CLINICAL PHARMACY PRACTICE

Introduction to Clinical Pharmacy: definition, evolution and scope of clinical pharmacy, international scenario of clinical pharmacy practice, national scenario of clinical pharmacy practice,pharmaceutical care

Drug therapy review: drug therapy monitoring including medication order review, chart endorsement, clinical review and pharmacist interventions

Clinical Pharmacy Services: patient medication history interview, basic concept of medicine andpoison information services, basic concept of pharmacovigilance, hemovigilance, materiovigilance and AEFI, patient medication counselling, drug utilisation evaluation, documentation of clinical pharmacy services, quality assurance of clinical pharmacy services, ward round participation

Patient Data Analysis: patient's case history - its structure, significances in drug therapy management, common medical abbreviations and terminologies used in clinical practice

Communication skills: verbal and non-verbal communications, its applications in patient care services

Interpretation of lab data:hematological tests, renal function tests & liver function tests

Lab Data Interpretation: tests associated with cardiac disorders, pulmonary function tests, thyroid function tests, fluid and electrolyte balance, microbiological culture sensitivity tests

Medicines Information Services: definition and need for medicine information service, medicine information resources, systematic approach in answering medicine information queries,preparation of verbal and written response, establishing a drug information centre

Poison Information Services: definition, need, organization, functions of poison information centre

PHARMACOTHERAPEUTICS-I

Etiopathogenesis and Pharmacotherapy of Cardiovascular system:: hypertension, congestivecardiac failure, acute coronary syndrome, arrhythmias, hyperlipidemias

Etiopathogenesis and Pharmacotherapy of Respiratory system: asthma, chronic obstructiveairways disease, drug induced pulmonary diseases

Etiopathogenesis and Pharmacotherapy of Endocrine system: diabetes, thyroid diseases

Etiopathogenesis and Pharmacotherapy of Hematological diseases: anemia, deep vein thrombosis, drug induced hematological disorders

Etiopathogenesis and Pharmacotherapy of Gastrointestinal system: peptic ulcer diseases, reflux esophagitis, inflammatory bowel diseases, jaundice, hepatitis, cirrhosis, diarrhea, constipation,drug-induced liver disease

Etiopathogenesis and Pharmacotherapy of Dermatological Diseases: psoriasis, eczema, scabies, impetigo, drug induced skin disorders

Etiopathogenesis and Pharmacotherapy of Ophthalmology: conjunctivitis, glaucoma

Etiopathogenesis and Pharmacotherapy of Bone and joint disorders: rheumatoid arthritis, osteoarthritis, gout, osteoporosis

HOSPITAL AND COMMUNITY PHARMACY

Introduction to hospitals: definition, classification, organizational structure

Hospital Pharmacy: definition, relationship of hospital pharmacy department with other departments, organizational structure,legal requirements, work load statistics, Infrastructural requirements, hospital pharmacy budget and hospital pharmacy management

Hospital Drug Policy: pharmacy & therapeutics committee, infection control committee, research & ethics committee, management of medicines as per NABH

Guidelines for Hospital Management: hospital formulary guidelines and its development, developing therapeutic guidelines, drug procurement process, methods of inventory control, methodsof drug distribution, intravenous admixtures, hospital waste management

Education and training: training of technical staff, training and continuing education for pharmacists,pharmacy students, medical staff and students, nursing staff and students, formal andinformal meetings and lectures, drug and therapeutics newsletter.

Community Pharmacy Practice: definition, roles & responsibilities of community pharmacists, and their relationship with other health care providers, research in community pharmacy practice

Community Pharmacy management: legal requirements to start community pharmacy, site selection, lay out & design, drug display, super drug store model, accounts and audits, good dispensing practices, different softwares& databases used in community pharmacies. entrepreneurship in community pharmacy

Prescription: legal requirements & interpretation, prescription related problems

Responding to symptoms of minor ailments: head ache, pyrexia, menstrual pains, food and drugallergy

OTC medication: rational use of over the counter medications, medication counseling and use of patient information leaflets, adverse drug reaction monitoring in community pharmacies

Medication adherence: definition, factors influencing adherence behavior, strategies to improvemedication adherence, patient referrals to the doctors

Health Promotion: definition and health promotion activities, family planning, health screeningservices, first aid,smoking cessation, child care, mother care

National Health Programs: role of community pharmacist in malaria and tuberculosis control
programs

Home Medicines review program: definition, objectives, guidelines, method and outcomes

CLINICAL RESEARCH

Drug development process: introduction, various approaches to drug discovery, investigational new drug application submission, ethics in biomedical research, ethical issues in biomedical research, principles of ethics in biomedical research, ethical committee [institutional review board], its constitution and functions, challenges in implementation ofethical guidelines, ICH, GCP guidelines and ICMR guidelines in conduct of clinical trials, drug safety reporting

Clinical trial study team: roles and responsibilities of investigator, study coordinator, sponsor, roles and responsibilities of monitor and contract research organization

Types and designs used in clinical research: planning and execution of clinical trials, various
phases of clinical trials, bioavailability and bioequivalence studies, randomization techniques (simple randomization, restricted randomization, blocking method and stratification), types of researchdesigns based on controlling method (experimental, quasi experimental and observational methods), time sequences (prospective and retrospective), sampling methods (cohort study, case control study and cross sectional study), health outcome measures (clinical & physiological, humanistic and economic)

Clinical trial documents: guidelines to the preparation of protocols, investigator's brochure, informed consent form, guidelines to the preparation of case report forms, contracts and agreements, dairy cards

Clinical trial start up activities: site feasibility studies, site/investigator selection, pre-study visit, investigator meeting, clinical trial agreement execution, ethics committee document preparation and submission

Investigational product: procurement and storage of investigation product

Filing procedures: essential documents for clinical trial, trial master file preparation and maintenance, investigator site file, pharmacy file, site initiation visit conduct, report and follow up,clinical trial monitoring and close out

Preparation of monitoring visit: review of source documents, CRF, ICF, IP storage, accountability and reconciliation, study procedure, EC communications, safety reporting

Conduct of monitoring visit: monitoring visit reporting and follow-up

Quality assurance and quality control in clinical trials: types of audits, audit criteria, audit process, responsibilities of stakeholders in audit process, audit follow-up and documentation, audit resolution and preparing for FDA inspections, fraud and misconduct management, data management

Close out visit: Study related documents collection, Archival requirement, Investigational Productreconciliation and destruction, Close-Out visit report

Infrastructure and system requirement for data management: electronic data capture systems, selection and implementation of new systems, system validation and test procedures, coding dictionaries, data migration and archival

Clinical trial data management: standard operating procedures, data management plan, CRF & data base design considerations, study set-up, data entry, CRF tracking and corrections, data cleaning, managing laboratory and ADR data, data transfer and database lock, quality control and quality assurance in CDM, data mining and warehousing

PRINCIPLES OF QUALITY USE OF MEDICINES

Introduction to quality use of medicines (QUM): definition and principles of QUM, key partners and responsibilities of the partners, building blocks in QMC, evaluation process in QMC,communication in QUM, cost effective prescribing

Evidence based medicine: definition and concept of evidence based medicine, approach and practice of evidence based medicine in clinical settings

Essential drugs: definition, need and concept of essential drug, national essential drug policy andlist

Rational drug use: definition, concept and need for rational drug use, rational drug prescribing, role of pharmacist in rational drug use

Medication errors: definition, categorization and causes of medication errors, detection and prevention of medication errors, role of pharmacist in monitoring and management of medication errors

QUM in various settings: hospital settings, ambulatory care/residential care, role of health care professionals in promoting the QUM, strategies to promote the QUM, impact of QUM on E-health,integrative medicine and multidisciplinary care

QUM in special population:pediatric prescribing, geriatric prescribing, prescribing in pregnancy and lactation, prescribing in immune compromised and organ failure patients

Regulatory aspects of QUM in India: regulation including scheduling, regulation of complementary medicines, regulation of OTC medicines, professional responsibility of pharmacist, role of industry in QUM in medicine development

Pharmacovigilance: definition, aims and need for pharmacovigilance, types, predisposing factors and mechanism of adverse drug reactions (ADRs), detection, reporting and

monitoring of ADRs, causality assessment of ADRs, management of ADRs, role of pharmacist in pharmacovigilance.

PHARMACOTHERAPEUTICS-II

Nervous system: epilepsy, Parkinson's disease, stroke, headache, Alzheimer's disease, neuralgias,pain pathways, pain management

Psychiatric disorders: schizophrenia, depression, anxiety disorders, sleep disorders, drug induced psychiatric disorders

Renal system: acute renal failure, chronic renal failure, renal dialysis, drug induced renal disease

Gynecological disorders: dysmenorrhea, hormone replacement therapy

Infectious diseases - I: general guidelines for the rational use of antibiotics and surgical prophylaxis, urinary tract infections, respiratory tract infections, gastroenteritis, tuberculosis,malaria, bacterial endocarditis, septicemia

Infectious diseases - II: meningitis, HIV and opportunistic infections, rheumatic fever, dengue
fever, H1N1, helmenthiasis, fungal infections

Oncology: general principles of cancer chemotherapy, pharmacotherapy of breast cancer, lung
cancer, head & neck cancer, hematological malignancies, management of nausea and vomiting,
palliative care

CLINICAL PHARMACOKINETICS AND THERAPEUTIC DRUG MONITORING

Introduction to clinical pharmacokinetics: compartmental and non compartmental models, renal and non-renal clearance, organ extraction and models of hepatic clearance, estimation and determinants of bioavailability, multiple dosing, calculation of loading and maintenance doses

Designing of dosage regimens: determination of dose and dosing intervals, conversion from intravenous to oral dosing, nomograms and tabulations in designing dosage regimen

Pharmacokinetics of drug interaction: pharmacokinetic drug interactions, inhibition and induction of drug metabolism, inhibition of biliary excretion

Pharmacogenetics: genetic polymorphism in drug metabolism, cytochrome P-450 isoenzymes, genetic polymorphism in drug transport and drug targets, pharmacogenetics and pharmacokinetic / pharmacodynamic considerations

Introduction to pharmacometrics: introduction to Bayesian Theory, adaptive method or dosing with feedback, analysis of population pharmacokinetic data

Altered pharmacokinetics: drug dosing in the elderly, drug dosing in the paediatrics, drug dosing in the obese patients, drug dosing in the pregnancy and lactation, drug dosing in the renal failure and extracorporeal removal of drugs, drug dosing in the hepatic failure

Non linier mixed effects modelling: the structural or base model, modeling random effects, modeling covariate relationships, mixture model, estimation methods, model building techniques, covariate screening methods, testing the model assumptions, precision of the parameter estimates and confidence intervals, model misspecification and violation of the model assumptions, model validation, simulation of dosing regimens and dosing recommendations, pharmacometrics software

Therapeutic drug monitoring: overview of TDM, individualization of drug dosage regimen (variability – genetic, age, weight, disease and interacting drugs), indications for TDM, protocol forTDM, pharmacokinetic/pharmacodynamic correlation in drug therapy

TDM of drugs used in the following conditions:cardivascular disorders- digoxin, lidocaine, amiodarone, psychiatric conditions- lithium, fluoxetine, amitriptyline, organ transplantations- cyclosporine, cytotoxic agents- methotrexate, 5-FU, cisplatin, antibiotics- vancomycin, gentamicin, meropenem, seizure disorders- phenytoin, carbamazepine, sodium valproate

PHARMACOEPIDEMIOLOGY AND PHARMACOECONOMICS

Introduction to Pharmacoepidemiology: overview of pharmacoepidemiology, aims and applications

Drug use measures: monetary units, number of prescriptions, units of drug dispensed, diagnosis and therapy surveys, prevalence, incidence rate, unit of drugs dispensed, defined daily doses and prescribed daily doses, medications adherence measurements, outcome measures of drug use

Concept of risk: measurement of risk, attributable risk and relative risk, time - risk relationship and odds ratio

Applications of Pharmacoepidemiology: role of Pharmacoepidemiology

Pharmacoepidemiological Methods: Qualitative models - Drug Utilization Review (DUR), applications of pharmacoepidemiological methods, Quantitative models - Case reports, case series, cross sectional studies, cohort and case control studies, calculation of odds' ratio, meta-analysis models

Drug effects study in populations: spontaneous reporting, prescription event monitoring (PEM),post marketing surveillance (PMS), record linkage systems

Introduction to Pharmaco-economics: definition, history of Pharmaco-economics, need of Pharmaco-economic studies in Indian healthcare system

Cost categorization and resources for cost estimation: direct costs, indirect costs, intangible
costs

Outcomes and Measurements in Pharmaco-economics:: clinical outcomes, economic outcomes, humanistic outcomes, Quality Adjusted Life Years (QALY), Disability Adjusted Life Years (DALY), Incremental Cost Effective Ratio (ICER), average cost effective ratio, person time, willingness to pay, time trade off and discounting.

Pharmaco-economic evaluations: definitions, steps involved in pharmaco-economic evaluations

Various Pharmaco-economic models: Cost Minimization Analysis (CMA), Cost Benefit Analysis (CBA), Cost Effective Analysis (CEA), Cost Utility Analysis (CUA), Cost of Illness (COI),Cost Consequences Analysis (COA)

Applications, Advantages and disadvantages of the Pharmaco-economic models: pros and cons of pharmacoeconomics, role of pharmacoeconomics

Quality of Life (QOL) & Health related quality of life (HRQOL):: definitions, steps involved, applications, advantages and disadvantages of QOL & HRQOL measurements

Quality of Life (QOL): need for measurement of QOL, common QOL measures

Health related quality of life (HRQOL): need for measurement of HRQOL, common HRQOLmeasures

Pharmaco-economic analysis: definitions, steps involved in pharmaco-economic analysis, applications of decision analysis and decision tree, sensitivity analysis, Markov modeling

Software used in Pharmaco-economic analysis: databases and analyzing devices

Applications of Pharmaco-economics: applications of Pharmaco-economics, role of Pharmaco-economics in various disease management states

RESEARCH METHODOLOGY AND BIOSTATISTICS

General research methodology: research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques

Biostatistics: definition and introduction, application, sample size, importance of sample size, factors influencing sample size, dropouts, null hypothesis, P values, degree of freedom, interpretation of P values

Basic statistical tests: statistical tests of significance, type of significance tests, parametric tests, non-parametric tests, students t test, chi square test, analysis of variance (ANOVA), correlation coefficient, correlation and regression, wilcoxan rank tests

Medical research: history, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality

Declaration of Helsinki: history, introduction, basic principles for all medical research, additional principles for medical research combined with medical care, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees

CPCSEA guidelines for laboratory animal facility: goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, location of animal facilities to laboratories, anaesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals