

# ORGANIZATION OF CLINICAL PHARMACOLOGY UNIT AT THE INSTITUTE OF MEDICAL SCIENCES, SRINAGAR

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## INTRODUCTION

The Institute of Medical Sciences, Srinagar is being developed with the objectives of providing facilities of specialized medical care, postgraduate medical education and developed investigative, therapeutic and supportive services, the Institute will offer an opportunity to the scientific community to work together within an intellectual milieu to find solutions to the problems of human suffering.

The Institute is a modified version of the National Institutes already existing in our country and its design considerations are based on the needs of the patients and the community. Although, it is a tertiary organisation in terms of its scope and magnitude, its activities will also reach out to the families in their home environment, making it an integral part of the socio-medical organization of the State.

In collaboration with the two medical colleges, their associated hospitals and other health institutions in the State, the Institute is developing all such specialities, super-specialities and sub-specialities, which are important from the point of community needs and are either not represented or are inadequately developed in the region.

## OBJECTIVES

Clinical Pharmacology is one such speciality which is being developed at the Institute as an independent discipline with the following objectives.

### (a) *Service objectives*

(i) therapeutics, (ii) drug assay, (iii) clinical toxicology, (iv) pharmacokinetics and (v) adverse reaction surveillance.

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**(b) Research objectives :**

(i) clinical drug trials, (ii) evaluation of plant medicines and (iii) community pharmacology.

**(c) Educational objectives :**

(i) training programmes and (ii) information on new drugs.

**(d) Administrative and regulatory objectives :**

(i) drug policies and (ii) liaison with outside agencies.

**Operational policies :**

The Clinical Pharmacologist by virtue of his training is the most appropriate person to be consulted whenever problems in therapy or suspected adverse reaction to drugs occur. Multiple drug therapy is probably the most common cause of such adverse reactions. One of the functions of Clinical Pharmacology Unit of the Institute will be to offer consultancy in therapeutics.

To enable rational use of drugs and to facilitate calculation of drug dosage on a scientific basis, to study drug interactions and to understand why a drug is not effective or is inducing side effects at low doses, or in other words to monitor drug therapy, it is essential that the Clinical Pharmacology Unit is backed up by laboratory facilities to measure plasma levels of circulating drugs in patients. The department, therefore, will have a Drug Assay Laboratory which in the initial stages will offer facilities for assay of drugs like digitalis, salicylates, phenytoin, warfarin, amytryptiline, gentamicin and barbiturates etc. In collaboration with Clinical Chemistry Unit, the department will endeavour to establish the Poison Treatment Centre in due course.

Critical patients demanding intensive-care for revival, restoration or sustenance of their vital functions are often on multiple drug therapy, posing added problems of pharmacokinetics. Monitoring drug therapy in such patients assumes critical importance. The department with its supporting drug assay laboratory will offer facilities for charting out therapy in such patients.

Drug reaction surveillance will constitute an important function of the department and the techniques deployed will include voluntary reporting, active surveillance of hospital patients, surveillance of patients under a particular suspected drug therapy, surveillance of a particular side effect etc. An adverse Drug Reaction Registry will be set up and through prospective surveillance, efforts will be made to establish epidemiological basis of such

reactions. Para-professionals like pharmacists and nurses who are concerned with direct patient-care will be associated in this programme so that reporting of drug reactions becomes a standard hospital practice.

A bed complement of 10 has been assigned to the **Clinical Pharmacology Unit** for studies in human pharmacology and pharmacokinetics. These studies will include phase-I trials with new drugs. Collaborative phase-II and phase-III studies will also be conducted with the clinical departments. Since such studies often demand a prolonged hospital stay of two to three weeks, in each case, availability of clinical pharmacology beds will serve as an incentive to the clinicians to join hands in such studies. The department will also assist the clinical departments in formulating research designs and analysing the results of such trials.

The State of Jammu and Kashmir is a herbal treasure and therefore, clinical evaluation of plant medicines will constitute an important research activity of the department. Since the therapeutic effect of such remedies would already be known, double blind and controlled clinical trials of such remedies will be undertaken after preliminary toxicology studies in animals.

The Institute is designed to represent all the three tiers of health delivery system. Each of these tiers will cover a defined geographical area and population group. This broad-based organizational structure of the Institute will serve as an experimental model where different patterns of health delivery system will be subjected to vigorous and continuous scientific enquiry. Studies on community pharmacology on drug usage, practicing habits of physicians, self administration of drug etc. will be carried out within a population of 100,000 around the Institute in urban as well as rural settings.

In collaboration with the Medical College, Srinagar the department will organize teaching programmes for medical students, nursing staff and pharmacists etc. in clinical pharmacology and drug usage. Training facilities at doctoral and post-doctoral levels will also be developed in a phased manner,

Uptodate knowledge about the plethora of drugs being released in the market and their comparative merits in regard to therapeutic effectiveness and clinical toxicology is seldom available. The department will therefore, devise means to spread such information by participation in grand rounds, seminars etc. and through the publication of a Drug Bulletin.

The Institute will have a Drug Committee to formulate, administer and evaluate drug policies regarding prescription, administration and usage of drugs. Head of the

Clinical Pharmacology Unit will logically be an important member of the said committee to advise on additions and deletions of drugs in the Institute formulary and modifications in drug prescribing policies of the hospital.

The Clinical Pharmacology Unit will have liaison with the National Drug Regulatory Agency in regard to the need to introduce or withdraw drugs from the Indian market on the basis of their clinical effectiveness or reported toxicity, respectively. A liaison with the pharmaceutical houses will also be established to ensure the availability of vital and life saving drugs on the inventories of the Institute, at all times.

#### **Staffing :**

The professional hierarchy of the Institute shall include Senior Consultants and Consultants. Professors and Associate Professors will fall under the category of Senior Consultants and Assistant Professors and Lecturers under that of Consultants. Each Senior Consultant, whether a Professor or an Associate Professor will head a unit consisting of one Senior Consultant, one Consultant and two Senior Residents in addition to their personal staff. Further each department will consist of one or more units depending upon its clinical, investigative, therapeutic or supportive load of work.

It is envisaged that some of the units will have extra work load of specific nature which will demand an additional consultant and resident staff. For example trauma work under Orthopaedics, head injuries under Neruo-surgery, burns under Plastic Surgery etc.

At the time of initial appointment a Senior Consultant will be selected as a Professor or Associate Professor depending upon his professional background and expertise. In the case of an Associate Professor, his upgradation to the post of Professor shall be by promotion on the recommendation of the Apical Selection Committee of the Institute. Likewise a Consultant will be selected as Assistant Professor or Lecturer and upgradation of a Lecturer to that of an Assistant Professor will be by promotion. Upgradation from the level of a Consultant to that of the Senior Consultant, however, will be by open selection.

A department having more than one unit will be headed by one of the Professors on rotational basis for a period of three years, during which he will be designated as Director Professor. Associate Professors of such a department, however, will not be eligible for this appointment unless none of the units is headed by Professor. In such cases one of the Associate Professors will be designated as Head of Department and not Director Professor. In a department having only one unit, Director Professor or Head of Department, as the case may be, will continue as such without rotation.

Keeping in view the objectives and operational policies of the department, one unit has been created in the department of Clinical Pharmacology with one post of Senior Consultant, one post of Consultant and two posts of Senior Residents. One additional post of a Consultant and two posts of Senior Residents are provided for drug assay and clinical toxicology. Secretarial assistance in the form of one Senior Stenographer, a Typist Clerk and two Hospital Attendants are also provided as per the norms of the Institute.

The number of Junior Residents will be determined by the clinical as well as laboratory commitments and also the teaching and research programmes of the department.

A Nurse Epidemiologist will be an additional member to the nursing team of the clinical pharmacology ward. Technical staff for drug assay and clinical toxicology laboratories, animal and laboratory attendants etc. will be provided depending upon the work load.

Since the surveillance of adverse drug reactions and formulation of drug policies of the Institute will be programmed through the HCL-8C computer, assistance of a Systems Analyst and/or statistical staff will also be provided if considered necessary.

#### **Physical facilities :**

The Clinical Pharmacology Unit having 10 beds will share a 33 bedded progressive patient-care ward with Clinical Haematology Unit (12 beds) and Endocrinology Unit (10 beds). One isolation room provided in the ward will be common to all the three units.

Since the primary objective of a ward is to facilitate the nurse to hear and see all that matters and to react to every situation with utmost efficiency and minimum physical and emotional stress, parameters like observability, noise and disturbance, privacy and isolation, ventilation and lighting, communication and recreation, graded nursing etc. have been given special emphasis while designing the ward unit.

The Drug Assay and Toxicology Laboratories having an area of 60 sq. meters and located next the Clinical Chemistry Laboratory constitute an integral part of the 'Clinical Laboratory Complex'. Additional facilities for glassware washing and sterilization, storage of supplies, animal rooms and consultant's room etc. are also provided.

A versatile system for sample receipt and preparation combined with report distribution is being developed for which adequate space has been ear-marked within the Clinical Laboratory Complex.

An elaborate description of the physical facilities referred to above justifying the functional criteria for a balanced and sound layout planning, and work-flow criteria for maximum economy of physical and emotional stress to the patients and the staff, is under active consideration of the Working Group and will be published separately in the near future.