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Compton, Wyatt; Dennis, Brody; Clark, Payton; Smith, Caleb A.; Nees, Danya; Hughes, Griffin; Vassar, Matt

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Title: Family Medicine Journals' Endorsement of Reporting Guidelines and Clinical Trial Registration: A Cross-Sectional Analysis

Authors: Wyatt Compton, M.B.A., M.S.[1], Brody Dennis, B.S.[1], Payton Clark, B.A., B.S.[1], Caleb A. Smith, B.S.[1], Danya Nees, B.S.[1], Griffin Hughes, B.A., B.S.[1], & Matt Vassar, Ph.D.[1,2]

1. Office of Medical Student Research, Oklahoma State University Center for Health Sciences, Tulsa, Oklahoma
2. Department of Psychiatry and Behavioral Sciences, Oklahoma State University Center for Health Sciences, Tulsa, Oklahoma

Corresponding Author: Mr. Wyatt Compton, Oklahoma State University Center for Health Sciences, Address: 1111 W 17th St., Tulsa, OK 74107, United States, Email: wyatt.compton@okstate.edu, Phone: 918-625-5959

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Abstract

Background: Family medicine, vital for patient care but underfunded, prompts an evaluation of how family medicine journals endorse, require, and advocate for reporting guidelines (RGs), clinical trial, and systematic review registration.

Aim: Assess endorsement and requirement of RGs, and the stance on clinical trial and systematic review registration in family medicine journals, impacting research quality and transparency.

Design and Setting: A cross-sectional analysis of 43 "Family Practice" journals, identified through the 2021 Scopus CiteScore. Editors-in-Chief were contacted to confirm article types. Data extracted from "instructions to authors" pages focused on RG recommendations, requirements, and trial registration.

Method: To ensure confidentiality and prevent bias, authors independently extracted data on RG utilization, adherence, and clinical trial registration provide a overview of research standards.

Results: Of 43 journals, the most recommended guidelines were CONSORT (69%), PRISMA (58%), and STROBE (60%). The most required were PRISMA (16%) and CONSORT (11%). Clinical trial registration was recommended or required by 67% of journals. Additionally, 40 out of the 43 (93%) journals cited at least one reporting guideline in their instructions to authors.

Conclusion: Family medicine journals exhibit varied endorsement and requirement patterns for RGs and clinical trial registration. While guidelines like CONSORT, PRISMA, and STROBE are acknowledged, caution is needed in presuming a direct link to enhanced research quality. A nuanced approach, promoting diverse reporting guidelines and rigorous study registration, is essential for elevating transparency and advancing research standards in family medicine.

Keywords: Reporting Guidelines; Family Medicine; Clinical Trial Registration; Research Quality; Transparency in Research

How this fits in: Prior to this research, the endorsement and requirement of reporting guidelines (RGs) and clinical trial registration in family medicine journals were not well-documented. RGs and trial registration are valuable tools that can improve research quality and reduce bias. This study adds critical insights by revealing that while some family medicine journals endorse RGs and clinical trial registration, many do not, potentially impacting the quality and transparency of research in this field. Clinicians should be aware of this variability in practices to better evaluate the quality and reliability of reaching findings within the field of family medicine.

Introduction

Every year, more than 7 million scientific papers are published across over 20,000 academic journals, with publication rates varying by field and specialty.[1] Presently, the field of family medicine has 45 actively publishing journals with a Scopus Citescore, a relatively small number compared to other domains like internal medicine, which boasts 143 active journals with Citescores on the same database.[2] Family medicine is a broad and important area of medicine, with over 100,000 physicians practicing in the field.[3] Family medicine physicians provide the highest number of health care encounters in the United States, such as managing terminally ill patients, identifying health threats within a community, and advocating for accessible health care for all.[4,5] Given the extensive scope of family medicine and its contribution to patient care, robust medical research is essential. From 2002 to 2006, family medicine departments received $187 million in grants from the National Institutes of Health, accounting for only 0.20% of the total $95.3 billion awarded during that period.[5] This disparity underscores the need for a focused examination of research practices in family medicine, particularly in the context of reporting guidelines (RGs) and clinical trial registration.

Reporting guidelines serve as checklists to authors when conducting a specific type of research study design. These guidelines facilitate reporting of information needed in an article to be used as strong evidence for clinical decisions, to be reproduced by other researchers, and to be understood by readers.[4] One example of an RG is the Consolidated Standards of Reporting Trials (CONSORT) used to mitigate bias and increase transparency in clinical trials. Plint et al. found that when journals endorsed the CONSORT RG, the amount of reported data items and the quality of research increased.[6] Likewise, Panic et al. determined that when journals endorse the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guideline, both methodological and reporting quality of published studies improved.[7] To further champion the dissemination of RGs, the Enhancing the Quality and Transparency of Health Research (EQUATOR) Network was established with the goal of maximizing the transparency and reporting quality of clinical research.[8] To date, the EQUATOR Network hosts over 500 unique RGs for various study designs including CONSORT, PRISMA, and Strengthening the Reporting of Observational Studies in Epidemiology (STROBE).[8] However, it is essential to understand that while RGs contribute to comprehensive reporting, they are not direct indicators of research quality or a measure for reducing bias.[9]

In addition to the use of RGs, another strategy to improve transparency of study results is the requirement of clinical trial registration. Prospective clinical trial registration has been associated with a reduced risk of bias. A study for pediatric randomized controlled trials found that incomplete adherence to trial registration had a higher risk of bias sequence generation and allocation concealment when compared to prospectively registered trials.[10] Additionally, Lindsley et al. found an association with increased reporting bias, detection bias, performance bias, allocation concealment, and random sequence generation with unregistered clinical trials.[11] Despite this association, there is evidence that bias continues to be a central issue in medical research. An extensive review by McGauran et. al. identified multiple types of reporting bias in clinical trials across 50 different interventions (pharmacologic, diagnostic, surgical, and preventative interventions).[13] Jones et al. found many trials have discrepancies in the primary outcomes between registration and publication, with some as great as 50%.[12] Prospective registration of clinical trials is a fundamental step in ensuring transparency and reproducibility of studies, yet it is often overlooked. In an effort to address these issues, the International Committee of Medical Journal Editors

(ICMJE), an organization dedicated to improving medical research practices, mandates that any clinical trial to be published in their network of journals must be registered prior to the commencement of the study.[14]

Academic journals can play a central role in the advocacy of RGs and prospective clinical trial registration by requiring or recommending the use of these tools within their "instructions to authors" webpages. However, to our knowledge, the rate of recommendation/requirement of RGs and clinical trial registration by family medicine journals has not been thoroughly studied in the current literature. Family medicine, encompassing a wide range of healthcare services, significantly influences patient outcomes. Research quality and transparency in this field are not merely academic concerns but have direct implications for patient care.[15] Thus, the goal for the present study is to evaluate the rate at which family medicine journals advocate for the use of RGs and clinical trial registration.

Methods

Study Design

Using the STROBE checklist, we conducted a cross-sectional analysis of family medicine journals' policies and guidelines for authors.[16] Additionally, our protocol, raw data, analysis scripts, extraction forms, and standardized email prompts were uploaded to Open Science Framework (OSF) in order to promote transparency and reproducibility.[17]

Search Strategy

With the aid of a medical research librarian, all clinical journals within the subcategory of "family practice" were identified using the 2021 Scopus CiteScore tool as our exclusive database for journal selection.[2] Scopus was chosen for its comprehensive coverage and relevance to family practice medicine, ensuring consistency and uniformity in our dataset. This decision aligns with the specific scope of our research, focusing on a well-defined subcategory where Scopus provides the most relevant and comprehensive information. To validate the accuracy of the identified top-twenty journals by Scopus, we cross-referenced them using the h5-index provided by Google Scholar Metrics, which is a tool with extensive coverage of scholarly journals and the ability to capture a broader range of citation metrics.[18] This provides an additional layer of verification to enhance the robustness of our journal selection process. During the review process on Scopus, we followed standard practices for literature review and journal identification. It is important to note that Scopus itself does not provide specific guidelines for conducting reviews within its interface. We would like to emphasize that, in line with our goal of inclusivity, we did not apply any additional limiters during the search process. This approach was adopted to provide a comprehensive representation of currently active clinical journals in family practice medicine, and it ensures transparency in our methodology.

Eligibility

All currently active journals that publish clinical research regarding family practice medicine were eligible for inclusion in our study. If a journal was written in a language other than English, we used Google Translate to translate the language into English.[19,20]

Exclusion Criteria

Discontinued journals were excluded as to prevent the unfair assessment of inactive journals. Journals that lacked clear contact information for communication with the editorial office were also excluded. This decision was made to avoid evaluating journals without the opportunity to seek input on the journal's publication policies from the editorial team. Finally, academic books were excluded from our sample.

Data Collection Process

For each journal, two investigators (WC, BD) extracted data from the "Instructions to Authors" webpage in a masked, duplicate fashion and recorded this data in a standardized Google Form designed *a priori* by investigators CAS, DN, and MV. Upon completion of extraction, the two investigators (WC, BD) were unmasked to reconcile one another's data and resolve any discrepancies. If a discrepancy was unable to be resolved, a third investigator (PC) was consulted.

Data Items

Extracted data items from each journal included the journal editor response rate, journal title, five-year impact factor, whether EQUATOR Network was mentioned, ICMJE acknowledgements in "Instructions to Authors", and continent of journal publication. ICMJE acknowledgments refers to a statement by the journal in which they endorse the criteria for ethical and transparent reporting of research set forth by the ICMJE. We extracted statements for each journal's "Instructions to Authors" in regard to RGs. A description of the RGs of interest can be found in Table 1.

Additionally, we extracted statements from each journal about clinical trial registration at databases including Clinicaltrials.gov, World Health Organization (WHO) International Clinical Trial Registry Platform, the International Prospective Register of Systematic Reviews (PROSPERO), or any other trial registry.

We categorized each given guideline or study registry policy as required/compulsory, recommended, or not required/not mentioned. Guidelines and study registries with phrases such as "required," "must," "need," "mandatory," and "studies will not be considered for publication unless…" were interpreted as "required." Phrases such as "recommended," "encouraged," "should," and "preferred" were interpreted as "recommended." If language was unclear, categorization was decided in consensus between study investigators. If a journal directly referred readers to the EQUATOR network for guideline adherence instead of listing guidelines individually, we assumed that relevant guidelines for each included article type were considered.

To prevent the unfair assessment of journals for article types they may not accept, the editorial team of each journal was contacted via email about accepted article types. For each journal, the correspondent was emailed once a week for three weeks using a standardized email prompt designed by CAS. If no response was received after three weeks, no judgements were drawn in regard to the accepted article types and the journal was scrutinized against all data items assessed.

Investigator Training
Prior to extraction initiation, authors (WC, BD) underwent training to ensure consistent interpretation of scope, rationale, and implementation of methods led by CAS, DN, and MV. After training, authors (WC, BD) underwent a practice exercise that involved data extraction from five journals not in our sample set in a masked, duplicate manner. When the data extraction was complete, the authors (WC, BD) were unmasked and discussed any discrepancies. Once this training was finished, authors (WC, BD) commenced data extraction from the full study sample.

Outcomes
Our primary outcome for this study was to measure the proportion of family practice journals' "Instructions to Authors" that recommend/require the use of reporting guidelines relevant to common biomedical study designs. Our secondary outcome was to record the proportion of journals that recommend/require clinical trial registration.

Data Synthesis
Data summarization was carried out via R (version 4.2.1) and RStudio. The following information was synthesized: (1) frequencies and percentages of guidelines referenced in the study sample and (2) the frequencies and percentages of journals referencing clinical trial registration. Because this research is an assessment of simple frequencies at the level of academic journals rather than individual studies, an analysis for bias was not required during the production of this manuscript.

Results
Journal Characteristics
This cross-sectional analysis identified 45 family medicine journals per Scopus CiteScore. The journal, *Asia Pacific Family Medicine*, was excluded from the study due to the discontinuation of the journal. In addition, *Family Practice Management was* excluded after an email response from an editor indicated the journal does not focus on family medicine research. In total, 43 journals were included for data extraction. The final dataset of included journals can be found in Supplementary Table 1.

Five-year impact factors for included journals ranged from 0.42 - 6.92 (mean = 3.20, standard deviation [SD] = 1.83). There were 27 journals with no listed five-year impact factor at the time of analysis. In terms of geographical distribution of editorial offices, 19 were in Europe (19/43, 44%), 12 were in Asia (12/43, 27%), 6 were in North America (6/43, 14%), 6 were classified as "Other" (6/43, 14%). Email inquiries were given three weeks for responses; at the conclusion of three weeks, only nine of 43 (9/43, 21%) journals responded. Study designs not accepted by individual journals are described in Supplementary Table 1 and were excluded from analysis.

Reporting Guidelines
In our analyzed sample, three journals (of 43, 7%) did not make any mention of reporting guidelines (RGs). Among the journals, 23 (of 43, 51%) made references to the EQUATOR network, and 30 journals (of 43, 70%) included an ICMJE statement. The most frequently cited reporting guidelines were CONSORT (81% of journals), followed by PRISMA (74%) and STROBE (62%). The least referenced

reporting guideline was QUOROM (5% of journals). Other guidelines like CHEERS, PRISMA-P, and TRIPOD were each referenced by three journals (7%), while MOOSE received a single mention (9%). For a comprehensive breakdown of individual journal policies concerning reporting guidelines, please refer to Supplementary Table 1.

Clinical Trial Registration

In terms of clinical trial registration, 14 journals failed to mention clinical trial registration policy (14/43, 33%). Twenty-four journals required registration (24/43, 56%), 4 journals recommended registration (4/43, 9%), and one journal did not accept clinical trials (1/43, 2%). The journals requiring clinical trial registration can be found in Table 2.

Discussion

Summary

Our examination revealed that the majority of family medicine journals do not explicitly refer to the utilization of reporting guidelines (RGs), except for CONSORT, PRISMA, and STROBE. Slightly more than half of the journals have requirements for clinical trial registration, while approximately one third of them do not make any mention of it. It is unsurprising that QUOROM had the lowest likelihood of being required or recommended, given its replacement by PRISMA in 2005, as documented in prior literature.[21,22] Notably, the EQUATOR network was cited by over fifty percent of the journals included in our study. Additionally, we observed that one third of the journals lack an ICMJE statement. These findings collectively suggest that, while a substantial number of journals incorporate ICMJE statements and reference the EQUATOR network, a significant proportion fail to acknowledge or advocate for the majority of existing RGs. This could impact the comprehensiveness of reporting, though not necessarily the quality or bias of research outcomes.

Comparison with Existing Literature

Previous studies highlight the benefits of RG adherence. A study performed by Moher et. al analyzed the benefits of adherence to CONSORT guidelines across four journals over the span of four years (1994-1998).[21] In this study, three of the journals that adopted CONSORT guidelines (*BMJ*, JAMA, and *The Lancet*) were compared to one journal that did not (*The New England Journal of Medicine*). It was found that the three journals that endorsed the CONSORT guidelines had a statistically significant improvement in the quality score reports for randomized controlled trials over the journal that did not adopt CONSORT guidelines.[6] This study demonstrates that the adherence to CONSORT guidelines may improve the quality of research reporting. Of the forty-three journals we sampled, only six required that authors adhere to CONSORT.[23] Meerpohl et al. found that only one-fifth of pediatric journals mentioned CONSORT, with only three requiring adherence.[23] Thus, while family practice journals mention CONSORT at a higher rate than pediatric journals, there is still room for improvement. Similar findings regarding journal endorsement have been observed with PRISMA for systematic reviews. Nawijn et al.[24] assessed the reporting quality of systematic reviews (SRs) and meta-analyses (MAs) in emergency medicine using the PRISMA statement. The top five emergency medicine journals were scrutinized for SRs and MAs published between 2015 and 2016. While reviews indicating PRISMA adherence did not consistently show better reporting than non-adherent reviews, journals that mandated reporting guideline adherence

exhibited higher reporting quality. This finding suggests that active enforcement of reporting guidelines, such as requiring PRISMA endorsement, can enhance the overall reporting standards in research.

Clinical trial registration is federal law in the United States, however many studies still fail to prospectively register their trials, resulting in bias.[25] A study comparing the registered and published primary outcomes in randomized controlled trials found that less than half of the trials adequately registered their trial with clear primary outcomes.[26] Lack of proper registration can lead to selective outcome reporting, which is where changes to the outcomes reported favor statistically significant results rather than statistically non-significant results.[26] Similarly, a study by Killeen et al. analyzing surgery randomized controlled trials found that discrepancies in published primary outcomes and registered primary outcomes arose when studies failed to prospectively register their trials.[27] Requiring clinical trial registration is essential to prevent publication bias and selective outcome reporting bias as well as maximize transparency of clinical trials.[11] Our study shows that approximately half of the journals surveyed enforce clinical trials to be registered. All family medicine journals should require prospective registering of clinical trials, as unregistered trials have been shown more likely to display favorable or biased results.[11] Among other barriers, clinical trial registration may be a reason that some authors submit their studies to journals with less strict requirements. However, clinical trial registration should be strictly enforced to ensure accountability and study reproducibility within the field of family medicine.

Implications for Research and/or Practice

The study's findings have notable implications for future research and clinical practice in the field of family medicine. The observed limited incorporation of reporting guidelines (RGs), with explicit mentions primarily centered around CONSORT, PRISMA, and STROBE, suggests a potential area for improvement in family medicine journals' reporting standards. While it's important to note that adherence to RGs does not necessarily equate to assured research quality, promoting their wider adoption could positively influence the comprehensiveness of reporting. This cautious interpretation aligns with the understanding that RGs serve as guides for comprehensive reporting rather than direct indicators of research quality or bias reduction. Additionally, the identified lack of emphasis on clinical trial registration in a substantial portion of the surveyed journals indicates a gap in ensuring transparency and minimizing bias in clinical trial reporting. Encouraging family medicine journals to consider and, where appropriate, enforce prospective clinical trial registration remains crucial for preventing publication bias and enhancing study reproducibility. The study's recommendations for promoting awareness of RGs and clinical trial registration emphasize a nuanced perspective, acknowledging their role in comprehensive reporting without presuming a direct link to research quality.

Strengths and Limitations

This study has many strengths. For example, this study was conducted based upon a protocol designed *a priori*. Secondly, the data extraction process was conducted in a masked, duplicate manner, which is considered the “gold standard” technique for studies involving the extraction of data from publications. Finally, all materials relevant to the conduction of this study have been uploaded on the public platform OSF for the purposes of transparency and reproducibility.[17] This study is not without limitations, however. Despite our efforts to communicate with journal editorial teams, we had poor correspondence. This may have limited the accuracy of our interpretations of journal webpages and policies for publication. Furthermore, the cross-sectional nature of our study limits the generalizability of our findings

to this specific point in time as journal policies, editorial practices, and federal laws are often subject to change.

Conclusion

This cross-sectional analysis of "Instructions to Authors" of family medicine journals found that many journals lack guidance for RG adherence by prospective authors. Approximately one-third of these journals do not mention clinical trial registration. To enhance research reporting and reduce bias in family medicine, journals should be encouraged to enforce appropriate RGs and prospective clinical trial registration, though it is important to note that RG adherence enhances reporting transparency and should not be equated with research quality or bias reduction.

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Table 1. Reporting Guidelines and Study Designs

Study Design	Respective Reporting Guideline
Animal Research	ARRIVE
Case Reports	CARE
Clincal Trials	CONSORT
Clinical Trial Protocols	SPIRIT
Diagnostic Accuracy	STARD
	TRIPOD
Economic Evaluations	CHEERS
Observational Studies in Epidemiology	MOOSE
	STROBE
Qualitative Research	COREQ
	SRQR
Quality Improvement	SQUIRE
Systematic Reviews and Meta-Analyses	PRISMA
	QUOROM
Systematic Review and Meta-Analysis Protocols	PRISMA-P

Abbreviations: ARRIVE, Animal Research: Reporting of In Vivo Experiments; CARE, Case Reports guidelines checklist; CHEERS, Consolidated Health Economic Evaluation Reporting Standards; CONSORT, Consolidated Standards of Reporting Trials; COREQ, Consolidated Criteria for Reporting Qualitative Research; MOOSE, Meta-Analysis of Observational Studies in Epidemiology; PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses; PRISMA-P, Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols; QUOROM, Quality of Reporting of Meta-analyses; SPIRIT, Standard Protocol Items: Recommendations for Interventional Trials; SQUIRE, Standards for Quality Improvement Reporting Excellence; SRQR, Standards for Reporting Qualitative Research; STARD, Standards for Reporting Diagnostic Accuracy Studies; STROBE, Strengthening the Reporting of Observational Studies in

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Table 2. List of Journals Requiring Prospective Trial Registration
African Journal of Primary Health Care and Family Medicine
Anatolian Journal of Family Medicine
Annals of Family Medicine
Attencion Primaria
Attencion Primaria Practica
Australian Journal of General Practice
BMC Primary Care
Canadian Family Physician
Computer Assisted Surgery
Eurasian Journal of Family Medicine
European Journal of General Practice
Family Medicine
Family Medicine and Community Health
International Journal of Community Based Nursing and MIdwifery
Journal of Family and Community Nursing
Journal of Family Nursing
Malaysian Family Physician
Osteopathic Family Physician
Pediatria i Medycyna Rodzinna
Practitioner
Revista Cuidarte
Semergen
Terapevticheskii Arkhiv
The Lancet Healthy Longevity