

Editorial

## Future directions for *The Spine Journal*: managing and reporting conflict of interest issues

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The purpose of this editorial is to describe new requirements for submission of articles to *The Spine Journal (TSJ)* and explain basic changes in *TSJ* editorial processes. We believe fundamental changes in reporting and publication processes are essential to preserve scientific integrity and public trust. As clinical research is the primary guide informing medical decision making for physicians and patients, we have a primary professional obligation to ensure the clarity and validity of published evidence, and this goal must be given our highest priority.

Compelling evidence suggests that our current publishing models have proven inadequate to the task. In particular, biomedical literature confirms that funding sources and conflicts

of interest have real and sometimes dramatic effects on the reported outcomes of clinical studies that cannot be explained by research design [1–6]. The odds of favorable outcomes reported in studies funded by pharmaceutical companies or device manufacturers are two to eight times greater compared with studies with funding from other sources. The recent review of recombinant human bone morphogenetic protein-2 (rhBMP-2) trials in spinal surgery underscores the need for the spine research community to overhaul editorial processes. We must ensure a high standard of integrity to meet our own responsibilities as well as in the face of considerable public, media, and governmental skepticism [7]. Particularly disturbing were the findings in the rhBMP-2 review that demonstrated a widespread failure to accurately disclose substantial conflicts of interest; trial designs that likely inflated the benefits of rhBMP-2 and exaggerated the morbidity of alternative treatments; and promoted unsupported claims regarding the basic safety profile of rhBMP-2 over nearly a decade of peer-review publications [1–5].

Tables 1 and 2 outline proposed changes in *TSJ* editorial and publication process. *The Spine Journal* will more closely follow many of the guideline proposals recently published by the Institute of Medicine [8] and explicated for orthopedic research by Gelberman et al. [9]. With these changes, we hope to make clear in each study we publish both the presence and magnitude of potential conflicts that may influence how study data are collected, analyzed, interpreted, and reported.

In addition to the disclosures recommended by International Committee of Medical Journal Editors [10], Consolidated Standards of Reporting Trials (CONSORT) guidelines [11] and those required by the North American Spine Society (NASS) [12], *TSJ* will ask authors to incorporate both study funding sources and a study-specific appraisal of potential conflict of interest-associated biases in the text of the manuscript. These funding and other financial relationships will

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The disclosure key can be found on the Table of Contents and at [www.TheSpineJournalOnline.com](http://www.TheSpineJournalOnline.com).

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Table 1  
Organizational management of COI\*

Editor-in-chief and deputy editors for “Evidence and Methods”	Are precluded from speakers’ bureau agreements, commercial (device/pharmaceutical) entities, non-ACCME–accredited speaking arrangements, or commercial (device/pharmaceutical) scientific advisory boards; are not allowed consulting arrangements with commercial (device/pharmaceutical) entities (excepting government or nonprofit associations) May not chair or receive revenues from fellowship programs wholly funded by single-source industry backing nor have any interest, ownership (regardless of percentage), or employment in a device or biologic distributorship (POD). May not contract new royalty arrangements, projects that might result in future royalties, or stock agreements during time of service Universal disclosure, including dollar amounts in ranges for each financial association, will be published for each editor for public review
Deputy editors for subject areas and special features	May not engage in commercial (device/pharmaceutical), non-ACCME–accredited speaking arrangements nor have any interest, ownership (regardless of percentage), or employment in a device or biologic distributorship (POD). Must be recused from reviewing manuscripts with potential COI Universal disclosure, including dollar amounts in ranges for each financial association, will be published for each editor for public review
Associate and advisory editorial board members	Must complete a universal COI disclosure (Ref.) and be recused from reviewing manuscripts with potential COI
Ad hoc reviewers for special topics	Case-by-case approval
Authors	Universal disclosure, including dollar amounts in ranges for each financial relationship, will be published for each author for public review. The financial associations relevant to the specific article being published will be included in the “Methods” section

COI, conflict of interest; POD, physician owned distributorship.

\*Source: Policy on COI in Leadership Positions Revision Approved by NASS Board of Directors, June 2011 [12].

be reported in the “Methods” section and will include the magnitude of financial association, that is, specific dollar amounts within ranges. It will be expected that authors will discuss these potential sources of study bias in the “Discussion” section of their article as a matter of routine, similar to discussions of other biases and limitations usually addressed.

We do not believe that any investigator should be precluded from research authorship because of financial interests or specific funding relationships. However, as indicated in the spine and general medical literature, financial relationships are an undisputable source of potential bias; the presence or absence of these relationships should be clearly, unambiguously, and completely reported as part of the study’s strengths and limitations.

Citing funding sources and their roles is just one part of the CONSORT guidelines for reporting controlled trials [11]. Authors of controlled trials will also be required to follow the general CONSORT guidelines as a condition for publication in *TSJ*. Reports of noncontrolled trials and other clinical studies submitted to *TSJ* must also follow the CONSORT guidelines for reporting harms (adverse events and complications) [13]. This structured reporting includes the analysis of complication rates with measures of precision (eg, 95% confidence intervals) rather than p values alone, which may be especially misleading in small trials and with uncommon adverse events [13].

To prevent conflicts of interest from adversely affecting the review of manuscripts, the *TSJ* review process will

Table 2  
Proposed journal practice changes to promote literature integrity in spine publications

Three-tier review of clinical studies before decision by editor-in-chief	Manuscripts will be reviewed and vetted by three tiers of evaluators: peer review (2–3 reviewers); review and comment by deputy editors for subject area; review and comment by deputy editor for “Evidence and Methods”
“Evidence and Methods” review	All clinical study manuscripts will have an “Evidence and Methods” deputy editor review in addition to the subject area deputy editor review with attention to methodological rigor, the proper reporting of sources of error and potential bias, and appropriate interpretation of results in light of the study’s strengths and limitations
Author disclosures will include dollar amount ranges with publication	Reporting of financial disclosures will follow a universal disclosure policy requiring dollar amount ranges for each author [12]
Funding sources and topic-specific COI reporting	Funding sources and topic-specific COI of authors will be reported in the “Methods” section in clinical research studies
Conflict of interest/industry support as analysis variable in research	Where appropriate in systematic reviews or evidence-based guideline reports, appropriate adjustment for financial interest and industry sponsorship should be included in the analysis of strength of evidence
Reporting of randomized and controlled trials	CONSORT guidelines will be required for reporting results of randomized or controlled trials
Methodology limitations by potential bias	“Discussion” section to include a review of systematic bias metrics for the specific field when industry sponsorship and relationships are known
Safety profiles of new technology defined by statistical analysis	Complication rates in clinical studies should include an estimate of precision for safety analysis and should follow the CONSORT guidelines for reporting harms [13]

COI, conflict of interest; CONSORT, Consolidated Standards of Reporting Trials.

preclude conflicted peer reviewers and editorial board members from participating in the evaluation of specific submitted manuscripts (Table 1).

The *Spine Journal* has now two Deputy Editors for “Evidence and Methods.” In addition to the usual evaluations by reviewers and deputy editors with expertise in the submission’s subject area (eg, neurosurgery), all clinical studies considered for publication will also have an “Evidence and Methods” deputy editor review. This process should better ensure methodological rigor, the proper reporting of sources of error and potential bias, and appropriate interpretation of results in light of the study’s strengths and limitations. As with other potential sources of influence and bias, the roles of study funding, support and sponsorship on design, conduct, analysis, and reporting will receive close attention in the review process.

The above changes are integral to our new three-tier process of manuscript review (Table 2). Manuscripts will receive the usual peer review by reviewers with subject area expertise, a second-tier review by subject area deputy editors (ie, surgical area experts, rehabilitation area experts, etc.) with limited potential financial conflicts, and a third-tier review by “Evidence and Methods” deputy editors with no potential conflicts.

The final review will be by the editor-in-chief. The editor-in-chief is appointed by the NASS Board of Directors after detailed vetting by the Conflict of Interest Review Panel as part of the selection process. The Board has determined that the editor-in-chief, with whom the final publication decision ultimately resides, should be held to the most stringent level of conflict management, including divestment of conflicting assets (Table 1). We believe that the redundancy and transparency of this three-tier review process will significantly enhance the quality and fairness of reviews and ultimately improve the quality of manuscripts published in *TSJ*.

The intention of these changes is not to limit readers’ access to new information but to provide transparency and balanced context. For several years, podium and poster presentations at the NASS meetings (as well as other professional societies) have required a more comprehensive documentation of disclosures than any of the peer-reviewed journals in the field. Although the full-length, peer-reviewed, and published study is considered the gold-standard product, competing interests are often poorly disclosed. As revealed in *TSJ*’s assessment of the promotion of rhBMP-2 in the industry-sponsored peer-review literature, these essential disclosures and the enormous magnitude of those financial relationships were not clear in any of those seminal articles.

In the previous methods of publication, clinicians and researchers reviewing the evidence base for any number of topics in spine care could not, by reading the article itself, consistently assess potential financial biases or relationships. Our goal is for the reader of a clinical study to be able to make an informed judgment about the article’s “Results and Conclusions” from the descriptions at hand, including the study’s design, conduct, data, analysis, strengths, and limitations, including the sponsor’s and authors’ potential financial biases.

Conflicts and the role of potential biases are of primary importance in evaluating the strength of a study. This information should be immediately available with publication; that is, this vital information should not require searching a labyrinthine corporate registry or deciphering the fine print on a journal’s Web site. Readers and other interested parties should not have to wait for exposes in the *Wall Street Journal*, Congressional subpoenas, or the findings of Federal Grand Juries to discover these important considerations.

It is our hope that we can learn and move on from the rhBMP-2 story [7]. We believe it is imperative, moving forward, to more critically evaluate the design limitations of new studies, explicitly detail for the reader potential sources of systematic or reporting bias, and provide transparency in the review and publication process of studies promoting various interventions and technologies. We would strongly encourage other journals in related fields to consider implementing these or similar strategies. These are long, long overdue. Authors and readers should understand that we all strive for a common standard of excellence in publication and the highest integrity of research we present to the public.

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