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A Critical Assessment of the Quality of Reporting of Ethical Protections in Medical Papers Published in Turkey

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Abstract

The Declaration of Helsinki (DoH), the International Committee of Medical Journal Editors (ICMJE) recommendations, and the Committee on Publication Ethics (COPE) guidelines outline the basic principles for ethical conduct and publication of human-subject research, most notably informed consent (IC) and research ethics committee (REC) approval. This retrospective observational study was a first study to investigate the quality of reporting of these protections in a selected sample of medical papers published in Turkey. A total of 573 research articles published in the official journals of six leading Turkish medical schools between January 2018 and December 2020 were searched for information on obtaining (i) REC approval, (ii) written IC from research subjects or their legal guardians/representatives, and (iii) an REC-granted IC waiver when it was found, as stated in the DoH, "impossible or impracticable to obtain consent" from research subjects. Similarly, a total of 166 case reports were searched for a statement about publication-specific IC, as was recommended by COPE. Despite a statistically significant improvement over the years, the overall rates were found to be unsatisfactory. The protections were particularly misused or underused in retrospective research, where the rates of reporting written IC (15.41% vs. 48.61%) and REC approval with date and reference number information (45.38% vs. 61.11%) were significantly lower than in prospective research ($p < .05$). Both the practices of seeking and granting an IC waiver when no IC was obtained were extremely rare (n = 3). It was also found that the requirement of structured ethical information in research papers was associated with higher levels of ethics compliance, and that medical publishing in Turkey needed specific improvements, including better implementation of the protections already adopted in principle, clearer instructions for authors, more rigorous editorial scrutiny, and greater commitment to rejecting substandard submissions.

Keywords

Declaration of Helsinki, ethical protections, human research, informed consent, journals, research ethics, research ethics committees

Introduction

Since its adoption by the World Medical Association in 1964, the Declaration of Helsinki (DoH) has remained fundamental to the ethical guidelines on medical research involving human subjects and, more contemporarily, human material and data. Specifically, since its second revision in 1975, the DoH has included stipulations on the ethical publication of medical research, which have been gradually amplified. In parallel, the post-2000 period has seen the widespread recognition of other documents for medical and academic publishers, including the International Committee of Medical Journal Editors' Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals (ICMJE, 2019) and the various guidelines issued by the Committee on Publication Ethics (COPE). Today, the principles outlined in these texts have been adopted in the publishing policies of thousands of scholarly journals, given the TR Index alone.

The TR Index (Tr. *TR Dizin*) was created and is updated by the Turkish Academic Network and Information Center (Tr. abbr. *ULAKBİM*) within the Scientific and Technological Research Council of Turkey (*TÜBİTAK*), the multi-mission agency for improving, funding, and leading academic and industrial research in Turkey, in line with national goals. The TR Index is primarily aimed at bringing Turkey-based journals publishing scientific content in conformity with the international standards of academic publishing. It indexes all journals accepted by the relevant Turkish authorities, i.e., the Council of Higher Education (*YÖK*) and the Interuniversity Board (*ÜAK*), for use in the processes of academic promotion based on professional publishing. The journals are selected according to various criteria, with a special focus on rigorous peer-review and ethical

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