UNIVERSITY OF LONDON

Programme Specification 2020–2021

Pharmacoepidemiology and Pharmacovigilance

Postgraduate individual module

Important document – please read

SHORT COURSE MODULE SPECIFICATION

Academic Year (student cohort covered by specification)	2020-21
Module Code	PCM100
Module Title	Postgraduate Professional Development course in Pharmacoepidemiology and Pharmacovigilance
Module Organiser(s)	Luigi Palla and Angel Wong
Faculty	Epidemiology and Population Health London School of Hygiene & Tropical Medicine http://www.lshtm.ac.uk/eph/
FHEQ Level	Level 7
Credit Value	**CATS** 30 **ECTS** 15
HECoS Code	n/a
Mode of Delivery	Distance Learning
Mode of Study	Directed self-study, through online materials via the Virtual Learning Environment
Language of Study	English
Pre-Requisites	None
Accreditation by Professional Statutory and Regulatory Body	None
Module Cap (Maximum number of students)	None
Target Audience	If you are working in the pharmaceutical industry or the drug regulatory authorities then this course may be of interest to you.
Module Description	This course covers the fundamentals of pharmacoepidemiology, its conduct, practical uses and limitations in determining the effects of medications in large groups of people. The statistical basis underpinning pharmacoepidemiology will also be introduced, stimulating students to integrate statistics and epidemiology to gain competence in critically appraising pharmacoepidemiology studies. Further, key elements of pharmacovigilance and its basis within drug regulation will be presented and , within the risk management elements of the course, students will gain insight into how pharmacoepidemiology and pharmacovigilance are combined in the investigation of the effects of medicines.
Duration	Students may access the online study materials at any time from 1 November and work through the material until the start of the June examinations. Tutorial support for this distance learning module is available from the beginning of November through to the end of May.
Entrance requirements	Applicants will normally have a science, biomedical or biostatistical background, hold a second-class honours degree of a United Kingdom university (or equivalent) in a science, medical, statistical or related

	subject (e.g. biological sciences, chemistry, physics, medicine, dentistry, pharmacy, statistics) and will have some experience in the area. However, previous experience will be taken into account in all cases (e.g. working in a pharmaceutical company or drug regulatory authority for at least six months, in a scientific role).
Student selection	Students will be selected based on meeting the entrance requirements specified above. This module is available to be studied by students who are interested in studying a Postgraduate Professional Development course in Pharmacovigilance and Pharmacoepidemiology. This module is also open to LSHTM research degree students.
Fees	The fee for this short course will be £4,260 in 2020-2021 payable in one instalment to the University of London prior to the start of the course.
Last Revised (e.g. year changes approved)	May 2020

Module Aim and Intended Learning Outcomes

Overall aim of the module
The overall module aim is to: • equip students with a basic understanding of the concepts and practice of pharmacoepidemiology and pharmacovigilance, and to apply these skills to a currently unresolved drug safety issue.

Module Intended Learning Outcomes
Upon successful completion of the module a student will be able to: 1. be able to demonstrate an understanding and critically evaluate issues surrounding the risks and benefits of drug use in humans including the cause, manifestations and consequences of adverse drug effects (ADEs), the manner in which these are detected and monitored, and the related historic and legal frameworks; 2. be able to understand and critically compare fundamental statistical, economic and epidemiological concepts and methods; 3. gain an understanding of and reflect critically upon important pharmacoepidemiological concepts and methods and how these methods can be applied to specific drug issues; 4. be able to assess and critically analyse the results of pharmacoepidemiological studies, including critical appraisal of the study question, study design, methods and conduct, statistical analyses and interpretation; 5. understand how new medicines are assessed for their cost-effectiveness as well as efficacy and safety, before being recommended for use; 6. be able to use the techniques and approaches covered in the taught element of the module, plus their own experience, to evaluate issues presented to them in the format of a project, and, where relevant, develop recommendations for the best option or options.

Indicative Syllabus

Session Content
The module is expected to cover the following topics: **Pharmacoepidemiology** Students will learn about the fundamentals of pharmacoepidemiology, its conduct, practical uses and limitations in determining the effects of medications in large groups of people. The statistical basis underpinning pharmacoepidemiology will also be introduced, and students will integrate statistics and epidemiology to gain competence in critically appraising pharmacoepidemiology studies. Individual sessions are as follows: • Introduction to Pharmacoepidemiology and Pharmacovigilance • Introduction to critical appraisal of trials • Essential Statistics for Epidemiology Part I - Descriptive Statistics • Essential Statistics for Epidemiology Part 2 - Inference • Design and Usefulness of Observational Studies • Measures of occurrence and measures of effect • Selection and information bias • Confounding and Interaction • Case only designs • Propensity scores • Critical Appraisal of Systematic Reviews & Meta-Analysis I • Critical Appraisal of Systematic Reviews & Meta-Analysis II • Correlation and linear regression • Logistic regression • Survival analysis • Critical Appraisal of Cohort Studies • Power and Sample Size • Critical Appraisal of Case-Control Studies • Introduction to comparative effectiveness research • Electronic Healthcare Records in Pharmacoepidemiology: Pragmatic Randomised Controlled Trials • Introduction to Pharmacoepidemiology and Applications in the Pharmaceutical Industry • Introduction to comparative effectiveness research. **Pharmacovigilance** Students will be introduced to the key elements of pharmacovigilance and its basis within drug regulation. Within the risk management elements of the course, students will gain insight into how pharmacoepidemiology and pharmacovigilance are combined in the investigation of the effects of medicines. Principles will largely be demonstrated within the European legislative context, whilst recognizing these general principles apply more broadly throughout the world. Individual sessions are as follows: • Pharmacovigilance and Spontaneous ADR reporting systems: A Regulatory Perspective

Session Content
• Overview of Pharmaceutical Risk Management • Vaccine Risk Management • Medications in Pregnancy • Guidelines on Pharmacoepi, and Pharmacovigilance: Role of CIOMS, ICH, ISPE, ENCePP • Statistical Methods of Signal Detection within spontaneous reporting systems • Signal Prioritisation • Regulatory Pharmacovigilance – the EU perspective • Drug Safety Decision Making Using Evidence from a Range of Sources • Post-marketing benefit-risk assessment.

Health economics

Students will be introduced to the fundamental concepts involved in assessing the cost effectiveness of health technologies and methodologies used to assess the health related quality of life. Real world examples will be used to illustrate concepts. Individual sessions are as follows:

- The role of pharmaceutical data in NICE's appraisal of new & current health technologies
- Assessing the Health Related Quality of Life

Case Study: A Health Technology Appraisal.

Project

A project integrating the course thematic areas listed above will enable students to demonstrate their global understanding of pharmacoepidemiology and pharmacovigilance. A currently live drug safety issue will be selected, for which students will be given a selection of study reports (usually 5 or 6). The task is to critically appraise the evidence, to make decisions based on the totality of the evidence, and to make suggestions for future regulatory action and research.

- Broadly, the project contains the following sections:
- A section to introduce the subject (which will differ from year to year).
- A critical appraisal of each of the individual studies provided, including an assessment of their strengths and weaknesses
- An overall assessment of the possible causal association presented in the papers.

A recommendation of any regulatory action students think is warranted based on the evidence provided.

Teaching and Learning

Notional Learning Hours

Type of Learning Time	Number of Hours	Expressed as Percentage (%)
Directed self-study	100	33%
Self-directed learning	60	20%
Assessment, review and revision	140	47%
Total	**300**	**100%**

Teaching and Learning Strategy

Learning is self-directed against a detailed set of learning objectives using the materials provided. Students are strongly encouraged to participate in the module-specific discussions and real-time tutorials available on Moodle to obtain tutor support, and to make use of LSHTM online library resources. In addition, written feedback is provided on submitted assignments.

For the project, learning is self-directed against a detailed set of learning objectives using the materials provided. The course tutors will provide guidance and feedback through the relevant forums. They are not there to re- explain concepts covered in the module, to teach extra material, or to proof- read material that will be submitted for assessment. Additionally the course tutors will provide feedback on a brief written submission midway through the project.

In particular, the project will require about 100 hours, approximately divided as follows:

Teaching and Learning Strategy
Self-directed learning (*Project only*) Background reading: 4 hours Note-making/consolidation: 32 hours Online (Moodle) discussions: 4 hours Assessment, review, revision (*Project only*) Preparation and writing of interim summary/Report: 50 hours Student-led academic adviser guidance and feedback: 10 hours

Assessment

Assessment Strategy
During the course there are a number of formative assessments including exercises, interactive workshops and exam practices. These assessments are aimed to monitor the study progress of the students; therefore, they do not contribute to the final mark of the course. The summative assessment is conducted via an unseen written examination and a project. The unseen written examination comprises two parts – one short-answer examination (75% of the unseen examination grade) and one multiple-choice examination (25% of the unseen examination grade). This examination will comprise 60% of the final mark for the module. The project will make up 40% of the final mark for the module. The project report will be judged on the students' appreciation of the issues, their ability to make a critical evaluation of the evidence, and the appropriateness and justification of their recommendations. Both the unseen examination and the project need to be passed with a grade of 50% or more in order to pass the module.

Summative Assessment

Assessment Type	**Assessment Length** (i.e. Word Count, Length of presentation in minutes)	**Weighting** (%)	**Intended Module Learning Outcomes Tested**
Exam	One short-answer examination (75%) and one multiple-choice examination (25%).	60%	1,2,3,4 and 5
Project	4,000 words	40%	1,2,3,4 and 6

The unseen examination for this module, PCM100, will coincide with the written examinations for the in-house LSHTM PEPI course, which are held once a year, in June (including resits).

Examinations will be taken in a student's country of residence, in one of over 650 examination centres worldwide (arranged mainly through Ministries of Education or the British Council).

A list of examination centres can be found here.

A local fee will be payable direct to the examination centre. This fee is in addition to the course/module fee and is set by, and paid directly to, the individual examination centres. The level of local examination centre fees varies across the world and neither the University of London nor the LSHTM have any control over the fee amount.

For the project there are two milestones to be met:
February: Submission of a brief interim summary of work on the project
May: Submission of the final project report.

Resitting assessment
Resits will accord with the LSHTM's Resits Policy

Resources

Indicative reading list

Papers:

Coloma PM et al, Postmarketing Safety Surveillance, *Drug Saf* (2013) 36:183-197

Lindquist M, The need for definitions in Pharmacovigilance, *Drug Saf* (2007), 30: 825-830

Rothman KJ, Six persistent research misconceptions, *J Gen Intern Med* (2014) Jul;29(7):1060-4

Videos:

How does the NHS in England work: https://www.kingsfund.org.uk/audio-video/how-does-nhs-in-england-work

Drug discovery and development process (Australia): https://www.youtube.com/watch?v=0bmftXTdBbY

Drug discovery and development process (USA): https://www.youtube.com/watch?v=3Gl0gAcW8rw

Other resources

A mixture of teaching modes will be used, including:

1. Electronic interactive materials provided through the School's online learning site, Moodle. Materials will include fully interactive self-directed sessions on each topic, audio/video lectures and case study vignettes, a compendium of key references (relevant papers and reports published in the last 5 years). These will be updated yearly to capture up-to-date knowledge and debates. The materials are self-explanatory and include guidance on their use. Students will also access other online materials, participate in module- specific discussion forums, real-time/recorded Collaborate tutorial sessions and access the LSHTM online library resources.
2. Interactive events with key experts on specific topics or to mark milestones in the teaching programme, online discussions and webinars.

The Module Organiser and tutors use Moodle as their primary means of communication with students and use it to make available a range of materials for studying the module. Students are also encouraged to participate in module-specific discussions on Moodle; make use of the online library facilities and will be required to submit assignments via an online assignment management system.

Students will be provided with all the material required for the project at the start of the module. They are not required to do any further literature searches or use additional material, but may supplement the material if they wish.

Teaching for Disabilities and Learning Differences

The module-specific site on Moodle provides students with access to the module learning materials and online reading list (containing both essential and recommended readings), and additional resources including supplementary exercises and optional lecture recordings (where appropriate). All materials posted up on Moodle areas, including computer-based sessions, have been made accessible where possible.

The LSHTM Moodle has been made accessible to the widest possible audience, using a VLE that allows for up to 300% zoom, permits navigation via keyboard and use of speech recognition software, and that allows listening through a screen reader.

For students with special needs, reasonable adjustments and support can be arranged – details and how to request support can be found on the University of London Worldwide website at https://london.ac.uk/applications/how-it-works/inclusive-practice-access-arrangements