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Fraud in anaesthetic research and publication

“Most people say that it is the intellect which makes a great scientist. They are wrong; it is character”.

– Albert Einstein

Dr. Praveen Neema wrote in his editorial, “Generation of new knowledge is not an everyday affair”.^[1] The world of Medicine is strongly moving away from opinion-based medical practice to evidence-based medical practice. Evidence-based medicine comes with a strong scientific foundation for clinical work, reproducibility, quality and safety in medical practice and can decide between “Good and not so Good” clinical practice. Independent clinical research advances disease treatments and improves the lives of patients. Research in Medicine is a necessity to know the truth and to gain knowledge. Naturally, the researcher always has the desire to be recognized as the leader. Ronald Miller observed that anaesthesiology may be in danger of becoming a “trade union” of technicians unless there is a continual rejuvenation and development of new clinically relevant knowledge.^[2] The unfortunate linking of career enhancement of faculty members to the philosophy of “Publish or Perish” is pushing the fence-sitters towards committing fraud. A few investigators do not even hesitate to perpetrate fraud on the community for reputational gain or other cheap reasons like industrial incentives.

The time has come where scientific researchers can no longer afford to ignore a wide range of egregious misuse of their responsibilities, which can threaten the very basic integrity of science. Such practices are abhorrent to the civilized society. Fraud in science and medicine has been going on for a very long time, with some breathtaking examples – so many, that you could write a book about it.^[3] Fraud is a disastrous phenomenon that has reached the anaesthesia community as well.

Scientific misconduct is the violation of the standard codes of scholarly conduct and ethical behaviour in professional scientific research. It is the “Intention or gross negligence leading to fabrication of the scientific message or a false credit or emphasis given to a scientist”. Fraud is detected because of the simple rule of science. The self-corrective nature of science is cold comfort, and it is good to know that science can detect fraud even if it does take too long. The words “scientifically tested” or “scientifically proven” carry most sacred feelings in the community. Hence, scientific fraud damages public trust in science and in scientists.

We know that only those scientists detected while committing a fraud are fraudsters, but we do not know how many of them go undetected. Because a heavy focus on fraudsters may conveniently divert our attention from the fraudster within us all.^[4] Examples of fraud include violation of ethical standards, plagiarism, undeclared conflicts of interest, issues of authorship, ghostwriting, duplicate publication, claiming to have performed a pioneering operation and making up enough clinical trial data or fabricating data to get papers published in prestigious journals. In addition, even suppression of information or the failure to publish those significant findings that are adverse to the interests of the researcher himself or sponsors also amounts to misconduct and fraud. A study has even revealed that over one-fifth of the authors of all published studies in medical journals have performed little or nothing at all as real contributors. Conflict of interest is declared in only a few of the sponsored studies.

There is pressure on the scientists to publish, but they are inadequately trained in the methodology of research, ethics and good practice. Because the system of publication works on trust, we tend to get a feeling

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that you can get away with anything. "As most liars know – and the rest will learn – the more involved and complicated a lie becomes, the harder it is to keep from getting caught"; simple lies can be revealed simply, complicated lies take time to sort out. Money from any source can be a potential corruptive influence in science. Researchers who receive funding will always make sure that the money keeps coming, no matter what the source of the funding might be.

Major frauds detected in the recent past have a long-lasting impact on the future of Medical Science.

In December 2010, the International Anaesthesia Research Society announced retraction of the paper "Cardiopulmonary Bypass Priming Using a High Dose of a Balanced Hydroxyethyl Starch Versus an Albumin-Based Priming Strategy" by Prof. J. Boldt^[5] for falsification of data. Joachim Boldt, who carried out research into hydroxyethyl starch (HES), was stripped of his title Professor at the University of Giessen in February 2011 as 89 of the 102 studies published by him did not have Institutional Review Board (IRB) approval, and were retracted because IRB approval for the research was misrepresented.

US anaesthesiologist Dr. Scott Reuben^[6] admitted to fabricating data in at least 20 clinical studies published mainly in US anaesthetic journals, which led the editors of those periodicals to issue a series of formal statements and retractions. On 24 June 2010, US District Judge Michael Ponsor handed down a 6-month sentence to the anaesthesiologist Scott Reuben, who pleaded guilty earlier this year to falsifying research on the use of analgesics Celecoxib (Celebrex; Pfizer) and Rofecoxib (Vioxx; Merck) for post-operative pain management and, subsequently, fabricating data in a paper published in *Anaesthesia and Analgesia*. The Reuben episode has left the practice of multimodal analgesia in shambles.

Fujii *et al.* studied Granisetron in the prevention of post-operative nausea and vomiting (PONV). Later, Kranke and others became sceptical when they read that the side-effects were almost always identical in all groups. Of 47 articles published by Fujii *et al.* in 13 articles, the frequency of headache was reported to be identical in all groups. They concluded that there must be an underlying influence causing such incredibly nice data reported by Fujii *et al.*^[7]

The awareness campaign has yielded a few results too.

The paper "Urdaneta F, Willert JL, Beaver T, Naik B, Kirby DS, Lobato EB. Effects of a new phosphodiesterase enzyme Type V inhibitor (UK 343-664) versus milrinone in a porcine model of acute pulmonary hypertension"^[8] was voluntarily retracted by the authors after hearing the publicity of fraud (retraction announced in *Ann Thorac Surg* 2011;91:338).

Dr. Steven L. Shafer of Columbia University, Editor-in-Chief of *Anesthesia and Analgesia* said, "My commitment to 'unimpeachable integrity' means that credible allegations of misconduct are not ignored or swept under the rug, but are pursued relentlessly, and sometimes at considerable personal cost".^[9]

But, how can we overcome this aberrant attitude affecting the Medical community?

1. A committed Editorial Board and peer reviewer system must be in place
2. Create an awareness regarding the potential for piracy, plagiarism or fraud in institutions where any type of research is conducted. Students should be introduced to a code of practice at the beginning of their career
3. Ethics committees and Head of the Institutions should insist on high standards for storing and inspection of data by the research team and vouch for integrity of the study results. Create our own Codes of Good Research practice and follow them rigorously
4. Institutional self-assessment is one promising approach to assessing and continually improving integrity in research
5. The peer reviewers should use technology to their benefit to prevent fraudulent activities
6. Journal editors should issue a retraction when they learn that their journal has published a tainted article
7. A periodic metaanalysis of current issues/topics can throw light on fraudulent results
8. Delink publications from promotions, because glorifying your routine work is an art mastered by a selected few persons
9. Parallel recognition and appreciation of skills and clinical excellence for career enhancement.

There is an analogy here to detection of terrorism. The fraudster or the terrorist is always likely to be one step ahead of the authorities.^[10] Unfortunately, today, most countries in the world either do not have a system of regulation or have not shown interest in regulating such fraud. In response to growing anxiety about the

integrity of a few scientific medical authors, a group of British Medical Editors founded the Committee of Publication Ethics (COPE) in 1997. Presently, COPE is involved in providing guidelines on Good Practice, even while encouraging medical research. They are also involved in publishing an annual report on misconduct in publications.

Fraud or misconduct in medical research is a social disease, perpetrated by a few bizarre and psychologically disturbed individuals. Currently, several countries have no established system to prevent such fraud or deal with established cases. It is a necessity to re-establish the human trust in scientific results. And, good conduct comes not from intellect but from integrity and mindset.

“Rather fail with honour than succeed by fraud”.

– Sophocles

SS Harsoor, SB Gangadhar

Prof. of Anaesthesiology, Siddhartha Medical College,
Tumkur, Karnataka, India
E-mail: harsoorss@hotmail.com

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