

RESEARCH SEMINAR

When: Friday 2 October 2009
3.30- 5.00pm
followed by drinks & nibbles in Level 5 Training Room MFB

Where: Medical Foundation Auditorium
92-94 Parramatta Road, Camperdown

Map ref:

1. campus map <http://db.auth.usyd.edu.au/directories/map/building.stm?location=01B>
2. local street map <http://www.whereis.com/index.htm?ref=homeMap#session=MjE=>

3.30pm Welcome: Professor John Simes

3.35pm [Dr Lisa Askie](#)

[Open access clinical trials through trial registries](#)

The Australian New Zealand Clinical Trials registry now houses details about more than 3000 clinical trials, including 1200 trials currently recruiting participants in Australia / New Zealand. How this information is being utilised both now and potentially in the future to ensure people have open access to clinical trials will be discussed.

3.50pm [Ms Rhana Pike](#)

[Golden do's and don't's of manuscript preparation](#)

This is a talk about preparing to publish your research in a peer-reviewed journal — up to the submission stage — with some tips on strategy and writing.

4.05pm [Professor Val Gebski](#)

[Valid and dodgy statistics – getting it right](#)

The statistical analysis presented in publications underpins the science and credibility of the study. If the statistical analysis is the appropriate one, the credibility of the results will be established. If inappropriate analyses are presented, there will be doubt about the study conclusions. Consequences if inappropriate analyses may include:

- a) Abandonment of potentially important questions
- b) Optimism of the value of ineffective therapy
- c) Confusion regarding the clinical value of the intervention.

The talk will discuss some of these issues and present examples from published study reports.

4.20pm [Professor Val Gebski](#)

Combined primary endpoints: flavor of the month

Composite end points capture the number of patients who have one or more of several events of interest. They are becoming common in clinical trials, particularly in cardiology as they reduce sample size requirements and to capture the overall impact of therapeutic interventions. There are nevertheless key principles which need to be considered when reporting composite outcomes in randomised trials, especially they form the primary trial endpoint. These principles will be developed and illustrated from published studies.

4.35pm [Ms Adrienne Kirby](#)

Non-inferiority and equivalence trials: a user's guide

A new intervention is easier to administer, but may not have the same efficacy as the existing standard. How can we test that the new drug is not much worse?

A brief introduction to equivalence and non-inferiority.

THE PRESENTERS:

Dr Lisa Askie is Director of the Systematic Reviews and Health Technology Assessment team, Manager of the Australian New Zealand Clinical Trials Registry and a Senior Research Fellow in the Sydney School of Public Health. Her background is in paediatrics, midwifery and perinatal medicine. Lisa spent 2003-2005 at the UK Cochrane Centre in Oxford as a postdoctoral research fellow and joined the CTC in September 2005. Lisa's research interests include prospective meta-analysis, individual patient data reviews and trial registries.

Ms Rhana Pike is responsible for academic publications at CTC and was previously a managing editor of medical journals. She is a member of the Board of Editors in the Life Sciences (US), vice-president of the Australasian Medical Writers Association, and has degrees in science and psychology.

Professor Val Gebski is head of biostatistics and research methodology at the NHMRC Clinical Trials Centre which he joined in 1988. He has extensive knowledge of clinical trial methodology, conduct and analysis and is the Group Statistician for a number of national collaborative clinical trials groups in oncology. He has a BA and MStat and is also involved in curriculum development and teaching in the Masters of Public Health, Clinical Epidemiology and Medicine at the University of Sydney. He is the statistical examiner for the Royal Australian and New Zealand College of Radiologists.

Ms Adrienne Kirby is a senior biostatistician and is the study statistician for the LIPID long-term follow-up and for the ASPIRE trial. Research interests include multiple-event data analysis (LIPID, with Malcolm Hudson), ROC curves, survival regression analysis and prognostic models. Adrienne runs a one-day-per-week statistical clinic for staff at the Sydney University Clinical School at Nepean Hospital. She is involved in all of the teaching activities of the biostatistics group.