ETHICAL WRITING

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It is about writing.

Research ethics are paramount:

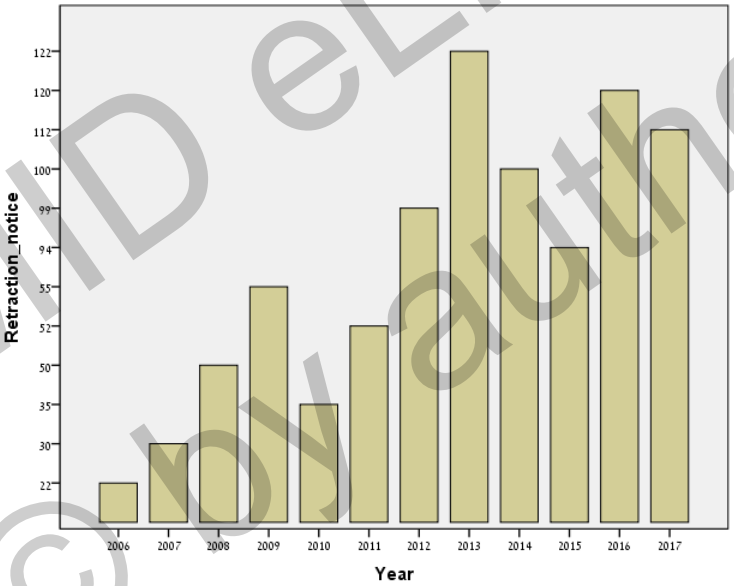
- Assure participants' safety.
- Assure participants' autonomy.

Not ethical (writing ethics):

- Fabricated data.
- Plagiarism.
- Undeclared conflicts of interest
- Multiple publications from the same database when there's no reason to do that.
  - As an example: publications from large databases
- Biased reporting of results.
- Authorship problems

Fabricated data: difficult to identify by peer-reviewers or editors

- Retraction notices in PUBMED by year:



Fabricated data: how to identify them? One case:

- 1992: Ram B Singh: Randomised controlled trial on the effects of dietary intervention to prevent further heart attacks in susceptible patients; BMJ.
- Cited over the years by 350 other publications.
- Expression of concern. BMJ 2005;331:266: "… we have reasonable grounds to doubt the validity of the 1992 paper…"

White C. Suspected research fraud: difficulties of getting at the truth. BMJ 2005;331:281-8.

Fabricated data: how to identify them? One case (2):

- Dr Singh:
  - first author on 28 full articles between 1989 and 1993
  - published five large intervention trials within 18 months.
  - Peer-reviewer: “…extraordinarily impressive nature of some of these results…”
  - Similarity of groups of patients from the same years described in different publications, different interventions
  - Original records are not available: “…records had been eaten by termites…”

Fabricated data: how to identify them?

- Ask for the original data: outliers, overdispersion, underdispersion and correlations or lack of it.
- Compare to what is known from the literature
- Baseline variables: too similar or too different and different than expected?
- Last digit preference when none is expected

Many times not an one-time offence.

Fabricated data: how to identify them?: references

- Pogue JM, Devereaux PJ, Thorlund K, Yusuf S. Central statistical monitoring: detecting fraud in clinical trials. Clin Trials. 2013 Apr;10(2):225-35.

- Al-Marzouki S, Evans S, Marshall T, Roberts I. Are these data real? Statistical methods for the detection of data fabrication in clinical trials. BMJ. 2005 Jul 30;331(7511):267-70.

- Buyse M, George SL, Evans S, Geller NL, Ranstam J, Scherrer B, Lesaffre E, Murray G, Edler L, Hutton J, Colton T, Lachenbruch P, Verma BL. The role of biostatistics in the prevention, detection and treatment of fraud in clinical trials. Stat Med. 1999 Dec 30;18(24):3435-51.

- Mascha EJ, Vetter TR, Pittet JF. An Appraisal of the Carlisle-Stouffer-Fisher Method for Assessing Study Data Integrity and Fraud. Anesth Analg. 2017 Oct;125(4):1381-1385.

Suspicion of fabricated data: what to do about it?

- Peer reviewers and editors can raise the suspicion and check for inconsistencies, but cannot fully investigate or obtain proof.
- Address the person in charge (dean, rector, hospital manager) of the institution in the affiliation.
- What if difficult to find, no response, or non existent?

Plagiarism

- Most journals are checking automatically online for plagiarism.
- OK to quote directly if identified as a direct quote.
- Text recycling: copying from your own published articles, especially in the Methods.
- A nice turn of phrase copied by young people who are not English speakers.

Undeclared conflicts of interest

- Assessment of Conflicts of Interest in Robotic Surgical Studies: Ann Surg. 2017 Jul 11. [Epub ahead of print]
  - Studies that had undeclared payments were more likely to recommend robotic surgery compared with those that declared funding (odds ratio 4.29, 95% confidence interval 2.55-7.21).

- Ask for disclosure. And when disclosed?
  - A clearer answer for guidelines, position papers, reviews.
  - Original research?

Multiple publications from the same database: thin slices: Studies from the National Health Insurance Research Database in Taiwan

Article's title
Herpes zoster is associated with prior statin use: A population-based case-control study.
Statins can increase the risk of herpes zoster infection in Asia.
Balanitis is a risk factor for herpes zoster.
Increased Risk of Herpes Zoster in Diabetic Patients Comorbid with Coronary Artery Disease and Microvascular Disorders: A Population-Based Study in Taiwan.
High Risk of Herpes Zoster among Patients with Advance Acute Kidney Injury–A Population-Based Study.
High Prevalence of Herpes Zoster in Patients With Depression.
Increased Risk of Herpes Zoster Following Dermatomyositis and Polymyositis: A Nationwide Population-Based Cohort Study.
Increased incidence of herpes zoster and postherpetic neuralgia in adult patients following traumatic brain injury: a nationwide population-based study in Taiwan.
Short-term dipeptidyl peptidase-4 inhibitor use increases the risk of herpes zoster infection in Asian patients with diabetes.

Multiple publications from the same database: thin slices: Studies from the National Health Insurance Research Database in Taiwan (2)

Article's title
Association between herpes zoster and alopecia areata: A population-based study.
Dyshidrosis is a risk factor for herpes zoster.
Increased risk of varicella zoster virus infection in inflammatory bowel disease in an Asian population: a nationwide population-based cohort study.
Increased incidence of herpes zoster in adult patients with peptic ulcer disease: a population-based cohort study.
Asthma status is an independent risk factor for herpes zoster in children: a population-based cohort study
Adult asthma is associated with an increased risk of herpes zoster: A population-based cohort study
Increased risk of herpes zoster in children with cancer: A nationwide population-based cohort study
No increased risk of herpes zoster found in cirrhotic patients: a nationwide population-based study in Taiwan.
Association between herpes zoster and end stage renal disease entrance in chronic kidney disease patients: a population-based cohort study.

Multiple publications from the same database: thin slices: Studies from the National Health Insurance Research Database in Taiwan (3)

Article's title
Increased risk of chronic fatigue syndrome following herpes zoster: a population-based study.
Herpes zoster infection associated with acute coronary syndrome: a population-based retrospective cohort study.
Herpes zoster and subsequent risk of cancer: a population-based study.
Herpes zoster is associated with an increased risk of subsequent lymphoid malignancies-A nationwide population-based matched-control study in Taiwan.
Herpes Zoster Is Associated with An Increased Risk of Subsequent Lymphoid Malignancies—A Population-Based Matched-Control Study in Taiwan.
Herpes zoster correlates with pyogenic liver abscesses in Taiwan
Herpes zoster infection increases the risk of peripheral arterial disease: A nationwide cohort study
Herpes zoster as a risk factor for osteoporosis: A 15-year nationwide population-based study
Risk of depressive disorder among patients with herpes zoster: a nationwide population-based prospective study.

Defenses for editors and peer-reviewers: Ask the author:

- Have you published other risk factors for the same affliction from the same (or similar) database?
- Are these risk-factors taken into account in the present analysis, and your analysis proper adjusted for multiple comparisons?
- Have you included in your analysis strong risk factors and confounders that were found in studies other than yours?
- Do you guarantee that no other risk factors for the same disease will be published from your database?
- Have you published (or do you plan to publish) the association of this risk factor with other diseases?

Multiple publications from the same database

- Not always a bad thing: there are good reasons to do that.
- Be sure to quote every publication that issued from the same database.

Avoid biased reporting of results:

- Distinguish between statistical and clinical significance.
- Be clear about the flow of patients/observations in the study.
- Always report actual numbers and not only p values or ORs or RRs.
- Always give numerator and denominator for rates or percentages.
- Don’t manipulate illustrations.
- For life-table analysis, report the number of patients available at the beginning of each time interval.
- Report on missing data and what did you do about it.
- Avoid over-fitting in multivariable analysis.
- Detailed reporting of multivariable analysis.

Thank you