

Endorsement of ICMJE's Clinical Trial Registration Policy: a survey among journal editors

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ABSTRACT

Background: Since 2005, the International Committee of Medical Journal Editors (ICMJE) requires researchers to prospectively register their clinical trials in a publicly accessible trial registry. The Consolidated Standards of Reporting Trials (CONSORT) statement has supported this policy since 2010. We aimed to evaluate to what extent biomedical journals have incorporated ICMJE's clinical trial registration policy into their editorial and peer review process.

Methods: We searched journals' instructions to authors and performed an internet survey among all journals publishing reports of randomised controlled trials that follow ICMJE's Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals (n = 695), and/or that endorse the CONSORT statement (n = 404) accessed in January 2011. Survey invitations were sent to the email addresses of the editorial offices and/or editors-in-chief of included journals in June 2011.

Results: For 757 ICMJE and/or CONSORT journals, we identified that they published RCT reports. We could assess the instructions to authors of 747 of these; 384 (51%) included a statement of requiring trial registration, and 33 (4%) recommended this. We invited 692 editorial offices for our survey; 253 (37%) responded, of which 50% indicated that trial registration was required; 18% cross-checked submitted papers against registered

records to identify discrepancies; 67% would consider retrospectively registered studies for publication. Survey responses and specifications in instructions to authors were often discordant.

Conclusion: At least half of the responding journals did not adhere to ICMJE's trial registration policy. Registration should be further promoted among authors, editors and peer reviewers.

KEYWORDS

Outcome reporting bias, publication bias, trial registration

INTRODUCTION

Clinical trials provide essential evidence on the effectiveness and safety of healthcare interventions. Unfortunately, many studies remain unpublished and results are often presented selectively in trial reports.¹ Since positive and favourable results are more likely to get published than negative and inconclusive ones,² the medical literature and systematic reviews are at risk of bias, with an overrepresentation of promising results and an underrepresentation of adverse effects.^{3,5}

In response to accumulating evidence of selective publication and reporting in the biomedical literature, the International Committee of Medical Journal Editors (ICMJE) introduced a policy in 2005 that requires researchers to register their clinical trial in a publicly accessible trial registry before the enrolment of the first patient, in order to be considered for publication.^{6,7} Trial registration improves access to clinical trial data, allows the easy identification of unpublished studies by clinicians, researchers and reviewers,⁸⁻¹¹ and provides journal editors and peer reviewers with the opportunity to discover and prevent selective reporting of results. Since 2010, ICMJE's trial registration policy is also supported by the Consolidated Standards of Reporting Trials (CONSORT) Statement.^{12,13}

Although the number of registered trials has grown explosively since 2005,¹⁴ it is unknown how well journals currently adhere to ICMJE's registration policy and whether they consider publication of unregistered or retrospectively registered trials, cross-check submitted papers against registered data, and manage discrepancies between the two. We aimed to evaluate to what extent journals that announced to follow ICMJE's Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals¹⁵ and journals that endorse the CONSORT statement, have incorporated trial registration into their editorial and peer review process. For this aim we examined their instructions to authors and performed a survey distributed to the editorial offices of these journals.

MATERIALS AND METHODS

Identification of journals

In January 2011, all journals following ICMJE's recommendations (ICMJE journals; member list obtained at <http://icmje.org/journals.html>) and/or endorsing the

CONSORT statement (CONSORT journals; list of adopting journals obtained at <http://www.consort-statement.org/about-consort/consort-endorsement/consort-endorsers---journals/>) were identified, along with their webpages, and the email addresses of their editorial offices and editors-in-chief. If the latter information was not provided, we tried to identify it through the Google search engine.

To find out whether these journals publish reports of randomised controlled trials (RCTs), one author scanned their webpages and published issues. Journals that did not publish RCTs and journals for which we were unable to obtain this information were excluded. The RCT publication status of each journal was confirmed by a second reviewer, with discrepancies being resolved through discussion. If necessary, a third party made the final decision. Included journals were subdivided into general and speciality journals.

Instructions to authors

Between January and September 2011, one author extracted data from the instructions to authors of included journals (*table 1*). Here we excluded journals without a webpage and journals that only provided instructions to authors in languages other than English. All extracted data were confirmed by a second reviewer. Here, also, discrepancies were resolved through discussion, if necessary with a third party. We assessed whether the journal made a statement about endorsement of ICMJE's or CONSORT's recommendations, and whether a link to these guidelines was provided. We categorised such links as webpages (providing an internet-link to a web address containing the recommendations of either two), suitable references (providing a reference to an article describing ICMJE's criteria published in or after 2004, or to an article describing CONSORT's criteria published in or after 2001), or obsolete references (providing a reference to an ICMJE article published before 2004, or a CONSORT article published before 2001). In addition, we checked whether

Table 1. Information provided in the instructions to authors of ICMJE and CONSORT journals

	All journals (n = 747)	Journals on ICMJE list only (n = 366)	Journals on CONSORT list only (n = 271)	Journals on both lists (n = 110)
Statement about following ICMJE's recommendations	542 (73%)	253 (69%)	197 (73%)	92 (84%)
Statement about following CONSORT's recommendations	408 (55%)	95 (26%)	230 (85%)	83 (76%)
Statement about policy regarding trial registration	417 (56%)	153 (42%)	191 (71%)	73 (66%)
Registration: required	384 (51%)	137 (37%)	181 (67%)	66 (60%)
Registration: recommended	33 (4%)	16 (4%)	10 (4%)	7 (6%)
Registration: no notification of registration policy	330 (44%)	213 (58%)	80 (30%)	37 (34%)
Reference to specific trial registry provided	261 (35%)	62 (17%)	149 (55%)	50 (46%)

the instructions to authors contained a statement about the journal's policy regarding trial registration and, if so, whether registration was required or recommended, and whether specific trial registries were suggested.

Survey among editors

For the survey among editors, we excluded journals for which we were unable to identify an email address. Some editorial offices manage more than one journal. When the contact information of such journals overlapped, we considered these journals as a single potential survey responder.

In July 2011, included journals were invited to participate in our online survey through an email to the editorial office. When this email address was not available or not working, we sent the invitation to the journal's editor-in-chief. Two reminders were sent out, each a month apart. We used SurveyMonkey software (www.surveymonkey.com) to collect responses, which was open until November 2011.

The survey consisted of eight multiple choice questions, some with an option to further clarify chosen answers. One question addressed the respondent's function within the journal's editorial staff; the other questions addressed the journal's policy regarding trial registration and to what extent this policy was incorporated into the editorial and peer review process (table 2).

Analysis

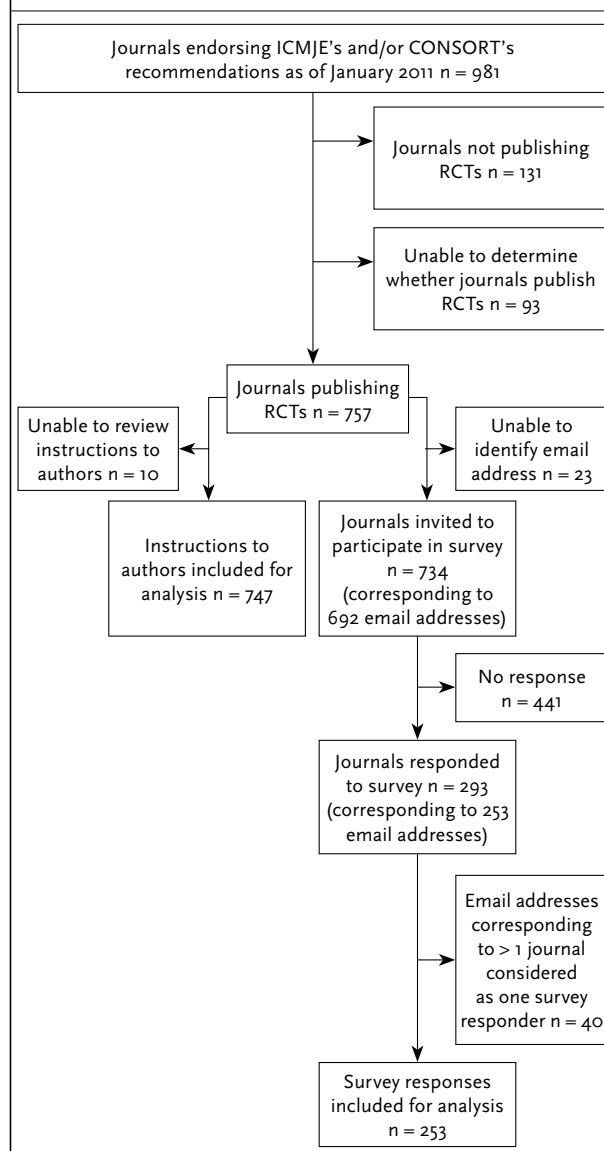
Data are reported as frequencies and percentages. Incomplete surveys were included in the analysis, for which all available responses were used. Chi-squared test statistics were used to evaluate differences between ICMJE journals and CONSORT journals, between general and speciality journals, and between higher and lower impact journals. For this last analysis, we categorised journal impact factors into quartiles. When a journal had no impact factor, it was categorised in the lowest quartile. When a single person responded on behalf of several journals, we took the average of the impact factors for these journals.

P-values of 0.05 or less were considered statistically significant. Data were analysed using SPSS version 22.0.

RESULTS

In January 2011, there were 695 ICMJE journals and 404 CONSORT journals. Of these, 118 journals were on both lists. We excluded 224 journals because they did not publish RCTs (n = 131), or because we were unable to obtain this information (n = 93) (figure 1). The final study sample consisted of 757 journals: 69 (9%) were general journals, and 688 (91%) were speciality journals.

Figure 1. Flowchart of ICMJE and CONSORT journals through the study



Results from examination of instructions to authors

Since we were unable to assess the instructions to authors of ten journals, due to language restrictions (n = 6) or because a website was lacking (n = 4), we included 747 journals in this analysis (figure 1). Data extracted from the instructions to authors are provided in table 1.

Of the ICMJE journals, 345 (73%) made a statement about following ICMJE's recommendations. Of these, 291 provided a link to ICMJE's webpage, 15 provided a suitable reference (published after 2004) containing ICMJE's recommendations, and 26 provided a reference to an obsolete publication. Of the CONSORT journals, 313 (82%) made a statement about endorsement of the CONSORT statement. Of these, 280 provided a link to CONSORT's

Table 2. Summary of responses to survey among ICMJE and CONSORT journals				
	All responding journals	Journals on ICMJE-list only	Journals on CONSORT-list only	Journals on both lists
<i>What is your journal's policy regarding registration of clinical trials?</i>				
Total number of respondents	232	119	79	34
Registration required	117 (50%)	60 (50%)	35 (44%)	22 (65%)
Registration recommended	57 (25%)	26 (22%)	24 (30%)	7 (21%)
Not (yet) implemented	58 (25%)	33 (28%)	20 (25%)	5 (15%)
<i>What is your journal's policy regarding registration of observational studies?</i>				
Total number of respondents	232	119	79	34
Registration required	19 (8%)	13 (11%)	4 (5%)	2 (6%)
Registration recommended	76 (33%)	37 (31%)	21 (27%)	18 (53%)
Registration not necessary	137 (59%)	69 (58%)	54 (68%)	14 (41%)
<i>Is the ICMJE's clinical trial registration policy included in your journal's 'Instructions to Authors' section?</i>				
Total number of respondents	226	115	77	34
Yes	142 (63%)	72 (63%)	44 (57%)	26 (77%)
No	84 (37%)	43 (37%)	33 (43%)	8 (24%)
<i>Is the ICMJE's clinical trial registration policy incorporated into your editorial and peer review processes?</i>				
Total number of respondents	216	110	73	33
Yes	99 (46%)	41 (37%)	35 (48%)	23 (70%)
No	117 (54%)	69 (63%)	38 (52%)	10 (30%)
<i>For submitted manuscripts, does your journal cross-check the reported data in the manuscript against the prospectively registered data?</i>				
Total number of respondents	206	103	70	33
Yes	37 (18%)	16 (16%)	12 (17%)	9 (27%)
No	169 (82%)	87 (85%)	58 (83%)	24 (73%)
<i>What do you do when discrepancies are found between the reported data in the manuscript and the prospectively registered data?</i>				
Total number of respondents*	34	16	9	9
We do not act on that	5 (15%)	2 (13%)	1 (11%)	2 (22%)
Discrepancies are resolved between authors and editors	29 (85%)	14 (88%)	8 (89%)	7 (78%)
<i>Does your journal consider manuscripts for publication when the underlying trial has been registered after enrolment of the first patient?</i>				
Total number of respondents	202	101	69	32
Yes	103 (51%)	54 (54%)	34 (49%)	15 (47%)
Yes, under certain conditions	33 (16%)	13 (13%)	11 (16%)	9 (28%)
No	66 (33%)	34 (34%)	24 (35%)	8 (25%)
*Only journals that had answered 'Yes' to the previous question (indicating that they cross-checked reported and registered data) were included in the analysis of this question.				

webpage, eight provided a suitable reference (published after 2001) containing CONSORT's recommendations, and ten provided an obsolete reference. ICMJE member journals stated significantly less often on their webpage that they required trial registration (37%) than journals that had adopted CONSORT only (67%), or journals that had adopted both (60%, $p < 0.0001$). No

significant difference was found between the proportion of general journals mentioning that trial registration was required (42%), compared with speciality journals (52%, $p = 0.12$). Specific trial registries that were recommended by journals making a statement about requiring or recommending trial registration were most often ClinicalTrials.gov

(n = 116), International Standard Randomised Controlled Trial Number register (n = 81), the Australian New Zealand Clinical Trial Register (n = 59), or the Netherlands Trial Register (n = 55).

Results from survey

We were unable to identify an email address of the editorial office and/or editor-in-chief for 23 of the 757 included journals (figure 1). Some email addresses corresponded to two journals (n = 2), three journals (n = 1), or 39 journals (n = 1). We sent the invitation to 692 email addresses and between June and November 2011, 253 (37%) of these responded, including 51 partially completed surveys.

The following persons participated in the survey: 140 (55%) editors-in-chief, 52 (21%) managing editors, 24 (10%) editors or associate editors, 18 (7%) administrators, and 19 (8%) other types of employees. We found no evidence of selective response: 35% of the journals that made no notification on trial registration in their instructions to authors responded to the survey, compared with 38% of the journals that required registration, and 40% of the journals that recommended registration. This difference was not significant (p = 0.67).

Answers to specific questions are provided in table 2. Only 50% (95% CI: 45-56%) of the respondents indicated that their journal required trial registration. Significantly more journals with an impact factor in the upper quartile (above 3.5) required registration (76%) than those in the lower three quartiles (42%, 38% and 46%, p < 0.0001). There were no significant differences in trial registration requirement between ICMJE journals, CONSORT journals, and journals that had adopted both (50%, 44% and 65%, p = 0.14), nor between general and speciality journals (55% and 50%, p = 0.60). Less than one-fifth of the respondents, and 22% of the journals requiring trial registration, cross-checked the reported data in the manuscript against the registered data. Journals that cross-checked the data did not always act in case of discrepancies.

Two-thirds of all the responding journals, and 56% of the journals that indicated to require trial registration also considered study reports for publication when the underlying trial was registered after enrolment of the first patient.

Discrepancies between instructions to authors and survey responses

Journals' trial registration policies as indicated in the survey and specifications in the instructions to authors were often not concordant (table 3). For a quarter of the journals that responded that trial registration was required, we were unable to find a corresponding statement on registration in the instructions to authors.

We were also unable to find a statement on trial registration in the instructions to authors of 25% of the journals that

Table 3. Concordance between journals' registration policies as defined in the instructions to authors and according to survey responders

Registration policy as found in instructions to authors:	Registration policy according to survey responder		
	Required (n = 115)	Recommended (n = 57)	Not implemented (n = 57)
Required (n = 118)	87 (76%)	17 (30%)	14 (25%)
Recommended (n = 12)	3 (3%)	7 (12%)	2 (4%)
No notification on registration policy (n = 99)	25 (22%)	33 (58%)	41 (72%)

indicated that such a statement was available. In contrast, we found a statement on trial registration for 28% of the journals that had responded that such a policy was not included in their instructions to authors. Such discrepancies were found in 37% of the journals with an impact factor in the lowest quartile, compared with 29%, 20% and 19% in those in the higher three quartiles (p = 0.11).

DISCUSSION

Although the ICMJE has required prospective trial registration since 2005 and CONSORT has supported this policy since 2010, at least half of the journals following ICMJE's Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals and/or endorsing the CONSORT statement do not adhere to this registration policy.

Only half of the journals responding to our survey indicated that trial registration was required. Two-thirds considered trials for publication that were registered after study initiation, against the ICMJE recommendation about prospective registration. These findings are in line with the results of previous studies, which have shown that about half of the published RCTs are registered after study completion, or are not registered at all.¹⁶⁻²⁰

Four-fifths of the responding journals in our analysis did not cross-check submitted papers against registered records, even when requiring trial registration. This provides authors with the opportunity to publish their results selectively. A number of studies have shown that this happens frequently. Discrepancies between registered and published outcomes have been found in up to half of published trial reports.^{8,16,18,19,21} A survey among peer reviewers showed that only one-third of them compared submitted manuscripts with registered trial information and reported any discrepancies to the journal editors.²² These results indicate that it is still fairly easy for authors to

get around the ICMJE's trial registration requirement and to publish unregistered and improperly registered studies. We found that half of the journals indicated in their instructions to authors that trial registration was required. Another recent evaluation scrutinised the instructions to authors for a random selection of 200 biomedical journals publishing clinical trial reports. The authors concluded, based on information on journals' webpages, that only 28% required registration.²³

In our study, journals' registration policies were frequently absent from webpages and information provided in the survey sometimes differed from the instructions to authors. It seems that survey responders were not always aware of the content of the instructions to authors of their own journals; this applied to a quarter of the journals indicating that they required trial registration and to a quarter of the journals without a registration policy. Citations referring to ICMJE's or CONSORT's recommendations were often lacking or obsolete in adopting journals. Similar deficiencies in instructions to authors have been found in previous studies. An evaluation of author guidelines of 167 medical journals in 2003 showed that a quarter of those mentioning CONSORT and more than half of those mentioning ICMJE provided obsolete references.²⁴ In another analysis, a survey was sent to journal editors about endorsement of the CONSORT statement. The study authors observed that a positive response about mentioning CONSORT in instructions to authors could not be confirmed in a quarter of cases.²⁵ In 2010, *BMJ* and *The Lancet* both published a statement in which they indicated that, from then on, they would strongly recommend authors to also register observational research.^{26,27} Although this policy led to some controversy in the biomedical literature,^{28,29} our survey indicates that more than a quarter of the ICMJE and/or CONSORT journals currently recommend registration of observational research, and a minority even requires it.

A number of elements in our analysis deserve consideration. The response rate to our survey was only 37%, and we cannot exclude selective participation. Although response rates did not significantly differ between journals that indicated in their instructions to authors that trial registration was required and those that did not, it is conceivable that journals without an active implementation of ICMJE's registration policy felt less motivated to participate. If this is the case, we may have even overestimated adherence to ICMJE's policy. We had to exclude 93 journals because we were uncertain whether they published RCT reports, mostly due to language restrictions. Data extraction, performed by a single author, was confirmed by a second one, but we may have missed information regarding registration policies in instructions to authors.

Our study was performed six years after ICMJE's trial registration policy was introduced, which should have

given journals enough time to incorporate the policy into their instructions to authors, and into their editorial and peer review process. Our survey did not address reasons for not yet complying with ICMJE's policy. Future studies should focus on the question why many ICMJE and CONSORT journals currently do not follow these requirements, and which steps should be taken before they are willing to apply them into their editorial and peer review process. This way, barriers can be identified and potential solutions can be developed.

Selective reporting and non-publication of research findings lead to a waste of valuable research efforts and compromise the reliability of the biomedical literature.³⁰ There have been many examples in which the effectiveness of healthcare interventions was overestimated when solely based on published results. How can we expect medical practitioners to adequately perform evidence-based medicine when the published literature is strongly biased by positive findings? We observe a tendency towards more transparency in health research, and initiatives such as CONSORT and ICMJE's trial registration policy represent important examples. These initiatives have led to undisputable improvements: the quality of reporting has visibly increased,³¹ and the number of registered trials and national trial registries has grown substantially over the past decade. Unfortunately, adoption tends to go slowly. There is still a long way to go before the scientific community can fully profit from the potential benefits of trial registration. Journal editors and peer reviewers – especially those supporting ICMJE's and/or CONSORT's recommendations – should be further encouraged to require prospective registration from each clinical trial that is presented to or reported in their journal.

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DISCLOSURES

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