Do Case Reports Require Ethical Approvals?

Clearing ethical issues is one of the important steps in biomedical/clinical research. What are the issues to be concerned while writing or publishing a case report? Any research, involving human subjects, requires approval by a corresponding ethical compliance body. The name of such body might differ from country to country, but usually it is called institutional review board (IRB). Case reports and studies intended for quality improvement are often considered not research and do not need IRB approval. Nevertheless, there should be some processes of clearing those studies with respect to ethical handling of patients and related data. Perhaps, it is part of standard healthcare guidelines and regulations. In another words, case reports submitted for publication do not strictly meet the criteria of research. Although a case report (defined as a retrospective analysis of one, two, or three clinical cases) may be illustrative, it does not meet the national policy for the protection of human subjects' definition of research, which requires an investigation that contributes to generalizable knowledge about a disease or condition. Instead, a case report is intended to develop information to be shared for medical or educational purposes. Many institutions therefore do not require any kind of review for publishing case reports. Case reports can sometimes reveal patients’ very personal information that may even possibly lead to their recognition by readers of the report, particularly if photographs are used. Increasingly, journal editors are requesting a copy of a signed consent form, before agreeing to publish case reports (1). A clear justification usually needs to be provided if a case report is submitted for publication without formal and specific written consent from the patient or guardian or in the case of a death, from the next of kin (1).

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References