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Does impact factor influence the ethics of the instructions provided to journal authors? ☆

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Objective: Verify whether a journal's impact factor is a mechanism that modifies the ethical requirements described in the instructions provided to authors of articles published in Brazilian medical journals.

Methods: 48 selected journals were divided into two groups: impact-factor ($n = 24$), and no-impact-factor ($n = 24$). The number of ethical requirements was compared between both groups based on a specific research protocol, ranging from zero to six points, analyzing the presence of an approval by a research ethics committee; reference to the fact that the research follows the precepts of the Declaration of Helsinki and the rules of Resolution 196/96; use of an informed consent; information about the authors' conflicts of interest; and a request for registration of clinical trials in the Brazilian Clinical Trials Registry.

Results: The average score of the impact-factor group was significantly higher than that of the no-impact-factor group (3.12 ± 1.03 vs. 2.08 ± 1.64 , $p = 0.0121$). When each ethical requirement was compared between the groups, there was significant difference only between the requirement of an informed consent and the disclosure of conflicts of interest ($p < 0.05$).

Conclusion: The impact factor is a determinant factor on the ethics included in the instructions to authors of articles in scientific journals, showing that higher-quality journals seek better-designed articles that are conscientious at the beginning of the research.

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O fator de impacto influencia na ética das instruções aos autores de uma revista?

R E S U M O

Palavras-chave:

Sistemas de avaliação das publicações

Objetivo: Verificar se o fator de impacto de um periódico é um mecanismo modificador dos quesitos éticos descritos nas instruções aos autores de revistas médicas nacionais.

☆Study conducted at Universidade do Estado do Pará, Belém, PA, Brazil.

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Fator de impacto
Artigo de revista

Métodos: Foram selecionadas 48 revistas divididas em dois grupos: grupo com fator de impacto ($n = 24$), e grupo sem fator de impacto ($n = 24$). Foi comparada a quantidade de quesitos éticos entre os dois grupos baseados num protocolo de pesquisa próprio, variando de zero a seis pontos, analisando a presença de aprovação por Comitê de Ética em Pesquisa; citação de que a pesquisa segue os preceitos da Declaração de Helsinque e as normas da resolução 196/96; uso de Termo de Consentimento Livre e Esclarecido; informação sobre os conflitos de interesse dos Pesquisadores; e solicitação para que os estudos clínicos sejam cadastrados no Registro Brasileiro de Estudos Clínicos.

Resultados: A média da pontuação do grupo com fator de impacto foi significativamente maior que o grupo sem fator de impacto ($3,12 \pm 1,03$ vs. $2,08 \pm 1,64$, $p = 0,0121$). Quando cada quesito ético foi comparado entre os grupos, houve diferença significativa apenas entre a solicitação do TCLE e o conflito de interesses ($p < 0,05$).

Conclusão: O fator de impacto é um fator determinante na ética contida nas instruções aos autores das revistas científicas, mostrando que as revistas de maior qualidade buscam artigos com melhores desenhos e que sejam criteriosos quando do início da pesquisa.

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Introduction

The protection of the research subject is growing around the world, from World War II¹ to the present time, with a great participation of society in research ethics committees. Several ethical and bioethical atrocities happened during World War II, which led to the emergence of the first international document for protection of the research subject, the Nuremberg Code.²

Thereafter, another international document of great importance was formulated in the attempt to reduce unethical research: the Declaration of Helsinki. In its second edition, the Declaration proposed the creation of independent committees that would evaluate the research projects, before they begin, minimizing ethical atrocities.^{3,4}

In Brazil, these documents contributed to the formulation of policies for protection of individuals participating in researches, which led to the publication of resolution 196/96 of the National Health Council of the Brazilian Ministry of Health, which guides and regulates medical research in the country, creating and implementing a system of Human Research Ethics Committee (HREC), all managed and supervised by the National Research Ethics Committee (Comissão Nacional de Ética em Pesquisa – CONEP).⁵⁻⁷

This evidences the importance and relevance of ethics in the preparation and publication of scientific researches. The instructions provided to authors have played an important role in the preparation of articles, as they restrict or prevent the publication of studies that do not comply with the described ethical guidelines, inhibiting researchers to commit ethical atrocities, such as those from the past.^{8,9}

Some studies conducted in Brazil have analyzed the instructions provided to authors of several journals⁸⁻¹²; however, these studies only reported ethical failures in instructions. The present study is unprecedented because it verifies whether a journal's impact factor is a mechanism that modifies the ethical requirements described in the instructions provided to authors of articles to be published in Brazilian medical journals.

Methods

This work was a cross-sectional and observational study. The sample consisted of 48 Brazilian medical journals distributed in two groups pursuant to the Journal Citation Reports (JCR):¹³ the impact-factor group, composed by the Brazilian medical journals that have the highest impact factors ($n = 24$); and the no-impact-factor group, composed of Brazilian medical journals with no impact factor ($n = 24$).

Brazilian medical journals with impact factor were selected at the JCR website using the 2010 impact factor. Journals were classified by first selecting the Brazilian journals and then selecting only medical journals. These journals were classified in a descending order of impact factor, and all 24 journals were included. Journals in the no-impact-factor group were randomly selected by an external researcher, who selected 24 journals through the Webqualis/CAPES website.¹⁴

For this selection, the journals were requested to submit the instructions provided to authors via the Internet, in addition to a "B4" qualification or higher, provided that they did not have an impact factor, regardless of being directed to the general public or to specialists. All studied journals have their articles available in an electronic format and, within the impact-factor group, there are 19 specialized medical journals and five general journals. Within the no-impact-factor group, there are 20 specialized medical journals and 4 general journals.

A score system was used in order to evaluate the ethical requirements in the instructions to the authors of the selected journals. The protocol used was an adaptation to the Brazilian reality of the protocol proposed by Chaliar et al.¹⁵ In that protocol, there are six ethical requirements that should be described in the instructions to the authors as follows: 1) Approval by the HREC; 2) A reference to the fact that the research follows the precepts of the Declaration of Helsinki; 3) A reference to the fact that the research is in compliance with the Resolution 196/96 of the National Health Council of the Brazilian Ministry of Health; 4) Authorization from the subject agreeing to participate in the research through the informed

Table 1 – Distribution of the number of impact-factor and no-impact-factor journals in the different scores obtained.

Note / Group	Impact-factor group (n = 24)	No-impact-factor group (n = 24)
Zero	0 (0%)	7 (29.16%)
One	0 (0%)	2 (8.33%)
Two	8 (33.33%)	3 (12.5%)
Three	8 (33.33%)	7 (29.16%)
Four	5 (20.83%)	4 (16.66%)
Five	3 (12.5%)	1 (4.16%)
Six	0 (0%)	0 (0%)
Average	3.12	2.08

Source: Research protocol. $p = 0.0121$ (Student's t-test).

consent – FIC; 5) Information about the authors' conflicts of interest; and 6) A request for registration of clinical trials in the Brazilian Clinical Trials Registry. One point was attributed to each ethical requirement identified in the instructions to authors; thus, a journal's score may vary from zero to six points.

In order to perform the statistical analysis, Student's t-test was used to compare the scores of several journals from the impact-factor and no-impact-factor groups, and Fisher's exact test was used to compare each requirement individually between the groups. A p-value < 0.05 was adopted for significance.

Results

The average score of journals of the impact-factor group was 3.12 ± 1.03 ; the lowest was 2, and the highest, 5. The average score of the no-impact-factor group was 2.08 ± 1.64 ; the lowest was 0, and the highest, 5. There was a statistically significant difference between the groups ($p = 0.0121$). The distribution of the scores between both study groups is described in Table 1.

For the studied requirements (Table 2), only the requirement related to the reference to the use of an informed consent and the researchers' conflicts of interest proved to be statistically significant between the groups.

In the first studied requirement, regarding the research assessment by a HREC, 21 (88%) journals of the impact-factor group had this requirement to the authors in their instructions, while 16 (67%) journals of the no-impact-factor group required this approval.

Regarding the requirement to mention the declaration of Helsinki and resolution 196/96 of the National Health Council of the Ministry of Health, in both the impact-factor group and the no-impact-factor group nine journals (37.5%) met the first criterion and four (16.67%) met the second criterion.

Regarding the requirement that interviewees should sign an informed consent, seven (29.16%) journals of the impact-factor group had this requirement, while in the no-impact-factor group only one (4.6%) journal made this requirement. There was a statistically significant difference between the groups ($p = 0.0479$).

22 (91.67%) journals of the impact-factor group required the researchers' conflicts of interest to be disclosed, while 13 (54.16%) journals of the no-impact-factor group made this requirement. There was a statistically significant difference between the groups ($p = 0.0078$). With respect to the registration of clinical trials with the Brazilian Clinical Trials Registry, half of the journals (12) in the impact-factor group and seven (29.16%) journals in the no-impact-factor group required such registration.

Discussion

In most cases, the instructions to authors are the only means of communication between researchers and the editorial standards of a scientific journal.¹⁰ Such document should inform a potential author regarding everything they should know before submitting an article for publication. The inclusion of ethical prerogatives in this space is essential not only to avoid ethical and bioethical atrocities but also to ensure the quality of the studies submitted.

In Brazil, the approval of the preliminary research by research ethics committees has been mandatory since 1996.⁵⁻⁷ However, some of the study journals, especially in the non-impact-factor group, do not mention that research projects must be approved by a HREC. The values found in this study are similar to Sanderberg's findings.⁹

Table 2 – Comparison between the presence and absence of each ethical requirement assessed in the impact-factor and no-impact-factor groups.

Note / Group	Impact-factor group (n = 24)		No-impact-factor group (n = 24)	
	n	%	n	%
Approval by a research ethics committee	21	87.50	16	66.66
Declaration of Helsinki	9	37.50	9	37.50
Resolution 196/96	4	16.66	4	16.66
Use of an informed consent*	7	29.16	1	4.16
Disclosure of conflicts of interest*	22	91.66	13	54.16
Brazilian Clinical Trials Registry	12	50.00	7	29.16

* $p < 0.05$ (Fisher's exact test).

Source: Research protocol.

Regarding scientific journals with impact factor, only three (12%) did not present such requirement, which demonstrates their awareness of the relevance and requirement of approval of the research by a HREC. This increases the quality of the research published in the journals, given that HRECs act as ghost authors;¹⁶ as ethical corrections are made, another result is the correction of methodological misconceptions that may influence the ethics of the research, thereby improving them. With respect to ethical and bioethical documents that guide researches in Brazil, both groups had the same number of journals requiring references to the Declaration of Helsinki and to resolution 196/96 in the articles submitted. However, this number was low, similar to those found in a 1999 study,⁹ showing that, after 13 years, there were no significant changes regarding the importance assigned to these declarations, despite the fact that resolution CNS 196/96 is the document with greater ethical prevalence in biomedical research carried out in Brazil.

The informed consent is a document with irrefutable ethical value and, usually, the only connection between the research subject and the research itself.¹⁷ It also serves as an agreement between the parties. Based on this document, the research subject acknowledges the research in which he/she is willing to participate, his/her rights and duties, in addition to the safety provided by this instrument, which ensures the person the possibility of refusing to participate in the research at any time.⁶ Despite its importance, this was the criterion that has obtained the lowest score in both groups; in the no-impact-factor group, only one journal made this requirement.

This fact may be due to the journals' assumption that the approval of an article by an HREC depends on the approval of the informed consent model used by such committee, rendering this information unnecessary.

Conflicts of interest are a major ethical point, as the manipulation of results by the pharmaceutical industry and major biotechnology companies may compromise thousands of people.¹⁸ Information about possible connections between the researchers and these institutions should be detailed in the articles and is of great relevance to readers, in order to filter the results of the research. According to the results of this research, the journals that had an impact factor required clarification of potential conflicts of interest more often than those that did not. That is observed because, in theory, journals included in the impact-factor group have higher quality and publish a higher number of clinical studies or researches with new drugs than those in the no-impact-factor group.

The registration of clinical trials is a new system in Brazil, started in 2007.¹⁸ Albeit recent, this registry is important and of great value, as it prevents the same research being performed more than once, since information on registered clinical trials is available to the public on the website. This registry serves to inform research subjects about the status of the research in which they are participating, as well as to disclose and benefit the most from the results of these studies.¹⁹ However, due to the recent introduction of the system, few journals require that the articles submitted are registered. As in all other requirements, again, it was possible to notice that most journals requiring registration of clinical trials belonged to the impact-factor group.

The study groups showed significant differences, evidencing that the impact-factor group is more conscientious regarding the ethical requirements in the instructions provided to authors. Such fact occurs not only as a result of a strict editorial staff, but also as a result of the need to adjust to major article indexing databases, which is essential to obtain a high impact factor.²⁰

By analyzing criteria individually, there was a significant difference between the groups regarding the requirement of an informed consent and disclosure of conflict of interest, thus, these are the main factors that influenced the difference between the study groups.

In effect: do the journals requiring a greater number of ethical requirements do so because they have a high impact factor or, on the contrary, do they have a high impact factor because they follow ethical criteria? It can be inferred from the results that the greater the impact factor, the more journals require the ethical requirements, increasing their quality and their impact factor. These elements cause a ripple effect in which both readers and research subjects are benefited; the former benefits from the access to better-quality articles, and the latter take part in studies that are more and more committed to ethics.

It was observed in this study that journals with greater impact factor present a greater stringency in the selection of the articles to be published, selecting those with better design and those that are careful in the beginning of the research. Despite this remark, ethical requirements should be the same for high and low-impact journals; in addition to being concerned with the quality of the research, researchers should also remember to ethically respect and protect research subjects.

It must also be emphasized that this research was limited to the study of the ethical requirements present in the instructions to authors, and the editorial reality may differ from that described in these documents. These ethical requirements, due to their high scientific relevance, should be provided in the instructions to authors, from which researchers base conduct of their study.

Conclusion

The impact factor determines the ethics included in the instructions to authors of articles in scientific journals, evidencing that journals with higher impact factors stand out due to higher-quality articles that show ethical respect, present well-prepared initial study designs, and follow strict criteria in the beginning of the research.

However, publishers' awareness is still necessary to end differences in ethical requirements between impact-factor and no-impact-factor journals. Publishers should guide and require compliance with ethical guidelines provided in the instructions to authors of all journals, respecting current standards so that authors respect basic ethical guidelines during their research, thus protecting research subjects.

Conflicts of interest

The authors declare no conflicts of interest.

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