MODULE SPECIFICATION

Academic Year (student cohort covered by specification)	2021-22
Module Code	CTM207
Module Title	Design and Analysis of Epidemiological Studies
Module Organiser(s)	Sheila Harvey, Julia Langham
Contact Email	CTsupport@lshtm.ac.uk
Faculty	Epidemiology and Population Health London School of Hygiene & Tropical Medicine http://www.lshtm.ac.uk/eph/
FHEQ Level	Level 7
Credit Value	**CATS** 15 **ECTS** 7.5
HECoS Code	100962 : 100473 : 101335
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	All of the Clinical Trial (CT) elective modules assume familiarity with the material and terminology introduced in the core CT modules, including a knowledge of basic statistics. Students who do not have a background in clinical trials may need to spend some time familiarising themselves with terminology before they can successfully complete any of the CT elective modules. Prior reading is not required before registering on this module. Students will be provided with core texts at the beginning of the module.
Accreditation by Professional Statutory and Regulatory Body	Not currently accredited by any other body
Module Cap (Maximum number of students)	There is no cap on the number of students who can register for this distance learning module.
Target Audience	Optional module for all the students on DL MSc Clinical Trials, PG Diploma Clinical Trials. Also open to any other student

	who meets pre-requisites for the module and who wishes to learn about design and analysis of epidemiological studies.
Module Description	In this module, students will be introduced to principal features of major observational study designs, understand their relative strengths and weaknesses, and learn about the different types of epidemiological measures, including disease frequency and effect that are possible across different designs. Students will consider the rationale for determining which study design is most appropriate. The module covers the risk of bias and confounding in observational studies and the techniques to minimise these in the study design and in analysis. It also covers the rationale for the use of multivariable analysis and interpretation of measures of effect derived from a multivariable analysis. Students will earn how to critically appraise an observational study and interpret finding based on an assessment of the impact of bias and confounding that might affect results.
Duration	Distance learning module studies begin in early October. Students may start their studies at any time once they gain access to Moodle and therefore the study materials, and work through the material until the start of the June examinations (although assessment submission deadlines which are earlier than this must be observed).
Last Revised (e.g. year changes approved)	2021

Programme(s) This module is linked to the following programme(s)	**Status**
PGDip/MSc Clinical Trials (Distance Learning - University of London Worldwide)	Elective

Module Aim and Intended Learning Outcomes

Overall aim of the module
The overall module aim is to: • provide a critical understanding of the key considerations in planning, design, analysis and interpretation of observational epidemiological studies as a complement to clinical trials.

Module Intended Learning Outcomes (ILOs)
Upon successful completion of the module a student will be able to: 1. demonstrate knowledge of strengths and weaknesses of alternative epidemiological observational study designs 2. evaluate theoretical and practical design issues to determine the most appropriate design for a research question 3. demonstrate understanding of the methods to minimise bias and confounding in study design and analysis 4. demonstrate understanding of the role of different statistical methods, including multivariate analysis, used in observational studies 5. demonstrate critical appraisal skills and interpret study findings.

Indicative Syllabus

Session Content
The module consists of 11 Computer-Assisted Learning (CAL) sessions. The titles of the sessions are as follows: 1. Overview and Introduction to Epidemiology 2. Observational Study Designs and Interpretation 3. Challenges in choosing an exposure and outcome 4. Measures of Occurrences and Effect 5. Cross-Sectional Studies 6. Cohort Studies 7. Case-Control Studies 8. Confounding and interaction 9. Bias 10. Introduction to multivariable analysis 11. Summary of study module.

Teaching and Learning

Notional Learning Hours

Type of Learning Time	Number of Hours	Expressed as Percentage (%)
Directed self-study	60	40
Self-directed learning	30	20
Assessment, review and revision	60	40
Total	**150**	**100**

Teaching and Learning Strategy
Learning is self-directed against a detailed set of learning outcomes using the materials provided.

Teaching and Learning Strategy
To support their self-directed learning, students are strongly encouraged to: • post questions for tutors or fellow students and participate in the module-specific discussion board forums available on Moodle. • submit a Tutor Marked Formative Assignment (TMFA), for which personalised written feedback is available. Students are provided with written feedback on submitted TMFAs. This is not compulsory and does not contribute to the overall module grade. • work through the Self Assessed Formative Assignment (SAFA), for which self-assessment tools are provided. This is not compulsory and does not contribute to the overall module grade. • work through the Self Assessed Mock Examination (SAME), for which self-assessment tools are provided. This is not compulsory and does not contribute to the overall module grade. • learn from written feedback from tutors on submitted Assessed Assignments (AAs). • join real-time tutorials via Collaborate, available on Moodle, to obtain additional tutor support: at least two tutorials are available, one focusing on assignments, and one for exam preparation. • make use of LSHTM online library resources. • make use of Examiners' Reports which include previous assessed assignment and examination questions and specimen answers.

Assessment

Assessment Strategy
The assessment strategy for CTM207 is designed to support progressive student learning through optional formative assessments, which can be self-assessed (SAFA) or tutor-marked with feedback (TMFA), a summative written assessed assignment (AA) and a formal examination. The FAs and AA have the same word-length and scenario-based short question format to build skills, and encourage students to engage with the study materials. They encourage M-level thinking through questions which challenge students to consult study materials and to reflect and problem-solve. They support attainment of ILOs by collectively testing across the range of learning outcomes. The AA is designed to test whether students are going beyond reiteration of the materials, and using M-level skills of criticality, and wider reflection. The word limit gives sufficient text allowance to demonstrate these skills within a succinct and focused writing style. The examination questions are also written to test core learning and M-level skills and should be answered with the same criticality as should be demonstrated in the AA, but may be answered without recourse to the study materials. For all CTM207 assessments the application of key learning to scenario-based questions encourages students to develop the skill of using core learning to respond to real-life problems encountered in the design and conduct of observational studies. On this module, two past AA papers, and three past examination papers, all with specimen answers, are also available for practice and self-assessment.

Summative Assessment

Assessment Type	**Assessment Length (i.e. Word Count, Length of presentation in minutes)**	**Weighting** (%)	**Intended Module Learning Outcomes Tested**
Assessed Assignment	The Assessed Assignment has a maximum word length of 2000 words	20	1-5
Exam	2hrs 15mins	80	1-5

Timed examinations for DL modules are held once a year, in June (including resits). Examinations in 2021/22 will either be taken in a student's country of residence in one of over 650 examination centres worldwide or will be held online. If the June 2022 module exam is held at a local examination centre, a local fee will be payable direct to the exam centre. This fee will be in addition to the module fee and is set by, and paid directly to, the individual examination centre. 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. If the June 2022 module exam is held online, no additional exam entry fee will be payable. (Note that for those resitting module assessments, a fee will be payable.)

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

Resources

Essential resources

The following materials are provided to students after registration for this module once a year in October:

- Computer Assisted Learning (CAL) materials provided electronically through the online learning site Moodle, for self-directed study
- E-books as below
- Online reading.

E-books

- Bhopal, R.S., *Concepts of epidemiology: integrating the ideas, theories, principles and methods of epidemiology*. 2nd ed. 2008, Oxford: Oxford University Press
- Kirkwood, B.R. and J.A.C. Sterne, *Essential medical statistics*. 2nd ed. 2003, Malden, Mass.: Blackwell

Examples of online reading

- L Bailey (2005) *Introduction to Epidemiology*. Open University Press.
- D Coggon, G Rose, D Barker (2003) *Epidemiology for the Uninitiated*. BMJ Books.
- L Gordis (2014) *Epidemiology*. Saunders & Co.
- MH Katz (2011) *Multivariable analysis: a practical guide for clinicians and public health researchers*. Third edition. Cambridge University Press.
- CJ Mann (2003) Observational methods. Research design II: cohort, cross-sectional, and case-control studies. *Emerg Med J* 20(1): 54-60.

In addition to the materials above, students are given access to the LSHTM Virtual Learning Environment: Moodle (for online discussions forums etc.) and the LSHTM online library resources.

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