

Ethical standards adopted by Brazilian journals of medical specialties

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SUMMARY

Objective: To review ethical standards contained in guidelines to authors of Brazilian scientific journals in several medical specialties and see if there is any standardization available. **Methods:** This is an exploratory study evaluating Brazilian scientific journals classified on the Portal of Journals on Health Sciences of the Virtual Health Library in all medical specialties regarding guidelines to authors submitting manuscripts and concerning ethical standards for research in humans. Data were collected and categorized for the presence of the following variables: Ethics Committee approval; Helsinki Declaration and/or Resolution 196/96, informed consent; ethical standards; uniform requirements; patients' confidentiality and no ethical references. The association among the variables was also examined. **Results:** Out of a total of 8,701 journals, 95 were included in the current study. The variables were investigated, with each one's frequency being verified. Eighty per cent were referred for an Ethics Committee approval; 43.15% of Helsinki Declaration; 43.15% of informed consent; 9.47% of ethical standards; 32.63% of uniform requirements and 15.78% of patients' confidentiality were referenced. In the whole sampling, 9.47% of journals do not mention any ethical reference as a guide to authors submitting manuscripts. An association among variables occurred in 61% of the sample. **Conclusion:** Ethical aspects of submitting manuscripts were mentioned in over 90% of the guides to authors of national scientific journals and no standardization at all is available.

Keywords: Ethics; bioethics; ethics committees; research.

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INTRODUCTION

Ethics in scientific research has been a much discussed and addressed subject over the last two decades^{1,2}. From evidence of abuse of insertion of humans into research, several measures started being taken.

The Helsinki Declaration was firstly published in 1964 during the 18th World Medical Assembly, held in Helsinki, amended in 1975 (Tokyo), 1983 (Venice), 1989 (Hong Kong), 1996 (Somerset West), 2000 (Edinburgh) and 2008 (Seoul), and reports the importance of ethical principles upon conducting a study in humans, encompassing informed consent obtainment and the experimentation protocol submission to an independent committee. The document reports experiments that are out of this declaration norm should not be accepted for publication³.

The Uniform Requirements for manuscripts submitted to biomedical journals, edited by the International Committee of Medical Journal Editors, which reference the Helsinki Declaration and the Ethics Committees responsible for human experimentation protocols, have given journals homogeneous characteristics⁴.

The Resolution 196/96 of the National Health Council⁵ was presented as a tool for medical research procedure control, referring to the importance of the subject consent, as well as a prior project approval by an Ethics Committee. Following the experiment, the results must become public whether they are favorable or not.

Obtaining a consent from the patient so that the study can be conducted translates into the agreement to participate in the study, understanding the risks and benefits involved, assuming a position to be revoked at any time with no detriment to his(her) treatment⁶.

In Brazil, the number of clinical studies conducted yearly is large and the search for publications, preferably in journals with a major impact factor, is growing larger. These journals having a recognized scientific pattern, in turn, become increasingly stringent in appraising the manuscripts to be published with regard to ethical principles observed during the study conduction⁷.

It's remarkable that every journal has its norms and criteria to select articles and, with this regard, the observation of ethical aspects as a part of guidelines provided to authors in several journals might be questioned, since there are different normalizations among them.

This study objective was to analyze ethical standards inserted into directions to authors in Brazilian scientific journals in several medical specialties and see if there is any standardization.

METHODS

Exploratory study evaluating Brazilian scientific journals classified on the Portal of Journals on Health Sciences of the Virtual Health Library (BVS) regarding directions to authors submitting manuscripts concerning ethical standards observed in research in humans.

Journals in 29 medical specialties were investigated: Allergy and Immunology, Anesthesiology, Cardiology, Surgery, Dermatology, Endocrinology, Gastroenterology, Geriatrics, Gynecology, Hematology, Homeopathy, Medicine, Emergency Medicine, Internal Medicine, Nephrology, Neurology, Obstetrics, Ophthalmology, Oncology, Orthopedics, Otorhinolaryngology, Pathology, Pediatrics, Perinatology, Pneumology, Psychiatry, Radiology, Rheumatology, and Urology.

The electronic access to all specialty journals listed above on the BVS page was done.

The inclusion criteria were journals from Brazil allowing online access to instructions to authors submitting manuscripts.

Exclusion criteria were international journals, as well as those with publication and/or indexation closed and those not allowing electronic access to instructions to authors.

Then the publication norms were searched on the electronic page of each national journal. With the instructions to authors being the object of the present study, it was directed to the categorization of contents on ethics in research. They were investigated for the presence or absence of the following variables:

- **Approval by the Ethics Committee:** journals reporting a prior approval by a Research Ethics Committee was required for research in humans;
- **Helsinki Declaration and/or Resolution 196/96:** journals reporting the research must comply with the Helsinki Declaration;
- **Informed consent:** journals reporting the informed consent was required for information release;
- **Ethical norms or standards:** journals reporting only the following of ethical standards was a requirement, without mentioning other criteria;
- **Uniform Requirements:** journals referencing the Uniform Requirements for manuscripts submitted to biomedical journals proposed by the International Committee of Medical Journal Editors;
- **Patient confidentiality:** journals mentioning confidentiality of names, images or initials of patients involved in the research;
- **No ethical reference:** journals not mentioning ethical aspects to authors submitting their manuscripts.

The data collection was done in order to check dichotomously (yes or no) whether the variables were referenced individually or associated with each other upon reading the instructions to authors. Individually means only one variable was shown in the text; associated means two or more variables were reported.

The chi-squared test was used to find out any statistical difference between journals with and without ethical norms, considering 5% the risk assumed by the investigator, with the probability to reject the null hypothesis < 0.05 .

RESULTS

Out of 8,701 journals registered on the Portal of Health Sciences of the BVS, 95 met the inclusion criteria. Thirty-seven national journals were excluded, 17 for not allowing online access to instructions to authors and 20 for closed publication and/or indexation.

The results were analyzed by considering the frequency (%) of each variable searched.

In 90.53% of national scientific journals searched, there was at least on ethical norm reported in the guide to authors, but nine journals (9.47%) had no mention to ethical aspects in the appraisal of manuscripts submitted (Table 1). There was a statistically significant difference between journals with and without ethical references ($p < 0.001$). For independent variable analysis, see Table 2.

Among the 95 national journals evaluated, 26.31% had three of the ethical criteria evaluated in the instructions to authors, followed by 23,15% with two criteria. Eight journals (8.42%) cited four criteria and only 3.15% of journals reported all of the variables. In 20% of journals evaluated, only one ethical standard was cited. Therefore, the association between ethical standards investigated occurred in 61.05% of national scientific journals (Figure 1).

DISCUSSION

Developing an investigation according to ethical precepts is a key aspect, and it is an investigator's duty to protect life, health, privacy and dignity of a human being participating in studies.

The sixth Code of Medical Ethics, in force in Brazil since April 13, 2010, provides its extension to physicians involved in research and teaching. Articles 99, 100 and 101 of Chapter XII report the physician shall not participate in any kind of experience that violates human dignity; fail to obtain the approval of the protocol for a study in humans, as well as fail to obtain the informed consent statement from the patient or legal representative for the conduction of the study after proper explanation about the project nature and outcomes⁸.

Over the last decades, there has been an expansion of the number of journals, but their reliability is linked to a strict editorial policy for publishing the scientific articles. In this setting, the ethical rules increasingly required for the manuscript preparation are included^{1,2,7}. The study approval by an Ethics Committee, the informed consent statement collected among the study subjects and the adoption of confidentiality for images, names or initials are some of the issues that should be observed by authors involved in research projects.

The emergence of the International Committee of Medical Journal Editors and the publication of the Uniform Requirements for Manuscripts Submitted to Biomedical Journals, also known as Vancouver Requirements, have tried to give a uniform characteristic to journals, although the authors only use them to standardize the bibliography⁴.

Table 1 – Brazilian journals classified according to the presence or not of mention to ethical norms

Journals by specialty	With ethical norms	Without ethical norms
Hematology	01	00
Homeopathy	01	01
Emergence Medicine	00	00
Internal Medicine	00	00
Nephrology	01	00
Neurology	02	00
Gynecology and Obstetrics	02	00
Ophthalmology	02	00
Medicine	37	06
Allergy/Immunology	00	00
Cardiology	08	00
Anesthesiology	01	00
Endocrinology	01	00
Geriatrics	01	00
Dermatology	01	00
Gastroenterology	02	00
Surgery	04	00
Oncology	02	00
Radiology	02	00
Rheumatology	01	00
Orthopedics	03	00
Otorhinolaryngology	05	00
Pathology	03	00
Pediatrics	03	01
Perinatology	00	00
Urology	01	00
Psychiatry	08	01
Pneumology	03	00
Total	95	09
	90.53%	9.47%

Source: FM/UFG

Table 2 – Ethical standards evaluated and percentage of journals they were shown in

Ethical standards evaluated	% of journals
Ethics Committee	80
Helsinki Declaration/Resolution 196/96	43,15
Patient consent	43,15
General ethical standards	9,47
Uniform Requirements	32,63
Patient confidentiality	16,78

Source: FM/UFG

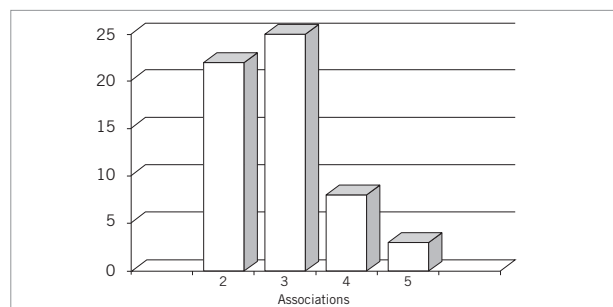


Figure 1 – Number of associations among variables.

The current study shows there is a concern, among scientific journal editors, about the ethical principles, since they were mentioned in over 90% of journals, something different from studies conducted in the 1990s. Sardenberg *et al.*², analyzing 139 journals, found that in 79% of them there were no ethical norms, underpinning Amdur and Biddle¹, who assessed 102 English language scientific journals for ethics in human studies and found half of them did not require the Institutional Review Board approval for publication. Tavares Neto *et al.*⁹ also evaluated Brazilian journals and concluded 50% of the guidelines mentioned the study approval by the Ethics Committee, whereas 35% determined the text approval citation.

Although previous investigations have found out failures in ethical guidance to authors^{1,2,10,11}, this study shows a number of journals have not fit those guidelines yet, since nine of them (9.47%) make no mention to ethical norms. It is worth considering that the more explicit the instruction criteria are, the clearer it will be for the author that the journal is really concerned about the subjects in the study and consequently about the material to be published.

The association of all variables studied, found in only 3.15% of journals, shows most of them make a nonstandard reference to the variables the editors consider the most relevant, such as the study approval by the Ethics Committee, found in 80% of the journals assessed. If we take into account that three criteria of ethical references in the guidelines to authors would be considered optimal, only 26.31% of journals would appear on the list.

According to Borracci *et al.*¹¹, the obtaining of an informed consent statement is variable among articles in Argentine publications of cardiovascular studies. According to the authors, around 50% of studies addressing invasive procedures do not report ethical aspects, which correspond to the percentage found in this study, 43.15% of journals if we consider the variable informed consent. The study by Pellizzon *et al.*⁷ concludes the compliance with ethical principles of research was mentioned in the Guidelines to Authors in 90% of the journals, a level matching the current study.

Is the study approval by the Ethics Committee without obtaining an informed consent from the subject a correct proceeding? Among the journals now studied, only 37.89% mentioned the Ethics Committee approval, whether associated with other criteria or not, with no mention to the patient consent. Bauchner reports that in two publications on the British Medical Journal in 1997, two randomized trials were performed with the Ethics Committee approval, but with no informed consent from the subjects¹². It is also important to mention that the item ethical considerations for submitting manuscripts to biomedical journals provided by the International Committee of Medical Journal Editors only requests the authors

to prove the manuscript is in accordance with ethical standards and the Helsinki Declaration⁴.

Therefore, the importance of concerning about the bioethical aspects applied to scientific research is realized, as the subject must be viewed as a citizen and a social being, stressing the essence of bioethics is freedom, which is expected to entail commitment and responsibility¹³.

The scientific production growth should be accompanied by standardization of guidelines to authors, which is considered important for improving the quality of publications. Ethical norms must be clear and specific. In this survey, the great guideline variability in instructions to authors is observed among the journals, as there is no norm standardization and no standardization in presenting the instructions to authors, making the clear perception by an author more difficult. A specific item for ethical criteria in all journals would make the instructions more objective to the investigator.

The methodological stringency or the manuscript evaluated, as well as a strict editorial policy in ethical items will reflect the final product to be published, thus offering the reader a great credibility.

CONCLUSION

The ethical aspects upon submitting manuscripts were mentioned in over 90% of instructions to authors in national scientific journals and there is no kind of standardization.

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