FOUR REASONS WHY CLINICAL LABS MATTER

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Objectives

1. Recognize the four significant roles of clinical laboratory in health care.
2. Develop a plan to create this vital part of hospital or clinic facility.
3. Utilize the list of suggested materials towards the realization of basic clinical laboratory in your facility, then adopt the WHO guidelines for national accreditation.

"WITHOUT LABORATORIES
MEN OF OF SCIENCE
ARE SOLDIERS
WITHOUT ARMS".

-- LOUIS PASTEUR

“MEDICINE
IS A
SCIENCE OF UNCERTAINTY
AND
AN ART OF PROBABILITY”.

-- Dr. William Osler

COVID-19 Pandemic

"THE BATTLE AGAINST COVID-19
WITHOUT LABORATORY TESTING
IS LIKE FIGHTING INVISIBLE ENEMIES".

-- Frontline Doctors

Four Reasons Why CLM

BACKBONE
OF
INFECTION CONTROL

In the absence of laboratory testing, infection containment is like fighting an invisible enemy.

- CASES IN POINT

  - Detection of Methicillin Resistant Staphylococcus aureus was relatively unknown in a large number of our hospitals.

  - Recognition and awareness of deadly parasites in feces through innovative and sustainable procedure.

Ensures safe hospital environment from infectious microorganisms.

- CASES IN POINT

  - All patients in a hospital intensive care unit in another country contracted Pseudomonas due to poor equipment maintenance.

  - Dialysis patients infected with infectious microorganisms like E. coli and Staphylococcus aureus due to poor dialysis machine maintenance.

Detection of carriers of pathogenic bacteria among hospital employees.

- CASE IN POINT

  - In another hospital from another developing country, a nurse turned out to be a carrier of highly infectious Methicillin resistant Staphylococcus aureus.

Second Reason Why CLM

ASSISTS IN DRUG THERAPEUTIC MONITORING

Precise antibiotic therapy, as oppose to shotgun antibiotic treatment that triggers the emergence of antibiotic resistance, is another product of good laboratory.

- CASES IN POINT
  - Wazir Ahkbar Khan Hospital in Kabul Afghanistan
  - Hospital in African country where patients are now attracted due to evidence-based antibiotic therapy.

Third Reason Why CLM

SHARPENS
DIAGNOSTIC
DECISION MAKING

Laboratory tests are intended to enhance physicians' diagnostic capabilities and medical intervention strategies, BUT negated by…

- CASES IN POINT
  - Errors due to substandard operating procedures.
    - Only one out of 13 appendectomy procedures is real case of appendicitis.
  - Lack of skills
    - 90% of patients blood samples were erroneously called malaria positive.
  - Antiquated laboratory equipment
    - In a bush mission hospital, hemoglobin test is done with 1902 Sahli Hb meter using wrong reagent.

Fourth Reason Why CLM

PRACTICAL REMUNERATIVE SOLUTION TOWARDS SUSTAINABILITY

Good and efficient laboratory provides strong financial support to stakeholders.

- CASE IN POINT
  - One AHI member health care facility in the Caribbean in financial trouble.

ESSENTIAL ITEMS TO START BASIC CLINICAL LABORATORY

Cost of a basic laboratory is around $16K

1. Semiautomated chemistry machine (Statfax model 3300 - $2.7K)
2. Hematology analyzer (QBC plus - $3K)
3. Two units binocular microscopes ($2K)
4. Two units centrifuge ($800)
5. Four pipettors ($500)
6. Glassware: graduated cylinders, flask, test tubes - $500
7. Routine chemistry reagents, supply for a year depending on sample volume ($1K)

Additional items for a basic laboratory

8. Annual supply of hematology reagents. ($1K)
9. Hematocrit centrifuge. ($300)
10. Microbiology incubator. ($2K)
11. Microbiology consumables and culture media for a year. ($1.4K)
12. Accessories like inverter-charger for clean power, distilled water maker. ($500)

Initial hands on training is 4-6 weeks

- Questionable laboratory results and hard to identify organisms never encountered before are resolved through WhatsApp social media platform.

- Equipment troubleshooting and repair are conducted in the same manner.

Next step is the development and implementation of laboratory quality standards by **WHO.**

- Laboratory level
  - ➢ Laboratory head, with the involvement of the staff, leads out to make the improvements in quality standards starting with easy-to-implement changes like the following:
    - ❑ SOP for sample collection including phlebotomy.
    - ❑ SOP for a particular analyte like, glucose, cholesterol, etc.
    - ❑ SOP for specimen rejection.
    - ❑ Appointment of Quality Manager.
    - ❑ Appointment of Safety Officer.
    - ❑ Develop Organizational Chart
  - ➢ Meeting with the users of the lab service to keep them inform of the efforts being done to improve quality of service.

Job Description of Quality Manager

- Responsible to the laboratory head.
- Responsibilities
  - ❑ Monitors quality management system and ensuring policies are implemented.
  - ❑ Daily monitoring of all internal quality control procedures.
  - ❑ Ensures laboratory participates in external quality control assurance and corrective action taken on the results, if necessary.
  - ❑ Investigates non-compliance to quality standards and corrective action taken.
  - ❑ Training staff in the use of quality systems.
  - ❑ Writing and implementing quality policies.

Job Description of Safety Officer.

- Appointee is responsible to the laboratory head.
- Responsibilities
  - Establishing the safety policy in consultation with the laboratory head.
  - Implementing safety policy.
  - Assisting in the design and maintenance of the safety policy.
  - Providing orientation and training all staff in the safety program.
  - Submitting regular reports on safety status to the laboratory head.
  - Maintains accident records.
  - Investigates all laboratory accidents.
  - Documents regular safety inspections.

Safety Rules Samples for Clinical Laboratory

- No eating, drinking and applying cosmetics.
- No mouth pipetting.
- Lab gown must be worn at all times and gloves when required.
- Work surfaces must be decontaminated at the end of the day and immediately after spillage.
- Wash hands when leaving the laboratory.
- Avoid formation of aerosols or splashing of sample specimens.
- All contaminated waste or reusable materials must be decontaminated before disposal or use.

More Safety Rules

- Access to the laboratory must be restricted to authorized personnel only.
- Report all accidents and incidents immediately and appropriate action taken to prevent further occurrences.
- Staff must be adequately trained both in performance of duties and work safety.
- All waste must be appropriately marked before disposal.
- Ensure the efficacy of all disinfectants used for disinfection.

□□SAFETY RULES ARE MANDATORY FOR ALL STAFF □□

Sample Operating Procedure (SOP)

Standard Operating Procedure

(Name of the Laboratory)

Number	Effective date	Pages	Author	Authorized by
C-001	DD-MM-YYYY	3	XXX	XXX
Version	**Review period**	**Number of copies**	**Approved by**	**Date**
1	1 year	5	XXX	DD-MM-YYYY

Location	Subject
Chemistry	Blood Glucose
Function	**Distribution**
Glucose Testing	QA manager, Master file

Sample Operating Procedure (SOP)

1. Scope of Testing
    - 1.1 Personnel
    - 1.2 Sites (Lab, nurses if they do venipuncture)
2. Purpose
    - 2.1 Methodology/Theory
    - 2.2 Clinical implications
3. Specimen
    - 3.1 Patient instructions
    - 3.2 Collection instructions
        - 3.2.1 Type and source
        - 3.2.2 Container volume
        - 3.2.3 Transport
        - 3.2.4 Interferences

Sample Operating Procedure (SOP)

4. Reagents
    - 4.1 Required reagents
    - 4.2 Reagents preparation procedure
    - 4.3 Storage requirements
5. Materials
    - 5.1 Consumables
    - 5.2 Equipment
6. Quality
    - 6.1 Calibration
        - 6.1.1 Calibrator
        - 6.1.2 Preparation and Storage
        - 6.2.3 Frequency
        - 6.2.4 Troubleshooting
        - 6.2.5 Documentation

Sample Operating Procedure (SOP)

- 6.2 Control
  - 6.2.1 Controls
  - 6.2.2 Preparation and Storage
  - 6.2.3 Frequency
  - 6.2.4 Acceptance Limits
  - 6.2.5 Corrective Actions
  - 6.2.6 Documentation
7. Procedure
   - 7.1 Step 1, Step 2 and so on.
8. Results
   - 8.1 Calculations
     - 8.1.1 Full Equation
     - 8.1.2 Example
   - 8.2 Dilutions

Sample Operating Procedure (SOP)

8.3 Criteria for Determining Normal, Abnormal, Critical or indeterminate Evaluation.

8.3.1 Follow-up for indeterminate results

8.3.2 Follow-up for out-of-range results, reference method limitations

8.3.3 Follow-up for value exceeding critical limits

9. Method Parameters

9.1 Reference Range

9.2 Critical Value

9.3 Reportable Range

9.4 Interfering Substances

Sample Operating Procedure (SOP)

10. Reporting
    - 10.1 Results Transcription
    - 10.2 Laboratory Information System
11. Procedure Note
    - 11.1 Precautions
    - 11.2 Safety
12. Related Documents
    - 12.1 Instrument Operation
13. References

Sample SOP Training Document

Hospital Name

XXXXX Training Document

Trainee_____ Trainer _____

Trainer Initials	Trainee Initials	The following has been explained and or demonstrated and the trainee understands.
		Purpose of this procedure • The purpose of this procedure is to • This procedure is performed by • This procedure should be performed every
		Materials needed •
		Procedure •

I have read and understand SOP C-XXX-YYYY

Trainee signature _____ Date _____

Comments:

GRACIAS

MERCI

THANK YOU