Professional medical writing support and the quality of randomised controlled trial reporting: a cross-sectional study

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ABSTRACT

Objectives: Authors may choose to work with professional medical writers when writing up their research for publication. We examined the relationship between medical writing support and the quality and timeliness of reporting of the results of randomised controlled trials (RCTs).

Design: Cross-sectional study.

Study sample: Primary reports of RCTs published in BioMed Central journals from 2000 to 16 July 2014, subdivided into those with medical writing support (n=110) and those without medical writing support (n=123).

Main outcome measures: Proportion of items that were completely reported from a predefined subset of the Consolidated Standards of Reporting Trials (CONSORT) checklist (12 items known to be commonly poorly reported), overall acceptance time (from manuscript submission to editorial acceptance) and quality of written English as assessed by peer reviewers. The effect of funding source and publication year was examined.

Results: The number of articles that completely reported at least 50% of the CONSORT items assessed was higher for those with declared medical writing support (39.1% (43/110 articles); 95% CI 29.9% to 48.9%) than for those without (21.1% (26/123 articles); 95% CI 14.3% to 29.4%). Articles with declared medical writing support were more likely than articles without such support to have acceptable written English (81.1% (43/53 articles); 95% CI 76.6% to 89.9% vs 47.9% (23/48 articles); 95% CI 33.5% to 62.7%). The median time of overall acceptance was longer for articles with declared medical writing support than for those without (167 days (IQR 114.5–231 days) vs 136 days (IQR 77–193 days)).

Conclusions: In this sample of open-access journals, declared professional medical writing support was associated with more complete reporting of clinical trial results and higher quality of written English. Medical writing support may play an important role in raising the quality of clinical trial reporting.

INTRODUCTION

Publication in a peer-reviewed journal remains the gold standard for disclosing clinical study results, but it has been estimated that only about half of biomedical research is published in full, and failure to publish is associated with negative study findings.1 The pharmaceutical industry in particular has been criticised for incomplete reporting of clinical studies.2 The complete and transparent reporting of clinical studies is important to allow others to appraise and interpret the results fully.3 Researchers and clinicians can misjudge the benefits or risks of therapies when study details are not fully disclosed.

Reporting guidelines provide advice on how to disclose research methods and findings.4 The Consolidated Standards of Reporting Trials (CONSORT) checklist describes the information that should be included when reporting randomised studies.5 Although the adoption of the CONSORT checklist by journals has improved the reporting of...
randomised controlled trials (RCTs), adherence to reporting guidelines remains suboptimal. In particular, details of the prespecified primary outcomes, sample size calculation, randomisation, and allocation concealment are often inadequately disclosed, leaving the reader unable to confirm whether the studies were adequately planned and conducted.

Clinicians understand the importance of disseminating research findings but report lack of time as a major barrier to doing so. Authors may enlist the help of professional medical writers, who do not usually meet the criteria for authorship of the article. Such work is undertaken under the direction of the study authors and is subject to strict guidelines. Medical writing is not ghostwriting, which occurs when writing contributions are not disclosed in a manuscript. Given the size of the biomedical literature and an estimated prevalence of professional medical writing support of 6–11%, it is perhaps surprising that few studies have evaluated the impact of professional medical writing support on the quality and speed of scientific reporting. In this cross-sectional study, we aimed to examine the relationship between declared medical writing support and the quality and timeliness of articles reporting RCTs. Timeliness of acceptance was measured by the time between manuscript submission and editorial acceptance by the journal; manuscript preparation time was not assessed.

**METHODS**

**Sample selection**

We examined the reporting of the results of RCTs of pharmacological interventions published in BioMed Central journals (text box). A pilot study in other journals yielded an insufficiently large sample of articles with declared medical writing support. BioMed Central journals endorse the CONSORT statement and have been used in previous studies of adherence to the CONSORT guidelines. We conducted a search on 16 July 2014 using the BioMed Central website to identify articles that described the results of RCTs. No limits were set for the year of article publication. The search terms used are shown in figure 1.

We divided the articles reporting the results of RCTs into two groups according to whether or not they acknowledged the support of professional medical writers. Articles with declared medical writing support were identified using the search terms ‘medical writer’, ‘medical writing’ and ‘editorial assistance’ (figure 1). The remaining articles were identified as the group without declared medical writing support. To reduce the size of this group in a systematic, unbiased way, articles were selected on the basis of their page number. (In BioMed Central journals, each article is assigned a single page number.) Test searches showed that restricting the page numbers to 1–7 would yield a similar

**Figure 1** Overview of the study design. The terms TIAB and PG allow searches to be specified on the basis of title/abstract and article page number, respectively. RCTs, randomised controlled trials.
number of articles to that in the group with declared medical writing support.

Eligibility criteria
All primary reports of parallel-group, randomised trials of pharmacological and food supplement interventions were included. Full articles were reviewed and the presence or absence of declared medical writing support was confirmed. Articles without acknowledgements were excluded. Duplicates, reviews, post hoc analyses and study protocols were also excluded. For the purpose of data collection, the two groups of articles were then combined and sorted alphabetically by title.

Data extraction
The published version of each article was evaluated. We assessed the completeness of reporting of RCTs by scoring articles using a subset of 12 items from the 2010 CONSORT checklist that have previously been shown to be poorly reported. Methodological details analysed were the specification of the primary outcome (item 6a), sample size calculation (item 7a), method of generating the random allocation sequence (item 8a), type of randomisation (item 8b), mechanism to implement the allocation sequence (item 9), who generated the allocation sequence (item 10), who was blinded (item 11a), and description of the similarity of interventions (item 11b) (see online supplementary table S1). The other items that we examined were the publication of a participant flow diagram (item 13), dates defining recruitment and follow-up periods (item 14a), details of trial registration (item 23), and access to the study protocol (item 24). For each article, inclusion of these 12 CONSORT checklist items was assessed independently by two reviewers who were blinded to the objectives of the study. Each item was rated as being completely described, incompletely described, absent or not applicable. In cases in which there was a discrepancy in the rating, a third reviewer adjudicated.

For overall acceptance time, we extracted the dates of article submission and editorial acceptance. When prepublication history was available, data were obtained for the time taken for completion of the first round of peer review and for submission of the response to reviewers. Data were also extracted for the quality of written English, as assessed by peer review: the BMJ-series journals ask reviewers to rate the quality of written English as ‘Acceptable’, ‘Needs some language corrections before being published’ or ‘Not suitable for publication unless extensively revised’.

We classified articles according to the funding source, as stated in the acknowledgements, competing interests, or disclosures section of the manuscripts. Studies were classified as industry funded if this was declared in the article, or if one or more authors had an affiliation with the pharmaceutical industry or other commercial organisation. Articles were classified as part-industry funded if this was stated or if a commercial organisation supplied the study treatment but was not otherwise involved in the study.

Data analysis
To assess the association of adherence to CONSORT guidelines with declared medical writing support, a relative risk (RR) was calculated with 95% CIs for each of the 12 selected CONSORT items, dichotomised as completely described versus not completely described (incompletely described or absent). Ratings that were not applicable were not included in the analysis. Many articles with medical writing support are funded by industry; hence, a subanalysis was conducted to examine the association of medical writing support with the reporting quality of industry-sponsored studies. Logistic regression was conducted with medical writing support as the independent variable, complete description of at least 50% of the items as the dependent variable and year as a covariable. No formal sample size or power calculation was performed: the size of the study was determined by the number of articles with medical writing support in the study sample. Statistical analysis was conducted using STATA (V13). Medians and IQRs were calculated using Microsoft Excel.

RESULTS
Characteristics of the articles assessed
Our initial electronic search identified 305 potentially relevant articles reporting the results of RCTs with declared medical writing support (figure 1). Following manual review, 110 articles from 44 different journals were confirmed as eligible for inclusion in the group of articles with medical writing support. The distribution of the search terms used to identify medical writing support was: ‘medical writer’ (12.7%); ‘medical writing’ (43.6%); ‘editorial assistance’ (21.8%) and ‘medical writing’ and ‘editorial assistance’ (21.8%). There were 10 688 potentially relevant articles without declared medical writing support; after filtering on page number, 387 articles remained. After manual review, 123 articles from 57 different journals met the eligibility criteria for inclusion as RCT reports without declared medical writing support. For both groups, most of the excluded publications were study protocols or secondary reports.
of RCTs. Overall, articles that met the inclusion criteria were from 74 different journals.

Articles with declared medical writing support described studies with a higher median number of randomised patients than articles without this support (159 patients (IQR 65.75–407.75 patients) vs 43 patients (IQR 21–82 patients)) (table 1). Almost all articles with declared medical writing support were industry funded (98.2%). In contrast, only 31.7% of articles without medical writing support were funded by industry. The first identified article without declared medical writing support was published in 2001. The first article with declared medical writing support was published in 2005, and there was an increase in the number of declared medical writing support over the study period (see online supplementary figure S1).

Completeness of reporting
For 6 of the 12 CONSORT items assessed, a higher rate of complete reporting was observed in articles with acknowledged medical writing support than in those without (figure 2). These were specification of the primary outcome (RR 1.77; 95% CI 1.47 to 2.13), sample size calculation (RR 1.39; 95% CI 1.10 to 1.75), type of randomisation (RR 2.03; 95% CI 1.17 to 3.53), publication of a participant flow diagram (RR 1.96; 95% CI 1.48 to 2.61), provision of dates defining recruitment and follow-up (RR 2.04; 95% CI 1.32 to 3.17), and details of trial registration (RR 1.64; 95% CI 1.34 to 2.01). RR could not be calculated for item 10 (who generated the allocation sequence) because it was fully described only in articles with acknowledged medical writing support. For the other five items, there was no

Table 1 General characteristics of the included studies

| Medical writing support (n=110) | No medical writing support (n=123) |
|--------------------------------|----------------------------------|
| Number of journals that articles were published in | 44 | 57 |
| Number of authors, median (IQR) | 7 (5–9) | 6 (4–8) |
| Articles published on behalf of a study group | 12 (10.9%) | 4 (3.3%) |
| Number of patients randomised to study, median (IQR) | 159 (65.75–407.75) | 43 (21–82) |
| Year of publication | | |
| 2001–2004 | 0 | 17 (13.8%) |
| 2005–2007 | 12 (10.9%) | 25 (20.3%) |
| 2008–2010 | 31 (28.2%) | 34 (27.6%) |
| 2011–2014 | 67 (60.9%) | 47 (38.2%) |
| Funding source | | |
| Industry | 108 (98.2%) | 39 (31.7%) |
| Part-industry | 2 (1.8%) | 23 (18.7%) |
| Non-industry | 0 | 61 (49.6%) |

Figure 2 Differences in the reporting of CONSORT items between articles with and without acknowledged medical writing support. *Relative risk could not be calculated for item 10 because all articles in the group without acknowledged medical writing support were assessed as having been incompletely described. CONSORT, Consolidated Standards of Reporting Trials; NA, not applicable.
association between medical writing support and completeness of reporting.

A sensitivity analysis for completeness of reporting is shown in online supplementary table S2. The proportion of articles that completely reported at least 50% of the CONSORT items assessed was higher for those with declared medical writing support than for those without declared medical writing support (39.1% (43/110 articles); 95% CI 29.9% to 48.9% vs 21.1% (26/123 articles); 95% CI 14.3% to 29.4%). In the subanalysis looking at industry-funded articles, those with declared medical writing support were more than twice as likely as those without declared medical writing support to report at least 50% of studied items completely (38.0% (41/108 articles); 95% CI 28.9% to 47.8% vs 17.9% (7/39 articles); 95% CI 8.1% to 34.1%). When looking at articles without acknowledged medical writing support, there was no association between funding source and the completeness of reporting.

A logistic regression analysis showed that year of publication was associated with quality of reporting (OR 1.18; 95% CI 1.06 to 1.32). Thus, the odds of reporting at least 50% of items completely increased every year by 18%. Taking into account publication year, the OR of reporting at least 50% of CONSORT items completely for articles with declared medical writing support was 1.88 (95% CI 1.03 to 3.42). Online supplementary figure S2 shows the mean proportion of complete items stratified by year of publication and the presence or absence of medical writing support. For each year, the mean proportion of completely reported items was higher for articles with medical writing support than for those without.

**Quality of written English**

Articles with declared medical writing support were more likely than those without to have been rated by all the reviewers as having acceptable written English during peer review (81.1% (43/53 articles); 95% CI 67.6% to 90.1% vs 47.9% (23/48 articles); 95% CI 33.5% to 62.7%). The proportion of articles with the corresponding author having an affiliation from a country where English was the first language was similar for both groups: 49.1% and 50.4%, respectively, for articles with and without medical writing support.

**Time from manuscript submission to editorial acceptance**

Overall, the median acceptance time was 31 days longer for articles with declared medical writing support than for those without (167 days (IQR 114.5–231 days) vs 136 days (IQR 77–193 days)). For both study groups, the median number of versions submitted was three. Considering the subgroup of industry-funded studies with and without declared medical writing support (n=107 and n=39 articles, respectively), those with declared medical writing support had a longer median acceptance time than those without (169 days (IQR 113–232 days) vs 104 days (IQR 77–180 days)).

To identify possible reasons for this delay in acceptance, the time taken for different steps in manuscript processing was analysed for articles with this information. Median time from submission to completion of peer review and median time to respond to reviewers were longer for articles with medical writing support than for those without (see online supplementary table S3). The time from response to reviewers to editorial acceptance was similar for both groups of articles. This pattern remained when the analysis was restricted to industry-funded articles (see online supplementary table S4).

**DISCUSSION**

Declared professional medical writing support was associated with improved completeness of reporting in our observational study of reports of RCTs published in a series of open-access journals between 2000 and 2014. In the absence of declared medical writing support, there was no difference in the completeness of reporting between articles reporting industry-funded trials and non-industry-funded and part-industry-funded trials. Completeness of reporting was enhanced across a range of important items from the CONSORT checklist, including the specification of the primary outcome, and details of the sample size calculation and randomisation. The complete reporting of the design and conduct of clinical studies is at the heart of evidence-based medicine. The effects of interventions can be exaggerated or underestimated in studies with poor methodology, and researchers can assess the likelihood of bias only if the methods and results are completely reported.21 22 Articles with declared medical writing support were also associated with better quality of written English than those without. There are sound reasons to believe that the involvement of professional medical writers improves the overall quality of articles. Medical writers specialise in developing peer-reviewed manuscripts and other scientific documents, and commonly receive training in Good Publication Practice.23

The findings of our study also suggest that overall compliance with CONSORT guidelines is lacking. Even with professional medical writing support, fewer than half of the articles reported at least 50% of studied CONSORT items completely. As well as authors, both peer reviewers and journal editors have a responsibility for ensuring that articles adhere to reporting guidelines. However, peer reviewers often fail to notice important deficiencies in the reporting of RCTs.19 In fact, they may not understand the importance of checking the compliance of articles with CONSORT guidelines, possibly as a result of insufficiently explicit instructions regarding their role.24 From our own experience, checking an article for compliance with the full CONSORT checklist would take approximately 1 h. We would recommend that this is a specialised task that could be undertaken by journal editors, or even by professional medical writers.

This study looked at the quality of published articles in a real-life situation. No limit was set on the year of article submission, study design or setting.
publication, although the study is limited by the date of inception of BioMed Central (2000). Since this was not a
randomised study, the characteristics of the two groups of articles differ in some respects, in addition to the involve-
ment of medical writing support. The key differences between the two groups of articles were that those with
declared medical writing support were almost exclusively sponsored by industry and were published more recently
than those written without medical writing support. However, it seems unlikely that the results of this study
can be attributed to these differences between the two
groups of articles. Thus, in the subset of industry-funded
trials, completeness of reporting was even more strongly
associated with medical writing support. Furthermore,
for each year of publication, the mean proportion of
complete items was higher for articles with medical
writing support than for those without. Articles with
declared medical writing support were associated with a
slightly longer overall acceptance time than articles
without this support. One limitation of this assessment is
that the measure of timeliness may not correspond to
steps in the submission process that are the responsi-
bility of the medical writer. The delay in overall acceptance was
attributable to the additional time taken for peer review
and for the authors to respond to reviewers. Articles that
declared medical writing support tended to describe
larger trials than those without, and had more authors,
suggesting that these articles may have reported more
complex research and therefore taken longer to review or,
possibly, underwent greater scrutiny by peer reviewers.
Likewise, queries from peer reviewers may be more com-
plicated for articles with medical writing support than for
those without.

Our findings are based on the assumption that the
enhanced quality of reporting observed can be attributed
to medical writing support. It was not possible to dis-
count the influence of some potential confounding
factors, such as the expertise of the authors of the
article (eg, the presence of a statistician) or the quality
of the clinical study report available. However, medical
writers generally are more familiar with publication
guidelines than investigators, and their role would nor-
mally include ensuring that the manuscript complies
with journal submission criteria and compliance with
reporting standards. It should also be noted that there
are international guidelines regarding the content to be
included in clinical study reports and, in fact, these
documents are usually written by medical writers.

The classification of articles in our study was based on the
veracity of the acknowledgement of medical writing
support. The importance of acknowledging medical
writing support is stated in guidelines on Good Publica-
tion Practice and, according to the editorial policy of BioMed
Central, medical writing support should be acknowledged
explicitly. Although we cannot rule out the possibility
that some articles were written with undeclared writing
support, this would tend to underestimate the true differ-
ences between the two groups. Finally, the articles that met
the inclusion criteria for our study were from 74 different
journals, but it remains to be seen whether our findings
are applicable to journals other than those published by
BioMed Central. The articles included in this study may
not be representative of those published in journals that do
not endorse the CONSORT checklist (ie, the effect of
medical writing support may be increased if authors do not
receive guidance from the journal). Conversely, the effect
of medical writing support may be reduced in journals that
ensure compliance with CONSORT criteria.

A systematic review published in 2003 found that there
was insufficient research to assess the effects of profes-
sional writing assistance on biomedical publishing. Only
one other study has evaluated the association of declared
medical writing support and the completeness of report-
ing. This analysis was restricted to a single journal in
which there were very few non-industry-sponsored studies
and the overall completeness of reporting was high;
although articles that declared professional medical
writers were more likely to comply with the CONSORT cri-
teria, the effect was small. A study of articles published in
the Dutch Journal of Medicine found that editing for scien-
tific content and written English, tasks that are often
undertaken by medical writers, significantly improved the
style and readability of manuscripts. It has previously
been suggested that, in addition to raising the standard of
publications, professional medical writer involvement can
speed up the publication process, however, there is
limited evidence to demonstrate the acceleration of manu-
script acceptance with medical writing support and,
in the current study, overall acceptance time was slightly
longer in the group with medical writing support.

Clinical trials can help to advance the treatment of
patients only if the methods and results are fully dis-
closed. The reporting of industry-sponsored studies
appears to be improving over time, and a recent study
showed that industry-funded trials were more likely to
comply with legal reporting obligations than trials
funded by government or academic institutions. Our
results suggest that the enhanced reporting seen in
industry-funded trials may be attributable to professional
medical writing support. Even so, when only approxi-
mately half of research is published in full and many
publications do not disclose important information, much
research effort is wasted. In fact, it has been pro-
posed that professional medical writing support should
be used to address the backlog of unreported clinical
study results. The results of this study suggest that this
support could also improve the quality of RCT reporting.
Medical writing support is often funded by industry and,
as a result, has sometimes attracted controversy. There
is no place for ghostwriting (ie, the unacknowledged
use of medical writers) in manuscript development.
According to the results of surveys, the overwhelming
majority of authors (84–88%) valued the assistance pro-
vided by professional medical writers, in particular in
editing manuscripts and ensuring conformity with report-
ring guidelines such as CONSORT.
legitimate role that medical writers can play is acknowledged in guidelines on Good Publication Practice.\textsuperscript{14} 

CONCLUSIONS 

There remains a need to improve the quality of reporting of clinical studies. The disclosure of important information regarding clinical studies, which is needed when determining the validity and generalisability of findings, may be enhanced with professional medical writing support. 

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Competing interests WTG, PF, RW and CCW are medical communication professionals employed by Oxford PharmaGenesis. KY is a former employee of Oxford PharmaGenesis. PF, RW and CCW are shareholders of Oxford PharmaGenesis. CCW holds shares in AstraZeneca and Shire Pharmaceuticals. SH is a member of the CONSORT group. EW is the owner of Sideview, which provides training and consultancy in medical writing, and has previously worked as a medical writer. 

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**Supplementary figure 1** Year of article publication, stratified by medical writing support.

*Adjusted to number of articles per 12 months.*
**Supplementary figure 2** Mean proportion of complete items, stratified by year of publication and medical writing support.

The graph shows linear trend lines, which were calculated using Microsoft Excel.
**Supplementary table 1** Criteria used for assessing the completeness of reporting, based on the 2010 CONSORT checklist

| Definitions used to assess the completeness of reporting (CONSORT item and number) |  |
|---|---|
| **Specification of the primary outcome (6a)** |  |
| *Complete*: primary/main outcome defined and fully described |  |
| *Incomplete*: outcome present, but not defined as such |  |
| **Sample size calculation (7a)** |  |
| *Complete*: method of power calculation included |  |
| *Incomplete*: planned sample size mentioned but values or methods not reported |  |
| **Method of generating random allocation sequence (8a)** |  |
| *Complete*: specific method of randomisation given (e.g. random number table) |  |
| *Incomplete*: non-specific method given (e.g. “automated randomisation system”) |  |
| **Type of randomisation (8b)** |  |
| *Complete*: full details of randomisation given |  |
| *Incomplete*: type of randomisation described but no details given |  |
| **Mechanism to implement allocation sequence (9)** |  |
| *Complete*: both the mechanism used and how the allocation was concealed were present |  |
| *Incomplete*: either the mechanism used or how the allocation was concealed were described |  |
| **Who generated the allocation sequence (10)** |  |
| *Complete*: description of who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions |  |
| *Incomplete*: one or two of these described |  |
Definitions used to assess the completeness of reporting (CONSORT item and number)

**Who was blinded (11a)**

*Complete:* blinding status of all groups (participants/investigators/assessors) defined

*Incomplete:* blinding status of one or more groups described

*Absent:* stated as “single-blind” or “double-blind” only

*NA:* open-label study

**Description of the similarity of interventions (11b)**

*Complete:* relevant similarities described (appearance/taste/smell/volume/method of administration)

*Incomplete:* described only as ‘identical’, ‘matching’ or ‘corresponding’ etc.

*NA:* treatment defined as open label or interventions stated as too dissimilar to blind

**Publication of a participant flow diagram (13)**

*Complete:* diagram showed number of patients enrolled, numbers excluded and lost to follow-up, and reasons for exclusion or loss to follow-up

*Incomplete:* diagram included patient flow and numbers enrolled but was missing some information

**Dates defining recruitment and follow-up periods (14a)**

*Complete:* period of study/recruitment and follow-up period fully defined

*Incomplete:* only one of the above periods defined

**Details of trial registration (23)**

*Complete:* registration number stated in text

*NA:* study conducted before the International Committee of Medical Journal Editors recommendation that clinical trials should be registered at or before the time of first patient enrolment

**Access to the study protocol (24)**

*Complete:* protocol number and location/registry stated

For the full list of items on the CONSORT checklist, see: [http://www.consort-statement.org/](http://www.consort-statement.org/)

CONSORT, Consolidated Standards Of Reporting Trials; NA, not applicable.
## Supplementary table 2

| Proportion of articles correctly reported | ≥50% | ≥66.6% | ≥75% | ≥90% | 100% |
|-----------------------------------------|------|--------|------|------|------|
| No medical writing support              | 21.1%| 4.9%   | 1.6% | 0    | 0    |
| Medical writing support                 | 39.1%| 18.2%  | 9.1% | 0.9% | 0    |
Supplementary table 3 Time to complete different stages of article processing

| Duration, days | Medical writing support (n=55) | No medical writing support (n=64) |
|---------------|-------------------------------|----------------------------------|
| Peer review   | 87 (55–122)                   | 55 (35.5–86.75)                  |
| Responding to reviewers | 60 (35–83)                  | 32 (17–58.25)                    |
| Editorial acceptance | 49 (23–96)                  | 50 (29.75–98.75)                 |
| Submission to editorial acceptance | 206 (164–264)             | 162.5 (104.25–217.5)             |

Data are presented as median (interquartile range).
**Supplementary table 4** Time to complete different stages of article processing (industry-funded articles only)

| Duration, days                  | Medical writing support (n=55) | No medical writing support (n=18) |
|--------------------------------|--------------------------------|----------------------------------|
| Peer review                    | 87 (55–122)                    | 50.5 (37.75–74.25)               |
| Responding to reviewers        | 60 (35–83)                     | 28 (13–67.75)                    |
| Editorial acceptance           | 49 (23–96)                     | 50 (39.5–113.25)                 |
| Submission to editorial        | 206 (164–264)                  | 161 (103.5–270.25)               |
| acceptance                     |                                |                                  |

Data are presented as median (interquartile range).