The Sudbø affair: Lessons to be learnt by editors

Author: Harvey Marcovitch; presented to a conference organised by the Lancet and the Norwegian Library of Science, December 2006
Can editors police scientific fraud?

- *Am J Cardiol* (Darsee)
- *NEJM* (Darsee)
- *Am Heart J* (Slutsky)
- *BMJ* (RB Singh)
- *Nature* (Woo Suk Hwang)
- *Science* (Schön)
- *Lancet* (Sudbø)
- Most others (Many – undiscovered)
How is fraud detected?

- Colleagues (usually junior)
- Other whistleblowers
- Reviewers
- Readers
- Regulatory bodies
- Editors
- Statisticians
Why editors detect few cases

• Normally trust authors
• Paper not within specialty knowledge
• Initial paper triage is cursory
• Lack of statistical expertise
• Effect of conflict of interest
• Hunger for high impact papers
What can editors watch for?

• Authors unlikely to have sufficient resources
• Data ‘too good to be true’
• Findings hard to believe
• Paper submitted by back door
• Author puts undue pressure on editor
• Reviewer reports concern
Outside help

- Reviewers are poor at detecting errors
  Schroter et al. BMJ 2004; 328: 673-8
- Statisticians are better
  Al-Marzouki et al. BMJ 2005; 331: 267-70
- ‘Googling’ may pick up plagiarism
  Weeks. BMJ 2006; 333: 706
Prevention

- Publish clear rules about authorship or contributorship, conflicts of interest, ethical approval, trial registration, prior publication, copyright etc.
- Ensure authors complete checklists re the above
- Persuade publishers to promote ethical guidelines for their journals
Action

• Editors’ responsibility is to ensure the issue is pursued, usually by the author’s institution (ICJME)
• Seek advice (journal ethics committee; journal legal adviser; COPE algorithms)
• Frequently remind institution if necessary
• Contact regulatory authority if appropriate
Action

- Be prepared to take up complaints about ‘old’ publications
- Remember that dishonest people are often dishonest more than once
- Publish declarations of concern, corrections, retractions as appropriate
Action

• In preparing this talk I found non-retracted Medline references to:
  – Summerlin
  – Darsee
  – Chandra
  – Singh
  – Pearce
  AND
  – Sudbø
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 Commision, 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
Committee on Publication Ethics

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
Committee on Publication Ethics

Tramèr et al. 1997

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

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<tr>
<td>Unduplicated trials (16)</td>
<td>9.5</td>
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<td>Duplicated trials (3)</td>
<td>3.9</td>
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<tr>
<td>Skewed result with duplicate data</td>
<td>4.9</td>
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<td>(i.e. 3 trials included twice)</td>
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<td>True result</td>
<td>6.4</td>
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*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?

- 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

- Breaches of protocol etc 11
- Inaccurate or false reporting 3
- Falsifying research 3
- Falsifying ethical approval 1
- Falsifying co-authors’ signatures 2
- Failing to report misconduct 1
- Diverting research funding 1
### Who are the whistleblowers?

- Pharmaceutical industry: 7
- An editor: 2
- A ‘professional whistleblower’: 2
- Patient’s relative: 2
- Ethics committee: 1
- Colleague: 2

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