

# Ethical Issues in Medical and Scientific Publishing

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There are known knowns. These are things we know that we know. There are known unknowns. That is to say, there are things that we know we don't know. But there are also unknown unknowns. There are things we don't know we don't know. (*Ref: Someone, Somewhere, Someday!!!*)

# How big is the challenge?

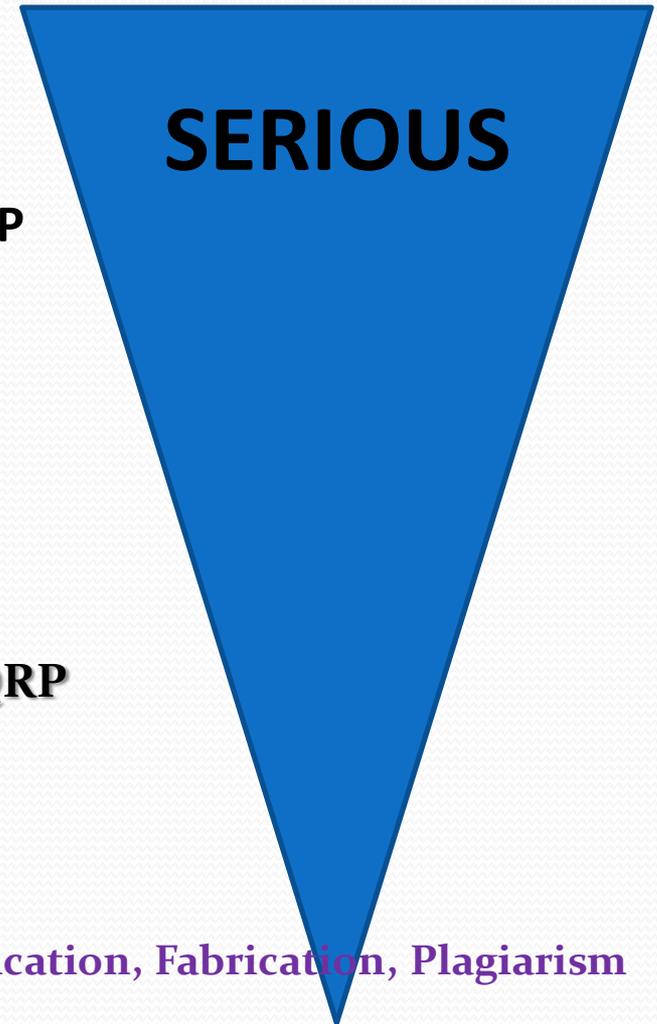


# Types of Scientific Misconduct

- Fabrication of data or cases
- Willful falsification of data
- Plagiarism
- No ethics approval
- Not admitting missing data
- Ignoring outliers
- No data on side effects
- Gift authorship
- Redundant publication
- Inadequate literature search

FFP

QRP



QRP= Questionable Research Practice; FFP = Falsification, Fabrication, Plagiarism

# How Big is the Problem?!



Up to **200,000 of 17 million** articles in Medline database may be duplicates, or plagiarized!!!

*Errami & Garner. Nature 451, 397-399 (2008)*

# Patient Safety and Privacy

- Ethics Committee Approval
  - Where does clinical practice end and research begin?
  - Are standards the same for public institutions vs. private practices?

# Patient Safety and Privacy (cont.)

- **Patient informed consent**
  - “Nothing about me without me”
  - Do patients understand whether or not they will be identified?
  - Do patients understand how their data will be used in research?
  - Do patients understand the associated benefits and risks?
  - What about research in children, mentally disabled, or in different cultural settings?

# Authorship

- Who qualifies?
- Is order important?
- How to solve unusual circumstances?
- How to avoid authorship misuse?
- “Publication is not the end, but the beginning...”

# Authorship Criteria

- **Vancouver guideline** states that an author **MUST**:
  - **Substantially contribute** to study conception and design, data acquisition, analysis
  - and interpretation
  - **Draft or revise** the article for intellectual content
  - **Approve** the final version
- An author must participate in **ALL three steps**

# Authorship order

- Authors are ranked in order of magnitudes of their **input** into the research
- **First Author**
  - Conducts and/or supervises the data analysis and the proper
  - Presents and interprets the results
  - Puts paper together and submits the paper to journal

# Authorship Order (cont.)

- Co-Author(s);
  - Makes **intellectual contributions** to the data analysis and contributes to data interpretation
  - **Reviews each paper draft**
  - **Must** be able to present the results, defend the implications and discuss study limitations

# Authorship Unusual Circumstances

## Authorship Contributors

- What about people who contribute significantly but do not meet all three criteria and what about large multi-center studies?
  - Two new categories: Contributors & Acknowledged Individuals
- When author number exceeds a specified threshold:
  - Contribution instead of authorship

# Authorship Unusual Circumstances

## Authorship Contributors

- Multicenter trials
  - List of clinicians and study-organizations
  - A statement of the contribution of each individual

# Authorship

## Acknowledged individuals

- Staff who made a direct contribution to a study but did not fulfill the criteria for authorship:
  - General support
  - Technical help
  - Statistical, graphics
  - Library support
  - Critical review of the paper drafts

# Authorship Misuse

- Gift (guest) authors
  - Confer a stamp of authority
  - No intellectual contribution
- Ghost (omitted) authors
  - Neglected authors who made major contributions
  - Professional (paid) writers
- ***Both to be avoided at all costs***

# Conflict of Interest



# Conflict of Interest

- Conflict of interest exists when an author (or the author's institution), reviewer, or editor has **financial** or **non-financial (personal) relationships** that inappropriately influence (bias) his or her actions (such relationships are also known as *dual commitments, competing interests, or competing loyalties*).
- These relationships vary from being negligible to having great potential for influencing judgment.
- **Not all relationships** represent true conflict of interest.

# How Should I Say it?

- *Conflict of Interest: None.*
- *The authors have no conflict of interest to declare.*
- *None of the authors have conflict of interest related to the information described in this paper*
- *The following authors have conflict of interest:...*

