



BRIEF COMMUNICATION

Reporting of ethical committee approval and patient consent in the *Portuguese Journal of Pulmonology* and in the other Portuguese medical journals with impact factor[☆]

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KEYWORDS

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Abstract

Introduction: Reporting of ethical committee (EC) approval and patient consent in publications involving human subjects may be lower than recommended. In this paper this ethical issue was analysed in the *Portuguese Journal of Pulmonology* and in the other two Portuguese medical journals with impact factor indexed in the ISI Web of Knowledge.

Methods: Reporting of EC approval and patient consent was searched in all publications involving human subjects published in the *Acta Médica Portuguesa*, *Acta Reumatológica Portuguesa* and *Portuguese Journal of Pulmonology*, from the 1st July 2010 until the 30th June 2011. The search also looked for the involvement of vulnerable and potentially identifiable subjects.

Results: Most of the analysed publications, which included a considerable proportion of vulnerable (23%) and of potentially identifiable case reports (14%), were case reports (49%). Overall EC approval ranged from 0% to 28%, in case reports and prospective studies, respectively, whereas overall patient consent ranged from 0% to 26%. There were not statistically significant differences in results among the selected journals.

Conclusions: Reporting of EC approval and patient consent in the three leading Portuguese medical journals has been lower than in their leading world counterparts. This should be taken into account and further audited in future, not only for the protection of the research subjects but also to maintain public trust in the process.

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PALAVRAS-CHAVE

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Revista médica

Referência a aprovação de comissão de ética e a consentimento dos doentes na Revista Portuguesa de Pneumologia e noutras revistas médicas portuguesas com fator de impacto
Resumo

Introdução: A referência a aprovação de comissão de ética (CE) e a consentimento dos doentes, nas publicações que envolvem humanos, poderá ser inferior à recomendada. Neste artigo, esta situação foi analisada na *Revista Portuguesa de Pneumologia* e nas outras 2 revistas médicas portuguesas com fator de impacto indexadas na ISI Web of Knowledge.

Métodos: A referência a aprovação de CE e a consentimento dos doentes foi pesquisada em todas as publicações que envolveram humanos na *Acta Médica Portuguesa*, *Acta Reumatológica Portuguesa* e *Revista Portuguesa de Pneumologia*, de 1 de julho de 2010 a 30 de junho de 2011. A pesquisa incluiu a avaliação do envolvimento de doentes vulneráveis e potencialmente identificáveis.

Resultados: A maior parte das publicações analisadas, que incluíram uma proporção considerável de doentes vulneráveis (23%) e de casos clínicos potencialmente identificáveis (14%), foram casos clínicos (49%). Globalmente, a aprovação de CE variou entre 0% e 28%, nos casos clínicos e nos estudos prospetivos, respetivamente, e o consentimento dos participantes entre 0% e 26%. Não se registaram diferenças estatisticamente significativas nos resultados entre as revistas estudadas.

Conclusões: A referência a aprovação de CE e a consentimento dos doentes nas 3 revistas médicas portuguesas mais cotadas foi inferior à das suas congéneres mundiais. Estes resultados devem ser tidos em consideração e reavaliados em futuras investigações, tendo em vista a proteção dos participantes e a confiança da sociedade nos procedimentos envolvidos.

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Introduction

Most leading medical journals follow the uniform requirements for manuscripts submitted to biomedical journals of the International Committee of Medical Journal Editors (ICMJE).¹ In the same way, they require reporting of ethical committee (EC) approval and patient consent, according to the Helsinki Declaration, before a manuscript involving human subjects is accepted for publication.^{1,2} This is the rule, except in some situations, which may be considered for EC evaluation exemption, related to studies on normal educational practices, observations of public behaviour or case reports where the participants cannot be identified.^{3,4} However, reporting of EC approval and patient consent in publications involving human subjects may be lower than recommended, even among leading world medical journals.⁵ In this paper reporting of EC approval and patient consent in publications involving human subjects was analysed in the *Portuguese Journal of Pulmonology* and in the other two Portuguese medical journals with impact factor indexed in the ISI Web of Knowledge (ISI Wok).⁶ To the best of our knowledge this is the first time this issue has been addressed in a Portuguese medical journal.

Methods

A search was conducted of reporting of EC approval and patient consent in all publications involving human subjects published, from 1st July 2010 to 30th June 2011, in the three Portuguese medical journals with impact factor

indexed in the ISI Wok: the *Acta Médica Portuguesa*, the *Acta Reumatológica Portuguesa* and the *Portuguese Journal of Pulmonology*.⁶ The search also included looking at whether vulnerable subjects, such as children or psychiatric patients were involved. In addition, we also considered whether potentially identifiable subjects in case reports had been included, when potentially identifying photos, or initials of names, with indication of patient's race, age, gender, profession or address were presented.^{1,3} The manuscripts included were categorized as randomized trials, prospective or retrospective, observational studies or case reports (Table 1). Briefly, randomized trials included studies in which participants were recruited and randomly assigned to groups which would be subject to intervention or not; observational studies included cross-sectional, case-control and cohort studies in which participants were retrospectively or prospectively non-randomly recruited; and case reports included single and case report series, as well as medical images and letters published with information about the participant subjects. Reviews, editorials, commentaries or other publications that did not include direct participation of human subjects were excluded. For statistical inference the results were estimated as proportions with 95% confidence intervals.

Results

There was overall a high proportion of published case reports (49%) compared with observational studies (51%) and randomized trials (0%), in the three leading Portuguese medical

Table 1 Number of analysed publications, by study type, published in the three leading Portuguese medical journals, from the 1st July 2010 until the 30th June, 2011, as well as of manuscripts involving vulnerable and potentially identifiable subjects, with indication of the percentages (%) of Ethical Committee (EC) approval and of patient consent reporting, with 95% confidence intervals (95% CI).

	<i>Acta Médica Portuguesa</i>			<i>Portuguese Journal of Pulmonology</i>			<i>Acta Reumatológica Portuguesa</i>			Overall										
	<i>n</i>	EC approval		Consent		<i>n</i>	EC approval		Consent		<i>n</i>	EC approval		Consent						
		%	(95% CI)	%	(95% CI)	%	(95% CI)	%	(95% CI)	%	(95% CI)	%	(95% CI)	%	(95% CI)					
Randomized trials	0					0					0									
Non randomized studies	48	8	(0–16)	31	(18–44)	22	32	(12–52)	41	(20–62)	18	28	(7–49)	44	(21–67)	88	18	(10–27)	19	(11–27)
<i>Prospective</i>	28	14	(1–27)	54	(35–73)	12	50	(21–79)	58	(30–96)	13	38	(11–65)	54	(27–81)	53	28	(16–38)	26	(14–38)
<i>Retrospective</i>	20	0	(0–16)	0	(0–16)	10	10	(0–29)	20	(0–45)	5	0	(0–56)	20	(0–55)	35	3	(0–15)	9	(0–18)
Vulnerable subjects	13	15	(0–35)	46	(19–73)	6	17	(0–47)	33	(0–71)	0					19	16	(0–33)	0	(0–17)
Case reports, images or series	39	0	(0–9)	0	(0–9)	15	0	(0–20)	0	(0–20)	37	0	(0–9)	0	(0–9)	91	0	(0–4)	0	(0–4)
<i>Vulnerable subjects</i>	17	0	(0–18)	0	(0–18)	3	0	(0–56)	0	(0–56)	3	0	(0–56)	0	(0–56)	23	0	(0–14)	0	(0–14)
<i>Potentially identifiable</i>	6	0	(0–39)	0	(0–39)	2	0	(0–66)	0	(0–6)	5	0	(0–56)	0	(0–56)	13	0	(0–23)	0	(0–23)
Total number of publications	77	4	(1–9)	14	(9–22)	47	17	(9–30)	23	(14–37)	55	8	(4–18)	15	(8–26)	179	8	(5–12)	16	(12–22)

journals (Table 1). There was also overall a considerable number of vulnerable subjects participating in all analysed studies (23%) and of potentially identifiable subjects in case reports (14%).

EC approval, among journals, ranged from 0% to 50%, in case reports and prospective studies, respectively, and overall from 0% to 28% (Table 1). Patient consent among journals ranged from 0% to 58%, in case reports and in prospective studies, respectively, and overall from 0% to 26% (Table 1).

Overall EC approval was significantly higher in prospective studies (28%, 95% CI: 16–38%) than in retrospective studies (3%, 95% CI: 1–15%) and case reports (0%, 95% CI: 0–4%), but there were no statistically significant differences in results among the selected journals.

Discussion

This study evidenced an overall low proportion of randomized clinical trials (0%) and observational studies (51%) in the three leading Portuguese medical journals, compared with the *New England Journal of Medicine*, the *Lancet* and the *BMJ*, among others, where those studies accounted for 29% and 56% of all publications, respectively.⁵

Twenty three percent of the publications of the Portuguese journals included vulnerable subjects, compared with 35% in the other leading international journals.⁵ On the other hand, 14% of the case reports of the Portuguese journals included potentially identifiable subjects, whereas that has not been reported for the other journals.⁵ In this context, authors and editors should consider that patient photos and other potentially identifying details may often be irrelevant and thus could be omitted or presented in a different way (e.g. expressions such as ‘‘M.J., a 57-year-old divorced, member of the nursing faculty’’ should be substituted by ‘‘A female patient in her mid 50’s’’).⁷ On the other hand, if omission or rephrasing of patient details is not possible, formal written informed consent should be obtained,^{1,3} as falsifying data to conceal personal details is not acceptable.⁷

Overall reporting of EC approval was low in the Portuguese medical journals, with a maximum of 28%, in prospective observational studies, compared with the international journals, where reporting of EC approval reached a maximum of 93% in randomized controlled trials and 60% in cohort studies.⁵ It was a similar picture for overall reporting of consent in case reports; this was 0% in the Portuguese journals, compared with 11% in the international journals.⁵ These low levels of EC approval and consent reporting in the Portuguese medical journals may be partially connected with the publication of a high proportion of retrospective studies and case reports that may be exempt of such ethical requirements.^{3,4} Moreover, Portuguese medicine may be more centred in a paternalist doctor model, than in autonomous patient model, relegating for a second plan the need of the patient consent for publication. This may particularly be true of case reports, where there are still many doubts about the right balance between the need to publish relevant information *versus* respect for the patient autonomy.³

In conclusion, reporting of EC approval and patient consent in the three leading Portuguese medical journals was

lower than in their leading world counterparts. Editors and authors need to take note of this and there should be a more thorough audit process in future research. This is needed not only for the protection of the research subjects but also to maintain public trust in the process,⁸ although a low level of EC approval and consent reporting in published manuscripts does not necessarily mean absence of approval, or consent, or poor ethical conduct.⁹

Ethical disclosures

Protection of human and animal subjects. The authors declare that no experiments were performed on humans or animals for this investigation.

Confidentiality of data. The authors declare that no patient data appears in this article.

Right to privacy and informed consent. The authors declare that no patient data appears in this article.

Conflicts of interest

The authors have no conflicts of interest to declare.

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