



**Committee on
Publication Ethics**



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

www.publicationethics.org.uk

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 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*)**

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

