THE CAMBRIDGE STATISTICS DISCUSSION GROUP

Tuesday 1st February 2011 7:15 for 7:45

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What constitutes adequate strength of evidence?

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Abstract: Adequately sized randomised controlled trials represent the gold standard for testing efficacy and safety of therapies, but they are not the only means of doing so. 'One size' doesn't fit all when designing trials across very diverse therapeutic areas. Evidence-based medicine is an ideal goal but does not automatically imply large randomised controlled trials.
It is unacceptable to cut corners in study designs for no good reason, or where doing so will likely lead to uninterpretable results or misleading conclusions. Arguments will be presented why randomised controls (even very small trials) might be preferable to uncontrolled studies. Arguments in favour of 'nothing to lose' from trying new experimental therapies may not be sufficient and in some cases may be completely wrong. We need to identify the situations in which the certainty and course of disease is such that we can circumvent the need for traditional randomised controlled trials, and then match those situations with cases where practical and ethical constraints strongly encourage us to do so. Published examples of 'strength of evidence' and 'grades of recommendation' scales again indicate that one size does not fit all and acceptable grades of recommendation need to be context-specific.

Speaker: Simon has spent 25 years working in clinical trials, mostly in the pharmaceutical industry but also including five years at the UK and European regulatory agencies. He currently works for Roche as a global statistical and regulatory consultant. He is a former president of the International Society for Clinical Biostatistics; he is an associate editor of *Statistics in Medicine*, on the editorial board of *Pharmaceutical Statistics* and joint editor of the *Journal of the Royal Statistical Society*. He has published widely in statistical and medical journals, is author of one book '*Dictionary for Clinical Trials*' and is joint editor of the '*Textbook of Clinical Trials*' both published by Wiley. He is chairman of the External Advisory Panel for the Department of Statistics at Oxford University; an external examiner at the London School of Hygiene and Tropical Medicine; and an Associate on the faculty at Johns Hopkins University in Baltimore. He also serves on the West London Research Ethics Committee in London.

Directions: The main entrance is reached from Clarkson Road by going along the footpath to the right of the Newton Institute, and turning left through the gatehouse towards the main building (Pavilion A), which has a glass front and a curved grassed roof. The main entrance is in the middle of the glass front. Free Parking is available after 5pm on Clarkson and Wilberforce Roads and by entering the site off Wilberforce Road. Admittance may be difficult after 7:45.

Provisional Next Meetings:
23rd February – David Pencheon (NHS Sustainable Development Unit) on 'Head in the sand or Line in the sand: measuring progress of the public sector into a low carbon world'.
23rd March – Ian Nimmo-Smith (MRC).
Supper: Some members eat regularly in the University Centre before each meeting at **5-45pm**. Feel free to join them.
Subscriptions: of 1 pound are now due for attending the 2010-2011 session.
Secretary: Peter Watson, MRC Cognition and Brain Sciences Unit, 15 Chaucer Road, Cambridge CB2 7EF; telephone 01223 355294 Extension 801; E-mail peter.watson@mrc-cbu.cam.ac.uk.

Take a look at our website: http://www.mrc-cbu.cam.ac.uk/people/peter.watson/csdg.html