

# Research transparency promotion by surgical journals publishing randomised controlled trials: a survey

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## Research

**Keywords:** Data sharing, Conflict of interest declaration, CONSORT guidelines, Randomised controlled trial

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## Abstract

**Objective** To describe the surgical journal position statement on data-sharing policies (primary objective) and to describe the other features of their research transparency promotion.

**Methods** Only “SURGICAL” journals with an impact factor superior to 2 (Web of Science) were eligible for the study. They were not included if there were no explicit instructions for clinical trial publication in the instructions for authors and if there were no RCT published between January 2016 and January 2019. The primary outcome was the existence of a data-sharing policy in the instructions for authors. Details on research transparency promotion were also collected, namely the existence of a “prospective registration of clinical trials requirement” policy; a “COIs” disclosure requirement and a specific reference to reporting guidelines such as CONSORT for RCT.

**Results** Among the 87 surgical journals eligible, 82 (94%) were included in the analysis: 67 (77%) had explicit instructions for RCT and of the remaining, 15 (17.2%) had published at least one RCT between 2016-2019. The median impact factor was 2.98 [IQR=2.48-3.77] and in 2016 and 2017, the journals published a median of 11.5 RCT [IQR=5-20.75]. Data-sharing statement instructions (primary outcome) were ICMJE-compliant in four cases (4.88%), weaker in 45.12% (n=37) and inexistent in 50% (n=41) of the journals. As for data-sharing statements, no association was found between journal characteristics and the existence of data-sharing policies (ICMJE-compliant or weaker). A “prospective registration of clinical trials requirement” was associated with ICMJE allusion or affiliation and higher impact factors. Journals with specific RCT instructions in their OIA and journals referenced on the ICMJE website more frequently mandated the use of CONSORT guidelines.

**Conclusion** Research transparency promotion is still limited in surgical journals. Uniformization of journal requirements vis-à-vis ICMJE guidelines could be a first step forward for research transparency promotion in surgery.

## Background

Surgical journals have a key role to ensure transparency, openness, and reproducibility[1]—features that are expected to increase value and reduce waste in the research they publish[2]. The highest editorial standards are expected when it comes to randomised controlled trials (RCT) because their importance is paramount in drafting guidelines that can impact medical practice worldwide. Surgical interventions are highly invasive and trials participants always put themselves at risk with uncertain benefits. It results an implicit social contract imposing an ethical obligation that the results lead to the greatest possible benefit to society [3].

The latest breakthrough was the adoption by the International Committee of Medical Journal Editors (ICMJE) of a policy that encourages RCT data sharing and requires a data-sharing statement to be included in the reports of published clinical trials[4]. Other aspects of research transparency promotion have been previously promoted such as registration of the trial[5], adoption of the CONSORT statement[6] and declaration of conflicting interests (COI)[7]. However, transparent practices in the surgical community could be suboptimal as suggested by the underreporting of COI[8].

If we hypothesize that publishers can be the first motivators for research’ transparency promotion, it is all the most important to review current publishers’ practices and policies in relation to the transparency of the research.

The aim of this study is to describe the surgical journal position statement on data-sharing policies (primary objective) and to describe the other features of their research transparency promotion.

## Methods

This survey of surgical journals was registered with a protocol in the Open Science Framework on February, 25<sup>th</sup> 2019.

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## Eligibility criteria and Journal selection

Two reviewers (NL and AG) used Web of Science to select journals classified in the “SURGICAL” category with an impact factor superior to 2. Surgical journals were not included if there were no explicit instructions for clinical trial publication in the instructions for authors and if there were no RCT published between January 2016 and January 2019. Two authors (NL and AG) independently extracted the data. Disagreements were resolved by consensus or in consultation with a third reviewer (DB). The list of journals was extracted in December 2018 and the official instructions for authors (OIA) were downloaded on January 13–14, 2019.

Our primary outcome was the existence of a data-sharing policy in the instructions for authors. Types of policies for data sharing were described using the following classification: “ICMJE compliant” (policies explicitly stating that the data-sharing statement was mandatory), “Weaker policy” (policies stating a data-sharing statement could be included in the paper), “None” (no mention of any data-sharing policy). Details on research transparency promotion were also collected, namely the existence of a “prospective registration of clinical trials requirement” policy; a “COIs”

disclosure requirement and a specific reference to reporting guidelines such as CONSORT for RCT. Various journal features were also extracted (see Table 1). Journal impact factors were extracted from the Web of Science data base and the number of RCT published between January 2016 and January 2018 was extracted from Pubmed (we initially planned to evaluate the number of RCT published in 2016, 2017 and 2018 but this was not possible because at the time of data extraction, all RCT published were not fully indexed in Pubmed). ICMJE “affiliation” was defined as journals referenced as “Journals stating that they follow ICMJE Recommendations” at:

<http://www.icmje.org/journals-following-the-icmje-recommendations>.

## Statistical analyses

Analyses of all included journals were performed using open source R statistical software (<http://www.r-project.org/>). Quantitative variables were expressed with median and the interquartile range (IQR) and compared with the Mann-Whitney U test. Qualitative variables were expressed as a percentage and compared with a Chi-squared test or Fisher test as appropriate. Univariate exploratory analyses were performed to explore the associations between journal features and the various transparency policies. Multivariate analyses were planned but not run owing to sparse data.

## Results

Among the 87 surgical journals eligible, 82 (94%) were included in the analysis: 67 (77%) had explicit instructions for RCT and of the remaining, 15 (17.2%) had published at least one RCT between 2016–2019 (*Figure 1* details the selection process). The characteristics of these journals are detailed in *Table 1*. The median impact factor was 2.98 [IQR = 2.48–3.77]. In 2016 and 2017, the journals published a median of 11.5 RCT [IQR = 5–20.75]. The publishing model was “hybrid” in most cases (89.02%) and North America was the principal geographical area of journal editorial committees (56.10%). Data-sharing statement instructions were ICMJE-compliant in four cases (4.88%), weaker in 45.12% (n = 37) and inexistent in 50% (n = 41) of the journals. COI disclosure was mandatory in 77 journals (93.90%). A reference to CONSORT guidelines was made in 24 journals (29.27%). Prospective registration of clinical trials was mandatory in 53 cases (64.63%). *Figure 2* presents the relationship between the different research transparency promotion items and journal impact factors and the number of RCT published between 2016 and 2018. The associations between journal features and the different transparency policies are presented in *Table 2*. As for data-sharing statements, no association was found between journal characteristics and the existence of data-sharing policies (ICMJE-compliant or weaker). A “prospective registration of clinical trials requirement” was associated with ICMJE allusion ( $P < 0.001$ ) or affiliation and higher impact factors ( $P < 0.001$ ). Journals with specific RCT instructions in their OIA ( $P = 0.04$ ) and journals referenced on the ICMJE website ( $P = 0.03$ ) more frequently mandated the use of CONSORT guidelines. No other pertinent association was found.

## Discussion

We noted low rates of implementation of data-sharing policies, i.e. 50 % of the journals had no explicit policy included in their instructions for authors. When explicit, these policies were rather allusive and weaker than the ICMJE recommendation that make a data-sharing statement mandatory for RCT. Of course, we studied a moving target and one could argue that the ICMJE position on data sharing was fairly recent (data extracted 6 months after the ICMJE statement) and that a number of journals did not have the time to implement it when our survey was conducted. However, this policy was announced in 2017[9] and 35 (43%) journals are listed on the ICMJE website. Interestingly, implementation of older policies was also suboptimal, even for making a specific reference to reporting guidelines such as CONSORT for RCT which date from 1996 [6]. Except for COI disclosure, those policies were mostly non-binding. These disappointing results are not new. In 2014, Chapman et al.[10] warned about sub-optimal transparency policies in 10 leading surgical journals.

We considered a journal’s policies presented on its website as a surrogate marker of implementation of these policies. However, it is possible that editors of journals with a policy do not implement them in an optimal manner [11] or, conversely, that a journal with no specific policy documented on the website requires authors to comply with some of the features we explored. Of note, previous research has shown that journal requirements can have a significant impact on changing researcher practices [12] but an obvious next step is to explore the transparency features of the published RCT in these journals.

Of concern, we found no association of research transparency items with impact factors nor with the number of RCT published except for prospective trial registration among the surveyed surgical journals. This is of concern since impact factor (rounded to the nearest two decimals) is misused as a surrogate to assess the quality of a given journal and sometimes of an individual paper.[13,14]

## Conclusions

As part of a wider movement [15], we suggest that indicators of quality such as prospective audits of policies and published papers must be used to assess journals instead of journal impact factors. We encourage surgical journals to be part of the move to improve their research transparency promotion. Uniformization of journal requirements vis-à-vis ICMJE guidelines could be a first step forward for research transparency promotion in surgery.

## Declarations

*Ethics approval and consent to participate:* For this type of study, formal consent is not required.

*Consent for publication:* Not applicable

*Availability of data and material:* Study protocol is already available on Open Science Framework. Data extracted and statistical code is available on Open Science Framework.

*Competing interests:* All authors have completed the ICMJE uniform disclosure form at [http://www.icmje.org/coi\\_disclosure.pdf](http://www.icmje.org/coi_disclosure.pdf) (available on request from the corresponding author) and declare that (1) No authors have support from any company for the submitted work; (2) None has relationships (travel/accommodations expenses covered/reimbursed) who might have an interest in the work submitted in the previous three years. None have no relationship with any company that might have an interest in the work submitted; (3) no author's spouse, partner, or children have any financial relationships that could be relevant to the submitted work; and (4) none of the authors has any non-financial interests that could be relevant to the submitted work.

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## Author's contributions

Study concept and design: DB, FN

Acquisition of data: NL, AG, DB

Analysis and interpretation of data: DB, NL, FN

Drafting of the manuscript: DB, NL, FN

Critical revision of the manuscript for important intellectual content: FN, KB, LS, AG

Statistical analysis: DB, FN

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## Abbreviations

RCT: Randomised Controlled Trial

ICMJE: International Committee of Medical Journal Editors

COI: Conflict of Interest

OIA: Official Instructions for Authors

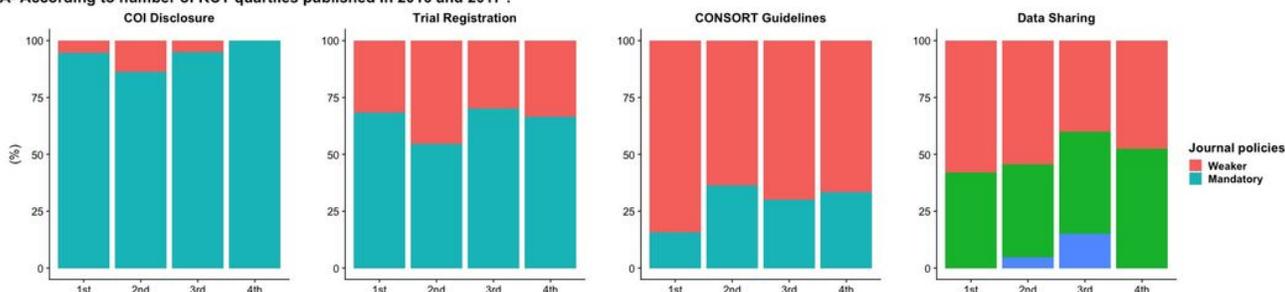
IQR: Interquartile interval range

## Tables

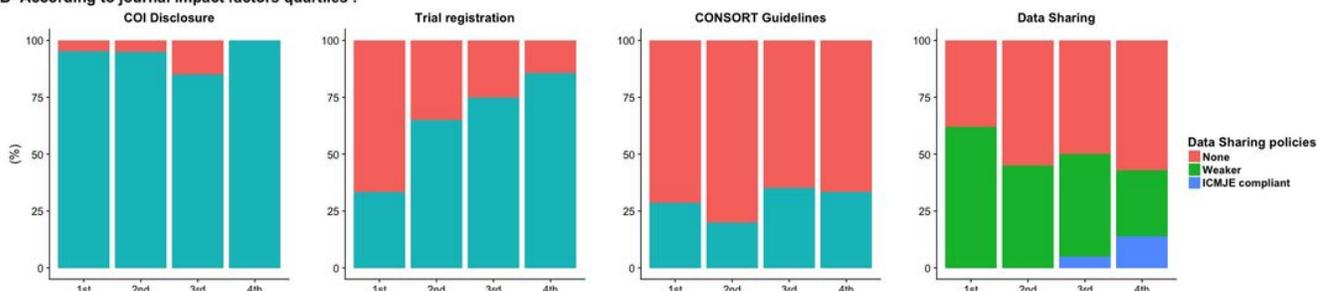
Due to technical limitations, tables are only available as a download in the supplemental files section

## Figures

**A- According to number of RCT quartiles published in 2016 and 2017 :**



**B- According to journal impact factors quartiles :**



**Figure 1**

Journal selection process. RCT = randomised controlled trial.

## Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [Table1JDSproject.xlsx](#)

- [SuppTable1.xlsx](#)
- [SuppFig1final.jpg](#)