Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

European Journal of Obstetrics & Gynecology and Reproductive Biology 249 (2020) 70–71

Contents lists available at ScienceDirect

European Journal of Obstetrics & Gynecology and Reproductive Biology

journal homepage: www.elsevier.com/locate/ejogrb

Editorial

Fabricated data – should we quarantine? A novel tool for risk assessment is proposed

ARTICLE INFO

Article history:
Received 2 April 2020

Keywords:
Fabricated data
Fraudulent data
Risk assessment tool
Quarantine

In this issue of this Journal, I am publishing a fast track paper submitted by Bordewijk et al. [1]. It raises a significant and worrying issue surrounding data integrity, particularly from randomised control trials. A careful and systematic analysis of 35 trials published by Badawy and Abu Hashim over a 10 year period indicates that their data was unlikely to have derived from real recruited patients.

I raised the suspicion of potential fraudulent papers being submitted to EJOG at the annual EJOG Editorial Board meeting in September 2017, and thereafter at every subsequent annual Board meeting. A common risk identification was when randomised control trial manuscripts were submitted to our Journal within days of completing recruitment. In some instances two papers from the same Institution were submitted to our Journal and by chance only it was identified that the same cohort of patients had been recruited in the same time period for the two trials. On occasion the ethics approval letter was post-dated after completion of the trial. Therefore, the identification of such risk papers was a chance finding and not necessarily identified by the peer review process.

In my opinion, I estimate that up to 20% of published papers in the world literature are likely to fall into this fabricated fraudulent risk category. This may not be a unique issue restricted to our own specialty, as originally highlighted by Carlisle & Loadsman [2], or indeed in non-medical disciplines such as building engineering (Jorge De Brito, Editor-in-Chief, Journal Building Engineering, personal communication). Another way of identifying the scale of the problem might be to assess the number of authors who fail to comply to a request for their original data for IPD analysis [3].

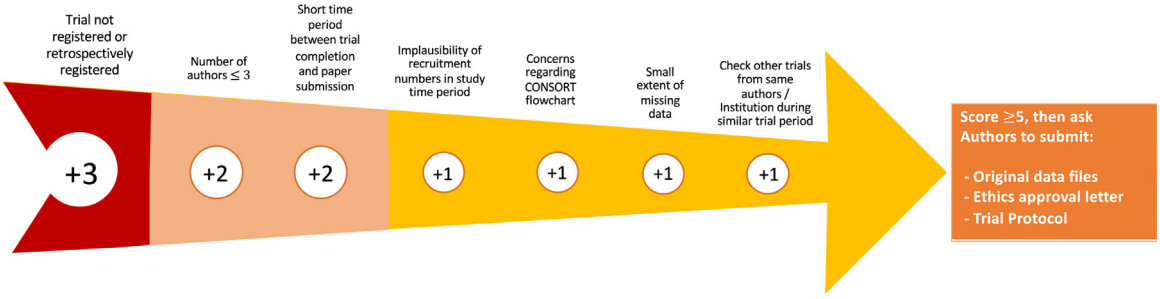
In cases of suspected fabricated data, Journal editors are expected to follow COPE guidelines (https://publicationethics.org/files/Fabricated%20data%20A.pdf). We have followed such templates but in most instances authors do not respond nor do their institutions, resulting in our Journal rejecting the paper. This led to some papers being published in other Journals, which still resulted in fraudulent data being meta-analysed and informing clinical guidelines that alter clinical practice.

Unfortunately COPE guidelines do not allow authors or institutions to be black listed. Publishers also have an ethics code that do not allow sharing of information with other Editors in Chief or Journals unless it is under extreme circumstances under strict guidelines for legal reasons (privacy and confidentiality). This means that as Journal editors we are restricted in stopping any suspicious or fraudulent data from being published.

An alternative approach is to retract papers after publication, which we have done at EJOG [4]. Such an approach means (permanently) quarantining fabricated data by the process of tombstoning suspicious papers, a process most of us are now akin to in the current COVID-19 pandemic. We should regard all fabricated data as virulent and fatal. This process can be long-winded and take months or years to complete, but does protect the integrity of future clinical guidelines. Is it not our duty to protect patients and therefore undertake such drastic measures against Publishers and COPE guidelines and restrictions?

It is a matter of urgency that all Editors of all Journals collectively become vigilant and aware of potential ‘at risk’ papers. A quick risk scoring tool such as the one proposed below should be used to identify suspicious papers and the need to request for further information:

https://doi.org/10.1016/j.ejogrb.2020.04.020



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Received 2 April 2020