

Reporting ethics approval and informed consent of *in vivo* researches in dental journals

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Abstract: *Aim.* To assess reporting of ethics approval and patient consent for *in vivo* researches published in dental journals.

Method. Nine journals from the category “Dentistry, oral surgery & medicine” (Journal Citation Reports) were randomly selected using a systematic sampling technique. Only manuscripts reporting *in vivo* researches from the 1st issue from 2018 volume of selected journals were analyzed.

Results. Ninety six manuscripts were assessed. Ethics approval was mentioned in 69,8%, frequently with an identifier, it being usually obtained from an ethics committee associated to an university. Informed consent was usually stated to be obtained (60% of human studies), usually as written signed forms. There was noticed a similar behavior to obtain or not both research ethics approval and informed consent. Ethics research was better reported in experiments than observational studies, and in journals with a higher Impact Factor.

Conclusions. Ethics approval and patient’s informed consent are generally well reported in the “top” dental journals. For improvements, additional training of the researches, requesting these data at manuscript submission, and inquires of the journals’ editors when missing would be beneficial. Better standardization on reporting them, as key information required and language used, is also recommended.

Key Words: research ethics, ethical approval, ethics committee, dentistry, oral medicine.

INTRODUCTION

In vivo researches on animals and humans bring important evidence that increase the body of knowledge in the medical field, contributing to improving the outcomes of medical procedures. Even so, their implementation often raise ethical and legal issues, regulations being made in order to conduct the researches in a safe and socially responsible manner [1]. For research involving human subjects the principles of conducting research is set out by the Declaration of Helsinki [2, 3]. The animal experiments should be conducted by the ethical guideline known as the 3Rs – Replacement, Reduction and Refinement [4]. But generally there are many laws and regulations, both international norms

and standards, and national ones (the latter vary greatly among different countries, even regarding important differences of fundamental ethical issues), that should be known by researchers and followed when conducting *in vivo* researches [5].

Among the issues raised in established standards and regulations for conducting *in vivo* research, obtaining the ethics committee approval, and informed consent in human studies are two well-known aspects. Ethics committee approval should be obtained before research beginning, when appropriate, being desired to become a moral reflex for researchers [6]. Patient’s informed consent is seen as a very important aspect of research ethics, it being included in ethics regulations and is meant to protect subject’s autonomy regarding

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study inclusion, one's welfare, desire and interest being seen as rising above the society interest and welfare [7-9]. Reporting research in scientific journals often requires to include information on adherence to ethical conduct. Many scientific journals request data on ethical conduct, usually the minimum stated being upon ethics approval of the research from the appropriate regulatory authority, and upon obtaining informed consent in human studies. These data are included in some journals in short separate sections in full-text manuscript. Especially researches on humans have a wide variability, and ethics approval or even informed consent are issues debatable that stir controversy in some cases (e.g., need for ethics approval for case reports, or informed consent for retrospective studies) [10].

The aim of this manuscript was to assess reporting of two parameters integrated to research ethics (i.e., ethics committee approval, and patient consent for studies on humans) for *in vivo* researches published in dental journals indexed in Journal Citation Reports.

METHODS

Original research articles reporting *in vivo* researches published in dental journals were analyzed. The procedures that lead to the selection of the dental journals that contained the analyzed articles was the following.

Journals' inclusion criteria were: journals included in the category "Dentistry, oral surgery & medicine" from SCIE from Journal Citation Reports; journals with a 2017 Journal Impact Factor, as indicated in Journal Citation Reports (Clarivate Analytics, 2018). There were excluded: the journals to which the authors did not have access to full text articles (were used either were open access journals, or journals available through the Library of "Carol Davila" University of Medicine and Pharmacy, Bucharest); the journal that did not include at least one *in vivo* original research.

Journals were randomly selected using a systematic sampling technique. The sampling frame used was the list of the journals included in the category "Dentistry, oral surgery & medicine" from SCIE from Journal Citation Reports. The journals were ranked according the 2017 Impact Factor. The sampling interval

used was $k=10$. Initially, a random number between 1 and 10 was chosen (i.e., in this study this number was 4, therefore the first included journal was the one ranked the 4th). Afterward, every 4+kth ranked journal was selected. If one journal did not meet the eligibility criteria, the next journal that did was selected, and afterward the next 10th journal was included. From the 91 journals included in the category "Dentistry, oral surgery & medicine", a sample of 9 journals was used.

From the selected journals, the articles from the 1st issue from 2018 volume were analyzed. There were included only the articles that reported *in vivo* original researches, both animal and human studies.

The articles were accurately read and information regarding to two parameters integrated to research ethics were registered, i.e. ethics committee approval for the study, and patient informed consent for studies on humans. Regarding the ethics approval of the study the following were recorded: stating that ethics approval for the research was obtained; specification of the committee that gave the ethics approval; mentioning of the identifier (an identification code) of the ethics approval for the research. For the human study there was recorded the mentioning of request of patient informed consent for study inclusion, and if it was used a written signed form. Beside this, it was registered the research type, animal or human study, and for the latter if it was an observational or experimental study.

Data was analyzed by descriptive statistics. Chi-square test and non-parametric Kruskal-Wallis test were used for group comparison. Results were considered significant at $p < 0,05$

RESULTS

From the 9 selected journals, a total of 96 articles met the inclusion criteria and were analyzed (Table 1). The great majority of the *in vivo* researches presented results of human studies, only a few of them were reporting data from animal studies. From humans studies, most were observational studies. All animal studies were experiments.

Ethics approval. Generally, in most of the articles there was mentioned that ethics approval was obtained (67 manuscripts out of 96; 69,8%), this being

Table 1. The dental journals selected and corresponded numbers of articles analyzed, as reporting results of *in vivo* researches

Journal title abbreviation (ISSN)	2017 IF/rank	Volume (issue)	No of articles
Clin Oral Implants Res (0905-7161)	4,305/4	29(1)	11
J Periodontal Res (0022-3484)	2,878/14	53(1)	10
Int J Oral Maxillofac Surg (0901-5027)	2,164/24	47(1)	15
J Oral Maxillofac Surg (0278-2391)	1,799/34	76(1)	27
Head Face Med (1746-160X)	1,606/44	14(1)	7
Dent Traumatol (1600-4469)	1,414/54	34(1)	2
Br J Oral Maxillofac Surg (0266-4356)	1,26/65	56(1)	13
J Periodontal Implant Sci (2093-2278)	1,072/75	48(1)	3
J Dent Sci (1991-7902)	0,619/85	13(1)	8

IF – Impact Factor

found in all experimental studies on humans, in almost all animal studies, and the majority of observational studies on humans (Table 2). From human studies, experimental studies registered a statistically significant higher frequency of obtaining ethics approval compared to observational studies, chi-square test, $X^2(1)=6,207$; $p=0,013$. Regarding this aspect in observational studies on humans, when approval was not obtained sometimes there was found a statement on mentioning the absence of its requirement, this being in some cases sustained by the decision of an ethics committee, who gave an exemption for the respectively study protocol.

From the 11 researches that did not mentioned at all the approval of ethics committee, one was an animal study, and the rest were observational studies on humans. In the article that reported animal research there was stated that there were followed the guidelines of the Animal Research Committee of the University. From the article that reported observational researches on humans, 7 were case report, 1 presented two cases, 1 was retrospective (data was collected from patients' medical records), and for the remaining 1 it was unclear why approval was not requested, and informed consent was not mentioned either (e.g., as mentioning that for the accuracy of data collection an oral and extra-oral examination was performed to the patient by two specialists).

Regarding the 10 researches in which regarding ethics approval was mentioned "not required", these were all observational studies on humans. From the latter, 3 were case reports, 2 were case series presenting 3 patients, 2 were retrospective (was mentioned study type and also that data was collected from patients' records), and in 1 was mentioned that approval was not needed because data use was collected as part of a service audit (not for research). For the remaining 2 was rather

unclear regarding why ethics approval was not asked for. Most probably one was retrospective and used patients' medical records for data collection, but the other one was prospective with a six-month follow-up with clinical examinations for data collection (e.g., of mouth opening). Generally, just over half of the studies that mentioned obtaining an ethics approval gave specific information on it, mentioning an identifier. This conduct was noted in almost all experimental studies on humans, over half of *in vivo* studies on animals, and just over half of the observational studies who stated obtaining ethics approval.

Most of the ethics committee that gave approval were associated to medical universities, but were also some associated to hospitals, research institutes, and national or local institutions (e.g. National Health Service ethics committee).

Articles that reported research with an ethics approval were published in journals with the highest mean 2017 Impact Factor, while the articles mentioning ethics approval was not required registered the lowest mean value (Fig. 1). Group difference was not statistically significant, Kruskal-Wallis test $X^2(3)=4,403$; $p=0,221$.

Informed consent. Mention of obtaining informed consent was found in the majorities of the manuscripts reporting researches on humans (51 out of 85; 60%) (Table 2). It was mentioned in all experimental studies, in the great majority being also referee to obtain a written or signed form. In the observational studies, obtaining informed consent was mentioned in just over half of the articles, and a written form was found in just over third of them. Experimental studies registered a statistically significant higher frequency of reporting obtaining informed consent compared to observational studies, chi-square test, $X^2(1)=8,423$; $p=0,004$.

Articles in which was mentioned that informed

Table 2. Data on reporting research ethics and informed consent in the selected dental journals

Research ethics		Animal experiments (n=11)	In vivo human studies(n=85)	
			observational (n=74)	experimental (n=11)
Ethics approval				
Status	given	10	46	11
	exemption	0	8	0
	mentioned "not required"	0	10	0
	not mentioned	1	10	0
Committee from	university	5	42	9
	hospital	2	9	0
	country/town	1	2	2
	research institute	1	0	0
	unclear	0	1	0
Identifier	given	6	24	8
Informed consent				
Status	given		40	11
	mentioned "not required"	NA	6	0
	not mentioned		28	0
Form	written/signed	NA	26	8
NA – not applicable				

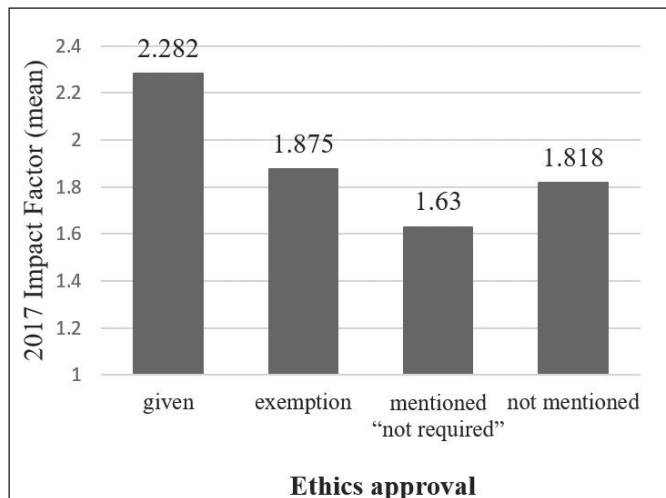


Figure 1. Ethics approval related to 2017 Impact factor.

consent was requested had a higher impact factor compared to the others (Fig. 2). Group difference was not statistically significant, Kruskal-Wallis test $X^2(2)=0,279$; $p=0,870$.

Ethics approval and informed consent relationship.

There was noticed a relationship between obtaining research ethics approval and informed consent. In the majorities of the studies for which ethics approval was obtained the informed consent was obtained too (42 manuscripts out of 57), while in the majorities of the studies in which ethics approval was not obtained the informed consent wasn't obtained also (19 manuscripts out of 28). The difference between groups was statistically significant, i.e. chi-square $X^2(1)=13,501$, $p<0,001$.

DISCUSSION

This study's results suggest that overall ethics approval and patient's informed consent are well reported in the "top" dental journals, i.e. were mentioned to be obtained in the majority of them; ethics approval usually was mentioned with an identifier, and most frequently was given by an ethics committee associated to a medical university; informed consent was usually stated to be obtained, frequently as a written signed form. From human studies, both ethics approval and informed consent were better reported in experiments than observational studies, and generally was noticed a similar behavior of reporting them, e.g. when reporting obtaining ethics approval informed consent was reported to be obtained too. There was also observed a tendency for reporting better research ethics in journals with a higher Impact Factor.

Some specialist argue that researches in humans should be published with evidence that it was approved by a research ethics committee [11]. Even so, depending on research design, this is a debatable aspect. If ethics approval is mandatory for experimental *in vivo* studies, the same aspect for observational studies is not so clearly stated. By this study findings, obtaining ethics approval in

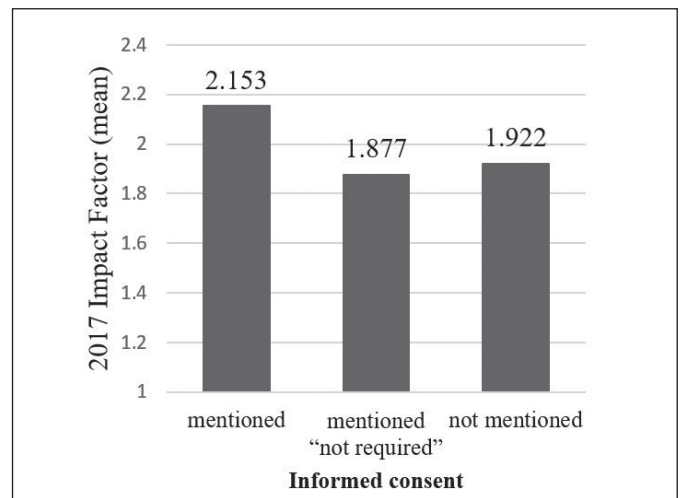


Figure 2. Informed consent related to 2017 Impact factor.

a common practice in experimental studies, on humans or animals, but not so common in observational studies, these results being similar to some previous studies [12]. Some ethics committee found, including for the researches reported in these analyzed article, that the research should be given an exemption or waiver from ethics approval, or sometimes even for an inform consent. Some examples in this regard may be the situation when data are collected retrospectively from medical records, or by using a questionnaire that has a low risk of harm, or even in case of a case report [13, 14]. Regarding this issue there are some differences between countries or even ethics committees. National culture generally influences behavior and perception of many factors, including some related to research ethics, a simple example being the difference observed in adherence to research ethics [15]. Maybe the best conduct would be consulting an ethics committee before beginning a study, and if appropriate granting an exemption.

Journals sometimes require ethics approval of the research during submission, this information being included in the instruction for the authors who submit them. By Navaneetha, for researches published in 2011, almost half of the dental journals he analyzed requested approval from ethics committee and almost one third insisted on obtaining and reporting informed consent, it concluding that a significant proportion of them did not give these instructions to the authors [16]. International Committee of Medical Journal Editors (ICMJE) indicates that authors should ensure the research is in accordance with the Helsinki Declaration, seek approval form an ethical review body, but editors should form their own judgment if the research was appropriate [17]. Therefore, in order to develop better practice in this regard it would be best to include these aspects in all journals' guides for authors. For improving conducting and reporting research findings it would be recommended to establish a more standardization way of reporting them, e.g. as key information required and language used [12]. Most probably the high adherence to obtaining research ethics

approval observed in this sample of dental journals was related also to journal requests to include data on it in the submitted manuscripts.

Informed consent was disclosed with a frequency lower than ethics approval in the analyzed dental journals, which is a fact similar to other researchers previously conducted on same theme [12, 18]. Informed consent is an ethical requirement for researches on humans, and it has both moral and legal values [19]. In case of autonomous patients is being given by the patient itself or his legal representatives. In the case of minors, both parents and child should be informed and involved in giving consent [20].

This study results presents a similar situation compared to others. Analyzing 5 well recognized general medical journal Schroter *et al.* [12] found that ethics approval was not mentioned in 31% of articles, and consent in 47% of them. Pitak-Arnrop P *et al.* [18] analyzing same issue in oral and maxillofacial surgery journals found that ethics approval was documented only in 22% of manuscripts, and individual patient consent in only 25%. Murphy analyzing same situation in Otolaryngology journals found that 49.9% lacked a statement of ethics approval and 42.9% lacked disclosure of informed consent [21]. Even so, the articles analyzed in this research were published in well-ranked journals, indexed in Journal Citation Reports, could be seen as leading or “top” journals, and are recently published, increasing attention being given nowadays to these aspects. Even so, most probably these results are not representative for all dental journals.

Research limitations include the relative low numbers of journals analyzed, as considering only

“top” journal were included, most probably situation being quite different for other journal samples. Either, considering a relative well-situation was found, these journals could be a model to be followed by others. Also, there were not analyzed all journals from the category “Dentistry, oral surgery & medicine”, therefore could be errors related to studying only a sample of them. Other study limitation is related to the analysis of need of research ethics and informed consent in various types of observational studies, this aspect not being taken into analysis as lacking consensus and being highly debatable.

CONCLUSSION

Ethics approval and patient’s informed consent are generally well reported in the “top” dental journals, both being better reported in experiments than observational studies. Further research should be conducted to observe the situation in other dental journals. To reach improvements in this regard, additional training of the researches on this issues, requesting data on researches at manuscript submission, and inquirements of the journals’ editors when information in this regard is missing would be beneficial. Better standardization on reporting them, as key information required and language used, is also recommended.

Conflict of interest. The authors declare that there is no conflict of interest.

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