



MATH38072 - 2007/2008

General Information

- Title: Medical Statistics
- Unit code: MATH38072
- Credits: 10
- Prerequisites: MATH10401, MATH20701
- Co-requisite units: None
- School responsible: Mathematics
- Members of staff responsible: Dr. [Chris Roberts](#) (University Place 1.318, Telephone 55196, email: chris.roberts@manchester.ac.uk)

Specification

Aims

This course unit introduces the application of statistical ideas and methodology to medical research.

Brief Description of the unit

Randomised controlled trials are planned experimental studies on human subjects designed to assess the benefit of medical treatments. Other important areas of application of statistical methods in medical research are epidemiological studies, which investigate the possible causes of disease from observational data, diagnostic studies, which methods of disease diagnosis and meta-analysis, which considers combining information from multiple studies. Many of the major developments in modern statistics have been motivated by problems in medical research. Whilst briefly outlining other areas of application in medical research, the lecture course will introduce the statistical issue associated design and analysis of randomised controlled trials and in meta-analyses.

Learning Outcomes

On successful completion of this course unit students will

- understand the statistical issues in the design and analysis of clinical trials;
- be able to apply statistical methods to the design and analysis of randomised controlled trials including parallel group, cross-over trials and cluster randomised trials;
- understand the statistical methods used for meta-analysis.

Future topics requiring this course unit

None.

Syllabus

1. Introduction to medical statistics. Randomised controlled trials: historical background and ethical issues concerning randomised experimentation on human subjects.
2. Design and organisation of randomised controlled trials. Types of bias and methods for controlling bias including blinding and placebo treatments.
3. Sample size estimation for continuous and binary outcome measures.
4. Methods of treatment allocation including simple randomization, random permuted blocks, stratification and minimization.
5. Implications of equivalence and non-inferiority hypotheses for sample size and statistical analyses.
6. Statistical methods for the analysis of parallel group trials including methods for the adjustment for baseline data.
7. Implications of protocol deviations and the motivation for the intention-to-treat principle.
8. Multiplicity issues: sub-group analysis and multiple outcomes.
9. Alternatives designs for randomised controlled trials: cross-over trials and cluster randomised trials.
10. Meta-analysis and publication bias.

Textbooks

- Matthews, JNS, *An Introduction to Randomized Controlled Clinical Trials*, 2nd edition 2006, Chapman & Hall/CRC Press

The first edition (2000) is also adequate for this course and there are copies of both in the John Rylands Library

Teaching and learning methods

Two lectures and one examples class each week. In addition students should expect to spend at least four hours each week on private study for this course unit.

Assessment

Coursework: weighting 20%

End of semester examination: two hours weighting 80%

Arrangements