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The Frequency of Reporting Ethical Issues in Human Subject Articles Published in Iranian Medical Journals: 2009–2013

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Abstract Researchers should strictly consider the participants' rights. They are required to document such protections as an ethical approval of the study proposal, the obtaining "informed consent", the authors' "conflict of interests", and the source of "financial support" in the published articles. The purpose of this study was to assess the frequency of reporting ethical issues in human subject articles published in Iranian medical journals during 2009–2013. In this cross-sectional study, we randomly reviewed 1460 human subject articles published in Iranian medical journals during 2009–2013 in two Persian and English language groups. Data collection was carried out by assessing articles, focusing on the documentation "ethics committee approval", patients' "informed consent", "financial support", "confidentiality", and "conflict of interest". Of 1460 evaluated articles, 443 (30.3%) reported "ethics committee approval", 686 (47.0%) reported "informed consent", 594 (40.7%) reported "financial support", and 341 (23.4%) reported "conflict of interest". 13% of the articles referred to patients' confidentiality in their text. There was a significant association between these ethical documentations and the year of publication. Articles published in English language journals reported "ethics committee approval", "financial support", and "conflict of interest" significantly more than Persian language journals, but the frequency of "informed consent" was similar. Ethical documentation rate in Iranian medical journals is not

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up to the expected standards of reputable journals which might be related to a lack of awareness and the education of the authors and the journal's editors. Precise reporting of ethical considerations in medical articles by authors are recommended. It is suggested journals and policymakers pay more attention to reporting this issue while providing standard guidelines in this regard.

Keywords Ethics · Journalism · Medical journals · Research · Iran

Introduction

Ethics is a system recognized to provide the rules of conduct for the practice of medicine or science. The aim of this system is to maximize human well-being by applying explicit evaluative frameworks (ICMJE 2016; WMA 2013). In the field of research, respect for human dignity, protecting the participants' rights, and protecting them from potential risks are the essential ethical principles. Many national and international declarations and regional regulations have been published on this matter. The Declaration of Helsinki (1964) established ethical principles that have been accepted by almost all countries and scientific societies around the world. Ethics for the guidelines of human research are based on ethical standards and human rights, which were listed in the Helsinki statement, regardless of race or nation (Heidari et al. 2012; WMA 2013, 2014; Claudot et al. 2009).

Researchers, institutions, and journals' editors should be responsible for safeguarding the rights and welfare of subjects participating in research (Al-Gaai et al. 2012). According to the latest International Committee of Medical Journal Editors recommendations (2016), authors should indicate whether the procedures followed during research were in accordance with the ethical standards of the responsible ethics committee and the Helsinki Declaration. Source of the "financial support", the institutional address, and the "conflict of interest" must be stated in the publication. Research reports noncompliant with the principles of this declaration should not be accepted for publication (ICMJ 2016; Krimsky and Rothenberg 2001; Qureshi et al. 2012).

The accuracy of results in published articles is very important because they are used to build the bases of modern medicine. Prestigious scientific journals try to provide complete and accurate information about scientific research (WMA 2013). Therefore, journals' editors, in order to keep the readers' confidence in the journal, consider the integrity of ethics compliance in a human subject manuscript submitted to their journals (Salamat et al. 2013; Carlson and Ross 2010; Benos et al. 2005).

Protection of human subjects in a research means: the obtaining "informed consent" from the participants, approval of the study proposal by an independent institutional review board (IRB) or ethics committee, determining the source of "financial support", and maintaining "confidentiality". The obtaining written "informed consent" should be considered in any research involving the human subjects, unless the related ethics committee excludes the protocol from the obtaining such consent (WMA 2013; US 2009). Another issue of focus is the

authors' "conflict of interests" (COI), which refers to any relationship that can inappropriately affect the authors' judgment, for example, existing any financial gain (Henley and Frank 2006).

Previous studies have investigated some of these issues and reported that in general adherence to the suggested principles was poor, but there have been improvements over time. These studies more focused on reporting ethical considerations in the clinical trials, in single specialties, or a special group of the patients or journals (Heidari et al. 2012; Al-Gaai et al. 2012; Schroter et al. 2006; Taljaard et al. 2011; Navabi et al. 2013; Koushan et al. 2014; Meschia and Merino 2003; Myles and Tan 2003).

In Iran, proposals for performing a research should normally submit to the Vice-Chancellery for Research Department of any medical universities for evaluation. During this process, they will automatically be sent for review by Ethics Committee of the University. After their approval, the research can be started. However, after reporting the results of those studies to be published in the journals, it is the duty of the editors and journals' staff to screen the conformity of what has been written in the articles with standard international ethical guidelines. This is the step that some major points in reporting can be missed.

In September 2013, there were 261 medical journals published in Iran (according to the Publication Commission of the Iranian Ministry of Health and Medical Education report that time). We found only two studies conducted to investigate the current status of publication ethics in Iranian journals. Navabi and colleagues reported that only 15.3% of the dental clinical trials published between 2001 and 2011 stated the ethical approval and 50.4% of them reported that an "informed consent" had been obtained (Navabi et al. 2013). Another study on Iranian medical journals published in the Persian language showed that the ethical misconducts included the lack of "ethics committee approval" (81.7%), unstated "informed consent" (45%), and not mentioning the "financial support" providers (56.9%) (Koushan et al. 2014). Other studies focused on the journals' policy addressed in their "instruction to authors" (Heidari et al. 2012; Salamat et al. 2013). Despite the ethical guidelines for research and publication, documented evidence about reports of the ethical protections in published articles in Iranian medical journals is not available. So this study was designed to investigate the frequency of reporting ethical protections in the human subject articles published in Iranian medical journals during 2009–2013.

Materials and Methods

In this cross-sectional study, 261 journals approved by the Publication Commission of the Iranian Ministry of Health and Medical Education from January 2009 to September 2013 were evaluated. Of them, 119 journals were published in English language and 142 journals in the Persian language. Using the table of random numbers, 50 journals of each category were selected. Of them, 4 articles [original article, brief (short) communication, or case report] in each year (2009–2012) and 2 articles for 2013 were selected. Articles reporting research on non-human subjects

were excluded and case reports were evaluated separately to be presented in another manuscript. Finally, a total of 1460 original and brief reports which studied the human subjects were included. "The human subject" was defined as a person whom a researcher obtains data about, through the intervention or interaction with the subjects.

The data collection was done by assessing the articles, focusing on publication year, country in which the study was performed, the Journal's indexing information, the study type (interventional or observational study), and the documentation of ethical consideration during the study including the "ethics committee approval", the patients' "informed consent", the "financial support", the "conflict of interest", and the patients' "confidentiality".

The "ethics committee approval" was considered if any of the following sentences had been mentioned in the articles: **"**Research ethics committee approved the protocol", "The study was exempt from approval", or the registration number related to the project approval was mentioned.

The patient's "informed consent" was considered if any of the following items were found: "patients gave "informed consent" to participate in the study", "all subjects gave written or oral consent", " parents agreed to take part "," there were no refusals ", and "consent was waived".

The "confidentially" was ensured by retrieving the following sentences: "the data were collected anonymously", "the participants' confidentiality and privacy were respected", or similar sentences denoting the same perception.

The "financial support" was reported in the article if any of the following sentences could be seen in the texts: "This work was a part of a thesis from the X University and was conducted and funded by…", "This study was supported by…", "The authors would like to appreciate… University for financial support", or the authors declined to receive any "financial support".

The authors and researchers' "conflict of interests" were evaluated by retrieving the following sentences: "There is no "conflict of interest" in this article", "No CoI was declared", or if any specific financial relations was reported.

Statistical Analysis

All the articles were coded and reviewed by two independent examiners. Before analyzing information, to ensure the reliability of the data, analytic procedures were undertaken and agreement coefficient between examiners across all of the variables in this study was calculated (Kappa = 0.93). Then the main data were analyzed using SPSS software (Version 17.0, SPSS Inc., Chicago, Illinois, USA). The Chi square test was used to compare the variables. P value < 0.05 was defined as statistically significant.

Results

Table 1 shows the frequency of evaluated articles during the study period. Most of them were conducted in Iran (92.7%) and 7.3% were from other countries.

Table 1 Frequency of evaluated articles during the study period

Journals	2009	2010	2011	2012	2013	Total
English language	154 (22.4)	149 (21.7)	150 (21.8)	159 (23.1)	76 (11.0)	688 (100.0)
Persian language	169 (21.9)	167 (21.6)	170 (22.0)	175 (22.7)	91 (11.8)	772 (100.0)
Total	323 (22.1)	316 (21.6)	320 (21.9)	334 (22.9″)	167 (11.4)	1460 (100.0)

443 (30.3%) out of 1460 evaluated articles addressed the "ethics committee approval" in their texts that 380 (85.77%) of them also referred to the relevant ethics committee name. The frequency of mentioning "ethics committee approval" was improved over the study period from 2009 to 2012–2013 ($p = 0.006$) and was better mentioned in the interventional study compared with observational studies ($p < 0.001$). It was also significantly better reported in studies conducted outside Iran (52.8 vs. 28.6%, $p < 0.001$) and the articles published in the journals indexed in Medline/PubMed or Thompson databases ($p < 0.001$) (Table 2).

Only 686 (47.0%) articles had documented obtaining the patients' "informed consent", of them in 435 (63.4%) the type of consent had been mentioned (47 verbal, and 388 written). No significant correlation was found between reporting the "informed consent" and the publication year ($p = 0.115$), location ($p = 0.959$), and the journals' indexing ($p = 0.434$). It was, however, correlated with the study type ($p < 0.001$) (Table 2).

The "financial support" was mentioned in 594 (40.7%) articles which were improved over the time ($p < 0.001$) (Table 2).

The "conflict of interest" was reported in only 341 (23.4%) articles. The frequency of its mentioning was improved over the study period from 2009 to 2013 ($p < 0.001$) (Table 2).

13% of the articles referred to the patients' "confidentiality" in their text. A significant association between mentioning the patients' "confidentiality", the publication year ($p < 0.001$), the study location ($p < 0.04$), and the journal's language ($p < 0.001$) was seen (Table 2).

Articles published in English language journals reported: the "ethics committee approval", the "financial support", the "conflict of interest", and the "confidentiality" significantly more than Persian language journals ($p < 0.001$), but the frequency of the patients' "informed consent" was similar ($p = 0.585$) (Table 2).

Discussion

Our results indicated that overall the reporting of research ethical considerations in the human subject articles published in Iranian journals is inadequate. High-quality Iranian journals that could present their articles in the international databases, such as Thompson databases, PubMed, and Scopus, were more sensitive to report these ethical issues.

Table 2 The frequency of ethics considerations in Iranian journals' articles evaluated between 2009 and 2013 (N = 1460)

	Publication period					*p* value	Study location		*p* value	Journal indexing				*p* value
	2009	2010	2011	2012	2013		Iran	Outside of Iran		Thompson	Medline/ PubMed	Scopus	Other database	
Mentioning ethics committee approval														
Yes	80 (24.8)	86 (27.2)	94 (29.4)	129 (38.6)	54 (32.3)	0.002	386 (28.6)	57 (52.8)	< 0.001	82 (51.9)	66 (57.9)	66 (40.7)	229 (22.3)	< 0.001
No	243 (75.2)	230 (72.8)	226 (70.6)	205 (61.4)	113 (67.7)		966 (71.4)	51 (47.2)		76 (48.1)	48 (42.1)	96 (59.3)	797 (77.7)	
Mentioning patients' informed consent														
Yes	135 (41.8)	149 (47.2)	162 (50.6)	165 (49.4)	75 (44.9)	0.180	635 (47.0)	51 (47.2)	0.959	82 (51.9)	56 (49.1)	79 (48.8)	469 (45.7)	0.455
No	188 (58.2)	167 (52.8)	158 (49.4)	169 (50.6)	92 (55.1)		717 (53.0)	57 (52.8)		76 (48.1)	58 (50.9)	83 (51.2)	557 (54.3)	
Mentioning financial support														
Yes	94 (29.1)	103 (32.6)	131 (40.9)	176 (52.7)	90 (53.9)	< 0.001	551 (40.8)	43 (39.8)	0.848	90 (57.0)	54 (47.4)	67 (41.4)	383 (37.3)	< 0.001
No	229 (70.9)	213 (67.4)	189 (59.1)	158 (47.3)	77 (46.1)		801 (59.2)	65 (60.2)		68 (43.0)	60 (52.6)	95 (58.6)	643 (62.7)	
Mentioning conflict of interest														
Yes	44 (13.6)	66 (20.9)	85 (26.6)	102 (30.5)	45 (26.9)	< 0.001	278 (20.6)	64 (59.3)	< 0.001	90 (57.0)	74 (64.9)	52 (32.1)	126 (12.3)	< 0.001
No	279 (86.4)	250 (79.1)	235 (73.4)	232 (69.5)	122 (73.1)		1074 (79.4)	44 (40.7)		68 (43.0)	40 (35.1)	110 (67.9)	900 (87.7)	
Mentioning confidentiality														
Yes	24 (7.4)	26 (8.2)	37 (11.6)	46 (13.8)	59 (35.3)	< 0.001	171 (12.6)	21 (19.4)	0.044	19 (12.0)	20 (17.5)	26 (16.0)	127 (12.4)	0.280
No	299 (92.6)	290 (91.8)	283 (88.4)	288 (86.2)	108 (64.7)		1181 (87.4)	87 (80.6)		139 (88.0)	94 (82.5)	136 (84.0)	899 (87.6)	

Table 2 continued

	Study type		*p* value	Journal language		*p* value
	Observational	Interventional		Persian	English	
Mentioning ethics committee approval						
Yes	271 (25.8)	172 (42.2)	< 0.001	120 (15.5)	323 (46.9)	< 0.001
No	781 (74.2)	236 (57.8)		652 (84.5)	365 (53.1)	
Mentioning patients' informed consent						
Yes	419 (39.8)	267 (65.4)	< 0.001	358 (46.4)	328 (47.7)	0.619
No	633 (60.2)	141 (34.6)		414 (53.6)	360 (52.3)	
Mentioning financial support						
Yes	416 (39.5)	178 (43.6)	0.154	283 (36.7)	311 (45.2)	0.001
No	636 (60.5)	230 (56.4)		489 (63.3)	377 (54.8)	
Mentioning conflict of interest						
Yes	258 (24.5)	84 (20.6)	0.111	22 (2.8)	320 (46.5)	< 0.001
No	794 (75.5)	324 (79.4)		750 (97.2)	368 (53.5)	
Mentioning confidentiality						
Yes	139 (13.2)	53 (13.0)	0.910	79 (10.2)	113 (16.4)	< 0.001
No	913 (86.8)	355 (87.0)		693 (89.8)	575 (83.6)	

Chi Square test, All data presented as n(%)

Only, 598 (40.7%) of the 1460 evaluated articles reported their sources of "financial support" in the text (45.2% in English language journals and 36.7% in Persian language journals, respectively). A research on the articles published in five public administration journals (*Administration and Society, American Review of Public Administration Public Administration, Public Administration Review and Journal of Public Administration Research and Theory*) from the years 2000–2012 showed 32.6% documentation rate for research funding sources (Jordan and Gray 2014). Heidari and colleagues by reviewing 151 journals' "Instruction to authors" reported that 64.9% of them had requested authors to disclose their "financial supports" in their articles (Heidari et al. 2012), Koushan and coworkers found a rate of 43.1% for reporting the "financial support" in the articles published in Persian language journals from 2011 to 2012 (Koushan et al. 2014). This finding shows that even journal editors were not sensitive enough to seek such financial conflicts in the manuscripts submitted to their journals, while a study on 268 trials published in five high impact medical journals from 1999 to 2000 showed 89% rate for reporting of the "financial supports" (Gross et al. 2003). Although compared with the high impact journals the overall rate of reporting the "financial support" in Iranian medical journals is not adequate, our results show an improved trend from 2009 (29.1%) to 2013 (53.9%).

In the present study, 13% of evaluated articles referred to the patients' "confidentiality". It was better reported in English language journals than Persian journals (16.4 vs. 10.2%, respectively). Navabi and colleagues evaluated this issue in the clinical trials published in Iranian dental journals between 2001 and 2011. They found that 99.5% of the articles had not mentioned the "confidentiality" of subjects' personal information (0.5% was mentioned) (Navabi et al. 2013). However, Heleny and others reported 26% rate of the "confidentiality" documentation in the physical therapy publications between 1996 and 2001 (Henley and Frank 2006). Although we found evidence of improvement in reporting of "confidentiality" over the time in Iranian medical journals (7.4% in 2009 vs. 35.3% in 2013, $p < 0.001$), it seems that investigators, as well as editors, must pay special attention to the patients' confidentiality and disclose this ethical requirement in their publications.

Another item assessed in the present study was the "conflict of interest". 23.4% of the evaluated articles had declared the authors' conflict of interest. This issue was more frequently mentioned in English-language Iranian medical journals and the studies performed outside of Iran. Also, an improved trend in the "conflict of interest" reporting was found in Iranian journals from 2009 to 2013. Although two previous studies demonstrated that 44.4–53.8% of Iranian journals had a specific policy on the "conflict of interest" as one of the publication ethics principles (Heidari et al. 2012; Salamat et al. 2013), we found low documentation rate in this issue especially in Persian language journals (2.8%). While a recent study, in Iran, reported that 55% of the articles published in Persian language Iranian journals mentioned the authors' "conflict of interest" (Koushan et al. 2014). This difference could be due to the difference in study years. They reviewed articles published from 2011 to 2012, while in our study the published articles from 2009 to 2013 were evaluated. In a global comparison the prevalence of reporting the authors' conflict

of interest in four widely cited general psychiatric journals was 47% (Roy H. Perlis et al. 2005) and in other general medical journals was 29–43% (Gross et al. 2003; Jagsi et al. 2009). Compared with such studies, the prevalence of reporting the "conflict of interest" in Iranian journals is low, which might be related to the lack of awareness and education of authors and journal's editors; although an ongoing improvement was observed from 2009 (13.6%) to 2013 (26.9%).

The reported rate of the "informed consent" in our study was 47.0%. Navabi and co-workers found that the frequency of reporting "informed consent" was 50.4% in the clinical trials published in Iranian dental journals during 2000–2010. They concluded that "most Iranian dental clinical trial reports failed to consider important ethical principles" (Navabi et al. 2013). However, in a review on students' Ph.D. theses (2007–2012), 59.5% of them had ethical approval, while only in 4.3% the obtaining "informed consent" was clearly elaborated (Bahmanabadi et al. 2014). Better rates were reported in other international studies, which ranged from 50 to 70% (Henley and Frank 2006; Taljaard et al. 2011; Schroter et al. 2006; Bavdekar et al. 2008; Myles and Tan 2003). Another report from Iran showed 55% rate of the "informed consent" declaration in Persian language journals (Koushan et al. 2014), which is more than what we found in our study (46%) in Persian language medical journals. In the present study, the "informed consent" was better reported in the interventional than observational studies (65.4 vs. 39.8%, respectively). This pattern might have resulted from the current attention of Publication Commission of the Iranian Ministry of Health and Medical Education to trial registration as well as the journals' editors to the publication of interventional studies. In a review of the clinical trials published in *British Medical Journal, Journal of the American Medical Association, The Lancet, and New England Journal* between 1993 and 1995, documentation of "informed consent was reported 79.8% (Ruiz-Canela et al. 1999). In a random samples of trials before and after 1997, Yank and Rennie also found documentation rate of the "informed consent" from 62% to 82% in the *Annals of Internal Medicine, British Medical Journal, Journal of the American Medical Association, The Lancet, and The New England Journal of Medicine* (Yank and Rennie 2002). It shows that the rate of addressing "informed consent" in interventional studies has improved, but still needs more attention.

We found that the "ethics committee approval" was mentioned in 443/1460 (30.3%) articles that 380 of them (85.77%) referred to the name of the relevant ethics committee. Also, this issue was better reported over the time. Schroter and colleagues found that the ethical approval was mentioned in 69% of manuscripts published in five general medical journals between February and May 2003. They reported that 43% of the articles named the ethical committee that approved the study (Schroter et al. 2006). Navabi and others found that the frequency of reporting the "ethics committee approval" was 15.3% in clinical trials published in Iranian dental journals during 2000–2010 (Navabi et al. 2013). In our study, this rate was 42.2% in the interventional studies. The frequency of reporting "ethics committee approval" in Iranian medical journals published in Persian was 15.5%. Koushan and co-workers found similar results to ours in the Persian articles group. They observed that such approval was not reported in 81.7% of the articles (Koushan et al. 2014). Reporting the "ethics committee approval" was significantly higher in Iranian

English-language journals. Also, Iranian authors documented the "ethics committee approval" less than the foreign authors (28.6 vs. 52.8%). Although the report of such approval in Iranian medical journals' articles have shown improvement, it is still low compared with other journals worldwide (ranged 63–78%) (Yank and Rennie 2002; Myles and Tan 2003; Meschia and Merino 2003; Schroter et al. 2006; Taljaard et al. 2011). This could suggest a lack of education among Iranian authors and less attention to this issue in Iranian journals and academic centers.

This lack of attention to ethical considerations mentioned in the literatures is not limited to the Iranian authors or journals. For instance, of 821 human subject articles published in Saudi Arabian medical journals between 1979 and 2007, only 8.6% documented obtaining the ethics committee approval and the "informed consent", with a significantly higher rate for the interventional studies (19.4%), the studies since 2000 (19.7%), and the studies performed outside Saudi Arabia (15.9%) (Al-Gaai et al. 2012). In another survey, two Indian journals in 2006 were evaluated, in which the rate of the "ethics committee approval" and the "informed consent" documentation were 29.53 and 46.94%, respectively (Bavdekar et al. 2008).

Poor knowledge about the ethics and poor academic writing skills among the Iranian authors (Astaneh and Masoumi 2011), different approaches to ethical issues disclosures by Iranian Medical journals (Heidari et al. 2012; Salamat et al. 2013), and the lack of journals' staffs training can be considered as main causes of inadequate ethical documentation rate in Iranian journals' articles. Journals' instructions for authors play important roles in this matter. They must be exactly structured, matched with the available international ethical guidelines to avoid unethical publications. Generally, higher-impact journals have more comprehensive instructions that are upgraded regularly than lower-impact ones (Gasparyan et al. 2014).

This study has some strength points; it is the most recent study in looking at the reporting of ethical consideration in the human subject articles published in Iranian medical Journals. None of the previous studies have assessed all Iranian journals. We included all Iranian medical journals and studied all ethical considerations in their publications. We did not focus purely on one study design, single medical specialty, patients' population, or journals.

Conclusion

Documentation rate of ethical conducts in human subject articles in Iran was not acceptable compared to what we already saw in reputable journals that can be caused by some factors including the lack of knowledge of editors, inappropriate articles screeing at journal offices, and finally improper peer review. Therefore, it is suggested (1) both journals' editors and authors be trained for academic writing skills and the ethical considerations by educational workshops and short courses. (2) Researchers and students should be obliged to mention ethical issues in their articles by competent authorities and local ethics committees. (3) Policymakers pay more attention to reporting the ethical issues in published articles with providing standard guidelines in this regard.

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Compliance with Ethical Standards

Conflict of interest The authors hereby certify that this is an original, unpublished work that is not under consideration elsewhere. We have no conflicts of interest to disclose.

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