

Principles and practice of Laboratory science (Laboratory medicine).

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Objectives of the lecture.

1. The students to understand the principles of laboratory medicine in clinical practice.
2. The students to learn the organisation of a medical laboratory.

Laboratory science:

- (Laboratory medicine).
- The science of the **laboratory diagnosis** of medical diseases and conditions by **laboratory investigations (tests)** .
- Referred to is discipline involved in:
- **Selection, provision, and interpretation of diagnostic testing using primarily samples*** from a patient.

Field of Laboratory medicine:

1. Research
2. Administration
3. Teaching activities
4. Clinical service

Importance of laboratory diagnosis in clinical practice.

(Why)

1. History + Physical examination + **laboratory diagnosis**=Confirm diagnosis/obtain valuable information about patient's condition.
2. Laboratory diagnostic tests are **not** therapeutic.
3. Laboratory diagnosis assists in more **effective** management and **cost containment**.

Indications for requesting laboratory investigations (tests): (when)

1. **Confirm** a clinical suspicion (make a **definitive diagnosis**).
2. Establish the **severity** of the condition.
3. **Exclude** a clinical diagnosis.
4. Assist in **selection, optimisation, and monitoring** of treatment.
5. Provide a **prognosis**.
6. **Screening** for disease (before symptoms and signs appear).
7. **Establish and monitor** the severity of a **physiological** disturbance

Field of laboratory medicine includes:

1. **Clinical chemistry & molecular diagnosis***
2. **Microbiology** (bacteriology, parasitology, virology, mycology).
3. **Hematology**
4. **Hemostasis and thrombosis**
5. **Blood banking** (transfusion medicine)
6. **Immunology**
7. **Identity test**
8. **Cytology and anatomical pathology (histopathology)***

Importance of Laboratory medicine (LM):

- **One** of the fundamental tools used in making decisions in the practice of **clinical medicine**.

Evidence-based medicine (EBM)*

- Defined as the **conscientious, judicious, and explicit** use of the **best evidence** in making **decisions** about the **care** of individual patients.
- **Goal** of EBM is to incorporate the **best evidence** from clinical research into **clinical decisions**.

EBM and LM*.

- Services of LM are important **tools** for the doctor to answer **diagnostic questions** and assist in **decision making**.
- Tools are called **diagnostic tests** (also known as *laboratory tests* or *laboratory investigations*).

What is Evidence-based LM (*EBLM*)

- Is the application of **principles** and **techniques** of EBM to LM.
- Clinician requesting an investigation has a **question** and must make a **decision**.

EBLM

- Is defined as the **conscientious, judicious, and explicit** use of **best evidence** in the use of LM investigations for assisting in **decision making** about the **care** of individual patients*.

EBLM

Best test →

EBM

Best evidence →

Best Decision

Types of diagnostic questions addressed in LM* about the patient.

- **4 scenarios** typified by the questions:
 1. What is the **diagnosis**?
 2. Can **another diagnosis** be ruled out?
 3. What is the patient's **prognosis**?
 4. How is the patient **doing**?

What is the diagnosis?

- Diagnosis is **required** by the doctor
- Diagnostic conclusions lead to a **decision** and **some action** and often an **intervention** (**chemotherapy** or **surgery** or **none**) to **improve** patient's condition.

Can another diagnosis be ruled out?

- The test result **excludes** a diagnosis.
- Also referred to as “**rule out test**”

What is this patient's prognosis?

- Assessment of **risk***

How is the patient doing?

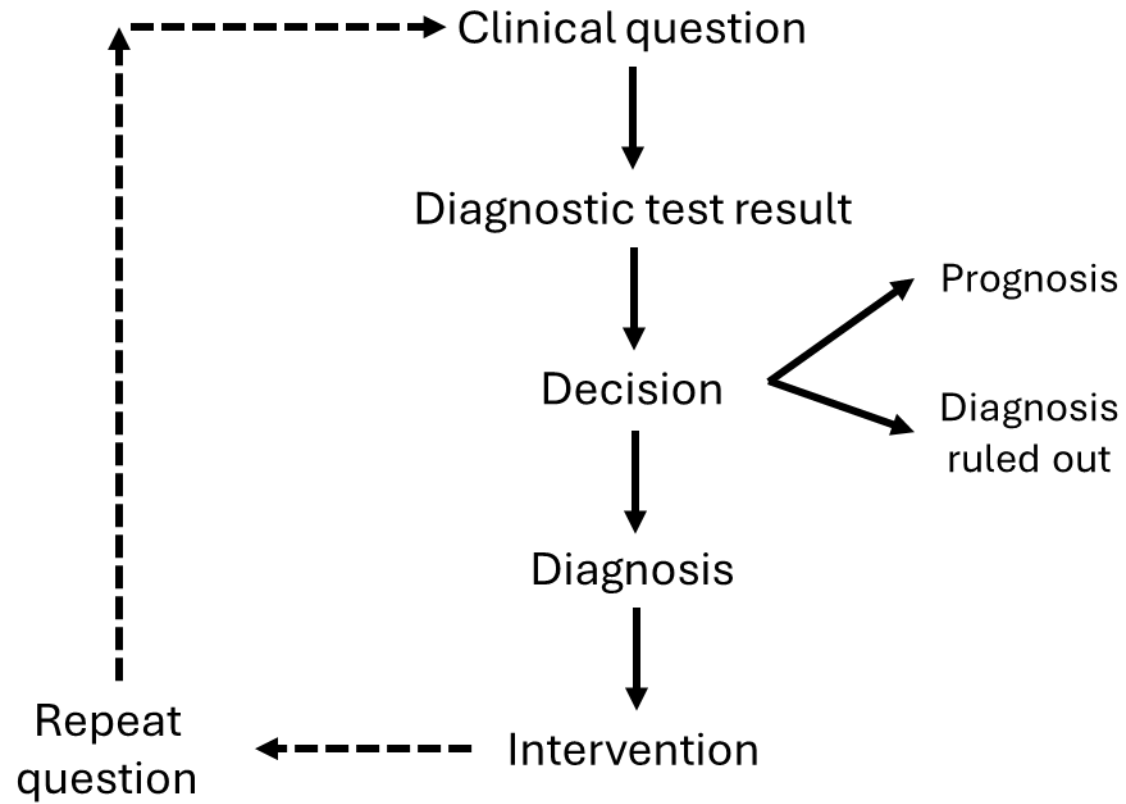
- concerned with patient **management**

In all the above scenarios:

3 components present:

1. **A question**
2. **A decision**
3. **An action**

Schematic representation of 4 common decision-making steps*



Choice of laboratory investigations.

- Based on **subjective** clinical judgment

Application of laboratory medicine.

1. Hospital/health centre:

- Outpatients
- Inpatients

2. Community survey:

- Sick and healthy individuals

3. Screening centre

- Apparently healthy individuals

Clinical specimens (samples) in LM.

Examples:

1. **Stool**
2. **Urine**
3. **Blood**
4. **Bronchial-alveolar lavage (wash)**
5. **Biopsy** (piece of body tissue)

6. **Secretions** (bronchial, saliva)
7. **Discharge** (pus, vaginal, urethral)
8. **Impression** (ulcer)
9. **Body fluids** (Cerebral Spinal Fluid, pleural, semen, cervical mucus, peritoneal, synovial)

Processing samples from patient.

Involves:

1. Collection
2. Transportation
3. Handling
4. Examination
5. Reporting the results.

Organization of a medical laboratory.

- Ensure **accurate** laboratory results (**best evidence**)
- Essential **elements** of a medical laboratory include:
 1. **Building**
 2. **Personnel**
 3. **Equipment**
 4. **Reagents/ chemicals/ test kits**

- 5. Visual aids**
- 6. Waste disposal system**
- 7. Safe work environment (Safety)**
- 8. Standard Operating Procedure (SOPs)
Manual**

Building.

1. Work space.
2. Power supply.
3. Gas supply.
4. Water supply.
5. Ventilation.

Personnel.

- **Qualified** laboratory scientists/technologists/technicians/assistants required for **quality assurance**.
- Teamwork for **internal consultations**.
- Supervision for **quality control**.

Equipment.

- **Appropriate** equipment required for different laboratory tests.
- End users (laboratory staff).
- Installation and commissioning by contractor.
- **Service** contracts.

Examples of some equipment in medical laboratory;

- **Microscopes**
- Centrifuges
- Fridge/freezers
- Incubators
- pH meters
- Shakers
- Chemistry analysers
- Haematology analysers
- PCR machine

Reagents/chemicals/test kits.

- Proper labelling of containers.
- Correct colour of containers.
- Shelves labeled
- Expiry date of reagents/chemicals.
- Expiry dates for test kits (**shelf-life**).

Safety measures.

- **Safe work environment**
- Provided by use of equipment called **Biosafety Cabinets (BC)**.
- BC provide **primary containment** of **potentially infectious** materials.
- Protection for **personnel, product, and environment**.
- There are **3** classes of BC

Biosafety Cabinets



Class I



Class II



Class III



Class I:

- Is an **open-front negative** pressure cabinet.
- provides **personnel** and **environmental** protection, but **not product** protection.

Class II:

- Is an open-front, **ventilated** cabinet.
- Provides **personnel, environment** and **product** protection.

Class III:

- **Totally** enclosed **ventilated** cabinet of **gas-tight construction**.
- Operations conducted through attached rubber gloves.
- Is maintained through negative air pressure when in use.
- For **highly** infectious samples

Waste disposal.

- Dustbin, waste bags labeled with a **hazard sign** available at all times for solid disposal.
- Chemical/reagents disposed according to laid down procedures.

Visual aids.

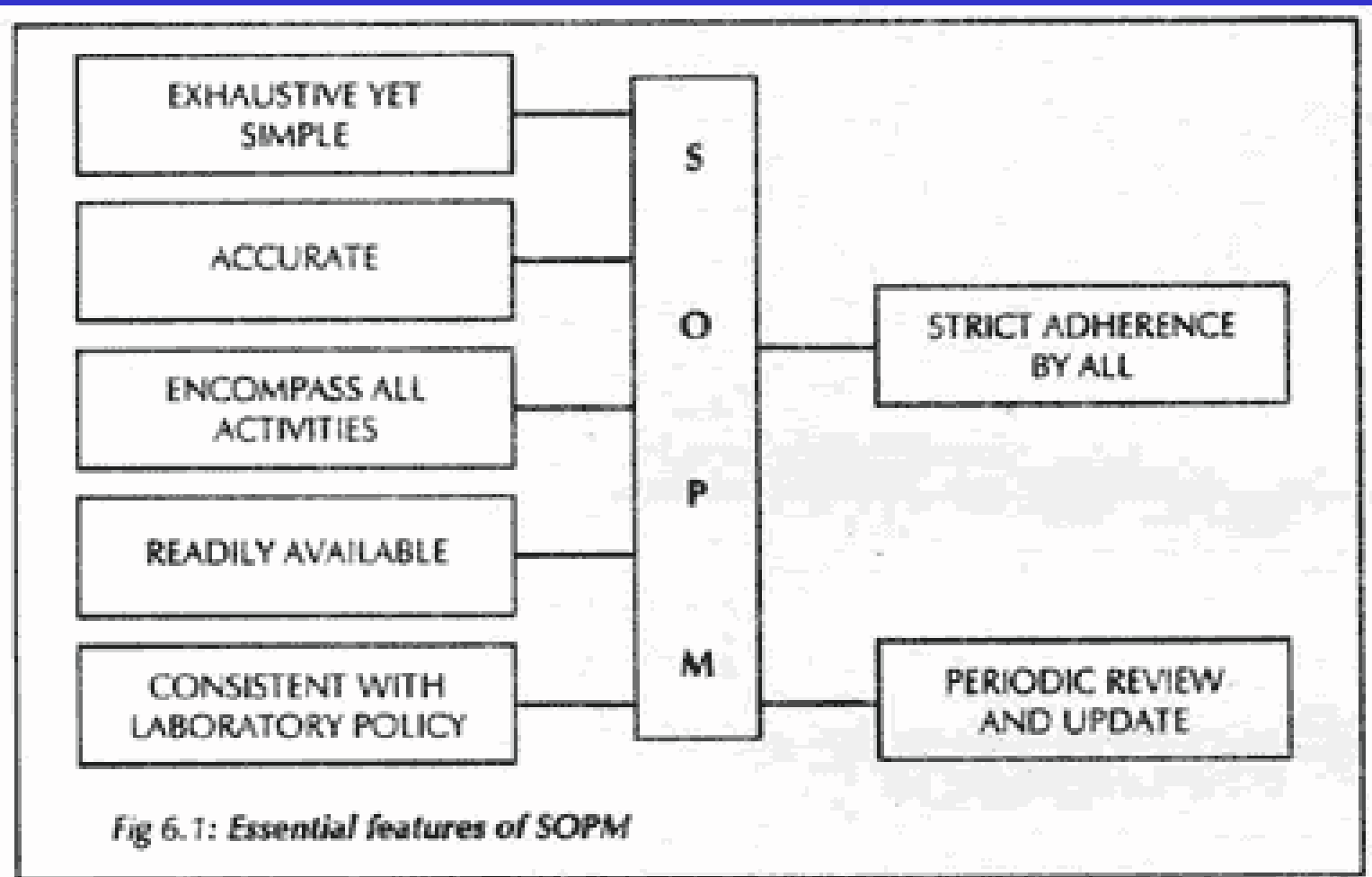
Reference materials:

1. Algorithms (Flow charts).
2. Diagrams.
3. Pictures.

Standard Operating Procedure Manual (SOPM/SOP).

- **Most important document** in a laboratory.
- Describes in **detail** the complete techniques for performing tests.
- Ensures that **consistent** and **reproducible results** are generated.
- Instructions in SOP Manual **must** be **strictly adhered** to by **all** laboratory staff.

- Essential features of SOPM



Essential components of a SOPM

i. **Abbreviated administrative structure diagram.**

Indicating the line of authority in the laboratory.

ii. **Laboratory safety instructions.**
including emergency measures.

iii. Specimen collection.

- **Condition** under which the sample collected properly.
- **Techniques** for selection, collection.
- **Transportation** of specimens.
- **Criteria** for the rejection of a specimen.
- **Action** to be taken in case the sample is rejected.

iv. Inoculation procedures.

- Media required for each specimen, type and **plating** or **inoculation** technique used for this purpose.
- The temperature, duration and environment in which the samples are to be incubated.

v. **Details of procedures**

- Detail the steps in performing a test indicating **differential tests**, flow charts or keys as well as identification criteria.

Differential tests.

Description in detail regarding the following for each test:

- Title
- Principle
- Material (e.g. colony to be tested)
- Reagents:
 - a)Source
 - b)Preparation technique
 - c)Storage technique

- **Standards** and **controls** to be used.
- Directions for performing the test.
- Interpretation of results.
- Commonly encountered problems and their solution.

vi. Antimicrobial susceptibility testing.

- Organism that can be tested and the antimicrobial agent which is to be used for testing.

- vii. Serological testing (immunological tests).**
(Includes details as given above under heading differential tests).
- viii. Referral to higher laboratories**
Describes how to use the reference laboratories.

ix. Quality control.

- a) Time and frequency** for performing quality control steps for media, reagents, antibiotic discs, sera.
- b) Control** results are acceptable/not acceptable (**supervision**).
- c) Recording** of results and the actions to be taken if deviations occur.

x. Reporting.

- Reporting results.
- Tests taking a longer time for completion.
- Preliminary reports issued.

xi. Preventive maintenance.

- For various equipment and materials used in the laboratory.

Summary of SOPM/SOP.

- Contains description of **approved** procedures for various laboratory tests.
- Is a **reference** handbook.

Quality control.

- A **process** of setting standards to make sure a laboratory test is done **correctly**.
- Involves:
 - i. Equipment
 - ii. Reagents/chemicals/diagnostic kits
 - iii. Personnel

Quality assurance:

- A **systematic measurement**, comparison with a **standard**, monitoring of processes and an associated feedback loop that confers **error prevention**.
- National/international reference laboratory **supervision**.
- Ensures **best results** leave a particular laboratory

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