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Ethical Issues in Medical Publishing

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Elsevier Pharma
Publishing Workshop
3rd February 2009

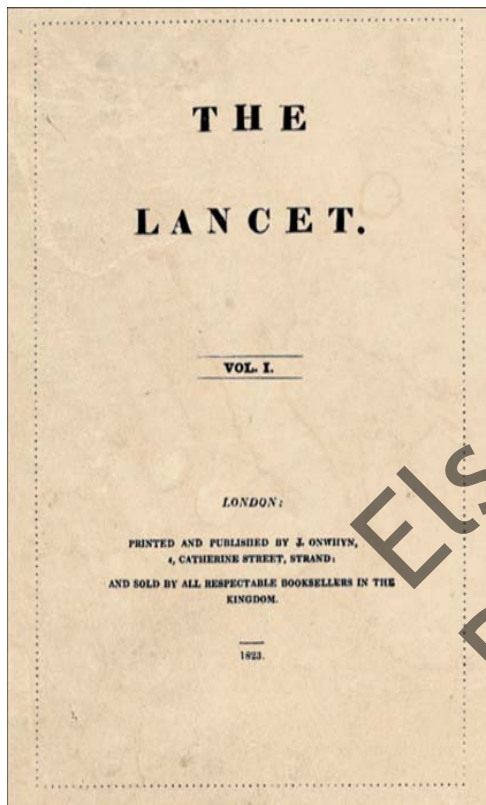
Topics

- About The Lancet
- Unethical behaviour of Lancet's authors
- "Ethical" requirements at The Lancet
- Web-resources

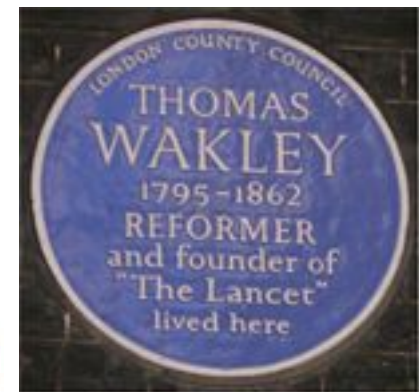
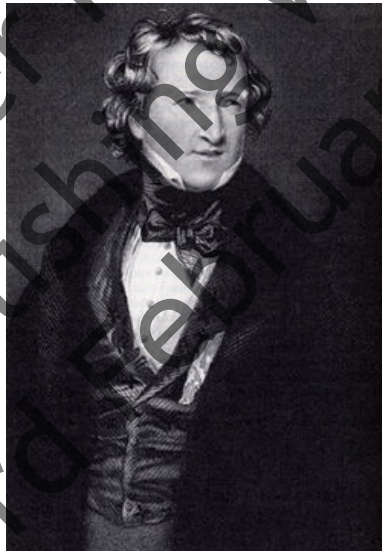
The Lancet

The Beginning

THE LANCET



1823



Thomas Wakley (1795-1862)

- Surgeon
- Parliament Member

The Lancet

THE LANCET

The Elsevier Connection

- Acquisition

- 1991

- Unique status

- A separate department within Elsevier
- Editorial team
 - Internal (all Elsevier employees)
 - Full editorial independence



THE LANCET

The Lancet

THE LANCET

Today

- World's leading weekly independent general medical journal
 - IF is 28.6
- Focuses on all aspects of human health
 - Clinical
 - Public Health
 - Health Policy
 - Human Rights
- Topic coverage is international & global
- 10,000 unsolicited submissions a year
- Editorial offices in London and New York.

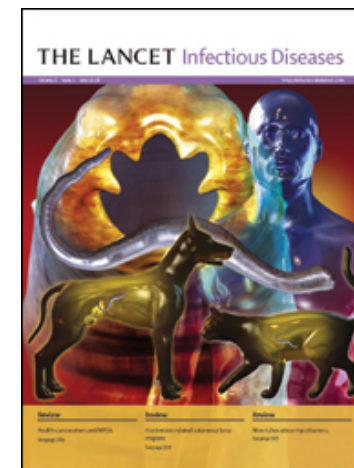


The Lancet

THE LANCET

Today

- Three specialty journals
 - Monthly publications
 - Editorial staff in London
- Local language editions



The Lancet

Media Coverage and Contacts



www.thestar.com

boston.com

The Boston Globe

The New York Times

ON THE WEB



THE WALL STREET JOURNAL.
ONLINE

The Washington Post

CHICAGO SUN-TIMES

suntimes.com

San Francisco Chronicle

NORTHERN CALIFORNIA'S LARGEST NEWSPAPER

The Miami Herald

Herald.com

EL PAIS.es

Le Monde.fr

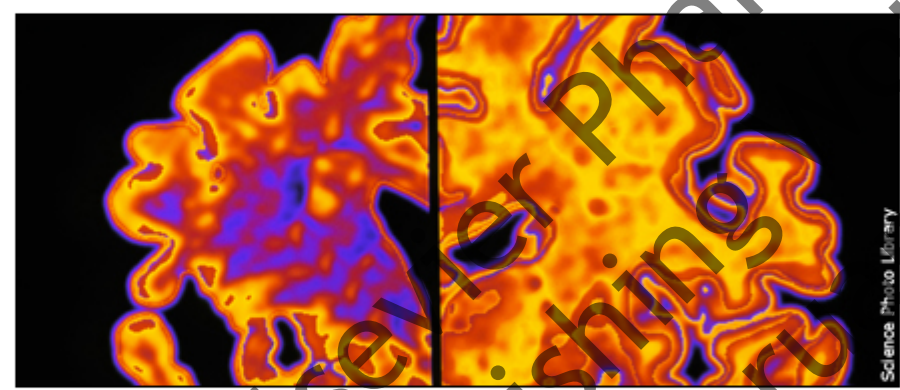
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thelancet.com today - Wednesday July 23 2008



Dimebon for Alzheimer's disease: assessment of cognition, behaviour, and global function in patients with mild-to-moderate Alzheimer's disease. A research article highlights how Dimebon improves the clinical course of Alzheimer's disease, including improvements after 12 months use.

US Election Blog: this week, the two Presidential candidates communicated health-care messages to Hispanic and African American voters.

Everolimus treatment for kidney cancer: patients with metastatic renal cell carcinoma treated with everolimus were compared with placebo for rates of progression-free survival.

Antiretroviral therapy for HIV-infected children in sub-Saharan

The Lancet Journals



THE LANCET

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Content

"Advances or illuminates medical science or practice, or that educates or entertains our readers..."

- **Aims to:**
 - Change clinical practice
 - Create debate
 - Educate



Content

Change Practice

Articles

- Routine submissions
- **Fast track submissions**
- Calls for papers

Educate

Commissioning:

- Seminars
- Reviews

Selecting:

- Case reports
- Clinical pictures

Debate

Writing:

- Editorials

Commissioning:

- Comments
- World Report
- Perspectives

Selecting:

- Viewpoints/Essays

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The Lancet

Clinical Trials

- Phases I, II and III
 - Novel substance for a novel indication
 - Strong or unexpected beneficial or adverse response
 - Novel mechanism of action
- Protocol review service
 - Lancet's commitment to peer-review the data
- Fast-track process:
 - Online FT submission
 - External review within 48 hours
 - Online and print publication within 4 weeks
- Article:
 - Protocol joint submission
 - CONSORT guideline compliance
 - Introduction to contain summary of previous research & meta-analysis
 - 3000 words and 30 references

THE LANCET

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Unethical Behaviour of Lancet's Authors

Case Examples

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Fraud Case (1): Singh

- 2002:
 - *"Effect of an Indo-Mediterranean diet on progression of coronary artery disease in high risk patients (Indo-Mediterranean Diet Heart Study): a randomised single-blind trial"* by **Singh RB**, Dubnov G, Niaz MA, Ghosh S, Singh R, Rastogi SS, Manor O, Pella D and **Berry EM**.
 - Calls from Richard Smith from the BMJ and local Indian investigators
- 2005
 - *"Expression of Concern"*
 - Raw data not available ("termite problem")
 - Reference citation post-dated the time of study's onset
- Learning Points:
 - Lack of study protocol
 - Authors' role and responsibilities for data creation vs. data integrity
 - Investigation responsibility—journal vs. institution vs. funding agency
 - Reviewer—from same country to use as a rule?

Fraud Case (2):

Sudbo

- 2005
 - *"Non-steroidal anti-inflammatory drugs and the risk of oral cancer: a nested case-control study"* by [Sudbø J, Lee JJ, Lippman SM, Mork J, Sagen S, Flatner N, Ristimäki A, Sudbø A, Mao L, Zhou X, Kildal W, Evensen JF, Reith A, Dannenberg AJ](#).
- 2006
 - Call from the hospital regarding the patient's database used
 - Oral admission of data fabrication
 - "Expression of Concern"
 - Retraction
- Learning Points:
 - Finding made by the originating institution
 - Authors' role and responsibilities for data creation vs. data integrity
 - Norwegian law for scientific misconduct

Fraud Case (3):

Strasser

- 2007
 - "Autologous myoblasts and fibroblasts versus collagen for treatment of stress urinary incontinence in women: a randomised controlled trial" by Strasser H, Marksteiner R, Margreiter E, Pinggera GM, Mitterberger M, Frauscher F, Ulmer H, Fussenegger M, Kofler K, Bartsch G."
- 2008
 - "Department of Error"
 - Correction of funding source, conflicts of interest, author affiliations
 - "Expression of Concern"
 - Trial registration number is incorrect
 - Missing documents for ethical approval and study conduct
 - Retraction
 - Lack of ethics committee approval (documents provided were all copies)
 - Senior author claims he had no part in the study ("guest authorship")
 - Doubts that the study was ever conducted
- Learning Points:
 - "Stunning" results need extra care
 - Authors' role and responsibilities for data creation vs. data integrity
 - Austria announced the creation of The National Agency for Scientific Integrity

Conflict on Interest Case (1): Wakefield

- 1999
 - "Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children" by **Wakefield AJ**, Murch SH, Anthony A, Linnell J, Casson DM, Malik M, Berelowitz M, Dhillon AP, Thomson MA, Harvey P, Valentine A, Davies SE, Walker-Smith JA
- 2004
 - "Retraction of an Interpretation" (Partial Retraction)
 - MMR litigation
- Learning Points:
 - Unusual Col
 - Authors' knowledge and collective responsibility

Conflict of Interest Case (2):

Unpublished

- Authors were commissioned to write a series of four review papers on controversies in obstetrics.
- A year later, the first (diagnostic) paper written by the leader of the series arrived coincidentally at the time when a research article from a different group on a related topic was accepted. The commentary editor approached the series leader to invite him to write the accompanying commentary.
- The commentary team withdraws the invitation upon the author's revelation that he has a directorship position at a **university spin out company** that deals with fetal cell-based diagnosis, despite the fact that the company so far had no profit nor any pending patents.
- The commentary editor alerted the commissioning editor and it was then discovered that the author did not reveal this information as a conflict of interest to the commissioning editor for the series paper.
- The author was asked to withdraw the submission of the series paper, which created anger, frustration and a letter of complain to the ombudsman.

Conflict of Interest Case (2):

Unpublished

- Learning Points:
 - Coincidental finding
 - Non-published work
 - “Uncorrectable” since not public knowledge
 - Can create a “damaged” relationship with a particular journal
 - Who is to blame?
 - Author
 - Assumption of what constitutes a CoI
 - Non-profit university spin-out company and/or non-profit foundation
 - Editorial staff
 - Lack of clear information on the differential CoI requirement for a review vs. a research type article

“Ethical” Requirements at The Lancet

- Signatures:
 - Author's contribution
 - Acknowledged individuals
 - Conflicts of Interest
- Data
 - Systematic Literature Review & Meta-analysis
- Permissions
 - Patient Consent and Institutional approval
- Statements:
 - Conflicts of Interest
 - Role of the Funding Source

Authorship Criteria

- Vancouver guideline:
 - Substantially contribute to study conception and design, data acquisition, analysis and interpretation
 - Draft or revise the article for intellectual content
 - Approve the final version

An author must participate in all three steps.

- Lancet requirement:
 - Contributory signatures are a must for acceptance.

Authorship

Unusual Circumstances

- What about:
 - People who contribute significantly but do not meet all three criteria?
 - Large multi-center studies?

- Two new categories:
 - Contributors
 - Acknowledged Individuals

Authorship

Unusual Circumstances

■ Contributors

- When author number exceeds a specified threshold
- Multicentre trials
 - List of individual clinicians and study-organizations

■ Acknowledged Individuals

- Staff who made direct contribution
 - Technical help
 - Statistical, graphics or library support
 - Critical review of the paper drafts
 - *Editorial & writing assistance*

■ Lancet requirement

- Signatures of all acknowledged individuals agreeing to be acknowledged

Authorship Misuse

- Gift (guest) authors
 - Confer a stamp of authority
 - No intellectual contribution

- Ghost (omitted) authors
 - Neglected authors who made major contributions
 - *Professional* (paid) writers

Both to be avoided at all costs.

Systematic Literature Review & Meta-analysis

- Adequacy & Scope & Completeness

- Research redundancy
- Funding redundancy
- Patient Safety

The case of Ellen Roche: Johns Hopkins University and Hexamethonium

- PubMed

- Perils of 1966

- Lancet requirement

- Information must be included in the article's Introduction section.
 - Reference to be mentioned or analysis to be performed by the authors

Patient Consent and Approval

- Ethics Committee Approval
 - Where does clinical practice end and research begin?
 - Are standards the same for public institutions vs. private practices?
- Patient informed consent
 - "*Nothing about me without me*"
 - Whether or not they will be identified?
 - How their data will be used in research?
 - Do they understand the associated benefits and risks?
 - Research in children, mentally disabled, or in different cultural settings?
- Lancet requirement
 - Information on how and who must be included in the Methods section.

Conflicts of Interest (CoI)

Definition and Types

- *"A **Conflict of Interest** exists when an author (or an author's institution), reviewer, or editor has a financial or personal relationship that inappropriately influences or biases his/her actions (relationships also known as dual commitments, competing interests, or competing loyalties)."*
- Perceived vs. Real (actual) CoI
 - Affect perception
 - Create biased results and interpretations

Conflicts of Interests

Causes

- Direct financial conflicts:
 - Employment
 - Stock/share ownership
 - Grants (travel or research)
 - Patents
- Indirect financial conflict:
 - Honoraria
 - Consultancies to investment industry
 - Paid expert testimony
 - Mutual fund ownership
- Intellectual & Career (personal) conflict:
 - Competition
 - Promotion
- Personal belief
- Lancet requirement:
 - List and signatures from all authors
 - Differs for a research article versus a review piece

The Role of the Funder (RoF)

- Who is the study's funder?
- Who controlled design, data collection, analysis and data interpretation?
- Who controlled the writing and publication decision?
- Did the corresponding author have full access to all the data?
- **Lancet requirement:**
 - Methods section to include a paragraph as an answer to the above questions.
 - Funding source to be declared in the acknowledgement section.

Funding Source

Issues

■ Financial incentives

- Control of Data:
 - Contracts with (no) restrictions
 - Sponsors (not) be able to veto publication
 - *Dr. Betty Dong, UCSF, Boots and Synthroid: The "Thyroid Storm" case*
 - *Dr. Nancy Olivieri, U. of Toronto, Apotex and Deferiprone*

■ Publication Biases

- Greater likelihood that positive result studies will be:
 - Submitted for publication
 - Published
 - Published quickly
- Attempts to prevent the problem:
 - Disclosure of design of all clinical trials is urged
 - Clinical trial registration is currently enforced
 - Disclosure of results of all clinical trials is under discussion

CoI and RoF Solutions

- **Transparency and disclosure**
 - Disclose everything
 - Let the editor (*not author*) decide what constitutes a CoI
- **Firm guidelines**
 - Clear author and reviewer instructions
 - Vary from journal to journal (too strict or not strict enough)
 - Different for research article versus review paper
- **Mistake admission**
 - Post-publication corrections

*"CoI/RoF is an additional **information** for the reader."*

Publication Troubles

- Factual Errors
 - Publication of corrections
- Misconduct
 - Scientific (research driven)

Scientific Misconduct

The "Big" Ones

- Fabrication
 - Making up of research data
- Falsification
 - Manipulation of existing research data
- Plagiarism
 - Taking credit for others' text and ideas
 - Extent matters
 - Literal copying
 - Substantial copying
 - Paraphrasing (human judgement?)
 - Unintentional
 - Self-plagiarism?
 - Cultural differences?

Scientific Misconduct

The "Minor" Ones

- Repetitive Publications
 - Duplication
 - Same publication in different languages
 - "Salami Slicing"
 - Several publications from same research

Creates problems:

- Introduces a bias into medical evidence
 - Distorts systematic reviews and meta-analyses
- Usually unknown to one or more authors
- Violates copyright laws

Scientific Misconduct

The "Other" Ones?

- Irresponsible authorship
- Failure to declare a CoI
- Self-citation
- Selective publication of data
 - Suppression and non-publication of negative data
 - Over-publication of positive data
 - Editors fault?

Scientific Misconduct

Actions

- How it is identified?
 - Editors and Reviewers
 - Researchers (when not able to reproduce data)
 - Whistleblowers
 - Journalists
- Who investigates?
 - Editors, Publishers and/or Whistleblowers
 - Institutions and Funders of Research
 - Professional Societies
 - Regulatory Bodies
 - Office of Research Integrity
- What is to be done?
 - Retraction (whole or partial)
 - "Expression of Concern"
 - Long-term punishment?

Misconduct Solutions?

- Internal self-regulation
 - Ombudsman--- *The Lancet*
 - Journal's Ethical Committee--- *British Medical Journal*

- External Committees
 - WAME--- Statement
 - ICMJE--- Guidance
 - COPE (*Code of Conduct for Editors*) --- Advisory

- Other
 - International Congress on Peer-review in Biomedical Publications
 - World Conference on Research Integrity

Ethical Web Resources

- Council of Science Editors
www.councilscienceeditors.org
- World Association of Medical Editors
www.wame.org
- International Committee of Medical Journal Editors
www.icmje.org
- Committee on Publication Ethics
www.publicationethics.org.uk
- Lancet's Information for Authors
www.thelancet.com/authors/lancet/authorinfo

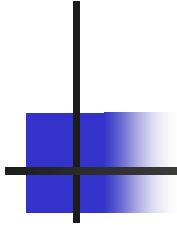
Elsevier's Resources

- "Publishing Ethics" Statement and Resource Kit
 - www.elsevier.com/wps/find/intro.cws_home/publishing
 - www.elsevier.com/publishingethicskit
- "Standard Operating Procedures" Editorial Manual
 - www.elsevier.com/wps/find/editorsinfo.editors/sopethics
- Conflict of Interest Policy
 - www.elsevier.com/wps/find/authorshome.authors/conflictsofinterest
- Legal guide to plagiarism
 - www.elsevier.com/wps/find/editorsinfo.editors/ethicshelpdesk
- Full member of COPE (January, 2008)
 - Only publisher so far to do it

To Remember...

*"...Publication is not the end,
but the beginning..."*

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Questions?