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**
- **<u>All</u> 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**
  - **<u>Agreed</u> 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*)**

Unduplicated trials (16)	**9.5**
Duplicated trials (3)	**3.9**
Skewed result with duplicate data (i.e. 3 trials included twice)	**4.9**
True result	**6.4**

*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**

Bekelman et al. Scope and impact of financial conflicts of interest in biomedical research. A systematic review. JAMA 2003; 289: 454-65.

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