

Editorial

GOOD RESEARCH AND PUBLICATION PRACTICE IN BIOMEDICAL SCIENCE

IJPP receives about 225 manuscripts every year. With time, we expect this number shall increase. These manuscripts are sent to experts for review and evaluation, and they, based on their perceptions and knowledge, give their comments about the research study and its presentation. In specific terms, an accomplished reviewer gives comments on the originality and quality of the study questions and hypothesis, the rationale of the study, the scientific merit of study design, the validity of the methods used, data analysis, and finally, the language and overall presentation of the manuscript. Based on these comments, the editorial board accepts it with or without modifications, suggests the authors for a major revision and resubmission of the manuscript, or rejects the paper. In this whole process what is important is to follow good research and publication ethics; this involves stringent practice of good conduct by the scientists at each step of research and publication. Many referees and the editorial group have noted that good practice in research and publication is not sufficiently guarded in many cases. We have a strong suspicion that misconduct in research and publication arises to a great extent from mere ignorance about the good research and publication practice. Since the future of biomedical sciences in India is promising, it becomes imperative that we learn very closely what is meant by good practice in research and publication, and observe it. In this article we address some of the issues related to good practice in research and publication in biomedicine.

Study aim and design¹

One of the most important initial issues for good research practice is to frame a well thought-out study design based on a strong rationale and viable hypothesis. This is generally dependent upon good appreciation and analysis of available literature in related and relevant areas. This is followed by development of a well-planned study model. It is generally advantageous to perform pilot studies using a research protocol to seek answers to specific questions and to form a working research protocol thereof. In any case, a working research protocol along with the consideration for *post hoc* analysis should be a consensus article agreed by all contributors, collaborators and participants. Issue of statistical analysis should also be addressed early in the study design to attribute strength to the research protocol and to interpret results in a valid and dependable manner.

Ethical approval

The issues of ethics do vary from set up to set up, from institution to institution, and from journal to journal. Generally, use of human tissues in research should conform to the highest ethical standards. Animal experiments require full compliance with relevant ethical and regulatory principles.

Data analysis¹

While data collection, presentation and analysis should be done appropriately, unintended but inherent bias might creep into these processes. Therefore, it is important that the authors do mention any issues of bias that may exist in the study design, or may emerge in the process of data collection and analysis. Similarly, if *post hoc* analysis of data is done, it should be clearly indicated. In any case, fabrication and falsification of data are considered as major misconduct in research and publication, and such behaviour should be penalized in no uncertain manner.

Authorship

There are differences in the opinion about the criteria of the authorship. It is however a minimal definition that the author of a paper should have made at least some contribution to the scientific content of the paper. In other words, if there is no task that can reasonably be attributed to a particular individual, then that particular individual should not be credited with authorship. Thus, it is important to note that gift authorship is not a good practice.

Redundant publication

Redundant publication occurs when two or more full papers share the same experimental objectives, data and conclusions even if the language and presentation are different.

Plagiarism and piracy

The use of anybody else's ideas, data and interpretation, published or unpublished, totally, partially or conceptually, at any stage of planning, research, writing and publication, without any reference to the original source and without permission, if necessary, constitute plagiarism and piracy. Unintentional similarities however may occur because of the strong influence of background knowledge, paradigm, and notions at a given period of time; but that can generally be deciphered on investigation.

Dealing with misconduct

While dealing with alleged misconduct in research or publication, it is essential that the investigating bodies and individuals should examine the actual intention of the author(s), rather than the act itself, and it should be done with full honesty and transparency, and should aim at foolproof evidence. It is to be recognized that a complaint of misconduct in research is a very serious issue, and therefore it is unethical to charge a scientist or a group of scientists with misconduct without impeccable evidence. On the other hand, it is also undesirable that a case with some indications of misconduct is not

appropriately investigated. A responsible reviewer should blow the whistle in case the reviewer finds some indication of misconduct. However, the reviewer should take sufficient care while reporting it either to the editor or to the authors, maintaining full confidentiality.

At the end, two very important ideas need to be highlighted.

1. Gyroscope ethics versus radar ethics

Peter Sandee defined two forms of ethics in science: radar ethics and gyroscope ethics. Scientists exhibit personal moral responsibility for what they do and they cannot just leave it to an outside agency to decide what is good and what is wrong. Moreover, scientists generally prefer to follow stringent discipline about their activities in science and research, and they wish to take part in public debate and discussion concerning ethics in research and publication. Thus, it appears that good practice in research and publication in biomedical sciences is guaranteed only when it is gyroscopic in nature, in which moral constraints are self-imposed.

The gyroscope ethics, as in other fields of life, empowers the scientists and science in an effective way.

2. Promote and practise good conduct rather than only discouraging misconduct

These two approaches are not merely semantic variations of a single concept; rather they are fundamentally different approaches with two different, apparently

obscure, goals. Promotion and practice of good conduct in research and science involves active positivism, while discouraging misconduct involves negation of negative process. Hence, the latter, by itself, is a non-sustainable approach in the long term. Given the fact that scientists generally possess high intellect and lofty faculty, it is relatively easy also to frame and practise consensual good codes which are practical, rather than framing a taxonomy of misconduct in research and publication.

So, those who are group leaders, watch dogs, reviewers and mentors of science with different rights and responsibilities should take note of these two points and try to be introspective to practice them in their day to day work.

Finally, scientists in all related fields of biomedicine should be actively encouraged to hold discussion and debate amongst themselves and with peer groups at large on different issues concerning good research and publication conduct and ethics.

Those who are especially interested to learn more about ethics in research and publication may study the COPE (Committee on Publication Ethics) Reports 1999 and 2000, which form the global consensus in this regard. COPE was set up by Michael Farthing (Chairman, COPE), Richard Smith (Editor, BMJ) and Richard Horton (Editor, Lancet) in 1997. These reports are available at a website: www.bmjpub.com/publicationethics/cope. Furthermore, a book named 'On Being a Scientist: Responsible Conduct in Research' published by the

National Academy of Sciences in 1994 (visit www.nap.edu/readingroom/books) may be consulted. Some portions of this book and the COPE Reports may be obtained solely for educational purposes directly from the respective websites. The present article has relied heavily on the concepts promulgated in these two sources.

A note on research design and statistical analysis

D.R. Cox once mentioned that scientists often behave like Procrustes in the use of research design and statistics in their research. Procrustes is a mythological character. He was a cruel highwayman and owned a rather long bed and another very short bed. He forced his captives to fit the long bed by stretching them. He sawed off the legs of his captives to fit them in the short bed. A scientist sometimes does something similar. He checks a standard statistics book, finds out a design and statistical technique that seemingly fits to his research protocol and data, and then makes the data to fit the Procrustean bed, often with an inappropriate ignorance. This of course does not constitute fraud, but of course it does constitute poor research practice.

On the contrary, the scientist should ask: what is the question or what are the questions being asked in the proposed study? Once the questions are well structured and focussed, two basic points are to be addressed. First, what are the best treatments and layout. Second, what constraints might be there on the experimental units. Thus, he approaches three basic tenets of experimental research

design: treatments, layout and response. The treatments are the way to answer the questions. We need prior information to select befitting treatments. Effectiveness, accessibility, feasibility, cost effectiveness, levels and number of treatments, mode of nesting experimental units or modules, and maintenance of these need to be addressed while designing the treatments. These lead to the layout of the study design. The layout part of the study design allows the treatments to answer the question either in an unbiased manner or at least with a bias that is quantifiable. In the layout, we consider the possibility of including some stratification in our design so that the treatment effects can be easily detected. We assess the answers to the questions by appropriate measurement of responses by experimental units. Thus, the treatments in the best-fit layout design provide estimates avoiding bias, and then based on the estimates we can partition variation by means of statistical methods appropriate to the type of data and study layout.

Before applying statistical tests, we should allow the data to speak first, meaning thereby that the researcher should be well acquainted with the data. Thus, it is important that the researcher draws figures, measures variations, and does various other things with the data so that the researcher develops a clear mental image of the data. Then, one applies statistical methods to analyse the results. In this, it is also very important that one applies appropriate tests based on fulfilment of assumptions, type of layout and data, and the nature of questions. To this end, one should understand the tests that one is

going to use. Statistical analysis of research results is not just application of some arbitrarily chosen statistical formulae. One should therefore avoid the temptation to apply a test from the software programme just because it is available, or some other group has used the same in a comparable or a similar study design. There is always a strict necessity of testing the assumptions and validating software calculation. In this connection, Ivan Valiela in his book 'Doing Science' writes, "Often, a well-drawn figure, with measures of variation and a clear visual message, is a far better way to examine, show, and understand your data than complex calculations done by a software package and presented in a fancy though perhaps indiscernible graphic."

While it is largely correct that much in science has been done in the past without the services of statistics, the laborious trekking through statistics and design tends to sharpen the focus of the meaning of the results obtained in most cases. Our primary interest lies in doing science, rarely in statistics *per se*. Yet, statistics helps us in

the way we perform and analyse research and to increase signal-noise ratio.

Various programs and learning materials are available on the Internet. The website : www.cpb.uokhsc.edu/pkin/soft.html provides lists of software packages with comments. Besides, there are many common computational programs and statistical softwares available in the market. Users should however validate the programs before use. Also, interested scientists may explore a learning material at the website : <http://spssp.clarion.edu/mm/RDE3/start/RDE3start.html> on Research Design Explained. There are also many books available in the market, which provide robust background and operative knowledge about study design and statistical analysis for biomedical sciences. Many of them (e.g., Sokal RR and Rohlf FJ, Biometry, 1995, Freeman; Glantz SA, Primers of Biostatistics, 1997, McGraw-Hill; Valiela I, Doing Science, 2001, Oxford University Press) are quite helpful for a large section of scientists involved in biomedical research.

NOTICE

The Editorial Board has recently noted that a report entitled, 'Cardiorespiratory changes associated with graded exercise and determination of aerobic power in male medical students (18-19 years)' by Dalia A. Biswas and Sanjay R. Kher published in IJPP 1996 (40: 79-82) bears striking similarities in content with a report entitled, 'Cardio-vascular changes during graded exercise' by Venkatesh et al. published in IJPP 1988 (32: 305-309). Furthermore, Biswas and Kher published a Letter to the Editor in IJPP 2001 (45: 122-124) along the same lines. There is no reference to the study of Venkatesh et al. in either of these papers by Biswas and Kher. Again, in the Letter to the Editor, the authors did not refer even to their own 1996 paper. IJPP regrets the publication of these papers by Dalia and Kher which carry hints of plagiarism and multiple publishing. IJPP is committed to uphold both the quality and ethics of science and scientific publication, but timely detection of all irregularities is impossible for the editors. IJPP urges the contributing scientists and authors to help us to maintain the highest standards in quality and ethics of scientific publication.