Ethics

- (noun) the moral system or set of principles particular to a certain person, community or group, etc.
- Chambers 21st Century Dictionary
- ‘Who might be hurt by this action?’

The players

- Researchers / authors
- Reviewers
- Journal editors

Who could get hurt?

- Other researchers / authors
  - …but perhaps more importantly
  - patients

Ethical issues in science publishing

- (Research misconduct)
- Publication misconduct
  - unethical behaviour by authors, reviewers or editors relating to the publication of research

Ethical themes

- Promoting research integrity
- Transparency
- Editorial standards & processes
- Ownership of ideas and expression
Promoting research integrity
- Require appropriate approvals
- Ask reviewers to comment on study ethics
- Report cases of suspected misconduct

Transparency
- Who did the work?
- Who funded the work?
- Anything else we ought to know?

Enhancing transparency
- List individuals' contributions (avoid gift and ghost authors)
- Include funding details (& role of funder in publication)
- Declare competing interests

Contributor list
- S&T were involved with study design and data interpretation, U performed statistical analysis, V&W collected data, T prepared the first draft, all authors reviewed the final version

Conflict of interest
- Exists when an author, reviewer or editor has financial or personal relationships that inappropriately influence (bias) his/her actions
- Also known as dual commitments, competing interests, competing loyalties

Competing interests may be:
- Financial
  e.g. share ownership / employment
- Personal
  e.g. partners, relations involved
    (should you review a paper by your ex-wife?)
- Other
  e.g. religious, political, ethnic
    (what do readers need to know?)
**Responsible publication**

- Has all or part of this study been published before?
- Have all the outcomes been reported?
- Are *post hoc* analyses identified?

**Publication bias**

<table>
<thead>
<tr>
<th>Over-published (redundancy)</th>
<th>Under-published (non-publication)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Statistically significant findings</td>
<td>Statistically non-significant findings</td>
</tr>
<tr>
<td>Results that favour sponsor's product</td>
<td>Negative results</td>
</tr>
</tbody>
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**Why does this matter?**

- Publication bias distorts the literature
- Evidence-based medicine relies on meta-analyses and systematic reviews
- Findings of meta-analyses can be skewed by duplicate data

**Tramèr et al. 1997**

Impact of covert duplicate publication on meta-analysis: a case study

Ondansetron: number needed to treat (NNT*)

- Skewed result with duplicate data (3 trials included twice) | 4.9
- True result (excluding duplicates) | 6.4

* A lower NNT indicates greater efficacy

**Melander et al. 2003**

Evidence b(i)ased medicine – selective reporting from studies sponsored by pharmaceutical industry: review of studies in new drug applications
Melander et al. 2003

The pooled analyses of published data generally gave larger differences in response rate than did the estimates from all submitted studies… The overestimates are due to selective reporting.

Conclusion

- Over- (redundant) publication or under- (selective / non) publication can give rise to misleading conclusions from meta-analyses.
- These could lead to inaccurate recommendations and thus harm patients.
  - This type of misconduct is not easy to detect by peer review.

Proposals to reduce publication bias

- Trial registration
  - Now a requirement for ICMJE journals (from July 05)!
- Trial identifiers (e.g. ISRCTN)

Trial registration:
ICMJE statement Sept 2004

- ICMJE member journals will require registration in a public trials registry.
- Trials must register at or before the onset of patient enrolment (i.e. prospectively).
- Policy applies to any trial starting enrolment after 1 July 2005 (other trials to be registered by 13 Sept 2005).
- www.clinicaltrials.gov = meets requirements.

Plagiarism

- "to copy (ideas, passages of text, etc.) from someone else’s work and use them as if they were one’s own" (Chambers Dictionary)
- "ranges from unreferenced use of others' published and unpublished ideas … to submission under 'new' authorship of a complete paper" (COPE guidelines)

Responsibilities of reviewers and editors

- Declare competing interests
- Ensure that reviewer is qualified (= a peer)
- Inform the editor who actually did the review (e.g. if passed onto a colleague)
- Treat material in confidence
- Take steps to avoid biased review
- Deliver courteous and timely reviews.
Reviewer misconduct

- Cistron submit DNA sequence for interleukin-1 (IL-1) to Nature
- Paper reviewed by Gillis (Immunex): reject
- Sequence published in *PNAS* (corrected)
- Cistron and Immunex file patents for IL-1
- Immunex patent contains 7 errors from original (rejected) Nature paper
- Cistron sues Immunex ($21mn settlement)

Rennie 1999

Editor misconduct

Sir Cyril Burt, Editor *Brit Jnl Stat Psychol*

- published 63 articles under his own name
- frequently altered authors’ texts without permission, often misrepresenting their intention and adding favourable references to his own work
- wrote a letter under an assumed name to the editor (himself) and a reply under another name in order to belittle the work of a rival

Rennie 1999

The things that will destroy us are:
- politics without principle
- pleasure without conscience
- wealth without work
- knowledge without character
- business without morality
- science without humanity
- and worship without sacrifice

Mahatma Gandhi