Ethics of medical research and publication

The Indian Journal of Orthopaedics (IJO), an official journal of the Indian Orthopaedic Association (IOA) is one of the very few journals from the country (across all specialties) which is indexed with Science Citation Index (SCI) - expanded and therefore has to maintain a high publication standards. The journal strives to publish as many articles from the IOA members as possible. However, it has been observed that in spite of the huge amount of good quality clinical work being done in the country, the number of manuscripts from Indian authors is few. Moreover, many a times, in spite of the quality of the content being very good, publication has to be declined because of poor presentation or design. In order to help authors to improve the quality of their manuscripts and understand the review process better, the editorial team has decided to come out with a series of editorials. The previous two editorials in this series, one on indexing and other on plagiarism,[1,2] were well received by the readers. This editorial focuses on the ethics of medical publication.

The moment a research is conceived, especially if it involves human participants, ethical issues come into play. The World Medical Association (WMA) developed a set of ethical principles regarding human experimentation for the medical community called the Declaration of Helsinki (DoH).[3] It is widely regarded as the key document on human research ethics. This document contains 32 points. According to this document, "the primary purpose of medical research is to improve prophylactic, diagnostic, and therapeutic procedures and the understanding of the etiology and pathogenesis of disease."[3] It further states that "even the best proven prophylactic, diagnostic, and therapeutic methods must continuously be challenged through research for their effectiveness, efficiency, accessibility, and quality."[3] Most research involves a team effort, and some junior members of the team who may be playing a substantial or lead role may not be aware of the ethical issues involved in human research though all researchers are equally abide by ethical principles. It is the duty of the senior researchers to discuss everyone involved in the project, make them aware about the ethical issues that need to be addressed.

Authors must know that irrespective of where or how a research is done, patients confidentiality, right to anonymity, and privacy is of paramount importance.[3] During the whole course of the conduct of the research till its final submission for possible publication, the authors must ensure that any information which reveals patient identity such as name and hospital number is avoided. A common mistake that should be avoided is submitting clinical photographs which reveal the patient identity. IJO, like many other journals, wants that only the images of affected areas must be provided to preserve patient anonymity. The patients' face must be completely removed rather than just the eyes being blurred. If it is necessary to show patient's face then proper consent from patient is taken.

Authors must also understand that patients consent, given for medical management or surgery by the caregiver, should not be assumed to be blanket consent. A separate informed consent must always be taken if the researchers plan to use patient data for research purposes. Moreover, approval from an Institutional Review Board, Ethics Committee, Departmental Board of Study, or an equivalent authority of competence is mandatory for any human research.[3] A statement about the same in the material and method section must be made. Omission of the same may be a ground for technical or outright rejection of the manuscript. Sometimes, the editorial team may want to see a copy of the approval, and authors must keep it handy. It is also the morale duty of the researchers to ensure that the patients are not harmed. If at any time during the study, the authors feel that the patients interests are being harmed they must stop the study.

During the conduct of the study, fabrication (presenting unsubstantiated facts or data) and falsification (changing or selecting certain data to achieve desired results) should be strictly avoided.[4] If there is any missing datum, which usually is the case in most studies, no effort must be made to hide it. It should be reported with appropriate reason. It is also a good idea to involve a statistician early in your study so that design of the study and statistical tools can be fine-tuned. Doing an underpowered study and then misusing statistics to defend your results is also a type of ethical misconduct.

Based on the type of research, one is conducting, there are a number of broad consensus statements such as Consolidated Standards of Reporting Trials (CONSORT statement) for randomized controlled trials; Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA statement) and Strengthening the Reporting of OBservational studies in Epidemiology (STROBE statement) for observational studies, which researchers must use as templates not only to increase their chances of publication but also

avoiding any ethical misconduct.[5-7] The Enhancing the QUAlity and Transparency of health Research (EQUATOR network) (website: http://www.equator-network.org) is a very good network which provides a comprehensive collection of reporting guidelines that can be used based on the design of the study. It is a good idea that all research team members make themselves familiar with these statements at the time of start of the study so that they have a clear plan in their mind. All clinical trials done in India should be registered with the Clinical Trials Registry of India (CTRI) (website: http://ctri.nic.in) set up by the Indian Council of Medical Research, and authors should provide the CTRI number along with the manuscript.

Once the study is complete and ready for submission, the first ethical issue that comes up is on authorship: Who should be listed as authors and in what order? The International Committee of Medical Journal Editors consensus statement is a useful guide and must always be followed.[8] Only those researchers who are involved in the conception and design, acquisition of data or analysis and interpretation of data, and drafting the article or revising it critically, must be listed as authors.[8] General supervision of the research group is not sufficient for authorship.[8] As a rule and good practice, the order of authorship should be based on the relative contribution of each author. Both honorary and ghost (not naming an author who has made a significant contribution) authorship should not be done.[9,10] Names of other researchers who have helped but who do not qualify to be authors may be declared in the acknowledgment section.

Plagiarism of any form, intentional or unintentional, must be strictly avoided.[2] If any of the authors has a doubt that some part of the manuscript may be plagiarized, they must run it through a plagiarism detecting software (www.ithentical.com, www.turnitin.com, www.plagiarism.org, etc.) to avoid embarrassment later.[11] The authors must also ensure that they do not submit their manuscript to more than one journal at any given time. This is extremely important from the copyright point of view and may sometimes lead to serious consequences, to the extent of the article be retracted and disciplinary proceedings being initiated against the authors according to the Committee on Publication Ethics guidelines (website; http://publicationethics.org). Junior researchers in their enthusiasm to get their work published may want to retort to this method, but the senior members must actively discourage them from doing it.

All authors must explicitly disclose all their personal or institutional conflicts of interest and source of funding for the research being submitted for possible publication.[12] This not only helps the editors but also the readers to interpret the results of the study more judiciously. Authors must always ensure that the conclusions they present should always be based on the results from their study and should not be influenced by the monetary or other benefits they may have gained as a result of conducting the study.

Most reputed journals including the IJO have a robust system of peer review. Peer review ensures that only the highest quality research is published, and errors and oversights corrected.[13] Following the review process, most authors would be asked to do a major or minor revision of their work. As an ethical rule authors must take the reviewers comments positively and must answer the concerns raised systematically and within the stipulated time frame. This helps the journal to meet their submission to decision time guidelines. Sometimes, queries might be raised by the editorial team even after a manuscript has been accepted and authors must again respond to them quickly. Once a manuscript is published, queries may be raised by the readers formally in the form of letter to editors of informal communication. Again it is the authors' moral duty to respond to these questions. All records and data pertaining to the study must be maintained for a sufficient period of time so that they can be produced anytime for scrutiny if desired by readers, other researchers, agencies, or editorial teams.

The animals in experimental studies are used for research. They should be used if strict ethical 'animal use guidelines' are followed. They are used if there is clear benefit, with animal experiments to the environment, animals or humans. The optimal standards of animal health and care should be followed.[15] The "best practice in research involving animals will embody the principles of the 3Rs (replacement, reduction and refinement) and a paper must also demonstrate that the study has adhered to these. Further details of theses principles can be found on the National Centre for the Replacement, Refinement and Reduction of Animals in Research website (http://www.nc3rs.org.uk/the-3rs).[16] Animals should not be used if there are alternative approaches available.

The WMA Declaration of Geneva binds the physician with the words, "the health of my patient will be my first consideration."[14] Further, the DoH states that "In medical research on human participants, considerations related to the well-being of the human participant should take precedence over the interests of science and society."[3] If all members of a research team follow these words in letter and spirit, a number of ethical issues which crop up during the conduct and publication of medical research, especially involving human participants, would be taken care of automatically.

To summarize both authors and publishers have ethical obligations. "Reports of experimentation not in accordance with principles laid down by 'Declaration of Helsinki', should not be accepted for publication.[13]

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