The International Biometric Society Australasian Region Conference
29th November – 3rd December 2015

Workshop 3: Causal inference in randomised trials

Presenter: Dr Richard Emsley, Senior Lecturer in Biostatistics, Centre for Biostatistics, Institute of Population Health, The University of Manchester.

Biography: After completing a PhD in biostatistics at The University of Manchester, UK, I worked as a post-doctoral research associate investigating the design and methods of analysis of trials of complex interventions in mental health. In October 2009, I was awarded a 3 year MRC Career Development Award in Biostatistics to continue aspects of this research. In October 2012, I was appointed Lecturer in Biostatistics in the Centre for Biostatistics, and promoted to Senior Lecturer from August 2015. I am a Visiting Lecturer at the Institute of Psychiatry, Psychology and Neuroscience, King's College London. I am a member of the UK MRC North West Hub for Trials Methodology Research, Secretary of the UK MHRN Methodology Research Group, and the initiator and Chair of the steering group for the UK Causal Inference Meeting (UK-CIM).

Requirements: This workshop will assume that participants have a basic knowledge of the standard analysis of RCTs, including linear and logistic regression models.

Software: The workshop will focus on worked examples, modelling issues and the key assumptions, and how these methods can be implemented in standard statistical software. It will include worked examples and their illustration in statistical software (Stata), but will not require participants to use or have prior knowledge of any particular software package.

Course aim and content:
Randomised trials provide a gold standard design for assessing the effectiveness of an intervention or treatment, based on an intention to treat analysis. However, this suffices to only answer a narrow question about the effectiveness of offering the intervention, based on comparing the average outcome between randomised groups. A series of different question could ask "what is the effect of actually receiving the intervention?", "how does the intervention work?", and "who does the treatment work best for?" To answer these questions, we require different analysis approaches, using methods drawn from the causal inference literature.

This workshop aims to introduce participants to the statistical methods underpinning the concepts of causal inference in randomised trials.

AM: The morning session will give an introduction to the terminology of causal inference, the analysis of randomised trials following the intention-to-treat principle, and the problem caused by departures from randomised allocation. The complier average causal effect as an alternative estimand, and we will show how this can be estimated using instrumental variables, and the links with g-estimation and structural mean models.

PM: The afternoon session will introduce the concept of mediation analysis, describing both its potential and outlining the major difficulties. To begin with, we will concentrate on what has been termed "statistical mediation analysis" and introduce standard approaches for constructing inferences for mediation parameters in the single mediator model using simple regression and structural equation models, and discuss assumptions made by such analyses. We will then extend these concepts to what has been termed "causal mediation analysis" which further relaxes these assumptions to allow causal effect estimation in the non-linear case and to allow for treatment × mediator interactions. We will introduce approaches that can deal with measured post-randomisation confounders and hidden confounders in trials. Finally, we will briefly introduce methods for testing for interactions with multiple baseline factors to inform decision treatment rules.

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