Fraud and Misconduct in Research

Sabine Kleinert,
Senior Executive Editor, The Lancet
Vice-Chair of the Committee on Publication Ethics

CHEIA, Annual Conference
Warwick, Sept 2008
• Definitions of Research Misconduct
• How big a problem is it?
• Research Ethics vs Publication Ethics
• How to deal with misconduct
• How to prevent misconduct
• Role of editors, funders, and institutions
• Unsolved issues
Definitions of Research Misconduct

Different bodies/countries, different definitions

For example, http://ori.dhhs.gov

» “Fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.”

» in 2000 added: “serious deviation and intention”
Definitions of Research Misconduct

“serious deviations from good scientific practice” - Norway

“intentional distortion of the research process” - Sweden

“violation of good scientific practice” - Finland

“acts which falsify or distort the scientific message” - Denmark
Definitions of Research Misconduct

- Fabrication of data or cases
- Wilful distortion of data (Falsification)
- Plagiarism
- No ethics approval
- Not admitting missing data
- Ignoring outliers
- No data on side effects
- Gift authorship
- Redundant publication
- Inadequate literature search
How big a problem is it?

SCIENTIFIC MISCONDUCT

How Prevalent Is Fraud? That’s a Million-Dollar Question

Charles Turner still doesn’t know whether his experience was like finding a rare bad apple in the barrel. But he is sure that there was something rotten in the survey data going into his federally funded study of sexual behavior. And he knows that it has taken him 2 years to pluck out the spoiled fruit and piece together a clean report for a collection manager who was troubled by the apparent overproductivity of one interviewer. A closer look revealed that the worker was faking results; the address of one interview site, for example, turned out to be an abandoned house. The worker was dismissed, and others came under suspicion.

After “a horrible 6 months,” all line smart don’t discuss the issue. And the incident never became public, he says, because no one was ever publicly accused of wrongdoing and the institute chose to avoid the risk of litigation.

How often does misconduct like this occur? There appears to be no consensus on the answer, although science historian Nicholas Stenbeck of the University of Michigan, Ann Arbor, co-chair of the conference, has drawn up a range of estimates. At the low end is an estimate of 1 fraud per 100,000 scientists per year. That’s based on 200 official federal cases that fit a narrow definition that counts only fraud, data fabrication, and plagiarism out of a community.
How big a problem is it? –
a few high-profile rogue cases?

Hwang Woo-Suk,
South Korea, 2005
How big a problem is it?–
How big a problem is it?

Documented cases 1 in 10 000
Know of an undisclosed case 1-13 in 100
Major deviation found in audit 1 in 10
Misrepresentations in fellowship applications 1 in 5
Students willing to fake data 1 in 2

First ORI research conference, Nov 18-20, 2000
How big a problem is it?

Sandra Titus, James A Wells, Lawrence J Rhoades
Repairing research integrity

Nature 453: 980-2

Of 2212 researchers, 192 (8.7%) described that they had observed or had direct evidence of research misconduct in a total of 265 incidents (64 did not meet the ORI definition).

120 fabrication or falsification, 73 plagiarism, 8 unknown.

Amounts to 3 incidents per 100 researchers per year, or more than 2300 observations of potential misconduct by DHHS-funded researchers per year (ORI deals with only about 24)
How big a problem is it?
Research misconduct vs Publication misconduct

big overlap

Any research misconduct once published becomes publication misconduct

Publication misconduct (ie duplicate publication, redundant publication) influences research and clinical practice
COPE’s experience

- started in 1997 as “self-help” group of editors (Richard Smith, Richard, Horton, Mike Farthing) and about 60 members, now a registered charity with over 6000 members
- 4 meetings a year (Council and Forum)
- anonymous discussion of suspected misconduct cases
- advice to editors on how to proceed
- cases (and outcomes if available) on website
- annual conferences
- Code of Conduct and Best Practice Guidelines for Editors
- flowcharts on how to handle common misconduct scenarios
COPE’s flowcharts

Committee on Publication Ethics Flowchart

What to do if you suspect redundant (duplicate) publication

(a) Suspected redundant publication in a submitted manuscript

Reviewer informs editor about redundant publication

Thank reviewer and say you plan to investigate
Get full documentary evidence if not already provided

Check degree of overlap/redundancy

Major overlap/redundancy (i.e. based on same data with identical or very similar findings and/or evidence authors have sought to hide redundancy, e.g. by changing title, author order or not citing previous papers)

Contact corresponding author in writing, ideally enclosing signed authorship statement (or cover letter) stating that submitted work has not been published elsewhere and documentary evidence of duplication

Minor overlap with some element of redundancy or legitimate reanalysis (e.g. sub-group/extended follow up/discussion aimed at different audience)

Contact author in neutral terms/expressing disappointment/explaining journal’s position
Explain that secondary papers must refer to original
Request missing reference to original and/or remove overlapping material
Proceed with review

No significant overlap

Discuss with reviewer
Proceed with review

Note: ICMJE advises that translations are acceptable but MUST reference the original
## COPE’s experience

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<th>Year</th>
<th>No of cases</th>
<th>“Evidence of misconduct”</th>
<th>“Probably no misconduct”</th>
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<tr>
<td>Total</td>
<td>285</td>
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COPE’s experience

- Duplicate/redundant publication 77
- No ethics approval 34
- Authorship issues 31
- No or inadequate informed consent 30
- Falsification or fabrication 28
- Plagiarism 26
- Unethical research or clinical malpractice 19
- Undeclared conflict of interest 15
- Reviewer misconduct 8
- Editorial misconduct 6
- (miscellaneous 41)
COPE’s experience

Of 285 cases, 172 (60%) pre-publication
95 (33%) post-publication
How to deal with misconduct?
Common difficulties for editors

- Time consuming!
- No reply from authors
- No reply from head of institutions
- Inadequate investigation by institution
- No institution
- Managing/analysing raw data
- What to do, if alleged misconduct is unproven
How to deal with misconduct (institutions/investigating body)?

Don’t ignore!
Due process
Fair and speedy investigation (publish results), ideally independent
Inform all relevant stakeholders (journals, funders...etc)
Protection of whistleblowers
Appropriate sanctions and consequences
Case: The case of Jon Sudbø

- Nested case-control study
- 454 cases (oral cancer): 454 controls
- NSAID use: Hazard ratio oral cancer = 0.47 (95% CI 0.37-0.60)
- NSAID use: Hazard ratio CV death = 2.06 (95% CI 1.34-3.18)
What happened?

Submitted
Sept 6, 2005

Peer review

Editorial debate

Revisions

Acceptance

Publication online
October 7, 2005
January 13, 2006: the story broke

A chance discovery:
The Ekbom Commission

Expression of concern: Jan 21, 2006

Retraction: February 4, 2006
• Swift, thorough, independent investigation
• Report published
• Lessons learnt
Case: The case of Hannes Strasser

Autologous myoblasts and fibroblasts versus collagen for treatment of stress urinary incontinence in women: a randomised controlled trial


Summary
Background Preclinical studies have suggested that transdermal injections of autologous myoblasts can aid in regeneration of the uroepithelium and fibroblasts in reconstitution of the urethra’s submucosa. We aimed to compare the effectiveness and tolerability of ultrasonography-guided injections of autologous cells with those of endoscopic injections of collagen for stress incontinence.

Methods Between 2002 and 2004, we recruited 43 eligible women with urinary stress incontinence. 42 of these women were randomly assigned to receive transdermal injections of autologous myoblasts and 21 to collagen for stress urinary incontinence.

At 12 months, 38/42 completely continent vs 2/21 in controls

• 42 women randomly assigned to injections of autologous myoblasts and 21 to collagen for stress urinary incontinence
The case of Hannes Strasser

- paper published after peer review on June 30, 2007
- Lancet contacted by University’s Rector and members of ethics committee with concerns
- DoE published correcting CoIs, funding source, and affiliations of some authors Feb, 2008
- Lancet is being made aware of investigation by Government Body following a court case and a parliamentary question
- Expression of concern issued by Lancet May 3
The case of Hannes Strasser


- serious irregularities in study conduct including Consent procedure, data documentation, Patient insurance….etc

- doubts as to whether study as described ever existed
The case of Hannes Strasser

Coauthors distance themselves from paper claiming only honorary authorship

Rector of University dismissed by University governing body for allegedly unrelated reasons on Aug 21

Paper retracted by Lancet on Sept 6
“Austria, is a small country, and networks between power-brokers are small and tight. But something, it seems, is rotten in the state of Austria, and it needs to be faced and dealt with openly.”
Lancet Editorial on role and responsibilities of coauthors, accompanying the retraction:

“Coauthors abrogating responsibility is a recurrent theme in serious research misconduct cases…. Requiring signed statements on contributions is not enough to ensure that coauthors take responsibility for a study’s integrity as well as basking in the glory of a high-profile publication with all its associated credit.”
difficulties

• Took a reasonably long time
• Report is subject to Austria’s officials’ Secret Act and not made public
• University reacts defensively
• ??whistleblower dismissed

BUT: Austria is now thinking about setting up a national body to deal with research misconduct cases
How to prevent misconduct - journals/editors

• Only indirect influence
• Reporting standards (CONSORT, STROBE...etc)
• Promote honesty and transparency
  – Protocols, ethics approval, trial registration
  – contributor statements/guarantor
  – conflict of interest/role of sponsor
• Editorials/commentaries
How to prevent misconduct - journals/editors

?? Screening
• for plagiarism

• Figure manipulation

How to prevent misconduct - institutions

• Guidelines covering ALL aspects of research (but with clear consequences)
• Education (all researchers, including professors and students)
• Central documentation of protocols
• Central documentation/storage of raw data
• Random checks/audit
• Clear and transparent policies (CoI, intellectual property)
Role of editors, funders, and institutions
And how can we work together???
Unsolved issues

- Collaborative research (disciplines/institutions/countries – who is responsible?
- Does minor misconduct lead to major misconduct
- Is pressure to publish having an influence?
- Are commercially funded studies more or less likely to lead to misconduct?
- Which preventive actions work?
- Are international bodies needed to deal with research integrity?