Medical research hit by 60 frauds

By Rachel Ellis, Health Correspondent

A CRACKDOWN on doctors and scientists who carry out fraudulent medical research was launched yesterday.

Experts fear a growing number of scientific “breakthroughs” are in fact hoaxes, based on flawed or made-up research.

Patients are not always aware they are taking part in a medical trial and official approval to show the study is

MORE THAN 60 cases of scientific fraud have been detected in the past two years — putting patients at risk and undermining public confidence in research, doctors reported yesterday.

The cases were found among research papers submitted to a dozen medical journals whose editors have joined a group committed to uncovering fraud. There are 200 medical journals published in Britain and the fraudulent papers detected are likely to be only a fraction of the total.

The editors of the British Medical Journal and The Lancet called for a national body to be established with powers to investigate fraud and impose sanctions against the perpetrators on the board.

RESEARCH reports by doctors often contain fabrication, falsification and plagiarism which goes largely undetected, it was claimed yesterday.

Editors of medical journals subsequently gave birth to a healthy baby.

He was struck off after a GMC disciplinary hearing found he had falsified medical records to substantiate
Authors and Publication Practices
Research and Publication Ethics

Research

Integrity

Publication
Publication ethics:
The interested parties

Author

Reviewer

Editor
Scandal: Authors that put patients at risk

Medical Research Ethics:

Frauds

Top doctors

Publications

Stealing data

Lie, steal and tiddling

Research doctors

Last seen in the medical community, treatment and care for patients is now under threat. The Royal College of Physicians called for a national ethical review of treatment and care for patients. The College said that the medical profession needed to be more accountable and transparent in its dealings with patients.

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Authorship

Authorship credit should be based only on substantial contributions to:

• Conception and design or analysis and interpretation of data; and to

• Drafting the article or revising it critically for important intellectual content; and on

• Final approval of the version to be published

Authorship

- Participation solely in the acquisition of funding or the collection of data does not justify authorship

- General supervision of the research group is also not sufficient for authorship
The Committee on Publication Ethics (COPE)

• Founded 1997
• Self help group for editors
• Lobby group

www.publicationethics.org
COPE Guidelines on Good Publication Practice

THE COPE REPORT 1999

What they aim to do

These guidelines are intended to be advisory rather than prescriptive, and to evolve over time. We hope that they will be disseminated widely, endorsed by editors, and refined by those who use them.

1 Study design and ethical approval

Definition

Good research should be well justified, well planned, appropriately designed, and ethically approved. To conduct research to a lower standard may constitute misconduct.

Action

(1) Laboratory and clinical research should be driven by protocol; pilot studies should have a written rationale.
(2) Research protocols should seek to answer specific questions, rather than just collect data.
BY RACHEL ELLIS  
HEALTH CORRESPONDENT

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Patients are not always aware they are taking part in a medical trial and official approval to show the study is...
Publication misconduct

• Authors

Disputes
Dual submission
Conflicts of interest
‘Salami slicing’
Redundant publication
Publication misconduct

Other kinds of authors!

• ‘Gift’ authors

• ‘Ghost’ (professional) authors
Publication ethics

Authorship.......... 

or ‘contributorship’?
Can publication misconduct be prevented?

- Approval by all authors
- Submit to one journal at a time
- Disclose conflicts of interest
- Disclose previous publications
- Effective ‘guarantor’
Publication Ethics:

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BY JENN Health Correspondent

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Tippling the industry

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Research doctors and data

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Publication ethics

To whom are editors responsible?

- Readers
- Authors
- Reviewers
- Publisher / owner
- Other editor’s?
- The ‘scientific community’
- The wider community
‘Do we need an International Medical Scientific Press Council?’

Richard Smith, BMJ 2003
Editors’ code of conduct

General

• Custodians of the biomedical literature
• Meet the needs of readers and authors
• Ensure quality and improve the journal
• Champion freedom of expression
• Maintain integrity of the scientific record
• Be willing to correct errors
Editors’ code of conduct

Quality and correcting the record

• Describe peer review process
• Appeal mechanism
• Retract erroneous or fraudulent papers
• Maintain integrity of the scientific record
• Publish criticisms
Editors’ code of conduct

Other issues

• Standing by decisions made
• Ethics committee approval
• Consent for publication
• Confidentiality of submitted material
Editors’ code of conduct

Other requirements

• Guidance to authors
• Pursue misconduct
• Relationship to publishers and advertisers
• Conflict of interest
• Provide mechanisms for complaints
Publication ethics

Grey areas for editors?

• Responsibilities to other editors?
• Criteria for selection - ’Publish and be damned’
• Impact factors: Is it unethical to manipulate?
• Ethics and external relations - media, industry
Publish, and be damned……

‘Nature and Science are locked in such fierce competition for prestige and publicity that they may be cutting corners to get ‘hot’ papers…….’ Wall Street Journal
‘In this case the editors are definitely culpable…….. They chose reviewers they knew would be positive…..’

‘Given the exciting nature of the claims made by the papers we were certainly hoping that the outcome would be positive.’
MMR: more scrutiny, please

The public feels the media were too quick to report maverick claims

‘Not comprehensively challenged’

Dr Andrew Wakefield
Impact factors are too highly valued

“The more we couple the allocation of resources to publication in ‘top’ journals, the more we are effectively handing over direction of research to a small group of professional editors.”

Davies, Nature 2003
A CRACKDOWN on doctors and scientists who carry out fraudulent medical research was launched yesterday.

Researchers have already been arrested in a growing number of cases at British hospitals.ma in the UK and abroad. Researchers admitted there were lapses of trust and ethics in research, but it could not be allowed to be compromised by failures in governance and accountability.

Patients are not always aware they are taking part in a medical trial that may be damaging, and not being warned.

In the past, there have been cases where doctors have been accused of falsifying data. More than 50 cases have been detected in the past two years, and 10 doctors have been arrested.

On average, research fraud amounts to at least £12.6m a year.
Journals urged not to ‘hype’ study findings

- 127 press releases
- 9 prominent medical journals
- Only 23% releases noted limitations

JAMA 2002
Do editors manipulate impact factors? Is it unethical?
COPE case: An editor’s complaint

• An associate editor of a specialist journal complained to COPE because he/she had been sacked following a challenge to a Journal policy.
• The editor alleged that the journal’s editor-in-chief promoted a policy aimed at enhancing the journal’s impact factor. It was deemed unethical.
• Before papers were accepted for publication, authors were encouraged/coerced to cite wherever possible other papers in the journal.
• The associate editor, and it is said other journal staff, objected to this practice and regarded it as unethical.
‘I recently received a letter from one editor suggesting that, where possible, references to that journal should be included in manuscripts to that journal.’

Neuberger and Counsell, 2002
Self-citations in six anaesthesia journals and their significance in determining the impact factor

Fassoulaki et al, 2000
3. Reviewers

Publication Ethics: 

Medical 

Top doctor 

More than 50 cases of scientific fraud have been detected in the past two years—putting patients at risk and undermining public confidence in research, doctors reported.

By David Fletcher, Health Correspondent

The Lancet called for a national body to be established with powers to investigate fraud and impose sanctions against the perpetrators at the heart of experimental and clinical treatment out of control.

The colleagues of the造假 resulted in a significant number of patients at risk by experimental and untried treatments. Groundless manipulation and health scares damaging, it was warned. In a bid to stamp out it

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Publication misconduct

- Reviewers
  - Conflicts of interest
  - Plagiarism
  - Breach of confidentiality
Interested parties

Author <-> Reviewer

Editor
Revealing reviewers!

Rationale for open peer-review

- ‘They will do a better job’
- Ethically attractive
- Maximises reviewer accountability
- Protects against reviewer misconduct

Van Rooyen et al, Godlee et al, JAMA 1998
Publication Ethics:

Top doctor
tiddling
Research doctors

4. Publisher

Owner
Interested parties

Author

Reviewer

Editor

Publisher

Owner
‘59% of college students did not consider that oro-genital contact constituted “having sex”………..’

‘No matter who owns a primary source, peer-reviewed medical or scientific journal, the editor must have absolute freedom to publish what he or she chooses………..’
The sacking of JAMA

‘through his recent actions, [Lundberg] has threatened the historic tradition and integrity of JAMA by inappropriately and inexcusably interjecting [it] into a major political debate that has nothing to do with science or medicine’

E Ratcliffe Anderson, Jr 1999
Editorial freedom?

...or a licence to print?

Medical frauds hit by 60 scandals

Editorial freedom?

Top doctor accused of fiddling

Medical standards lie, steal and use their data

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Editorial freedom

...or a licence to print?
former editor

The New England Journal of Medicine

Editor of New England Journal of Medicine departs

Scott Gottlieb New York

The editor in chief of the New England Journal of Medicine has left office in a dispute over plans by a medical society to use the journal's name to sell new publications that would be only nominally controlled by the journal's top editor.

Dr Jerome Kassirer, the journal's editor in chief, has resigned after years of heated disagreements with the Massachusetts Medical Society, which publishes the journal.

The society's chief executive, Dr George Lundberg, said the society's efforts to use the journal's name to sell its newer publications, including two consumer newsletters, as well as several publications written for doctors, had stoked the medical society's ire by resisting earlier attempts to use the journal's name to sell its newer publications, including two consumer newsletters, as well as several publications written for doctors.

Dr Kassirer will take a seven month sab-

t, 'Honest differences of opinion…'

Demits office

Conflicts

Dr Jerome Kassirer, former editor of the New England Journal of Medicine

Changes in the publishing business mean there's nothing to stop the growth, he said. "But the people move quickly on decisions that used to be more deliberative and take more time."
The *Journal* and its owner - resolving the crisis

‘Behind this oblique explanation, lay a long-standing struggle between Kassirer and the society’s leadership over the latter’s ambitious plans to expand its role as a medical publisher, both in print and online, by launching and acquiring new publications, repackaging the *Journal’s* content for consumers….’

Marcia Angell, NEJM, 1999
Publication Ethics: Top doctor tiddling Medical Research doctors

5. Biomedical industry
Interested parties

Pharma
Author
Reviewer
Editor
Publisher
Owner
Marketing for the pharmaceutical industry?

• ‘Journals have devolved into information laundering operations for the pharmaceutical industry’
  Richard Horton, Editor the *Lancet*, 2004

• We will not become…’part of the cycle of dependency…..between journals and the pharmaceutical industry’
  *PLoS Medicine* 2004
Influence of funding source on outcome of trials

- Systematic review of 30 studies
- 13 /16 funded by the industry were favourable
- Industry studies 4 times likely to be positive
- 5 examined economics – all positive

*Lexchin et al, BMJ 2003; 326: 1167*
How to influence the outcome

- Select an inferior treatment
- Trial against a low dose of competitor
- Trial against a high ‘toxic’ dose
- Do trial that is too small to show a difference
- Select from multiple end-points
- Select ‘best centres’ from multi-centre trials
- Selective from sub-group analyses
- Present most impressive results –relative rather then absolute risk

A case under investigation

- New drug A compared with established drug B
- 2 almost identical trials – 3 closely related papers
- Inadequate cross-referencing
- ? Redundant publication
- Problem – only one trial produced significant results
- Selective combination of results
- Negative functional data on FDA website
- ‘Authors’ used *ad libitum* – some unaware of actions
Interested parties

Author

Reviewer

Editor

Publisher

Owner

Pharma
Prevention of misconduct

- Research training
- Research ethics
- Publication ethics
- Supervision
- Audit?