

NIHR Statistics Group 2nd Annual Conference

# Real World Medical Statistics



**Seventy five delegates attended the NIHR Statistics Group's Second Annual Conference entitled 'Real World Medical Statistics', held at the University of Sheffield on 21-22 June 2018.**

The meeting brought together NIHR statisticians and researchers with an interest in statistics for educational and information-sharing talks, breakout groups on hot topics, and networking. As we did last year, we plan to use the breakout groups as a springboard to identify key hot topics to be developed as new 'sections' which will complement our existing sections.

Invited speakers included Prof. Dave Jones (Dean of NIHR Faculty Trainees, pictured), Mike Batley (Policy Research, Evidence and NIHR Research Programmes), Prof. Richard Emsley (King's College London). Main points from the breakout group discussions are given on the next page.

## NIHR Statistics Group in brief

The NIHR Statistics Group was formed in 2012 with the aim of linking statisticians from across the NIHR infrastructure to share knowledge and expertise, and to help identify and promote best statistical practice for NIHR research. The Group currently has over 500 members, has held national events attended by >1500 delegates and published 18 papers discussing best practice.

www: <http://statistics-group.nihr.ac.uk>

Email: [nihr-stats@kcl.ac.uk](mailto:nihr-stats@kcl.ac.uk)

## EVENT PROGRAMME

Chair: Dawn Teare, University of Sheffield

### THURSDAY 21ST JUNE

Welcome and introductions

#### Breakout session 1

- Mendelian Randomisation
- Routine/Big Data
- Good Clinical Practice (GCP) for statisticians

#### Breakout session 2

- Statistical Analysis Plans
- Diagnostic/Prognostic Models
- Improving Understanding/Use of Statistics

**Prof Dave Jones, Dean of NIHR Faculty Trainees.** 'NIHR Academy & role of NIHR Statistics Group'

### FRIDAY 22ND JUNE

**Richard Emsley, King's College London**  
'Careful with causal inference'

#### Feedback from breakout sessions 1-2

#### Breakout session 3

- MRC Adaptive Designs
- Career Development
- Mediation Analysis

#### Breakout session 4

- Missing Data
- Routine/Big Data Future Plans
- PPI for Methods Research

#### Feedback from breakout sessions 3-4

**Mike Batley, Policy Research, Evidence and NIHR Research Programmes**  
'Working with Ministers and policy makers'

## NIHR STATISTICS GROUP

### Steering Committee

Janet Peacock (King's College London)  
Dawn Teare (University of Sheffield)  
Catey Bunce (King's College London)  
Simon Bond (Cambridge CTU)  
Sue Mallett (University of Birmingham)  
Alice Sitch (University of Birmingham)  
Sam Leary (University of Bristol)  
Laura Flight (University of Sheffield)  
Jacqueline Birks (University of Oxford)  
Andy Vail (University of Manchester)  
Matt Hallsworth (NOCRI)

# Breakout Groups—Brief Summary

## Mendelian Randomisation

- Derrick Bennett summarised the method that is gaining popularity
- Mendelian randomisation makes many untestable assumptions
- Discussions of a controversial paper that looked at the relationship between myopia and time in education

## Routine/Big Data

- Richard Jacques described a study that required acquisition and merging of ambulance and hospital data and described the enormous challenges involved
- Vicky Strauss described some of the methodological challenges involved in working with routine GP data

## Good Clinical Practice (GCP)

- GCP training is a requirement for a trial statistician & MHRA 'Grey Guide' is not familiar to applied statisticians outside of CTUs
- UKCRC initiative to establish statistician-specific GCP training is widely welcomed— we look forward to it being rolled out more widely

## Statistical Analysis Plans

- UKCRC Statistics Group guidance on writing SAPs was recommended
- The analysis outlined in the protocol and SAP should agree
- Worth considering publishing SAP as standalone paper

## Diagnostic /Prognostic Studies

- RCTs often not best design for evaluating diagnostic tests and prediction models due to large sample size requirements, time scales and complexity of tests/prediction models as interventions
- Future twice yearly half-day meetings of the NIHR diagnostic and prognostic studies group planned to further these issues

## Improving Understanding/Use of Statistics

- Discussed how reviewers often suggest inappropriate methods
- Agreed to create an online comprehensive list of resources available - with the facility to up-vote/highlight resources in NIHR Statistics Group website
- Funding for webpage sought

## MRC Adaptive Designs

- Adaptive designs may be needed because of high failure rate of investigative treatments across phases due to poor efficacy or safety profile
- Challenges with adaptive design include increased uncertainty about study duration, patient requirements and funding

- Design may complicate statistical inference, create unblinding issues
- MRC HTMR Adaptive Designs Working Group provides possible trial adaptations with case studies and practical advice for researchers

## Career Development

- Fixed term contracts problematic
- Having a non-statistician as your line manager
- Being the only statistician in your research group
- Encountering ceilings/inflexible criteria for progression
- Recognition of unique career pathways
- Future group activities: trial mentoring scheme at 2019 conference plus online resources to help staff achieve progression/promotion

## Mediation Analysis

- Kim Goldsmith emphasised that a mediator must be observed at the same time, or before the endpoint, not afterwards
- Mediator must be measured in all treatment arms in RCT and measure mediator at all possible time points
- Can build up simple models adding complexity incrementally (e.g. longitudinal model vs 1-timepoint-at-a-time model—adds robustness)
- Graeme MacLennan presented examples from a variety of medical fields showing lessons learnt over time/ experiences gained

## Missing Data

- Many pitfalls when using imputation methods
- Big data: No formal way to describe the process of data cleaning and the removal of missing data
- ITT analysis: When we have missing data, should we use complete cases or imputed data for our ITT analysis?
- Need for a definition of what is classified as 'big data'
- SAP include description of actions for different missing data scenarios

## Routine /Big Data Future Plans

- The group agreed to organise its 3rd meeting on CPRD in January 2019 in Oxford including data extraction, missing data and how GPs code data
- Other plans include training on using HES data

## PPI for Methods Research

- Methodologists not trained for, or used to, direct patient contact
- Generic methodological research (e.g. trial design) doesn't have clear patient group to target
- Important to target key stakeholders—not always patients, could be research funders etc
- Need to consider design, conduct and dissemination phases of methodological research