



# Ethics, Transparency and Independency in Scientific Publications. An Appeal to the International Community

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## Opinion

The Editor of the Millennium Issue of the Archives of Dermatology asked few opinion leaders to assess the state of the Art of our Discipline and to envision future developments. On January 1<sup>st</sup> 2000, Volume 136, N. 1 of the JAMA Dermatology was available for saluting the New Millennium. I contributed with a page entitled “The Renaissance of Dermatology: selected concepts beyond the skin” in which I tried to identify the “Diseases of Dermatology” and, more in general, the “Disease of Science” possibly bringing to illnesses pandemics and even death of our Discipline.<sup>1</sup> One of my main concerns was the reliability of the results of the double blind randomized clinical trials i.e. touching bases of the Evidence-Based Medicine (EBM), Good Clinical Practice and Ethics in Scientific Publication and Ethics, Transparency and Independency of Scientific Publications.

### Pseudoscience and science: who are you?

Karl Popper first identified the “Demarcation Problem” between pseudo and non-pseudo-science. Popper declared “falsifiability” the ultimate criterion of demarcation. Accordingly, Freud’s theories would never be disapproved because there was no chance of falsifiability considering that there was no Freudien testable hypothesis open to refutability. Michael Gordin in his wonderful “The Pseudoscience Wars” published in 2012 by University of Chicago (IL) Press stated that “no one in the history of the world has ever self-identified as a pseudoscientist”. Science is the understanding of the natural and social world following a systematic scientific methodology based on evidence.

Scientific Methodology is based on the following:

1. Objective observation

2. Evidence
3. Repetition always available
4. Experimental observation for testing hypotheses
5. Conclusions based on the experimental evidence
6. Critical analysis for verification
7. Critical exposure to scrutiny, peer review and assessment

I proudly confess to be part of the “Family of Science” and to spurn, to disdain and to loathe pseudoscience.

The sight or the smell of pseudoscience makes me sick. I’m not alone. According to Michael Gordin “no one in the history of the world has ever self-identified as a pseudoscientist”. We all are scientists or at least we think so.

### Evidence based medicine: the kingdom of science, the victory of ethics

In the Biomedical field EBM always brings the publication of data according to points 1-7 of the above paragraph. If this paradigm is infringed, pseudoscience and science will not be clearly demarcated i.e., they will not be demarcated at all.

### Limitations of EBM: philosophical and practical

In 1982<sup>2</sup> Tonelli commented that “under the current understanding of EBM, the individuality of patients tends to be devaluated, the focus of clinical practice is subtly shifted away from the core of individuals toward the core of population, and the complex nature of sound clinical judgement is not fully appreciated”. In 2015 George & Buyse<sup>3</sup> published an interesting article entitled “Data

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**Received:** 18 January, 2021

**Published:** 25 January, 2021

**Citation:** Torello Lotti. Ethics, Transparency and Independency in Scientific Publications. An Appeal to the International Community. *Derma Cosm Int J.* 2021;1(1):1–4. DOI: [10.53902/DCIJ.2021.01.000501](https://doi.org/10.53902/DCIJ.2021.01.000501)

fraud of clinical trials” describing some deviations from the principles of honesty and truthfulness of scientific research and publications. They reported about some prominent cases and exactly described the most common and dangerous example of fraud: the statistical fraud. On June 15<sup>th</sup> 2020 at 11.01 am the University of Illinois Board of Trustees published online Types of Bias of the Evidence - Based Medicine. Hereunder is the list of the Types of Bias;

- A. Publication bias - How similar are results from published versus unpublished studies? Watch for:
  - 1) Incomplete or selective reporting of outcomes
  - 2) Arbitrary limits such as language or choice of resources
- B. Truncation bias - Study is published in a briefer form with less details
- C. Time-lag bias - Delayed publication of findings
- D. Language bias - More likely to be published in English
- E. Citation Bias - Citation/non-citation of research findings
- F. Selective outcome reporting bias - Selective reporting of some outcomes but not others
- G. Location bias - Journals with different ease of access/levels of indexing in standard databases
- H. Multiple (duplicate) publications
- I. Database bias - Some databases are more likely to index certain languages/journals

Look at the source: Rothstein DHR, Sutton DAJ & Borenstein DM in 2006. Publication Bias in Meta-Analysis. Publication Bias in Meta-Analysis (pp. 1-7) doi: 10.1002/0470870168.ch1). For us who strictly adhere to the philosophy and practice of EBM this document is “croce e delizia”. Each and every night before sleeping with Angels we should read it and pray for the Authors of fraudulent studies who put patients and population at risk.

### The most dangerous EBM fraud: the statistical fraud

According to George & Buyse the death of EBM publications is based on the publication of clinical trials with statistical errors. In 2019 Karadeniz et al published an interesting paper entitled “Statistical errors in articles published in Radiology Journals”.<sup>4</sup> Authors evaluated 157 articles reviewed randomly and published in the years 2016-2017. Journals under evaluation were all indexed in the Science Citation Index or in Science Citation Index Expanded. Of the 157 articles published only 10 papers had no statistical errors while 147 had at least one significant statistical error. Interestingly there was no statistically significant difference according to Impact Factors of Scientific Journals. Reading the 35 papers and book chapters listed in the references of this manuscript it will be evident that each and every clinical investigation in different disciplines are subject to the same curse: we are continuously drowned by excellent papers published in excellent Journals which bring totally misleading EBM information to the Scientific Community.

### Ethics in scientific publication

Too many papers have been published about the Ethics in Scientific Publication. One could hypothesize that such excellent educational papers may represent the source of malicious inclinations of fraudulent Authors in nuce. The keywords of all these ethical papers will be: “editorial misconduct, retraction, scientific misconduct, editors, journals, peer review, study design, errors, statistical analysis, documentation, presentation, interpretation etc, etc, etc.” Here we are: Evidence Based Medicine is sick and EBM products are terribly ill. Will EBM and related products survive?

### Retractions

On December 15, 2020 The Scientist reported in its “Retraction Watch” the Top Retractions of 2020.<sup>5,6</sup> As 2020 was the year of the pandemic, COVID-19 loomed large in the world of retractions, too. According to our tracker in early December, 39 articles about the novel coronavirus have been retracted from preprint servers or peer-reviewed journals so far—a number we’re confident will grow. (That number does not include the retraction of an article from a Johns Hopkins student newspaper claiming that COVID-19 has had “relatively no effect on deaths in the United States.”) That’s out of a total of more than 1,650 retractions catalogued to date in 2020. Here are our picks for the most significant pandemic-related retractions:

1. The most spectacular flameouts involved a pair of articles that appeared in two of the world’s most prestigious medical journals. Both the Lancet and The New England Journal of Medicine were forced to remove articles that relied on data from a questionable firm called Surgisphere, which refused to share its results with co-authors and the editors involved. (The Lancet also retracted and replaced an editorial it had published that had cited the ill-fated paper.) Before it was discredited, the paper in The Lancet had tremendous influence, leading to the suspension of clinical trials on hydroxychloroquine. A third, influential Surgisphere study was taken down from the SSRN server at the request of a co-author. The withdrawal of the preprint, which was about potential benefits of the antiparasitic drug ivermectin, received little fanfare, let alone a retraction notice.
2. Although the Lancet article’s conclusions on hydroxychloroquine were ultimately disregarded, numerous studies to follow determined that the drug is ineffective against COVID-19. The dubious therapy, which President Donald Trump boasted of having taken, was also the subject of this preprint, which was withdrawn in May—but not before the Fox TV personality Laura Ingraham touted the study, as did Didier Raoult, the French scientist whose work with hydroxy early in the pandemic sparked widespread, if misguided, optimism about its use. A version of the paper that relied much less heavily on hydroxychloroquine in its conclusions was published in October in a special issue of a journal that Raoult edited. (So far, none of Raoult’s papers on the drug have been retracted, although an Elsevier-commissioned review of one of them found it to have “major methodological shortcomings” and be “fully irresponsi-

ble.” He did have an obviously unrelated 2013 paper retracted this year from PLOS ONE for suspicious images.)

3. Hydroxychloroquine also was at the heart of a clever “sting” operation by a pair of researchers in Europe who were alarmed by what they believed to be predatory behavior by the Asian Journal of Medicine and Health (AJMH), which had published a roundly criticized paper heralding the drug. They published a sham paper in the AJMH purporting to find that the SARS-CoV-2 virus was “unexpectedly deadlier than push-scooters,” and that hydroxychloroquine might be the “unique solution.” The journal reacted indignantly to being called out, retracting the hoax article, but left the initial paper intact—which was fine with the jokesters, one of whom told us, “yes the article deserves to be withdrawn—but it should NEVER have been published in the first place, that’s the beauty of the story.”

4. The same week as the Lancet and NEJM Surgisphere retractions, the Annals of Internal Medicine backtracked on a highly-cited paper it published in April that purported to find that masks were ineffective at preventing the spread of SARS-CoV-2. The article, which became a media—and social media—star, was woefully light on data, based in fact on just four subjects.

5. If lack of data was a problem for some papers, others suffered from a complete lack of common sense. Like this article, which claimed that COVID-19 resulted from 5G telecom energy. The quickly retracted paper earned the title of the “worst paper of 2020” from data-sleuth Elisabeth Bik.

6. In the category of “not retracted but should never have been published,” we’ll offer up this book chapter, which claims that the virus behind the COVID-19 pandemic hitched a ride to Earth on a meteorite.

7. Sticking with fantastical thinking, Science of the Total Environment must have been in that headspace when it published this paper claiming that wearing amulets could ward off COVID-19 (pro tip: they don’t). After an uproar on Twitter, the co-authors of the article called for its retraction, although the journal has yet to definitively remove—or replace—the work.

8. PLOS ONE issued an expression of concern for a paper it published in September suggesting that vitamin D might protect against severe COVID-19. The move came after criticism on Twitter by Gideon Meyerowitz-Katz, an epidemiologist in Sydney who pointed out, among other issues, that the study relied on a small number of patients and appeared to show a null result.

9. After a preprint they relied on for epidemiological data from China was withdrawn, researchers at Imperial College London corrected a paper that, in the words of The Washington Post, “helped upend U.S. and U.K. coronavirus strategies.” The study projected that COVID-19 would kill half a million people in the UK, and more than 2 million in the US, if restrictions were not put into place, which prompted the UK government

to implement social distancing and isolation measures. The authors told us they were confident that data available later had affirmed their overall findings.

10. Cellular & Molecular Immunology took three days to accept a paper about how COVID-19 might infect white blood cells—similar to HIV’s strategy—and then took three months to retract it after a researcher sent them a letter critiquing the study. The critic, Leonardo Ferreira, tweeted that “no primary #human #Tcells were used & the #flowcytometry data for #viral #infection was egregiously misinterpreted.” In the time before it was retracted, according to Altmetric, it earned coverage in New York magazine and other mainstream outlets, and was the subject of thousands of tweets.

### It wasn’t all COVID-19

1. Some journals used 2020 to purge what readers perceived to be offensive articles. In June, the venerable German title *Angewandte Chemie* retracted (without saying as much, until later) an essay by Brock University researcher Tomáš Hudlický, which lamented efforts to diversify his field. Sixteen members of the journal’s editorial board resigned in protest, and two were suspended.

2. The Journal of Vascular Surgery found itself in hot water after publishing an article arguing that physicians who posted pictures of themselves in casual clothes or bathing suits were acting in a “potentially unprofessional” manner. The essay, panned as out of touch and misogynistic, triggered the #med-bikini movement on Twitter—and, eventually, an apology from the journal.

3. Among the authors of the 5G–COVID-19 paper was Massimo Fioranelli, whose name also appeared on five other now-retracted articles in a special issue of the Open Access Macedonian Journal of Medical Sciences devoted to global dermatology. One of those asserted that “A black hole at the center of earth plays the role of the biggest system of telecommunication for connecting DNAs, dark DNAs and molecules of water on 4+N-dimensional manifold.”

4. One notable case was that of Jonathan Pruitt, a scientist in Canada who studies the sociology of spiders. Earlier this year, one of Pruitt’s co-authors became concerned about the veracity of his data, setting off an investigation that has led to eight retractions and counting.

5. The Pruitt case was one of at least a few examples in which affected scientists publicized their retractions widely, in a refreshing move. “I’m starting the year off with something I didn’t expect to ever do: I’m retracting a paper,” Kate Laskowski, a Pruitt co-author, announced on her blog. And Nobel Prize winner Frances Arnold of Caltech announced a retraction from Science before the retraction notice was even published.

The Top Retractions involve prestigious medical journals like The Lancet, The New England Journal of Medicine, The Cellular & Molecular Immunology and others. The Scientist Retraction Watch

offers some possible explanations of this debacle of EBM and Ethics in Scientific Publication. Some comments are frightening, more or less. Actually, in 2020 more than 1650 excellent retractions have been done.

### My humble retractions and my grandson question

I was lucky enough to get some papers consigned by me which were retracted in the same year 2020. They are discussing issues like "5g Technology and induction of Coronavirus in skin cells", "A Black Hole at the Center of Earth" etc.<sup>7,8</sup> My family is a traditional Italian family whose members love to meet around the table for the Sunday lunch. It's a priceless tradition. In my family there are scientists of high caliber and scientific credibility. They discussed about "my retractions" in a very funny way: they know me. They all were formed on the ethical principles and on the doubts which I described in the JAMA paper of the Millennium Issue. My grandson (5 years old) asked me directly: "why did you get your paper retracted?" I was laughing and one of my family members answered "ut scandala eveniant". Another member commented "life is a cabaret". My granddaughter stated "stop all these unless comments". 137 Universities, Journals, Tv, Bloggers etc. invited me for an interview about the content of the retracted papers. I didn't discuss about contents but about EBM, Ethics and mandatory Editorial scandals.

### Conclusion

Ethics, Transparency and Independency in Scientific Publications are suffering of a severe chronic-relapsing disease of science which will be solved by science only "if scandala eveniant". A Big scandal, I mean, will be the only way to restore Ethics in research and in Editorial processes.

### Acknowledgments

None.

### Funding

None.

### Conflicts of interest

Author declares that there is no conflict of interest.

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