Clinical Laboratory Management (Theory)

Total: 14 hours /week
Lecture: 8 hours/week
Tutorial: 0 hour/week
Practical: 6 hours/week
Lab: 0 hours/week

Course Description:

This course is designed to provide basic knowledge and skills on laboratory management, quality assurance (QAs) in laboratory practice & Laboratory Practices. Good quality management, QAs & lab practice plays a vital role in improving quality of lab services and safety to community as well as operators. This course provides the students with knowledge to develop confidence, effectiveness, efficiency, accountability in laboratory management and quality work.

Course Objectives:

At the end of the course, the students will be able to:

- Implement appropriate quality assurance program
- Design a functional laboratory.
- Ensure safe & healthy laboratory management.
- Perform all routine and some special laboratory procedures independently and accurately,
- Implement bio-safety and waste management measures.
- Build confidence on laboratory procedures before OJT.

Course Content

Unit 1: Introduction to clinical laboratory management **10 hrs**

- Introduction and objective of the laboratory management
- Laboratory management framework
- National health care delivery system of Nepal in regard to Laboratory profession
- Code of conduct of medical laboratory profession.
- Level of clinical laboratories according to complexity and National guidelines

Unit 2: Department /section of clinical laboratory **6hrs**

- Different sections of clinical laboratory, corresponding services and their uses.
    - Patient communication (Delivery of information and reports)
    - Sample collection
    - Haematology
    - Blood banking
    - Clinical biochemistry
    - Microbiology

- Serology/immunology
- Parasitology
- Histopathology & Cytopathology
- Emergency lab
- Molecular Laboratory

- Services (range of tests done by CMLT or lab technician level)

Unit 3: Laboratory design: **6 hrs**

- Basic concept of laboratory organization:
  - Location,
  - Space requirement,
  - Light,
  - Ventilation,
  - Temperature control,
  - Humidity,
  - Electrical supply,
  - Water supply,
  - Sanitation,
  - Noise control,
  - Use of fume hood/safety hood
- Human resource in different levels of laboratory

Unit 4: Laboratory work flow **6 hrs**

- Description of work flow
  - Appropriate specimen collection,
  - Specimen organization and transport,
  - Laboratory investigation
  - Report preparation and patient communication.

Unit 5: Personnel management **4 hrs**

- Staff duty rotation
- Importance of continued medical education/training

Unit 6: Standard operating procedures (SOPs): **5 hrs**

- Introduction to standard operating procedure(SOP)
- Essential components of SOPs
- Significance of SOPs in clinical practices

Unit 7: Clinical laboratory Inventory Management: **10 hrs**

- Clinical laboratory records
- Requisition slips Test request form(TRF)
- Lab reports format of different section
- Record keeping and its importance
- Maintain stock inventory
- Maintaining expiry charts
- Important of instrument maintenance sheet Refrigerator Incubator
- Important of daily cleaning record sheet
- Logistics management

- Important of computer in lab
- Local information system LIS in modern lab

Unit 8: Lab hazards and lab safety: 10 hrs

- Lab hazards and lab safety
- Importance and uses of safety and protection in clinical laboratory practices
- of Preparation 0.5-1% hypochlorite
- Use and how to prepare spill kit
- Management of needle stick injury, spillages accident in laboratory and their first aid
- Common accident in lab and their first aid
- Material safety data sheet and hazardous chart symbols.
- Common laboratory hazards in clinical laboratory:
    - Unsafe premises,
    - Naked flames/fire,
    - Microbial hazards/biological,
    - Chemical and explosions,
    - Sharp and glass ware
    - Unreliable water supply
    - Infestation by ants, rodents.
- Laboratory Safety measures
    - Personal protective equipment (PPE)
    - Health and safety of the staff
    - Equipment and procedural safety

Unit 9: Total quality management (TQM) and Quality Assurance & QAs 15 hrs

- Introduction,
- Total Quality Management Framework.
    - Quality Assessment
    - Quality Assurance
    - Quality Laboratory Procedures
    - Quality Control
- Internal Quality Control
- External Quality Control
- Quality Control charts – L-J chart
- Terminologies used in Quality Assurance program/ Selection of analytical methods
    - Accuracy
    - Precision
    - Sensitivity
    - Specificity
    - Standard
    - Control (Positive, Negative, High, normal, low sera)
    - Standard deviation (SD)
    - Coefficient of variation (CV)

- Mean
- Use of control and calibration in laboratory in practices

- Sources of error
  - Pre-analytical
  - Analytical
  - Post-analytical
- Method of improving laboratory reports

Unit 10: Bio-safety and bio-security: 10 hrs

- Introduction to bio-safety and bio-security
- Risk group classification of micro-organisms: risk group 1 to risk group 4
- Concept of Bio-safety levels: BSL 1 to BSL 4
- Laboratory waste management:
  - Segregation of waste
  - Uses of color-coded bins: red, blue, yellow, green, black, white bins, Sharp bins
  - Treatment & disposal of waste
- Concept of 3R (Reduce, Reuse and Recycle)

Unit 11: Medical ethics 6 hrs

- Medical ethics and its principles
- Confidentiality
- Ethical consent
- Accreditation: Brief introduction to:
  - National Public Health Laboratory (NPHL) Teku, Nepal
  - International standardization organization (ISO-in lab)
  - National Accreditation Board for Testing and Calibration Laboratories (NABL)
  - The College of American Pathologists (CAP) & Clinical laboratory improvement Amendments (CLIA)
- Nepal health provisional council (NHPC)
- International Certification boards

References Books

- Carl A Burtis, Edward R Ashwood, David E Bruns, Teitz (2008) Text book of clinical chemistry and molecular diagnostics, Elseviers
- Cheesbrough M, (2004) District laboratory practice in tropical countries, Cambridge University press
- Bharucha C. et al (1970), A handbook of medical laboratory technology, Christian Medical College, vellore

Unit	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**Total**
Unit Hours	10	6	6	6	4	5	10	10	15	10	6	88
Marks	9	5	5	5	4	5	9	9	15	9	5	80

Clinical Laboratory Management (Practical)

Practical: 66hrs

- **Perform basic computer skills on word and excel.**
- **Lab related practical:**
    - Observe different departments in lab (biochemistry, microbiology, hematology, parasitological, collection etc)
    - List out the instruments, glassware, accessories used, along with their uses.
    - Observe and practice specimen collection
    - Perform coding of sample received/collected.
    - Transport and process specimen
    - Assist to prepare duty rotation
    - Prepare SOPs for different tests (Glucose, hemoglobin, gram stain, urine routine examination)
    - Collect different report formats and daily maintenance sheet
    - Assist to prepare computerized reports
    - Maintain lab records, use computers in record keeping.
    - Observe use of IQC materials
    - Identify different hazards in lab and use of hazard symbols
    - Use personal protective equipment in lab and follow safety measures
    - Segregate waste, use proper color coded bins and safe disposal of waste
    - Prepare and use incidence report charts
    - Observe management of inventory and maintain stock records
    - Practice on vacutainer system for blood sample collection
    - Prepare 0.5 & 1 % hypochlorite solution
    - Calculate Mean, CV, SD value

Clinical Practice I (Microbiology and Parasitology)
(Hospital/Laboratory Based)

Students will be posted in hospital/laboratory with microbiology and parasitology facilities for 8 weeks at the end of course (i.e. in third year) for clinical practice. For this, students must be posted in all related Departments/Section of diagnostic laboratory on rotation basis.

Course Description

This clinical practice program is designed to help the students to apply the comprehensive knowledge and skills learned in the training institute on actual situations. The program is offered after completing twelve weeks institution-based training in the third year.

Course Objectives

At the end of the course, the students will be able to:

1. Perform all routine and some special laboratory procedures independently and accurately as mentioned below, and
2. Build confidence in laboratory procedures.

Placement schedule

The whole class of students will be divided into five groups and placed in the following sections of the pathology department.

S.N.	Practical Areas	Duration
1.	Microbiology Lab.	5 Weeks
2.	Parasitology Lab	4 Weeks
	Total Duration	**9 Weeks**

Skills to be performed during the clinical practice

Each student should perform the following skills independently and accurately during the clinical practice.

A. Bacteriology

- Microscopy
- Sample collection
- Sterilization and safety precautions
- Gram stain
- AFB stain (Tuberculosis/ leprosy)
- Urine culture/ sensitivity
- Blood C/S
- Pus culture/ sensitivity
- Stool C/S
- Throat swab C/S
- Body fluid C/S
- Wound swab C/S

B. Immunology/Serology

- Widal test
- RPR (VDRL)test
- Rheumatiod Arthritis factor (RA factor) test
- Antistreptolysin 'O' (ASO)test
- C-Reactive Protin (CRP) test
- Aldehyde test
- HIV I-2 antibody spot (Quick) test
- HBs Ag spot (Quick) test
- Anti HCV spot (Quick) test
- TPHA (Treponema pallidum Hemagglutination) test

C. Parasitology

- **Urine Analysis**
  - Routine/Microscopic examination
  - Protein
  - Glucose (sugar)
  - Specific gravity
  - Bile salt Bile pigment
  - Reducing substances
  - Acetone/Ketone
  - Urine pregnancy test (Qualitative)
  - Chyle
  - Urobilinogen
  - Benedict test
  - Sulfosalicylic acid test

- **Stool Examination**
  - Routine/Microscopic Examination
  - Occult blood test
  - Reducing Substances
  - Concentration method for parasitic ova & cysts
  - H. pylori antigen test

D. Miscellaneous:

- Perform semen analysis.
- KOH & germ tube test for fungal study.
- CSF/body fluid for:
  - Cell count (TLC & DLC)
  - Sugar estimation.
  - Protein estimation.

Students should be present in the departments at least 90% of the allotted days to be eligible to sit in the final examination. Students will have to perform all tests under the supervision of departmental staff and may be allowed to perform tests independently if the supervisor finds them perfect. Students should keep their practical record (logbook) signed periodically by their supervisor/instructor at the end of the posting in each subject.

Clinical Practice II (Hematology and Blood Banking)
(Hospital/Blood Bank Based)

Students will be posted in hospital/blood bank with hematology and blood banking facilities for 8 weeks at the end of course (i.e. in third year) for clinical practice. For this, students must be posted in all related Departments/Section of diagnostic laboratory and blood bank on rotation basis.

Course Description
This clinical practice program is designed to help the students to apply the comprehensive knowledge and skills learned in the training institute on actual situations. The program is offered after completing twelve weeks institution-based training in third year.

Course Objectives
At the end of the course, the students will be able to:

- Perform all routine and some special laboratory procedures independently and accurately as mentioned below, and
- Build confidence on laboratory procedures.

Placement schedule
The whole class of students will be divided into five groups and placed for the following sections of the pathology department.

S.N.	Practical Areas	Duration
1.	Hematology and Blood Banking Lab	9 Weeks
	Total Duration	**9 Weeks**

Skills to be performed during the clinical practice

Each student should perform the following skills independently and accurately during the clinical practice.

A. Hematology and Blood banking

- Total leucocyte count (TLC)
- Differential leucocyte count (DLC)
- Erythrocyte sedimentation rate (ESR)
- Packed call volume (PCV)
- Hemoglobin (HB)
- Bleeding time (BT)
- Clotting Time (CT)
- Prothrombin Time (PT)
- Activated Partial thromboplastin time (APTT)
- Platelet Count
- RBC Count

- Reticulocyte Count
- Blood grouping (ABO)
- Rh typing
- Cross matching
- Coombs tests
- RBC indices (MCV, MCH & MCHC)
- Hemoparasites (M.P, MF)

Students should be present in the departments at least 90% of the allotted days to be eligible to sit in the final examination. Students will have to perform all tests under the supervision of departmental staff and may be allowed to perform tests independently if the supervisor finds them perfect. Students should keep their practical record (logbook) signed periodically by their supervisor/instructor at the end of the posting in each subject.

Clinical Practice III (Biochemistry, Histopathology and Cytopathology) (Hospital/Laboratory Based)

Students will be posted in hospital/laboratory with Biochemistry, Histopathology and Cytopathology facilities for 8 weeks at the end of course (i.e. in third year) for clinical practice. For this, students must be posted in all related Departments/Section of diagnostic laboratory and blood bank on rotation basis.

Course Description
This clinical practice program is designed to help the students to apply the comprehensive knowledge and skills learned in the training institute on actual situations. The program is offered after completing twelve weeks institution-based training in third year.

Course Objectives
At the end of the course, the students will be able to:

- Perform all routine and some special laboratory procedures independently and accurately as mentioned below, and
- Build confidence on laboratory procedures.

Placement Schedule
The whole class of students will be divided into five groups and placed for the following sections of the pathology department.

S.N.	Practical Areas	Duration
1.	Biochemistry Lab	5 Weeks
2.	Histopathology & Cytopathology Lab	5 Weeks
	Total Duration	**10 Weeks**

Skills to be performed during the clinical practice

Each student should perform the following skills independently and accurately during the clinical practice.

A. Biochemistry

- Preparation of different types of reagents for the estimation of
  - Glucose
  - Urea
  - Creatinine
  - Uric acid
  - Total Protein
  - Albumin Globulin
  - Albumin Globulin ratio
  - Amylase
  - Lipid profile
  - Bilirubin
  - ALT (SGPT)

- AST (SGOT)
- Alkaline phosphates
- Sodium
- Potassium
- Chloride
- Calcium

Note: Prepare standard graph of various test.

B. Histopathology & Cytopathology:

- Microscopy
- Prepare fixatives and fixation of tissue
- Collect, transport and fix histopathological and cytopathological specimens.
- Process the grossed tissue
- Cut sections
- Prepare reagents and stains used for Hematoxylin &eosin stains, PAS/Alcian blue and ziehl- Neelsen stain.
- Prepare reagents and stains used for Giemsa and Papanicolaou stain
- Stain the section by H/E and Ziehl-neelsen stain
- Prepare cytological fixative and fixtion of cells
- Prepare cytological smears and stain with pap method
- Stain FNAC smears by Giemsa and pap method.
- Mount stained smears/sections
- Perform Aceto-orcein staining for Barr bodies.

Students should be present in the departments at least 90% of the allotted days to be eligible to sit in the final examination. Students will have to perform all tests under the supervision of departmental staff and may be allowed to perform tests independently if the supervisor finds them perfect. Students should keep their practical record (logbook) signed periodically by their supervisor/instructor at the end of the posting in each subject.

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