

STATISTICS IN ANAESTHESIA

Analysis of practices to promote reproducibility and transparency in anaesthesiology research

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Abstract

Introduction: Reliable, high-quality research is essential to the field of anaesthesiology. Reproducibility and transparency have been investigated in the biomedical domain and in the social sciences, with both lacking to provide necessary information to reproduce the study findings. In this study, we investigated 14 indicators of reproducibility in anaesthesiology research.

Methods: We used the National Library of Medicine catalogue to search for all anaesthesiology journals that are MEDLINE indexed and provide English texts. PubMed was searched with the list of journals to identify all publications from January 1, 2014 to December 31, 2018. We randomly sampled 450 publications that fit the inclusion criteria for our analysis. Data extraction was then conducted in a blinded, duplicate fashion using a pilot-tested Google form.

Results: The PubMed search of these journals identified 171 441 publications, with 28 310 being within the time frame. From the 450 publications sampled, 444 full-text publications were accessible. The majority of publications analysed did not have a statement regarding availability of data (164/188), analysis scripts (187/188), or study materials (160/188).

Conclusions: Anaesthesiology research needs to improve indicators of reproducibility and transparency. By making research publicly available and improving accessibility to detailed study components, primary research can be reproduced in subsequent studies and help contribute to the development of new practice guidelines.

Keywords: anaesthesiology; evidence-based medicine; reproducibility; research design; statistics

Editor's key points

- There is a reproducibility crisis in science, and many reported results are not reproduced in subsequent experiments.
- Rigorous methods increase the likelihood that reproducible findings will be obtained.
- In order to allow assessment of the rigour of the methods, and to enable checking appropriateness of results and inferences, researchers must provide detailed experimental methods, including analysis scripts and raw data.
- Most articles in anaesthesia journals do not provide protocols, raw data, or analysis scripts.

The process of peer reviewing, analysing, critiquing, and, eventually, reproducing trials is the cornerstone for creating high-quality, reliable, transparent, reproducible, evidence-based publications.¹ However, published reports may provide only limited summaries of a research study, and these published reports often fail to include key study components—raw data, detailed protocols, materials, and analysis scripts—that provide more comprehensive study details. Access to this additional information enables further analysis and verification of the conclusions from the original research.² When researchers strive for transparency and allow primary research to be reproducible, we will see improved efficiency,³ self-correction,⁴ and credible published literature.⁵ Because of the vital importance of accurate research and its direct influence on patient care, publishers of high-impact journals

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have initiated guidelines to help improve the reproducibility and transparency of research. For example, the *British Journal of Anaesthesia* and *Anesthesia & Analgesia* provide statements in their authorship guidelines encouraging raw data to be available to readers; however, raw data are not required to be submitted for public viewing.^{6,7} Access to raw data is encouraged by these journals for statistical reproducibility,⁸ additional analysis,⁹ participant-level meta-analyses,¹⁰ and the merging of future or existing datasets.¹¹

High-quality reproducible research is essential to the field of anaesthesiology. New research establishes the evidence base for clinical practice guidelines, modifies established protocols, and updates the standard of care for anaesthesiologists. Because of the implications of research on patient care, credible science should catalyse change and must be supported by reliable evidence. Studies have been performed in the biomedical and social sciences which demonstrated very few authors providing the necessary information for their studies to be reproduced; however, practices that promote reproducibility and transparency have never been evaluated in anaesthesiology research.^{12,13} In this study, we queried indicators of reproducibility to assess the current climate of anaesthesiology research. These indicators, as listed earlier, include statements and physical availability of study materials, data, analysis scripts, and protocols. A random sample of recent anaesthesia publications from all MEDLINE indexed journals were evaluated to determine if such indicators were present in addition to other study characteristics. Results from this investigation may be used to establish a baseline for comparison in future studies.

Methods

This was an observational, cross-sectional study design. We referenced the methodology by Hardwicke and colleagues¹² and Wallach and colleagues¹³ to decide which reproducibility characteristics to use and the study designs that are associated with them (Table 1). Our Google form was based on the one used by Hardwicke and colleagues¹² but created by an investigator with increased study types, funding options, and 5-year impact factor. This study did not involve human participants and was not subject to oversight by an institutional review board per the United States Code of Federal Regulations.¹⁴ We report our study in accordance with guidelines for meta-epidemiological methodology research.¹⁵ We uploaded our protocol, data extraction form, and other necessary materials for public viewing on the Open Science Framework (<https://osf.io/n4yh5/>).

Journal selection

We used the National Library of Medicine (NLM) catalogue to search for all relevant journals using the subject terms tag Anesthesiology[ST]. This search was performed on May 29, 2019. The inclusion criteria required that journals provided full-text publications in English and were MEDLINE indexed. The list of journals in the NLM catalogue fitting the inclusion criteria were then extracted using the electronic International Standard Serial Number (ISSN) or the linking ISSN when the electronic ISSN was unavailable. This series of ISSNs was then used in a PubMed search to identify all publications within these journals. We limited the sample to publications from January 1, 2014 to December 31, 2018 then randomly sampled 450 publications that fit the inclusion criteria for our analysis

(<https://osf.io/7sk9m/>). We used OpenEpi version 3.0 to conduct a power analysis to estimate sample size. Data availability was the primary outcome because of its importance for study reproducibility.¹² The population size of studies published in MEDLINE indexed journals from which we selected our random sample was 28 310, with a hypothesised frequency of 18.5% for the factor in the population (which was based upon data obtained by Hardwicke and colleagues¹²); a confidence limit of 5%; and a design factor of 1. Based on these assumptions, our study would require a sample size of 230. To allow for the attrition of publications that would not meet inclusion criteria, we randomly sampled a total of 450 publications. Results from our previous studies have found that approximately 40% would be excluded after screening.^{16,17} Thus, a sample size of 450 should be adequate to achieve the 230 studies needed for analysis. Previous investigations, upon which this study is based, have included

Table 1 Types of studies in anaesthesiology.

Characteristics	Variables		
	N (%)		
Type of study N=296	No empirical	142 (48.0)	
	Clinical trial	38 (12.8)	
	Case study	27 (9.1)	
	Laboratory	22 (7.4)	
	Cohort	21 (7.1)	
	Meta-analysis	12 (4.1)	
	Chart review	10 (3.4)	
	Survey	8 (2.7)	
	Case series	5 (1.7)	
	Commentary	3 (1.0)	
	Case control	1 (0.3)	
	Multiple	1 (0.3)	
	Cost effect	0 (0.0)	
	Other	6 (2.0)	
Study participants N=296	Animals	17 (5.7)	
	Humans	119 (69.9)	
	Both	0 (0.0)	
	Neither	160 (2.5)	
Country of journal publication N=296	USA	211 (71.3)	
	South Korea	6 (2.0)	
	UK	32 (10.8)	
	Australia	8 (2.7)	
	Japan	12 (4.1)	
	France	4 (1.4)	
	Canada	3 (1.0)	
	Italy	8 (2.7)	
	India	3 (1.0)	
	Poland	7 (2.4)	
	Unclear	2 (0.7)	
	Other	0 (0.0)	
	Country of first author N=296	USA	101 (34.1)
		China	7 (2.4)
UK		23 (7.8)	
Netherlands		9 (3.0)	
Japan		8 (2.7)	
France		10 (3.4)	
Canada		19 (6.4)	
Italy		13 (4.4)	
India		11 (3.8)	
Australia		14 (4.7)	
Unclear		2 (0.7)	
Other		79 (26.7)	

random samples of 250 publications in the social sciences and 150 publications in the biomedical sciences.

Data extraction training

The two investigators responsible for data extraction (OO and DR) underwent a full day of training to ensure inter-rater reliability. The training included an in-person session that reviewed the project study design, protocol, Google extraction form, and examples of where information may be contained using two sample publications. The investigators were then given three example publications from which to extract data in a blinded fashion. After data extraction, the pair reconciled differences between them by discussion. This training session was recorded and listed online for reference (<https://osf.io/jczx5/>). As a final training exercise, investigators extracted data from the first 10 publications of their sample. The investigators held a meeting to reconcile any differences in the data before extracting data from the remaining 290 publications.

Data extraction

Data extraction on the remaining 290 publications was then conducted in a duplicate, blinded fashion. A final consensus meeting was held with both investigators to resolve disagreements. A third investigator (DT) was available for adjudication but was not needed. We extracted data using a pilot-tested Google form based on the one provided by Hardwicke and colleagues¹² with additions. This form queries information necessary to be reproducible, such as the availability of materials, data, protocols, or analysis scripts (<https://osf.io/3nfa5/>). The data extracted varied based on the study design with studies having no empirical data being excluded (e.g. editorials, commentaries [without reanalysis], simulations, news, reviews, and poems). Case series and case studies were excluded from extracting reproducibility characteristics, as they are not expected to have predetermined items such as detailed materials, protocols, and raw data. In addition, meta-analysis and systematic reviews were evaluated for having materials (search strings and data collection forms) but were not expected to have raw data (since they used secondary study data).¹³ In our Google form, we included the 5-yr and most-recent-year impact factor, when available. We also expanded the study design options to include: cohort studies, case series, secondary analyses, chart reviews, and cross-sectional studies. Finally, we expanded the funding options from public, private, or mixed into the more specific categories of university, hospital, public, private/industry, non-profit, or mixed. At the request of peer reviewers, we omitted portions of the data we extracted which were prespecified in our protocol. This was done to streamline the results in the published report; however, all removed data—the transparency indicators—have been included in [Supplementary Table S1](#).

Evaluation of replication and whether publications were included in research synthesis

For empirical studies, excluding meta-analysis and commentary with analysis, we searched the Web of Science to determine if the publication was cited in a replication study, meta-analysis, or systematic review. The Web of Science additionally lists information important for our study, such as the country of journal publication, 5-yr impact factor (when

available), and most recent impact factor with the year it represents.

Statistical analysis

We report descriptive statistics for each of our findings with 95% confidence intervals (95% CI) using analysis functions within Microsoft Excel. The total number of publications containing each variable will be presented with the proportion of the extracted sample. The 95% CI are calculated using the formula for Wilson's CIs of proportions and reported within brackets.¹⁸

Results

Publication characteristics and availability

Our search of the NLM catalogue identified 86 anaesthesiology journals, but only 36 fit the inclusion criteria. The PubMed search of these journals identified 171 441 publications, with 28 310 being within the time-frame. From the 450 publications sampled, 444 full-text publications were obtained (99%) ([Table 1](#)). Other sample characteristics are shown in [Table 1](#) and [Supplementary Table S1](#).

Reproducibility criteria

The presence of several reproducibility criteria were analysed, including statements and availability of protocols, raw data, materials, and analysis scripts ([Table 2](#), [Fig. 2](#)). Of the 231 publications containing empirical data, 169 were assessed for a materials availability statement. Case studies, case series, and commentary with analysis studies were excluded from this evaluation ([Fig. 1](#)) as we did not expect these studies to have materials such as surveys or software.¹² Of the studies evaluated, most did not include materials availability statements (160/169, 95% [95% CI: 90%–97%]). The availability of raw data, analysis scripts, study protocol, and preregistration was accessed in 188 studies. Case studies and case series were excluded from this evaluation ([Fig. 1](#)). Most of these studies did not provide a data availability statement (164/169, 87% [95% CI: 82%–91%]). Of the studies with statements, only one provided all raw data necessary to reproduce the study findings. The majority of publications did not provide a data analysis script statement (187/188, 99% [95% CI: 97%–100%]). Similar to analysis scripts, a majority of the publications did not contain a preregistration statement (147/188, 78% [95% CI: 72%–84%]). Additional information is available in [Table 3](#) and [Supplementary Table S1](#).

Replication and evidence synthesis

The publications were analysed for their number of citations in replication studies or systematic reviews/meta-analyses. Of the 231 publications containing empirical data, 204 studies were included in this analysis; meta-analyses, systematic reviews, and commentaries with analysis were excluded ([Table 2](#)). None of the 204 studies were cited by a replication study and most of the publications were not cited by a systematic review or meta-analysis (173/1204, 88%; [Supplementary Table S2](#)).

Table 2 Factors Analysed. The factors examined in each article were based upon study type. Additional information about coding and extraction is accessible at: <https://osf.io/x24n3/>

Reproducibility criteria		Impact on research transparency and reproducibility
Articles		
Is the article available publicly or restricted by a paywall?	Includes all studies (N=300)	Reproducibility can be enhanced by providing open access to research articles. This accessibility can lead to increased replication studies and data sharing by the scientific community.
Funding		
Is the funding source or absence of funding included in the article?	Includes all studies (N=296)	Decision making and application in research can be modified by the source of financial support.
Conflict of interest		
Does the article disclose any conflict of interest or state that none exist?	Includes all studies (N=296)	Transparency can be demonstrated by including a statement of potential conflicts of interest. This provides an opportunity for any potential bias to be disclosed.
Evidence synthesis		
Are there any reported citations of the study being by a meta-analysis or systematic review?	Empirical studies* (N=154)	Inclusion of articles in a meta-analysis and systematic review facilitates the production of new studies.
Protocols		
Is a protocol availability statement included in the article?	Empirical studies† (N=122)	In order to reproduce a study, a complete and through protocol is necessary.
Which elements of the protocol were included?		
Materials		
Is a material availability statement included in the article?	Empirical studies‡ (N=107)	Restrictions to the accessibility of materials used in a previous study can negatively impact the validity of a subsequent replication study.
How does the article state the materials are available?		
Are the materials accessible from the statement provided?		
Raw data		
Is a data availability statement included in the article?	Empirical studies† (N=122)	Top ranking journals (Nature, The Lancet, Annals of Internal Medicine) are more frequently requiring studies to have data availability.
How does the article state the data are available?		
Are the data accessible from the statement provided?		
Does the article provide all the raw data that would be required for replication?		
Are the names of the data files easily identifiable?		
Analysis scripts		
Does the article provide an analysis script availability statement?	Empirical studies† (N=122)	Analysis scripts are unique sets of instructions that can be used in a replication study to mirror previous data analysis.
How does the article state the analysis scripts are available?		
Are the data accessible from the statement provided?		
Preregistration		
Is a preregistration statement included in the article?	Empirical studies† (N=122)	Reporting bias like P-hacking and outcome switching can be reduced by pre-registration.
Which organisation was the article registered with?		
Was the preregistration accessible?		
Which elements of the preregistration were available?		

* 'Empirical studies' have empirical data and include the following studies: chart review, secondary analysis, case series, clinical trial, cohort, case-control, meta-analysis, systematic review, commentaries (with data analysis), laboratory, case reports, and cross-sectional study designs. Meta-analysis and systematic review were excluded because of this category not being applicable.

† Case series and case reports were excluded because they lack reproducibility criteria, which were performed by Wallach and colleagues.

‡ Case series, case reports, meta-analysis, systematic review, or commentaries with analysis were excluded because of this category not being applicable.

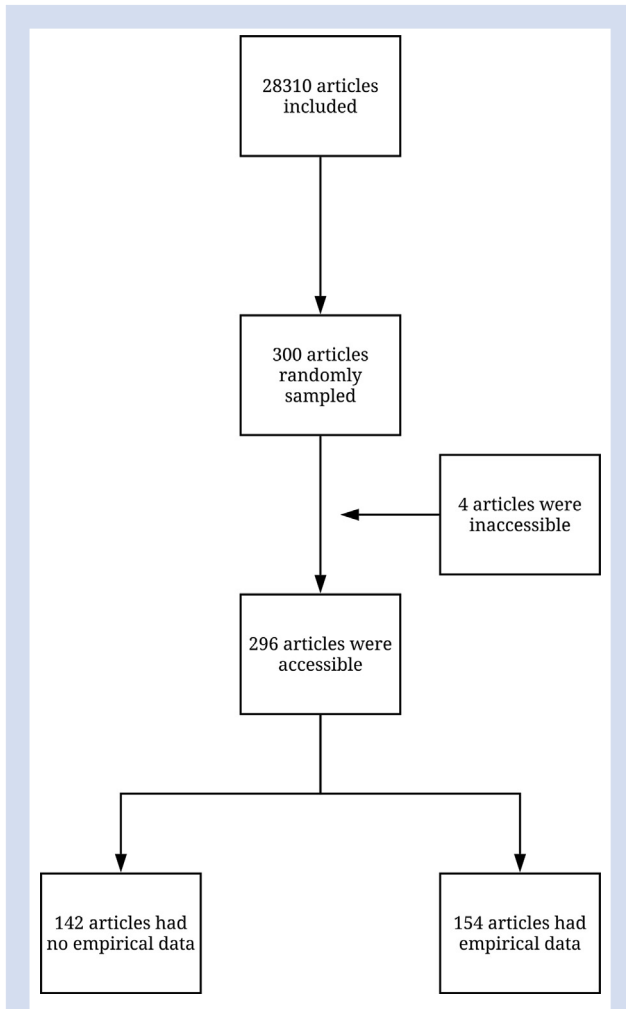


Fig 1. Flow diagram for inclusion and exclusion of studies.

Discussion

To our knowledge, this is the first study attempting to objectively quantify specific indicators of reproducibility in the field of anaesthesiology. The majority of the publications in our sample failed to make key study components available. Materials and protocols were not routinely accessible, many authors did not provide raw data, only one publication provided an analysis script, and the majority were not preregistered. There were no published replication attempts in our sample of publications. Our findings are similar to those found in the biomedical and social science literature. These studies underscore the lack of reproducible research and potential pitfalls for subsequent investigators.^{13,19} Publications failing to provide key study components can have unintended consequences when others attempt to replicate the research or when it is included in a meta-analysis or systematic review. Seitz and colleagues²⁰ conducted a systematic review on exposure to general anaesthesia and the risk of developing Alzheimer's disease. When pooling the primary studies, only a single study specified the time duration between exposure to

general anaesthesia and assessment of dementia. This lack of reporting prohibited the authors from estimating a pooled effect estimate for this important outcome.²⁰ Had better reporting been performed by the primary study authors, this analysis would have been possible.

The lack of publicly available protocols, materials, and data in anaesthesiology literature is concerning. These research methodologies allow for independent verification of results and for ensuring that researchers actually did what they planned to do. In order for improvements to occur, it will be necessary for multiple stakeholders to come together within the anaesthesiology community to address this issue more broadly. Later, we outline recommendations being adopted inside and outside of medicine that may be useful to the field of anaesthesiology. Here, we focus on the role of academic journals and funders, although, certainly, the researchers themselves, peer reviewers, institutional review boards, and others play a role in this improvement.

In a recent article, Adam²¹ describes efforts by the *British Journal of Anaesthesia* to improve study reproducibility by considering reproducibility beyond the methods and results. The journal's editor-in-chief has created a novel approach for arriving at more accurate conclusions by involving independent reviewers to write discussions and conclusions during the peer review process when provided with the submitter's raw data. The idea would attempt to eliminate the original authors' conflicts of interests and allegiance biases. These biases can alter the interpretation of their results. Although we did not inquire about reproducibility with regards to drawing conclusions from submitted data and methodology, this seems to be an additional measure journals could consider taking in order to ensure published material is not misconstrued. The journal *Anesthesiology* uses custom software designed to evaluate a study's adherence to reporting guidelines such as the Consolidated Standards for Reporting Trials (CONSORT) and Animal Research: Reporting of *In Vivo* Experiments (ARRIVE). Outside of medical research, novel approaches are also being explored. *The American Journal of Political Science* requires manuscripts accepted for publication to provide sufficient materials in the text and supporting materials for independent researchers to verify the analytic results. Upon submission of the final draft, these materials are verified that they do, in fact, reproduce all results in the manuscript by an independent statistical group at a university. After this confirmation process, the dataset is deposited online. Thus, publication in the journal is contingent upon authors providing all necessary materials and successful verification of all data. We encourage journals to address reproducibility at the submission stage. Authors should make materials and data available in open repositories to support subsequent research projects. If journals do not want to require authors to provide this information publicly, there should be a statement within the text identifying if and how these materials may be accessed. Journals could play an important role in fostering reproducibility as it has been found that topics related to this concept are often missing from the instructions to the authors.²² *PLOS ONE* used a data sharing policy requiring a statement from authors and to provide raw data when possible. This policy has increased the availability of data in public repositories to 20% compared with 10% before the policy.^{23–25} This outcome demonstrates the potential room for improvement across all journals and an example of how it has been done successfully.

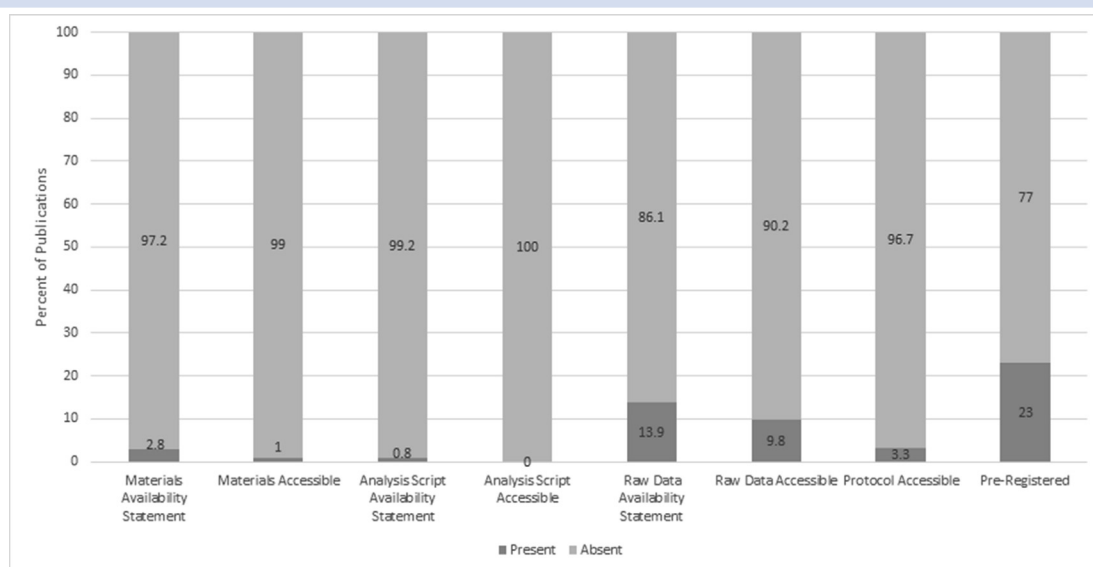


Fig 2. The portion of publications that include indicators of reproducibility.

Table 3 Reproducibility criteria.

Characteristics		Variables	
		N (%)	95% confidence interval
Data availability statement N=122	Some or all data available	16 (13.1)	8.2–20.2
	Data not available	1 (0.8)	0.1–4.5
	Statement not present	105 (86.1)	78.8–91.1
Material availability statement N=107	Some or all data available	2 (1.9)	0.5–6.6
	Materials not available	1 (0.9)	0.2–5.1
	Statement not present	104 (97.2)	92.3–99.0
Protocol available statement N=122	Complete protocol	4 (3.3)	1.3–8.1
	Statement not present	118 (96.7)	91.9–98.7
	Analysis scripts N=122	Some or all analysis scripts available	1 (0.8)
Analysis scripts N=122	Analysis scripts not available	0	0
	Statement not present	121 (99.2)	95.5–99.9
	Preregistration statement N=122	Preregistered	28 (23.0)
Not preregistration		0	–
Statement not present		94 (77.0)	68.8–83.6

The future of reproducible research does not rest solely on the shoulders of academic journals. Researchers and future researchers should have increased awareness of reproducibility practices through training courses or even undergraduate research classes. The National Institute of Health has placed an emphasis on training future research scientists through their Rigor and Reproducibility initiative. This initiative has provided increased opportunities for researchers to receive training through online modules and webinars.²⁶ The National Institute of Health has gone further than training as to incentivise reproducible research practices through grant funded opportunities available on their website.²⁷ In addition to government funded initiatives, research practices can be learned through undergraduate courses that count towards college degrees.²⁸ Harvard has created such courses and allows students to enrol in one specifically dedicated to

'Principles, Statistical and Computational Tools for Reproducible Science' through an online platform.²⁹ Courses such as these could be implemented easily by institutions that hire undergraduate researchers to disseminate information about reproducible practices.

Our study has both strengths and limitations. Concerning its strengths, our study examined a wide range of anaesthesiology publications published across several journals. The random sample of these publications used in this study should improve the generalisability of our findings. We used double data extraction throughout the data collection process. This form of data extraction, which incorporates two coders who are blinded to the decision making of the other, is considered the gold standard by the systematic review community and is advocated by the Cochrane Collaboration.³⁰ Additionally, we have provided our study protocol, data, and other pertinent

materials to improve the reproducibility and transparency of this study. Regarding its limitations, our data collection was sampled from publications dated from 2014 to 2018 and is meant to be a general overview rather than a complete analysis of anaesthesiology publications. Our data collection is also limited to publications in the field of anaesthesiology. We recommend investigating reproducibility and transparency in other fields of medicine as there is often overlap which can contribute to the development of clinical guidelines and protocols. For example, the recent Enhanced Recovery After Surgery protocol developed for Cardiac Surgery published in *JAMA Surgery* included several RCTs and meta-analyses that would not necessarily have been found in specific anaesthesiology journals.³¹

In conclusion, anaesthesiology research needs to drastically improve with regards to reproducibility and transparency. This analysis is consistent with previous studies in biomedical and social science research. We speculate our findings are also consistent in other fields of medicine; however, we recommend further analysis in order to catalyse change in those fields. Our goal of this study is to offer a foundation for publishers to consider when evaluating the validity of a study and for authors and researchers to consider when developing their primary research projects. By including these indicators in primary research, anaesthesiology publications can become more valid, transparent, and reproducible. By making research easily accessible online and by improving accessibility to the detailed study components (raw data, materials, protocols, and analysis scripts) primary research can be reproduced in subsequent studies and help contribute to the development of new practice guidelines, helping change patient care through evidence-based conclusions.

Authors' contributions

Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work. Drafting the work or revising it critically for important intellectual content. Final approval of the version to be published: all authors.

Declarations of interest

The authors declare that they have no conflicts interest.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.bja.2020.03.035>.

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