



Cases in Publication Ethics

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Objectives

- Describe common ethical issues in preparing & publishing biomedical manuscripts ...and how to avoid them!
- Understand how manuscripts are assessed by editorial offices for potential ethical issues



“The role of ethics in research extends through the moral obligation to report that research and to do so in an honest, transparent, and timely manner...”

Summerskill, et al
THE LANCET 373:992, 2009



“Publish or Perish”

- Published manuscripts are the currency of the academic world:

- Promotion
- Funding

“...fierce competition in scientific disciplines and increasing necessity to publish may lead authors to engage in questionable behavior”

Errami, Nucleic Acids Research, 37:D921, 2009

Jailed for Faking Data

A researcher working for a US pharmaceutical company's Scotland branch is sent to prison for falsifying safety test data on experimental drugs due for clinical trials.

April 18, 2013



WIKIMEDIA, STEAKPINBALL

A British scientist has this week (April 17) been sentenced to 3 months in prison for falsifying pre-clinical data for experimental drugs, reported [The Daily Telegraph](#). It is the first time a researcher has been jailed under scientific regulation laws introduced in the United Kingdom in 1999.

Steven Eaton, who worked at US pharmaceutical company Aptuit's site near Edinburgh, Scotland, performed liquid chromatography analyses to assess drug concentrations in blood, which helps to determine what doses of drug can safely be given to subjects in clinical trials. But in 2009, supervisors at Aptuit noticed irregularities in Eaton's

Scientists behaving badly

To protect the integrity of science, we must look beyond falsification, fabrication and plagiarism, to a wider range of questionable research practices, argue **Brian C. Martinson, Melissa S. Anderson** and **Raymond de Vries**.

Serious misbehaviour in research is important for many reasons, not least because it damages the reputation of, and undermines public support for, science. Historically, professionals and the public have focused on headline-grabbing cases of scientific misconduct, but we believe that researchers can no longer afford to ignore a wider range of questionable behaviour that threatens the integrity of science.

We surveyed several thousand early- and mid-career scientists, who are based in the United States and funded by the National Institutes of Health (NIH), and asked them to report their own behaviours. Our findings reveal a range of questionable practices that are striking in their breadth and prevalence (Table 1). This is the first time such behav-

Table 1 | Percentage of scientists who say that they engaged in the behaviour listed within the previous three years (n = 3,247)

Top ten behaviours	All	Mid-career	Early-career
1. Falsifying or 'cooking' research data	0.3	0.2	0.5
2. Ignoring major aspects of human-subject requirements	0.3	0.3	0.4
3. Not properly disclosing involvement in firms whose products are based on one's own research	0.3	0.4	0.3
4. Relationships with students, research subjects or clients that may be interpreted as questionable	1.4	1.3	1.4
5. Using another's ideas without obtaining permission or giving due credit	1.4	1.7	1.0
6. Unauthorized use of confidential information in connection with one's own research	1.7	2.4	0.8 ***
7. Failing to present data that contradict one's own previous research	6.0	6.5	5.3
8. Circumventing certain minor aspects of human-subject requirements	7.6	9.0	6.0 **
9. Overlooking others' use of flawed data or questionable interpretation of data	12.5	12.2	12.8
10. Changing the design, methodology or results of a study in response to pressure from a funding source	15.5	20.6	9.5 ***

Martinson, Anderson, de Vries *Nature* 435:737, 2005



- Publicationethics.org
- Established in 1997 by a small group of journal editors in the UK
- >10,000 members worldwide from all academic fields.
- Membership is open to editors of academic journals and others interested in publication ethics.
- Advises editors and publishers on all aspects of publication ethics and, in particular, how to handle cases of research and publication misconduct.
- Provides a forum for its members to discuss individual cases.

Verified Author?



CASE 1: AUTHORSHIP

What makes an author?

- You (Researcher) have finished the first draft of a manuscript on your research study.
 - This study was your idea.
 - You received assistance from a Professor in another country with data analysis.
 - Your lab assistant helped in preparing experimental design and maintaining equipment.
 - Two fellows provided feedback on manuscript
 - Advisor provided guidance on concept and design, revised the manuscript.
 - Your Department Chair mentored you through manuscript writing process, but did not actually do any writing and has not looked at a draft.

Who meets criteria for Authorship?

- Assuming that all people have approved the final manuscript and agree to be accountable for the work...
- Who should be listed as an author?
 - Why?
- Who should be listed in the Acknowledgments?
 - Why?

Authorship criteria (icmje.org)

- Substantial contribution to conception or design of work OR acquisition, analysis or interpretation of data, AND
- Drafting article or revising it critically for important intellectual content, AND
- Final approval of the draft, AND
- Agreement to be accountable for all aspects of the work.
- Authors should meet all 4 conditions

What people did

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- Advisor provided guidance on concept and design, revised the manuscript.
- Your Department Chair mentored you through manuscript writing process, but did not actually do any writing and has not looked at a draft.

Authorship- Case Resolution

- Using ICMJE criteria, only the researcher and advisor would qualify as authors
 - Assuming that they agree to be accountable for the work, they fulfill all 4 conditions of authorship
- All others should be listed in the Acknowledgments section

Why all the fuss?

- In our “publish or perish” world, everyone wants to be an author
- But should everyone be listed?



Sure... Everyone wants the praise



But what about the consequences?



Issues with not meeting authorship criteria

- Who takes responsibility for the data?
 - Who has seen the data and verified that the results are valid?
- Dilutes the meaning of authorship
 - How does one determine someone's contribution to the field?
 - Implications for promotion, etc.

Author Responsibilities

- Originality
- Citations and context
- Conflicts of interest
- IRB and/or clinical trials registration
- Appropriate disclosures
- Authorship
- Ethical conduct
- Consequences
 - Funding bodies, institutions, medical literature



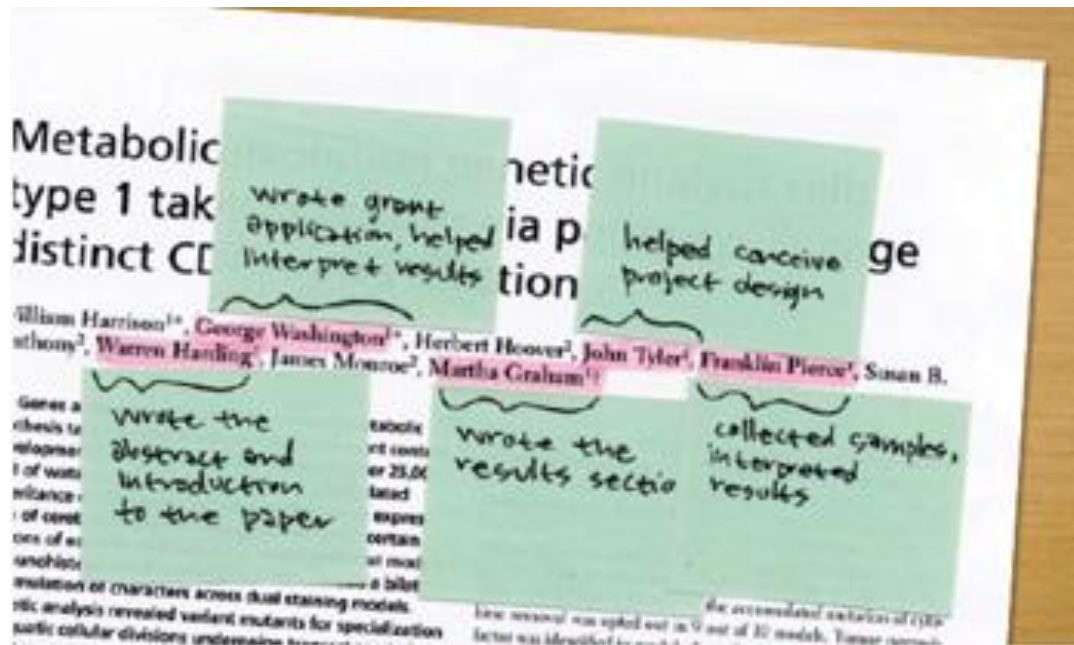
What does not constitute authorship?

- Funding acquisition
- Data collection
- Statistical analysis
- General supervision of research group
- Writing/Editing
- Department Chair



Being inclusive

- If you think that certain people should be authors, you need to make sure that they meet all of the criteria!



Early authorship discussion is key

- Decide who will do what early on
- Create list of who will be listed as an author, in what order, and why
 - Check journal's Guide for Authors



Changing authorship after submission

- Very time consuming and likely will delay decision
 - Explanation of change
 - E-mails from each author usually are required
 - According to COPE flowcharts

Summary

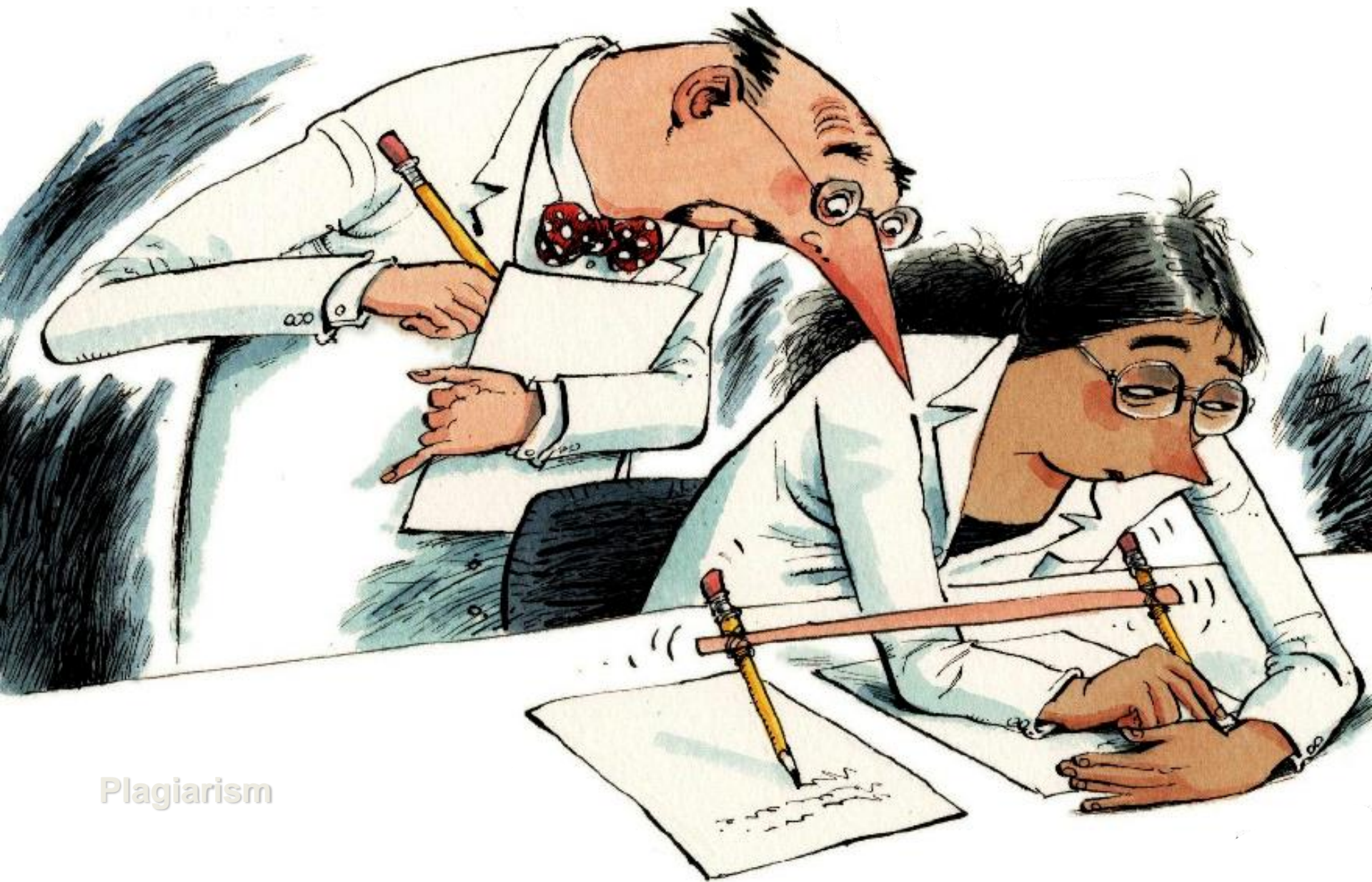
- Discuss authorship early and often
- Make sure all authors fulfill all ICMJE criteria
- Contact journal if changes to author list after submission, including author order
- Disclose in the Acknowledgments anyone who contributed, making sure to include affiliation and conflicts of interest



CASE 2: PLAGIARISM, REDUNDANT PUBLICATIONS, AND SALAMI SLICING

Plagiarism case

- Journal A receives a paper from Author A and sends it out for review
- Reviewer A sends in her review:
 - “I really like this paper. It is very well-written. However, I liked it a whole lot better when I wrote the paper.”



Plagiarism

What Is Plagiarism?

“Plagiarism is the appropriation of another person’s ideas, processes, results, or words without giving appropriate credit”

Office of Research Integrity

<http://ori.hhs.gov/policies>

Accessed April 14, 2009

Tools available for the detection of plagiarism

- iParadigm's "Ithenticate" (www.ithenticate.com)
- "Turn it in's" originality checking (www.turnitin.com)
- CrossRef CrossCheck (www.crossref.org)
- eTBLAST
(<http://etest.vbi.vt.edu/etblast3/>)

The Case of the Redundant Publication(s)

- Journal A published a manuscript analyzing a large national public-use dataset to assess an aspect of quality of care for children from one demographic group versus children from another demographic group (labeled “Comparison A”).
- The dependent variable was the level of quality of care received by children nationally, and the independent variable was “Comparison A” (i.e., one demographic characteristic versus another demographic characteristic).

The Case (con't)

- One year later, the same group of authors submitted a manuscript to the same Journal A analyzing the same dataset, assessing the same dependent variable (quality of care) for subgroups of “vulnerable children.”
- The dependent variable was again the quality of care received by children nationally, and the independent variables were “Comparison A”, as well as 3 other demographic comparisons

The Case (con't)

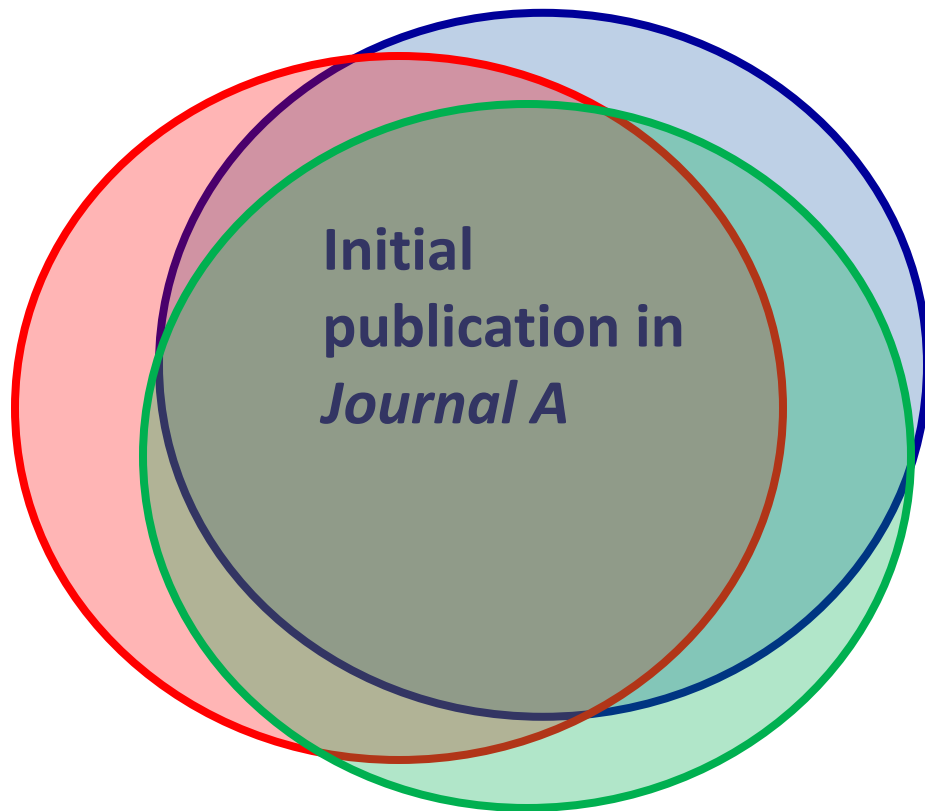
- At the same time, one of the journal's editors had reviewed a paper for Journal B in which the same group of authors analyzed the same dataset, assessing the same dependent variable by “Comparison A” as well as by specific state in the US.
- If you were the editor, what would or should you do?

Ethical Concerns in Publications

- Redundant publications
 - Submitting a manuscript with essentially the same data to more than one journal, usually with a slightly different interpretation, without informing the editors
- Data fragmentation (salami slicing)
 - Submitting two or more manuscripts from the same study in which the data have been cut too thin, and are better presented in a single paper



The Case

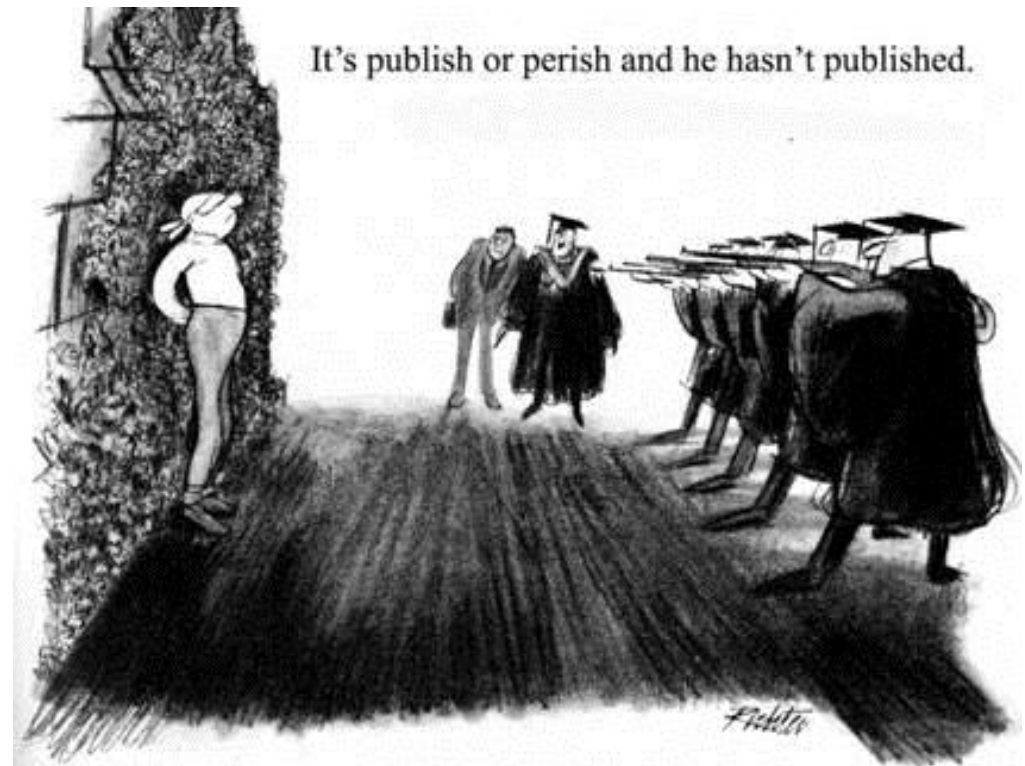


**Second submission to
Journal A:
Salami Slicing**

**Third submission to *Journal B*:
Redundant Publications**

Why do authors submit redundant publications and slice salamis?

- Academic pressure
- Desire to distribute the findings (often new, naïve, exuberant researchers)
- Don't understand the harm



What's the harm from redundant publications or salami slicing?

- Can lead to an exaggeration of the findings
 - Due to multiple publications
 - In systematic reviews
- Wastes resources
 - Journal resources
 - Peer review system
- Distorts the academic reward system
 - Number of publications may not equal the “value” of the work

Why don't editors or journals stop redundant publications and salami slicing?

- Unaware in most cases
- Don't publicize the problem
- Lack a clear definition for both redundant publication and salami slicing
- Generally, there is no punishment when this is discovered



Potential Scenarios

Redundant Publications

- Paper submitted to a pediatric journal and also a journal from another discipline
- Further analyses of data beyond the original paper
- Repeating paper in a non-peer reviewed supplement
- Using the same subjects for different purposes

Salami Slicing

- A survey study with multiple papers presenting findings from different questions that are best combined
- A database analysis in which different independent variables related to a dependent variable are presented as separate papers

Office of Research Integrity, US DHHS

- *“If the results of a single complex study are best presented as a “cohesive” single whole, they should not be partitioned into individual papers...”*
- *“Furthermore, if there is any doubt as to whether a paper submitted for publications represents fragmented data, authors should enclose other papers (published or unpublished) that might be part of the paper under consideration.”*

What journals are doing

- Use software programs to identify duplications
- Identify overlapping manuscripts during the peer review process
- Require authors to disclose all manuscripts submitted, in press, or published from the same study
- Act on suspicious cases
 - Notify authors and the other journal
 - Inform indexing services, funding sources, or author's institution

Guidelines for Authors

- Have frank discussions among the authors about the issue of multiple publications
 - Read the guidelines in journals and the Office of Research Integrity
- Reference all other manuscripts from the same study in the current manuscript, including “in press” articles
- Submit copies of other manuscripts (including those under review and in press)
- Identify the larger study in a specific, unique manner so readers and systematic reviews can identify papers
- Contact the journal editor to discuss the issue

So where do you draw the line?

One or more publications?

- No single rule
- Review the ethical guidelines
- Talk to your coauthors and mentors
- Ask yourself – what would you do if the truth was publicized?





CASE 3: REVIEWER MISCONDUCT?

Study A

- Study A received in December 2011 and sent out for review
- Reviews received and rejected by journal in January 2012

Study B

- Study B similar objectives but more developed than Study A received 1 year later
- Study sent for review
- Study accepted and published.

The call

- The journal editor gets an email from Division director of the 1st author of Study A raising some concerns and wants to talk; does not want to put his concerns in writing.
- Here is the story:
 - Author of Study A feels that her paper is very similar to Study B
 - One of the reviews she received suggested expanding the scope of the study, which is what Study B did
 - She is worried that author of Study B was a reviewer for Study A
 - If so, worried that author of Study B “stole” her idea
- Mentor asks editor to look into it.
- What would you do?

Sleuthing...

- Had Paper A been submitted elsewhere before *this journal*, or presented at meeting?
- Yes!
 - Sent to journal 1 about one year before:
Reviewed by ? and rejected
 - Sent to journal 2: Reviewed by ? and rejected
 - Sent to *journal 3 (this journal)*: Reviewed by **Author B** (and others) and rejected
- What would you do?
- Is it intellectual theft?
- Is it plagiarism?

More data collection

- Called editor of Journal 1: not reviewed by Author B
- Called editor of journal 2:
 - Author B had indeed been one of the reviewers of paper at Journal 2
 - Some concern, although papers were pretty different
 - Very hard to prove that ideas were stolen
 - Editor decided to contact the Author of paper B (and twice reviewer of paper A) to discuss with him

Calling the author-reviewer

- Editor calls Author B
- Explains the situation, careful not to be accusatory
- Author B feels that the papers are pretty different
- He reports that he had been working on this before reviewing Study A; got the initial idea after seeing a paper published in this journal 2 years before

Closing the loop

- Editor called mentor back, and explained findings and thoughts
- Offered to speak with Author A
- She declined
- Mentor was satisfied and thanked the editor for his efforts.

- Respect the confidentiality of peer review and not reveal any details of a manuscript or its review, during or after the peer-review process, beyond those that are released by the journal
- Not use information obtained during the peer-review process for their own or any other person's or organization's advantage, or to disadvantage or discredit others



CASE 4: CONFLICT OF INTEREST?

Is this a conflict of interest?

- A group of authors submits a paper on the effectiveness of Drug A vs. Drug B.
- The paper concludes that Drug B is more effective than Drug A.
- One of the reviewers notes that 2 of the authors are paid consultants and give lectures on behalf of the company that manufactures Drug B.

Is this a conflict of interest?

- You are reviewing the academic portfolio for an assistant professor who has applied for promotion.
- The assistant professor has 4 first-author publications, all in a low-impact journal.
- You have never heard of the journal, so you look it up and discover that this assistant professor's spouse is the editor-in-chief for the journal.

Conflicts of Interest...

...exist when a participant in the peer review process (author, reviewer, and editor)

“...has financial or personal relationships...**that inappropriately influence** (bias) his or her action...”

ICMJE Uniform Requirements (October 2008)

Financial disclosure

(<http://www.councilscienceeditors.org/>)

- All funding sources
 - gov, industry
- All products
 - reagents, equipment
- Financial relationships:
 - employment
 - consultancies
 - stock
 - honoraria, expert testimony
 - patents

Other (non-financial) Competing Interests

- Professional
 - Collaborators/Competitors
 - Ex-employees/Associates
 - Institutional Conflicts
- Conflicts Related to Recognition and Academic Success
 - Tenure and Promotion
 - Grants

Financial or other conflicts of interest

- “Authors should describe the role of the study sponsor” (ICMJE)
- Need not prevent a researcher from doing a study; nor bias the resulting report
- “However, they must be declared at submission; to withhold is to disguise biases“

Rennie, JAMA 266: 266,1991

Failure to Disclose

- Impact is far reaching
- “As editors of general medical journals, we recognize that the publication of clinical-research findings in peer-reviewed journals is the ultimate basis for most treatment decisions”

Davidoff, THE LANCET 358:856, 2001

Failure to Disclose

- Scientific articles that endorse or criticize a product are news; widely publicized
 - Direct impact on product sales
 - Clinical consequences

Impact

- Pfizer withheld data re: adverse drug effects in clinical trials
 - Curfman et al. Comparison of upper GI toxicity of Rofecoxib and Naproxen in patients with rheumatoid arthritis” N Engl J Med 343:1520 & 353:2813, 2005
- Drug was approved, and then there were many reports of side effects
- Drug had to be pulled from market
- Indicates impact of unethical communication of research results on public safety and trust in research

Conclusions

- Think about and discuss authorship early on
- Don't plagiarize others
- Don't plagiarize yourself
- Beware of potential or perceived conflicts of interest
- ASK if you're not sure!!!