राजकारी हम्लार ७६०९

Department of Clinical Pharmacy & Pharmacology University of Dhaka Faculty of Pharmacy Masters Program Credit and Grade Point System

Course Code	Name of the Subject		Credit		
		In-course	Final	Total	
PHP 601	Clinical Pharmacy	20	80	100	1
PHP 602	Advance Pharmacology	20'	80	100	4
PHP 603	Drug Use Management	20	80	100	4
PHP 604	Toxicology	20	80	100	4
PHP 605	Molecular Pharmacology	20	80	100	4
PHP 606	Clinical Research	20	80	100	4
PHP 607	Thesis work	++	-	200	8
PHP 608	Presentation			50	
PHP 609	Viva voce	<u> </u>		50	
	Total			900	36

Thesis Group (Proposed)

Non-Thesis Group (Proposed)

Course Code	Name of the Subject	Marks			Credit
		In-course	Final	Total	
PHP 601	Clinical Pharmacy	20	80	100	
PHP 602	Advance Pharmacology	20	80	100	4
PHP 603	Drug Use Management	20	80	100	• 4
PHP 604	Toxicology	× 20	80	100	4
PHP 605	Molecular Pharmacology	20	80	100	4
PHP 606	Clinical Research	20	80	100	1
PHP 601L	Clinical Pharmacy-Lab			25	
PHP 602L	Advance Pharmacology-Lab			25	
PHP 603L	Drug Use Management-Lab			25	1
PHP 604L	Toxicology-Lab			25	
PHP 605L	Molecular Pharmacology-Lab			25	1
PHP 606L	Clinical Research -Lab	-		26	
PHP 608	Research/protocol design and proposal writing presentation		· •	50	2
PHP 609	Viva voce	[50	
	Total			850	34

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PHP 601: Advanced Clinical Pharmacy

- 1. GI disorders: Aetiology, pathophysiology, clinical manifestations, principles of management and treatment of diarrhea, constipation, peptic ulcer disorders, GERD, ulcerative colitis, Crohn's disease and pseudomembranous colitis, ORT, super ORS, drug therapy for traveller's diarrhea, relevant case studies.
 - 2. Neurological disorders: Actiology, pathophysiology, clinical manifestations and clinical management of a) Alzheimer's disease, b) Parkinson's disease, c) Cerebrovascular disease and d) Schizophrenia, relevant case studies.
 - 3. Cardiovascular disorders: Aetiology, pathophysiology, clinical manifestations and clinical management of a) Hypertension, b) Cardiac arrhythmia, c) Congestive heart failure, d) Ischaemic heart disease, e) Myocardial infarction, f) Thrombosis and g) Hyperlipidemia, relevant case studies.
 - Skin disorders: (a) Eczema and psoriasis: Pathophysiology, clinical features, clinical types, treatment (b) Pressure sores and leg ulcers: Pathophysiology, aetiology, clinical signs and symptoms, investigations and treatment. (c) Drug induced skin disorders: diagnosis and treatment, relevant case studies.
 - Rheumatoid disorders: (a) Rheumatoid arthritis and osteoarthritis: Epidemiology, aetiology, pathophysiology, clinical manifestations, investigations and treatment (b) Gout and hyperuricemia: Epidemiology, aetiology, pathophysiology, clinical manifestations, investigations and treatment, relevant case studies.
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Malignant disorders:

Aetiology, pathophysiology, clinical manifestations, principles of management and treatment of major cancers including – colon, lung, skin, ovarian, breast, prostate cancers and leukemia, relevant case studies.

- Racial, gender and ethnic differences in drug response: Origins of genetic differences among peoples, genetic variation within and between populations, the uses of racial categorization of medicine, interplay of genetic, environmental and cultural factors, genetic polymorphisms in drug metabolism, drug targets and disease pathways, racial and ethnic variation in polymorphisms in drug metabolism, clinical relevance of genetic polymorphisms, examples of drugs showing varying effects among racial and ethnic groups.
- Patient counseling and interviewing techniques: What, who and when to counsel, format of counseling provided, counseling area, documentation of counseling, benefits and outcomes of counseling, counseling on non-prescription and prescription drugs, medication counseling tips, patients who should always be counseled and those who should be counseled at certain intervals, roles of pharmacists in reducing medication

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errors and in improving patient compliance and patient monitoring by effective counseling.

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Drug information services/resources: Needs for drug information, drug information resources and literature: primary, secondary and tertiary, information retrieval systems, example of online resources for drug related information.

PHR 601 L: Practical syllabus

- a) Case study of different diseases in Govt. hospitals or health complexes.
- b) Glucose, BUN and serum alkaline phosphates estimation.

NQ-2, SMAR-2, NS-1, NAN-2, NHA-1

PHP 602: Advanced Pharmacology

- 1. Receptors and drug action: Definition, receptors and ligand binding theory, mechanistic concepts, relationship between drug concentration and therapeutic effectiveness, potency and efficacy, graded and quantal dose response, features of receptors, agonist and antagonist, transmembrane signaling mechanism, specific receptor example: nicotinic acetylcholine receptors, sodium channels, glutamate receptors, G-protein coupled receptors, receptor desensitization and turnover.
- 2. Pharmacology of ion channels and enzymes: Transduction mechanisms as targets of drug action, voltage sensitive ion channels-structure and function, K⁺ channels, ion channel mutations and their consequence, voltage sensitive Ca⁺² channels and the pharmacology of their inhibitors, agonists at β-adrenoceptors, pharmacology of Na⁺/K⁺ATPase and gap junction.
- 3. Neuropharmacology: Molecular and cellular mechanisms, ion channels and neurotransmitters, synaptic potentials and transmission, chemical synaptic potential, principles of neuropharmacology, key neurotransmitters, amino acid transmitters: glutamate, GABA, glycine; catecholamine: dopamine, noradrenaline, 5-HT; Acetylcholine and receptors, glutamate receptors, GABA and its reception, catecholamine receptor, Serotonin receptors, the opiate receptors, Antiepileptic drugs, Neurodegenerative disorders: pathophysiology and therapeutic approaches of stroke, Parkinson's disease, Alzheimer's disease, Huntington's disease.
 - 4. Optic disorder: Definition, types, causes, signs and symptoms, prevention, treatment and classification of: cataract, glaucoma, color blindness, chalazion, blurry vision, burning eyes, black eyes, blepharitis, Bell's palsy, astigmatism, amblyopia, acanthamoeba.
 - 5. Cancer biology and therapy: Introduction to biology of cancer, DNA repair defects and cancer, specific oncogenes, tumour suppressor genes, molecular biology of p53, apoptosis, modes of treatment: radiotherapy, chemotherapy, biological therapy including immunology.

Other chemotherapeutic targets including vascular targets, abnormal tumor physiology, anticancer drugs and their mechanism, molecular mechanisms of resistance. Relapses, metastasis, carcinogenesis and genetic predisposition, diagnostic tests and prognostic factors.

6. Pharma Cogenetics and Pharmacogenomics: Introduction, definition, SNPs and other polymorphisms. RFLP and direct sequencing as methods of studying polymorphisms. Pharmacogenetics of cytochrome p 450. e.g. CYP2D6, CYP2C9, CYP2C19, CYP3A4, CYP2A6. Role of NAT2 and CYP2EI in tuberculosis. Role of different polymorphisms in Lung diseases. Methods of studying prominent SNP susing any software. Pharmacogenetics of cancer, psychiatric disease, receptor etc.

7. Gene therapy: Gene expression, Vectors for Gene Therapy, Antisense and antigene therapy, RNA interference: RNA splicing, ribozyme, DNA chips, application of gene therapy: recent progress in drug development in gene therapy.

8. Bioinformatics: Biologically informative macroniolecules (DNA, RNA, Proteins) and flow of information, Definition and concepts, importance of bioinformatics, biological database, primary sequence database, and protein sequence database, DNA sequence database, genome resource database and browsers, multiple sequence alignment, importance of multiple sequence alignment for drug design, Proteins structure alignment, Phylogenetics, Metabolic pathways and networks: importance in drug desigr ing.

PHR 602 L: Practical Syllabus

As designed by the course teacher

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PHP 603: Drug Use Management

- Problems of Irrational Use of Drugs 1.
 - Background, Definition of rational use of drugs. Factors effecting irrational use of drugs, Impact of irrational use of drugs. Examples of irrational use of drugs. Drug use patterns in developed and developing countries. Changing drug use patterns, Learning about drug use problems, Changing drug use, problems. Collecting data to learn about drug use, Quantitative methods for learning about drug use.

Sampling To Study Drug Use 2.

Introduction, Definition, Different sampling methods Non-probability sampling methods, Probability sampling methods, Sample size, Practical aspect of sampling, Case studies.

Drug Use Indicator Study:

Introdction, Major drug use indicators : Prescribing indicators, Patient care indicators study, Sampling Issues, Undertaking the survey, Data collection and entry Analyzing dfregentation. Different types of forms, Field visit to identify data sources.

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4. Changing Drug Use Practices

Factor influencing drug use. Intervention strategies: Educational, Management and regulatory stratagies. Farmework for changing drug use practices, Example of coordinated intervention strategies, impact of training, Changing drug use practices and different case studies, Principle of persuasive fact to face Education, Principles of effective persuasive approaches. Advantages of persuasive face to face Education, Selecting and training of educational program, Practical exercise.

5. Decisions Making for Rational Use Intervention

Introduction, Stages in attacking a drug use problem, Framework for formative and intervention studies, Needs assessment, Intervention, Options, study designs, Dangers of a pre-post study, Intervention testing, Planning and intervention Preparation of research proposals.

6. Role Of Dispensers in Promoting Drug Use Management

Introduction, Definition of dispenser, Dispensing process, Proper and improper dispensing, Impact of improper dispensing, Dispensing practices to enhance rational use of drug, Method to improve complain with therapy, Public Vs private sector dispensing Patients choice.

7. Effective Public Education

Introduction, Patients, role, Concept of disease etiplogy. Concept of cure, Concepts about the therapeutic values of drugs, Effect of promot or and marketing on the use of drugs, Social marketing Global public education initiatives related to drug use, Developing a public education strategy. Effective communication systems public education campaigns on drug use, Examples of public education forms.

8. Standard Treatment

Introduction, Importance of standard treatment guidelines, Standard treatment in the therapeutic process, Advantages of standard treatment. Key features of standard treatment, Development of standard treatments, Implementation of standard treatments, Standard treatment guidelines in different Countries, Case studies, Standard treatment guidelines for health centers, Designing effective printed educational materials, Relevance to common drugs use decisions, Case studies.

PER 603 L: Practical syllabus

1. Sampling health care facilities for drug use Indicator studies.

- 2. Collection analysis and interpretation of data for prescribing indicators
- 3. Collection. analysis and interpretation of data for patient care indicators
- 4. Collection analysis and interpretation of data for health facilities indicators.

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PHP 604: Advanced Toxicology

- 1. Basic concepts in toxicology : A course overview, including the assessment of toxic substances, their impact on health and target organs. Introduction to toxicology, design o toxicity testing. Acute and chronic toxicities. Toxicity study in animal models.
- 2. Toxic responses to drugs and chemicals: Classification of different types of responses according to the biochemical basis and manifestation of toxic effect. Genotoxicity : mechanism of genotoxicity and carcinogens.
- 3. The biotranformation of toxins, their inactivation and removal from the body: An introduction of biotransformation. The cytochrome p450 system-its function, mechanism of action and regulation. Glutath line and glutathione-S-transferase-its function, mechanism of action and regulation, superoxice dysmutase mechanism of action and regulation, superoxide dysmutase, mechanism of action of different antioxidants.
 - The mechanism of toxin action : DNA damage and its repair, mutagenicity and carcinogenicity, Cell death and apoptosis. Nuclear hormone receptor mediated toxicity peroxisome proliferators and environmental bestrogens, Neurotoxicity, intra cellular free radicals, Risk assessment and toxicity testing.
- 5. Reactive intermediates; Types of meta ol cally generated reactive intermediates and their role in drug toxicity, Eposidation as d drug toxicity, N-Oxidation and drug toxicity, toxicity and sulpher xenobiotics.
 - Target organ toxicity: Organ and tissue specific toxicity.
 - Pathological and abnormal states: Efforts of various disease processes on drug metabolism elimination and toxicity.
 - Genetic differences: Species and strain differences in experimental animals. Genetic polymorphism in human drug metabolis n and development of different toxicities.
 - Toxicology of heavy metals; Sources and diagnosis of lead, arsenic and mercuty poisonin. Acute and chronic toxicities of heavy metals, their mechanism of action. Pharmaceutical and toxicological effects, metabolism and treatment of the poisoning. Heavy metal antagonist: role of EDTA, dimercaprol and penicillamine in the treatment of heavy-metal poisoning, their mode of action and side effects.

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PHR 604 L: Practical Syllabus

- 1. Study of liver toxicity and kidney toxicity.
- 2. Toxic effects of drugs on hematological parameters
- 3. Histopathological study of different organs after drug administration.

PHP 605: Molecular Pharmacology

Organization and expression of the human genome

Organization of the human genome, organization of the human genes, human gene expression etc.

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Human multigene families and repetitive DNA

Principles of repetitive DNA and multigene families, extragenic repeated DNA sequences and transposable elements etc.

Gene expression regulation in eukaryotes

Regulation during mRNA and protein synthesis, i.e. post-transcriptional and posttranslational regulation, protein-DNA interaction, protein-RNA interaction, medical genetics, antisense and anti-gene technology, RNA interference.

4. Cell cycle and growth regulation

Cell cycle phases, checkpoints and the r regulation, cyclins and cyclin-dependent kinases, regulation of cell cycle by E2F and Rt, cell cycle activation, inhibition and cancer, drugs target ng regulation of cell cycle or targeting cell cycle regulators and checkpoints as therar sutic strategies in cancer.

Onco jenes and cancer

Natur and genetics of cancer, oncogenic pathylays leading to cancers (e.g. Notch, Wnt, EGFR, Akt/PKB, mTOR, Ras, TGF-[, Jak-51AT, EP300, etc.); signaling mediated by oncogenes; proto-oncogenes and tume: supple sor genes; multistep tumorigenesis; stem cell concept in cancer; cancer sten cell, epithelial-to-mesenchymal transition and cheme therapy resistance – role in prol feration, invasion and metastases and strategies to overcome drug resistance in cancer.

6. Genetics of complex human diseases

Mutat on and human diseases, genetics of cystic fibrosis, genetics of Gaucher disease, the genetics of Wilms' tumour, genetics of mitochendrial DNA-associated disease, diabetes, coronary artery disease and other common diseases.

Gene manipulation

Overview of DNA cloning, cutting and joining DNA molecules, plasmid as cloning vector for use in E. coli, expression in E. coli, analyzing DNA sequence, PCR sitedirected mutagenesis, introducing genes into animal cells.

8. Molecular pharmacology techniques

Cell lines used in molecular pharmacology, generation and manipulation of cell lines, characterization and application of cell lines, fluorescent labelling of drug targets, fluorescently labeled ligands, resonance energy transfer techniques, epifluorescence and

confocal microscopy, cellomics, radio-ligand binding assays, modeling of drug target

PHR 605 L, Practical syllabus

As designed by the course teacher

PROPOSED NEW COURSE:

PHP 606: Advanced Clinical Research



INTRODUCTION TO CLINICAL RESEARCH

Definition, Types and Scope of Clinical Research, Good Clinical Practices Drug Development Process Careers in Clinical Research



ETHICS IN CLINICAL RESEARCH

Ethical Theories and Foundations,

Ethics Review Committee and Informed Content Process, Integrity & Misconduct in Clinical Research

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Conflicts of Interest

Research Invol ing Persons at Risk for In paire 1 Decision-Making, Protections for Vulnerable part cipants: research on children, research on pregnant women; Ethical issues specific to certain types of research: randomized clinical trials, research on previously

REGULATIONS IN CLINICAL RESEARCH

Evolution and History of Regulations in Clinical Research, Patents US Regulatory Structure, IND, NDA, ANDA, Post Drug Approval Activities, PMS, FDA Audits and Inspections EU Regulatory Affairs, EMEA Organization and Function, Bangladesh Regulatory System, Schedule Y-Rules and Regulations

24 CLINICAL RESEARCH METHODOLOGY

Designing of Protocol, CRF, e-CRF, IB, ICF, Introduction to epidemiology: defining terms and history, epidemiologic triad, objectives, causality, Models, hypotheses in epidemiology, SOP Pharmaco-epidemiology, Observational Study Designs: Designing Cross-Sectional and Cohort Studies, Designing Case-Control Studies, Designing a Randomized Blinded Trial, BA/BE Studies Report Writing, Publication

E CLINICAL RESEARCH MANAGEMENT

Preparation of a successful clinical study, Study management, Project management Documentation, Monitoring, Audits and Inspections Pharmacovigilance, Training in clinical research, Supplies and vendor management

4. BIOSTATISTICS AND DATA MANAGEM INT $\int L_{1}K^{1}$

Importance of statistics in clinical research, st.: stical considerations at the design, analysis andreporting stage. Getting started with S. 3, Data manipulation (PROCS: PRINT, CONTENTS, SORT), Summary statistics FRC CS:MEANS, FREQ, UNIVARIATE, CORR), Plots and charts (PROCS: UNI 'AR ATE, GPLOT/SGPLOT, SGPANEL, GCHART, BOXPLOT), T-tests (PROCS M AN 3, TTEST), Chi-square tests (PROCS: FREQ), Nonparametric tests (PROCS:MPA HWAY), Linear regression(PROCS:REG, GLM), ANOVA (PROCS: ANOVA, GLM) Legistic regression (PROCS:LOGISTIC), Survival analysis (PROCS: LIFETEST, PHR) G), Poisson regression (PROC GENMOD), Data manipulation for longitudinal data (DA [A GTEPS, PROC TRANSPOSE), Plotting longitudinal data (PROCS: GPLOT, SGPLOT) Longitudinal modeling (PROCS: GENMOD, MIXED)

PHR 606 L: Practical syllabus

As designed by the course teacher