

## Brief communication (Original)

# Endorsement and implementation of high impact factor medical journals on the International Committee of Medical Journal Editors (ICMJE) policy of mandatory clinical trial registration

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**Objective:** We determined the proportion of highest impact factor journals that follows the ICMJE policy of clinical trial registration and identified factors associated with policy implementation.

**Study design and setting:** Ten highest impact factor journals from ten specialties were identified from the 2009 Journal Citation Reports. Instructions for authors were reviewed for the statements regarding the trial registration. If the registration policy was mentioned in the instructions, the published articles were assessed to determine if the policy was actually implemented. The publishers, membership in Committee on Publication Ethics, journal vintage, etc., were analyzed for association with the policy implementation.

**Results:** Of 87 relevant journals, 58.6% endorsed the policy and 35.6% strictly implemented it. Factors for journals associated with strict clinical trial registration policy implementation were Internal Medicine specialty (OR 19.19; 95% CI: 2.21, 166.50;  $p = 0.007$ ), ICMJE's URM followers (OR 7.14; 95% CI: 2.62, 19.46;  $p < 0.001$ ), longer years of publication (OR for every 10 year 1.31; 95% CI: 1.16, 1.49;  $p = 0.001$ ), and higher impact factors (OR for every 1 JIF 1.70; 95% CI: 1.25, 2.32;  $p = 0.001$ ).

**Conclusion:** Only one third of the highest impact factor journals strictly implemented ICMJE policy. Associated factors were identified.

**Keywords:** Associated factors, clinical trial registration, endorsement, impact factor, implementation, policy

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Clinical trial registry has been established for many purposes [1]: to build up a database on clinical trials, to diminish the unnecessary redundancy of clinical trials, to facilitate patients' access to clinical trial information, to improve the transparency of clinical trials, and to counterbalance publication bias. Thanks mainly to the latter purpose, the International Committee of Medical Journal Editors (ICMJE), in September 2004, published a statement about mandatory prospective clinical trial registration [2] and included it in the Uniform Requirements for

Manuscripts Submitted to Biomedical Journals (URM). Medical journals have gradually adopted the policy, but there are many medical journals that still publish non-registered trials.

The objective of this study was to determine the proportion of medical journals that has endorsed and implemented the clinical trial registration policy, classified by medical specialties. The potential factors associated with the policy endorsement and implementation were also studied.

## Materials and methods

Ten highest impact factor journals from ten specialties were identified from the 2009 Journal Citation Reports, Science Edition (Thomson Reuters, 2010). The journals' latest versions of the instructions

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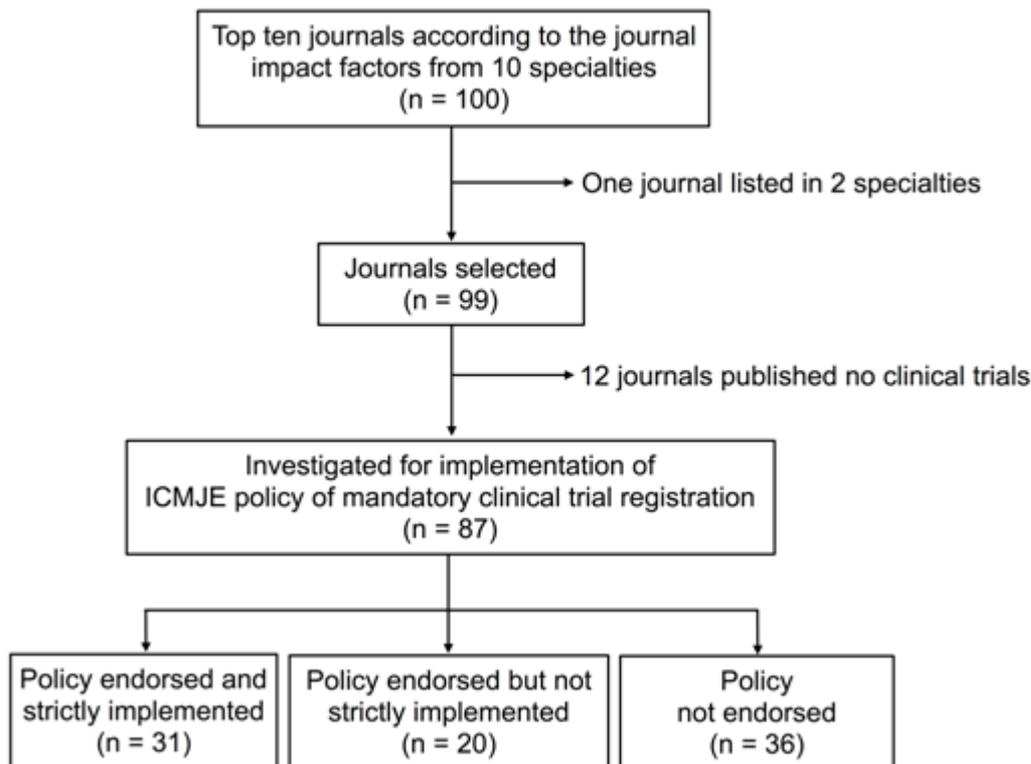
to authors, (last accessed on November 30, 2010) were retrieved and reviewed. Only the journals that have published clinical trials were considered “relevant” and included in the study. The definition of clinical trials in our study followed that of the World Health Organization International Clinical Trials Registry Platform (WHO-ICTRP) [3]. Clinical trials published in the latest issue of the journals (November-December 2010) were carefully read to see whether there was any trial registration number. If the numbers were not present, the WHO-ICTRP search portal [4] was accessed to identify if the published trial had ever been registered anywhere in the ICMJE accepted registries.

The main outcome was the numbers of journals that have strictly endorsed and implemented the policy. Journals were classified into 3 categories. If a journal did not have a statement regarding clinical trial registration policy in the instruction to authors, then it was classified as “policy not endorsed”. If the prospective clinical trial registration policy was in the instructions to authors, and all of the relevant clinical trials were published with the trial registration identification number, it was classified as “policy endorsed and implemented”. But if it published some trials without trial identification numbers, as searched

via WHO-ICTRP, then it was classified as “policy endorsed but not strictly implemented”. For a trial registration to be considered “proper” it must have been prospectively registered, i.e., the registration date not later than the date of first patient recruitment.

For each journal, we also identified the owner (company) by accessing the journal’s website, whether a journal was on the list of publications that follow the ICMJE’s URM [5], whether the editor was a member of Committee on Publication Ethics (COPE) [6], years of publication identified from the journal’s website, and the Journal Impact Factor (JIF) from the 2009 Journal Citation Reports. Then we analyzed whether any of these factors were associated with the policy endorsement and implementation.

The overall proportions of journals that endorsed and implemented the ICMJE policy of mandatory clinical trial registration and their 95% confidence intervals (CI) were estimated. Association between various factors with strict implementation of the policy were determined by odds ratios (OR) using logistic regression implemented under generalized estimating equations (GEE) framework in order to account for clustering on specialties. Data was analyzed using Stata version 10 (StataCorp, College Station, TX). Statistical significance level was set at 0.05.



**Figure 1.** Study algorithm

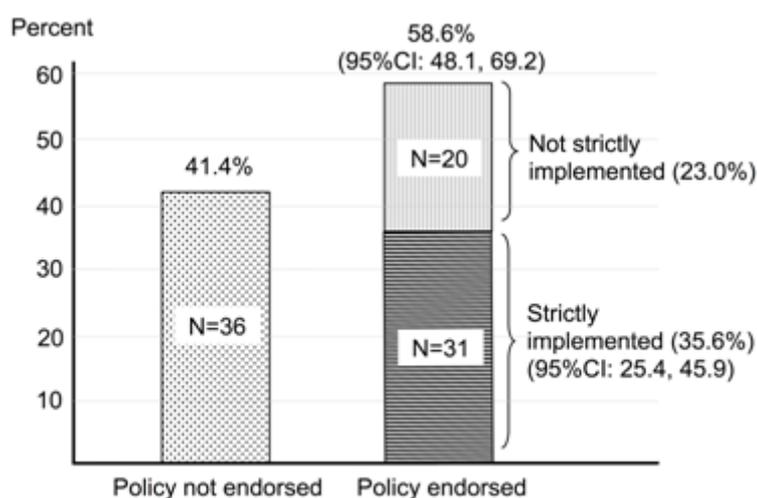
**Results**

Ten major specialties were identified: Internal medicine, Surgery, Obstetrics and Gynecology, Pediatrics, Ophthalmology, Otolaryngology, Orthopedics, Anesthesiology, Rehabilitation, and Psychiatry. The first ten journals with the highest impact factors for each of these specialties were selected. Among the selected 100 journals, one was listed for two specialties (Figure 1). Of the unique 99 journals, 12 journals (12.1%) were not relevant as they were not journals that published clinical trials.

Among the remaining relevant 87 journals,

51 journals (58.6%; 95%CI: 48.1, 69.2) endorsed the ICMJE policy of mandatory clinical trial registration (Figure 2). However, only 31 journals (35.6%; 95%CI: 25.4, 45.9) strictly implemented the policy.

Percentage of specialty journals that endorsed and implemented ICMJE policy varied widely across specialties can be seen in Table 1. Almost all journals under specialty of internal medicine (8 out of 9) endorsed and strictly implemented the policy. This specialty also had the highest median of journal impact factors, 13.355.



**Figure 2.** Overall proportion of journals that endorsed and implemented the ICMJE policy of mandatory clinical trial registration (n = 87).

**Table 1.** Journal impact factor classified by medical specialties and their proportion of policy endorsement and implementation.

Specialty	Journal Impact Factor of the highest ten journals (Median, IQR)	Numbers of journals that published clinical trials	Policy endorsed and strictly implemented	Policy endorsed but not strictly implemented	Policy not endorsed
Internal Medicine	13.355 (9.845-25.731)	9	8	1	0
Surgery	4.227 (4.066-5.376)	9	3	4	2
Obstetrics and gynecology	3.585 (3.185-3.942)	7	4	1	2
Pediatrics	3.563 (2.895-4.538)	7	4	1	2
Ophthalmology	3.632 (2.955-4.131)	8	4	0	4
Otolaryngology	2.134 (1.943-2.235)	9	2	0	7
Orthopedics*	2.779 (2.612-3.348)	10	1	3	6
Anesthesiology	3.348 (2.893-4.075)	10	0	6	4
Rehabilitation*	2.252 (2.096-2.411)	10	1	3	6
Psychiatry	7.230 (5.617-11.424)	9	4	2	3

IQR=interquartile range, \*One journal was listed in two specialties

Factors that were significantly associated with having the policy endorsed and strictly implemented were Internal medicine-related journals (OR = 19.19; 95% CI: 2.21, 166.50;  $p = 0.007$ ), ICMJE's URM followers (OR = 7.14; 95% CI: 2.62, 19.46;  $p < 0.001$ ), greater number of years of publication (OR for every 10 year = 1.31; 95% CI: 1.16, 1.49;  $p = 0.001$ ), and higher impact factors (OR for every 1 JIF = 1.70; 95% CI: 1.25, 2.32;  $p = 0.001$ ) as shown in **Table 2**.

## Discussion

The idea of clinical trial registration is not new. The real impact on biomedical publishing had not really been felt until ICMJE issued a statement in 2004 and eventually included it in the URM. The main purpose then was to reduce selective reporting. Since then, a number of journals have pledged to follow suit by adopting the URM. However, there were concerns that researchers, especially ones from developing countries, might lose some competitive edge through registration [7]. It was also observed that trial registration was associated with improved reporting quality [8].

The highest impact factor journals were used in our study because they were more likely to be read and cited and to have more impact in their fields. We gathered the information from the journal instructions

to authors and the published articles, not from an actual survey of the journal editors. Also, policy endorsement can be changed with the likelihood that more journals will endorse and implement the policy over time. The poor rate of policy endorsement and implementation at the moment was not surprising. The Consolidated Standards of Reporting Trials (CONSORT) was first published over 15 years ago with the objective of improving the quality of reporting of randomized controlled trials. It has been recommended in the URM. Yet less than 40 percent of high impact factor journals mentioned the statement in their instructions to authors [9].

The clinical trial registration policy has been declared and adopted for over six years but the actual implementation rate remains quite low. The latest edition of the Declaration of Helsinki [10] also includes the prospective registration of human trials, but only about one third of the high impact factor journals endorse and implement the policy. Raising awareness among researchers and journal editors might improve the implementation rate.

## Acknowledgement

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**Table 2.** Factors associated with journal policy endorsement and implementation.

Factors	Number of journals	% Policy endorsed and strictly implemented	OR (95% CI)	<i>p</i> -value
<i>Specialty</i>				
Others	78	29.5	1	
Internal Medicine	9	88.9	19.19 (2.21, 166.50)	0.007
<i>Owner of the journal (Company)</i>				
Elsevier	21	42.9	1	
Lippincott Williams & Wilkins	12	16.7	0.27 (0.05, 1.53)	0.138
Wiley	11	27.3	0.50 (0.10, 2.44)	0.391
Others	43	39.5	0.75 (0.32, 1.78)	0.514
<i>Journal listed as following ICMJE's URM</i>				
Non-followers	60	21.7	1	
Followers	27	66.7	7.14 (2.62, 19.46)	<0.001
<i>Editor as member of COPE</i>				
Non-members	30	43.3	1	
Members	57	31.6	0.57 (0.23, 1.39)	0.216
<i>Years published of the journal (every 10 years)</i>				
	87	not applicable	1.31 (1.16, 1.49)	0.001
<i>Journal impact factors (every 1 JIF)</i>				
	87	not applicable	1.70 (1.25, 2.32)	0.001

OR=Odds Ratio, 95% CI=95% confidence interval, ICMJE=International Committee of Medical Journal Editors, URM=Uniform Requirements for Manuscripts Submitted to Biomedical Journals, COPE=Committee on Publication Ethics, JIF=Journal Impact Factor

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