Introduction to Pharmacoepidemiology Course Syllabus

Module name: Professional electives

Module Number in which the course exists: 18

Course title: Introduction to Pharmacoepidemiology

Course code: Phar 4181

Course EtCTS: 5

EtCTS credits: 5 (This course needs a total of 5 x 27 = 135 working hours to spend in each teaching and learning as well as assessment activities). The distribution of these hours will be as follows

- Lecture: 48 hours
- Project work: 14 hours
- Presentations=10 hours
- Case studies/journal club=10 hours
- Tutorial: 8 hours
- Home study: 38 hours
- Assessment=7 hours

Pre-requisite if any: Successful completion of pre-requisite modules

Course Description

The goal of the course is to introduce pharmacoepidemiology and drug safety and research application for post-marketing drug safety surveillance. The course will describe how to develop a research protocol and conduct a research, describe various health care data sources used for research, and discuss how pharmacoepidemiology contribute to pharmacy practice, such as, drug utilization review, assessment of drug therapy, and adverse drug reaction monitoring. A series of case studies from thalidomide to cisapride to cerivastatin will be also discussed in class. Students can have a better understanding of Pharmacoepidemiologic research, drug safety regulatory, pregnancy registry, and risk management.

q. Course Objective:

Upon completion of this course, the students will be able to:

- ☞ Describe the purposes and scope of pharmacoepidemiology
- ☞ Describe and explain basic concepts in pharmacoepidemiology and its relevance for public health and for health policy making.
- ☞ Describe the relationship between national drug policies and Pharmacoepidemiology

- ☞ Describe the basic pharmacoepidemiologic concepts and measures of drug-related occurrence and its effect in population;
- ☞ Discuss common study designs and methods used in pharmacoepidemiological studies.
- ☞ Explain the applications of pharmacoepidemiological methods for studies of effects and adverse effects of drugs and economic consequences.
- ☞ Assess the relevance and limitations of various pharmacoepidemiological research designs
- ☞ Describe systems for the reporting of adverse effects and their use for pharmacoepidemiology.
- ☞ Apply pharmacoepidemiologic principles in practice.
- ☞ Discuss Pharmacovigilance in drug development
- ☞ Evaluate drug safety case studies and policy implications based on the medical and pharmacy literature.

Skills and abilities:

On successful completion of the course, the student should be able to:

- ☞ Review and evaluate pharmacoepidemiological studies.

Week	Contact hrs	Topic/sub-topic/chapter	Reading materials	Remark
1	4	1. Introduction 1.1. What is Pharmacoepidemiology? 1.2. Contributions of Pharmacoepidemiology	Reference 2 & 4	
2	4	2. National medicinal drug policies: their relationship to Pharmacoepidemiology	Reference 2, 3 & 4	
3	4	3. National medicinal drug policies: their relationship to Pharmacoepidemiology….. 3 Premarketing applications of Pharmacoepidemiology	Reference 1&2	
4	4	2. Study Designs 4.1 Observational studies	Reference 2,3 & 4	
5	4	4.1.1 Descriptive studies	Reference 2,3 & 4	
6	4	4.1.2 Analytical studies	Reference 2,3 & 4	
7	4	4.2 Experimental studies	Reference 2,3 & 4	

		4.2.1 Randomized Clinical Trial (RCT)		
8	4	4.2.2 Community Intervention Trails (CITs) 4.3 Selection of study designs	Reference 2,3 & 4	
9	4	5. Drug Utilization 5.1 Definition 5.2 Drug-centered and patient-centered approach in drug use studies	Reference 2,3 & 4	
10	4	5.3 Indicator based approach in drug use studies 5.3.1 Prescribing indicators 5.3.2 Patient care indicators 5.3.3 Facility specific indicators	Reference 2,3 & 4	
11	4	5.4 The social aspects of drug us	Reference 2,3 & 4	
12	4	5.5 The economic aspects of drug use	Reference 1,2,3 & 4	
13		5.6 Studies of patient compliance	Reference 1,2,3 & 4	
14	4	6 Pharmacovigilance 6.2 What is pharmacovigilance?	Reference 2,3 & 4	
15		6.3 Pharmacovigilance methods	Reference 1,2,3 & 4	
16	4	6.4 The need for effective drug safety programs 6.4 Elements of drug safety programs	Reference 1,2 & 3	

Mode of delivery:

- Illustrated Lectures and case studies
- Active learning methods (brain storming, buzz group, discussion, etc)
- Individual and group exercises and assignments
- Presentations and participation in class discussion
- Case studies

Mode of assessment:

- Quizzes and tests: 30%
- Attendance : 5%
- Case studies:5%
- Assignments (group or individual):20%

- Written final exam: 40%

LEARNING MATERIALS:

- Recommended Readings:
  1. Pharmacoepidemiology, 4th edition, Storm B. L. (Ed), John Wiley and Sons Ltd, England, 2005.
  2. Textbook of Pharmacoepidemiology, Storm B. L. And Kimmel S.E. (Eds), 2007, John Wiley, New Jersey.
  3. Pharmacoepidemiology – An Introduction, 3rd edition, Hartzema A.G., Porta M., Tilson H.H., (Eds), 1998, Cincinnati OH, Harvey Witney Books Company.
  4. Remington's: The Science and Practice of Pharmacy, 21st edition, University of The Sciences in Philadelphia, 2005, USA.