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Director, Council of Science Editors

Chair, GMC Fitness to Practice Panels

COPE COMMITTEE ON PUBLICATION ETHICS

Journal discipline	Number
Medicine	689
Life Sciences	420
Arts & Humanities	385
Economics, finance, industry, business	288
Psychology, Social & behavioural science	284
Engineering & Technical	178
Computer Science	151
Chemistry	150
Environmental Science	111
Education	107
Physics	105
Earth Sciences & Geography	95
Dentistry, Veterinary Science, Nursing	83
Math, Statistics	82
Law	25
Astronomy, Astrophysics, Space Science	19

COPE COMMITTEE ON PUBLICATION ETHICS

Cases discussed 1998-2008

• Duplication/redundancy	92
• No ethics approval	42
• Authorship issues	42
• Falsification/fabrication	36
• Plagiarism	36
• No or inadequate consent	33
• Unethical research or clinical malpractice	28
• Undeclared conflict of interest	22
• Reviewer misconduct	10
• Editor misconduct	7
• Other	49

What do the following have in common?

- DNA content as a prognostic marker in patients with oral leukoplakia. NEJM 2001;344:1270-8
- Influence of resection of aneuploidy on mortality in oral leukoplakia. NEJM 2004;350:1405-1413
- NSAIDs and risk of oral cancer: a nested case-control study. Lancet 2005;333:1359-66

- Jon Sudbø

- Dentist 1985
- Physician 1994
- PhD thesis, University of Oslo 1993-2001
- Private practice
- 38 publications in peer reviewed journals
- Successful bid for $10m grant 2005
- Admitted to fraud 2006
- Removed from practice/research 2007
- Reinstated in dental practice 2009

Sudbø: the investigation

- 69 of his 150 cases should have been excluded
- Duplicated data from individual patients
- Published ages not backed up by raw data
- No REC application or approval
- No patient consent
- Lancet data ‘invented’

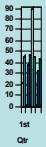
Rogues Gallery

Hendrik Schön, USA
(1 paper every 8 days in 2001)

Hwang Woo-Suk,
South Korea, 2005

Eric T Poehlman,
Canada, 2005
(& prison 2007)

Hans Werner Gottinger
?100 plagiarised papers



Publication Ethics

- Honesty and integrity are essential if the public is to be protected and science validated
- Researchers, editors, publishers and sponsors are all responsible

Why does it happen when journals exist to enhance the academic database?

- and… enhance seniority and income
- and… increase publishers' profits
- and (in biomedicine) … enhance pharmaceutical company profits

How frequent is research misconduct?

- **1.97% of scientists admitted fabrication/falsification**
- **33.7% admitted other 'questionable research practices (qrp)'**
- **14% report fabrication/falsification by colleagues**
- **72% report observing 'qrp' by colleagues**

How many scientists fabricate & falsify research? A systematic review & meta-analysis of survey data. Fanelli D PLoS ONE 2009;4:e5738

How honest are researchers?

- 107/194 NHS consultants had observed research misconduct
- 11 admitted personal misconduct
- 35 said they might do it in future
- Geggie J Med Ethics 2002;28:207

Duplicates and plagiarisers

- 62,213 Medline citations

- 0.04% with no shared authors highly similar = plagiarism

- 1.35% with shared authors highly similar = duplication

- So there may be 3500 plagiarised and 117,500 duplicate papers

- **Déjà vu—A study of duplicate citations in Medline**
  Mounir Errami et al *Bioinformatics 2008;24:243-9*

•Ojuawo A. Milla PJ. Lindley KJ. **Non infective colitis in infancy: evidence in favour of minor immunodeficiency in its pathogenesis.**
East African Medical Journal. 74(4):233-6, 1997
Held at BMA Library, No longer received
UI: 9299824

•Ojuawo A. St Louis D. Lindley KJ. Milla PJ. **Non-infective colitis in infancy: evidence in favour of minor immunodeficiency in its pathogenesis.**
Archives of Disease in Childhood. 76(4):345-8, 1997.
Held at BMA Library, Currently received
UI: 9166029

- Dr S Dutta-Roy erased by the GMC in November 2007
- Plagiarised the work of colleagues
- Invented a co-author (Dr Kupp), whom he blamed for the plagiarism

FFP is ‘serious’

But ‘questionable research practices may have greater impact on patients or the public health

Duplicate publication

- Impact of covert duplicate publication on meta-analysis

  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

Tramer et al BMJ 1997;315:635-40

Accentuating the positive

- A systematic review shows company sponsored research less likely to be published
- Company sponsored studies more likely to have outcomes favouring the sponsor than studies with other sponsors
- None of 13 studies that analysed methods reported studies funded by industry were of poorer quality
- Where are the negative studies?

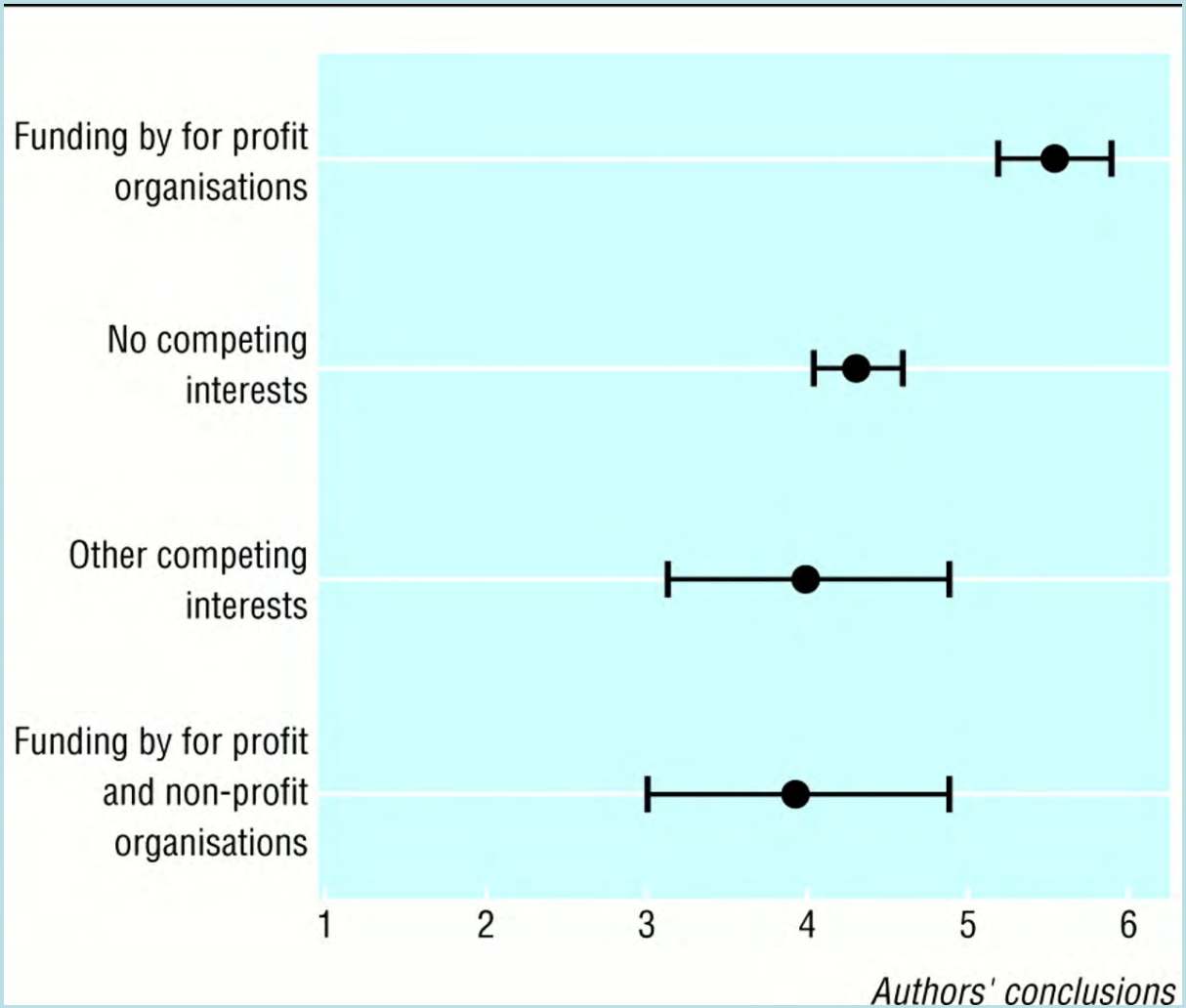
Joel Lexchin, Lisa A Bero, Benjamin Djulbegovic, and Otavio Clark
Pharmaceutical industry sponsorship and research outcome and quality: a systematic review ***BMJ* 2003; 326: 1167 - 1170**.

Not just researchers

- Positive trials are more likely to be submitted. *(Rogue authors and sponsors)*
- Positive trials are more likely to be published. *(Rogue editors)*
- Positive trials are more likely to be published quickly. *(All three)*

Stern and Simes ***BMJ*** *1997;*315:640-645 ***JAMA*** 2002;287:2825-2828

BMJ systematic reviews: ‘Positive spin’ v funding and disclosure



Kjaergard, L. L et al. BMJ 2002;325:249

BMJ

Competing interests

- Analysis of 789 articles from major medical journals - 1 in 3 lead authors had financial interests in their research—patents, shares, or payments for being on advisory boards or as a director
- A quarter of US researchers have received pharmaceutical funding
- Half have received “research related gifts”

- **Bekelman JE, Li Y, Gross CP. Scope and impact of financial conflicts of interest in biomedical research. A systematic review. JAMA 2003; 289: 454-65.**

Competing Interests (2)

- A review of 1534 cancer studies in 8 leading journals in 2006
- 29% declared COI; 17% declared industry COI
- Industry funded studies more likely to focus on treatment (62% v 36%)
- Randomised trials more likely to report positive survival outcome if COI present (29% v 14%)

Jagsi et al Cancer 2009;115:2783-2791

Competing interests

- Non-financial conflicts may be more common
  - Political
  - Personal likes or dislikes
  - Institutional jealousy or favouritism
  - Religious

How is fraud detected?

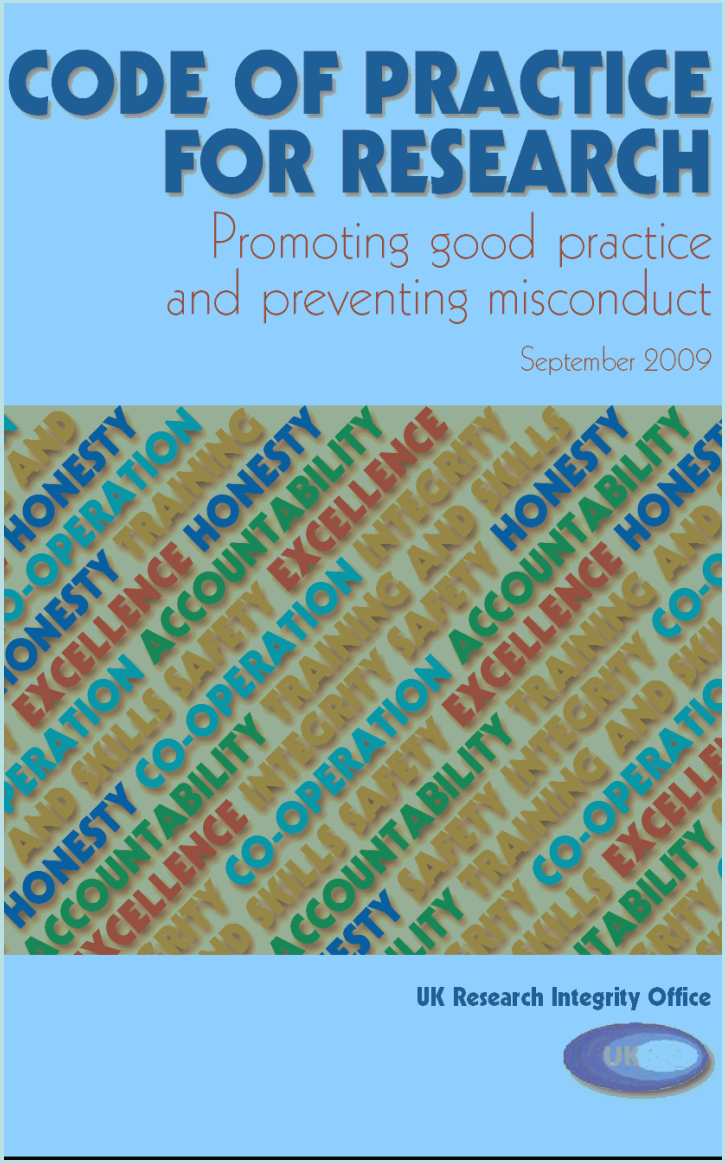
- Colleagues (usually junior)
- Other whistleblowers
- Reviewers
- Readers
- Regulatory bodies
- Editors (plagiarism software/photoshop)
- Statisticians
- Sponsors
- Publishers

Why do researchers not detect fraud?

- Junior researchers fearful for their job
- Overwhelmed by charisma
- Bullying and threats
- Not trusting their own suspicion
- Lack of support from institution
- Turning a blind eye

Academic responses

- Not all institutions have robust systems
- UK universities and research councils have rejected a mandatory supervisory body to investigate and regulate research practices
- UKRIO procedures published 2009 are advisory only


CODE OF PRACTICE
FOR RESEARCH
Promoting good practice
and preventing misconduct
September 2009
UK Research Integrity Office

Academic responses

- A Croatian government report finds a senior researcher guilty of serial plagiarism and duplication: the Univ. of Zagreb tells it to get lost.
- Paper retracted for plagiarism by Stem Cell Dev J: University of Newcastle says: ‘submitted in error’ and blames junior author.
- A senior academic is currently under GMC investigation for alleged ‘cover-up’ of research misconduct

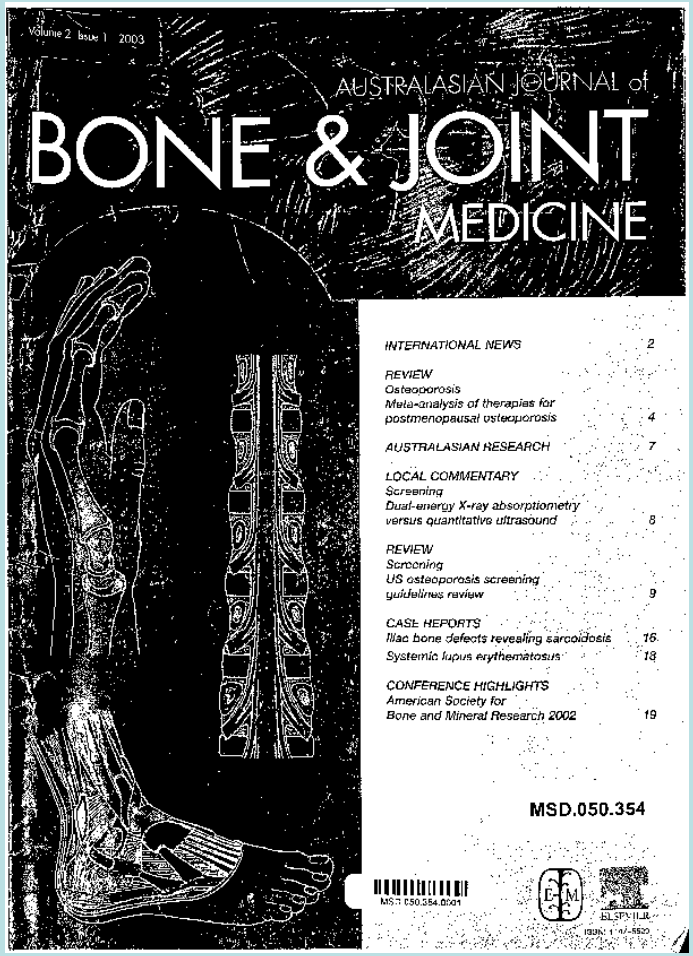
Can we trust sponsors to prevent misconduct?

Sponsors and misconduct

- The overwhelming majority of allegations of research misconduct reported to the UK General Medical Council has come from the pharmaceutical industry.

- But…..

Can we trust publishers?



- This journal was published by Elsevier, paid for by Merck and contained only reprinted or summarised papers favourable to Merck products. No disclosure made of sponsorship

Data manipulation

- **Reporting Mortality Findings in Trials of Rofecoxib for Alzheimer Disease or Cognitive Impairment A Case Study Based on Documents From Rofecoxib Litigation**
- **Bruce M. Psaty, MD, PhD; Richard A. Kronmal, PhD**

- *JAMA.* 2008;299(15):1813-1817.

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
- Cannot afford image screening or plagiarism detection software

What do 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

What do (some) editors watch for?

- Blurred images
- Cloned region within an image
- ‘Blowout’ (no pixel structure)
- JPEG compression
- Use of touch-up tools for cloning & healing

Seeing is believing J Cell Biol 2006;172:9

Plagiarism detection

crosscheck

4 | International Herald Tribune
Thursday, November 30, 2006

Panel urges tighter rules for science publications

Stem cell scandal prompted review

By Nicholas Wade

Fraudulent stem cell reports that shook the scientific world could have been prevented by extra review procedures, according to a panel appointed by Science, the journal that published the claims.

Donald Kennedy, the editor of Science, said the journal would accept the panel's major findings.

A South Korean researcher, Hwang Woo Suk, reported in Science in 2004 that he had generated embryonic stem cells from an adult human cell, the necessary first step in proposed schemes for growing replacement tissues from a patient's own cells. In a second report, in 2005, he claimed that he could perform this step routinely and efficiently, using very few human eggs.

Both reports proved to be fabrications, and the journal formally retracted the papers last January.

The fraud came to light not through any of the formal checking procedures in the scientific process, but because a whistle-blower in Hwang's lab spoke to a South Korean television station.

Science has long taken the position that its reviewing procedures work well but cannot be expected to detect deliberate fraud; therefore, no change is necessary. But the spectacular nature of the fraud prompted deeper thought on the part of leading journals.

After reviewing the paper record of how the Hwang reports were handled, a panel headed by John Brauman, a chemist at Stanford University, recommended four changes in Science's procedures on Tuesday.

A risk-assessment method should be developed to flag high-visibility papers for further review, the panel said. Also, authors should specify their individual contributions to a paper, a reform aimed at Hwang's stratagem of allowing another researcher, Gerald Schatten of the University of Pittsburgh, to be the lead author of one of the reports even though he had done none of the experiments.

The panel advised online publication of more of the raw data on which a report is based. It also suggested that Science, Nature and other leading journals establish common standards to prevent authors bent on deceit from favoring journals with laxer standards.

What should editors do? (Science investigation)

- Demand trial registration
- Risk stratify papers
- Clarify contributions/responsibilities of authors
- Make primary data available to reviewers/readers
- Act in concert with other “high-profile journals”
- Use plagiarism & data manipulation technology

JAMA proposals

- Trial registration
- Strict authorship rules
- Consider impact of funding
- For-profit sponsors subservient to academics
- Independent stats analysis
- Sanctions on miscreants
- No sponsored medical education

…and publishers?

- A code of conduct is in press
- Some of the largest scientific and academic publishers have joined COPE

…..but

- Reprints can make millions
- Journals are produced claiming to be academic but are actually promotional

Trial registration failing?

- 176/323 trials published in major journals in 2008 not properly registered
- 46/147 properly registered trials had a different primary outcome on publicn.
- Of 23 evaluable, 19 had outcomes changed to reflect favourable results

JAMA 2009;302:977-84

Trial registration failing

- Of 677 trials registered and completed by 2005, only 311 traceable through Medline
- 60% reported their primary outcomes
- (FDA now require updating ClincalTrials.gov with outcomes within 2 years)

PLoS Med 2009;doi:10.1371/journal.pmed.1000144

Guidelines & Codes of Conduct

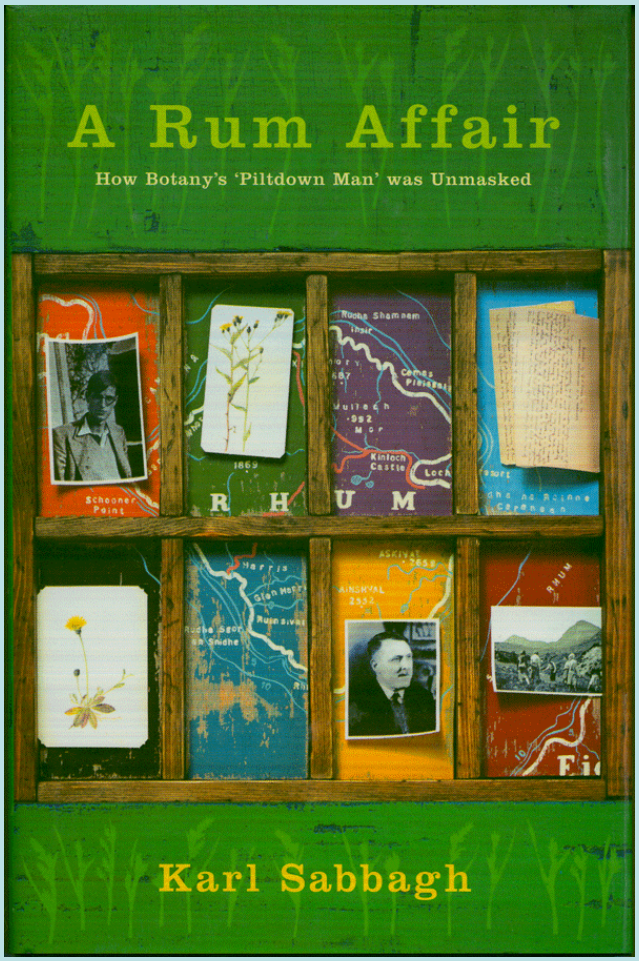
- World Association of Medical Editors www.wame.org
- International Committee of Medical Journal Editors www.icmje.org
- Committee on Publication Ethics www.publicationethics.org
- Council of Science Editors www.councilscienceeditors.org

Scientific Misconduct Blog

http://scientific-misconduct.blogspot.com

- About all manner of corporate pharmaceutical scientific misconduct and related curious incidents. If you're not outraged, you're not paying attention.

And it’s not just medicine



‘Remember that truth alone is the matter that you are in search after; and if you have been mistaken, let not vanity seduce you to persist in your mistake.’

Henry Baker, The Microscope Made Easy, 1742