

Statisticians on RECs

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20 April 2015

How I got started

- ▶ Consulting job in NHS hospital
- ▶ Shared corridor with lay REC Chair
- ▶ Statistical queries every month
- ▶ After a few months, “Why don’t you join?”
- ▶ That was 1995 – much more formal now!

What followed

- ▶ REC member for 20 years
- ▶ Chair for 5 years
- ▶ 7 RECs
- ▶ c. 2000 studies
- ▶ Other project work for Health Research Authority
- ▶ NHS employer sees the benefit – some time provided

What's involved in starting a study

- ▶ Design it, then in order:
- ▶ Get funding (industry, grant, internal)
- ▶ Sponsor approves the proposal
- ▶ Submit to Research Ethics Committee for their opinion
- ▶ Management approval at each study site

What is the distinctive role of the REC?

- ▶ REC acts as a proxy for the interests of people who might take part in the study
- ▶ Need to make sure that the study is a fair ask for participants
- ▶ And that participants are properly informed, and so can make a free decision
- ▶ By contrast, sponsor assesses the science, and is responsible for study conduct

The REC must weigh up...

- ▶ Risk and inconvenience to participants
- ▶ Benefit to knowledge, and to participants
- ▶ Need to strike a balance, but no fixed rule
- ▶ Needs a committee, not an algorithm
- ▶ Variety of views round the table

Discussing the studies

- ▶ One or two members introduce each study
- ▶ Then others give their views
- ▶ Applicants are invited to attend for questions, and most do, and are pleased that they did
- ▶ Discussions are well-informed
- ▶ Strong views can lead to passionate debate
- ▶ Periodic “shared debates” where several RECs review the same application
- ▶ Some variation is acceptable, some not

Not all RECs are the same

- ▶ Only some RECs are allowed to review drug studies (this is the law)
- ▶ Some other studies are best directed to a REC that regularly sees them (good practice)
- ▶ Medical devices (wide ranging)
- ▶ Adults lacking capacity
- ▶ Children
- ▶ Research tissue banks
- ▶ Research databases
- ▶ Prison-based studies
- ▶ Qualitative research

RECs do not assess the science

- ▶ It's not our job to assess the value for money of the research
- ▶ But there is a problem if participants' time and goodwill are misused
- ▶ So we do need to assure ourselves that the science is sound
- ▶ The research sponsor should give us this assurance
- ▶ Poor science – no benefit, so no acceptable risk or burden level – don't do the study

What do REC statisticians do?

- ▶ Provide assurance to REC members that the proposal is statistically sound
- ▶ Quiz the applicant where necessary
- ▶ Sample size (but not effect size?)
- ▶ Randomisation, blinding
- ▶ Analysis, publication plan
- ▶ We are seen as the methodological experts
- ▶ That gives us a wide-ranging brief
- ▶ Tact and diplomacy are key attributes
- ▶ End up as Chair if you're not careful!

Statistical quality of the proposals?

- ▶ Industry (pharma) – will have had a lot of statistical input, but mostly in-house
- ▶ Industry (SMEs) – more varied
- ▶ Funded by major grant giver (e.g. MRC, NIHR) – already had substantial independent review
- ▶ Funded by smaller grant giver – could need care and attention
- ▶ Own account (NHS and students) – will need a careful look

Example of problem-solving

- ▶ Proposing a case-control study
- ▶ Researcher consulted statistician by email
- ▶ But, on the REC form, “cases” were those with the risk factor, and “controls” lacked it
- ▶ So the sample size was wrong
- ▶ I was first to notice the misunderstanding
- ▶ Had to be tactful when researcher attended
- ▶ Advised face-to-face meeting with statistician
- ▶ Sorted!

Who are the REC statisticians?

- ▶ Some work for NHS (NIHR etc.)
- ▶ Some are academics
- ▶ Some are from industry
- ▶ Some are self-employed
- ▶ Some are retired
- ▶ BUT there aren't enough to go round!

What's the workload?

- ▶ 10–11 meetings per year (not all can attend every time)
- ▶ 4–6 studies per meeting, maybe 4 hours
- ▶ Reading beforehand
- ▶ Simpler studies get dealt with by sub-committees of 3 (“Proportionate review”)
- ▶ Expectation is two-thirds of the meetings, less if you do sub-committees
- ▶ HRA offers training, initial and refreshers, standard is one day per year

What are the perks?

- ▶ Expenses
- ▶ Catering
- ▶ Intellectual workout
- ▶ But no pay! (not from HRA anyway)
- ▶ Good for professional development – vast variety of studies
- ▶ Mentoring by existing member (specific scheme for statisticians being set up)

Summing up

- ▶ RECs do a vital public service
- ▶ Being a statistician on a REC is a satisfying role
- ▶ Gives you a “buzz”
- ▶ We need more statisticians
- ▶ Medical background not essential
- ▶ Your employer ought to see the added value