

Short Course in Pharmacoepidemiology and Pharmacovigilance at the London School of Hygiene and Tropical Medicine

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Abstract

Demand for education in pharmacoepidemiology is widespread, and has resulted in the short course at the London School of Hygiene and Tropical Medicine. This course is designed as an introduction but requires some scientific background to understand it. The course occurs annually, and covers basics of epidemiology, statistics and drug surveillance systems as applied particularly to drug safety issues. A successful completion results in a certificate from the University of London, and the course is accredited for continuing pharmacy and medical education purposes.

The London School of Hygiene and Tropical Medicine (LSHTM) is an internationally renowned centre involved in teaching and researching all aspects of tropical medicine, public health and epidemiology, and is located in the heart of London, England. It has several members of staff actively involved in research work around aspects of drug safety. In response to requests for the provision of specialised training in pharmacoepidemiology by those working in the field, both in the UK and Europe, a short course in pharmacoepidemiology and pharmacovigilance (PEPI) was established in 1997 and has been running annually ever since.

1. Aims of the Course

The course seeks to:

- enable an understanding of issues surrounding the risks and benefits of drug use, including the causes, manifestations and consequences of ad-

verse drug effects (ADE) and the manner of detection of ADE

- introduce participants to fundamental epidemiological, statistical, and economic concepts and methods
- enable an understanding of historical and legal aspects of drug safety issues
- equip participants with skills for further learning in these areas.

2. Structure of the Course

The course is divided into three blocks of teaching during the first half of the year, with self-directed learning in-between. The first block of teaching lasts 4 days during February, the second is 3 days in April, and the third is also 3 days during June. Teaching takes place at the LSHTM and thus requires students to be within easy travelling distance of the centre of London for these periods.

Students must submit a 3000-word project at the end of the course and also take a written exam in early July.

The course involves about 55 hours of formal teaching and contact time, 70 hours of self-directed study and 50 hours project work.

3. Who Should Apply?

The course is introductory and is aimed at personnel concerned with the safe use of drugs in developed countries, including those working in, or intending to work, in the following:

- the pharmaceutical industry (involved in drug development, licensing and surveillance)
- regulatory bodies involved in licensing and surveillance
- health services involved in drug policy and prescribing issues
- health policy decision making agencies.

We have also had a wide range of other participants including a medical journalist, academics and GPs. The skill mix of participants undoubtedly enriches the course. Applicants should have a science, medical or biostatistical background and should hold at least a second class honours degree in an appropriate subject. Previous experience in drug affairs is an advantage but is not vital.

4. Content of the Course

Teaching on the course covers the basics of epidemiology, statistics and issues relating specifically to pharmaceuticals. There is a mixture of lectures, small group work and discussion groups, and we encourage self-directed learning, especially in relation to the project work. All students are allocated an academic tutor, who can advise on the project, starting at the early planning stage.

Typical subjects covered on the course are as follows:

- criteria for assessing causality
- why do adverse drug events occur?
- designing a pharmacoepidemiological study
- critical appraisal of case-control, cohort and randomised studies
- use of databases
- introduction to pharmacoeconomics
- interpreting statistics.

Teachers are experts in their fields and are drawn from the LSHTM, medical staff with pharmaceutical companies, academics and staff at regulatory agencies.

5. Accreditation

The course is accredited for continuing medical and pharmacy education purposes, and all participants who successfully complete the course receive a certificate from the LSHTM (University of London).

6. Conclusion

The course has proved popular with students and has had consistently good evaluation reports. It has fostered a rich environment for learning and also for social interaction between students from many different countries. London is an exciting city to study in and the LSHTM is situated close to many renowned tourist attractions. We would encourage all those who are interested to contact the course secretary, Ms Deborah Curle (tel: +44 (0) 2079272489, or email: deborah.curle@lshtm.ac.uk). Currently, the tuition fees for the course are £2 500 per person. Places are limited to about 16 per annum, so early application is advisable.

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