"This prospectus is made under the provisions of the Universities Act, the Postgraduate Institute of Medicine Ordinance, and the General By-Laws No. 1 of 2016 and By-Laws No. 2 of 2016 for Degree of Doctor of Medicine(MD) and Board Certification as a Specialist"

POSTGRADUATE INSTITUTE OF MEDICINE

UNIVERSITY OF COLOMBO, SRI LANKA

PROSPECTUS

BOARD CERTIFICATION IN CLINICAL PHARMACOLOGY AND THERAPEUTICS (CPT)

2011

Speciality Board in Clinical Pharmacology
Board of Study in Multidisciplinary Study Courses

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Prospectus for Board Certification in Clinical Pharmacology and Therapeutics (CPT)

1. Introduction

The training programme leading to Board Certification in Clinical Pharmacology and Therapeutics (CPT) will be conducted by the PGIM. This programme will be conducted by the Speciality Board in Clinical Pharmacology and report to the Board of Management through the Board of Study in Multidisciplinary Study Courses. The Speciality Board in Clinical Pharmacology will comprise of clinical pharmacologists representing the different Faculties of Medicine in the country, representatives from Boards of Study of the PGIM which have close relevance to training of clinical pharmacologists, representatives from the Department of Health Services, co-opted members and an overseas advisory panel.

2. Justification

2.1. **The need for clinical pharmacologists in the Ministry of Health (MoH):** The Director/Medical Technology and Supplies (D/MT & S) and Director/Medical Supplies Division (D/MSD) are the two focal points for dealing with drugs in the MoH. If the Ministry has the services of clinical pharmacologists the present problems that it is facing such as procurement problems, delays, poor quality drugs, drugs going out of stock, wastage, big expenditure on local purchase could be reduced. The limited health care budget could be used more optimally.

2.1.1 The D/MT&S and D/MSD have to play a key role in implementation of the National Medicinal Drug Policy. Hence these offices will need people who have understanding on Drug Policy and its implementation.

2.1.2 Registration of Pharmaceuticals is a specialized subject. Evaluation of registration files, efficacy safety data etc are important functions that are done in other countries by pharmacologists with training in these areas

2.1.3 Promoting rational drug use starting from selection of appropriate drugs for state sector based on current evidence and considering cost effectiveness and thereby effective management of drug budget, can be best achieved by appointment of clinical Pharmacologists with specialist knowledge in these areas.

2.1.4 For proper implementation of the Cosmetics Devices and Drugs (CDD) Act pharmacologist input is needed. Evaluation of drug promotion, advertisements, and the overall effect on the society are areas where clinical pharmacologists have expertise.

2.1.5 A National Drug Information Centre (DIC) is a long felt need. The existing "centre' could be upgraded and kept under the supervision of a clinical pharmacologist appointed by the Ministry of Health.

These posts need the support of clinical pharmacologists who have a sound knowledge on pharmaceuticals. Presently, as there are no such personnel in these sections of the MoH, it has to lean heavily on outsiders, especially academic departments of pharmacology. If the Ministry has its own trained officers, the administration and provision of services would be much more efficient and much more work, drug audits, economic analyses etc could be done, apart from what is presently done by academic pharmacologists on a voluntary basis. As health is a devolved subject under the 13th amendment the provincial health administration may also need specialists trained in CPT.

2.2. **The need for clinical pharmacologists in the Hospitals:** Most teaching hospitals in the developed world and also in the region have clinical pharmacologists attached to them. Often they function as general physicians with specialized knowledge in clinical pharmacology. The Ministry of Health in Sri Lanka has a single pharmacologist, and presently he is attached to the Medical Research Institute (MRI). However for a country with a population of 19 million we will definitely need a lot more clinical pharmacologists. Some areas where expertise of clinical pharmacologists are utilised in other countries are listed below.

2.2.1 Adverse drug reactions (inclusive of the drug interactions) are an important cause for morbidity and mortality. They are a common reason for hospital admission. There aren't any data on this problem in Sri Lanka. The country would benefit by having trained clinical pharmacologists to investigate and manage these patients.

2.2.2 Medication errors are being recognized globally as an emerging health care problem. In the recent future it will become necessary for the hospitals to have appropriate systems in place to handle these problems.

2.2.3 Therapeutic drug monitoring (TDM) is an important aspect of patient care. Measurement of levels of antimicrobials (eg.aminoglycosides), paracetamol lithium, anticonvulsants, cyclosporine are routine in most overseas hospitals. Sri Lanka will need people trained in this field to supervise TDM work.

2.2.4 Similar to other specialists, the clinical pharmacologists are consulted to optimize patient management, *eg.*, dosage adjustments, managing adverse drug reactions, advise on avoiding drug interactions etc.

2.2.5 Providing drug information at institutional level and giving leadership to drug information services. Clinical pharmacologists in several countries function in an advisory capacity in managing drug overdoses and poisoning.

2.2.6 Implementing activities towards rational drug use. These include implementation of antibiotic policies, coordinate the development and implementation of patient management guidelines etc. Clinical pharmacologists give leadership in hospital Drug and Therapeutics Committees (DTC) and help in managing drug supplies, manage the drug budget etc. Their input will reduce wastage of drugs and resources.

2.2.7 They also manage clinical trial units and contribute to monitoring of clinical trials are conducted in the hospitals and provide services to research and clinical ethics committees.

2.2.8 Most clinical pharmacologists in other countries possess expertise in toxicology and they function in managing poisoned patients and giving leadership to poison units and poison information centres. These are some areas where adequate expertise is presently lacking in our hospitals to meet the demand of increased load of poisoned patients. If clinical pharmacologists are there they could undertake such functions.

2.2.9 Education of various categories of hospital staff on use of medicines and effective management of clinical pharmacy services.

2.2.10 Carry out research related to rational drug use, adverse drug reactions, drug utilisation studies which could form the basis for implementation of changes and policies

All the above tasks that are carried out by clinical pharmacologists in other countries are relevant to Sri Lanka also. Therefore, to begin with, at least the Teaching Hospitals should get the services of the clinical pharmacologists to improve the quality of services. It must be highlighted here that unlike some specialities which require provision of additional infrastructure when appointing specialists to those fields (e.g. provision of expensive equipment, theatre facilities etc), such additional resources are not needed when appointing clinical pharmacologists.

2.3. **The need for clinical pharmacologists in the universities:** Pharmacology is the only para-clinical discipline in the universities where presently there is no established training programme for postgraduate training in Sri Lanka. The establishment of a training programme in this speciality is long overdue. Presently the academic staffs of

Departments of Pharmacology are undergoing training in the disciplines of clinical medicine, paediatrics or anaesthesia. Some of them are doing these specialities simply because specific training in CPT is presently not available through the PGIM. As more and more new universities are being established, there is a greater need for training of clinical pharmacologists to the universities also. The PGIM being part of the university system, has a responsibility for training of the academic disciplines needed for the universities also. Recently the Sri Lanka Medical Council (SLML) which has a supervisory role on undergraduate and postgraduate medical education wrote to the PGIM about the need for starting postgraduate training programs in basic sciences.

2.4. **The need for clinical pharmacologists in the local pharmaceutical industry:** There are no medical professionals trained in clinical pharmacology in the local pharmaceutical industry. Clinical pharmacologists in the industries could contribute constructively towards appropriate promotion of medicines, new drug development, clinical trials, bioequivalence studies, drug information and pharmacovigilance. They can create a conducive environment in the industry towards better use of medicines.

2.5. **Private sector:** The private sector in health care is expanding rapidly and it is likely that some of the bog private hospitals will also need the services of clinical pharmacologists.

3. Objectives of Training

The primary purpose of postgraduate training in clinical pharmacology is the development of a physician who has the appropriate level of knowledge, skills, attitudes and competence to work independently and effectively as a consultant in clinical pharmacology. Patient centred approaches and team work are of vital importance. Training should be enjoyable in order to facilitate the learning of the trainee and encourage developing an approach towards lifelong learning.

4. Duration of programme 3 ½ years

As in other sub-specialities an additional period of about 3 years after MD (Part II) is needed to complete the training in CPT.

5. Course structure:

Stage I – Entry Point
Stage II – Local 2 years
Stage III – Overseas 1 year
Stage IV – Board Certification

5.1. **Stage 1**: Successful completion of all the stages leading to MD (General Medicine) Part II, conducted by the Board of Study in Medicine. Those candidates who want to take up clinical pharmacology after following specialties other than Clinical Medicine will be enrolled at points parallel to the point of entry in the Clinical Medicine training programme. Other specialities whose trainees may be considered for final training in CPT include paediatrics, anaesthesia, oncology and psychiatry.

5.2. **Stage II: local training in CPT**

5.2.1. Eligibility to enter the Stage II will be successful completion of MD (General Medicine) Part II examination

5.2.2. Stage II will consist of at least one year of training in CPT locally and will be extended to two years if overseas training period is only one year

5.2.3. The local training component will comprise of 12 identified modules, in training units identified for each module. The candidate will be assessed on each module based on the training log maintained, supervisors reports and a portfolio developed demonstrating evidence of achieving the expected competencies by a panel of examiners appointed by the Board of Study. These modules can run concurrently, but should be completed at least within one year

of local training, which could either be continuous or interrupted by a period of foreign training.

5.2.4. It is required that a candidate has to complete the compulsory modules identified before entering Stage III.

5.3. **Stage III**: At least one year training in CPT in an Institution/Centre overseas, which is recognized by the Speciality Board for training in CPT.

5.4. **Stage IV**: On return to Sri Lanka, after successful completion of assessments in CPT and completion of stages I, II and III of the training programme, the trainee will have to appear for an appropriate exit examination. Once the candidate has passed the exit examination, the candidate will be recommended for board certification in CPT.

6. Method of selection of trainees

6.1. Entry requirements: The Senior Registrar level candidate who has completed PGIM MD (Medicine) Part 1 and Part II examinations successfully. General professional training acquired between these exams (*ie*. Part I and Part II) is a sufficient prerequisite for undertaking specialist training in CPT.

6.2. Selection criteria: Selection will depend on the MD (Part II) rank, preference of candidate and number of vacancies available for training in CPT each year based on an assessment of total country requirements for clinical pharmacologists. In general only a few trainees (2 to 3) will be enrolled annually. Candidates from specialties other than General Medicine, eg, Paediatrics, Anaesthesiology could be considered for selection into the training programme.

7. Training requirements

7.1. To acquire knowledge, skills and attitudes in the areas outlined in the curriculum (Section 13)

7.2. Maintain a case record book of required number of cases specified by PGIM (case record book) - this will be during the General Medicine Training period.

7.3. Maintain a Log Book – (Section 9)

7.4. Develop a portfolio demonstrating the acquisition of knowledge, skills and attitudes outlined in the curriculum of CPT (Section 15) This is to be done during post MD training period

7.5. Complete a research project in the discipline of clinical pharmacology – Section 11); This is to be done during post MD training period.

7.6. Carry out regular teaching for undergraduates and postgraduate trainees in the field.

7.7. Attend workshops, conferences, and training sessions related to CPT, ethics, research methodology, clinical trials, statistics

7.8. Present papers at meetings and conferences and write articles for publication in journals.

7.9. Complete prescribed course work from recommended local and overseas courses such as in toxicology or pharmacoepidemiology.

8. Coordination of the programme

A coordinator for the CPT training programme will be appointed by the PGIM who will coordinate the training in the different components, arrange assessments and assist in the completion of training of the trainees.

9. Log Book (Training Record Book)

A log book should be maintained by the trainee, which will be regularly inspected and signed by the supervising consultant in CP at three monthly intervals. The trainee should record procedures and trainings undertaken, clinical meetings and teaching sessions attended, research carried out etc. The trainee should produce this log book at the assessments and other times when requested.

10. Development of portfolio

During post MD training period, the trainee will be expected to develop a portfolio to show evidence of professional development and acquisition of knowledge skills and attitudes stated in the curriculum This would include writing up on tasks undertaken, and completed and reflection on these activities, including writing up of cases relevant to CPT with extensive reading and reference, research carried out, participation in clinical trials, evaluation of drug dossiers submitted for registration, handling of ADR reports, drug information queries, evaluation of research proposals submitted for approval by the ethical review committee, student teaching activities and any other relevant tasks undertaken with the approval of mentor/supervisors. Each trainee will have an identified clinical pharmacologist as the mentor for this purpose approved by the Board of Study. In summary the portfolio should provide evidence that the trainee is competent in all identified areas of the curriculum in CPT.

11. Research

Trainees should undertake a research project in the area of CPT during the post-MD period. The research proposal should be submitted to the Board of Study and approval obtained before starting the research. The trainee should have a supervisor approved by the Board of Study. A detailed report on the research project should be submitted to the Board of Study for evaluation. The report should follow the basic guidelines in preparing of such documents.

12. Assessments

12.1 Introduction

Six assessments are planned during the post-MD training period, each assessment being held at approximately 6 monthly intervals. Each trainee has to submit a portfolio and be able to satisfy the examiners that the trainee has obtained adequate competence in the compulsory modules (Modules 1 to 11) of the curriculum. These compulsory modules may be completed during the local training or during the foreign training or during both periods of training. The assessment methods will be (i) progress report by the supervisors (ii) assessment of the portfolio (iii) portfolio based oral examination (iv) research. The assessments will be carried out by a panel of examiners appointed by the Board of Study.

The marks allocation of the assessments is given below in the Table.

12.2 Marks allocations table

Timing	**Assessment methods**	**Marks allocation**
End of 6 months	Progress report	2.5
	Portfolio	2.5
	Viva	2.5
	Research proposal	2.5
	Total marks	**10**
End of 12 months	Progress report	5
	Portfolio	5
	Viva	5
	Research -proposal/progress report	5
	Total marks	**20**
End of 18 months	Progress report	5
	Portfolio	5
	Viva	5
	Research - progress report	5
	Total marks	**20**
End of 24 months	Progress report	5
	Portfolio	5
	Viva	5
	Research - progress report	5
	Total marks	**20**
End of 30 months	Progress report	5
	Portfolio	5
	Viva	5
	Research - progress report	5
	Total marks	**20**
End of 36 months	Progress report	2.5
	Portfolio	2.5
	Viva	2.5
	Research – final report	2.5
	Total marks	**10**
Final Marks		**100**

12.3. First year assessments

These two assessments will be conducted in Sri Lanka.

12.4 Second year assessments

These may be conducted in Sri Lanka or in the country of foreign training.

12.5 Third year assessments

The fifth assessment may be conducted in Sri Lanka or in the country of foreign training. The sixth and final assessment will be done after return to Sri Lanka.

At each assessment a mark of 60% and above is considered as a pass and a mark below 50% is considered as a fail. Failure warrants re-training for a minimum period of 3 months and re-assessment to pass the assessment. A mark between 50% and 60% at the six monthly assessment will warrant review by the examination panel to identify specific areas that require supervised training and re-evaluation that must be assessed and certified as passed.

12.6 Exit Examination and Board Certification

On return to Sri Lanka, after successful completion of assessments in CPT and completion of stages I, II and III of the training programme, the trainee will have to appear for an exit examination which will have MCQ and SEQ components. Once the candidate has passed the exit examination, the candidate will be recommended for board certification in CPT. Candidate will be suitable for board certification if scored 60% or more in each assessment and passed the exit examination. Those candidates having adverse comments on professional conduct will be dealt with according to PGIM guidelines.

13. Local training modules, training units and the trainers

13.1 Stage I: Successful completion of MD (General Medicine or Anestesiology) references.

13.2 Stage II Two years of local post MD training. The trainee will be posted to a General Medicine unit (six months) and Paediatrics (6 months) ward (fist year) or an appropriate unit specified by the Specialty Board in Clinical Pharmacology for training as a Senior Registrar in the second year. Throughout the training as a Senior Registrar the trainee will be attached to an academic clinical pharmacology unit which has been approved by the Board of Study in Multidisciplinary Study Courses.

During this period, in addition to designated duties as a Senior Registrar in the ward (2 to 3 days of the week), the trainee has to attend to training relevant to clinical

pharmacology as arranged with a clinical pharmacology unit (in a Medical Faculty). This would include training in identified training units for modules of local CPT training, such as the Drug Regulatory Authority(DRA) Medical Supplies Division(MSD), National Drug Quality Assurance Laboratory(NDQAL), State Pharmaceuticals Manufacturing Corporation (SPMC) and State Pharmaceuticals Corporation (SPC). The trainee has to include a detailed report of training undertaken in the portfolio.

13.3 Modules for local training and training units identified

13.3.1 Module 1: Academic clinical pharmacology: Departments of Pharmacology in the Faculties of Medicine. Specific Departments to be identified based on training that can be offered and the PGIM recommendations for training units.

The overall objectives of Modules 1 and 2 are to give a comprehensive knowledge about the various drugs that are acting on the different systems in the body. Both the theoretical aspects as well as clinical aspects will be covered here. More detailed objectives relevant to modules 1 and 2 are given in section 15.2.

13.3.2 Module 2: Clinical Pharmacology and Therapeutics: Clinical Medicine Unit and an academic department of pharmacology.

13.3.3 Module 3: Regulatory Pharmacology – Drug Regulatory Authority

The general objective is to be knowledgeable about the Cosmetics Devices and Drugs (CDD) Act and implementation of regulatory activities in Sri Lanka. The functioning of the Technical Evaluation Committee and the Drug Evaluation Sub-Committee will be studied. More specific objectives for this module are given in section 15.5.

13.3.4 Module 4: Medicines Management (procurement, distribution and supply): Medical Supplies Division

The general objective is to be knowledgeable about the process of procurement of drugs for the State sector. The trainee is expected to become familiar with the various steps in the procurement process. More specific objctives are given in sections 15.2 and 15.8.

13.3.5 Module 5: Industrial Pharmacology: SPMC, State Pharmaceutical Corporation (SPC), pharmaceutical industry.

The general objective is to be knowledgeable about the state of drug manufacture in Sri Lanka. The student may have to visit a manufacturing plant also

13.3.6 Module 6: Clinical Trials: In a unit which conducts clinical trials, preferably according to GCP guidelines

The general objective is to get a comprehensive knowledge about all aspects of clinical trials, ranging from design to implementation and analysis. More specific objectives are given in sections 15.1, 15.6, 15.7 and 15.11.

13.3.7 Module 7: Drug Information and Adverse Drug Reaction (ADR) monitoring: National Pharmacovigilance Centre, Department of Pharmacology, Colombo, Adverse Effects Following Immunization (AEFI).

The general objective is to be able to recognise, manage, report, prevent Adverse Drug Reactions(ADR). More specific objectives are given in sections 15.9 and 15.12.

13.3.8 Module 8: Laboratory module: Quality testing of pharmaceuticals, Good Laboratory Practice, Therapeutic Drug Monitoring – in NDQAL, MRI

The general objective is to be knowledgeable about laboratory practices pertaining to practice of pharmacology. The trainee is expected to get a general idea about the type of tests done during quality assurance of pharmaceuticals. In addition details of therapeutic drug monitoring will be covered here

13.3.9 Module 9: Essential Medicines List, rational use of medicine and drug utilization : MSD, academic departments of pharmacology

The general objective is to be knowledgeable about the EML, criteria for selection of essential medicines, their use etc. More specific objectives are given in section 15.4.

13.3.10 Module 10: Clinical Toxicology: In Clinical Toxicology Unit, University of Peradeniya and National Poisons Centre, NHSL

The general objective is to be able to advise on management of patients admitted with poisoning. More specific objectives are given in section 15.10

13.3.11 Module 11: Clinical Pharmacology in special situations **(**children, pregnancy, elderly and in organ failures): Lady Ridgeway Hospital, DMH, Clinical Medicine Unit and academic Department of Pharmacology.

The general objective is to be competent about the principle of drug use in children, elderly, in cardiac, renal and hepatic disease etc. More specific objectives are given in section 15.14

13.3.12 Module 12: Pharmacoeconomics and Pharmacogenetics Module: Any research team doing such work locally.

The general objective is to be competent about the economic aspects pertaining to drug use in communities. Pharmacogenetics covers genetic aspects of variation of drug metabolizing enzymes in communities, their inheritance etc. More detailed objectives are given in section 15.3.

For completion of some of these modules such as clinical toxicology or pharmacoepidemiology, relevant course work from existing PGIM or overseas course acceptable to the Study Board may be recommended.

14 Foreign training units and trainers

14.1 The overseas training period will be at least one year with hands on experience in CPT. The centre should ideally be an academic unit of CPT which will provide training in areas that are not available in Sri Lanka. These include clinical trial units conducting healthy volunteer studies, pharmacokinetic and pharmacodynamic studies, therapeutic drug monitoring, carrying our research in pharmacoeconomics, drug utilisation, monitoring and evaluation of new chemicals for registration, overseas drug regulatory systems, monitoring adverse drug reactions, pharmacogenetics and personalised medicines etc.

14.2 The training opportunities that can be provided to the trainee should be obtained from the prospective supervisor. The training unit should be approved by the Specialty Board of Clinical Pharmacology and the Board of Study in Multidisciplinary Studies prior to any trainee embarking on training in a particular centre.

14.3 The supervisor should intimate to the PGIM the ability to provide the training prescribed in the curriculum, have appraisal meetings with the trainee and provide

supervisor's reports at the end of every 6 months of training based on the performance of the trainee.

15. Curriculum and Content of learning

At the completion of training, by a process of consolidation through the years of exposure in the training programme, facing a variety of experiences, the trainee should have acquired the following knowledge, skills, and attitudes to function as a specialist in CPT.

Most of the following sections have been adapted from the specialty training curriculum for Clinical Pharmacology and Therapeutics of the Joint Royal Colleges of Physicians training Boards in UK (1) to suit the local training requirements. Some sections are copied *verbatim* from the above document.

15.1 Undertake and interpret early phase studies of drug action in humans as per Good Clinical Practice (GCP) guidelines

Knowledge

- Describe theories of drug-receptor interactions and related concepts of agonists, antagonist, structure action relations, pharmacodynamics (PD), pharmacokinetics (PK), PK/PD interrelations, efficacy and potency.
- Recognise the meanings of surrogate endpoints, tolerability and adverse effects.
- Demonstrate knowledge of the principles of 'first into man' studies.
- Demonstrate knowledge and understand the limitations of preclinical studies in the early phase of human testing of biological products.

Skills

- Write trial protocols.
- Write and submit research ethics committee submissions.
- Able to recruit subjects for studies and obtain valid informed consent.
- Perform PD and PK studies in human volunteers (including cannulation and other skills relevant to their clinical area of expertise)
- Measure end points reliably.
- Record data accurately
- Analyse data including risk-benefit analysis and dose determination for definitive phase III studies.
- Identify, review and analyse relevant literature.
- Draft papers for publication.

- Ø Communicate with co-workers and agree on a final manuscript for submission.
- Ø Demonstrate communication skills in effective presentation of a paper at scientific meetings

Attitudes/Behaviours

- Ø Consult appropriately. Recognise the primacy of subject safety.
- Ø Appreciate the need for meticulous record keeping and research governance.
- Ø Appreciate the importance of communicating research data orally and written form and is diligent in writing and rehearsal.

15.2 Use pharmacological principles to optimize drug administration and drug effect

Knowledge

- Ø Describe the principles of correct choice of route of administration, absorption of drugs, metabolism and excretion of drugs, interpretation of drug concentration in body fluids, pharmacokinetics, drug assay PK-modelling, pharmacogenetics, PK-based drug interaction, personalised medicine.
- Ø Demonstrate knowledge of common analytical methods and their limitations.
- Ø Demonstrate knowledge of good laboratory practice (GLP)
- Ø Demonstrate knowledge in therapeutic drug monitoring

Skills

- Ø Construct and adjust dose regimens correctly.
- Ø Negotiate an acceptable regimen with the patient where appropriate.

Attitudes/Behaviours

- Ø Recognize the need for individualisation of therapy where necessary.
- Ø Recognize the importance of taking responsibility for repeated observation and ongoing patient follow-up on the wards, and for volunteer follow-up during clinical investigation.
- Ø Respect patient/subject autonomy.
- Ø Recognize the importance of concordance.

15.3 Use drugs rationally and cost-effectively

Knowledge

- Ø Demonstrate knowledge of the mechanisms of action and the modes of use of common therapeutic drugs.
- Ø Demonstrate knowledge of sources of individual variation; genetic, age-related, and gender- related (including pregnancy and lactation), and other sources of individual

variation especially co-existing renal, hepatic and other disease and drug interaction both beneficial and adverse.

- Ø Explain the roles of national and international agencies including the Drug Regulatory Authority in Sri Lanka, Medicines and Medical Devices Health Regulatory Agency (MHRA) in UK, European Medicines Evaluation Agency (EMEA), National Institute for Clinical Excellence(NICE) in UK , FDA in USA, Therapeutic Goods Administration (TGA) in Australia in ensuring rational and cost effective use of medicines.

Skills

- Ø Communicate effectively with individual patients, clinical colleagues and in committees.
- Ø Select drug and dose regimens rationally based on individual factors.
- Ø Develop prescribing policies, formularies and guidelines.
- Ø Evaluate guidelines on medicines utilisation in the context of Drug & Therapeutics Committees (DTC).
- Ø Write guidelines in medicines management for evaluation by DTC.
- Ø Make effective submissions to formulary committees for new drugs.
- Ø Audit drug utilisation.

Attitudes/Behaviours

- Ø Prescribe with due regard to general knowledge, combined with specific patient related information relating to demographic characteristics, drug history and individual preferences.
- Ø Respect the varied expertise of DTC members with diverse skills and backgrounds.
- Ø Participate in decision making/consensus building in the context of DTC.

15.4 Promotion of Essential Medicines List (EML) concept

Knowledge

- Ø Be aware of background which led to the development of the concept of essential medicines
- Ø Demonstrate knowledge on definition of essential medicines
- Ø Demonstrate knowledge on need for EML and criteria to select essential medicines
- Ø Demonstrate knowledge on principles on which EML is developed
- Ø Describe role played by Professor Bibile in the development of EML
- Ø Demonstrate knowledge on international and national activities related to EML

Skills

- Ø Ability to develop a EML for the country

- Ø Ability to develop EML for special groups

Attitude/behaviour

- Ø Promote the development and use of EML concept in the country

15.5 Contribute to effective drug regulation in the country

Knowledge

- Ø Demonstrate knowledge on the Cosmetics, Devices and Drugs Act (CDDA)
- Ø Demonstrate knowledge on what a registered drug is
- Ø Demonstrate knowledge on what criteria are used when drugs are registered in this country
- Ø Demonstrate knowledge on how drugs are scheduled and how drugs are supplied to state institutions
- Ø Demonstrate knowledge on how drugs are supplied to private institutions and how drugs are priced
- Ø Demonstrate knowledge on what a drug dossier is and what documents are included in a dossier
- Ø Demonstrate knowledge on functions of the Drug Evaluation Sub-Committee(DESC), Cosmetics Devices and Drugs Authority(CDDA) and Technical Advisory Committee(TAC).

Skills

- Ø Ability to evaluate drug registration dossier effectively
- Ø Function as an effective member of DESC, CDDA or TAC

Attitude/Behaviour

- Ø Form ideas about the appropriate drug policy for Sri Lanka
- Ø Have a critical attitude towards the local pharmaceutical industry

15.6 Evaluate critically literature relevant to clinical pharmacology including basic pharmacology, toxicology, and phase I, II, III and IV clinical trials and meta-analyses.

Knowledge

- Ø Demonstrate knowledge of basic pharmacology and clinical medicine at levels of competency defined in the Clinical Pharmacology training programme of the PGIM.
- Ø Know how to report misleading advertising claims to regulatory authority

Skills

- Ø Critically analyse papers regarding rationale cogency, experimental design, analytical methodology, method of analysis, potential sources of bias, confounding conflict of interest, appropriateness of discussion, and validity of conclusions.
- Ø Critically analyse advertising claims made for medicinal products.
- Ø Use electronic databases (e.g. Medline, Embase, Toxbase, Cochraine)

Attitudes/Behaviour

- Ø Respect ethical principles underlying peer review.
- Ø Participate in peer reviews
- Ø Communicate effectively in journal clubs, drug and therapeutics and audit committee meetings.

15.7 Design clinical trials, including phase III studies, and contribute to their execution and dissemination. Select prospectively appropriate statistical methods for planned experiments (including clinical trials), perform such analyses, and interpret the resulting statistical output, carry out clinical trials as per GCP guidelines.

Knowledge

- Ø Describe different trial designs
- Ø Demonstrate knowledge of the principles of controlled experiments, randomization, use of placebo and blinding.
- Ø Describe principles underpinning ethics of research on human subjects including duties, rights and utilitarianism.
- Ø Demonstrate knowledge of good clinical practice (GCP).
- Ø Describe sources of biological variation and explain the principles involved in quantifying this.
- Ø Describe common parametric and nonparametric tests including chi-squared, t-tests, ANOVA, Bonferoni correction and least squares and Spearman rank regression.
- Ø Analyse critically the pros and cons of sequential analysis.

Skills-

- Ø Select a trial design appropriate to the research question.
- Ø Write a research ethics committee (REC) application.
- Ø Justify a research proposal in terms that are understood by the lay members of an REC.
- Ø Able to recruit research subjects.
- Ø Screen potential subjects for inclusion/exclusion criteria.
- Ø Obtain valid informed consent.
- Ø Arrange visits of research subjects to clinical laboratory or research clinic.
- Ø Perform and/or supervise clinical measurements.

- Keep records to the standards required by the GCP.
- Contribute to writing papers and reporting findings by oral and poster presentation at meetings.
- Consult effectively with statisticians during the planning stage of complex experimental studies.
- Interpret P values and confidence intervals (CI) including CI of differences in the case of negative trials.
- Explain the biological meaning of non-inferiority trials.
- Explain absolute versus relative risk reduction.
- Use modern statistical packages.

Attitudes/Behaviour-

- Maintain absolute honesty.
- Does not embark on human investigation where an external sponsor has ultimate control over the right to publish or disseminate resulting information.
- Maintain meticulous attention to detail.
- Recognize the primacy of safety of the subjects.
- Maintain a professional relationship with study sponsors and their employees (Contract Research Organizations etc).
- Possess a self-critical attitude that only accepts an outcome that is understood.
- Demonstrate a willingness to consult appropriately.
- Undertake work in a patient and meticulous manner.

15.8 Describe and influence what determines the pattern of use of medicines (medicine management) in populations

Knowledge

- Identify factors that affect drug utilisation including effects of: social class, ethnicity, nationality, economic status, co-morbidity, age and gender (including pregnancy and lactation).
- Demonstrate knowledge of factors affecting public perception of drugs and their use in treating and preventing disease, including effects of media on medicinal utilization.
- Describe the role of the pharmaceutical industry in the public perception of drug use.
- Explain the role of government in licensing, pricing and cost-benefit analysis underpinning drug availability in the state sector.
- Explain the role of local groups (DTC and formulary committees) in defining the availability of medicines in a local health context.

Skills

- Ø Apply this knowledge in individual patient practice and in drafting, management guidelines.
- Ø Interact effectively with the media as well as in committees.
- Ø Handle potential conflicts of interest appropriately.

Attitudes/Behaviour

- Ø Respect ethnic diversity.
- Ø Respect individual autonomy.
- Ø Contribute to public education about drugs and their utilisation.
- Ø Respect the law relating to medicines in the country (e.g. the Drugs Act)
- Ø Engage in the reform of current practice in the country (e.g. via participation in public consultation on medicines utilisation, promoting rational prescribing).

15.9 Anticipate (and hence minimize), detect, manage, report and analyse adverse drug reactions (ADR)

Knowledge

- Ø Demonstrate knowledge of:
  - · Important (common and /or severe) adverse effects of drugs used in their area of clinical practice.
  - · The mechanisms where by drugs cause adverse drug reactions (ADR).
  - · Common clinical presentations of ADR.
  - · Appropriate management of suspected ADR.
  - · Explain how ADR are identified and reported. Explain the classification of ADR.

Skills

- Ø Manage common and serious ADR, including anaphylaxis, appropriately.
- Ø Use printed and electronic resources to identify unusual or uncertain ADR.
- Ø Analyse post marketing surveillance studies critically.
- Ø Report suspected ADR appropriately.

Attitudes/Behaviour

- Ø Alert to the possibility that clinical events are drug-related.
- Ø Prepared to share information and suspicions and eschew secretiveness for perceived future gain.
- Ø Consult with colleagues over judgements such as risk/benefit if rechallenge is planned.
- Ø Maintain a healthy scepticism of marketing strategies dressed up as post marketing surveillance.

15.10 Advise on cases of overdose or poisoning, and to manage such cases as are relevant to their clinical speciality

Knowledge

- Ø Demonstrate knowledge of mechanisms of action of important poisons, including therapeutic drugs commonly taken accidentally or deliberately in overdose.
- Ø Demonstrate knowledge of strategies for management of poisoned patients including: protection of staff and other patients, decontamination, resuscitation monitoring; antidotes used for digoxin, iron, and cyanide and cholinesterase inhibitors etc.

Skills

- Ø Access information effectively including via the National Poisons Units. Access and keep up to date with national guidance on chemical attack.
- Ø Develop diagnostic skills relevant to the epidemiological context of chemical attack.
- Ø Maintain up to date qualification in resuscitation skills.
- Ø Possess skills in managing overdose with paracetamol, aspirin, opioids, benzodiazepines and tricyclics, antiepileptics, antipsychotics, drugs of abuse.

Attitudes/Behaviour

- Ø Prepare prudently in the face of possible chemical incident, protecting self and other staff and avoiding self contamination.
- Ø Once prepared, accept necessary residual risk in order to care for poisoned patients.
- Ø Respect patients with behavioural and psychiatric problems, and consult appropriately with colleagues in provision of psychiatric support.

15.11 Recognise the principles of research ethics and contribute to the process by which ethical research in human subjects is promoted

Knowledge

- Ø Identify ethical principles on which human research rests.
- Ø Explain how decisions are made when ethical principles conflict with one another.
- Ø Justify the constitution/membership of research ethics committees (REC).
- Ø Demonstrate knowledge in the following areas: Appropriate terms of reference of REC.
    - · Appropriate terms of reference of REC.
    - · International guidance on ethical research in humans(e.g. the Declaration of Helsinki and ICH-GCP guidelines)
    - · The legal framework in which REC operate in Europe and the UK.

Skills

- Ø Analyse REC applications and information documents.
- Ø Ask pertinent questions from applicants and fellow committee members including specialists such as lawyers and statisticians.
- Ø Communicate effectively in an REC.

AttitudesBbehaviour

- Ø Respect confidentiality of information.
- Ø Conscientiously read submissions to REC of which the trainee should be a member.
- Ø Contribute to discussion in committee.
- Ø Be open minded and prepared to change a view in the light of discussion.

15.12 Provision of evidence based unbiased drug information

Knowledge

- Ø Demonstrate knowledge on different sources of drug information, their validity and sources available for special situations eg. pregnancy, children, organ failures

Skills

- Ø Ability to obtain all the necessary details from the inquirer in a drug information query.
- Ø Formulate appropriate questions in a drug information query.
- Ø Do a search in appropriate sources to obtain all known reliable information to the query
- Ø Communicate information effectively

Attitudes/Behaviour

- Ø Answer drug information queries professionally

15.13 Deal with pharmaceutical industry in a professionally and ethically acceptable manner

Knowledge

- Ø Demonstrate knowledge on ethical criteria of promotion of pharmaceuticals

Skills

- Ø Communicate effectively with representatives of the pharmaceuticals trade

Attitudes/Behaviour

- Ø Maintain appropriate professional relationships with the pharmaceutical industry
- Ø Disclose any conflicts of interest in professional activities

15.14 Speciality specific competencies in paediatric clinical pharmacology:

This section is adapted from "Level 3 training in paediatric clinical pharmacology and therapeutics" of the Royal College of Paediatrics and Child Health (2) to suit the local training requirements. Some components are copied *verbatim* from the above document. It covers eight topics; (1) Ethics of clinical trials in children, (2) Pharmacokinetic studies in children (3) Drug action and effect in paediatric patients, (4) drug toxicity (5) socio-political and regulatory aspects of use of medicines, (6) rational and cost effective use of medicines (7) practical challenges of conducting clinical trials in paediatrics, (8) education

Knowledge

- Ø Know the principles of ethical issues relating to drug research in children
- Ø Explain how drug research in children is regulated
- Ø Describe paediatric therapeutic drug monitoring,
- Ø Know effects of age and disease on drug metabolism and distribution
- ø Demonstrate use of population pharmacokinetics.
- Ø Know about drug concordance/adherence and dose-response relationships, paediatric formulation and drug delivery devices
- Ø Demonstrate the differences between drug toxicity in the developing child and adults, specific age-related drug toxicity and common clinical presentations of adverse drug reactions (ADRs) in children
- Ø Know about ADR surveillance schemes in relation to children (pharmacovigilance)
- Ø Know about licensing of medicines for paediatric patients and unlicensed and off-label use

- Know how health beliefs can affect paediatric therapy
- Know about the ethics of research in children and the process of informed consent
- Know about recruitment and retention of paediatric patients in a trial

Skills

- Be able to prepare and analyse critically a submission to an ethics committee of a clinical trial in children
- Be able to design clinical pharmacokinetic studies in children
- Be able to calculate clinical pharmacokinetic parameters
- Be able to design an appropriate study to investigate the clinical pharmacokinetics of a medicine in paediatric patients of different ages, using existing information about the medicine in relation to its metabolism and elimination in adults
- Be able to study pharmacodynamic effect in different ages
- Be able to detect, interpret and manage adverse drug reactions in paediatric patients as well as to be able to manage and advise cases of overdose and poisoning.
- Be able to design a clinical trial in children

AttitudesBehaviour

- Accept that the children need to be treated differently from adults
- Learn to communicate empathetically with parents
- Learn to work as a team with pharmacists, nurses and filed health workers

16 Board certification in CPT

Board certification will be recommended on successful completion of all stages of the training and assessments. This will include the exit examination also.

17 Number of specialists to be trained in each year: Approximately 2 to 3

18 Relevant Bibliography

1. Specialty training curriculum for Clinical Pharmacology and Therapeutics: Joint Royal College of Physicians Training Board, 5 St Andrews Place Regent's Park London, May 2007.
2. A framework of competencies for Level 3 training in Paediatric Clinical Pharmacology and Therapeutics. Royal College of Paediatrics and Child Health. 50 Hallam Street, London, UK. June 2006
3. Vocational Advanced Training in Clinical Pharmacology : Requirements for Physician Training in Australia 1999; Royal Australian College of Physicians
4. FCPS Part II, Clinical Pharmacology and Therapeutics, Prospectus, Syllabi, Requirements and Format of Examinations 1995; College of Physicians and Surgeons of Pakistan
5. Bateman D N, McInnes GT, Webb D J, Clinical Pharmacology and training in a changing world. *British Journal of Clinical Pharmacology 1999; **48**: 1-3*
6. Mucklow JC. Postgraduate education in clinical Pharmacology and Therapeutics. *British Journal of Clinical Pharmacology 1998; 339- 346.*
7. Clinical Pharmacology Scope, Organisation, Training. WHO Technical Report Series No 446, 1970, Geneva.