12 April 2013
NOCRI Meeting
Wolfson College, University of Oxford

Morning session 10:00 – 11:15

Formal welcome by Professor Doug Altman
Meeting Chaired by Jacqueline Birks

- The meeting's aim could provide a useful opportunity to share good practice and expertise in the design and analysis of laboratory studies.
- It was suggested that the meeting could act as a forum to help define and identify a clearer understanding of what is meant by the broad term 'laboratory studies' (measurement studies?) . There is currently no clear meaning/definition of the term and it is not a recognised discipline like epidemiology etc.
- When studies do not need ethical approval there is often a lack of planning and lack of protocol for study design as a consequence it is easy to be led by chance findings
- It is the second NIHR statistical meeting, the first having been held at KCL in April 2012. It was hopeful that this format would continue on a regular basis and expand to bring in other areas for discussion and a variety of expertise.

Dr Lucy Allen: The NIHR infrastructure and Statistics

- The NIHR has been established as a "Health research system" which provides support for world-leading research taking place in cutting-edge facilities.
- NIHR aims to deliver benefits for patients and the public, whilst also supporting the growth of the UK economy bringing investment from the life-sciences industry
- Establish NHS as a centre of excellence for research worldwide
- NOCRI Has both an internal and external facing role. Internally, NOCRI aims to develop research excellence supporting sharing of best practice, joint problem solving and collaboration. Externally the aim is to promote research and secure investment
- The need to work with NIHR to develop statistical support was noted. It is important to share best practice and solutions.
- NOCRI = relationship management
- Similar workshops planned for the future to continue to develop this important community

Dr Victoria Cornelius: Senior Lecture in Medical Statistics, KCL

- Emphasised the need for an informal and sharing environment to push the 'grass roots' of statistical involvement in laboratory studies
- Builds on from the feedback obtained from the 1st meeting in April 2012
- Forum to prompt original ideas for new papers and establish working groups for future activities.

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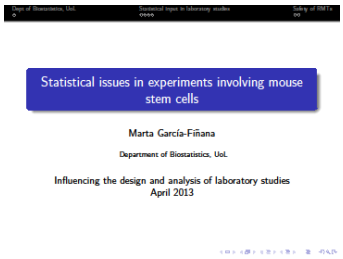
The NIHR infrastructure and Statistics

Dr Lucy Allen, Head of Research Infrastructure & Communications NIHR Office for Clinical Research Infrastructure (NOCRI)

Delegate presentations (analysis)

Statistical issues in experiments involving mouse stem cells

Dr Marta García-Fiñana, Senior Lecturer in Biostatistics, University of Liverpool



How to optimize, interpret and use quality control outputs from different genomic techniques for decision making in cancer clinical studies

Dr Francesca Buffa, Clinical Genomics Lead, University of Oxford

The challenge of analysing sequential repeated measures in prospective biomarker studies for the prediction of transplant outcomes

Dr Irene Rebollo Mesa, Lecturer in Biostatistics, King's College London

Studies of intra-individual biological variability

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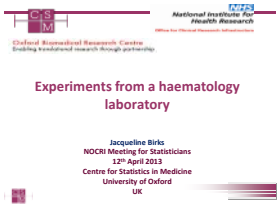
Alice Sitch, Research Fellow in Medical Statistics, University of Birmingham

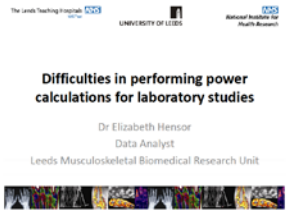
Studies from the haematology laboratory

Jacqueline Birks, NIHR OXBRC Senior Medical Statistician, Centre for Statistics in Medicine



Difficulties performing power calculations for laboratory studies

Dr Elizabeth Hensor, Data analyst, Leeds Musculoskeletal Biomedical Research Unit Centre



Delegate presentations (communication)

Barriers to effective communication between experimentalists and Statisticians

Dr Dawn Teare, Senior Lecturer in Genetic Epidemiology, University of Sheffield

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An NIHR statistician's interaction with laboratory studies

Dr Victoria Cornelius, Senior Lecturer in Medical Statistics, Kings College London

Difficulties of working with laboratory study data

Catey Bunce, Principle statistician, Moorfields Eye Hospital

Academic research including laboratory data in a paperless environment

Dr Kjell Pennert, Head of Research Data Management & Statistics Unit, The Royal Marsden NHS Foundation Trust

No presentation

Delegate presentations (laboratory)

A laboratory scientist's perspective

Dr Vikki Goss, Post Doctoral Research Scientist at Respiratory BRU Southampton

No presentation

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Workshop outcomes/discussion notes:-

Summary of research topics

Group 1

Suggestion: Develop Statistical Consultation Guidelines for Biomedical Research
(Audience) Statisticians to give to lab scientists to support discussion

Research aims and objectives, specific outcomes
Study planning and design to avoid bias, confounding use of randomisation, blinding sources of variation/replication, repeated vs independent measurement use of controls, effect sizes and samples size.
Recommended statistical analysis statistical support (and funding)

Group 2

Suggestion: Series of short articles similar in style to the BMJ stats notes series in (in journal like NATURE?)

Audience: Laboratory scientists;

Manifesto: there needs to be change!

Would need to be developed in conjunction with buy if from laboratory scientists eg. Somebody up the hill

One page articles manifesto – "why 3 replicates?"
Build on initiatives such as remark/consort
Involving clinical samples/not

Future meeting suggestions
Regular annual meeting open to lab scientists?
Online forum
Training? Online?

Group 3

Suggestion: Promoting, collaboration and more standardisation

We need collaboration from scientists/ clinicians involved in these studies. Suggest that we need to meet them ½ way and we as statisticians have to understand the way they work rather than demand they fit in with us.

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Could have a register for experiments (and encourage this a good practise top register all their experiments) rather than insisting on a protocol registration process . This could include a confidentiality window for 1(?) year. As its would be unrealistic to expect them to write a protocol for the smaller and more informal lab experiments undertaken.

Discussion across the group took place on whether it was acceptable to have many underpowered experiments taking place across 'laboratories' or if there should be emphasis on reducing this practise to encourage development of collaboration of laboratories/centers if they are unable to have sufficient samples to perform a powered study. It was felt that This was compared to how individual doctors used to perform RCTs with n=20 in just their centre which is now no longer acceptable.

Larger numbers – not only p value but more detailed analyses
Statisticians/analysis need to do things in a more standardised way.
Guidelines for statisticians in lab studies
Lab studies regulations and registry
Need for analytical protocol
Audience = lab and stats

Group 4

Suggestion: first need to define what we mean by 'laboratory study' as suggested by DA, then could develop a 'Frame work' (less informal version of reporting guidelines) in first instance.

Framework: would allow suggestion of systems/process to be put in place to improve research in this area.

Audience: laboratory scientists
What are the current issues?
- Sample size
- Poor reporting/unable to replicate studies
- Non reporting of NS results (publication bias)
- Too many small studies – should protocols be produced?

Framework needed.