Publication Ethics:
Part 5 - Retracted Literature

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Objectives

- Describe the impact of scientific misconduct, including data falsification or fabrication, failure to protect human subjects, and manipulation of data or images
- Describe at least two resources for detecting image manipulation
- Define types of corrections to published articles
- Describe a process for locating retracted literature

"Medical Madoff"*

- Over 12 years Scott Reuben published at least 21 studies on post-op pain in orthopedic surgery that were "pure fiction"
- Ten of those studies have been published in Anesthesia & Analgesia
- Editorial in A&A 2007 stated Rueben was at the "forefront of redesigning pain management protocols" with his "carefully planned" and "meticulously documented" research
- His fabricated data demonstrated that pre-op administration of COX2 inhibitors in combination with gabapentin and pregabalin were better at reducing post-op pain than first generation NSAIDs and less dangerous than narcotics

*http://www.scientificamerican.com
Latest Misconduct Case in the News*

Institutional and editorial misconduct in the MMR scare

Fiona Godlee, editor, BMJ

This week, in the last of his series of three articles on the secrets of the MMR scare (doi:10.1136/bmj.c7001), Brian Deer describes the events of 2004 when he first raised concerns about Andrew Wakefield’s research with the Lancet’s editor. Rather than calling for an investigation as Deer had expected, Richard Horton moved quickly—with Wakefield, his co-authors, and their former institution—to publicly deny all but one of Deer’s allegations. Six years later, at an estimated cost of £6m, the General Medical Council found all the allegations to be true.


Impact of Scientific Misconduct*

- 35,929 patients enrolled in 58 secondary studies before retraction
- Primary study cited a total of 581 times
- Primary study cited in 173 review articles (one was published in JAANP in 2009)
- 263 patients treated in the COOPERATE study (Nakao et al) published 2003

*Steer, RG. 2011 Journal of Medical Ethics; DOI:10.1136/jme.2011.043133

Possible Data Fabrication (COPE Case 01-08)

- A manuscript was received from a group of authors who had not submitted to the journal in question before. The review was extremely critical and the paper was rejected. In a covering letter the reviewer said that not only was the experimental design flawed, but he was also convinced that the experiment described had never been done. He had scanned Medline 1997–2001 and found seven other papers with the same first author each of which had a similar protocol, but in each case had used a different nutritional supplement. All the studies had been conducted on groups of 40 subjects who were given either a supplement or control substance over a period of one year. This implied that the authors had recruited over 300 subjects for these studies, which was hard to believe. The entry criteria for the study meant that the pool of eligible subjects was small, and the protocol was rigorous, not to say unethical, so it would have been difficult to have obtained informed consent.

- Should the other articles and/or the authors be investigated?
Image or Data Manipulation

- Intent is to give a false impression of the results of a study
- Images (micrographs, gels, radiological images) can be manipulated by enhancing or by simple reversal (turn one image upside down or backwards)
- Forensic tools available at http://ori.hhs.gov/tools/
- Results can be manipulated by removing outliers or changing data points
- Any such changes must be clearly explained in the text
- Careful manuscript preparation (using table features and protecting document images) can prevent some of these problems if they are unintended

Correcting the Literature

- An erratum is a correction of an error not sufficient to cause any change in the interpretation of the work
- A corrigendum is a correction of errors of greater significance that might cause a reinterpretation of the work
- A statement of concern is a notice made by the publisher that there may be a problem with the work and it is currently under investigation
- A retraction is a statement by the publisher that “removes” the work from the scientific record
- All are permanently linked to the involved article
This Erratum is a Corrigendum

Expression of Concern

Where are all the retracted articles?
- They remain in the journals (print and online)
- Authors must consider corrections, errata, and retractions when doing literature review
Finding retracted articles

- Guidelines from the International Council of Medical Journal Editors now require that authors verify they have not cited retracted articles "except in the context of the retraction"
- This adds one last step to your process before submission

Check each reference in Medline for retraction
Publication and Scientific Misconduct are Serious Issues

- Not worth the consequences
- If (when) you are caught, your reputation will be ruined
- You could be investigated by Office of Research Integrity
- You could face jail time
- You could be fined
- You could lose your professional license to practice
- Your degree could be revoked

Summary

- Hold students and colleagues accountable for their work
- Scrupulously follow ethical guidelines for the conduct of research
- Report suspected scientific misconduct
- Assure that any images used in publications are not enhanced or falsified in any way
- Do not base conclusions on retracted material