Quality of descriptions of treatments: a review of published randomised controlled trials

Sara Schroter,1,2 Paul Glasziou,2 Carl Heneghan2

ABSTRACT

Objectives: To be useable in clinical practise, treatments studied in trials must provide sufficient information to enable clinicians and researchers to replicate. We sought to assess the completeness of treatment descriptions in published randomised controlled trials (RCTs) using a checklist and to determine the extent to which peer reviewers and editors comment on the quality of reporting of treatments.

Design: A cross-sectional study.

Setting: Trials published in the BMJ, a general medical journal.

Participants: Fifty-one trials published in the BMJ were independently evaluated by two raters using a checklist. Reviewers' and editors' comments were also assessed for statements on treatment descriptions.

Primary and secondary outcome measures: Proportion of trials rated as replicable (primary outcome).

Results: For 57% (29/51) of the papers, published treatment descriptions were not considered sufficient to allow replication. Most poorly described aspects were the actual procedures involved including the sequencing of the technique (what happened and when) and the physical or informational materials used (eg, training materials): 53% and 43% not clear, respectively. For a third of treatments, the dose/duration of individual sessions was not clear and for a quarter the schedule (interval, frequency, duration or timing) was not clear. Although the majority of problems were not picked up by reviewers and editors, when they were detected only about two-thirds were fixed before publication.

Conclusions: Journals wanting to publish the research of use to practising healthcare professionals need to pay more attention to descriptions of treatments. Our checklist, may be useful for reviewers, and editors and could help ensure that important details of treatments are provided before papers are in the public domain.

ARTICLE SUMMARY

Article focus

Key messages

INTRODUCTION

Before dissemination, innovations in treatment require two things: (1) valid research that demonstrates the treatment's effectiveness and (2) a description of the treatment procedure sufficient to allow clinicians and others to apply the treatment in practise. Both elements require adequate reporting. The Consolidated Standards for Reporting Trials (CONSORT) statement on reporting randomised controlled trials (RCTs)1 was developed to help authors and editors improve the reporting of RCTs and has been widely accepted. It has been influential in improving the quality of reporting trials’ methods and results.2 However, less attention has been given to the second element: the description of the treatment being tested. For


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Treatments vary considerably in their complexity. At one end of the extreme are simple drug trials with fixed-dose drugs requiring only specification of the chemical entity, dose, frequency and duration of treatment. However, even drug treatments can require more detail if treatment requires titration, monitoring, complex delivery systems or co-treatments. Non-drug treatments require these same elements, but a physical, educational or psychological procedure—equivalent, of the chemical entity—is often far more complex. At the other extreme are multistage surgical procedures that may not be codifiable and require training in the institution that developed the procedure. Between these extremes are educational treatments, physical treatments such as physiotherapy and psychological treatments.

Two of CONSORT’s 22 items are directly relevant to clinicians applying treatments, or researchers who wish to replicate or extend the findings, adequate treatment descriptions are vital. Treatments vary considerably in their complexity. At one end of the extreme are simple drug trials with fixed-dose drugs requiring only specification of the chemical entity, dose, frequency and duration of treatment. However, the BMJ has a lengthy review process and is generally considered to publish high-quality research, so it is likely that the situation is worse for less-influential lower-impact factor journals with fewer resources.

We used two raters who were both academic general practitioners to assess the manuscripts. However, none of the papers in this study described treatments that our raters found too specialised to evaluate, so none were excluded.

### Table 1 Previous studies of adequacy of descriptions of treatments in trials

<table>
<thead>
<tr>
<th>Clinical issue</th>
<th>Number of trials</th>
<th>Number (%) replicable</th>
<th>Methods of deciding replicability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight loss interventions</td>
<td>63</td>
<td>62 (98)</td>
<td>Compliance with item 4 of CONSORT statement*</td>
</tr>
<tr>
<td>Treatments of brain tumours</td>
<td>74</td>
<td>68 (92)</td>
<td>Compliance with item 4 of CONSORT statement*</td>
</tr>
<tr>
<td>Treatments of Hodgkin’s lymphoma</td>
<td>241</td>
<td>231 (96)</td>
<td>Compliance with item 4 of CONSORT statement*</td>
</tr>
<tr>
<td>Back pain</td>
<td>24</td>
<td>3 (13)</td>
<td>Sufficient information on what happens before, during and after treatment</td>
</tr>
<tr>
<td>Implementation of guidelines</td>
<td>29</td>
<td>&lt;7 (16)</td>
<td>Assessed 6 elements: flexibility, timing, content, medium, deliverer and receiver. There is not an overall adequacy rating, but none was 100% and only 7/29 provided timing</td>
</tr>
<tr>
<td>Insulin initiation in type 2 diabetes</td>
<td>14</td>
<td>3 (21)</td>
<td>Only required that “some” detail was provided, not sufficient for replication; 41% also provided some detail on actual surgery administered</td>
</tr>
<tr>
<td>Surgical procedures intended</td>
<td>158</td>
<td>138 (87)</td>
<td>Provision of both starting dose and titration regime</td>
</tr>
<tr>
<td>Range of topics published in Evidence-Based Medicine Journal</td>
<td>55</td>
<td>36 (65)</td>
<td>Two general practitioners were independently asked whether they could use the treatment with a patient if they saw them the next day</td>
</tr>
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*Item 4 is: ‘Precise details of the treatments intended for each group and how and when they were actually administered’. Note: Each element is fully described in table 2.

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METHODS

Setting
We conducted the research in 2007 at the BMJ, a general medical journal, where we had access to all the backmatter associated with journal submissions. The BMJ publishes research on a wide range of clinical topics.

Development, refining and piloting of the checklist
Based on the work of Davidson et al,11 the CONSORT statement1 and our own analysis of poorly reported trials abstracted in the journal Evidence-Based Medicine,10 we designed an initial checklist of the minimal details that should be included in a description of a treatment in an RCT. We piloted this on the first 10 papers and then, based on problems identified, revised the checklist. The first 10 papers were then re-evaluated with the revised checklist. The revised checklist (table 2) included the following seven aspects: a description of where the treatment was delivered (setting); who delivered the treatment (provider); who received the treatment (recipient); details of the procedure including the sequencing of the technique (procedure); a description of the physical or informational materials used (materials); the dose/duration of individual sessions of the treatment (intensity) and the scheduling, that is, the interval, frequency, duration or timing of the treatment (schedule). Raters also completed an additional subjective global item to indicate whether the treatment was sufficiently described for them to replicate it if there were no resource or training constraints (no constraints).

Evaluation of published descriptions
We reviewed the given study design of all research papers published in the BMJ in a single year, 2006, and selected all RCTs for possible inclusion. Papers presenting only follow-up data or longer-term outcomes of a previously published trial were subsequently excluded as details of the intervention may previously have been reported. The full-length version of the published papers was then independently evaluated by two raters (PG and CH) for the clarity of reporting of key features of the intervention using our checklist. Our use of the term intervention refers to ‘the process of intervening on people, groups, entities or objects in an experimental study’.14 We did not evaluate the clarity of reporting of the treatment received by the control group. Both raters were blind to comments from editors and reviewers. Raters then discussed the results in person and disagreements were resolved through consensus discussion supervised by SS.

Evaluation of the review process
All back history (reviewers’ comments and editors’ notes) for the papers were obtained by SS from the BMJ’s electronic manuscript tracking system. SS collated all statements given on the clarity of the reporting of the treatment for each manuscript and anonymised the comments. SS then categorised the deficiencies using our checklist. PG then assessed whether the specified deficiencies had been addressed in the final published version.

RESULTS

We included 51 RCTs published in the BMJ in 2006. These papers described studies with a wide range of settings and treatments. Twenty-one (41%) involved the administration of a drug either alone or in addition to another therapy.

Replicability
Overall, assuming no resource or training constraints, both raters reported that 57% (29/51) of the treatments could not be replicated based on the description of the treatment as published. Studies of drug treatments were better described than non-drug treatments: 7/21 (33%) of drug treatments were considered non-replicable in comparison with 22/30 (73%) non-drug treatments.

Type of problems identified in published versions
We identified 99 problems, ranging in seriousness, with the descriptions of the interventions in the published versions. For each checklist item the proportion of trials with adequately described features ranged from 47% to 94% (figure 1). The most poorly described aspects of the treatment were the actual procedures involved including the sequencing of the technique—what happened and when (53% not clear), and the physical or informational materials used, for example, training materials (43% not clear). Aspects of the treatment better described included a description of where the

<table>
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<th>Table 2 Interventions checklist</th>
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<tbody>
<tr>
<td>Setting</td>
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<tr>
<td>Recipient</td>
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<td>Provider</td>
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<td>Procedure</td>
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<td>Materials</td>
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<tr>
<td>Intensity</td>
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<tr>
<td>Schedule</td>
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<tr>
<td>Missing</td>
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</table>

treatment was delivered (94% clear). For a third of the treatments described, the dose, duration or both individual sessions of the treatment were not clear and for around a quarter the schedule (interval, frequency, duration or timing) of the treatment was not clear.

Problems identified prior to publication

During the prepublication phase of the manuscripts, the reviewers, editors and editorial advisors reported 43 problems with the descriptions of the interventions. Most comments focused on the need for clarification of the sequencing of the technique described (procedure) and the patient group under study (recipient). Thirty-three per cent (14/43) of these problems were not fully fixed by the time the paper was published (as assessed by our raters; figure 2). Where reviewers and editors identified problems with descriptions of the setting, the provider, the materials and the schedule,

Figure 1  Elements of interventions—percentage clearly described. Note: Each element is fully described in table 2.

Figure 2  Papers where editors’ or reviewers’ identified a problem (prepublication), and whether it remained at postpublication.
these were improved by the time of publication. Problems that were not corrected largely concerned the descriptions of the procedures of the treatments, that is, it was not clear what happened and when. Table 3 shows the 14 problems identified at prepublication which were not sufficiently remedied in the published version.

### DISCUSSION

The majority of published trials in our study lacked important details describing the treatment. These details would be required for healthcare professionals to undertake these treatments in practise, or for other researchers to replicate, or build on, the findings in future studies. Many problems were easily rectifiable, such as clearer reporting on the sequencing of techniques, actual doses/durations of treatments and their scheduling. Although the majority of problems were not picked up by peer reviewers and editors, when they were detected only about two-thirds were fixed before publication.

Our findings are consistent with our earlier analysis of 80 RCTs and systematic reviews published in the journal Evidence-Based Medicine where approximately a half (51%) had an ‘inadequate’ description of the treatment.10 Evidence-Based Medicine abstracts journals in a
range of specialties and the similarity in results suggest that the results of this study are valid. Unlike, this study, our previous study did not quantitatively document the types of problems with the treatments described but focused on a global assessment of the replicability of the treatment and whether authors could provide the missing details when asked to do so. The current study went further than our earlier study in that it reports the frequency of poor reporting of specific aspects of trial interventions.

Our study has several limitations. First, we included only RCTs from a single year in one general medical journal and the results may not be generalisable to other journals. However, the BMJ has a lengthy review process and is generally considered to publish high-quality research, so it is likely that the situation is worse for less-influential journals with fewer resources. The BMJ strives to publish papers to ‘help doctors make better decisions’ and is very aware of the importance of good scientific reporting of research. As such it may pay more attention to reporting issues than other journals. We found that the BMJ reported these aspects of interventions poorly and this suggests that the situation may well be worse for other journals. Second, we evaluated RCTs published in 2006 and it is possible that there have been improvements in reporting, given the wider use of the internet and web appendices in recent years. Further research would be needed to test this. Third, we used only two raters who were both academic general practitioners to assess the manuscripts some of which could have described treatments they were not familiar with. However, all RCTs published in the BMJ describe treatments that should be familiar to general practitioners, as it targets a general medical readership. None of the papers in this study described treatments that our raters found too specialised to evaluate, so none were excluded. Our raters were also experienced academics interested in improving the reporting quality of trials and as such the results may represent the best-case scenario. Finally, we did not try to separately assess planned versus actual treatments, which may sometimes differ substantially and require specific description.

We identified a few other previous studies which have examined the adequacy of treatment descriptions (table 1). Most of the studies listed in table 1 are likely to have reported overestimates of replicability as only one asked whether there was sufficient information to allow replication. In developing summaries for systematic reviews of back pain, Glenton and colleagues found sufficient details ‘about what the treatment involved’ for patients in only 3 of 24 (13%) treatments, and used 32 other sources to obtain details for the other 21 treatments. Similarly a review of 29 guideline implementation studies found that the majority lacked details of how the intervention was carried out, for example, only 7 (24%) supplied details of timing. Three other studies simply checked the fourth CONSORT item. Similar problems have been identified in other areas. In a recent survey of 93 publications with novel questionnaires in JAMA, NEJM and BMJ, four printed the questionnaire in the article, three provided online access, but authors failed to provide questionnaires for 37 of 81 (46%) studies. For some clinical domains, improving the descriptions of treatments may require additional work to standardise and document the procedures prior to clinical trials.

Similar to many journals, BMJ authors are requested to complete the CONSORT statement when submitting a paper describing an RCT, but are not specifically asked to describe their interventions in detail. BMJ reviewers are not routinely instructed to comment on the replicability of treatments described in papers, but are instructed to check the CONSORT statement provided by the author. However, item 4 in the CONSORT statement appears insufficient to guide authors and reviewers in all the elements needed, and CONSORT have, so far, added three intervention extensions (non-pharmacological, herbal and acupuncture—http://www.consort-statement.org/extensions/), but these overlap, and a generic checklist with supplementary lists is needed.

Medical journals often send papers to reviewers who are practising clinicians in the area of interest and some may choose to comment on the reporting details of the treatment. However, limitations of peer review are well documented. In our study, peer reviewers infrequently commented on inadequate reporting of trial details. Insufficient instructions and guidance to reviewers and lack of training may compound the problem. However, even when some limitations were identified by reviewers at the prepublication stage they were not always remedied in the published version.

The incomplete treatment descriptions we found represent a substantial waste of the research budget, trial participants’ time and an opportunity cost for clinicians and patients. Though not surprising, the lower rates of adequate description of non-drug alternatives is unfortunate given the rapid growth of the pharmaceuticals budget, and the potential for non-drug therapies for alternative treatments. Funders, authors, journals and research users should all be concerned with this problem and work together to improve the situation.

Journals that wish to publish high-quality research of use to practising healthcare professionals need to pay attention to adequate descriptions of treatments. One element of any solution should be a simple checklist, such as the generic one we have developed, or specific checklists such as the CONSORT interventions extensions (http://www.consort-statement.org/extensions/). Such checklists may be useful for authors, peer reviewers and editors to help ensure that important details of treatments are provided before the paper is published and in the public domain. However, the effectiveness of such checklists needs to be further evaluated. Ideally the full intervention description should be published with the primary article, but this often is not feasible, for example, with manual procedures or extensive training.
materials. Since describing such study materials could add significantly to the length of papers, we suggest that editors encourage the use of web extras and/or links to study materials on authors’ or funders’ institutional websites; these should be checked for availability at the time of publication, since researchers may retire, move or for other reasons not respond after publication.

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Contributors SS had complete access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysed. No other staff at the BMJ were involved in the design and conduct of the study; collection, management, analysis and interpretation of the data and preparation, review or approval of the manuscript. SS, PG and CH designed the study; PG and CH rated the manuscripts for replicability; SS analysed the manuscripts’ backmatter; SS analysed the data; SS, PG and CH wrote the manuscript.

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Competing interests SS is employed full-time by BMJ Group.

Ethics approval We did not seek ethics committee approval for this study as it mainly involved the evaluation of published manuscripts in the public domain. Only SS had access to named reviewers’ and editors’ comments, who is a full-time employee of the BMJ Publishing Group and regularly reads such material as part of her job. On submitting to the BMJ, prospective authors are informed that their paper may be enrolled in a research study as part of improving the peer-review process and are given the opportunity to opt out of this.

Provenance and peer review Not commissioned; externally peer-reviewed.

Data sharing statement Extra data can be accessed via the Dryad data repository at http://datadryad.org/ with the doi:10.5061/dryad.h85k0.

REFERENCES