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Impact of the Mandatory Implementation of Reporting Guidelines on Reporting Quality in a Surgical Journal: A Before and After Study

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Contributorship Statement

RA: Study concept and design, data analysis, drafting, approval of final manuscript
AJF: Article selection, data collection, revision of draft, approval of final manuscript
KW: Article selection, data collection, revision of draft, approval of final manuscript
RC: Article selection, data collection, revision of draft, approval of final manuscript
HS: Article selection, data collection, revision of draft, approval of final manuscript
CL: Article selection, data collection, revision of draft, approval of final manuscript
DJ: Article selection, data collection, revision of draft, approval of final manuscript
CC: Article selection, data collection, revision of draft, approval of final manuscript

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BG: Data collection, data collection, revision of draft, approval of final manuscript

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Abstract

Background

Journals are an important conduit for the publication of research. However, the reporting quality of research has been shown to be lacking. We sought to determine if reporting quality could be improved, by mandating compliance with the relevant reporting guidelines during the submission process to a single surgical journal.

Methods

The policy above was implemented in the International Journal of Surgery (IJS), in March 2013. This involved requiring all authors submitting observational studies, randomised controlled trials (RCTs) and systematic reviews to submit completed STROBE, CONSORT and PRISMA Statement checklists respectively along with their paper, making them available to the editor and peer-reviewers. Articles were analysed in three distinct periods from 2012-2014, before and after guideline implementation by two independent teams.

Results

Our results show that overall STROBE compliance following implementation of the policy, increased by a statistically significant 12% (68% to 77%, p=0.00018). Similarly CONSORT compliance increased (50% to 70%) as did PRISMA compliance (48% to 76%). The items that improved the most were those providing greater details on study design, outcome definitions as well as measurement, how patients and quantitative variables were handled during the analyses and discussing limitations and detailing potential sources of bias.

Conclusion

Implementing a policy mandating the submission of a completed reporting guideline checklist for observational studies, RCTs and systematic reviews can increase compliance. We advocate this measure for other journals and for other study types.

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Background

Journals are an important conduit for the publication of research. However, the reporting quality of research has been shown to be lacking. Previous studies of surgical randomised controlled trials (RCTs) has shown that approximately half of the mandatory items for inclusion were omitted and this was consistent when looking at ophthalmic surgery and plastic surgery. [1–3] Reporting quality has similarly been shown to be lacking in observational studies[4] and in systematic reviews in plastic surgery. [5] This deficiency has also been shown to exist in medical studies. [6,7]

Poor reporting quality undermines proper critical appraisal of research. Readers need complete, clear and transparent information to assess research fully. Endorsing reporting guidelines is a first step with a Cochrane systematic review showing some benefit to this. Twenty five outcomes improved with a Consolidated Standards of Reporting Trials (CONSORT) endorsement with five being statistically significant. [17] However, the review concluded by saying that more robust mechanisms are needed to enhance compliance.

We sought to determine if the reporting quality of observational studies, RCTs and systematic reviews could be improved, by mandating compliance with the relevant reporting guideline during the submission process to a single surgical journal.

Methods

The policy above was implemented in the International Journal of Surgery (IJS), in March 2013 (in practice the practical implementation took from March to August 2013). This involved asking all authors submitting observational studies, RCTs and systematic reviews to submit a completed Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement, CONSORT or a Preferred Reporting of Items of Systematic Reviews and Meta-Analyses (PRISMA) checklist along with their paper, making it available to the editor and peer-reviewers. [8–10] Articles were analysed in three distinct periods, one before, one during transition and two after implementation of the policy:

Period 1(pre-implementation): July - Dec 2012

Period 2(peri-implementation): July – Dec 2013

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Period 3(post-implementation): July - Dec 2014

During this period, article abstracts were assessed issue by issue at www.journal-surgery.com to assess for eligibility. Where there was doubt, the full text of the article was downloaded. Observational studies were selected by two independent teams (KW/RC/CC and HS/CL/DJ) and populated to a pre-formatted Excel database. Each article was assigned a number and then scored according to the items of the appropriate reporting guideline by two teams acting independently. Each item was given a single mark. Where an item was subdivided into three or four parts, then each part was given the appropriate weighting i.e. 0.33 and 0.25 respectively. Where items were not applicable, they were extracted from the denominator to ensure the overall score was a fair reflection of compliance. In both article eligibility and scoring disagreements were referred to author AJF for dispute resolution if they could not be resolved by discussion beforehand between the two teams. The periods pre and post implementation are compared to assess for any statistically significant difference using either a t-test or the appropriate non-parametric test depending on the distribution of the data. Cohens kappa was calculated to determine inter-rater reliability.

Results

Results for each guideline are given in turn below. Following initial marking, it was noted that there was very poor concordance between teams (Cohens Kappa = 0.45), and so all papers were re-marked by AJF. All points were then discussed between AJF and a member of the original marking team until agreement was reached on a final score.

STROBE

The number of articles in each period and median compliance with the STROBE Statement is in table 1 below:

Table 1. Number of studies, median and range of compliance with STROBE Statement per periods assessed.

The 12% increase in STROBE compliance from period 1 to 3 was statistically

significant as shown by the two sample homoscedastic t-test comparing period 1 and 3 (p=0.00018). This test was performed after performing a normality test (mean absolute deviation to standard deviation ratio) and confirming a Gaussian distribution.

The items which improved the are listed below (table 2):

Table 2. Top five improved items in STROBE checklist.

CONSORT

There were no RCTs found in period 1.

Table 3. Number of studies, median and range of compliance with CONSORT Statement per period assessed.

Table 4. Top five improved items in CONSORT checklist.

A statistical test was deemed inappropriate given the lower numbers of RCTs.

PRISMA

A statistical test was deemed inappropriate given the lower numbers of systematic reviews.

Table 5. Number of studies, median and range of compliance with PRISMA Statement per period assessed.

Table 6. Top five improved items in PRISMA checklist.

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Discussion

Our results show that overall guideline compliance following implementation of the policy increased for observational studies by 13% (68% to 77%, p=0.00018), for RCTs by 40% (50%-70%) as well as for systematic reviews by 58% (48%-76%). The items that improved the most were those providing greater details on study design, outcome definitions and measurement, how quantitative variables were handled during the analyses and discussing limitations and detailing potential sources of bias. Our results also show that there is some time needed for adjustment of a journal's processes, editors and peer-reviewers to these changes, and hence no significant change was evident during the peri-implementation period (period 2).

An estimated US$240 billion is spent annually on heath research. [11] More than 15 million researchers authored over 25 million scientific papers between 1996 and 2011. [12] This enormous investment necessitates a focus on quality and transparency. Unfortunately, it is also estimated that 85% of research resources are wasted. [11] In recent times, transparency has become a major part of the healthcare research discourse. The principle of 'exposing problems to the sun' is a good one – open access, open science, open data and reporting guidelines have all been born from this rubric. Complete, clear and transparent reports aid critical appraisal and reproducibility, essential if other surgeons are to take on board a change to their clinical practice.

Poor reporting remains a fundamental problem within healthcare research. [7] The focus on solutions to these longstanding problems is important. Researchers, funders, editors, peer-reviewers and readers must recognise this problem and advocate robust and sustainable ways of enhancing reporting quality. Some journals do recommend adherence with reporting guidelines in their guide for authors (GFA). However, our own research in this area, has shown that 62% of the 198 surgical journals within the Journal Citation Report 2014 made no mention of reporting guidelines within their GFA.[13] Only 5% mandated one or more reporting guidelines, most commonly the Consolidated Standards of Reporting Trials (CONSORT) for randomised controlled trials (RCTs). [13]

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Despite recognition and updating of their GFA, author compliance is not guaranteed. Indeed, a recent systematic review assessing completeness of reporting in relation to the statement made within the GFA proved inconclusive. [14] Smidt et al showed that since the publication of the STARD statement, the quality of reporting of diagnostic studies improved slightly over time, more so in those journals who adopted the STARD statement. [15] Cobo et al performed a masked randomized controlled trial assessing the effect of reporting guidelines on the peer-review process. [16] They compared conventional peer-review to conventional review with an additional review looking for missing items from reporting guidelines. They saw an improvement in manuscript quality in favor of the additional review group. In addition, more papers with the additional reviews improved from baseline compared to the conventional review alone (43% *vs* 20%).

More robust mechanisms are needed and this is where mandating the submission of a completed reporting guideline checklist can be useful. Authors need to identify the page number upon which they have fulfilled each criterion and editors and peer-reviewers can cross-check their compliance. Our results show the usefulness of this measure.

A limitation of our work is that, there was no one specifically assigned to rigorously check compliance with the checklist. This was due to time constraints within the editorial process. This is reflected within our results, with compliance rising to 76.5% rather than 100%. We would hope compliance would continue to rise and this could be an area for further investigation. A further limitation is the initial discrepancies of marking which required re-marking amongst authors. As a result of this, we have implemented training for future research projects to ensure all researchers are to a standardised level. Finally, over the period 2011-13, the IJS had a change in impact factor as follows:

2011 – 1.293

2012 – 1.436

2013 – 1.650

The impact factors are published in June of the subsequent year, therefore fall into

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the published period 2012-14. Whilst the rise in impact factor could lead to better reported studies being submitted, we have previously shown no link between reporting quality and impact factor, so this link isn't well supported.

Conclusion

Implementing a policy mandating the submission of a completed STROBE, CONSORT and PRISMA checklist can increase compliance with these guidelines for the relevant study types. We advocate this measure for other journals and for other study types.

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Table 1. Number of studies, median and range of compliance with STROBE Statement per period assessed.

Period	Number of Observational Studies	Median Compliance	Range of compliance
1	25	68.4%	44% - 88%
2	77	67.2%	46% - 84%
3	50	76.5%	54% - 97%
Increase from period 1 to 3 = 13%			

Table 2. Top five improved items in STROBE checklist.

Item	Description	Percentage increase in compliance
12e	Statistical Methods - describe any sensitivity analyses	300%
6	Participants - for matched studies, give matching criteria and number of exposed and unexposed	103%
3	Bias - Describe any efforts to address potential sources of bias	83%
14c	Descriptive data - Cohort study—summarise follow-up time (eg, average and total amount)	81%
11	Quantitative variables - Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	77%

Table 3. Number of studies, median and range of compliance with CONSORT Statement per period assessed.

Period	Number of RCTs	Median Compliance	Range of compliance
1	0	N/a	N/a
2	3	50%	36-50%
3	10	70%	54-82%
Percentage increase from period 2 to 3 = 40%			

Table 4. Top five improved items in CONSORT checklist.

Item	Description	Percentage increase in compliance
8a	Sequence generation - method used to generate the random allocation sequence	200%
16	Numbers analysed - for each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	170%
13b	Participant flow - for each group, losses and exclusions after randomisation, together with reasons	140%
11a	Blinding - If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	140%
9	Allocation concealment - mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	65%

Table 5. Number of studies, median and range of compliance with PRISMA Statement per period assessed.

Period	Number of Systematic Reviews	Median Compliance	Range of compliance
1	4	48%	15%-78%
2	10	72%	63%-89%
3	14	76%	48%-96%
Percentage increase from period 1 to 3 = 58%			

Table 6. Top five improved items in PRISMA checklist.

Item	Description	Percentage increase in compliance

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20	Results of individual studies - for all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	243%
21	Synthesis of results - present results of each meta-analysis done, including confidence intervals and measures of consistency.	157%
23	Additional analysis - give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression	157%
14	Synthesis of results - describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	157%
12	Risk of bias in individual studies - describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	129%

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Highlights:

- Mandatory implementation of reporting guidelines implemented at IJS in March 2013
- Significant improvement in reporting guideline compliance since then
- Other journals should consider implementing mandatory reporting guidelines at time of submission

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