

The ethics of editors in Brazilian journals: developments and challenges

Ética dos editores de periódicos brasileiros: evolução e desafios

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ABSTRACT

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Introduction: One of the products of a research project is the publication of results in indexed journals. Thus, publishers occupy an important role in the task of ensuring that of scientific knowledge is ethically disseminated. **Objectives:** To update the 1999 study by Sardenberg et al, which analysed the conduct and ethical requirements in the Guidelines to Authors section of Brazilian scientific journals. **Methods:** Data were collected via the Internet on the journals' electronic pages and via manual search in university libraries. The variables analyzed were: approval by an Ethics in Research Committee (ERC), ERC accreditation by the National Ethics in Research Council (CONEP), indicating the register number, need to submit copy to the editor, mention to the use of Statement of Informed Consent Form (ICF) and Resolution CNS 196/96, and accreditation in the Clinical Trials Registry. **Results and discussion:** of the 139 journals analyzed by Sardenberg et al, 94 still exist, and 17% make no reference to the aspect of ethics. Resolution CNS 196/96 guidelines were widely publicized, which should facilitate editorial policies to adapt to its principles, as mentioned in 53.2% of the sample. There was a significant difference between journals with Qualis citation and in terms of their Qualis ratings and reference to the CNS Resolution approval by the ERCs. The required inclusion of registry number occurred in 18.1% of the sample, a copy was sent to the Editor by 34%, 7.4% of the ECRs were reported to be accredited, projects were approved in 78.7%, and accreditation in the Clinical Trials Registry was mentioned in 33%. **Conclusion:** There was an increase in all the variables studied, which revealed advances in the ethical conduct of the scientific journals analyzed.

Key words: Ethics, Research; Periodicals; Ethics Committees, Research.

RESUMO

Introdução: um dos produtos de um projeto de pesquisa é a publicação dos resultados nos periódicos indexados. Sendo assim, os editores ocupam importante papel na função de zelar pela eticidade na divulgação dos conhecimentos científicos. **Objetivos:** atualizar o estudo realizado em 1999 por Sardenberg et al., no qual se verificaram a conduta e exigência ética que constam na seção Instruções aos Autores de periódicos científicos nacionais. **Métodos:** coleta de dados via internet nas páginas eletrônicas das revistas e busca manual em bibliotecas universitárias. As variáveis analisadas foram: aprovação pelo Comitê Ético em Pesquisa (CEP), credenciamento do CEP pela CONEP, indicação do número do parecer, envio ao editor de sua cópia, citação do uso do Termo de Consentimento Livre e Esclarecido (TCLE) e da Resolução CNS 196/96 e credenciamento no Registro de Ensaio Clínicos. **Resultados e discussão:** dos 139 periódicos analisados por Sardenberg et al., 94 ainda existem, sendo que 17% não possuem referências éticas. As diretrizes da resolução foram amplamente divulgadas, possibilitando-se adequar a política

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editorial – mencionada em 53,2% da amostra – aos seus princípios. Houve diferença significativa entre a vinculação e Qualis dos periódicos e a citação da Resolução CNS 196/96 e aprovação pelo CEP. A exigência do número do parecer ocorreu em 18,1% da amostra, o envio de cópia ao editor do parecer em 34%, a exigência de o CEP ser credenciado em 7,4%, a aprovação do projeto em 78,7% e o credenciamento no Registro de Ensaio Clínicos em 33%. Conclusão: houve aumento de todas as variáveis pesquisadas, o que revelou avanço na conduta ética dos periódicos científicos analisados.

Palavras-chave: Ética em Pesquisa; Publicações Periódicas; Comitês de Ética em Pesquisa.

INTRODUCTION

One of the products from a research project is the publication of results in scientific journals (indexed journals). Thereby, editors play an important role ensuring an ethical dissemination of knowledge and applying the principles of bioethics towards subjects involved in the research.

Abuses in scientific research involving human beings have only become a cause for concern after World War II, when Nazi doctors conducted experiments in concentration camps with prisoners of war. After the defeat of Germany, the Allied forces prosecuted these doctors in the Court of Nuremberg, which originated the first document of an international character with rules for research on human beings, the Nuremberg Code of 1947. In 1964, the World Medical Association approved the Declaration of Helsinki, which was revised and updated several times over the years, the last being in Seoul, in 2008, with the differential of quoting the non-acceptance for publication of experiments off of its ethical principles.¹⁻⁵ Nevertheless, abuses in this type of research did not cease to exist. Beecher⁶ found that numerous research projects were carried out without ethical rigor in relation to subjects involved in the research.

In Brazil, the first guidelines and standards for research with humans were established by the No. 01/88 resolution from the National Health Council (CNS), an agency in the Ministry of Health. Currently, the guideline governing ethics in research is the No. 196 CNS resolution from 1996, which contains other additional standards and regulates the creation of Research Ethics Committees (CEP) that consequently imposes the requirement that all research involving humans be appreciated and approved by the ethics committee before its execution. CEPs are coordina-

ted by the National Commission of Ethics in Research (CONEP) which has, among other functions, that to ensure compliance with the resolution, monitor, and advise without policing.⁷⁻⁹

In 2004, the International Committee of Medical Journal Editors (ICMJE), along with the WHO, created a universal database of clinical trials registry, the Clinical Trials Registry Platform, whose goal was to make research results with medical intervention in humans public and transparent. Thus, journals editors receive the recommendation to only accept articles about clinical trials with medical intervention when duly registered in this database. The SciELO, Scientific Electronic Library OnLine, and LILACS, Latin American Literature and Caribbean Health Sciences joined this movement since May, 2007.⁹⁻¹¹

In Brazil, according to the WHO recommendations, the Brazilian Clinical Trials Registry (REBRAC) was created in July of 2008 through the GM No. 1345 ordinance. With this, all clinical trials performed in the country are made public; this ordinance is one more instrument of defense to safeguard the integrity and rights of volunteers participating in research projects.¹²

Because the research conducted by Sardenberg et al. in 1999² – in which the instructions to authors of 139 Brazilian scientific journals were analyzed – revealed that more than half of Brazilian journals did not care about the ethical aspects of studies accepted for publication, we sought to analyze, in this study, the current situation of this matter in the Brazilian context. Therefore, this study aimed to verify the conduct and ethical requirements from those 139 Brazilian scientific journals.

MATERIAL AND METHODS

The goals in the study conducted by Sardenberg et al.² were updated regarding the ethical conduct in the instructions to authors from 139 Brazilian scientific journals. This study investigated the current ethical conduct in the instructions from the same journals analyzed previously, highlighting that new variables were introduced for this evaluation.

The data were collected via internet on the pages from each journal through the SciELO, LILACS, and MedLine scientific databases and by manual search in university libraries in Juiz de Fora-MG, which are: President Antônio Carlos University, Salgado de Oliveira University, Federal University of Juiz de Fora, Medical and Health Sciences College,

and SUPREMA. The Qualis was analyzed through the Coordination for the Improvement of Personnel with Higher Level Education (CAPES) portal. The bibliographic survey was conducted between September, 2011 and March, 2012.

The research was based on the ethical aspects of the surveyed documents to follow up on the previous study² according to the following variables: approval of the research project by a CEP; CEPs accreditation on the CONEP; indication of the CEP's opinion number; communication to the editor through a copy of the CEP's opinion; citation in the publication about the use of TCLE or its requirement; registration at the Clinical Trials Registry; citation of the 196/96 CNS Resolution or Declaration of Helsinki; "Qualis" of the journal according to the classification proposed by CAPES and its link to societies, universities, and others.

The data were stored in the Access 2007 program, Microsoft® Corporation, USA. The program SPSS 13.0® SPSS Inc. was used for the statistical analysis; descriptive methods were used for the studied variables. The Student t-test was used to compare continuous variables and the Chi-square test for categorical variables. The critical value was set at 95% for the p-value and confidence intervals.

RESULTS

Out of the 139 journals surveyed by Sardenberg et al.², 94 (67.6%) are still in operation, the remaining 45 have closed down their publications.

The classification of periodicals by CAPES was: 4.3% possess Qualis A2 and B1, 5.3% Qualis B2; 30.9% Qualis B3; and 27.7, 25.5, and 2.1% Qualis B4, B5, and C, respectively. Out of the total sample, 34% are linked to universities, 58.5% to societies, and the remainder to other agencies.

The ethical questions in the instructions to authors were present in 53.2% of the journals mentioning the 196/96 CNS Resolution or the Declaration of Helsinki, and 28.7% cited the need to implement a Volunteer Informed Consent. The requirement of CEP's approval opinion number to be included in the article is present in 18.1% of the journals and the notification of the editor through a copy of this opinion in 34.0%.

The requirement that the CEP to which the research project was submitted is accredited in the CONEP was present in 7.4% of the journals, whereas the project's approval by the CEP is required by 78.7% of

them. About the latest ethical conduct, 33% of the scientific journals require the registration of clinical trials at the Clinical Trials Registry Platform.

The journals' qualification according to CAPES (Qualis) and its ethical editorial policies were analyzed statistically. The CEP's approval and citation of the 196/96 CNS Resolution presented statistical difference. The editorial policy between journals according to linking the citation of 196/96 CNS Resolution was also statistically significant.

DISCUSSION

The requirement of acceptance of studies with ethical rigor protects the scientific quality of clinical research and the subjects involved. Sardenberg et al. (1999)² reported that 79.1% of the analyzed periodicals did not show any reference to ethical issues in their instructions to authors; that percentage was only 17% in his study.

Over the years, the 196/96 CNS Resolution guidelines were widely disseminated, allowing the adequacy of editorial policies in national journals to its principles. In addition, the initiative of agencies disseminating scientific knowledge and that of WHO establishing the Clinical Trials Registry Platform enabled the adaptation to the existing standards.

To citation of the 196/96 CNS Resolution and Declaration of Helsinki was presented by 53.2% of the total sample. According to Hardy et al. (2004)¹³, 17 presidents of CEPs participants in the study claimed to have read the 196/96 CNS Resolution and followed its guidelines, however, 12 considered the guidelines difficult to fulfill in practice.

Hardy et al.¹⁴, in an interview with 46 leaders/directors and researchers in the field of Gynecology and Obstetrics, affirmed that 58% of researchers read and consulted the 196/96 CNS Resolution during their work and none of them considered it difficult to comply with. In the group of leaders/directors, 87% read and consulted the 196/96 CNS Resolution and only 10% of them considered it difficult to comply with. The fact that the CNS Resolution 196/96, which is a recommendation and not a law, is known by researchers and CEP directors contributes to increased compliance to its guidelines.

According to this study, a significant difference was observed between the link of periodicals and the resolution's citation; those linked to societies showed

the highest percentage of citation (62%). The CEP's approval and citation of the 196/96 CNS Resolution compared with the qualification of periodicals also presented significant difference. Thus, a positive aspect emerged: the main ethical parameters assessed in this study are being executed by editors.

A Volunteer Informed Consent (VIC) was cited in 28.7% of the journals in the present study, whereas Sardenberg et al.² observed this citation in only 0.7% in his sample. In the Nursing School CEP at USP¹⁵, the VIC was the motive of backlogs in 56.4% of the projects examined in the first six years of operation. This demonstrates the researchers' disregard towards the subjects involved in their research because the 196/96 CNS Resolution clearly instructs how the VIC should be done. The lack of interest on the part of researchers causes this because the 196/96 CNS Resolution is easy to access. In addition, the occurrence of any harm to subjects involved in research projects resulting from the lack of correct information in the consent about risks inherent in medical procedures during the research projects will entail in future lawsuits.^{15,16}

According to the 196/96 CNS Resolution, a research project involving human subjects can only be started after approval by the Research Ethics Committee (CEP). The requirements of inclusion of the CEP's approval and opinion number in the article and a copy of this opinion sent to the editor are mechanisms imposed by the journals for the practice of good science. In this study, the sending of this copy was required by 34% of the analyzed journals, the requirement of the opinion number by 18.1%, and the CEP's approval by 78.7%. Sardenberg et al.² observed that 12.2% of the journals made reference to the need for approval and/or analysis by the Ethics Committee; Tavares-Neto and Azevedo (2009)³ observed that in 50% of the surveyed journals.

All 18.1% of journals that require the opinion number to appear in the body of the article also require the CEP's approval. Among those requiring the notification to the editor by sending a copy of the opinion, 34% also require the CEP's approval. These data were statistically significant ($p < 0.05$).

Tavares Neto and Azevedo³, in their study with 20 Brazilian journals, concluded that none of them fulfilled the request for CEP accreditation at the CONEP. In the present study, 7.4% followed this instruction. About the latest ethical conduct proposed in Brazil, 33% of the journals require the registration of clinical trials at the Clinical Trials Registry Platform.

CONCLUSION

This study found that, over the years, with the evolution of an ethical consciousness in editors, an improvement in ethical conducts has been observed in several indexed Brazilian journals. For future generations, the maintenance of gained knowledge and improvement in ethics training of researchers are necessary. Above all, universities, producers of science, should include discussions on ethics in human research in their curricula to raise awareness in their students. The editors of scientific journals should also participate in this effort considering the requirement to comply to ethical standards in studies to be published. Therefore, the population will benefit from a humanistic quality in the scientific practice.

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