

Publication ethics

Dr. Hemalatha Somsekhar

Indian Council of Medical Research, New Delhi

CCRH

29-02-2008¹

Ethics, Guidelines & Law

- Ethics – correct behaviour dictated internally by one's own moral integrity
- Guidelines – Norms for correct behaviour laid but not forced
- Law – Correct behaviour governed externally or enforced by State

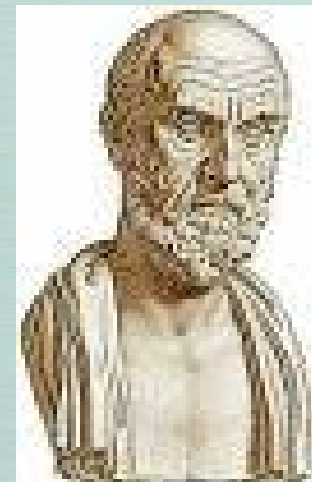
TRADITIONAL MEDICAL ETHICS

Rules for a good physician

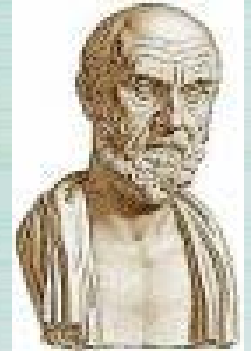
- Primary duty of physicians to their patients
- Prime concern- safety and best interest of patients
- Maintain confidentiality
- Avoid institutional entanglements that would compromise independent judgement
- Refrain from unsavory financial deals
- Refrain from advertising
- Professionalism with patients and colleagues

OLDER CODES OF MEDICAL ETHICS

- 10th Century BC – 400 AD :
Charaka Samhita (written code)
- 4th Century BC : Hippocratic Oath



Codes of Medical Ethics



- 10th Century BC – 400 AD : Charaka Samhita
- 4th Century BC : Hippocratic Oath
- 1846 : Code of Medical Ethics,AMA
- 1947 : Nuremberg Code
- 1948 : Universal Declaration of Human Rights (UN)
- 1956 : Code of Medical Ethics,MCI
- 1964 : Helsinki Declaration
- 2000 : Revised Helsinki Declaration
- 2000 : Delhi Medical Council Regulations

Guidelines

- 1979 : Belmont Report, USA
- 1980 : Policy Statement, ICMR, India
- 1993 -95 : Genetics, Human tissue, Xeno- transplantation (Nuffield Council, UK)
- 1982, 1991, 1993 : The WHO / CIOMS guidelines
- 1996 : ICH GCP Guidelines
- 2000 : NBAC report, USA
- 2000 : Revised ICMR guidelines 'Ethical guidelines for biomedical research on human subjects'
- 2002 : The Ethics of Research related to Healthcare in Developing Countries (Nuffield Council, UK)
- 2001 : Indian GCP Guidelines
- 2002 : Revised CIOMS Guidelines
- 2004 : ICMR ART Guidelines
- 2005 : Draft Guidelines for Stem Cell Research
- 2006 : ICMR Ethical guidelines for biomedical research on human participants

Research → Publication

- Most of the research gets translated to publication
- Research gets validated and accepted as quality work only after publication in reputed peer reviewed Journals

Hence,

- Publication ethics is extension of ethical research

Overview

- ❖ Unethical practice/misconduct/categories
- ❖ Why these occur
- ❖ Historical background
- ❖ Some case studies
- ❖ Unethical publication practices
- ❖ Clinical Trial Registry

What are Unethical Practices in Science?

- ❑ “Deliberate fabrication or falsification of evidence with the intention to deceive or misinform peers and other audiences of scientific knowledge”
- ❑ **Fabrication, falsification, plagiarism** or other practices that seriously *deviate* from those that are commonly accepted within the scientific community for *proposing, conducting, or reporting* research.
- ❑ It does *not* include honest error or honest differences in interpretations or judgments of data

US Federal Policy on Research Misconduct Office of Science and Technology Policy (OSTP)

Definition of misconduct:

- "research misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results".
- *December 2000*

US Federal Policy on Research Misconduct

Office of Science and Technology Policy (OSTP)

Categories of Unethical Practices

- ❑ **Three categories of activity commonly held to count as *serious misconduct***
 - **Fabrication** is **making up** data or results and recording or reporting them.
 - **Falsification** is **manipulating** research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
 - **Plagiarism** is the **appropriation of another person's** ideas, processes, results, or words without giving appropriate credit.

Federal Register, December 2000

Unethical practices in science and publication

- **Unethical patient research**
- **Research fraud and/or untrue data**
- **Selective or inaccurate publication**
- **Plagiarism**
- **Redundant publication**
- **Undeclared conflict of interest**
- **Inappropriate authorship**
- **Inappropriate acknowledgements**
- **Premature public statements**

Why do These Occur?

- Ignorance
- Pressure to publish
- Career prospects
- Publish or perish system
- Ambition, fierce competition
- Pressure from seniors
- Lack of knowledge on the ethics of scholarly writing

Historical cases

- **William Summerlin**
- **John Darsee**
- **Robert Slutsky**
- **Margot O'Toole, Thereza Imanishi-Kari and David Baltimore**

Cases from India

- **R. B. Singh**
- **V.J. Gupta**
- **Pattium Chiranjeevi**

Ethical research

- Good research – well justified, well planned, appropriately designed
- Approval from IEC
- Informed consent from participants

Substandard research may constitute misconduct

Data Analysis



- Appropriate analysis
- Suppression, Fabrication and falsification
– misconduct

Selective or inaccurate publication

Publication bias

- “Publication bias refers to the greater likelihood that studies with positive results will be published”
- *JAMA* 2002;287:2825-2828

Publication bias

- Positive trials are more likely to be submitted for publication
- Positive trials are more likely to be published
- Positive trials are more likely to be published quickly
 - Stern and Simes *BMJ* 1997;315:640-645
- **Where are the negative studies?**

What is plagiarism?

- ❑ “*plagiare*” (to steal)
- ❑ It is intellectual theft
- ❑ Plagiarism is stealing others ideas and contents of a paper (written or illustrative material) and passing it as ones own without acknowledgement
- ❑ Copying large portions verbatim from other papers is plagiarism even if references are given
- ❑ It is a serious scientific misconduct

Plagiarism includes:

- Investigators during the peer- review process taking ideas from others' grant proposals or articles and including them in their own publications.
- Students taking material from the Internet verbatim, without attribution, during write-ups of research.
- Faculty taking dissertation material from students and including it in publications without giving due credit.

Avoiding plagiarism

- Accidental or not?
- Always reference the work of others
- Put the words of others in quotation marks
- If you use something word for word it must be acknowledged.
- For short quotes, use quotation marks in the sentence.
For longer quotes indent the entire passage

If you have used a table, chart, diagram *etc.*, cite the source directly below.

- It is not enough to have cited the reference somewhere in the text.
- Seek permission to copy tables, figures etc.

Redundant publication

- Duplication

Duplicate publication is the practice of publishing the same information a second time without acknowledging the first publication. This practice not only wastes time and resources but can also distort the research record and endanger public health.

- Why does duplication matter?
- It is dishonest
- It breaches copyright so is intellectual theft
- It distorts systematic reviews and meta-analyses

Redundant publication

- ‘Salami slicing’
Salami publication (sometimes called bologna or trivial publication) is the practice of dividing one significant piece of research into a number of small experiments (least publishable units or LPUs), simply to increase the number of publications. This practice may distort the value of the work by increasing the number of studies that appear to support it. It also wastes valuable time and resources.
- Attempting to maximise publications by re-using data
- Acceptable if difference in message to different readership
- Unacceptable if degree of overlap is great

Conflict of interest

Conflict of interest has been defined as

❑ “..a set of conditions in which professional judgment concerning a primary interest (such as patients' welfare or the validity of research) tends to be unduly influenced by a secondary interest (such as financial gain).“

❑ It is a condition not a behaviour, and there is nothing wrong with having a conflict of interest. It is common.

- *British Medical Journal*

Conflict of interest



To be de declared by

- Authors
- Contributors
- Editor
- Reviewers
- Publisher

As a part of good practice

If there is doubt – better declare the facts

Conflict of interest

- Academic
- Financial
- Personal
- Commercial
- Political

Do NOT forget to declare competing interests especially in publications!

Inappropriate authorship

Authorship: ICMJE Guidelines

Authorship credit should be based only on

- 1) substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data;
- 2) drafting the article or revising it critically for important intellectual content; and
- 3) final approval of the version to be published.

Conditions 1, 2, and 3 must all be met.

Inappropriate authorship

- Commonest area of allegation of misconduct
- Simply providing cases is not authorship
- Must have made 'substantial contribution to research and publication'
- Take public responsibility for the data
- All qualifying authors must be included
- Most publications insist on descriptive note on role of each author / contributor

Acknowledgements

- Acknowledge the funding / sponsoring agency
- Don't acknowledge routine work or duty

www.icmje.org

Media

1. **Premature publication** in the mass media is a risk
2. Balanced view - point out where **evidence ends and speculation begins**
3. **Simultaneous publication** in the mass media and a peer reviewed journal is advised

Media

ICMR Guidelines

- **Researcher's relations with the media and publication practices** (responsible relations with media, confidentiality of study participants, consent for publication, authorship, misconduct, Consolidated standards of reporting trials (CONSORT))

Clinical Trial Registry

- Honest reporting begins with revealing the existence of all clinical studies, even those that reflect unfavorably on a research sponsor's product.
- The interests of the sponsor or authors notwithstanding, anyone should be able to learn of any trial's existence and its important characteristics.

Clinical Trial Registry

- The ICMJE member journals will require, as a **condition of consideration for publication**, registration in a public trials registry. Trials must register at or before the onset of patient enrollment.

Why is it important to register clinical trials?

CTRI Clinical Trial Registry, India

- It is important to register clinical trials for both **ethical and scientific reasons**. Registration of trials ensures **transparency, accountability and accessibility** of clinical trials and their results. Further, it promotes greater **trust and public confidence** in clinical research. Trial registration also helps to **prevent bias** generated by selective reporting of only "positive" findings as well as **reduce unnecessary duplication** of research through greater awareness of existing trials and results.

Committee on Publication Ethics (COPE) (www.publicationethics.org.uk)

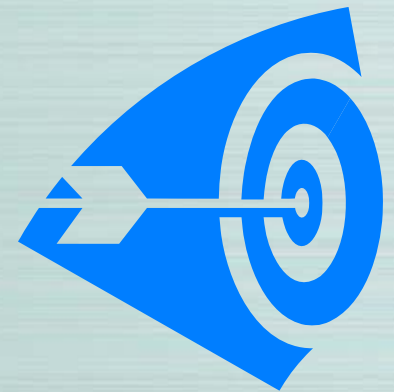
- Association of > 300 editors, mostly European based
- Meets regularly to discuss cases
- Publishes findings
- Provides codes of practice for editors
 - To address breaches of research and publication ethics
 - Define best practice in scientific publishing
 - Useful for authors, editors, readers, owners of the journals, publishers

COPE: Aspects covered

1. Study design and ethical approval
2. Data Analysis
3. Authorship
4. Conflict of interest
5. Peer review
6. Redundant publication
7. Plagiarism
8. Duties of editors
9. Media Relations
10. Advertising

Conclusion

- Ethical research and sound publication ethics go hand in hand
- Researchers, authors, editors, reviewers, publishers and sponsors should be aware and fulfill their responsibilities



Useful resources

- **COPE** (www.publicationethics.org.uk)
- **ICMJE** 'Vancouver Group'
(www.icmje.org)
- **ORI** (www.ori.dhhs.gov)
- **WAME** (www.wame.org)
- **CSE** (www.CouncilScienceEditors.org)

Acknowledgements

- Dr Harvey Marcovitch
Syndication Editor BMJ Publishing Group
Chairman, Committee on Publication Ethics
- K. Satyanarayana,
Sr Dy Director-General
Indian Council of Medical Research
- Dr Raviraj V Acharya
Professor of Medicine
KMC – Manipal