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Reporting guidelines of health research studies are frequently used inappropriately

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ABSTRACT

Objectives: Appropriate use of reporting guidelines of health research ensures that articles present readers with a consistent representation of study relevance, methodology and results. This study evaluated the use of major reporting guidelines.

Study Design and Setting: A cross-sectional analysis of health research articles citing four major reporting guidelines indexed in the Web of Science Core Collection (up to June 24, 2018). Two independent reviews were performed in a random sample of 200 articles, including clinical trials (N=50), economic evaluations (N=50), systematic reviews (N=50) and animal research studies (N=50). The use of reporting guidelines to guide the reporting of research studies was considered appropriate. Inappropriate uses included the use of reporting guidelines as a tool to assess the methodological quality of studies or as a guideline on how to design and conduct studies.

Results: Across all selected reporting guidelines, appropriate use of reporting guidelines was observed in only 39% (95% CI 32-46%; 78/200) of articles. In contrast, inappropriate use was observed in 41% (95% CI 34-48%; 82/200) and unclear/other use was observed in 20% (95% CI 15-26%; 40/200).

Conclusions and Relevance: Reporting guidelines of health research studies are frequently used inappropriately. Authors may require further education around appropriate use of reporting guidelines in research reporting.

Running Title: Appropriateness of Use of Major Reporting Guidelines in Health Research

Keywords: reporting guideline; systematic reviews; economic evaluations; clinical trials; animal studies; research reporting

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1.1 INTRODUCTION

Reporting guidelines help to ensure that the study design, including research objectives, methodology and results, is accurately and transparently reported by authors.1-5 The vast majority of reporting guidelines do not include recommendations for designing, conducting or analyzing studies and thus do not directly improve the design or conduct of a study or the quality of research conduct.6 However, adherence to reporting guidelines, including explicit descriptions and transparency in any deficiencies in study design, can minimize bias, improve reproducibility, and facilitate the clear, transparent and complete reporting of research findings.7 As such, better research design, conduct and quality may be a byproduct of proper reporting.6 8 Well-known reporting guidelines include those implemented in the reporting of randomized controlled trials (CONSORT - Consolidated Standards of Reporting Trials)9, observational studies (STROBE - Strengthening the Reporting of Observational Studies)10, systematic reviews and meta-analyses (PRISMA - Preferred Reporting Items for Systematic Reviews and Meta-Analyses)11, *in vivo* animal research (ARRIVE - Animal Research: Reporting of In Vivo Experiments)12 and economic evaluations (CHEERS - Consolidated Health Economic Evaluation Reporting Standards)13.

Unfortunately, use of reporting guidelines varies considerably. In some cases, authors have employed reporting guidelines in lieu of more appropriate assessment tools of methodological quality and for the purpose of quality assessment.14 15 Indeed, a 2010 bibliographic study of observational studies citing the Strengthening the Reporting of Observational Studies (STROBE) statement found that 9% of the papers inappropriately employed STROBE reporting guidelines to dictate study design and conduct.14 The extent of appropriate or inappropriate use of reporting guidelines for other major study designs , including systematic reviews and meta-analyses, economic evaluations, randomized clinical trials and preclinical studies in animal research, has yet to be determined.16 In this report, we reviewed health research publications that have cited the reporting guidelines for major study designs (that is, CONSORT, PRISMA, CHEERS and ARRIVE) to evaluate the appropriate use of reporting guidelines.

1.2 METHODS

Search and data collection

The protocol for this study was registered on Open Science Framework (https://osf.io/v46s2/). We engaged an experienced librarian to assist in developing the search strategy for the study. The digital object identifiers (DOIs) for each major reporting guideline, including the relevant DOIs for duplicate publications and explanation and elaboration articles discussing the eligible reporting guidelines, were identified and searched in the Web of Science (Clarivate Analytics, Philadelphia, PA, United States) Core Collection for all years (from inception to 2018). The Web of Science Core Collections includes Science Citation Index Expanded, Social Sciences Citation Index, Arts & Humanities Citation Index, Emerging Sources Citation Index, Conference Proceedings Citation Index – Science, and Conference Proceedings Citation Index - Social Sciences & Humanities. Only reporting guidelines published in English were searched in the

databases. All research studies, editorials and reviews citing the reporting guidelines were extracted (N=46, 326) from publication of the eligible reporting guideline to our last search date (June 24, 2018). A detailed assessment of the use of the major reporting guidelines in a random sample of 200 citing articles was performed. Randomization was performed using a computerized random sequence generator (https://www.random.org/sequences/). The study sample was equally stratified amongst the major reporting guidelines to include systematic reviews and meta-analyses citing PRISMA (n=50), randomized clinical trials (RCTs) citing CONSORT (n=50), economic evaluations citing CHEERS (n=50), and studies of animal research citing ARRIVE (n=50). A sample size of 50 randomly selected research articles that cited each of the four reporting guidelines was specified a priori in the protocol based on the bibliographic study by Da Costa et al (2010)14 that was able to sufficiently gain an understanding of the use of the STROBE statement in observational studies with a sample size of 32 studies. The title and abstract of the 200 randomly selected citing articles were independently screened by two of four authors (MK, JF, JW, LC) for eligibility for the study. Citing articles that did not report empirical research (e.g., study protocols, editorials, conference proceedings, letters and new items) were excluded. As well, the study design for the citing article had to match the reporting guideline for its use to be effectively assessed. For example, an article citing PRISMA had to be systematic review and/or meta-analysis in order to be included in the analysis. Any disagreements about inclusion of a citing article were resolved by discussion amongst the authors until an agreement was reached. This led to the exclusion of 6 articles and an additional randomization of 5 RCTs, and 1 economic evaluation study.

1.2.1 *Evaluation of reasons for citation*

After eligibility of the citing article was confirmed, the random sample of 200 citing articles of the major reporting guidelines, underwent an independent 2-stage review of the full-text to evaluate the use of the reporting guideline. In the first full-text review, the articles were evaluated using a standardized data extraction form by one of three authors (MK, JF or JW). A second, independent review using the same data extraction form was then performed on all articles extracted by one of two authors (LC or FCL). The level of agreement evaluating the citing studies between the first stage review and second stage review was assessed. Discordance between the categorizations in the two reviews was discussed amongst the study authors until an agreement was reached.

The randomly selected articles which cited the prespecified reporting guidelines (that is, CONSORT, PRISMA, CHEERS, ARRIVE) were classified according to the reason for citation: “appropriate use”, “inappropriate use”, “other” or “ unclear”. The rationale for the classification of reporting guidelines use has been published elsewhere.14 Classification was based on direct interpretation from the text of stated use of reporting guidelines and, when available, supplementary materials stating use of reporting guideline checklists. Use as a guide to report details of the study design and results (that is, what was done and what was found) was categorized as “appropriate” use. The definition of appropriate use of these reporting guidelines and text examples is provided in Box 1. Criteria for classification as “inappropriate” use included: use as a methodological (that is, research design or conduct) guideline; use as a tool to appraise the quality of study

reporting; use as an assessment tool of methodological quality; or cited to stress the importance of reporting guidelines. The use of reporting guidelines both appropriately and inappropriately in the same article was classified as 'unclear', while the use of reporting guideline in any other way than what was defined above was classified as 'other'.

Crude prevalence estimates (or proportions) of appropriateness of use were presented along with 95% confidence intervals (95% CI). A post-hoc analysis was performed to evaluate the impact of time elapsed since publication of the reporting guidelines and appropriateness of use. The relationship between appropriateness of use and time between publication years of the citing article and each reporting guideline was examined (medians and interquartile range) and presented in a boxplot. We fitted multinomial logistic regression for the appropriateness of use of reporting guidelines to check how it was influenced by the time between the publication years of the citing article and the reporting guideline. The three-category outcome variable indicated whether the use of the reporting guideline was "appropriate", "inappropriate" or "unclear or other". The odds ratios of inappropriate versus appropriate use (or unclear/other versus appropriate use) of each reporting guideline were estimated for every one-year increase of time. All data analyses were conducted in RStudio Version 1.2.5019 (RStudio, Inc; Boston, MA).

1.3 RESULTS

The Web of Science search identified a total of 29 publications for the 4 major reporting guidelines: CONSORT (n = 9), PRISMA (n = 8), CHEERS (n = 8), and ARRIVE (n=4). Table 1 presents the journals in which each reporting guideline was published, the number of citations received, and the date of publication. Of articles registered in the Web of Science database, these reporting guidelines were cited by 46,326 publications. The PRISMA statement related articles were the most frequently cited (36,407 citations; 79%), followed by CONSORT statement (7,555 citations; 16%), ARRIVE statement (1,891 citations; 4%) and CHEERS statement (473 citations; 1%). Following final randomization of the 200 articles citing the selected reporting guidelines, the full text of each article was analyzed (Figure S1). Inter-rater agreement for independent reviewers was high (≥ 92%).

The 200 reviewed articles are presented in Table S1. Across all selected reporting guidelines, appropriate use of reporting guidelines was observed in only 39% (95% CI 32-46%; 78/200) of articles (Figure 1). In contrast, inappropriate use was observed in 41% (95% CI 34-48%; 82/200) and unclear/other use was observed in 20% (95% CI 15-26%; 40/200). The majority of clinical trials (n = 32; 64%; 95% CI 50-77%) appropriately used CONSORT as a reporting tool (Table 2), 7 (14%; 95% CI 6-26%) uses were inappropriate, and 11 (22%; 95% CI 12-36%) were classified as other or unclear. Of the health economic evaluations, 21 (42%; 95% CI 28-56%) made an appropriate use of CHEERS, 13 (26%; 95% CI 15-40%) used CHEERS inappropriately and 16 (32%; 95% CI 20-46%) were other or unclear. The majority of systematic reviews and meta-analyses (n = 36; 72%; 95% CI 58-84%) used PRISMA inappropriately, and only 11 (22%; 95% CI 12-36%) uses were appropriate. Similarly, we found that 26 (52%; 95% CI 38-66%) studies involving animals inappropriately cited the ARRIVE guidelines as a methodologic guideline.

There were no studies that used the reporting guidelines as a tool of reporting quality or a tool to emphasize the importance of reporting guidelines.

The descriptive boxplots of time between publication years of the citing article and each reporting guideline by appropriateness of use categories are displayed in Figure S2. The odds ratio of improper use of the reporting guidelines over time since publication of the reporting guideline was derived from a multinomial logistic regression in order to quantify this relationship (Table S2). Except for the CHEERS reporting guideline, there was no association between year from publication of the citing article since publication of the PRISMA, CONSORT or ARRIVE guidelines and the appropriateness of using the respective reporting guidelines. For every one-year increase since publication of the CHEERS reporting guideline, authors of citing article were associated with an increasing trend to use the reporting guideline in a way that was classified as "unclear or other" compared to "appropriate" use (odds ratio 2.25; 95% confidence interval: 1.89 to 2.62).

1.4 DISCUSSION

Reporting guidelines present detailed recommendations for clear and transparent reporting of what was done and what was found in studies. The PRISMA statement was the most highly cited reporting guideline in our study, particularly in comparison to the CHEERS and ARRIVE reporting guidelines. However, this finding may simply be indicative of a larger number of published systematic reviews and meta-analyses in comparison to studies of economic evaluations and animal research. Appropriate use of reporting guidelines is a consequence of clarity of instruction in the original guideline, measures taken to further promote appropriate use including outreach, editorial training, policy and consistency of editorial application, and possibly other factors that have yet to be investigated in this setting. We identified a discrepancy in the use of these reporting guidelines in a random sample of studies in this citation analysis. In the majority of clinical trials, authors were found to appropriately use the CONSORT recommendations. By contrast, we identified a high proportion of publications that inappropriately cited the PRISMA, CHEERS and ARRIVE as a methodologic guideline. This is especially concerning for the use of PRISMA in systematic reviews and meta-analyses given that the PRISMA statement was observed to be very highly cited in this study. The discrepancy between the appropriate use of CONSORT as compared to the remaining reporting guidelines may stem from the complementary resources available to support the use of CONSORT. The web-based intervention (WebCONSORT) incorporates the original CONSORT checklist and different CONSORT extensions into one comprehensive platform to guide authors in the completeness of RCT reporting for biomedical journals and the writing aid tool, Consort-based WEB tool, facilitates CONSORT users to understand and implement the reporting guidelines. 17,18

Other study designs (that is, economic evaluations, systematic reviews and meta analyses, and animal studies) are limited in supplementary tools which may explain their inappropriate use. Reporting guidelines provide stepwise recommendations and rationale for the reporting of research studies. The detailed checklists outlined in the reporting guidelines may be incorrectly construed by authors as a tool to guide the design and conduct of research studies, which is

consistent with our study findings. Use of the reporting guideline as a tool to guide research methodology was consistently the most common reason for inappropriate use of the reporting guidelines. Although researchers may consider reporting guidelines at the inception and execution phase of research, authors and journal editorial staff are encouraged to comply with the objective of the reporting guidelines and use them exclusively as a guide to the reporting of research.8 19 Further studies are required to determine the consequences of the inappropriate use of reporting recommendations in research studies, including the impact on clarity, transparency and reproducibility of studies.

Approximately 20% of authors of RCTs citing CONSORT, economic evaluations citing CHEERS, and animal research studies citing ARRIVE were found to use an unclear citation of their respective reporting guideline (that is, cited the reporting guideline appropriately and inappropriately within the same article). Furthermore, this report highlighted a concern regarding the use of the CHEERS reporting guidelines, 12% of author citations were classified as "other". Compared with clinical studies, which may be limited to reporting consequences of an intervention only, economic evaluations can be complex in reporting several moving parts that can vary widely by type of economic evaluation, including resource use, costs, preference related information, and cost effectiveness results.13 In order to evaluate other areas that could affect appropriateness of use, we investigated the relationship between appropriateness of use and time between the year of publication of citing article and the year of publication of reporting guideline in a post-hoc analysis. There was no significant association between citing author use of reporting guidelines and time elapsed between publication of the CONSORT, PRISMA and ARRIVE reporting guidelines and the citing article. We found there was a significant relationship between years since publication of the CHEERS reporting guidelines and use of the reporting guidelines in a way that was categorized as "unclear or other". This would suggest that further education is needed to ensure the effective dissemination and proper understanding of the CHEERS reporting guidelines, particularly as time elapses.20 As an exploratory analysis, the results must be interpreted with caution and should only be considered hypothesis-generating.

Reporting guidelines have previously been aberrantly employed for the purpose of research quality assessment.14 15 As reporting guidelines were not developed to explain how research should be conducted, they should not be used as a tool to appraise research quality. A 2007 cross-sectional analysis of 512 articles citing the CONSORT statement, reported that 6% of the paper citations inappropriately used CONSORT guidelines as an assessment of study quality.15 In the aforementioned STROBE study by Da Costa et al (2010), there were no observational studies that were found to use STROBE as a tool to assess methodological or reporting quality.14 However, 79% of systematic reviews and meta-analyses of observational studies citing the STROBE statement inappropriately used it as a tool to assess methodological or reporting quality. This finding highlighted the inappropriate use of the STROBE statement as a quality measure in this subpopulation, but more importantly, demonstrated the lack of consensus about the gold standard with which to evaluate the quality (external and internal validity) of observational studies.21 The findings from our study showed that only

one systematic reviews and meta-analyses sampled (2%) inappropriately cited the PRISMA reporting guidelines as a quality assessment tool.

This study is strengthened by the use of a search algorithm that ensured inclusion of a broad crosssection of systematic reviews, meta-analyses, RCTs, economic evaluations and animal research studies citing major reporting guidelines. Furthermore, each of the randomly selected articles was reviewed for citation use by at least two authors independently to reduce bias. Although this study has several strengths, there are a few limitations with the methodology of the study. One limitation of our findings is the fact that only articles which cited the reporting guidelines were included. This search strategy allowed for a specific sample of publications but may have introduced selection bias, by excluding researchers that used the reporting guidelines and mentioned it in their manuscript without a formal citation. It is also difficult to determine how lack of institutional access to certain articles, particularly articles citing the CONSORT statement, may have influenced the study outcomes. However, it is unlikely that the sample studied (that is, the sample of citing articles accessible at our institution) would not be a truly representative sample of RCTs citing CONSORT in comparison to the other study designs examined. Although the previous study of the appropriateness of use of the STROBE guidelines14 was used to guide our study methodology, the differences in the analysis performed in this study, including the number of articles analyzed, the use of two independent review stages and the classification of "unclear" and "other" use of reporting guidelines, limit the direct comparison of these results to the STROBE appropriateness of use analysis. Finally, in this analysis, citation and statement of appropriate use of a reporting guideline in the manuscripts was a surrogate for actual use. It was therefore assumed that manuscripts stating that a reporting guideline was used for "reporting" adhered to the specified reporting items. Although comparable presumptions have been made in previous studies of citation use, this may have influenced our results.

1.5 CONCLUSION

Appropriate use of reporting guidelines helps to ensure that articles present all the necessary information that readers need to assess a study's relevance, methodology, validity and generalizability.7 Conversely, inappropriate use of reporting guidelines is concerning and may reduce replicability and increase ambiguity in research findings. In identifying evidence of inappropriate use of reporting guidelines, this report highlights the need for collaboration between key stakeholders (journals, academic institutions, funders) and authors to improve the use of reporting guidelines in effective reporting of scientific research.

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CONTRIBUTORS AND SOURCES:
LC, FCL, JW, MK, JF and DM contributed to the study design, data collection, extraction, analysis, and manuscript preparation. WC and DH contributed to data

collection, extraction, analysis and manuscript preparation. DA contributed to the study design, data collection, extraction and manuscript preparation.

BOX LEGENDS

Box 1. Examples of appropriate and inappropriate use of reporting guidelines

FIGURE LEGENDS

Figure 1. Examples of appropriate and inappropriate use of articles citing the analyzed reporting

TABLE LEGENDS

Table 1. Overview of major reporting guidelines and citations received

Table 2. Characteristics of articles citing major reporting guidelines

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Reporting Guidelines	Publication (Journal)	Publication Date	Citation Age (Years)	Total Citations
CONSORT				
	Journal of Clinical Epidemiology	August 2010	7.82	499
	Annals of Internal Medicine	June 2010	7.99	1255
	Obstetrics and Gynecology	May 2010	8.07	110
	BMC Medicine	March 2010	8.18	893
	Trials	March 2010	8.18	292
	BMJ-British Medical Journal	March 2010	8.18	1886
	Plos Medicine	March 2010	8.18	751
	Journal of Clinical Epidemiology (E&E)	March 2012	6.24	13
	BMJ-British Medical Journal (E&E)	March 2010	8.47	1856
Total				7555
ARRIVE				
	Osteoarthritis and Cartilage	April 2012	6.15	113
	Veterinary Clinical Pathology	March 2012	6.23	34
	Journal of Pharmacology & Pharmacotherapeutics	July 2010	7.91	200
	Plos Biology	June 2010	7.91	1544
Total				1891
CHEERS				
	European Journal of Health Economics	June 2013	4.99	31
	BJOG-An International Journal of Obstetrics and Gynaecology	May 2013	5.07	13
	Clinical Therapeutics	April 2013	5.15	4
	International Journal of Technology Assessment in Health Care	April 2013	5.15	57
	BMC Medicine	March 2013	5.17	84
	BMJ-British Medical Journal	March 2013	5.17	156
	Value in Health	March 2013	5.20	80
	Pharmacoeconomics	May 2013	5.07	48
Total				473

PRISMA				
	International Journal of Surgery	May 2010	8.08	1573
	Journal of Clinical Epidemiology	October 2009	8.73	2964
	Annals of Internal Medicine	August 2009	8.85	8425
	BMJ-British Medical Journal	July 2009	8.93	5239
	Plos Medicine	July 2009	8.93	8135
	Annals of Internal Medicine (E&E)	August 2009	8.86	1952
	BMJ-British Medical Journal (E&E)	July 2009	8.93	5117
	Plos Medicine (E&E)	July 2009	8.93	3002
Total				36407

Table 1. Overview of major reporting guidelines and citations received

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Classification	Reason for citation	Systematic Reviews and Meta-Analyses Citing PRISMA (*n* = 50)	Randomized Clinical Trials Citing CONSORT (*n* = 50)	Economic Evaluations Citing CHEERS (*n* = 50)	Animal Research Citing ARRIVE (*n* = 50)
Appropriate	Guideline for reporting of study	11 (22%)	32 (64%)	21 (42%)	14 (28%)
Inappropriate Use	Use as a methodological (ie, research design or conduct) guideline	35 (70%)	7 (14%)	13 (26%)	26 (52%)
	Use as an assessment tool of reporting quality	0	0	0	0
	Use as an assessment tool of methodological quality	1 (2%)	0	0	0
	Cited to stress the importance of reporting guidelines	0	0	0	0
Unclear or Other	Unclear	3 (6%)	11 (22%)	10 (20%)	9 (18%)
	Other	0	0	6 (12%)	1 (2%)
Inter-Rater Agreement		48 (96%)	46 (92%)	46 (92%)	46 (92%)

Table 2. Characteristics of articles citing major reporting guidelines

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Figure 1. examples of appropriate and inappropriate use of reporting guidelines

Appropriate

- "The study is reported according to the CONSORT 2010 statement."
- "The economic evaluation was analyzed in Microsoft Excel 2010 and was reported according to the Consolidated Health Economic Evaluation Reporting Standards."

Inappropriate

- "Experiments were conducted in accordance with current guidelines for the care of laboratory animals, ethical guidelines for the investigation of experimental pain in conscious animals and the ARRIVE Guidelines Checklist."
- "We designed our study as per the CONSORT guidelines for reporting clinical trials and STARD guidelines for reporting studies of diagnostic tests."

Unclear or Other

- "This study also has several strengths. The study was performed and reported in accordance with applicable guidelines."
- "The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement has been followed."
- "Healthcare payers must make decisions on how best to allocate these scarce resources, and economic evaluation of new and existing healthcare interventions is playing an increasingly important role in informing these decisions."

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Reporting Guideline	Definition of Appropriate Use
CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials[2]	To provide guidance for reporting all randomized, controlled trials
Consolidated Health Economic Evaluation Reporting Standards (CHEERS) Statement[5]	To provide guidance on reporting of health economic evaluations
Improving bioscience research reporting: the ARRIVE guidelines for reporting animal research[4]	To provide guidance for reporting animal research
Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement[3]	To provide guidance on the reporting of systematic reviews, meta-analyses and evaluations of interventions

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