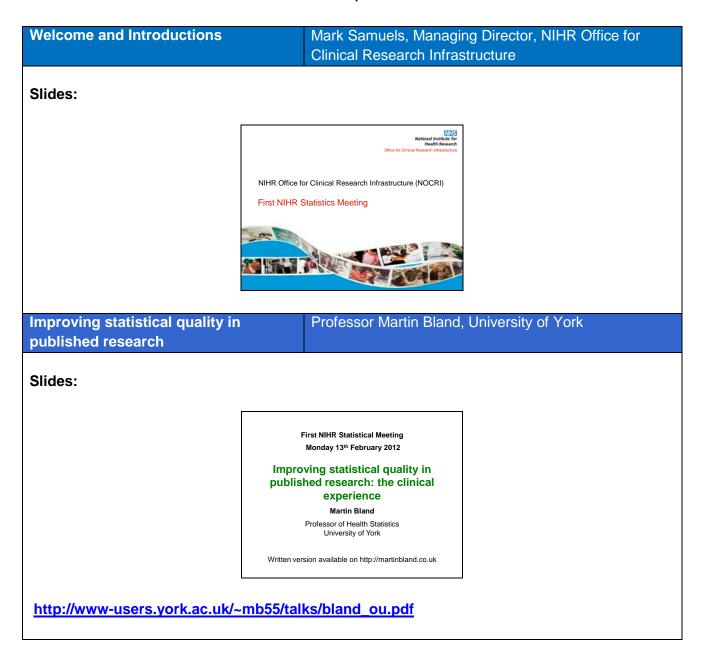




First NIHR Statistical Meeting Monday 13th February 2012

Robens suite, 29th floor Tower wing, Guy's Hospital London SE1 9RT

Report





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Sample size by design in complex intervention trials	Dr Toby Prevost, Kings College London		
Slides:			
National Institu Health Re	NIHR Statistical Meeting 13 th February 2012		
Sample	e Size by design in complex intervention trials		
	Toby Prevost Unit for Medical Statistics KCL		
Fred Smith Southam	Palmer Kinmonth Thompson		
Strategies for handling missing data in randomised trials	Ian White, MRC Biostatistics Unit, Cambridge		
Sides:			
	MRC Biostatistics Unit		
Stra	tegies for handling missing data in randomised trials		
	NIHR statistical meeting London, 13th February 2012		
	Ian White MRC Biostatistics Unit, Cambridge, UK		
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Models of infrastructure for statistical support in NIHR units		Professor Deborah Ashby, Imperial College London				
Slides:		·				
	Imperial College London					
	Models of Infrastructure for Statistical Support in NIHR units					
	Professor Deb Imperial Colleg					
Statistics permeates the entire NIHR. Despite this prevalence there are few opportunities to train this cohort of statisticians on professional schemes.						
Similarly to other areas of research, the NIHR can play a key role translating statistical developments emerging from basic science into the NHS for the benefit of patients.						
There is work to be done on a local level at the larger institutions to connect NIHR statistical support.						
Any future organisation of the NIHR statistical community must complement:						
 <u>The Royal Statistics Society</u> (especially in continual professional development) Statistics in the Pharmaceutical Industry 						

International Society for Computational Biology

Many statistical academic meetings are already organised. Their reach must extend into the NIHR where relevant, and where there are gaps (BRU/BRC/CLAHRC statisticians?) further groupings and meetings may be necessary. This must be determined by the statistics community.

A further challenge is ensuring effective involvement of patients and the public in the design and methodology of studies. There could be a role for <u>INVOLVE</u> here.



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The Vision for Real World Data – Harnessing the Opportunities in the UK		Dr Rick Lones, Bristol-Myers Squibb			
Slides:					
	The Vision For Real World Data – Harnessing the Opportunities for the UK Dr Rick Lones BM FFPM MRCGP Executive Medical Director, UK and Ireland, Bristol-Myers Squibb and Co-Chair, ABPI Real World Data Campaign Team 13 th February 2012				

There is a groundswell within industry for the UK to become a centre of excellence in the conduct of Real World Data studies.

The recently announced <u>Clinical Practice Research Datalink</u> will provide the UK with a unique environment to support the generation of Real World Data (RWD).

RWD methods will support the requirements of the proposed 'value based pricing' model for drug reimbursement.

Earlier conditional approvals may demand more intensive data collection from RWD studies.

A major challenge is linking the patient record given that NHS Trusts run independent IS systems.



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MRC Network of Hubs for Trials Professor Lucinda Billingham, University of **Methodology Research** Birmingham. Director, MRC Midland Hub for Trials Methodology Research Slides: **Improving Quality of Trials** through the MRC Network of Hubs for Trials Methodology Research Professor Lucinda (Cindy) Billingham Professor of Biostatistics Director, MRC Midland Hub for Trials Methodology Research Biostatistics Lead, Cancer Research UK Clinical Trials Unit University of Birmingham NIHR Statistical Meeting, London February 13th 2012 MRC Open call to NIHR investigators to apply for quarterly funding opportunities. There are also relevant workshop opportunities open to NIHR statisticians.

Access the Hubs' services in 'trials methodology for trialists and statisticians who encounter nonstandard methodological problems' by logging queries through the <u>Methodology Advisory Service</u> <u>for Trials</u> (MAST).

Workshop 1: Statistical Social Networking





Workshop 2: What are the benefits for statisticians linking into the NIHR Faculty? Questions:

1. What are the potential benefits for linking statistician across different NIHR units?

RDS Opinion:

- It will give a clearer picture of how components of the NIHR-funded infrastructure fit together. The RDS advise researchers and as such the offer will be enriched if they can sign post individuals to useful contacts and facilities in the NIHR infrastructure or beyond
- The RDS' are currently unclear about the specialties and focus of the NIHR infrastructure.

CLAHRCs:

• There are gaps between statisticians. It will bridge the gap across statisticians.

BRC Opinion:

- It will enable the sharing of expertise and methodologies as well as establish critical mass to help raise the profile of NIHR-funded statisticians nationally. It is the only way to deliver on the capacity of the existing NIHR-funded statisticians.
- It will support the identification of common problems and enable the community to tackle these problems together in an efficient manner. Analogous to the MRC Hubs in trial methodology, but moving beyond only trials. There is currently no support for observational and experimental lab data. This grouping could develop methodological research questions in collaboration.

BRU Opinion:

- It would allow collaboration to support funding applications
- Provide an opportunity to ensure no duplication of efforts.
- It could be an important resource to statisticians that are not part of CTUs/MRC Hubs and are therefore more isolated.

CTU Opinion:

- It would open up opportunities for effective mentoring as well as sharing of resources.
- It would be beneficial to help with finding members for Data Monitoring Committees and Trial Steering Committees





2. Do we need another statistical forum for NIHR statisticians over existing statistical forums such as the RSS and clinical trial methodology conference?

If so, what purpose should the forum take? e.g.

- Annual meeting with talks and workshops for educational purpose
- Informal setting providing the opportunity for members to present their work and discuss
- Smaller training meetings hosted by members

And what topics should be covered?

RDS Opinion:

- RDS' often require quick help to specific questions. Is it possible to bring together an NIHR stats service to answer such requests? It must be more specific than the existing med stats lists.
- Surveys could be used to canvas opinion on the types of meetings to run.
- Closer working with the NIHR funding streams and their programme managers would put the RDS' in a better position to support effective funding applications.
- Sessions on DMECs would be useful. Support is needed here.
- For diagnostic and other predictive tests, what is the best approach to sample size?

BRC Opinion:

- Specialised workshops would be of benefit. Themed calls to look at e.g. clustering for 6 months, follows by biomarkers for 6 months. These should be organised by the infrastructure to drive best practice and generate opportunities to collaborate on publications.
- Existing events can be advertised more widely through better communications. A registry mailing list plus newsletter emerging from this meeting would deliver this.
- Sample size for animal work bring more rigorous statistical approaches utilised in the clinic to the realm of pre-clinical work.
- A workshop on how to deal with difficult clinicians (consultancy skills workshop). RDS' are already thinking about this, and it was suggested that it could be beneficial to join up thinking and work together. Is there a possibly of getting an external consultant (such as the Royal Statistics Society) to run the day?

BRU Opinion:

- Disease area forums would be of benefit. There is also much work within the infrastructure on observational studies. There is a need to go beyond statistical support for clinical trials. Is it possible to effectively connect people by what they are doing – matrix of methodologies and disease areas.
- Provide an opportunity to discuss work and present it. Smaller meetings tackling specific interests will foster confidence and help individuals with difficulties.



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- Any NIHR-focussed events would be easier to justify spend.
- Sample size, alternative trial designs and proof of concept studies should be covered in addition to regular RCTs. Talks, workshops and case studies of study design.

CTU Opinion:

- An NIHR forum will give opportunities to feedback to the NIHR leadership on some of the central decisions. NIHR networking might build on existing CTU groupings.
- Different forums could be aimed at different levels of seniority to allow participants to gain the most value out of the days
- It could have a wider remit than current Clinical Trial-focussed meetings
- A coordinated approach to statistical and health economic input into trial design across the NIHR. The might involve bringing the RDS' BRCs and the HDA together.

CLAHRC Opinion:

• The CLAHRCs often do quite unique work and therefore such a grouping would help. With the existence of the Royal Statistics Society it is important not to duplicate efforts. The NIHR might consider a newsletter, online grouping, blog and webinars.

3. How should the NIHR statistical 'group' be structured?

CLAHRC Opinion:

• Given the CLAHRCs already meet for other reasons, there are existing opportunities to better connect CLAHRC statisticians.

BRU Opinion:

- Any directory must not have strict rules. Individuals should be able to join themselves. The NIHR portal can be used for central communications.
- The opportunity to present and discuss work would be beneficial. Further training is also necessary. It must be a fairly informal meeting where junior statisticians can discuss data and challenges freely. These could be smaller more informal meetings to exchange ideas.

BRC Opinion:

• A registry of NIHR statisticians could be built online. It must include those that did not attend the first meeting.

BRU:

• Any registry must not have too much structure, but give a broad idea of interest and specialty. Content must be user driven.





4. Are there benefits to creating an online support network?

Collate existing statistical resources and develop a dedicated forum. Consider the existing med stat forum and how any NIHR forum could complement it.

NIHR portal-based solution.

Actions / follow up:

1.

Create an identity & community

Create a support network: for 1) research & 2)support for statistical questions/discussion Create a resource network for Trials to help find members for DMCs and TSC Share resource such as sharing of training days and experience across units

2.

Workshop suggested by Units:

- Sample size for all different types of projects (BRU's)
- Talks and workshop forum (BRUs)
- Consultancy skills
- Information on funding streams(RDS)
- Session on DMECs and TSC (RDS)
- Methodology but online workshop (CLARCS)
- Issues around diagnostic testing
- Image analysis : design of studies

VC thoughts: Workshops need to be specific and targeted (and consequently small). Need to be put together by those who can be thought of specialist in the area but who are part of NIHR community and we should ensure this responsibility is spread among all units across the country. This facilitates knowledge transfer and best practise is encouraged across units. Occasionally workshops by (such the consultancy skills) could be arranged where external consultants take these.

In addition there should be an opportunity for isolated statisticians, who have limited ability to attend conferences, to present work in a small friendly environment.





3.

VC thoughts: what's definition of 'employed by NIHR' does this include statisticians funded through an NIHR grant?