures in divisions of pre-examination, test and post-examination. Pre-analytical, analytical, and post-analytical processes are similar to pre-research, test, and post-test procedures in modern laboratories.

The whole series of operations in research is called the workflow course. The workflow journey starts with the patient and finishes with monitoring and analysis of the data, as seen below.

Work flow course definition is a framework that must be considered when developing quality activities according to the quality paradigm or quality management framework. For instance, the outcome of an unsatisfactory selection or transportation cannot be accurate if a sample is compromised or changed. A late or missing or improperly written medical report will contradict all the time involved in conducting the test well.




The sophistication of the laboratory environment needs several aspects to be tackled in order to ensure laboratory consistency. Any of the following considerations include:

— Laboratories

— quality management protocols

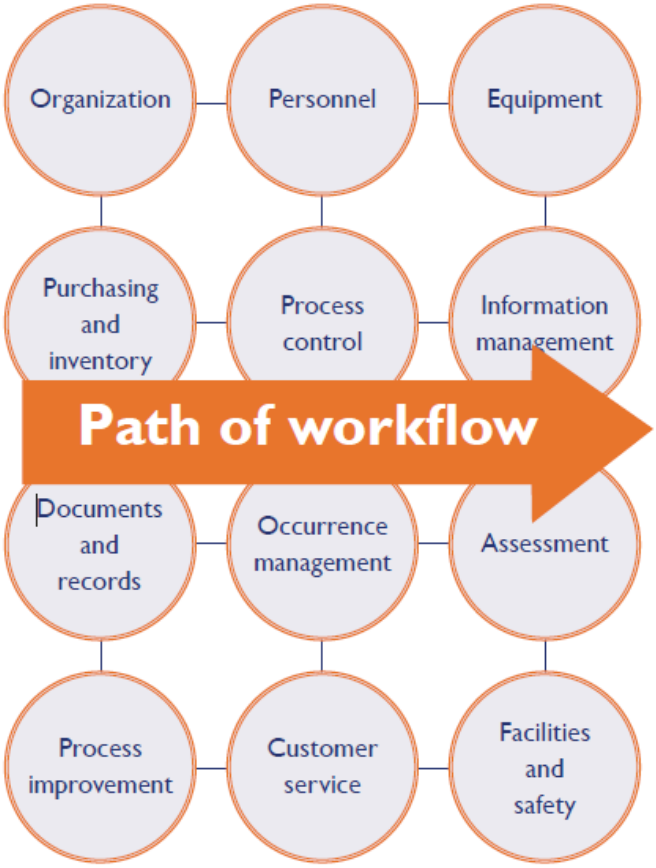
— correspondence and record keeping

— professional and expert personnel

— reagents and instruments of high quality.

## 1.3 QUALITY MANAGEMENT SYSTEM MODEL

The potential of a lab is improved if all activities and operations are organized in a comprehensible and viable manner. All laboratory activities are organized into 12 basic quality systems in this quality model. This qualitative systems are a number of organized practices that function as essential components for the implementation of risk. Each has to be tackled if the overall increase of laboratory efficiency is to be accomplished. This quality control framework model is completely compliant with ISO requirements and has been established by CLSI1.




The accuracy and efficiency of the workflow during relies on the effective handling of all critical quality.

In order to provide a working quality control framework, the laboratory organization and control must be structured to define and enforce quality policies. A solid organizational framework must be supported – management engagement is essential – and an execution and control process must be established.

Competent, engaged employee are the most valuable laboratory resources. The quality control framework discusses several aspects of personal management and supervision and teaches us that support and inspiration are essential.

Various types of machinery are used in the lab and any piece of equipment has to work correctly. Selecting the appropriate facility, fitting it appropriately, maintaining the accurate functioning of new machinery, and having a repair procedure, are both part of a quality control system equipment Management Policy.

Reagent and supply leadership in the research lab is often a difficult task. Nevertheless, careful buying and controlling the warehouse will save costs as well as ensure that materials and reagents can be accessed when needed. All reagents and materials are purchased and handled in a way designed to ensure that they are of high quality and that their use and maintenance are consistent and durable

Procedure management consists of many variables necessary to guarantee the accuracy of the measuring procedures in the laboratories. These considerations include testing quality assurance, proper sample handling, namely selection and storage, and verification and evaluation of the methods.

Procedure management components are common to laboratories; quality control was one of the first methods in the laboratories to be used and tends to play a part in guaranteeing the precision of tests.

Laboratories product is facts, mainly in the form of test reports. Details (data) must be closely monitored to maintain consistency and trustworthiness as well as usability for laboratory personnel and health professionals. Knowledge may be handled and transmitted by either document or computer software; these will be covered in the Information Processing portion.

Many of the 12 critical consistency systems overlap. The strong connection between "documents and documents" and "information processing" is a clear illustration. The laboratory has records to inform how stuff should be done, and laboratories still have several documents. Records should be carefully kept so that they are reliable and available.

An "occurrence" is an accident or an incident not to have occurred. A device is needed to identify, deal with and learn from errors and take steps to prevent certain issues or events from happening any further.

The evaluation method is a method for testing and matching laboratory results with expectations, standards or the output of other laboratory. The evaluation can be internal (with its own employees in the laboratory) or exterior ("conducted by a group or agency outside the laboratory"). Criteria for measuring lab quality are an integral part of evaluations and serve as benchmarks for evaluations

The main objective of a quality control method is to develop laboratory operations continuously, and this must be achieved systematically. There are a variety of tools to automate the operation.

In laboratory experience, the idea of customer care has always been underestimated. Though, labs are service organizations, and it is equally important to ensure that their customers are satisfied with their service. Considering its clients and evaluating their requirements will enable the laboratory to make the necessary changes.

There must be certain considerations in the quality control and protection of the buildings. Including:

– Security—which prevents undesirable threats and threats from accessing the lab.

– A containment system is designed to keep contaminants in the laboratory and to keep the environment unharmed.

– Security, covering processes and practices to deter harm to employees, tourists and the environment.

– Ergonomics—which discusses adaptation of facilities and equipment to enable comfortable and stable laboratory working conditions.

The 12 quality systems necessary to ensure precise, consistent and prompt lab outcomes and quality through laboratory activities must be discussed in the quality management system model. It is crucial to remember that 12 basic quality systems may be applied to fit the laboratory better. Implementation approaches can differ with the local scenario

Labs that do not incorporate a reasonable quality control scheme are guaranteed to have several mistakes and unnoticed issues. Implementing a scheme of quality control cannot guarantee a lab without errors but results in a high-quality facility that notices and avoids errors from repeating.

## 1.4 HISTORY OF LAB QUALITY MANAGEMENT

ISO 9000 describes quality management as "coordinated quality management practices that lead and monitor an organisation." This is closely linked to a quality system's defiance – "the corporate framework, personnel, processes and procedures necessary to enforce quality control". The principles of quality control that are currently practiced date back to the 20th century, and they are mostly a continuation of production and shop operations.

Commodity quality control was one of the early principles of quality improvement. Shewhart invented a predictive process management system that established laboratory quality control procedures in the 1920s. Prior to 1940, quality management techniques were not used in laboratories. Among those who contributed to Feigenbaum's idea were Kaoru Ishikawa, Arman Feigenbaum, and Genichi Taguchi. Among the most important developments of Galvin's work is his micro-scale error prevention.

## 1.5 INTERNATIONAL LABORATORY STANDARDS

Component of quality control is the evaluation, measurement of norm or benchmark results. The principle of quality control needs expectations to be established, and business is again at the forefront.

The ISO has developed industrial manufacturing requirements by adapting military specifications for machinery construction and manufacturing.

Besides offering quality guidelines for the production and service sectors, ISO 9000 manuals can be applied to many other types of businesses. As a reference to lab quality control standards, ISO 9001:2000 addresses them. Two ISO standards are specified c for labs:

"Towards ISO 15189:2007. Medical labs standard and expertise standards. Geneva: International Standards Organization, 2007. 2007.

Towards ISO/IEC 17025:2005. General research and calibration laboratory skill criteria. Geneva: International Standards Organization, 2005."

The Clinical and Laboratory Standards Institute or CLSI, previously known as the National Committee on Clinical Laboratory Quality, is another relevant universal level organisation (NCCLS). In establishing specifications, CLSI utilizes a consensus framework involving multiple stakeholders. The quality management framework concept used in this manual was created by CLSI. This model is built on 12 basic quality systems and completely compliant with ISO laboratory requirements.

CLSI has two records which in the lab are quite essential:

"□ A quality management system model for health care; approved guideline—second edition. CLSI/NCCLS document HS1-A2. Wayne, PA, NCCLS, 2004.

□ Application of a quality management system model for laboratory services; approved guideline—third edition. CLSI/NCCLS document GP26-A3. Wayne, PA, NCCLS, 2004."

Material in this guide is focused on the CLSI model and ISO 15189 norm for quality control. There are also other organisations of guidelines and several illustrations of lab guidelines. There are national quality guidelines in some countries for laboratories that explicitly refer to lab in that region. Certain lab requirements may extend to certain research areas or to particular experiments. For some programs and regions, the World Health Organization has defined guidelines.

# CHAPTER 2: FACILITIES AND SAFETY

## 2.1 OVERVIEW

Workplace and installations of the laboratory must be sufficiently designed that the workload can be carried out without affecting the efficiency and welfare of the workers in the laboratory, all health workers, patient role and the environment.

Chapter outlines important aspects for the architecture as well as protection of laboratories that avoid and monitor physical, chemical and biological threat exposure.

This chapter discusses mild to low-risk pathogens and contaminants rather than particularly hazardous compounds. Both diagnostic laboratories should be planned and coordinated as a general rule for biosafety level 2 or higher.


In order to safeguard the life of staffs and clients, to protect lab systems and machinery, and to maintain the climate, a lab security program is necessary.

Laboratory protection is very expensive to neglect. Secondary lab crash effects are:

“ loss of reputation

 loss of customers / loss of income

 negative effect on staff retention

 increased costs—litigation, insurance.”

Quality and protection are a significant problem for lab managers during laboratory operations. Mostly, developers and/or managers, who lack information about basic laboratory requirements, build the labs that they run, rendering the work of the director harder.

<u>As a laboratory director, it is important to:</u>

 to take part fully in planning and design phases of lab experimental installations;

 to review all possible threats and to implement simple organizational ideas to include an adequate and secure environment for laboratory work and clinical care;

 to include lab organisation while developing new science experiments or treatment testing;

<u>It is the duty of a quality manager (or designated safety officer) to:</u>

 build on a long and accurate overview of simple security regulations as well as structure,

 ensuring that staff are trained in their particular tasks before they start new tasks or methodologies;

 know the fundamental safety and biological safety issues in the work of moderated or low-risk chemicals and viruses;

<u>As a laboratorian, it is important to:</u>

 know specific protection principles and processes;

 consider basic problems in the field of safety and biosafety administration while dealing around and engaging with hazardous substances, biological samples and physical risks.

## 2.2 LABORATORY DESIGN

Be sure the patients and clinical specimens don't have popular routes when planning a laboratory or arranging workflow. Circulation pathways can only be constructed in rooms where tests are obtained between the public and biological content. The service desk for registered patients should be as next to the entrance door as practicable.

Access to rooms where specimens are handled or analysed or where harmful substances or other items are processed must be limited to approved individuals, normally technical laboratories and maintenance personnel. Pass restrictions may be achieved using door signals, alarms, and identity badges if required.

In order to determine where lab design changes might be required to avoid or decrease bridge hazards, observe the sample route as it travels through the laboratory during ability to introduce, analysis and comment phases. Evaluation paths include:

 Sample storage rooms – the configuration of the lab, which includes both the hall and the model preparation space entry, conserves time and resources.

  Field of test sample procedure — Specimens are centrifugated, distributed for various analyses and scattered for review into the relevant laboratory parts, when required. The sample collection area should be isolated, if necessary, from the research areas but nearby.

 Start with modifications that can be done quickly and have the most effects.

 Biological sample diffusion pathways among various laboratory sections—These pathways should be tested to minimize the possibility of infection. Hazardous waste paths should be segregated and never cross between clean and dirty laboratory equipment.

 After review of the tests, the findings must be adequately collected, correctly documented and sent to the appropriate individual in due course. The laboratory architecture should provide communications networks that are adapted to the scale and scope of a lab, including effective and accurate message transmission.

## 2.3 GEOGRAPHIC OR SPATIAL ORGANIZATION

Distribute the lab into sections with various access controls while arranging a test room, such that patients are separated from biological materials. When samples are actually stored, prepare for the right facility for a space organisation. Require for optimum organisation of the research lab:

Delineate experimental work—Either community experiments in a single room should be cared for, or bench area for individual tasks should be specifically delineated. Actions must be implemented to avoid samples from being cross-contaminated.

 Service room location—Service rooms for the accommodation of autoclaves, glassware washing sinks, culture media storage and sterilization etc... should be situated in a central zone to reduce travel distances and promote the movement of supplies, specimens and products. A conscientious member of staff should be appointed for the washing and care of the service rooms.

 “Location of activities with specific requirements, such as: - molecular biology—needs to be located during a separate space, with minimum two rooms, in order that preparation of DNA extracts isn’t performed within the same room as where the next steps (preparation of reagent mixes and DNA amplification) are performed; - fluorescence microscopy—requires a dark room with proper ventilation which must not be used for storage of stock materials and other chemicals; - ultraviolet systems for DNA gel photography—requires a dark room and appropriate eye protection equipment.”

When planning lab room, the lab director and security officer shall take into account specific requirements for appliances. There are some topics to consider:

 Entrance and repair access devices—This can ensure that there are no bodily access limits, such as gate and lift height, which might raise issues with the supply and implementation of computer industrial machinery.

 When the lab's main power source goes down, it is important to have backup power and an emergency generator.

 Controlling solvent waste from machines —

Solvents, by-products, and wastes generated by lab instruments and procedures pose a significant challenge to labs. Place the instruments in the laboratory after thinking carefully about how the liquid waste is treated. To avoid bacterial or hazardous contamination of chemical disposal facilities, comply with local and national liquid disposal standards.

## 2.4 PHYSICAL ASPECTS OF PREMISES AND ROOMS

An active ventilation system should be installed inside the lab, and enough room should be available for humans, carts, and carts to circulate.

A high roof is needed to allow for adequate airflow, and walls and ceilings should be painted or covered with material that facilitates cleaning. If there are edges between walls and floors, they should be easy to clean and disinfect.

Lab testing benches with materials which are sturdy and simple to clean should be installed. Pavers made of concrete are ideal for counter tops, if budgets permit, as they are easy to clean and do not corrode when disinfectants and cleaning chemicals are used. In addition, grout between these tiles will often harbour germs that harm them, so disinfecting them on a periodic basis is necessary. Wood can not be used because cleaning or disinfecting is not difficult and can worsen with time if subjected to antiseptics and cleaning products regularly.

Wood often supports the development of damp or degraded toxins. The downside to steel is that when it is treated with chlorine, steel rusts.

If more space is needed for equipment on the benchtop or for the display of job aids, then such work benches should be arranged based on the type of research being conducted. To avoid cross-contamination when performing microbiological experiments, workstations should be divided by pathogen types, allowing the researcher to isolate each pathogen separately.

Regular cleaning and preservation of laboratory areas is also essential. Following are some examples of areas that require regular attention:

 Benchtops – after exams have been completed and after all sample discharges or reagents have been purified and disinfected. The scientific personnel conducting the experiments are normally given this duty.

 The floors are washed by the cleaning personnel, unless limited access requires the technical workforce only to scrub the floors at the end of the day.

Depending on laboratory requirements, some parts of the lab can be planned for cleaning monthly or quarterly. Tops and walls, for instance, can need weekly washing, while products like fridges and cabinets may be planned for monthly cleanup.

Laboratory cleaning and disinfection, such as the date and name of the individual doing the cleaning should be registered.

## 2.5 SAFETY MEASURE MANAGEMENT PROGRAMME

Also a lab security officer is responsible for designing a safety scheme and coordinating effective safety procedures steps. In smaller labs, the laboratory manager or also the quality office can be responsible for laboratory protection. The measures to develop a curriculum for safety management involve:

• Produce a handbook to include written guidelines for laboratory protection and biosafety;

· Planning instruction in safety and education to educate employees to know about possible risks and as part of standard training, employees should learn universal precautions, the prevention of infection, radioactive waste disposal, and personal protective equipment (PPE) usage .

· Establish a framework to perform risk evaluations – original risk assessments and current laboratory safety checks to detect possible safety issues should be included in this system.

The supervisor should be responsible for ensuring that proper safety and biosafety support is available, such as:

 “PPE

 fire extinguishers and fi re blankets

 should have appropriate storage and cabinets for flammable and toxic chemicals

 eye washers and emergency shower

 waste disposal supplies and equipment

 first aid equipment.”

Policies to detail the safety standards to be practiced in the laboratory should be developed. Standard protection practices in laboratory include:

· Prohibiting or banning laboratory access;

- Cleaning hands following treating, removing gloves and leaving the laboratory with infectious or harmful products and animals;

- banning the use of food, drinking, smoking, touch and beauty products in the workplace;

• Banning mouth pipetting;

Bio-safety cabinets should be employed anywhere aerosol or splash processing is potential or where a significant number of infectious agents are required, or where elevated intensities or enormous amount of contagious mediators exist.

· Do not breathe in chemicals, vapours, fumes, aerosols, dust, or powder contaminated with chemicals, vapours, smoke, or aerosols;

· Chemicals reasonably stored as according known compatibility — chemicals that pose particular dangers or hazards must not be deposited on the floors or on chemical fumes caps, as needed A short-term storage period should be used for such materials, and the storage should be under proper protection (e.g. flammables in combustible cabinets).—

· protecting at all stages compressed gas cylinders;

· decontaminating everyday work surfaces; § decontamination of all crops, stocks and other managed waste by means of an autoclave, chemical disinfection, incinerator or other approved process prior to disposal;

· develop and manage a program for the management of insects and rodents;

· use of PPE as laboratory coats, such as caps, covers, helmets or face shields; • forbid the use of sandals and open-touch shoes when employed in the laboratory;

· disposal pursuant to laboratory policy of petroleum, biological and other pollution.

Monthly and annual exercises for fi re-boxes and laboratory evacuation procedures must be planned. The Safety Officer will use this opportunity to highlight hazards to laboratory personnel and to discuss relevant protocols for escape, managing accidents and general safety measures.

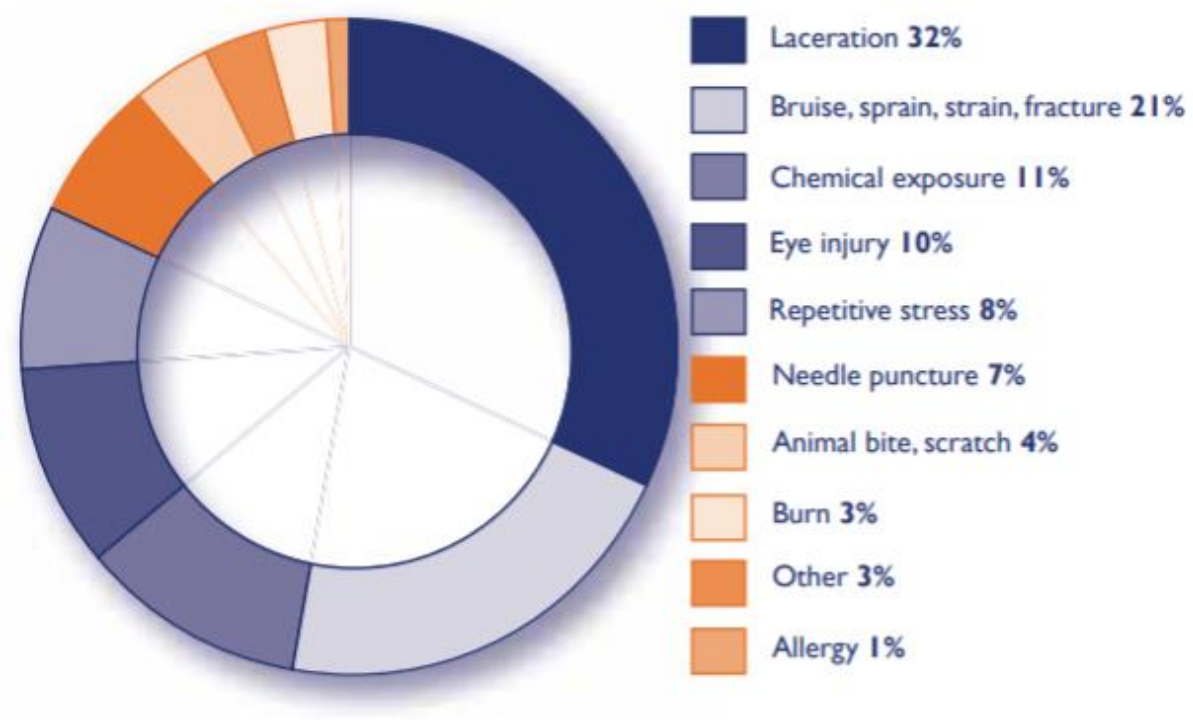
The handling of laboratory waste is a serious concern. All products that are inherently hazardous and toxic (including liquids and nuclear materials) must be specifically handled before disposal. Depending on the type of the waste, separate waste containers can be used and clearly marked by the color code. The handling of possibly hazardous toxic waste, such as sharpeners, needles or damaged glassware should be given specific consideration. Sharp containers on work benches must be visible to the employees in a suitable way.

Many brands that have alerts and safety protocols are globally recognised. References and tools contain links to websites that offer these labels.

## 2.6 IDENTIFICATION OF RISKS

Lab personnel face a large amount of threats, that differ according to the kinds of tasks and analyses carried out. Risk management is obligatory to monitor and reduce uncertainties for laboratory staff by the laboratory owner. A safety officer's support is essential in order to assess possible hazards and to implement effective protective action. It is vital that safety protocols are developed and explain what to do in the event of accident, injury or pollution. Furthermore, it is essential to monitor employee exposures to risks, measures taken when they arise, and protocols to avoid similar events.

The results of a survey of physical dangers faced by laboratory personnel undertaken by the Office of Laboratory Safety of the Howard Hughes Medical Institute are seen in the table. This research discussed only the physical hazards, but in several cases personal exposure and It has been reported that infections have occurred in high containment facilities; however, studies of laboratory-acquired infections that contribute to severe acute respiratory syndrome indicate that risks have not gone flat.




Laboratory machinery is a major cause of possible injuries to laboratory personnel and thus requires instruction in specialized protection procedures. Many laboratory instruments are prone to electrical discharges, which can emit harmful microwaves or radiation if not used or managed correctly. Protective preparation devices include autoclaves, centrifuges, condensed gas cylinders, and fume hoods.

It is especially important to use care when handling condensed gasses in the lab due to the unusual containers in which they are stored and the high pressure they are under. Cylinders are chains on the wall to prevent them from falling over. When the safety cap is shifted or put out of use, the valve of the cylinders must be secured.

Needles, split glass and other sharps must be properly treated and dispose of to avoid lab and cleaning infections. Directions for the correct discarding of cutting edge objects are as follows: The right technique is to hold the hand behind the needle and to pull the cover on the needle with the other hand.

 Put sharps into a punch-resistant sharp jar that is leak-resistant. Tag the "Sharps" jar. In the case of "sharps" that aren't biohazardous, default the marks and symbols of biohazards. Stick the bottle closely.

Lab glass and plate ware for disposal purposes are not known to be sharp. Glassware and plasticware in the lab contain any object which can puncture daily waste bags and thereby endanger waste handlers. For protection during transportation thru the house, lab glass must be stored in cardboard boxes. Carton boxes are required to store laboratory glass. A carton box should only be used if it is robust and has a maximum weight capacity of 40 pounds.

Laboratory glass polluted shall be adequately disinfected before disposal.

Never use boxes to delete:

 “sharps” or cutting objects

 containing biohazardous materials cannot be disposed of as normal solid waste.

 fluid wastes

 chemically infected lab glass or plastic

 chemicals cannot be disposed of as solid waste.

Laboratory workers face a real health and safety risk when exposed to harmful materials. Chemicals penetrate the body on three major pathways.

• Breathing — this is the main entry route when dealing with solvents; when gases are inhaled, absorption is very quick.

• Skin absorption – Absorption through the skin may cause contamination of the system; the degree of absorption depends on the condition of the skin. These hazardous substances include organic plums, solvents such as xylene and methylene chloride, organophosphate, contaminants and cyanide.

— Unintended ingestions are usually attributed to improper sanitation habits, such as laboratory feeding or smoking.

Both substances, including formulations and substances moved from their original tanks, should be identified with common terms, doses, and risks in the prevention or reduction of accidents resulting from exposure to hazardous chemicals. Additional details should also be registered, such as the day of issue, the time when chemical was opened and the time of expiry.

It is essential that contaminants are stored properly. Speak in a well-ventilated environment corrosive, poisonous and extremely reactive chemicals and lock them in a combustible cabinet at room temperature.

Radiochemical products need special precautions and specific bench with c-bench covers are required for handling label elements. Radioactive materials require specific c storage areas. Which should have suitable cover (PlexiglasTM, lead) and specify c waste containers in accordance with the chemical composition of litter and hazardous materials.

Substance Protection Data Sheet (MSDS) is a scientific newsletter that provides accurate risk and precautions.

1 Businesses must provide their consumers with the MSDS with any chemicals they produce or supply. Laboratories must take care specifications mentioned on it to ensure that the substances they use are treated and properly processed.

it provides:

 “product information;

 fire and explosion precautions;

 toxicology;

 health effects;

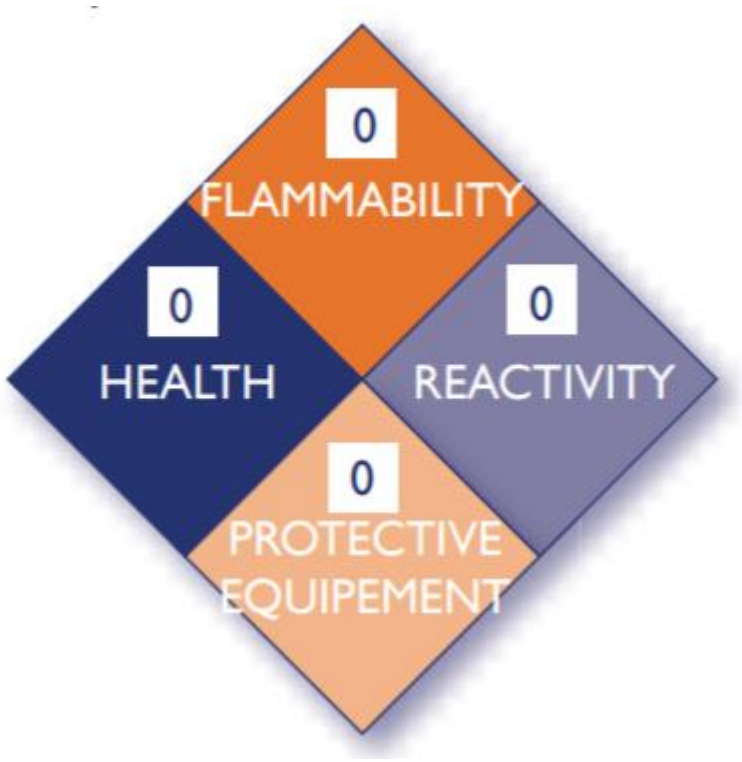
 recommended PPE;

 storage recommendations;

 leaks and spills—recommended actions;

 waste disposal recommendations;

 first aid.”




it should be:

 “available to all employees prior to use of hazardous materials;

 MSDS are kept close to where the hazardous material is used and located.”

In medical labs, research lab diseases are not uncommon. Based on the data in the following tables, the most common infections experienced by laboratories in the U.S. between 1979 and 1999 have been listed.

| Disease or agent | No. of cases |
|---|---|
| *Mycobacterium tuberculosis* | 223 |
| Q fever | 176 |
| Hantavirus | 169 |
| Hepatitis B | 84 |
| *Brucella* sp. | 81 |
| *Salmonella* sp. | 66 |
| *Shigella* sp. | 56 |
| Hepatitis non-A, non-B | 28 |
| *Cryptosporidium* sp. | 27 |
| Total | 910 |

| Disease | Probable source | Maximum distance from source | No. infected |
|---|---|---|---|
| Brucellosis | Centrifugation | Basement to 3rd floor | 94 |
| Coccidioidomycosis | Culture transfer, solid media | 2 building floors | 13 |
| Coxsackie virus infection | Spilled tube of infected mouse tissue on floor | 5 feet estimated | 2 |
| Murine typhus | Intranasal inoculation of mice | 6 feet estimated | 6 |
| Tularemia | 20 petri plates dropped | 70 feet | 5 |
| Venezuelan encephalitis | 9 lyophilized ampoules dropped | 4th floor stairs to 3rd or 5th floor | 24 |

In clinical specimens, aerosol is the key cause of pollution; exposure can occur over very vast distances. For this reason, the main aim of the spray cooling is to prevent the absorption of aerosols within and outside the lab. Number of constraints level 2 diagnostic laboratories, where operations relate only to intermediate risk diseases, should have adequate ventilation. In order to prevent spread of aerosol outside workspace or the whole lab, higher-containment labs

or working cabinet can maintain a constant internal airflow, as well as total filters of exhausted air.

## 2.7 EMERGENCY MANAGEMENT AND FIRST AID

Labs must have protocols in order to cope with injuries and emergencies by workers. General writing instructions for first aid should be formulated and made accessible to all workers to know what to do first and who, in the event of small cuts, contents, serious injuries or skin contamination, to call or notify.

It is only considered minor if the individual who spilled the chemical understands the chemical and its dangers, and knows how to clean up the spill properly. The measures that are suggested for the treatment of a minor spill include: Warning Colleagues, then cleaning the spill with correct disposal procedures; using polypropylene pads for caustic liquids, beneficial nematodes for mineral acids, soda bakers or polyethylene pads to soak up flame retardant liquids; neutralizing contaminants to clean the area.

Any spill that requires assistance from outside the laboratory community is considered significant. Major disturbances are handled by alerting colleagues, going to secure locations, and calling for officials to be notified.

The following measures should be taken if the surfaces have been contaminated by biological leaks:

1. “Define/isolate the contaminated area.

2. Alert co-workers.

3. Put on appropriate PPE.

4. Remove glass/lumps with forceps or scoop.

5. By applying absorbent towels to the spill, remove bulk and reapply if needed.

6. Apply disinfectant to towel surface.

7. Allow adequate contact time (20 minutes).

8. Remove the towel, mop up, and clean the surface with alcohol rub or soap and water.

9. Properly dispose of materials.

10. Should notify the supervisor, safety officer, and other appropriate authorities."

If laboratory staff is tainted by biological hazards owing to splashes or leaks, the next measures should involve:

1. "Clean exposed skin or body surface with soap and water, eyewash (for eye exposures) or saline (for mouth exposures).

2. Apply first aid and treat as an emergency.

3. Notify supervisor, safety officer, or security desk (after hours).

4. Follow appropriate reporting procedures.

5. Report to physician for treatment or counselling."

Lab staff must be vigilant to situations which may pose a danger to fires. If any liquid containing low flash points is near heating system components, such as hotplates, steam lines, or heating machinery, it will catch fire.

A minor fire in the laboratory is deemed extinguishable in 1-2 minutes. The right measures are to protect the fibre with an inverted beaker or wet towels. Using a fi re extinguisher if that fails. For big numbers, contact the municipal authority responsible, normally the division of fire and the Police Department.

Labs must have a suitable extinctor class in the research lab for electrical fires. It is generally acceptable to use an extinguisher of class BC or ABC. Every year, fire extinguishers should be tested and replaced when required. The laboratory staff should receive annual training on laboratory protection and hazardous waste management in relation to different types of fires and fire extinguisher usage. They must also learn how this type of fire extinguisher works.

# CHAPTER 3. PROCESS CONTROL SAMPLE MANAGEMENT

## 3.1 OVERVIEW

As a component of quality management, sampling is one of the most important elements.

Standard of the effort generated by a lab is just as high as the value of the materials used in research. The laboratory must be vigilant to ensure that the samples it collects fulfil all conditions for exact test results.

Suitable sampling handling is important for the quality and efficacy of tests and thus for the confidence of laboratory diagnosis. The findings of laboratories affect treatment choices which may have major effects on medical safety and results. To ensure good care, it is essential to have reliable laboratory reports.

Test inaccuracies can affect both hospital and laboratory costs for the duration of hospital stays. Laboratory quality may also be affected by in exactitudes, contributing to repeat tests involving loss of time, supply and reagents.

Written sample handling policies must be laid down and expressed in the lab manual. Elements to be dealt with consist of:

 “information needed on requisitions or forms;

 handling urgent requests;

 collection, labelling, preservation and transport;

 safety practices like leaking or broken containers, contaminated forms, other biohazards

 evaluating, processing and tracking samples;

 storage, retention and disposal.”

## 3.2 LABORATORY HANDBOOK

Lab should produce a lab manual in order to make sure that all tests are correctly handled and people taking specimens have the knowledge they need. This manual should be accessible in all specimen storage locations, even those far away from the laboratory.

Both laboratory personnel should therefore know the details contained in the manual and be able to address queries about the data contained in it. The lab manual is a valuable laboratory text. It must be held up to date and cited in the quality handbook of the lab.

Important material to be used in the lab manual:

 Information about key personnel such as name and phone numbers;

 “name and address of the laboratory;

 hours of operation of the laboratory;

 list of tests that can be ordered;

 detailed information on sample collection requirements;

 sample transport requirements, if any;

 expected turnaround times;

 description of how urgent requests are handled—this should include a list of what kinds of tests are done on an urgent basis, what are the expected turnaround times, and how to order these tests.”

Lab can supply the healthcare and laboratory staff responsible for the processing of samples regularly with training sessions.

## 3.3 COLLECTION AND PRESERVATION

It is the laboratory's duty to gather suitable and optimum materials, even if individuals who are not employed in the laboratory also perform the actual selection procedure. The sample will be taken by a nurse at the bed while the patient is treated in a hospital. A sample may be collected in a clinic by the health care professional.

The laboratory will help ensure healthy samples by supplying healthcare staff with details about the location, ensuring that suitable containers and collection materials are accessible, establishing a well-defined labelling scheme, and closely monitoring samples before entering the laboratory.

As part of the sample collection process, the research order must be filled. A form explaining all the details for proper handling and reporting must be available at the lab.

Important material for the research application type comprises of :

 “patient identification;

 tests requested;

 time and date of the sample collection;

 source of the sample, when appropriate;

 clinical data, when indicated;

 contact information for the health care provider requesting the test.”

# Field Data Collection Form

**General patient information**

Name:
Address:
Country:
County:
City/Town/Village:

**Tracking record number:**

Date of birth (dd/mm/yyyy):
Sex: F[ ] M[ ]
Nationality:
Occupation:

**Date of onset of illness (dd/mm/yyyy):**

**Clinical specimens**

| Unique ID No. | Type | Date of collection (dd/mm/yyyy) | Clinical diagnosis | Health status when specimens collected | Remarks |
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**Post mortem-specimens**
Date of death (dd/mm/yyyy)

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Name of person completing form:
Institution affiliation:
Contact details:
Date (dd/mm/yyyy): ___/___/_____

For an epidemiological study in the field, sample collection should be performed by completing an epidemiological survey form with name, number, demographic information, and a health status of the study subject. Further knowledge is needed to help determine the origins of an outbreak and identify possible connections.

Dependent on the examination and form of sample obtained, sample selection and processing can differ. For any examination that the laboratory carries out, it must carefully defy a sample selection procedure. When writing orders, the following should be taken into account.

· Planning of the patient—Some procedures entail the fasting of the patient. Special pacing problems may also occur with testing including blood glucose, opioid levels and hormone testing.

— The individual extracting the “sample” must correctly recognize the patient. During an interview, a family member may be asked questions, or an identification device may be used to obtain this information.

§ The type of sample used—Serum, plasma or entire blood can be used for blood testing. Other samples can need semen or spit. Microbiologists conduct research on a range of samples, so it is critical to examine each one in detail.

-Kind of container — Furthermore, the test container is essential because it affects the amount as well as any anticoagulants or preservatives that need to be added. It is impossible to regulate the volume of a jar if it's not designed to do so e.g. Vacutainer tubing, this must be explicitly defined. Any samples in microbiology will need special means of transport to retain microorganisms.

—All criteria for sample labelling at the point of processing must be outlined in depth in the collection directions.

Unique handling — Some samples, such as instant cooling, light safety or timely laboratory arrival, can need special handling. Some essential safeguards for protection should be clarified.

Patients often collect their own samples; for example, faecal parasitological samples. The labs must establish procedures to ensure that appropriate collection kits with safety warnings, labels and collection notes are provided to their patients. In order to improve patient understanding, patients' orders may be written in the lab's own language or presented as plain, easily understandable graphics.

Every section must be marked specifically by:

 "The name and surname of the patient"

In addition to hospital numbers, laboratories may assign unique identification numbers.

 Tests requested by the client;

 When and where the collection took place;

 A sample is collected by an individual whose initials follow.

An significant factor for successful lab work is the proper selection of samples.

Poor sample selection can result in the following problems:

 “delays in reporting test results

 unnecessary redraws/retests

 decreased customer satisfaction

 increased costs

 incorrect diagnosis or treatment

 injury

 death.”

# CHAPTER 4: PROCESS CONTROL: INTRODUCTION TO QUALITY CONTROL

## 4.1 OVERVIEW

Process control is an integral aspect of a quality improvement framework which relates to monitoring activities used in sample handling and analysis systems in order to guarantee that tests are correct and consistent. QC tracks events relevant to the (analytic) research process. The objective of QC is to identify, assess and resolve errors related to failures in the test procedure, external factors or the quality of the operator prior to the reporting of patient outcomes.

QC is the quality control component that meets quality criteria (ISO 9000:2000 [3.2.10]). Simply placed, "control" products from identified compounds and patient samples are investigated to track the quality and accuracy of the whole analysis procedure. For certification reasons, QC is needed.

In the year 1981, it utilized the expression "Global Quality Control" as a "collection of protocols for the continuous evaluation of laboratory and emergent outcomes." The terms QC and IQC are often used synonymously; for these terms, cultural environment and nation can affect preferences.

Due to the various definitions connected with the word "internal quality management" has been misleading in certain contexts in the past few years. Any test kit manufacturers have incorporated "built-in" controls in the construction of their packages, and often refer to them as internal controls. Some producers have their own defence mechanisms in the kits they market, which they describe as "internal controls," which means that they are actually intended for the kit of that producer. As defined by WHO in 1981, IQC can also be regarded as the quality management materials used when testing products.

The word “quality management” is used to prevent misunderstanding in this regard, Monitoring the accuracy and performance of all measuring materials by using control materials (analytical) step procedures.

Quality checks differ according to whether laboratory tests utilize approaches that yield quantitative, qualitative or semi-quantitative data. These exams vary in the following respects.

Calculations must be precise and reliable in quantitative tests, which measure a sample's content of an analyse. Calculation provides a numerical amount as an endpoint represented in specific measuring device. The outcome of a blood glucose examination, for example, could be 5 mg/dL.

An evaluation of qualitative features of a cell is a test of whether that cell possesses a particular feature, such as morphology. Qualitative tests include microscopic studies, the presence or absence of antibodies or antigens, and a variety of microbiological methods. Among the various tests is the urine dipstick, ketone tablet and serological agglutination.

Comparatively speaking, semi-quantitative exams do not employ quantitative analysis. The measurements are distinguished by the fact that they show an estimate of the level of the material tested. Results may be provided in terms of trace quantity, moderate quantity, or "1+, 2+, or 3+." Examples include urinary dipsticks, ketone tablet checks and serological agglutination procedures. In the case of other serologic tests, the results are also represented as titles — once again with a number but an approximation instead of an exact quantity.

Some microscopic examinations are called semi-quantitative, when a record is kept of the number of cells shown in low- or high-power areas. Microscopic urine testing, for example, could report 0-5 red blood cells.

Regardless of the sort of review being carried out, implementation and maintenance measures for the QC software include:

- to develop written policy and procedures, including remedial actions; to train all laboratory staff; to ensure full documentation; to evaluate quality control data;

·From: QC. is part of the quality control scheme and used to track the (analytical) monitoring process.

· QC aims at detecting, evaluating and correcting mistakes caused by device instability, environmental factors or operator success before reporting patient outcomes.

· Different quantitative, qualitative and semi-quantitative measurements are monitored through QC methods.

# CHAPTER 5: DISCUSSION, ANALYSIS AND FINDINGS

## 1. OVERVIEW

Quality assurance in clinical labs is such a critical concern when test reports are used to assist in the diagnosis, care prescription and patient progress monitoring. The results in the laboratory must be accurate, laboratory quality management protocols must be tracked and results recorded. Laboratory staff have the proper and legitimate duty to safeguard the best performing study conducted in the laboratory. This can be ensured by a robust quality improvement programme. The identification and treatment of patients needs medical laboratory facilities. Their facilities include the request arrangement, patient planning, selection of patients, sample acquisition, transportation, storage, sorting and review of clinical samples, and the corresponding confirmation, analysis, recording and advice of results. Therefore, medical laboratory facilities should address the interests of all patients, health care staff and other stakeholders. The purpose of the lab is not only to have correct data, but also to make use of suitable laboratory protocols and respecting the ethics, secrecy and protection of the patient on the correct customer within a reasonable timeline with regard to medical practice.

## 2. CONTROL AND MANAGEMENT OF QUALITY IN MEDICAL LABORATORIES

A laboratory's normal activities include management and control of quality. It is also considered only applicable to research procedures. From ordering the test to the patient charts, a quality control or quality assurance scheme should be established to maintain quality throughout the entire testing process. Quality management components are the processing of laboratory materials, analytical protocols and procedural control. Quality control is a quality assurance and a central aspect of effective health management; it is patient-orientated, unbiased, analytical and works in the context of a peer evaluation model. It offers several advantages such as those mentioned below. The desire to increase the standard of medical treatment while ensuring reliability and effectiveness is a core concept for healthcare regulators. The accreditation and quality management of medical laboratory services should be used as a tool to promote the commissioning and specification of technically competent, safe and reliable medical laboratories that continuously improve the patient experience by using: 1) Providing world-class quality and safety assurance to support better decisions to provide better care for more people.

## 3. IN MEDICAL LABORATORIES: QUALITY ASSURANCES

As soon as a research is requested, understanding to detail becomes a key concern for the accuracy of the laboratory findings. Strict quality improvement systems and quality management protocols guiding the practice of the healthcare professional, from the first processing of research specimens and documents to documentation of reports. We also separated activities into three key stages, to make it easy to see all the points where output is tracked and where input quality is significant.

## 3.1. ACTIVITIES PRIOR TO ANALYSIS ;- “PRE-ANALYTICAL”

What will happen when the test is organized and the sample is obtained. This dilemma would emerge where consistency arrives from the time of the evaluation and quality is ordered and becomes a key concern. Procedures for quality improvement include the following places: Test ordering method b) Specimen selection processes c). Laboratory transport, d. Specimen processing and storage, e). Increased use is being made of automated food ordering systems to eliminate sample selection and review appeal errors. Healthcare providers are able to enter test orders with less error on well-organized computer screens. Important: patients who do not meet the planning guidance or who provide healthcare professionals with inadequate knowledge damage the whole quality improvement initiative for a given evaluation.

## 3.2. ANALYTICAL ACTIVITIES

How are experiments carried out in a laboratory? We will have to wait and see what happens with this matter.This issue is to be seen at this point. Quality assessment protocols direct and supervise all relevant operations in the laboratory where the specimen is analysed, including: a). Repair and use of the instrument. (b) Research Regents. (c) Furnishings, (d) Staff, (e) Current testing and (f) other laboratory activities elements. Human error can be reduced when operations can be performed. A large number of research methods utilize automatic analysers. Most tools include internal computing structures for failure detection. Even in certain laboratories, external computer systems give the user an exceedingly abnormal performance.

## 3.3. ACTIVITIES DURING POST ANALYTICS

The time it takes for a test to run and results to be seen. A healthcare provider needs to keep track of examination results in the following ways:

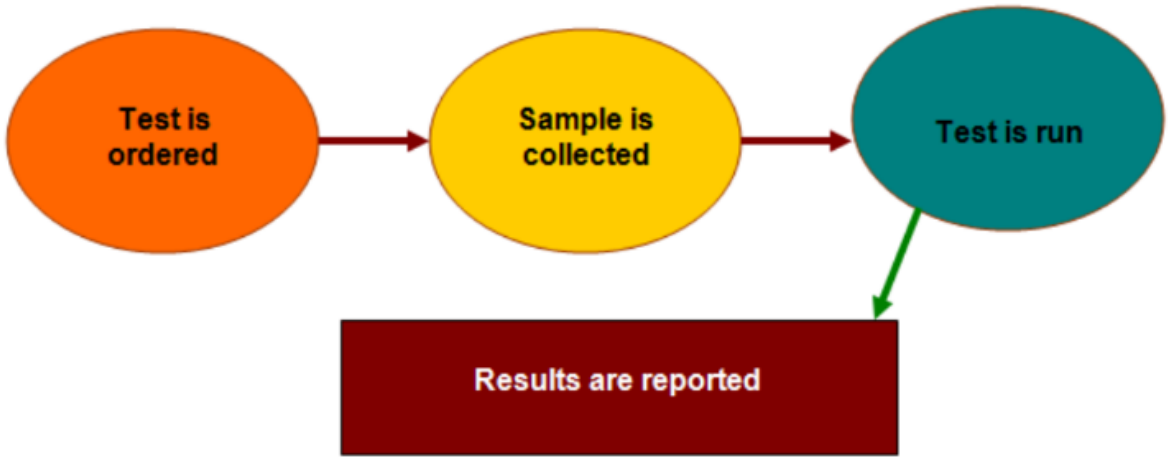
(a) Update to the relevant party;

(b) Timely data reporting;

(c) Field of reference included;

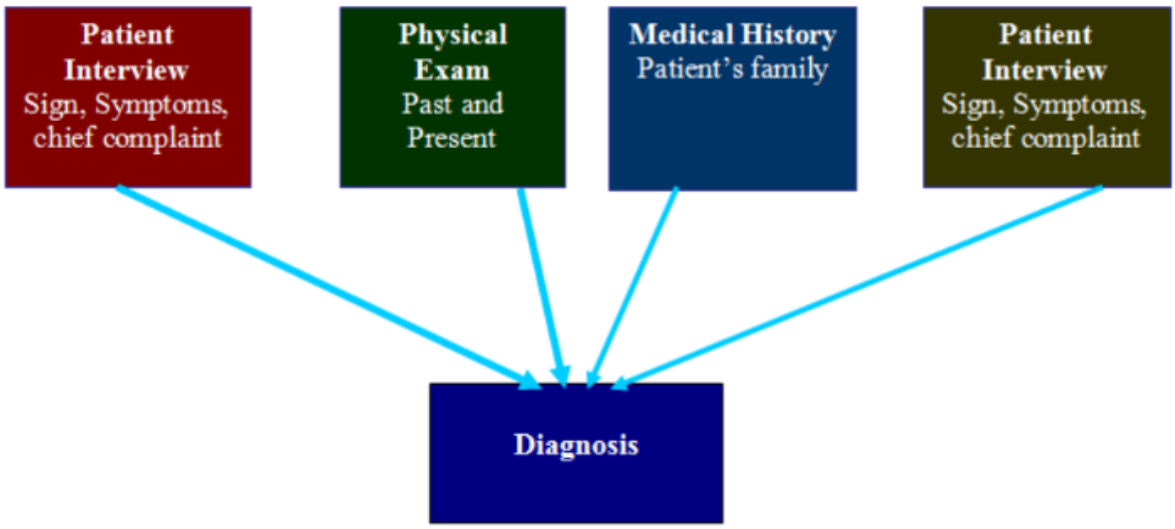
(d). Immediate notice.

If processes can be streamlined, monitoring mistakes can be eliminated. The majority of laboratory samples are compiled and handled by a computer system that is able to provide electronic reports to the health service provider.




## 4. CLINICAL EVALUATION OF TEST DATA: THE ROLE OF TESTING

Both related findings plus evidence from other sources are required to be evaluated by healthcare professionals before diagnosis is established and treatment plans have been developed. Careful assessment and analysis of the examination results enhances diagnostic efficiency and decreases the likelihood of medical mistakes. Health examination data is part of the evidence package to be taken into account as a healthcare worker requires a diagnosis. A re-test or other test might be necessary to validate the results.




## 5. MANAGEMENT OF ACCREDITATION AND QUALITY

Certification of healthcare labs means the certification of the quality framework and expertise of a laboratory by an autonomous, accredited body based on certain pre-defined criteria. Certification is performed regularly to ensure the preservation of quality and reliability of the findings generated in support of the laboratory's operations in clinical and public health. The method of accreditation necessitates:

(a) Recognition of the respected body

(b). Standards implementation and

(c) establishment of a laboratories evaluation system to certify that they are compliant along with specifications.

### 5.1. ACCREDITATION AND QUALITY MANAGEMENT: THE BENEFITS

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

For quality assurance to be effective, a quality framework needs to be specified. The quality assurance process pertains to ensuring goods or services are reproducible, traceable, durable, accurate, and reproducible. An organization's quality management system includes the organizational structure and resources required to achieve quality standards. Quality frameworks are defined by the International Quality Organization (ISO) as operations structures, roles, processes and services required to implement quality management. A quality system is composed of five components:

a) Management and structure of an organisation

b).Quality criteria,

c). Certification,

d). Training Exercise,

e). Evaluation

## 6.1. MANAGEMENT AND STRUCTURE OF AN ORGANISATION

Lab management is responsible for the planning, execution, management and enhancement of the quality system. Quality is the duty of all the organization's employees.

## 6.2. QUALITY CRITERIA

The framework of quality includes quality requirements. They are designed to ensure protection and accuracy. They must be followed to comply with legal regulations and to regulate the operation of the laboratory.

## 6.3. CERTIFICATION

Each material or guideline including policy declarations, quality guides, protocols, requirements, measurement tables, records, work descriptions, documentation of foreign origin such as rules, standards and inspection procedures shall be recorded in a book. Documents may be processed on paper or online.

## 6.4. TRAINING EXERCISE

The quality scheme is only as successful as the people who deal in it. If a philosophy cannot be translated into practice, it cannot be implemented as a quality scheme regardless of how effective it is on paper. Training can also provide an appreciation of the importance of consistency. Education should be focused on competencies and support for post-training should be followed.

## 6.5. EVALUATION

Lab management board intend to establish and incorporate value benchmarks to track and assess methodically the laboratory's contributions to patient care. If the software finds ways to strengthen the scheme, the management of the laboratory shall take necessary measures to tackle it. Inaccuracy correction must be applied aggressively.

# 7. SAFETY IN MEDICAL LABORATORIES

The primary focus of healthcare workers, including their employers, should be laboratory safety. In a healthy environment, health care professionals should provide consistent medical

care for employees and patients. Safety has not only been a philanthropic problem, although a legitimate imperative.

## 7.1 CHEMICAL AND PHYSICAL HAZARDS

“Physical hazards” are found on or around common appliances. Electric appliances, fire in laboratory equipment. Physical threats are mainly caused by electricity. Electric cables need to be well laid and free from any breaks or uncovered wires. Extension cables have many protection risks and can not be used even in an emergency. Fire is another possible occupational hazard. There are several types of fire protection signs: a). Fire extinguisher for various types of fire, b) locator fire extinguisher, c). In most labs, glassware is a procedure, but it may trigger injury. Only chip- and crack-free glassware can be included. Damaged glassware is weakened and can crack, causing damage. Broken glass, not bare hands, can be washed with a cleaner and a dustpan. Plastic ware can substitute glass containers in the laboratory as much as practicable. There are a number of risks associated with chemical hazards. Flammable, radioactive, caustic, corrosive, carcinogenic or mutagenic can be chemicals. Radiation is a risk that occurs during laboratory procedures that use radioisotopes. "Chemicals must be marked with details on hazards”. Defining the chemical's hazards can be done by labelling: corrosive products, hazardous substances, solvents inflammable, cancer risks.

## 7.1.0. SAFE STORAGE OF CHEMICALS

In appropriate places in safe environments, flame-retardant oils, condensed acids and condensed bases can be placed. For secure storage of various forms of dangerous chemicals, special cabinets are open. Personal objects, such as bags, can not be stored in storage so they overturn a bin for me. Colour coding of chemical container labelling by manufacturers to show correct handling simplifies the process.

## 7.1.1. CHEMICAL WASTE DISPOSAL

Both chemical substances must be correctly and regulatory predisposed. The laboratory manager or teacher must have specific disposal guidance.

## 7.2. BIOLOGICAL THREATS

Preventing acid splashing into the face or eyes and avoiding fire hazards or poisonous gases in pharmaceutical laboratories. Despite this, health professionals have to remain extremely cautious when treating HIV and AIDS, as well as the current spike in hepatitis B and hepatitis C infections.

### 7.2.1. COMMON PRECAUTIONS

The CDC developed the precaution standards in 1996 as an extension of the OSHA Blood Bore Pathogen (BBP) standard. Using Standards Precautions intensifies hygiene practices that require both patients and body fluids to be considered possibly contaminated with blood transmitted pathogens. Standards Infection Prevention Precautions:

Wash hands (smooth soap):

- wash hair, bodily fluids, secretions, excretions and infected objects after contact. Wash directly following removal of gloves and touch between patients. Keep other patients and environments free of microorganisms.

It is recommend wearing disposable gloves when dealing with blood, bodily oils, secretions, excretions and the like.. Just before contacting mucous membranes, put on sterile gloves and no intact skin. Change gloves on the same patient between activities and procedures after connecting to materials containing high microorganisms.

Remove gloves directly following use, when handling infected objects and soil and before moving to another patient and immediately wash hands to prevent micro-organism transmission to other patients or habitats.

Mask: protects the eyes, nose, mouth, in operations and during health care procedures likely to generate sparks or blood sprays, body fluids, excretions or secretions.

The gown should be worn during operations while dealing with a patient in order to prevent fabric soiling.

Environmental control: - observe hospital guidelines for normal treatment and floor, furniture, bedside appliances and other regularly affected areas. Never recap with both hands used needles.

- use of a private space for patients who have polluted the air or who may not help to ensure proper sanitation or environmental controls. Patient placements: If a private space is not open, please consult infection control.

## 8. CONTINUOUS LABORATORY QUALITY MANAGEMENT: A QUICK OVERVIEW


## 9. DESPITE CERTAIN SAFETY HAZARDS, THE LABORATORY HAS GENERAL RULES.

Therapeutic lab is clean to operate. Each employee must be accountable, apply healthy working habits and comply with and obey the following safety rules: Refrain from the game Do not feed, drink, chew, or use makeup in the field of function. Use a research apron or a buttoned lab coat and shut-off shoes. To avoid interaction with explosives, appliances or fires, pin long hair. Don't wear chains, wristbands, rings or other loose gems. Gloves and handles of toxic chemicals and biological samples should be used. Before, during, and right after lab

procedures, the work area should be cleaned and disinfected. Wash hands before and during every laboratory operation, remove gloves and at any time. Wear protective lenses, weapons with heavy chemicals and splashes wherever possible. Wipe up the spill quickly, utilizing the required spill style protocol. When dealing around chemicals or other products that give off dust or gases, use the proper mask or respirator. Follow the guidelines for the dealer to unlock all appliances. Take control of all appliances and store it appropriately. Report any electrical cords damaged or crushed, uncovered electrical wires, or equipment injury. Broken glass should not be handled with bare hands. Broom or vacuum the floor and use a bowl. Discharge within the unique glass pots. Do not admit visitors to the laboratory work-ground until they are fully clothed and briefed on matters of patient confidentiality and security. Report any injury to managers instantly.

# INTRODUCTION TO THE STUDY

As evidence based medicine has evolved there is increase in public awareness and a fear of legal hassles have made clinical laboratories and increasingly vital part of patient care by keeping quality assurance policies strict and generating quality reports is crucial. The laboratory test results affect approximately 60-70% of clinical decisions. Lab test results affect not only screening, diagnosis, prognosis and treatment, but also patient care. An integrated approach to Total Quality Management (TQM) is usually implemented as a cycle of the five Qs, which involves quality planning, high performance laboratory procedures, quality assessment, and quality improvement system of any laboratory committed to Good Laboratory Practice (GLP), encompasses all the activities in the laboratory that aim at providing accurate and timely reports. These activities are classified under structure, process, and outcome. Compliance means delivering relevant and appropriate medical aid as per the standards. The purpose is to ensure that all effective activities and processes are being executed properly, in a professional manner. The QAP system is implemented as a continuous process to monitor and evaluate every step of the lab's testing operation, from pre-analytical , analytical and post-analytical. A QMS consists of a Quality Assurance Program that provides a level of assurance and confidence that a service provided is up to the given level of quality.

In the **pre-analytical phase (pre-examination process**), clinical records are collected, examiners prepare and identify the patient, a primary sample is taken, transported to the laboratory, and analytical examination begins.

Processes related to the **analysis of samples (examination)**: Includes processing samples from the controls and patients.

During the Post-Analytical Phase (Post-examination processes), the exam results are reviewed, clinical materials are stored, samples are reviewed and the waste is disposed off, then exam results are formatted, released, reported and retained. The aim of quality assurance in clinical laboratories is also to identify the errors and the procedures used to detect and minimize them. According to many experts, 40% of errors occur during the pre-analytical process, 40% during the post-analytical process, and only 20% are during analytical processes. Periodic capture of QI helps to ensure effective implementation of QAP. Quality Improvement is defined as a method by which management, care, and support systems are monitored,

evaluated, and improved. A periodic assessment of the quality assurance process is necessary to monitor the shortcomings and improve the overall process. Thus, this study set out to gauge the prevailing QAP of the Clinical Biochemistry Laboratory in order to identify areas for improvement in terms of pre, examination and post-examination.

## AIM OF STUDY

In this we will examine the existing QAP (Quality Assurance Program) for the Lab and analyse the standard indicators across the phases of pre-analytical, analytical, and post-analytical phases.

## MATERIALS USED

In the this study, the Clinical Biochemistry Laboratory of a Multispecialty Teaching Hospital in Mysuru, Karnataka, India, carried out a retrospective analysis. A quality assurance and quality improvement study was conducted from January 2017 to December 2017 and No. JSSMC/IEC/07/01NCT/2018-19 serves as a letter of approval for institution-wide ethical clearance. During the evaluation of QAP implementation within the clinical biochemistry laboratory, three factors were considered: structure, process, and outcome. Categories and related sub-categories were drawn from literature, discussions with industry experts, and feedback from assessors. Adherence to the program was scored as fully compliant (score 10), partially compliant (score 5) and/or non-compliant (0). NABH and Health Care Providers rating system was used to develop this scoring pattern. This information was collected within the Rejection log, Critical alert log, Monthly redo's and Amended report log, QI log (all these logs were maintained by the clinical biochemistry laboratory as a component of the Laboratory data system (LIS). A Microsoft data analysis pack tool was used to examine the information collected.

## LITERATURE REVIEW, RESEARCH METHODOLOGY

Many practitioners of Quality Assurance Practices are routinely using the QAPs in their groups of diagnostic branches, especially labs that collect values in absolute quantities. The clinical biochemistry investigations account for more than one-third of all hospital laboratory exams. As the quality of laboratory testing and reporting is extremely crucial for the outcome of a health care delivery system, there is a high degree of dependence on laboratory results. A complete score of 290 is the result of evaluating the QAP within clinical biochemistry in terms of structure (maximum score assigned-130), process (maximum score assigned-130) and outcome (maximum score assigned-30). Infrastructure and equipment / personnel comprise the structure as it pertains to the essential resources. As part of this evaluation procedure, the checklist was constructed for infrastructure (adequate personal work spaces, ventilation, lighting and safety measures) and staff (credentialing and privileges), as well as equipment (kit installation, preventive maintenance, regular internal control measures and breakdown services). QAP included a well-defined "Quality Policy" pertaining to scope of services, laboratory personnel qualification, turnaround times, critical results, outsourcing, and lab safety, whose documentation had limited access for all technicians. All the quality procedures (SOPs) for collecting primary samples and operating the equipment as well as the experimental procedures were available and the documentation was adequate, according to the study. Written SOPs are periodically updated and screened. There were signboards and posters of the staff with contact information, scope of services, laboratory work flow, emergency codes, segregation of BMWs, hand washing, needle prick management, and quality policy displayed by the laboratory. As observed for this study, the laboratory fully met all the compliance criteria in this category (score of 10) and, therefore, received a maximum score of 130 in this category. An outcome is achieved by following the specified procedures and practices within the laboratory. A powerful and efficient Laboratory Data System (LIS) is available for clinical biochemistry labs; it is directly connected to the Hospital Data System (HIS). The equipment is periodically maintained and calibrated while all records are meticulously kept. In addition to daily IQCs and monthly QAPs, the records of these activities were carefully maintained and monitored. Laboratory safety precautions were adhered to during sample collection, equipment usage and experimental procedures according to the defined SOP. All the above parameters were therefore in full compliance (each scored 10/10). Aside from having qualified and trained staff, the technicians also

learned how to handle emergencies in hospitals (how to respond to hospital emergency codes) and how to manage biomedical waste. In addition, the adherence to those procedures was monitored using an internal checklist. As a result, the lab had full compliance in regards to training records. Clinical laboratory policy defined findings requiring the attention of a treating physician immediately and was well communicated to clinicians. As documented in the critical results alert log, critical alerts were communicated by telephone and text message. The data on the monthly have shown critical results is documented in the chart because the average time to inform the users of these critical alerts can also be shown. NABL ISO 15189 guidelines were followed for the release of all reports. Further, policies regarding sample rejection and amended reports recall were in place, and the details included within the registered databases. Thus, both of these parameters were fully compliant (score of 10/10, respectively). A TAT is the time from sample collection to report release. Individual laboratories define TAT based on stakeholder requirements. A monthly statistic of TAT was kept under a policy that defined various investigation times and had a mean of 93% of the criteria under the Process category adequately addressed (5/10). Despite the establishment of a Corrective And Preventive Action (CAPA) plan, preventive measures were not documented. Thus, the overall score under the "Process" category was 125 out of 130. The outcome category was determined by a number of parameters; the first, a comprehensive assessment of the quality of the services monthly, followed by periodic surveillance of results, and finally, a feedback survey from stakeholders (Doctors and Patients). An arrangement of periodic surveillance may be based on the requirement of stake holders, where structure, process, and results are evaluated in order to ensure improvement in the QMS overall performance. Quarterly, it was administered by the biochemistry department head. Evaluation of quality indicators and periodic surveillance were fully compliant within the outcome category, while feedback from stakeholders (patients and doctors) was partially compliant. Insufficient implementation of the feedback policy resulted in incomplete implementation of the policy, in which patients' feedback was collected, but doctors' feedback was not collected. Thus, the overall score under the "outcome" category was 25 out of a possible 30. Taking into account the functional phases of laboratory, the Quality Indicators were classified during the year 2017, An average of 70,370 investigations are performed in a month for the year 2017. The highest number of investigations are performed in July (90.318) and the lowest number are in February (59.514). Samples are collected, handled, and transported during the pre-analytical phase. Quality indicators of the pre-analytical

phase are evaluated from this point forward. A patient's care may be delayed and suboptimal if errors during this phase are not corrected. Since the study targeted quality indicators ranging from Quality indicator-1 to Quality indicator 3 a-h, subcategories were created. Testing was ordered with an incorrect request in QI-1. It is said to be that wrong requests are raised by mistake, confusion related to patient identification, test raised incorrectly, same test raised twice, and confusion with similar tests raised and the mistakes are reported on average 10 times per month, the highest number was reported in July (total 23). Using quality indicator 2, we analyse the number of requests with incorrect patient demographics, including incorrect name, age, sex, address, and wrong doctor/department details. The average number of requests with incorrect patient demographics is 30 per month, July had the largest number of requests with incorrect demographic information (35). This significant rise in the number of wrong requests (QI-1) and inappropriate tests requests (QI-2) is likely due to the remarkable number of investigations completed in July and accordingly a proportionate increase was observed. Sample collection, handling, and transport are basically included in QI-3 (3a-3h) Sample rejection was also indicated by 3a-3h. In laboratories, 46-68% of pre-analytical errors occur The total error rate in our study was 51% resulting from pre-analytical errors. As more than 50% of errors occur in pre-analytical phases, it is particularly critical that this phase is monitored closely because most of these errors can be avoided by providing adequate training to the phlebotomists, nurses, and other staff involved during sample collection and transportation. It is essential to ensure accuracy and precision of reports during the analytical phase, and this is accomplished through effective methods in Quality Indicators of Analytical Phase, Internal and External Quality Assurance Plans are included in the continuous quality assurance plan. Based on the number of unacceptable performances in the Internal Quality Control program and the External Quality Assurance Service program, the Coefficient of Variation plan was used to evaluate the performance altogether. The functional phase also encompassed equipment-related issues. In the survey, equipment issues ranging from minor issues for example: aspiration errors, tubing errors, water/cuvette quality issues, lamp failure to major equipment breakdowns based on a Root-Cause Analysis performed using an in-house troubleshoot checklist. In-house or external service engineers (in-house or company) maintained an equipment breakdown register to highlight the type of breakdown, the duration of downtime, and steps taken to resolve the issue. During the Post-Analytical Phase (QI 8-12), accurate, timely, reliable reports were released. Upon investigation, we observed that the lab had established

policies for TAT, amended report recall, and results alerts. In October, the adherence to TAT was at 88.25% (minimum) and reached 94% in May. In November, TAT improved from 88.25% in October to 90% after a reduction in downtime, as identified by the RCA. This reduction was caused by repeated and prolonged equipment downtime. Stakeholders agreed on critical alert parameters. As shown in a meta-analysis study performed by Wagar EA et al., across 163 clinical laboratories, this critical alert list was concurrent with the critical value alert system. A median number of critical value alerts was observed in the study of 539 (0.8%) per month. This study found that critical warnings were reported within 5 minutes on average to the care providers, which matched previous research that reported critical values within 1.5 to 8 minutes. Non-conforming results from previously released examinations are recalled, resulting in the release of the corrected examination reports as an "Amended Report". When a test result is corrected and updated upon finding conformities through its own procedures, the QMS or the clinician requesting the test. A typical number of amended reports was 7.6 per month in our study, similar to Valenstein PN et al, in which 1.5/1000 cases were amended. This is much less than that of other studies which comprised 60% of the entire amended reports. Typically, transcriptional errors were seen when technicians took manual entries for certain tests because the equipment was not implemented with the laboratory's existing information system.

| | | | Compliance (Score Achieved) | | |
|---|---|---|---|---|---|
| | | | 0 | 5 | 10 |
| **Category I = Structure** | | | | | |
| i. | Infrastructure availability | | | | √ |
| ii. | Adequate manpower and staffing | | | | √ |
| iii. | Quality policy:- | Scope of services | | | √ |
| | | Laboratory personnel qualification | | | √ |
| | | Turn Around Time | | | √ |
| | | Critical Results | | | √ |
| | | Outsourcing | | | √ |
| | | Lab Safety | | | √ |
| | | Reporting of results | | | √ |
| | | Quality Assurance Programme | | | √ |
| iv. | SOP for patient identification, preparation, collection, handling and disposal of samples | | | | √ |
| v. | SOP for equipment and experimental procedures | | | | √ |
| vi. | Signboards/Posters displaying the activities and services in the laboratory and the important contact numbers for communication at prominent areas | | | | √ |
| Score | | | 130 | | |
| **Category II = Process** | | | | | |
| i. | Availability of HIS and LIS tools | | | | √ |
| ii. | Periodic calibration and maintenance of equipment's record | | | | √ |
| iii. | Equipment's Calibration and traceability certificates | | | | √ |
| iv. | Daily Internal Quality Control Records | | | | √ |
| v. | Monthly External Quality Assurance Records | | | | √ |
| vi. | Documentation of corrective and preventive actions | | | √ | |
| vii. | Adherence to safety precautions checklist like infection control and laboratory waste management and periodic training for the same | | | | √ |
| viii. | Staff and Technician training records | | | | √ |
| ix. | Critical result alert log | | | | √ |
| x. | Rejection Log | | | | √ |
| xi. | Amended reports recall log | | | | √ |
| xii. | Adherence to Turn Around Time (TAT) | | | | √ |
| xiii. | Adherence to Standard reporting format | | | | √ |
| Score | | | 125 | | |
| **Category III = Outcome** | | | | | |
| i. | Monthly assessment of Quality Indicators | | | | √ |
| ii. | Periodic Surveillance of test results | | | | √ |
| iii. | Feedback from stakeholders | | | √ | |
| Score | | | 25 | | |
| Overall Scores | | | | 10 | 270 |
| Total Score | | | 280/290 | | |

| Sl No. | Phases | Subcategory | Parameters | Average/ month |
|---|---|---|---|---|
| I. | Pre-analytical | QI-1 | No. of test orders with wrong request | 10 |
| | | QI-2 | No. of requests with incorrect patient demographics | 30 |
| | | QI-3a | No. of unlabeled/ mislabeled samples | 0.6 |
| | | QI-3b | No. of samples with Incorrect Vacutainer | 1.4 |
| | | QI-3c | No. of venous samples for ABG | 22 |
| | | QI-3d | No. of samples-Haemolysed | 72 |
| | | QI-3e | No. of samples-Improper | 17 |
| | | QI-3f | No. of samples-clotted | 10 |
| | | QI-3g | No. of samples with insufficient volume | 17 |
| | | QI-3h | No. of samples collected at inappropriate time | 01 |
| II. | Analytical | QI-4 | No. of unacceptable performances in EQAS | 4.8 |
| | | QI-5 | No. of unacceptable performances in EQAS after correction with their previous samples | 0 |
| | | QI-6 | No. of parameters with CV >10% | 4 |
| | | QI-7 | Equipment related issues | 6 |
| III. | Post analytical | QI-8 | % of reports delivered outside TAT | 7.2 |
| | | QI-9 | % of critical values reported | 0.8 |
| | | QI-10 | Average time taken to communicate critical values in minutes | 5 |
| | | QI-11 | No. of reports issued with comments | 107 |
| | | QI-12 | Total No. of amended reports issued | 7.6 |
| | | | No of Amended reports due to transcriptional errors | 4 |

## CONCLUSION

Delivering relevant and effective patient care in accordance with standards is quality assurance. By measuring the efficiency of QI, it is possible to determine whether QAP is effective. In spite of the fact that setting up a typical protocol for capturing QI may sound daunting, it assists in improving our system of standard assurance while preventing us from future legal headaches. The QAP can be improved continuously by identifying the gaps within it. As a result of this study, the clinical biochemistry laboratory was able to assess and identify weaknesses within its quality management system. The present study contributes a basic checklist that can be easily incorporated for beginners working in smaller laboratories. The development of a more comprehensive full list of QI within the respective phases for a comprehensive assessment of QMS is needed in further studies. Furthermore, large-scale tests administered in various laboratories throughout the country should be conducted in order to develop a uniform and harmonized QMS program that can be used throughout the country by all clinical biochemistry laboratories.

Laboratory medicine is far more influential in terms of consistency and expense of health care as an entire since medical aid decisions are largely influenced by laboratory test results. Therefore, methods that mitigate test centre-related failures/ maximize the usage of laboratory tests may have a big impact on patient protection, care and intervention clinical deciding , health results, and costs. Quality management should consistently evaluate and develop essential tasks and job processes and their medical laboratory results. For the past 20 years , the standard control and development program within the medical laboratory has been largely acknowledged by the necessity of health professionals and therefore the general public. it's really critical for all healthcare professionals to stay the straightforward method of internal control within the lab, since this costs patients' lives and mortality and workers wellbeing and happiness. The results of effective internal control will improve the degree of health safety, satisfaction and protection and satisfaction of the workforce. Biological samples such as blood, body tissues, etc. are tested in medical laboratories and holds numerous toxic and radioactive material & hazardous hazards. The universal precaution to make sure safe and stable surroundings is suggested to all or any medical laboratory services providers. "Patient happiness is that the basis of quality" Quality assurance principles and statistics are often very complex.

However, all laboratories that conduct experiments need to understand and use language and fewer complex applications.

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