SOME THINGS TO CONSIDER WHEN ASSESSING THE USEFULNESS OF RESEARCH STUDIES

First Questions

BASIC QUESTIONS THAT SHOULD BE THE FIRST TO BE ASKED

- In which journal has it been published?
- Is that a reputable journal?
- Are submitted papers peer reviewed?
- Are peer reviewers anonymous or known to the authors?
- Is it the 'right' journal for the subject?
    - *If a paper on traumatic brain injury is published in a specialist cardiology journal, for example, you might wonder why.*
- Does / do the author(s) have any formal connection with the journal?
    - *Are they on the editorial board? As an extreme – do they self-publish the journal?*
- If you have cause to write to the corresponding author, does he/she reply promptly and helpfully to queries?

The Sample

A STUDY WILL BE ASSESSING THE EXPERIENCE OF A POPULATION AND, GIVEN THAT THE POPULATION WILL ALMOST CERTAINLY BE TOO LARGE TO BE INCLUDED IN ITS ENTIRETY, A SAMPLE WILL BE NEEDED. THESE QUESTIONS ASK ABOUT THE APPROPRIATENESS OF THAT SAMPLE

- Has the sample been taken from the population?
    - *A crucial question. The population should be defined and then the sample taken, not the other way round.*
- Is it large enough?
    - *Generally you can assess by considering the breadth of the confidence interval. Too wide means the results are unreliable and the sample too small.*
- Is it too large?
    - *Too large a sample means tracking difficulties and might mean that inappropriate subjects have been included.*
- Is the sample representative of the population?
- Have any members of the sample been excluded from the study?
- If so, why?
- If not, why not?
- Is the sample taken from an administrative database or has it been established specifically for the purpose of the research paper?
    - *Administrative databases are potentially unreliable as they are established for reasons other than research and the completion of database fields may not be very precise, nor are they necessarily well-checked. See Grimes DA. (2010) '*Epidemiologic Research using Administrative Databases. Garbage in Garbage out' *American College of Obstetricians and Gynecologists* ***116****, pp. 1018-9 and subsequent published correspondence in 2011*

The Study

THE STUDY WILL COMMENCE WITH A SAMPLE FROM THE POPULATION, WILL FOLLOW THAT GROUP FOR A PERIOD OF TIME, WILL IDENTIFY MEMBERS OF THE GROUP THAT EXPERIENCE THE EVENT OF INTEREST (DEATH, PROBABLY), AND WILL ANALYSE THE GROUP'S EXPERIENCE

- How has the sample group been followed-up?
- How many of the group were lost to follow-up?
- How were those lost to follow-up treated in the analysis?
    - *Excluded ab initio or included up to the date lost?*
- Was there scope for participant bias?
    - *I.e. could participants opt in or out of the study? If so, how many did so? Were reasons given in the study?*
- How were the deaths identified?
- Could some deaths have been missed?
- Could some of the group have been classed as dead when not in fact?
- How were mortality rates calculated?
- If they were included, then how were life expectancies calculated?
- Are there statements in the paper that originate in other papers and, if so, are they correctly reported?
    - *You may find that referring to papers listed in the bibliography merits the time spent*

The Statistical Analysis

- Has the analysis used appropriate statistical tests?
    - *The three major methods for mortality are the Cox proportional hazards regression analysis; the Kaplan-Meier analysis; and the census method*
- If the statistical tests used are obscure or not used by other researchers, why have they been used?
- Have the data been analysed according to the original study protocol?
- Did the data contain any outliers?
- If so, how have they been treated?
- If the study associates cause with effect, is it reasonable to do so?
    - *The well-known "correlation does not imply causation" fallacy. See http://www.tylervigen.com/spurious-correlations for ridiculous examples. Also beware the Roy Meadow trap, where events were treated as independent when in fact they were correlated.*
- If the study arrives at a conclusion that no other study has found, why?
    - *Remember the MMR Vaccine controversy?*
- Has the population been treated as a Normal Distribution when it shouldn't be?
    - *It's much easier to do the stats assuming a Normal population than to have to use non-parametric tests*
- Have confidence intervals been calculated and do the authors' conclusions correctly reflect them?
- Have any conflicts of interest or a financial disclosure been notified?

- *Not just notified, but if it's the case then a statement of 'no interest' should also be made. Do you believe the statement?*

- Have the CONSORT Guidelines been followed?
  - *This is a recommended format for reporting randomised controlled trials in medical journals – see Altman D. (1996) '*Better reporting of randomised controlled trials: the CONSORT statement*' BMJ, **313,** pp 570-1. See also* http://www.consort-statement.org/ *with the checklist and flow diagram. Needs some interpretation for the types of studies we tend to be interested in, but nonetheless useful.*
- Or have GOBSAT guidelines been followed?
  - *Good old boys sat around a table*

The Reference Population

FOR COURT PURPOSES, WE ARE GENERALLY INTERESTED IN WHETHER THE CLAIMANT IS 'ATYPICAL' AND THEREFORE MERITS SPECIAL TREATMENT IN THE DETERMINATION OF THE MULTIPLIER. IF NOT, THEN THE OGDEN TABLES MAY BE USED UNALTERED. ACCORDINGLY, THE IMPORTANT QUESTION IS: "IS THE CLAIMANT EXPECTED TO EXPERIENCE DIFFERENT MORTALITY FROM THAT OF THE POPULATION FROM WHICH THE OGDEN TABLES ARE DERIVED?" THUS IN ASSESSING RESEARCH STUDIES WE WILL WANT TO KNOW THE EXTENT TO WHICH THE SUBJECTS DIFFER FROM THE GENERAL POPULATION

- Has the reference population been correctly chosen?
- Has it been stratified by age and sex to match the study population?
- Has it been matched by year of experience?
  - *If the study is over a long period, then early experience may have been 40 or 50 years ago. General population mortality was higher at that time (there have been improvements over time) so the subjects in the study will have experienced higher mortality than 'now' notwithstanding any effects of the studied condition. Has this been appropriately allowed for?*
- If the study has taken place outside the UK, can we adjust the reference population back to UK experience?

Final Questions

APPLY COMMON SENSE

- Are the results credible?
- Did you find that you had to research beyond the paper to find out information that should have been included in the text?
  - *Was something being hidden, or was the omission just sloppy?*
- Is there some influence in the study that makes it 'right' in context but completely inapplicable to our particular claim?
  - *The study might be of patients receiving a particular treatment that's simply not available or appropriate in the UK*