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 informed 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)**

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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
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
The following has been explained and or demonstrated and the trainee understands.

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I have read and understand SOP C-XXX-YYYY

Trainee signature _____________________________ Date ____________________

Comments:
THANK YOU