



# Committee on Publication Ethics



## 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

[www.publicationethics.org.uk](http://www.publicationethics.org.uk)

# UK experience

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- **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

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- **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

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- **Institutions often drag their feet**
- **Investigations often inadequate**
- **Retirement or removal can halt process**
- **No legal authority**
- **Anxiety**



# UK Panel for Research Integrity

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- **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**



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# 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

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- 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**



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# 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.**



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# 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?

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- **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\*)**

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

\*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**



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# Conflict of Interest



# Undeclared conflict of interest

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- **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](http://www.publicationethics.org.uk))
- **ICMJE 'Vancouver Group'** ([www.icmje.org](http://www.icmje.org))
- **ORI** ([www.ori.dhhs.gov](http://www.ori.dhhs.gov))
- **WAME** ([www.wame.org](http://www.wame.org))
- **CSE** ([www.CouncilScienceEditors.org](http://www.CouncilScienceEditors.org))

And the journals' advice to contributors

