Dealing with publication & research integrity

Author: Harvey Marcovitch; presented to a joint working group of the Australian Research Council, National Health & Medical Research Council and Australian Vice-Chancellors’ Committee, August 2005
UK experience

• Scientific fraud highlighted by:
  – Whistleblowers
  – Medical journal editors
  – Pharmaceutical industry
Obstructions

- Investigation difficult & costly
- Individual & institutional denial
- Buck-passing
- Persecution of whistleblowers
- Employers’ conflict of interest
- Funders, learned societies & regulators limited locus
- Increasing internationality
Hopeful signs

• In the UK, governance policies can hold registered medical practitioners to account
• Research misconduct can represent ‘impaired fitness to practice’ under General Medical Council rules
• 18 case heard in last 8 years
Solutions: the Danish model

- Committees on scientific dishonesty have a legal basis
- Open access for complainants
- Chaired by High Court judge
- Published process
- Ad hoc panel may investigate
- Statutory sanctions

http://www.forsk.dk
Solutions: the Danish experience

• Legal standing (Danish Act 405 of 28.5.03)
  – ‘to ensure the scientific integrity of Danish research’

• Legal definition (Exec Order 933 of 15.12.98)
  – ‘…the existence of falsification or distortion of a scientific message or gross misrepresentation about a person’s involvement in the research’
But it isn’t plain sailing

• Lomborg ‘The Skeptical Environmentalist’
• Criticised as fraudulent in Scientific American
• Found fraudulent by DCSD
• Appeal upheld by Minister for Science, Technology & Innovation
• ‘Relied on published critique rather than conducting an independent analysis’
Solutions: Sweden

- Swedish MRC working group chaired by a judge
- Investigates & proposes sanctions
  - YET
- 50% of Swedish journal editors did not have mechanisms in place
Solutions: Finland

- National Research Ethics Committee ‘to promote discussion, disseminate information & take initiatives’
- University rector / research head must investigate within 60 days & may apply sanctions
- Appeal procedure to National Board on Research Ethics
  http://pro.tsv.fi/tenk/htkoengl.pdf
Solutions: Germany

• Joint Committee of German Science Research Council (DFG)
• Investigates & sanctions (e.g. reprimand, banned from DFG funding, banned from peer review)

http://www.dfg.de/cgi-bin/htsearch
Current situation in UK

- COPE advises suspicious editors
- Investigation passed to institutions
- Pharmaceutical industry (ABPI) investigates drug trial fraud
- GMC defines research misconduct as grounds for finding unfitness to practice
UK – frustrations

• Institutions often drag their feet
• Investigations often inadequate
• Retirement or removal can halt process
• No legal authority
• Anxiety
UK Panel for Research Integrity

• Led by Universities UK
• Supported by government
• Stakeholders include GMC, MRC, RCP, ABPI, Health Care Commission, Medicines Regulatory Agency
UKPRI – Key Roles

• Producing a Code of Practice
• Advising employers on implementation
• Appointment of expert panels
• Training University & NHS staff
• Holding a database
• Acting as whistleblowers’ clearing house
UKPRI – potential problems

- Voluntary, not mandatory Code
- Proposed panel = ‘The Great & the Good’
- Need for an appeals process
- Training, validation & CPD of panellists
- Conflicts of interest
- Non-funded or independent researchers
- Legal hurdles: Data Protection Act
  Human Rights Act
Lack of consent

- Invasive investigation of abdominal pain and constipation
- Author claims normal clinic protocol applied
- Unorthodox surgical procedure
- Institution claims normal practice
Inappropriate authorship
Inappropriate authorship

- Must have made ‘substantial contribution to conception and design of study or acquisition and / or analysis and interpretation of data’
- Must draft paper or revise critically for intellectual content
- Must give final approval to publication
Inappropriate authorship

• One or more co-authors should take public responsibility for the data
• All qualifying authors must be included
Inappropriate authorship

- Author 1 removes author 2’s name from revision
- Editor accepts author 1’s explanation
- University condemns author 1
- Author 2 demands retraction
- Lawyers threaten journal publisher
- Both authors seeking patent rights on the method described in the disputed paper
Plagiarism
Plagiarism

• ‘To copy ideas and passages of text from someone else’s work and use them as if they were one’s own’

• Unreferenced use of the ideas of others submitted as a ‘new’ paper by a different author
Plagiarism

- Epidemiological study of 30,000 patients
- Similar study published elsewhere
- Latter authors would not have resources
- Many authors geographically distant
- Medline search reveals a pattern

- Regulatory body unhelpful
Avoiding plagiarism

• Can it be accidental?
• Always reference the work of others
• Put the words of others in quotation marks
• Seek permission to copy tables, figures etc.
Redundant publication
Redundant publication

- Duplication
- ‘Salami slicing’

NOT:
- Previous presentation at a meeting
- Abstract pre-publication
- Agreed prior electronic publication
- Translation
- Referenced republished work
Duplicate publication

- Often revealed by reviewer or reader
- Often detected on electronic searching
- May be unknown to 1 or more quoted authors
- Second publication must be withdrawn
Why does duplication matter?

- It is dishonest
- It breaches copyright so is intellectual theft
- It distorts systematic reviews and meta-analyses
Tramèr et al. 1997

- Impact of covert duplicate publication on meta-analysis: a case study
  - Ondansetron: number needed to treat (NNT*)

<table>
<thead>
<tr>
<th>Type of Trials</th>
<th>NNT</th>
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<tbody>
<tr>
<td>Unduplicated trials (16)</td>
<td>9.5</td>
</tr>
<tr>
<td>Duplicated trials (3)</td>
<td>3.9</td>
</tr>
<tr>
<td>Skewed result with duplicate data (i.e. 3 trials included twice)</td>
<td>4.9</td>
</tr>
<tr>
<td>True result</td>
<td>6.4</td>
</tr>
</tbody>
</table>

*A lower NNT indicates greater efficacy
‘Salami slicing’

- Attempting to maximise publications by re-using data
- Acceptable if difference message to different readership
- Unacceptable if degree of overlap is great
Conflict of Interest
Undeclared conflict of interest

- Usually financial
- May be other industry links
- Conflicts affect conclusions
- Rates of disclosure are low
- Many journals do not have a policy
- Effect on readers unclear
Do authors declare conflicts?

• 3642 articles in the five leading general medical journals (*Ann Int Med, BMJ, Lancet, JAMA, New Eng J Med*)

• Only 52 (1.4%) declared authors' conflicts of interest

Hussain and Smith. Declaring financial competing interests: survey of five general medical journals. BMJ 2001; 323: 263-4
Are competing interests common?

- A quarter of US researchers have received pharmaceutical funding.
- Half have received ‘research related gifts’.
- Analysis of 789 articles from major medical journals: 1 in 3 lead authors had financial interests in their research.

GMC rules on research

• Benefits outweigh risks for therapeutic
• Very low risk in non-therapeutic
• Ethical approval essential
• Consent fully informed
• Confidentiality respected
• Projects must be finished (unless risky)
• Results recorded accurately
Cases determined 2000-2005

<table>
<thead>
<tr>
<th>Offence</th>
<th>Count</th>
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<tbody>
<tr>
<td>Breaches of protocol etc</td>
<td>11</td>
</tr>
<tr>
<td>Inaccurate or false reporting</td>
<td>3</td>
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<tr>
<td>Falsifying research</td>
<td>3</td>
</tr>
<tr>
<td>Falsifying ethical approval</td>
<td>1</td>
</tr>
<tr>
<td>Falsifying co-authors’ signatures</td>
<td>2</td>
</tr>
<tr>
<td>Failing to report misconduct</td>
<td>1</td>
</tr>
<tr>
<td>Diverting research funding</td>
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Who are the whistleblowers?

<table>
<thead>
<tr>
<th>Role</th>
<th>Count</th>
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</thead>
<tbody>
<tr>
<td>Pharmaceutical industry</td>
<td>7</td>
</tr>
<tr>
<td>An editor</td>
<td>2</td>
</tr>
<tr>
<td>A ‘professional whistleblower’</td>
<td>2</td>
</tr>
<tr>
<td>Patient’s relative</td>
<td>2</td>
</tr>
<tr>
<td>Ethics committee</td>
<td>1</td>
</tr>
<tr>
<td>Colleague</td>
<td>2</td>
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</table>

NB Some assumptions have been made where information is unclear.
Regulation in future

- UK panel for research integrity in health & biomedical sciences
- ‘To promote models of good practice in research governance, management and conduct’
- Members nominated by vice-chancellors, NHS CEOs, Royal Colleges etc.
- Supported by DES, DH, MRC, Wellcome
Useful sources of advice

- COPE (www.publicationethics.org.uk)
- ICMJE ‘Vancouver Group’ (www.icmje.org)
- ORI (www.ori.dhhs.gov)
- WAME (www.wame.org)
- CSE (www.CouncilScienceEditors.org)

And the journals’ advice to contributors