
Laboratory Management

Medical Laboratory Services (Laboratory results) are essential to all aspects of health care,and they should be:

• accurate

• reliable

• and timely

Note: 70% of clinical medicine decision making is predicated upon or confirmed by medical laboratory test results

If inaccurate results are provided, the consequences can be very significant, including:

1) Unnecessary treatment

2) Treatment complications

3) Failure to provide the proper treatment

4) Delay incorrect diagnosis

5) Additional and unnecessary diagnostic testing

Laboratory Management

The laboratory management task is to integrate and coordinate organizational resources to provide quality laboratory servicesas effectively and efficiently as possible.

Organizational resources include:personnel, equipment, money, time,and space

- Hence, management can be viewed as both a science and an art

- The successful management of a clinical laboratory today, like any other organization or institution, **requires the following:**

A. A wide range of skills

B. Built on strict principles of management science

— **Definitions management**

— **It is very difficult to give a precise definition of the term 'management'.**

1. Management involves the coordination and integration of resources to accomplish specific results

2. Management is a social process comprising a series of actions that lead to the accomplishment of objectives

3. Management is defined as "Getting from where we are to where we want to be with the least expenditure of time, money,and effort."

The definition contains four basic elements: Towards goals

The goals and objectives are aligned with the efficient delivery of laboratory services

 Through people

Directing 'leadership and direction' in a way in which professional laboratory technicians feel a sense of responsibility

 Using techniques

Material resources such as laboratory equipment, computers, etc.

 In an organization

In organizational units, it means a division of labor, protocols, procedures, and functional processing units

Managerial Duties and Responsibilities

1- The manager directs the affairs of the organization by setting goals and priorities which define the direction that the organization will take

2- The administrator manages or manages an organization within the framework of the various directions and policies given to him

3- He is not the one who sets bigger goals, but he is a technician who knows how to make the organization move efficiently to achieve its goal

4- A manager is responsible for managing or supervising the performance of an activity to achieve a specific goal or purpose

5- Oversees activities of others to help them accomplish specific tasks or efficiently perform scheduled activities

Laboratory managers are entrusted with three categories of resources (inputs): -

 Financial operating and capital budget

 Physical space, equipment, and supplies

 Human technical and support staff

A distinction of three levels in the management team of the laboratory

— Laboratory directors and administrators

 Retain ultimate responsibility in achieving goals,e.g.,changesin technology, capital investments, and services rendered are finalized by this level of laboratory management

— **Laboratory managers or chief technologists**

 They create and maintain an environment for laboratory professionals to function efficiently.

 They plan, organize, direct, and control jobs.

— **Laboratory supervisors**

 They focus on people and operational delivery of laboratory services.

Safety in laboratories

Microbes transmitted through the blood

They are the microbes that are found in human blood, tissues, or fluids, which may cause disease to humans, and these disease-causing bodies include "but are not limited to" hepatitis virus type (B) and hepatitis virus type (C)), And human immunodeficiency virus (AIDS).

Containment

It means using safe methods to deal with the pathogens of infection in the vicinity of the laboratory, where they are received and kept. **The purpose of containment** is to reduce or eliminate the exposure of workers within the laboratory, other people, and the environment to potentially hazardous agents. An example of containment is a centrifugal safety vessel, a closed container that prevents the escape of airborne spray during the centrifugation process.

Initial containment

Well-maintained biological safety cabinets are used and prefer the second category as well as other appropriate personal protective equipment and physical control devices in the **following cases:**

A. When performing laboratory procedures that may result in types of infectious aerosols, this includes the operations of concentrated expulsion, grinding, mixing, shaking operations, strong mixing, the opening of containers containing infectious substances whose pressure may differ from the surrounding pressure, and the operations of removing infected tissues taken from animals The embryo-forming eggs.

B. When infectious substances are used in large quantities or high concentrations. These materials can be introduced into centrifugation processes, and it is required to open these covers or safety containers that this be inside the biological safety cabinets

Remove pollutants

The removal of pollutants is a step that needs to be done regularly. It involves eliminating bacterial agents in microbiological laboratories and stopping their influence to protect workers in the laboratory and prevent contamination of laboratory procedures.

Cleansing

It is the use of antimicrobial agents on inanimate objects such as work surfaces, equipment ... etc., to eliminate all microbes that represent a potential danger to humans or threaten the experiment's safety.

Laboratory Biological Safety Plan (Lab)

It is a written document in which the risks that may be exposed to and all procedures, equipment, and constructions required to limit or reduce the exposure of laboratory workers to infection-causing agents or dangerous biological materials are recorded.

Dealing with sharp instruments and how to get rid of them

 Sharps such as scalpels, needles, and syringes (syringes) must be placed in the containers designated for this. It is forbidden to bend single-use needles after use, and it is not permissible to pull them out, break them, re-cover them or separate them from syringes (syringes) that are disposed of after use. It is also not permissible to handle it with your hands before disposal.

However, the best way to get rid of them is by placing them in non-porous containers placed in appropriate places, used specifically for the purpose of disposing of sharp instruments.

 The syringes should be completely disposed of after use.

 The greatest measure of precautionary measures must be taken when dealing with contaminated sharps such as needles, syringes, glass slides, droppers, capillaries, and scalpels. Plastic or coated capillary tubes should be used.

 It is forbidden to handle broken glassware directly by hand. Rather, it should be disposed of by mechanical means.

Waste disposal

 The waste (non-sharp) contaminated with materials produced by the human body is disposed of by placing it in penetration-resistant garbage bags.

 Labels of all types of waste must be attached.

 Liquid samples such as blood and urine should be sterilized and disposed of. And when necessary, bacterial cultures and infectious agents can be disinfected by adding chlorine at a concentration of 0.5% for a period of ten minutes before they are finally disposed of.

 You must follow the instructions issued by the Ministry of Health regarding how to dispose of medical wastes.

 The wastes that have been sterilized by steam can be disposed of along with other ordinary wastes.

 Human excreta, such as urine and stool samples, can be disposed of via sewage or toilet.

 Labeling materials used to grow samples, additives (reagents), and samples must be labeled. In addition, the waste must be placed in special containers that indicate its quality and the potential risk of infection.

 Cultures, tissues, and samples were taken from body fluids and placed in a container with a lid that prevents leakage during collecting, treating, storing, or transporting these materials.



Disinfection and sterilization operations

 Work surfaces should be disinfected with a dilute chlorine solution, and this is done routinely upon completion of work or spillage of any potentially infectious substance.

 Medium level disinfectants are used to disinfect surfaces in laboratory (laboratory) areas. Examples of these antiseptics are: dilute bleach solution, ethyl alcohol, isopropyl alcohol, phenol, or iodophor, which are used for sterilization purposes and are not intended for skin disinfection.

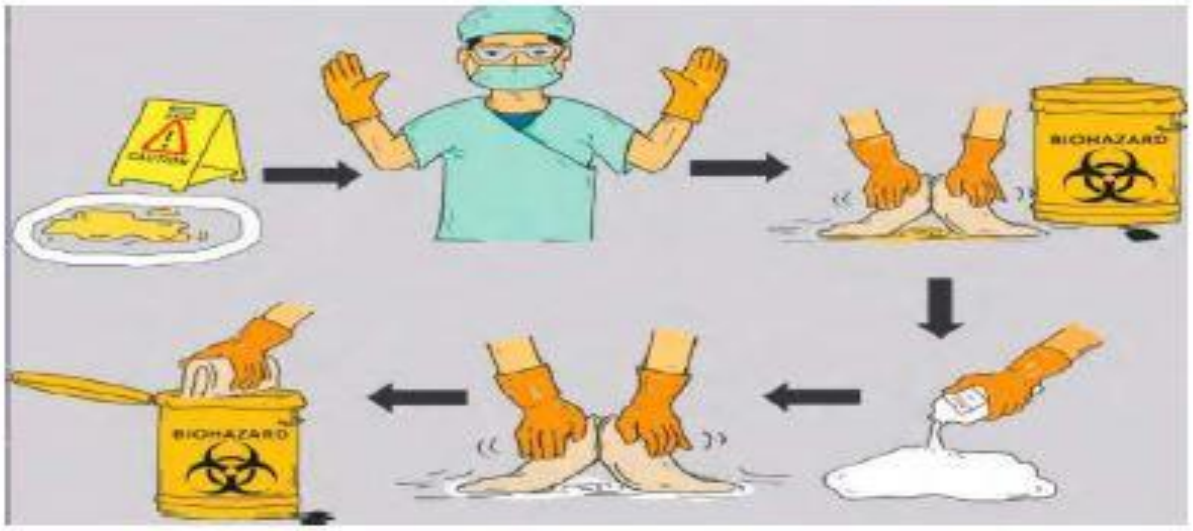
 Labels must be placed on containers containing hazardous materials

Procedures for cleaning up spilled materials in the laboratory

The laboratories must follow advanced procedures to deal with spills in the laboratory, and the laboratory should have a bag (or any container) containing the materials needed to cope with spills in the laboratory, which are: concentrated disinfectant (such as bleach or iodophor), a box of drying papers, pieces of sponge, gloves, Household rubber, tweezers to capture broken glass, and sterilization container.


SPILLAGE
الإسكابات السمية


BLEACH


CAUTION
BIOHAZARD
BIOHAZARD

Specimens handling

Introduction :_

Procedures for collecting, preserving, and transporting of specimen sufficiently stable to provide accurate and precise results suitable for clinical interpretation. Examples Biopsy; Blood Specimen Collection; Dissection; DNA typing ; Paracentesis; Urine Specimen Collection , if not handled safely, can pose a risk of infection to all people involved, including healthcare workers, patients, transport personnel and laboratory workers. Accurate analysis is crucial in determining the correct diagnosis, or detecting an infectious agent, so that appropriate and timely treatment can be given.

Prior to specimen collection, review the specimen requirements for each procedure. The accuracy of laboratory testing depends on careful patient preparation, collection, handling, storage and transportation of specimens.

Collection of specimens :- Always follow standard precautions when handling specimens

• Write details on the container immediately after taking the specimen, then place into the transport bag with the request form attached.

• Wherever possible take the specimen prior to commencing antibiotics.

• Where appropriate collect the specimen using sterile equipment and place in sterile containers. Ensure the outside of the container is free from contamination with body fluids.

• When taking swabs from a dry area i.e. nasal screening, the tip should be moistened in sterile normal saline.

• Do not over fill containers.

• Ensure the lid is immediately secured to prevent spillage in transport.

Labelling Specimens :- must be labelled correctly to prevent misdiagnosis and wastage. All specimens and microbiology forms must be clearly labelled with the correct patient details which include• Patients full name • Patients address

• Patients sex

• Date of birth

• NHS number

• Relevant clinical details e.g. type of specimen, any clinical symptoms, description of a wound, medical conditions e.g. diabetes

• Date and time of specimen collection •

Signature (unless electronic) and Destination for report

• Relevant medication history e.g. antibiotic history, date of collection, physician name and address, and clinical diagnosis .

High risk 'biohazard' specimens

High risk micro-organisms in hazard group 3 include;

• Tuberculosis (TB)

• Human Immuno-Deficiency Virus (HIV)

• Hepatitis B Virus (HBV)

• Hepatitis C Virus (HCV)

• Hepatitis E

• *E. coli 0157*

• *Salmonella typhi/paratyphi* (typhoid/Paratyphoid)

• Rabies

• Anthrax

• Prions

• Avian influenza e.g. SARS This list is not exhaustive , MRSA is not a high risk micro-organism.

Information on Turn Around Time (TAT): The TAT test information sheets is an estimate that may vary for some tests or during public health emergencies, outbreaks or exigent circumstances. The TAT does not apply to tests added on to existing specimens or on hold awaiting information to continue testing. The TAT for tests sent to reference laboratories is dependent on the reference laboratory testing schedule and timing. Test Information Sheets specify the type of container or collection kit that should be used to collect the sample

Storage specimens

Place the specimen in the biohazard bag and seal the bag.

Insert the completed requisition in the pocket on the outside of the sealed biohazard bag.

Most specimens should be stored between 2-8°C. Specific handling/storage information is included in the test-specific Kit

Specimen Containers

Testing accuracy depends on careful collection in the appropriate containers that will provide sufficient specimen. Listed below are the containers that are provided for collection.

Stopper Color	**Anticoagulant**	**Specimen Type**
Red	None	Serum
Red mottled	None; contains gel separator	Serum
Gold	None; contains gel separator	Serum
Pearl	EDTA	Plasma
Royal Blue	None	Serum
Yellow	ACD solution A	Plasma/whole blood

Culturese /Transettes

A sterile, disposable culture collection and transport system consisting of a plastic tube that contains a single or double rayon tipped swab and the appropriate transport media which will prevent drying of bacteria and maintain the proper pH. The following is a list of general guidelines for collection of microbiology cultures:

1- Observe the expiration date and the condition of the package, using only unexpired, unopened and undamaged collection and transport systems.

2- Collect an adequate amount of specimen with as little contamination from indigenous microbiota as possible to ensure the sample will be representative of the infected site.

3- After the specimen is collected, insert the swab into the plastic tube avoiding contamination with the external surface of the tube.

4- Label the outside of the specimen container with a patient last name and first name and a patient-specific identifying number (preprinted requisition label, social security number or date of birth).

- Indicate source of culture on requisition. ٥

<u>Specimen Packaging and Transport</u>

We would like all clients sending specimens to us to adopt a uniform specimen packaging procedure. In order to ensure the safety of our couriers, and to make our processing workflow as streamlined and trouble-free as possible, we ask that you follow these guidelines:

- All specimens should be contained in sealed plastic specimen bags.

The specimen bags should display the biohazard logo. -

-Each specimen bag should contain only one patient's specimen(s).

- Each specimen should be accompanied by the corresponding requisition sheet, folded and placed in the outside pocket of the specimen bag.

CRITERIA FOR SPECIMEN REJECTION

The following are criteria with which specimens will be rejected by the Clinical Immunology Laboratory:

1. Any blood or specimen not labeled properly. Proper labeling required by law consists of patient's first and last name, date and time drawn, physician and referring clinic.

2. Green top (heparin tubes) older than 48 hours, /if the viability is less than 80%, the specimen will be rejected.

3. Green top tubes received on ice. All green top tubes must be transported and stored at room temperature.

4. Grossly hemolyzed serum (red top tubes).

5. Blue top tubes not transported or stored on ice. Shipped citrated plasma (blue top tubes) will be rejected if not shipped frozen on dry ice.

6. Improper tubes sent for tests ordered.

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Thesis vs. Research Paper.

The thesis is a document which is written by students about higher education to gain an academic degree or qualification. While Research paper is a piece of academic writing, usually used as a requirement for a class. In research, you have to do independent research.

Both of them are academic writings. They both are having a similar internal structure like both containing:

1. introduction,

2. research methodology (Methods),

3. data analysis (results or findings),

4. interpretations (discussion),

5. conclusions,

6. etc.

but differ by:

1. purpose,

2. style of writing,

3. specific components.

There are many differences between the thesis and research paper:

1. The thesis is related to the statement of central questions or arguments of scholars which leads to further research, while a research paper is about to prove that central argument. It should mention and include all the main points that the research paper wants to address.

2. A thesis is much longer and takes up to years to complete while research papers are shorter and may take a few weeks or a month to complete.

3. The thesis should be the length, approximately 100–130 pages. While the research paper should be the length, one or more pages.

4. A thesis works towards interpreting data for proving or disproving the hypothesis. While a research paper analyses a single thesis statement from all possible angles.

5. Completing a thesis will get you a degree in itself. While research papers are a part of the coursework, usually completed for partial fulfillment of a degree.

6. The thesis may have more than one research goal while research papers have a single research goal.

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Thesis contents: It is prepared within a general structure that contains the following paragraphs:

1. English title

2. Quran verse

3. Certifications

4. Dedication

5. Acknowledgements

6. Summary (or Abstract)

7. List of Contents

8. List of Figures

9. List of Tables

10. List of Abbreviations

11. Chapter One: Introduction

12. Chapter Two: Review of Literature

13. Chapter Three : Materials and Methods

14. Chapter Four : Results and Discussion

15. Chapter Five : Conclusions and Recommendations

16. Chapter sex : References

17. الخلاصة صفحة باللغة العربية

18. العنوان صفحة باللغة العربية

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Notes about: How to write graduation research for fourth-year students

1. Do not place decorations in the frame of writing pages or on the search interface

2. The writing is in Times New Roman font, size 14.

3. commitment to side margin so that it does not exceed one and a half inches from the left and one and a quarter from the right.

4. The space between one line and another should be 1.5.

5. Indexing and numbering of search contents

6. The reference in the research are written in the manner of (Name and year) according to the following model:

Hepatitis B virus is a member of the *hepadnaviridae* virus family. The virus particle consists of an outer lipid envelope and an icosahedral nucleocapsid core composed of protein (Le, 2014).

During the early phase of viral infections, the production of pro-inflammatory cytokines and interferons (IFNs), besides the activation of natural killer (NK) cells and frequently observed (Zhang and Lu, 2015).

The hepatitis B viral genome is present in infectious particles in the form of 3.2kb partially double-stranded, relaxed circular DNA (rcDNA). Following infection, the virus gains entry into hepatocytes via its receptor, the human sodium taurocholate co-transporting polypeptide (NTCP), The viral genome is uncoated in the cytoplasm, then transported to the nucleus where the rcDNA is converted to covalently closed circular DNA (cccDNA), (Makokha *et al.*, 2019).

7. Writing the reference to references chapter as follows:

Le, V. (2014). Safe Blood Transfusion: Screening for Hepatitis B and Hepatitis C Virus Infections in Potential Blood Donors in Rural Southeast Asia.

Zhang, E., and Lu, M. (2015). Toll-like receptor (TLR)-mediated innate immune responses in controlling hepatitis B virus (HBV) infection. Medical microbiology and immunology, 204(1), 11-20.

Makokha, G. N., Abe-Chayama, H., Chowdhury, S., Hayes, C. N., Tsuge, M., Yoshima, T., Ishida, Y., Zhang, Y., Uchida, T., Tateno, C., Akiyama,

R., and Chayama, K. (2019). Regulation of the Hepatitis B virus replication and gene expression by the multi-functional protein TARDBP. Sci Rep, 9(1), 8462.

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The principles of research:

A scientific method of gathering and evaluating data to solve a problem is what we mean when we say research. The invention of new ideas generally comes from the process of research. Therefore, research is conducted by following the scientific method employed when trying to solve a problem.

The four basic principles of research are classified as autonomy, beneficence, non-maleficence, and justice. **The research principle of autonomy** determines the right to agree or disagree with the research, and the patient's healthcare methods need to be decided. **The research principle of beneficence** demonstrates the researchers must act in the welfare of the participants or patients. **The research principle of non-maleficence** determines to encourage more suitable rather than causing harm to the participants or patients. And finally, **the research principle of justice** indicates the uniform distribution of treatment. The principles of research are related to the concepts of ethical research. There is a consideration for the potential benefits to society and the dignity and safety of participants and patients taking part in the research.

All research studies are different, but some factors are standard to all good pieces of research. Following are the 13 principles of good research work which must observe to guarantee quality:

1. Objectivity: The objective of research work needs to be clearly described, and common precepts are used.

2. Use of scientific process: The research process must be explained in detail, allowing other researchers to repeat the research systematically.

3. Planning: The design needs to be prepared scientifically, and all aspects of resources, periods, constraints, and procedural factors are considered.

4. Continuity: The study has to be conducted in a way that the principle of continuity is guaranteed.

5. Integrity: The researcher must document weaknesses in procedural design with complete frankness and assess their impact on the results.

6. Reliability: The validity and reliability of data need to be examined with care.

7. Adequacy of Data: Data analysis must be sufficient to disclose its significance, and the approaches to analysis employed must be suitable.

8. Structure: This would mean that research is organized with the particular sequence as per the well-defined set of rules. Guessing and intuition in arriving at conclusions are discarded.

9. Logic: This means that the rules of logical reasoning well guide research, and the logical process of induction and deduction is used.

10. Empiricism means that research is connected to one or more facets of an actual situation and deals with concrete data, which gives a basis for the external validity of research outcomes.

11. Replicability: This principle enables research outcomes to be validated by replicating the research, thus creating a sound basis for the decision.

12. Economics: Research must be completed within the allotted financial resources

13. Time-frame: Frame research needs to be finished in the established time frame.

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The research process:

The Research Process is a process of multiple scientific steps in conducting the research work. Each step is **interlinked with other steps**. The process starts with the **research problem at first**. Then it advances in the **following steps sequentially**. Generally, a researcher conducts **research work within eight steps**. In research work, primarily, you require a Research Proposal. It is because the proposal approves the research project whether you achieve the ability to conduct research or not. So when you write a research proposal, present the detailed plans and specific objectives of your study correctly.

Steps of the research process:

The research process consists of actions or steps necessary to effectively carry out 9ioresearch and the desired sequencing of these steps. It consists of the **eight-step model** for researching according to **three-phase**:

A. phase i: deciding what to research

step i formulating a research problem

B. phase ii: planning a research study

step ii conceptualizing a research design

step iii constructing an instrument for data collection

step iv selecting a sample

step v writing a research proposal

C. phase iii: conducting a research study

step vi collecting data

step vii processing and displaying data

step viii writing a research report

The pilot study:

What is a pilot study

It is a small-scale preliminary study conducted to evaluate feasibility, time, cost, adverse events, and effect size (statistical variability) to predict an appropriate sample size and improve upon the study design before performing a full-scale research project. General guidelines, for example, use 10% of the sample required for a complete study.

Reasons for conducting pilot studies:

1- eliminate some variables to reduce the time of the interview

2- select appropriate sample

3- model of interview

4- estimate the time needed

5- assessing whether the research protocol is realistic and workable

6- to find potential difficulties

Introduction :- The introduction is the first chapter of your thesis (dissertation) and appears right after the table of abbreviations. It's essential to draw the reader in with a strong beginning. Set the stage for your research with a clear focus, purpose, and direction.

It is the primary paragraph in the scientific paper (thesis) that describes the research, and **it must highlight:**

1. Research question,

2. Its importance,

3. Review the historical background of the study,

4. Previous research in the scientific field in which the research is written,

5. It should review other methods and research conducted in the same context,

6. To the search itself and what it offers.

Therefore, the style for the first chapter consists of the following:

1. Introduction, when written, consists of **three main sections**:

A. The problem

B. The effect in general

C. The effect in special

1.1 Aim of the study

When choosing aims, you must select aims that differ from the aims of previous studies

highlight abstract is specifically written to attract the reader's attention to the study. No pretense is made of there being either a balanced or complete picture of the paper and, in fact, incomplete and leading remarks may be used to spark the reader's interest. In that a highlight abstract cannot stand independent of its associated article, it is not a true abstract and, therefore, rarely used in academic writing.

The abstract SHOULD NOT contain:

• Lengthy background or contextual information,

• Redundant phrases, unnecessary adverbs and adjectives, and repetitive information;

• Acronyms or abbreviations,

• References to other literature [say something like, "current research shows that..." or "studies have indicated..."],

• Using ellipticals [i.e., ending with "..."] or incomplete sentences,

• Jargon or terms that may be confusing to the reader,

• Citations to other works, and

• Any sort of image, illustration, figure, or table, or references to them.

Laboratory Techniques and Procedures Methods, procedures, and tests performed in the laboratory with an intended application to the diagnosis of disease or understanding of physiological functioning. The techniques include examination of microbiological, cytological, chemical, and biochemical specimens, normal and pathological. Disinfection and sterilization are essential for ensuring that medical and surgical instruments do not transmit infectious pathogens to patients. Because sterilization of all patient-care items is not necessary, health-care policies must identify, primarily on the basis of the items' intended use, whether cleaning, disinfection, or sterilization is indicated

Sterilization: Sterilization describes a process that destroys or eliminates all forms of microbial life and is carried out in health-care facilities by physical or chemical methods in anther mean The process of killing or removing bacteria and all other forms of living micro-organisms and there spares from preparation Essential concept in the preparation of sterile pharmaceutical products

Important of sterilization

Medical Sterilization: 1-Prevents the Growth of Diseases

In any medical tool/device used, bacteria come onto it. If left unchecked or not disinfected properly, it is highly likely that bacteria will grow.

2-Prevents the Spread of Diseases: - If surgical equipment is not properly sterilized, patients treated are exposed to a disease the previous patient had.

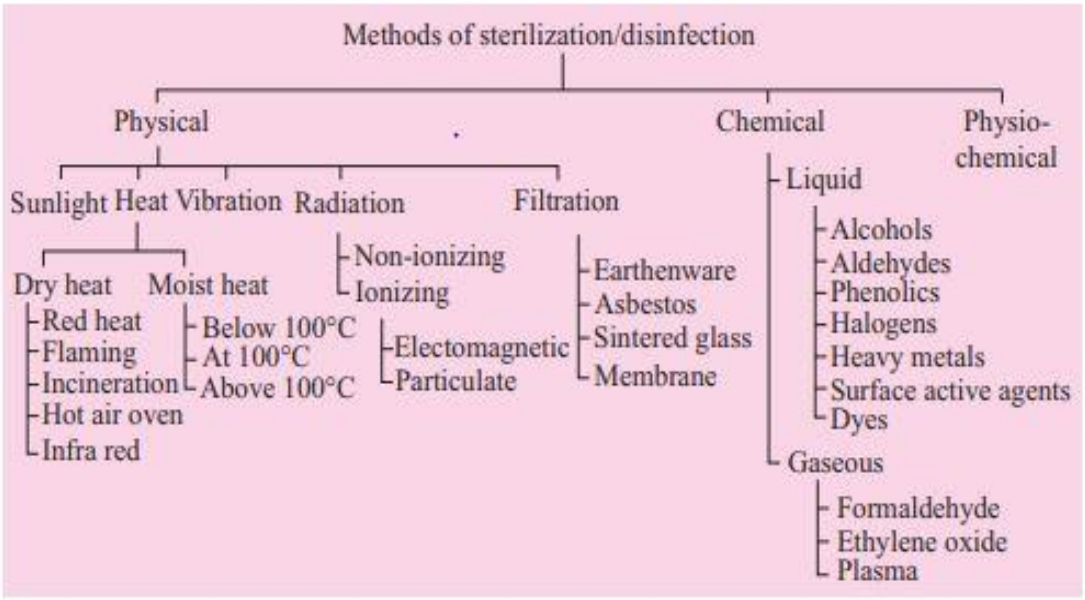
3-Prevents Double Surgeries:- If unsterilized equipment is used, it can cause an infection leading to another surgery later on in order to remove it. This is costly and can cause many life-threatening complications.

METHOD OF STERILIZATION

1. Physical method- a) Dry heat sterilization b) Moist heat sterilization c) Sterilization by radiation (gamma radiation)

2. Chemical method a) Gaseous sterilization b) Sterilization by disinfectant

3. Mechanical method Pass through bacteria-proof filter



Sl. No.	Physical Method of Sterilization	Instruments used
1	Dry Heat	Oven
2	Moist Heat	Autoclave
3	Radiation	Gamma-ray Chamber

DRY HEAT STERILIZATION

Instrument- OVEN : -specially designed instrument - electrically heated and thermostatically controlled. Expose at 160 ºC for 1 hour. Advantage it is suitable method for sterilization of substances destroyed by moisture. Disadvantage long heating time, high temperature.

MOIST HEAT STERLIZATION

Instrument AUTOCLAVE Heating process in autoclave - saturated steam under pressure is allowed to penetrated through materials for 15 minutes and temperature 121º c.

Advantage microorganism are killed most efficiency in lesser time due to high pressured saturated steam Disadvantage unsuitable for materials not withstanding temperature of 115ºC or more during heating

STERELIZATION BY RADIATION

Two techniques involved:

* Alteration of chemicals lead to form new compound in cells destroying the micro-organism itself

* Vital structure like nuclear protein are destroyed killing the micro-organism. e.g., Co-60 - used for gamma ray sterilization process. Gamma

rays – ∗ generally obtained from radio isotope(Co-60) during disintegration of unstable atoms , ∗ kill micro-organisms by isolating atoms of essential substance of cells present in them.

ADVANTAGE 1. No significance rise in temperature 2. Continuous process due to short exposure time.

DISADVANTAGE 1. May lead to color change. 2. Solubility of preparation leading to decomposition of certain materials.

CHEMICAL METHOD

Gaseous sterilization- ∗ Ethylene oxide used. ∗ Special type of chemical sterilization using gases and vapour ∗ The gas used is safe & non-inflammable. ∗ Now-a-days, ethylene oxide most widely used gaseous sterilization agent in medical science

Advantage: 1. It has penetration power quite useful for sterilizing surgical instruments (such as catheter, needles, plastics, disposables)

Disadvantages: 1. Very slow sterilization process 2. Very costly equipment

DISINFECTION

Decontamination - removal of microorganisms contaminating an object

Preservation - preventing methods of microbes-caused spoilage of susceptible products(pharmaceuticals, foods)

∗ Sanitization - removal of microbes that pose a threat to the public health, food industry, water conditioning θ sanitizer-an agent, usually a

detergent, that reduces the numbers of bacteria to a safe level, the disinfectants include

∗ Chemical agents ∗ Alcohols, aldehydes, halogen, phenols, surfactants, heavy metals ♣ e.g., ethylene oxide – most commonly used for sterilization ∗ Advantages: 1. Widely used in hospitals for materials that cannot withstand steam sterilization

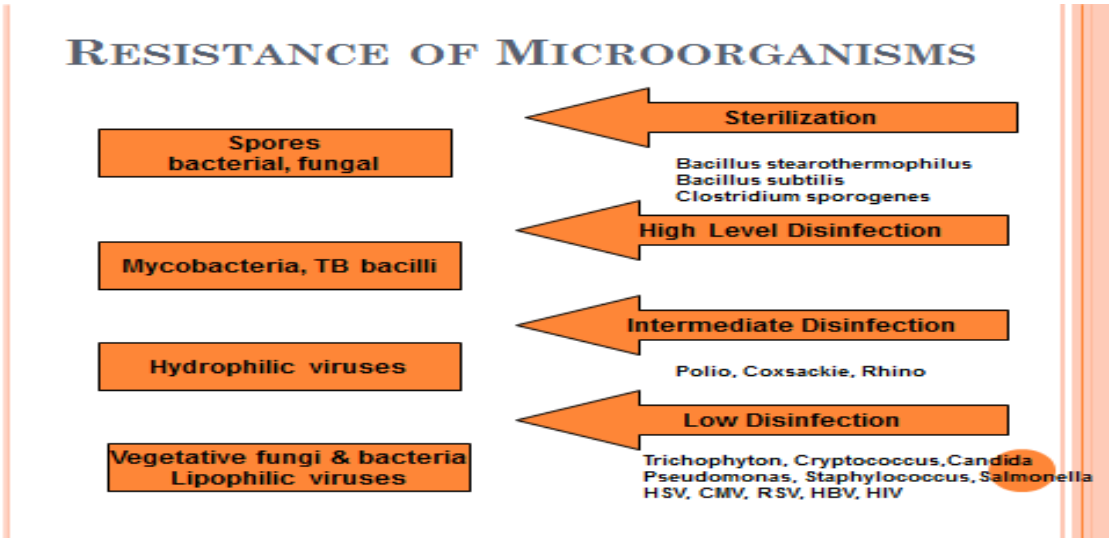
∗ Disadvantages 1. 40-60% humidity in sterilizing chamber

MECHANICAL METHOD

The solution to be sterilized is passed through depthfilter or screen-filter which includes

∗ Particulate filters ∗ Microbial filters ∗ Final filter ∗ Pharmaceutical solutions are sterilized by this method. ∗ The micro-organism are physically removed by absorption on the filter medium or by mechanism.

∗ Filtration filling and sealing processes are under a septic condition. ∗ Sterilization test must be done.



Tyndallization

Tyndallization (Fractional Sterilization). Heat labile media like those containing sugar, milk, gelatin can be sterilized by this method. Steaming at 100°C is done in steam sterilizer for 20 minutes followed by incubation at 37°C overnight. This procedure is repeated for another 2 successive days. That is 'steaming' is done for 3 successive days. Spores, if any, germinate to vegetative bacteria during incubation and are destroyed during steaming on second and third day. It leads to sterilization.

Indicators	Sterilization Methods	Principle	Device	Parameter monitored
Physical	Dry heat	Temperature recording charts	Temperature recording charts	Temperature
Chemical	Dry heat	Temperature sensitive coloured solution	Browne's tube	Temperature, Time
		Temperature sensitive chemical	A temperature sensitive white wax concealing a black marked	Temperature
Biological	Dry heat	Temperature sensitive microbes	Bacillus subtilis	D value

Laboratory premises

Objectives:

1. General design objective

2. Laboratory type and classification

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The primary goal in laboratory design is to provide a safe and accessible environment for laboratory personnel to do their work. The secondary goal is to allow for maximum flexibility for safe research and teaching use. Therefore health and safety risks must be anticipated and assessed carefully so that protection measures can be taken and incorporated into the design wherever possible.

Laboratory or factory : It is a place specially prepared for studies and experiments (for all scientific branches) for research, scientific preparations, discoveries, analyzes, or all activities .

Laboratories are usually located in scientific facilities such as schools, institutes, colleges and universities, as well as in hospitals, health centers, research centers, and research institutions in addition to government agencies that are concerned with monitoring and investigation procedures and providing recommendations such as police stations, quality control, food control and customs ports.

Types of laboratories

Laboratories require a deep understanding of the specific needs, purposes and risks associated with each of them. Some of these requirements are specific to an industry (e.g. pharmaceutical, chemical), or to an activity (e.g. small volume manufacture of high potent products, work with biological agents).

1. Analytical and Quality Laboratories

In analytical and quality laboratories products and materials are tested against conformity to specifications and the absence of impurities. These laboratories form an essential component within the production and the supply chain.

2. Biosafety Laboratories

The purpose of biosafety laboratories and suites is the containment of potentially harmful biological agents. The containment is achieved through a thoughtful combination of methods, facilities and equipment. The levels of containment go from BSL1 to the highest level of BSL4.

3. Cleanrooms

In cleanrooms the number of dust particles permitted per volume of air defines the classification of the clean room. All aspects of the people and materials flows, the mechanical systems and the room finishes are to be consistent with each other. The design and engineering needs to follow either “ISO 14644-1” – “FED STD 209E” – “BS 5295” or “GMP EU” classification.

4. Clinical and Medical Laboratories

These laboratories are equipped for diagnostic tests on tissue, blood and other patient samples. They can be subdivided into various processes such as pathology, serology, histology, virology, bacteriology and molecular biology with PCR-technologies.

5. Incubator Laboratories

Laboratories conducting microbiological, and cell or tissue culture work require incubators to protect these cultures from the environment. Parameters such as temperature, humidity, and O2 and CO2 levels need to be controlled.

6. Production Laboratories

Pilot production or small volume laboratories as a scale-up between R&D and commercial production, or for the production for clinical trials, form a category on their own. Such laboratories can be found in the pharmaceutical, biotech, and the science and technology sectors. Quite often special attention needs to be given towards containment and air quality.

7. Research & Development (R&D) Laboratories

This category covers a broad spectrum of laboratories with various risk qualifications and containment requirements such as: Bio Safety Laboratories, laboratories with radio-active risks etc. Also specialized laboratories for life sciences research are part of this category.

Biosafety levels

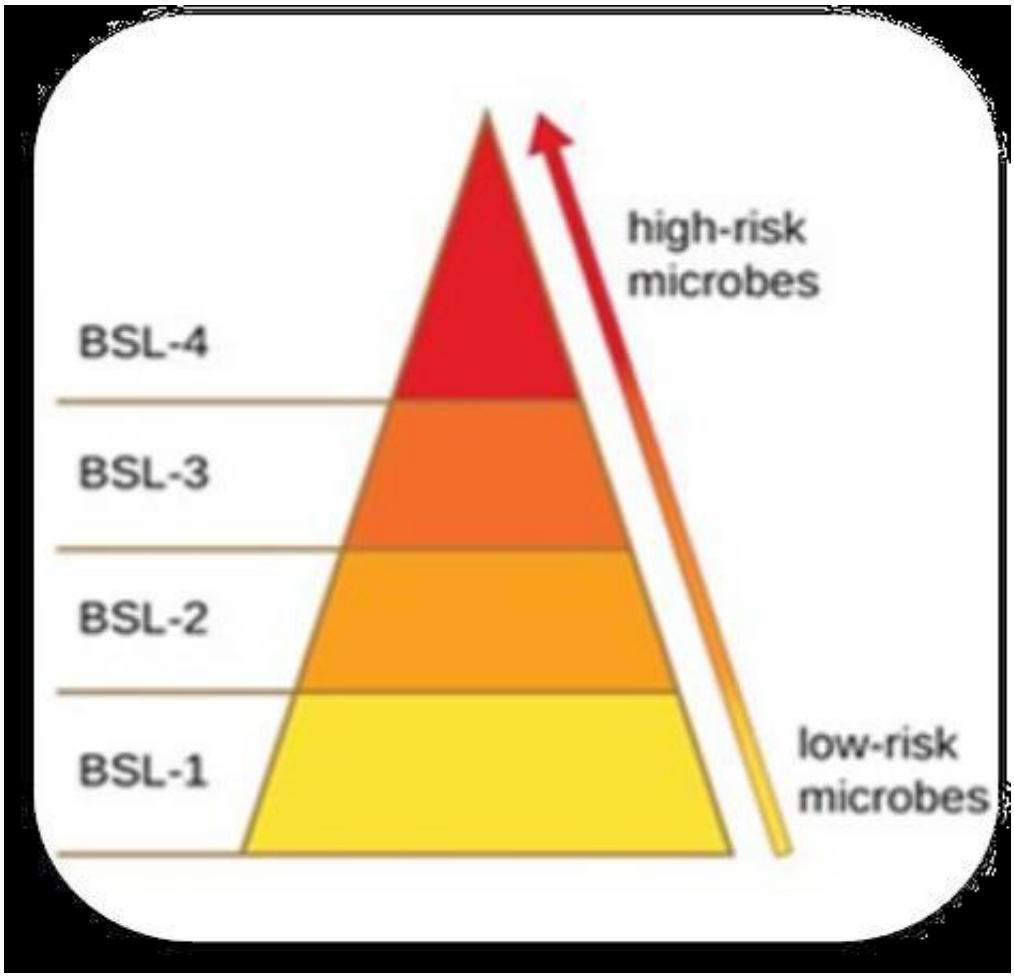
Biosafety levels (BSLs) are a combination of technical and activity laboratory machinery, safety equipment, and laboratory equipment suitable for conducting experiments (classification is based on hazards and possibilities arising from handling dangerous substances and infectious pathogens.

1. Safety Level I (BSL1) is appropriate when dealing with non-pathogenic agents of healthy individuals, which represent the lowest risks to laboratory personnel and the environment. Such as isolating and diagnosing microorganisms that do not cause any disease to humans or are of low risk and cause environmental damage only (E. coli).

2. Safety Level II (BSL2) is designed to deal with microbial pathogens of medium risk to humans and the environment, as it includes dealing with bacterial and viral agents that cause mild or moderate diseases to humans or pathogens that are not transmitted through inhalation or contact with them such as hepatitis A and B.

3. Safety Level III (BSL3) This level is usually intended for medical applications such as laboratory diagnosis and scientific research, or to work with agents that may be dangerous or fatal, that is, cause harmful diseases to humans after inhaling them, such as *Mycobacterium tuberculosis*, *Leishmania donovani and yellow fever virus*.This type of laboratory needs people with experience and culture in dealing with deadly pathogens,

where the work is under the supervision of specialized researchers, and the work area here is called the **warm zone.**



4. Safety Level IV (BSL4) is working at this level with microorganisms that cause serious or fatal diseases that are transmitted through breathing or obstruction, and that cannot be treated or vaccinated against, such as the Ebola virus.

Conditions and specifications of laboratories:

1. The quality of the laboratory and the tests must be determined, and the work area must be wide.

2. The air-conditioner must be designed to permanently pass air from outside the laboratory into it.

3. Laboratory rooms must be equipped with fans to draw air with special filters.

4. A special room must be provided for sterilizers to sterilize farms, blood samples and biological wastes.

5. A private pharmacy must be provided in the laboratory for the purpose of first aid and laundries.

6. A non-combustible construction is preferred

Classification of research

1. Descriptive studies.

A. Case reports and case series.

B. Correlation studies.

C. Cross-sectional studies.

2. Analytic studies:

A. Observational studies:

i. Case-control study.

ii. Cohort study.

B. Interventional (experimental)studies.

Second: Analytic studies

A. Observational studies:

i. Case-control study.

 The basic premise of analytical epidemiology is that disease does not occur randomly but rather undescribable patterns that reflect the underlying etiology.

 Consider **two groups:** everyone has the disease of interest (**cases**) and a comparable one in which everyone is free of the disease (**controls**).

Strengths:

1. It is relatively quick and inexpensive compared with other analytic designs.

2. It is particularly well suited to evaluatingdisease with a long latent period.

3. It is optimal for the evaluation of rare diseases.

4. It Can examinemultipleetiological factors for a single disease.

A limitation

• is inefficient for assessing occasional exposure

• cannot directly compute disease incidence rates in exposed and non-exposed individuals but can estimate the relative risk (odds ratio).

• The temporal relationship between exposure and disease may be challenging to establish in some situations.

• It is particularly prone to bias compared with other analytic designs, particularly selection and recall bias (In general, bias may affect the validity of the results by the possibility of exaggeration or underestimation.

Types of the case-control study

 Retrospective case-control study: if all the cases were already diagnosed at the time the investigator initiates the study**.**

 Prospective case-control study: if the study is begun and all the new cases that will be diagnosed within the next period of time will be included in the study.

How to conduct a case-control study

• Identify cases of disease of concern

• Identify appropriate non-diseased comparison group ("controls")

• Document exposures among cases and controls

• Calculate odds ratios (it measures the association between exposure and outcome).

• Perform statistical tests or calculate confidence intervals

ii. Cohort study.

 In epidemiology, the term cohort is defined as a group of people who share common characteristics or experiences within a defined time period (e.g., age, occupation, exposure to drugs, and vaccine).

 It is an observational analytic design, and it is also called (follow-up, longitudinal, incidence, and forward-looking study).

The distinguishing features of cohort studies are:

A. A cohort is identified before the appearance of the disease under investigation.

B. The study groups are observed to determine the frequency of disease among them.

C. The study proceeds forward from cause to effect.

Therefore, note that the framework of an observational study: **case-control** studies which proceed from ((**effect to cause**)) while **cohort** studies are to work from((**cause to effect**)).

B. Interventional (experimental)studies.

Aims:

1. To provide scientific proof of etiological or risk factors which may permit the modification or control of those diseases.

2. To providea method of measuring the effectiveness and efficiency of health services to prevent, control, and treat disease and improvethe community's health.

Types of Interventional (experimental) studies

1-Randomized controlled trials (i.e., those involving a random allocation process).

The basic steps in conducting the R.C.T. include the following:

A. Drawing up a protocol.

B. Selecting reference and experimental populations.

C. Randomization.

D. Manipulation or intervention.

E. Follow-up.

F. Assessment of outcome.

2-Non-randomized or non-experimental trial:

They are divided into three types:

A. Uncontrolled trials: control groups are not used, such as the effectiveness of pap tests for cervical cancer.

B. Natural control (natural experiments): Nature has separated the population into two groups; for example, with respect to cigarette smoking, people have divided themselves into two groups smokers and non-smokers.

C. Before and after comparison study(pre-post clinical trial): this study center round compares the incidence of disease before and after introducing preventive measures.

• A-without control

• B-with control

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Laboratory services

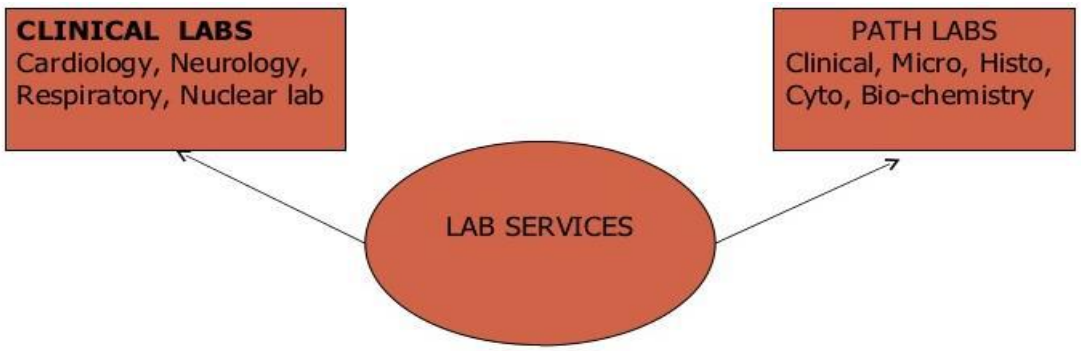
A medical laboratory is a place where tests are done on samples to get information about a patient's heath.

Laboratory services include testing materials, tissues, or fluids obtained from a patient or clinical studies to determine the cause and nature of the disease.

Laboratory services play a critical role in detecting, diagnosing, and treating disease. Samples are collected, and examination and analysis of body fluids, tissue, and cells.

The main services are:

- To perform diagnostic tests
- To identify organisms, like *E. coli* bacteria
- To count and classify blood cells to identify infection or disease
- To perform immunological tests to check for antibodies
- To match blood samples for transfections
- To analyze DNA



Lab equipment and LIS

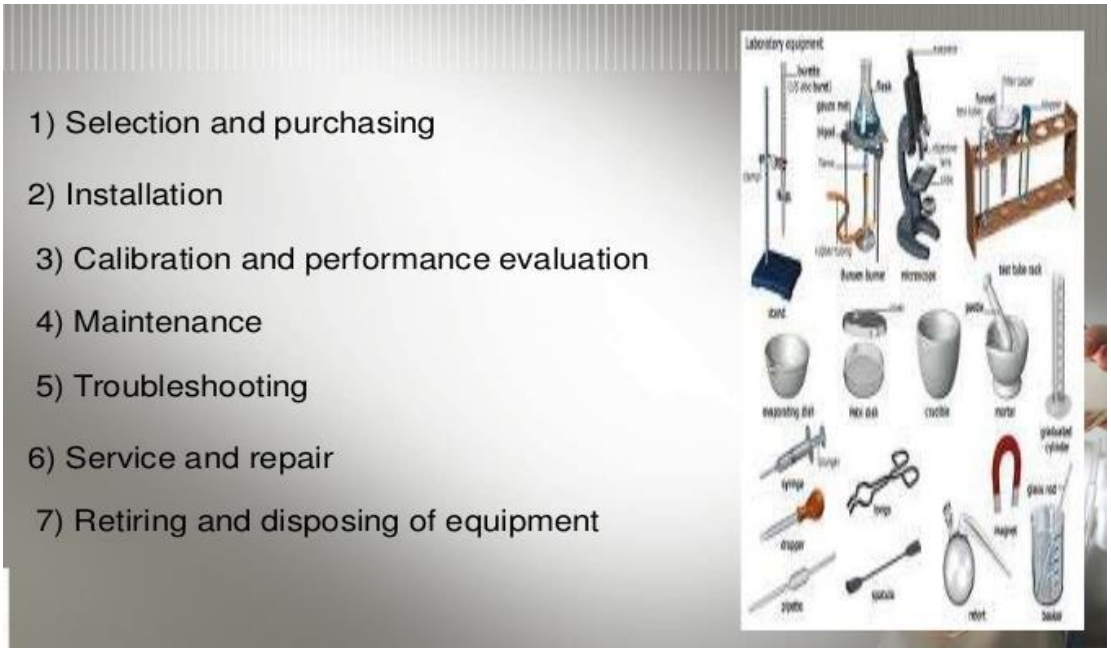
Planning for equipment

Basic instruments and equipment should be made available.

All vital equipment should be in duplicate or have an alternative arrangement.

Selecting the best instrument for the laboratory is a very important part of equipment management.

Follow elements should be considered during the management program in the lab



Lab equipment

Basic equipment for all types of routine investigations are:

A centrifuge is a laboratory device used to separate liquids based on their density.

A water bath is a device made of a metal bowl, most likely filled with hot water. It is used to incubate samples in water at a constant temperature for a long time. It is also used to heat reagents, dissolve some materials, and incubate environments.

A microscope is a device for enlarging small things that cannot be seen with the naked eye or showing the fine details of objects to discover their composition and study.
An autoclave is a metal pressure tank designed to heat aqueous solutions above their boiling point at standard atmospheric pressure for sterilization.
A pH meter is an instrument used to measure a specific liquid's pH (pH or basic level).
An incubator is a device used to grow and maintain microbial colonies or a cell colony.
Balance is used to measure the mass of objects and chemicals with very great accuracy

Other tools and glassware used in the laboratory

Standard flask It has a neck engraved with a sign (__) in the form of a circular line indicating the extent to which the surface of the liquid should reach, and there is a written indication of the size of the vessel.

Burette A graduated glass tube, at the bottom end of which is a plunger glass spout. Various sizes intended to be taken out
The conical flask The solution is transferred to it by the pipette. Easy to move. It is used to prepare, preserve, and measure chemicals and solutions.
Beaker It is a vessel used to stir, mix and mix liquids in chemical laboratories.
A test tube is a glass laboratory instrument with an opening from the top used to pour, transport, or mix solutions, chemicals, and liquids.

LIS

A lab information system (LIS) is a class of software that receives, processes, and stores information generated by medical laboratory processes. These systems often must interface with instruments and other information systems such as hospital information systems (HIS).
A LIS is a highly configurable application customized to facilitate a wide variety of laboratory workflow.

Planning

Planning is the process of drawing the goals to be reached within a certain period of time. From this definition, it can be said that planning answers the following questions:

What is the benefit of pre-planning for the laboratory?

What is the effect of failure to develop planning commensurate with health safety standards?

Who is primarily responsible for giving planning?

In your opinion, what are the specifications of a typical analytical laboratory?

Scientific laboratory design standards

□□The necessity of establishing laboratories in the form of an integrated center.

□□The laboratories, except for the pathology laboratory, must be located on the same site

The following must be observed

□□Determining the type and nature of the laboratory and the type of examinations that will be conducted in it.

□□The lighting shall be commensurate with the type and size of the work and sufficient to illuminate all sections of the laboratory.

□□The design of the walls, floor, and ceiling of a smooth material that is easy to clean. The floor should be designed from a non-slip material, not leaking water, and resistant to interaction with disinfectants, acids, and solvents.

□□Provide all laboratory rooms, especially the room designated for microbial farm work, with ultraviolet detectors, with the aim of permanent disinfection and sterilization of them in the event of leakage after completion of the work, in addition to providing them with a safety cabin and filters.

□□Biological safety cabins must be appropriately installed (away from doors and windows).

Occupational safety and health conditions

□□Protective means must be available

□□Allocating special places to evacuate people in the event of a fire

□□All emergency exits are lit up automatically

□□Putting stickers on each door of the laboratory rooms to prevent the entry of non-workers.

Laboratory quality system

The basic process of the laboratory is the initial process that consists of three stages:

The pre-analysis phase (taking the sample, receiving it in the laboratory, recording, and processing it)

The analysis phase (the actual laboratory examination and recording of the result).

The post-analysis phase (clearing the result, reporting on it, and saving it) In archives, disposal/preservation of the sample).

Quality standards in medical laboratories

 Get accurate test results.

 The patient is satisfied with the services provided by the laboratory.

 Follow safety and prevention standards, especially in the hematology department, to prevent the transmission of diseases to workers and patients who undergo medical tests.

 Laboratory hygiene, and the use of medical paws, especially when drawing blood samples from patients

 Putting a sticker on each sample bearing the name of the patient, the type of sample, and the examination required to be performed.

 Using correct and modern scientific methods in conducting analyzes.

Strategic Planning

A mental process that analyzes the internal and external environment of an organization.

Benefits:

1. Clarification of the future and predicting events
2. Predefining job options
3. Promote teamwork and accumulation of experience
4. Properly employing financial capabilities to achieve the best results
5. Improving the organization's perf.

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The role of the laboratory in diagnosing and controlling infection

Laboratory workers face the risk of exposure to microbes that cause diseases transmitted through the blood or as a result of exposure to the eyes or mouth of the spray or from exposure of the infected skin to blood and other body fluids. Performing secondary bacterial blood cultures, centrifugation, etc.

Types of risks in laboratories

1. Chemical hazards
2. Physical hazards
3. Engineering risks
4. Health risks
5. Personal risk
6. Fire hazards
7. Mechanical hazards

Steps in the risk assessment process

A. Risk assessment

B. Define the target group
C. Determine the severity
D. Take the necessary measures and procedures
E. Revision
F. Implement the plan

Dangerous biological materials

Are dangerous biological materials and microbes and include the following:

- Microbes that cause infection (bacteria, fungi, parasites, viruses, etc.) can cause diseases for healthy individuals or affect the environment and agriculture.
- Cultures of cells, fluids, human tissues, or major mammalian tissues.
- DNA recombinant DNA
- Animals from which diseases may be transmitted to humans.

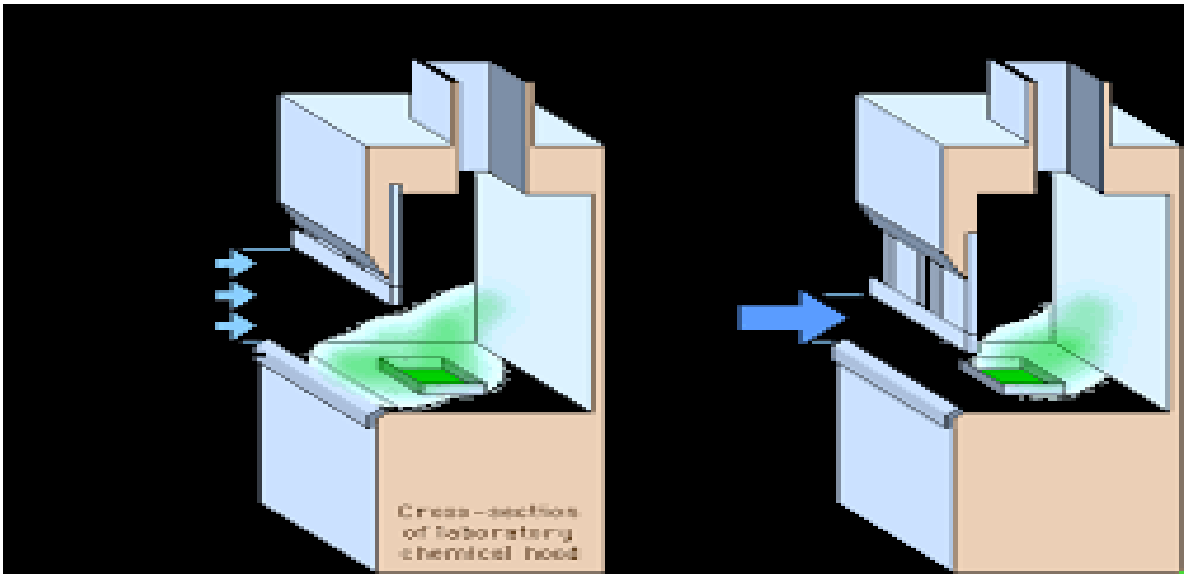
Hazardous substances

In general, hazardous materials can be divided into **physical factors** (such as needles, And glass), **chemical agents** (such as acids, alkalis), and **biological agents** (such as clinical samples microbial cultures), which may be harmful if used or handled inappropriately.

Biological safety cabin(Hood)

It is a major device for preventing the spread of infection. It is designed to draw air inside by mechanical methods used to prevent the spread of infectious airborne dispersal and aerosols emitted from some laboratory procedures.

There are three classes of biosecurity cabins: Class I, Class II, and Class III, and they are operated with the introduction of the user's hands and arms only. In these cabins, very dangerous pathogenic microbes are deal with it.



The role of the laboratory in infection control

1. Collect samples

2. Accurate identification and sensitivity testing

3. Laboratory information systems

4. Rapid diagnostic test

5. Reporting of laboratory data

6. Storage of living organisms

Personal protection tools

They are equipment that is placed on the body to protect it from risks in the laboratory

- ❖ Body robe
- ❖ The gags
- ❖ Safety glasses or face shield
- ❖ Gloves

How to deal with risks or reduce exposure to them?

Take note of the following when working

- Disinfect hands before and after wearing protective gear
- Do not touch the face
- Change gloves when they get dirty
- Not to wear loose clothing and accessories

 Not to eat or drink inside the laboratory

 Writing a report in the event of an occupational infection or needling

 Apply professional safety measures and caution when handling patient samples

Classification of medical laboratories

The world Health Organization (WHO) lists four kinds of levels of laboratories based on their biosafety.

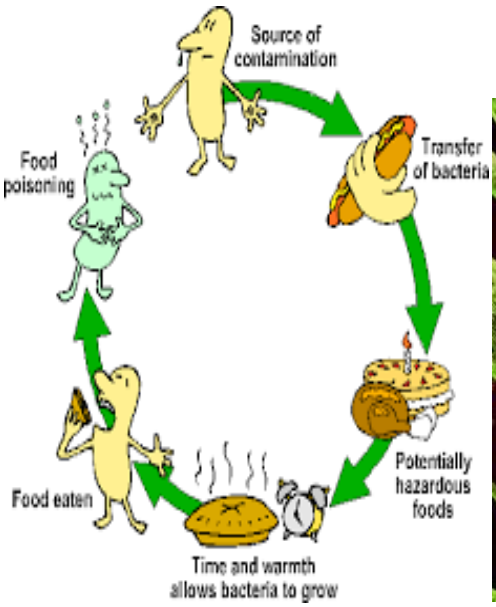
1**. Basic laboratory level I**

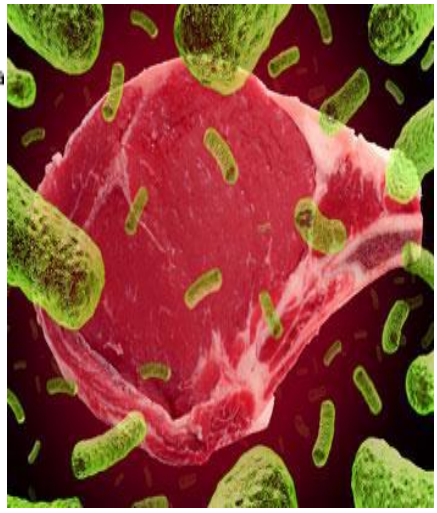
Basic laboratory level I is the simplest kind and adequate for work with organisms which have **low risk** to the individual laboratory personnel as well as to the members of the community.

-Such organisms are categorized under Risk Group I by WHO.

-These organisms are unlikely to cause human diseases.

Example, food spoilage bacteria, common molds and yeasts.





2. Basic laboratory level II

- Basic laboratory level II is suitable for work with organisms that predispose to **moderate risk** to the laboratory worker and a limited risk to the members of the community. Such organisms are categorized under Risk Group II by WHO.

-They can cause serious human diseases but not serious hazards due to the availability of effective preventive measures and treatment.

-Example, staphylococci, streptococci, entero bacteria except Salmonella typhi and others.

- Such laboratory should be clean, provide enough space, have adequate sanitary facilities and equipped with autoclave

3. Maximum containment laboratory

Maximum containment laboratory is intended for work with viruses, which predispose to a **high risk** for both laboratory personnel and the community.

 Such organisms are categorized under Risk Group IV by WHO.

 Example, Small pox, Ebola, Lassa fever and others.

Most of these organisms cause serious disease and readily transmitted from one person to another.

These laboratories are usually a separate building with strictly controlled access.

Classification of research

1- Descriptive studies.

A. Case reports and case series.

B. Correlation studies.

C. Cross-sectional studies.

2- Analytic studies:

A. Observational studies:

i. Case-control study.

ii. Cohort study.

B. Interventional (experimental)studies.

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First: Descriptive studies

- Describes the pattern of disease occurrence in terms of person, place, time model or host , agent ,environment model.
- Defines the relationships of disease to the population at risk.

ADVANTAGES OF DESCRIPTIVE STUDIES:

1. They use available data, so there is less time, less effort and money.

2. Describe disease patterns

Types of Descriptive studies:

A. Case reports and case series.

Case report:

The **individual**is the unit of observation available for study.clinical case with **"unusual"**clinical picture, they describe the experience of a single patient or

a small number of patients with a similar diagnosis reflecting unusual features of a disease.**They help in:**

- Formulation of a hypothesis suggesting an etiological association
- Represent the first clues in identification of new disease or epidemic.

Case series:

First case report may stimulate compilation of additional case reports. Acase series or(are collection of individual cases reportoccurring within a fairly short period of time.

B. Correlation studies.

They are based on aggregate measures of exposure and outcome from several populations.The **population**is the unit of observation available for study.

eg:there is a positive correlation between fat consumption and breast cancer in many nations.**ALSO,** Ecologicalstudies may be more appropriate than other designs when studying the impact of an exposure on a community level.

C. Cross-sectional studies, also known as **Prevalence study** or **Survey:**

1. Collection of data on several individuals at "one point" in time.

2. Determines prevalence at a point in time

3. Therefore, **Cross-sectional** is a prevalence study

4. The exposure and disease status are assessed simultaneously among individuals in a well-defined population.

5. Snapshot in time

Advantages of cross sectional study:

1. Provides information on frequency and characteristics of the disease

2. Standardized data collection tool.

3. Able to focus data collection in specific locations or specific groups of persons.

4. May make comparisons among study participants.

5. Relatively quick to do.

6. May be repeated to get data on trends.

Limitations:

1. Inability to determine the temporal relationship between exposure and disease.

2. May be biased by lack of participation

3. Reflects prevalent, not incident cases and thus results may be related to duration of disease, or survival with disease