Application of ethical principles

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Outline of presentation

- Ethical issues at different stages of the research process
- Why ethical review and oversight?
- Applying for ethical clearance: some points/tips
- Take home message

Ethics at different stages of research process

- Research proposal
  - Methodological issues
  - Information to prospective participants & consent form: risk-benefit analysis
- Data collection and analysis
  - Fabrication, Falsification, wrong analyses
- Reporting of findings
  - Plagiarism, copyrights, authorship, etc.
- Throughout all stages of research
  - ➢ Funding & conflict of interest, IPR, engagement, etc.
- Post-study issues: access to benefits, feedback,

Now there are ethical codes and guidelines

So why ethical review and oversight by ethics committees?

Why ethical review and oversight?

- There are still unethical research practices going on

- It may be a small proportion, but repercussions are far-reaching

- Unethical acts of commission or omission may be committed
  - intentionally
  - unintentionally

➢ Consequences are more or less the same

Alder Hey Hospital organ Scandal (UK)

- Organs and body parts removed without approval or consent
- For potential future research
- Some parts removed during routine procedures
- http://news.bbc.co.uk/2/hi/health/1136723.stm

Response from Alder Hey Hospital

- Alder Hey Hospital said removal of parts was "necessary" for post mortem and future research

- In 2003, Alder Hey Hospital paid families of victims a total £5 million as out-of-court settlements

- Alder Hey report revealed that over 104 000 organs, body parts, and whole bodies of foetuses and still-born babies were stored in 210 NHS Hospitals for possible future research

- http://news.bbc.co.uk/2/hi/health/1136723.stm

Unethical practices still occur

- Tuskegee case in USA: poor black syphilis patients not treated (by US Public Health Service) in order to study pathogenesis from infection to death (1932-1972)

- Trovan Trial: Pfizer tested its drug during a meningitis outbreak in Nigeria in 1996 without proper ethical approval nor proper consent

- Virodene study (UP): Treatment for HIV/AIDS tested in humans without proper review of design and without proper approvals

Prof. Hwang Woo-Suk in his lab

- http://www.nytimes.com/2014/03/01/world/asia/scientists-new-project-rebuild-after-cloning-disgrace.html

Prof. Hwang Woo-Suk in his lab

- Reported to have cloned a human embryo and produced a stem-cell line from it for the first time in global history

- The government named him a “supreme scientist” and issued postage stamp in his honour showing a paralysed man rising from a wheelchair

Fabrication of data

- ‘Cooking’ or ‘creating’ data

- South Korean Prof. Hwang Woo-Suk fabricated somatic cell nuclear transfer data and claimed that he had cloned a human embryo

- Many stakeholders were ashamed

Alleged falsification of data

Vioxx Lawsuit – How to Fil

www.drugwatch.com/vioxx/lawsuit/

Vioxx Lawsuit

AA

Vioxx, What is it? Its Uses and Interactions > Vioxx Lawsuit

Merck paid out billions of dollars to settle tens of thousands of Vioxx lawsuits filed by patients and their families.

Initially hailed as a superior non-steroidal anti-inflammatory drug (NSAID), Vioxx spent only a few years on the market before it was the focus of thousands of consumer lawsuits. Within five years of being approved by the U.S. Food and Drug Administration (FDA) for the treatment of arthritis and menstrual pain, the painkiller was linked to thousands of heart attacks, strokes and deaths. At the same time, the drug's manufacturer, Merck, vehemently denied any problems.

However, studies quickly found that Vioxx dramatically increased the chance for a fatal heart attack or stroke. One such study, called Vioxx Gastrointestinal Outcomes Research, or VIGOR, found a striking cardiovascular risk. Instead of pulling the drug from the shelves, Merck grudgingly agreed to allow a label change to reflect the heart risks but continued to publicly deny any problems.

On Sept. 30, 2004, after a second study confirmed the drug caused severe cardiovascular problems, Merck was forced to initiate a worldwide recall of Vioxx. However, by this time, up to 25

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Vioxx: Alleged falsification of data

- Clinical trial data used by Merck to have the drug licensed by the FDA were ‘flawed’: Academic authors given data to analyse (conflict of interest)
- Merck ‘ignored’ empirical evidence of side effects of the drug vioxx (rofecoxib), a prescription painkiller
  - E.g. a study called Vioxx Gastrointestinal Outcomes Research, VIGOR, found very high cardiovascular risks
- Merck did not withdraw the drug from the market; added a label reflecting the heart risks
- Over 38,000 people died from heart attacks or strokes after taking Vioxx: $4,85 billion paid in lawsuits, $23 million for charges that it mislead customers about the drug’s safety and efficacy

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1. A Grad Student Faked Data In an Important Gay Marriage Study

In late 2014, a paper published in *Science*, titled "When contact changes minds: An experiment on transmission of support for gay equality," made headlines around the world by showing that gay political canvassers, when conversing face-to-face with constituents for as little as 20 minutes, could influence the vote in favor of same-sex marriage. The study claimed that the effect lasted about a year, and that the favorable opinion had a tendency to spread within the voter's household

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www.sciencemag.org/content/298/5591/30.full

Science 4 October 2002:
Vol. 298 no. 5591 pp. 30-31
DOI: 10.1126/science.298.5591.30

NEWS OF THE WEEK

SCIENTIFIC MISCONDUCT

Bell Labs Fires Star Physicist Found Guilty of Forging Data

Robert F. Service

Like the mythical Icarus, whose waxen wings melted when he flew too close to the sun, the soaring career of Jan Hendrik Schön came crashing down to Earth last week. Schön, a 32-year-old physicist at Bell Laboratories in Murray Hill, New Jersey, faked experimental results in at least 17 published papers, according to a report released 25 September by a panel of independent investigators. Schön had been fired from Bell Labs the previous evening, after officials there received the report. The findings mark this as one of the most extensive cases of scientific misconduct in modern history and signal a low-water mark for Bell Labs, an institution already reeling from economic troubles of its parent company, Lucent Technologies.

"It's a big train wreck and very sad," says Lydia Sohn, a Princeton University physicist who was one of the first to point out Schön's apparent manipulation of data. "But this shows that the system of checks and balances in science works." Others were less consoled. "If this guy [had been] a little less blatant, he could have succeeded. That's the terrifying thing," says Paul McEuen, a physicist at Cornell University in Ithaca, New York.

The panel cleared Schön's co- authors of any direct scientific misconduct. But it left open questions that are likely to reverberate through scientific circles for years to come. Chief among them are whether papers Schön co-authored that were not reviewed by the committee are valid and whether Schön's co- authors, the journals that

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Economics of irreproducibility of preclinical research PLOS paper June 2015.pdf - Adobe Reader
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The Economics of Reproducibility in Preclinical Research

Leonard P. Freedman[1]*, Iain M. Cockburn[2], Timothy S. Simcoe[2,3]

1 Global Biological Standards Institute, Washington, D.C., United States of America, **2** Boston University School of Management, Boston, Massachusetts, United States of America, **3** Council of Economic Advisers, Washington, D.C., United States of America

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OPEN ACCESS

Citation: Freedman LP, Cockburn IM, Simcoe TS (2015) The Economics of Reproducibility in

Abstract

Low reproducibility rates within life science research undermine cumulative knowledge production and contribute to both delays and costs of therapeutic drug development. An analysis of past studies indicates that the cumulative (total) prevalence of irreproducible preclinical research exceeds 50%, resulting in approximately US$28,000,000,000 (US $28B)/year spent on preclinical research that is not reproducible—in the United States alone. We outline a framework for solutions and a plan for long-term improvements in reproducibility rates that will help to accelerate the discovery of life-saving therapies and cures.

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Malarone donation programme

- Glaxo-Wellcome, wanted research data to enable malarone, a malaria drug, to be registered for use in Europe and USA
- In 1999, Malarone Donation Programme (1 million free dosages) to East African countries
- Uganda and Tanzania rejected: post-study access
- Kenya accepted: after data collection and registration of malarone, it is not accessible to developing countries (1 adult treatment course of malarone was $42 in the year 2000 while average salary of a government officer in Kenya was $310)

Plagiarism: deliberate or inadvertent

Fending Off a Plagiarist -
chronicle.com/article/Fending-Off-a-Plagiarist/44680/

Advice

July 2, 2004

Fending Off a Plagiarist

By Kim Lanegran

A colleague on my campus calls me the "scourge of student plagiarists." I'm proud of that reputation. But I had an experience this year in which plagiarism nearly defeated me, shaking my faith in academe's core values as well as my ability to turn my students into honest scholars.

While I was resigned to fighting plagiarists in my classroom, I had not expected to have to fight one for credit for my own dissertation. A doctoral student at Northeast Urban University -- I'll call him Mr. X -- presented my dissertation as his own. He received a Ph.D. and took an excellent research job at Prominent African University. Through my subsequent efforts, he lost his degree, his job, and his reputation.

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Plagiarising inadvertently

Int J Tuberc Lung Dis Paper

- A review paper was published in 2005
- Vice Chancellor of the University of Zambia drew the attention of the Journal to plagiarized statements in the published paper
- The authors (supervisor and student) admitted to “lack of rigour”
- The journal retracted the paper in 2007
- Journal banned the authors for 5 years
- Various reactions from different stakeholders

German education minister loses Ph.doc [Compatibility Mode] - Microsoft Word

German education minister loses Ph.D. over plagiarized thesis

By Ben Brumfield, CNN

Updated 1038 GMT (1838 HKT) February 6, 2013

German education minister Annette Schavan arrives for a German government cabinet meeting on January 23 in Berlin, Germany.

Her doctoral thesis dealt with how we form our conscience. Turns out she plagiarized chunks of it.

Ad

Post Politics

Rand Paul denies plagiarism charges, blames 'haters'

35

By Aaron Blake October 31, 2013 Follow @aaronblakewp

Sen. Rand Paul (R-Ky.) says in a new interview that charges that he has plagiarized Wikipedia in his speeches are an effort by "haters" to bring him down.

MSNBC's Rachel Maddow first accused Paul of lifting passages from Wikipedia's summary of the movie "Gattaca." Other reports suggest he has used Wikipedia's verbiage while describing the movie "Stand and Deliver."

Paul said during an interview with Fusion that he sufficiently credited the

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www.usatoday.com/story/news/politics/2013/11/06/rand-paul-plagiarism/3451991/

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Rand Paul admits his plagiarism 'is my fault'

James R. Carroll, The (Louisville, Ky.) Courier-Journal 9:35 a.m. EST November 6, 2013

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59
1
84

Senator's office promises to be more careful in vetting material for his speeches.

Sen. Rand Paul R-Ky. speaks during the Values Voter Summit, held by the Family Research Council Action, Friday, Oct. 11, 2013, in Washington.
(Photo: Jose Luis Magana, AP)

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TOP VIDEOS

victim of "haters, but now

article. Buzzfeed also reported earlier that three

EN 03:26 PM

Turnitin report

Conscience; the definitions of conscience and its conceptions are varied and often contradictory in the literature. It has been said of conscience that it is moral sense of right and wrong, especially as felt by person and affecting his behaviour (oxford dictionary); that it is fallible (Broud), that it is infallible (Butler) ; that its ultimate basis is emotional (mill), that its ultimate source is rational (Rashdall); that it is the voice of God (Hartmann); or the voice of custom (Paulsen); that it is merely advisory (Nowell-Smith); that it is a command internally imposed (Mayo); that it is conscious (Butler), that it is not (any contemporary moral philosopher); that it is the disposition to have certain beliefs, emotions, and conations which, when operative, issue in conscientious actions (Broad); and it is conscientious action (Ryle). Clearly the views of

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Application of ethical principles in postgraduate research process

1. Research ethics go beyond ethical clearance and informed consent
2. Research ethics go beyond the research participants to cover all stakeholders

Risk-benefit analysis: systematic, logical

POTENTIAL RISKS	POTENTIAL BENEFITS
A. To individual participants	
➢	➢
B. To community/population	
➢	➢
C. To the Researchers/Institution	
➢	➢
D. To other stakeholders (e.g. funders, journals, etc.)	
➢	➢

Ethical clearance: some points/tips

- No study should be commenced before ethical approval is obtained

- Each student should apply for ethical approval for his/her own research project:

- Good research proposal important: shows that researcher is knowledgeable
  - chances of fabrication, falsification, plagiarism, etc minimised

Ethical clearance: some points/tips

- For children under 18yrs, proxy consent has to be obtained from legal guardian

- Samples can be used only for the purpose that was stated in the proposal and consent

- Information sheet should explain purpose of study, potential risks, potential benefits, a statement that participation will be voluntary and one can withdraw
  - Check if the ethics committee has templates and use them

Ethical clearance: some points/tips

- Samples can only be stored for future use if that is stated in the proposal and consent

- No consent is needed for secondary data analysis
-
- If your study involves animals, ethical clearance from animal ethics committee is needed

- For radioactive materials or GMOs, approval from a bio-safety committee may be needed

Ethical clearance: some points/tips

- If applicable include community engagement
- Publications, authorship and feedback (if applicable) can be included under dissemination of findings
- Ethical clearance has to be included in thesis/dissertation/research report
- Most journals ask for the ethical clearance
-

Take-home message

- Research ethics resulted from unethical studies
- There are 4 fundamental ethical principles upon which ethical codes and guidelines have been developed
- Principles of autonomy, beneficence, non-maleficence and justice

Take-home message

- The ethical principles aim to protect all stakeholders
- Unethical research still occurring
- Ethical issues include approvals, consent, authenticity of data, plagiarism, post-study benefits
-
- Ethics committees are part of checks and balances to ensure that research is conducted ethically
- Researchers should aim to be virtuous people

Thank you