

Editorial

Ethics in orthopedic research

The primary purpose of scientific work is to produce knowledge, understanding, in the form of ideas, assumptions, and hypotheses. "In the publication of his or her research, the physician is obliged to preserve the accuracy of the results" (Helsinki Declaration (§ 1.8) (World Medical Association, Declaration of Helsinki 1964). An important task for editors and referees is to assess whether manuscripts submitted for publication fulfil such basic requirements of scientific quality.

However, an article may very well be scientifically sound but ethically questionable. Protocols of all biomedical research involving human subjects should therefore be submitted for "consideration, comment and guidance to a specially appointed committee" (§ 1:2) (World Medical Association, Declaration of Helsinki 1964). In order to approve research, the committee shall determine that appropriate safeguards have been included in the study to protect the rights and welfare of these subjects. The core values relevant to such assessments may be summed up as follows:

1. The risk to subjects should be minimized and reasonable in relation to the importance of the expected knowledge.
2. Informed and voluntary consent should be sought from each subject or the subject's representative.
3. The subjects should be selected in such a way that burdens and benefits will be equitably distributed.

The principles and rules presented in declarations and guidelines are binding on physicians all over the world. Nevertheless, in spite of efforts to increase awareness of ethical issues in research, it seems to be insufficiently emphasized in postgraduate education and medical research training. Many articles leave the reader with serious doubts.

As indicated in the first core value, there are important links between ethical and scientific requirements. For instance, studies with an insufficient number of patients, poor design and inadequate randomization schemes should not be approved by an ethics committee. No knowledge of importance may reasonably be expected from such studies. Therefore, an emphasis

on the demand for scientific quality will also improve ethical standards.

The second core value requires informed and voluntary consent in all biomedical research on human subjects. Many orthopedic research projects focus on elderly patients, many of whom are demented or otherwise incapable of giving informed consent; some patients may only get disturbed by being told that they are part of an experiment. Is informed consent necessary in these circumstances?

—Yes! Both the Helsinki Declaration and the CIOMS guidelines (1993) address this issue in detail. The investigators' obligations as regards individual informed consent and "the proxy consent of a properly authorized representative", as well as the content of the information to the subjects or their representative and the inducement to participate are clearly specified.

When doing research on patients who are not capable of giving adequately informed consent, considerations related to the third core value become appropriate. In the CIOMS guidelines (but not in the Helsinki Declaration), specific recommendations for research involving, for instance, children and persons with mental or behavioral disorders are presented (§§ 5–6) (CIOMS 1993). It is especially emphasized that incompetent patients should not be subjected to research that might equally well be carried out on persons in full possession of their mental faculties.

What about manuscripts presenting studies not performed in compliance with these recommendations? Should editors and referees care?

—Yes, they should definitely care. The Helsinki Declaration states "Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication" (§ 1.8) (World Medical Association, Declaration of Helsinki 1964). Whether or not this principle should be adopted as editorial policy by scientific journals has been a matter of some controversy (Levine 1988, pp 27–31). For instance, this obligatory refusal of manuscripts on unethical research has been modified in the CIOMS guidelines to "may be considered" (CIOMS 1993, p 42). The reason for this modification is that it may be better to publish ethically questionable, but

scientifically sound, manuscripts together with editorials raising the ethical issues, rather than to create a false impression that no unethical research is performed by refusing them.

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