An Evaluation of Reporting Guidelines and Clinical Trial Registry Requirements Among Addiction Medicine Journals

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Context: Robust methodology and ethical reporting are paramount for quality scientific research, but recently, that quality in addiction research has been questioned. Avenues to improve such research quality include adherence to reporting guidelines and proper usage of clinical trial registries. Reporting guidelines and clinical trial registries have been shown to lead researchers to more ethical and transparent methodology.

Objectives: To investigate the reporting guideline and clinical trial registration policies of addiction research journals and identify areas of improvement.

Methods: We used Google Scholar Metrics’ h-5 index to identify the top 20 addiction research journals. We then examined the instructions for authors from each journal to identify whether they required, recommended, or made no mention of trial registration and reporting guidelines, including the Consolidated Standards of Reporting Trials (CONSORT), Meta-Analysis of Observational Studies in Epidemiology (MOOSE), Quality of Reporting of Meta-analyses (QUOROM), Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA), Standards for Reporting Diagnostic Accuracy Studies (STARD), Strengthening the Reporting of Observational Studies in Epidemiology (STROBE), Animal Research: Reporting of In Vivo Experiments (ARRIVE), Case Reports (CARE), Consolidated Health Economic Evaluation Reporting Standards (CHEERS), Standards for Reporting Qualitative Research (SRQR), Standards for Quality Improvement Reporting Excellence (SQUIRE), Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT), Consolidated Criteria for Reporting Qualitative Research (COREQ), Transparent Reporting of a Multivariate Prediction Model for Individual Prognosis or Diagnosis (TRIPOD), Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P), and the International Committee of Medical Journal Editors (ICMJE) guidelines. We performed the same analysis regarding requirements for clinical trial registration.

Results: Of the 20 journals included in this study, 10 journals (50%) did not require adherence to any reporting guidelines. Trial registration followed a similar trend; 15 journals (75%) did not mention any form of trial or systematic review registration, and ClinicalTrials.gov was only recommended by only 1 journal (5%).

Conclusions: Among top addiction medicine journals, required adherence to reporting guidelines and clinical trial registry policies remains substandard. A step toward fulfilling the National Institute on Drug Abuses’ call for improvement in transparency and reproducibility within addiction research should include all journals adopting a strict reporting guideline and clinical trial registry adherence policy.


Keywords: addiction, CONSORT, clinical trial registry, ICMJE, policy, PRISMA, reporting guidelines, research quality
The quality of addiction research has been questioned in a report released by The National Center on Addiction and Substance Abuse at Columbia University. As of 2008, more than 70% of trials included in Cochrane systematic reviews of interventions for addiction did not report the method of allocation concealment—a technique to prevent selection bias in trials, in which the person randomizing the patient does not know what the next treatment allocation will be—and failed to protect against selection bias. Vassar et al also found inadequate intervention reporting among randomized control trials (RCTs) investigating alcohol use disorder and evidence of selective outcome reporting bias among those examining addiction. Likely as a result of reports such as those, the National Institute on Drug Abuse issued a statement in 2013 calling for improvement in reproducibility and transparency in research. The importance of sound, quality evidence in addiction research cannot be overstated. In 2016, more than 42,000 people died in the United States due to opioid overdoses. Without continual development of effective interventions, patients will continue to suffer.

One promising method to address poor research quality is the use of reporting guidelines, which are checklists or flow diagrams that aim to improve transparency in research and eliminate elements in study design that lead to bias. A prominent reporting guideline in medical research is the Consolidated Standards of Reporting Trials (CONSORT) statement, which contains a 25-item checklist to help improve study design and reporting. CONSORT may enhance the ability of peer reviewers and readers to assess the quality of clinical trials by, for example, requiring authors to elaborate on the allocation concealment mechanism.

Many journals across various medical subspecialties require adherence to reporting guidelines, but universal adoption has not yet been achieved. The literature suggests that if journals universally adopted reporting guidelines, the quality, transparency, and reproducibility of the published literature would strengthen. However, many addiction journals do not currently suggest or require reporting guidelines for submission. For example, Vassar et al reported that only 4 addiction journals have identified as “endorsers” of the CONSORT guidelines. This lack of adherence to reporting guidelines by journals may be undermining the quality of research outcomes in addiction medicine and affecting patient care.

Similar to journals requiring adherence to reporting guidelines, the use of clinical trial registration is integral to achieving quality research outcomes. Registration of RCTs promotes transparency and accountability by recording study endpoints and encouraging comparison between what is registered and what is published. Clinical trial registries have proven so effective at preventing bias that many countries have passed legislation requiring researchers to prospectively register their studies. For example, in 2007, the United States established the Food and Drug Administration Amendments Act (FDAAA), which required all clinical trials to be registered with ClinicalTrials.gov before patient enrollment. Despite this requirement, previous studies have shown that 30% to 50% of clinical trial results remain unpublished for years after completion and many fail to meet even the most basic legal requirements set forth in the FDAAA. This negligence in meeting the FDAAA requirements, which have been in place for a decade, raises serious ethical concerns.

In this study, we investigated the reporting guideline and clinical trial registration policies of addiction research journals to identify areas for improvement in reporting standards.

**Methods**

To review the instructions for authors from addiction journals as they pertained to clinical trial registration and reporting guideline policies, we based our methods on similar previously published studies. This study did not meet the regulatory definition of human subject research as defined in 45 CFR 46.102
(d) and (f) of the Department of Health and Human Services’ Code of Federal Regulations28 and therefore was not subject to Institutional Review Board oversight.

We used Google Scholar Metrics’ h-5 index to identify the top 20 addiction research journals (Google, Inc.). We then examined the instructions for authors from each journal to identify whether they required, recommended, or made no mention of trial registration and reporting guidelines. A web-based search was performed on September 27, 2017 by 1 author (C.C.), who identified each journal’s instructions for authors and other relevant sections regarding manuscript submission. Each journal’s policy statement for the following guidelines were extracted: Consolidated Standards of Reporting Trials (CONSORT), Meta-Analysis of Observational Studies in Epidemiology (MOOSE), Quality of Reporting of Meta-analyses (QUOROM), Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA), Standards for Reporting Diagnostic Accuracy Studies (STARD), Strengthening the Reporting of Observational Studies in Epidemiology (STROBE), Animal Research: Reporting of In Vivo Experiments (ARRIVE), Case Reports guidelines checklist (CARE), Consolidated Health Economic Evaluation Reporting Standards (CHEERS), Standards for Reporting Qualitative Research (SRQR), Standards for Quality Improvement Reporting Excellence (SQUIRE), Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT), ConsolidatedCriteria for Reporting Qualitative Research (COREQ), Transparent Reporting of a Multivariate Prediction Model for Individual Prognosis or Diagnosis (TRIPOD), Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P), and the International Committee of Medical Journal Editors (ICMJE) guidelines. Any other policies mentioning clinical trial registration and systematic review registration requirements as well as recommended trial and review registries were also noted when appropriate.

Three authors (C.C., H.G., L.B.) reviewed the journal policy statements and determined whether a journal required, recommended, or did not mention each reporting guideline and trial registration. Terms such as “must” or “required” led the reviewers to grade the policy as “required,” while terms such as “should” or “suggest” led the reviewers to grade the policy as “recommended.” These terms were agreed upon before review, and the reviewers were blinded to the others’ decisions. If the reviewers disagreed, a 4th reviewer (J.C.) was available for adjudication. This information was entered into a custom Google spreadsheet (Google, Inc). If a journal did not publish a particular type of study relevant to a specific reporting guideline, we excluded that reporting guideline for that journal when calculating percent of adherence. For example, if a journal did not publish clinical trials, then the CONSORT statement was not relevant to that journal and was excluded. The above methods were previously described by Sims et al11 2016 in an analysis of reporting guidelines and trial registration adherence in emergency medicine journals.

Results

Of the top 20 addiction research journals as listed in Google Scholar according to their h-5 index, 12 journals (60%) had editorial offices based in North America, followed by 4 journals (25%) in the United Kingdom. The location of 2 editorial offices could not be determined (Table 1).

Reporting Guidelines

Journal adherence requirements to reporting guidelines is shown in Table 2. Of the 20 journals included in this study, 50% (10) did not require adherence to any reporting guidelines. The ICMJE and CONSORT guidelines had the highest rate of adherence, with both being mentioned by 25% (5) of journals. Of 4 journals that mentioned the CONSORT statement, only 2 required it (10% of total sample). CARE, CHEERS, SQUIRE, SRQR, SPIRIT, COREQ, TRIPOD, and PRISMA-P were not mentioned by any journals. The instructions for authors section of 10% (2) of the journals
<table>
<thead>
<tr>
<th>Journal</th>
<th>h-5 Index</th>
<th>Geographical zone of editorial office</th>
<th>Guideline</th>
<th>Registry</th>
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<tr>
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</table>

1 = Equator Network, 2 = ICMJE, 3 = CONSORT, 4 = MOOSE, 5 = QUOROM, 6 = PRISMA, 7 = STARD, 8 = STROBE, 9 = ARRIVE, 10 = CHEERS, 11 = SRQR, 12 = SPIRIT, 13 = COREQ, 14 = TRIPOD, 15 = SQUIRE, 16 = PRISMA-P, 17 = CARE, 18 = Clinical Trials.gov, 19 = WHO, 20 = Other/Generic (Trial), 21 = PROSPERO, EU = Europe, NA = North America, § = recommended, # = required, Grey Box = not relevant, as journal does not accept the study design requiring these guidelines; Empty Box = guidelines are relevant to the journal but not mentioned. (All data was extracted November 27th, 2017).
mentioned the Enhancing the Quality and Transparency of Heath Resources (EQUATOR) Network.

Registration

Of the 20 journals in our sample, 15 (75%) did not mention any form of trial or systematic review registration. ClinicalTrials.gov was recommended by 1 journal (5%). Trial registration specifically with the World Health Organization (WHO) was required by 3 journals (15%). Four journals (20%) required trial registration but did not specify a preferred or acceptable registry. The PROSPERO platform for systematic review registration was not mentioned by any of the journals in our sample. Complete data is available in Table 1.

Discussion

Half of the top addiction research journals do not require authors to use any form of reporting guidelines and 75% do not mention trial registries. Our findings parallel the results of similar studies in multiple areas of medicine. For instance, Sims et al\(^1\) found that less than half of highly-cited emergency medicine journals made any mention of reporting guidelines in their instructions for authors. Similar findings have been reported in orthopedic surgery, plastic surgery, and cardiovascular journals.\(^{13,14,29}\) These tools were designed to improve the quality of reporting in research and to help eliminate design elements that lead to bias.\(^7,8\)

Adoption of these guidelines by journals has been shown to improve the quality of reporting in those journals; specifically, journals that implemented the CONSORT guideline improved reporting quality faster than those that did not.\(^{30}\) Panic et al\(^31\) found that among gastroenterology and hepatology journals, those that endorsed the PRISMA statement in their instructions for authors showed an increase in quality of both reporting and methodology. Arguments could be made that researchers have a moral obligation to report their methodology with the utmost clarity so that readers can accurately assess the validity of the study.\(^32,33\) A lack of clear reporting hinders efforts by organizations such as the National Institute on Drug Abuse (NIDA) to increase the overall quality of addiction research through improved transparency and reproducibility.

Efforts have been made by other stakeholders to improve the quality of scientific research. The EQUATOR Network was established in 2006 with the goal of promoting the use of reporting guidelines.\(^34\) This network provides access to all of the reporting guidelines mentioned in this study and many others. In

<table>
<thead>
<tr>
<th>Study type</th>
<th>Relevant reporting guideline</th>
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<td>ARRIVE Guidelines</td>
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<tr>
<td>Clinical trials</td>
<td>CONSORT Statement</td>
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<tr>
<td>Diagnostic accuracy studies</td>
<td>STARD</td>
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<tr>
<td>Economic evaluations</td>
<td>CHEERS Statement</td>
</tr>
<tr>
<td>Observational studies in epidemiology</td>
<td>MOOSE Statement</td>
</tr>
<tr>
<td>Qualitative research</td>
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<td>Quality improvement studies</td>
<td>SQUIRE Checklist</td>
</tr>
<tr>
<td>Study protocols</td>
<td>PRISMA-P Statement</td>
</tr>
<tr>
<td>Systematic reviews and meta-analyses</td>
<td>PRISMA Statement</td>
</tr>
<tr>
<td>Case reports</td>
<td>CARE Checklist</td>
</tr>
</tbody>
</table>

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 Quality 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 Quality Research; STARD, Standards for Reporting Diagnostic Accuracy Studies; STROBE, Strengthening the Reporting of Observational Studies in Epidemiology; TRIPD, Transparent Reporting of a Multivariate Prediction Model for Individual Prognosis or Diagnosis.
2014, the National Institutes of Health (NIH) held a joint workshop with the Nature Publishing Group and Science in order to identify the areas of scientific research that could be improved to increase “reproducible, robust, and transparent” research. The members of this workshop came to an agreement on a core set of recommendations that were published on the NIH website. Among the recommendations, they stated that “journals should use a checklist during editorial processing to ensure the reporting of key methodological and analytical information to reviewers and readers.”

In 2014, the National Science Foundation (NSF) created a “Reproducibility Framework”—a set of recommendations to improve the quality and reproducibly of research—in which it called for the standardization of certain elements of research practices across different disciplines. Munafò detailed the creation of a “Manifesto for Reproducible Science,” which included 10 items for improving quality and transparency in science, including the use of reporting guidelines and the registration of studies in trial registries.

Registering RCTs in clinical trial registries is an important tool to combat publication bias. Publication bias is defined as bias that occurs when the decision to publish research is not based on the quality of the research alone, and is instead decided based on the hypothesis tested or the significance of effects detected; this can lead to distorted conclusions from systematic reviews and literature surveys. This distortion is, in part, because of exaggerated effect sizes produced from the selective publication of only significant results. For example, an investigation into the clinical trials that led to the widespread use of antidepressants found that the literature was flush with so-called “positive” studies, while those with negative results were either left unpublished or made to seem like they had a positive result. This bias toward positive, significant results led to an inflated effect size for all drugs involved, with a mean effect size increase of 32%.

Another example of bias in RCTs can be seen in the Cochrane systematic review of the osteoarthritis drug, celecoxib. While conducting the Cochrane review, the pharmaceutical company Pfizer refused to provide data from 3 studies, totaling 15,539 participants. Without this data Cochrane was unable to assess the risk of harm between treatment with celecoxib and placebo. Potentially useful missing data from RCTs can slow efforts to find successful treatment interventions. Without knowledge of this hidden data, patients can be exposed to ineffective or even harmful interventions, while, simultaneously, clinicians waste scarce health care resources.

To ensure the accuracy of our results, we attempted to contact via email the editor-in-chief for each of the journals in our study for further clarification on their requirements for authors, such as which study types they accept. Some of the editors responded, but many did not and we were unable to verify the journal’s requirements. Furthermore, we could not locate the email address for 1 editor, and another journal listed an email account that was no longer in service. We do not believe that this missing information significantly affected our results.

Reporting guidelines and clinical trial registration are components of current and evolving research standards. Osteopathic physicians and researchers should be familiar with their use and apply them when performing research studies. We also recommend that the popular reporting guidelines, such as CONSORT for RCTs and PRISMA for systematic reviews, be incorporated into medical education at all levels. During undergraduate medical education, reporting guidelines may be used to expose students to elements of sound study design, such as randomization processes in randomized trials. During residency, residents may use them when presenting at journal clubs and reporting results from scholarly activities.

**Conclusion**

We strongly recommend that all addiction medicine journals update their guidelines for authors to require the use of reporting guidelines. Authors should be directed to the EQUATOR network for guidance on
which guideline to use. We also recommend that these journals require clinical trial registration. Furthermore, the guidelines for authors within these journals should be easy to locate and provide clear and concise statements about reporting guideline requirements and clinical trial registration. By doing so, addiction research journals will play an important role in turning the tide on the battle against addiction and contribute to efforts set forth by the National Institute on Drug Abuse seeking to improve the transparency and quality of addiction research.

Author Contributions

Messrs Cooper, Gray, and Checketts and Ms Barcenas provided substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data. Dr. Vassar and Mr Torgerson drafted the article or revised it critically for important intellectual content; all authors gave final approval of the version of the article to be published; and all authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

References


