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Authorship and Contributorship

Influence of Authorship Order and Corresponding Author on Perceptions of Authors' Contributions

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Objective The majority of medical journals rely on the order of authors and who is listed as corresponding author to convey authors' contributions. How readers interpret authors' roles based on authorship order and corresponding author remains uncertain. We explored how, on the basis of authorship order and designation of corresponding author, academic leaders perceive authors' contributions to research.

Design We conducted a cross-sectional survey of chairpersons in the departments of surgery and medicine across North America (259 United States and 32 Canada). We developed hypothetical study and authorship bylines with 5 authors varying the corresponding author as first or last author. Respondents reported their perceptions about the authors' roles in study conception and design, analysis and interpretation of data, and statistical analysis, and their view of the most prestigious authorship position. We used multinomial regression to explore the effect of corresponding author, surgical versus medical chair, and country of respondent, with respondents' beliefs about author roles.

Results One hundred sixty-five chairpersons (144 United States and 21 Canada; overall response rate: 57%) completed our survey. When the last author was designated as corresponding, perceptions of the first author's role in study concept and design (odds ratio [OR], 0.25; 95% confidence interval [CI], 0.15-0.41, $P < .001$) and analysis and interpretation of results (OR, 0.22; 95% CI, 0.13-0.38, $P < .001$) decreased significantly. Overall prestige of the last author position increased significantly when designated as corresponding author (OR, 4.0; 95% CI, 2.4-6.4, $P < .001$). Respondents varied widely in their inferences about the contributions of the remaining authors irrespective of who was corresponding, with fewer than 40% attributing any particular role to authors 2 to 4. Our findings did not differ significantly by specialty or country of the respondent.

Conclusions Academic department chairs were influenced substantially by corresponding author designation. We further confirm that without authors' explicit contributions in research papers, many readers will remain uncertain or draw false conclusions about author credit and accountability.

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Ghost Writers and Honorary Authorship: A Survey From the *Chinese Medical Journal*

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Objective To estimate the prevalence of ghost authors and honorary authors among Chinese authors according to the authorship criteria defined by the International Committee of Medical Journal Editors (ICMJE).

Design The first authors who submitted manuscripts to the *Chinese Medical Journal* during September 1 to December 31, 2008, were surveyed by questionnaire. The questionnaire was designed with 3 questions: (1) Who made the final decision on the authorship of your manuscript submitted to the journal? (2) Is someone without contribution to the research listed as an author? (3) Has an English-language native speaker done something for you in preparation of the manuscript? If yes, is the speaker listed in the byline or acknowledgment section? The questionnaire was sent to the authors via e-mail. Authors working abroad or from overseas were excluded from the survey.

Results Among 268 authors who received the questionnaire, 231 (86%) authors responded and 220 (82%) authors had effective questionnaires. The byline of manuscripts was decided by the corresponding author for 40.9% of authors, by the first author for 33.6%, and by all authors for 25.5%. English-language speakers were involved in the preparation of manuscripts of 21.4% of authors, of whom 7.3% were listed as authors, 3.6% were acknowledged, 10.4% were neither listed in the byline nor acknowledged (ghost writers). Among respondents, 71.4% reported that all authors in the byline satisfied the authorship criteria, and 28.6% were unqualified but listed as authors (honorary authors), of whom 20.0% were heads of departments or institutions, 3.2% were friends of major authors, and 5.5% were others. The prevalence of honorary authorship was almost the same as the settlement of the byline by an individual author (28%) or by a group of authors (28.6%, $\chi^2 = 0.006$, $P > .05$). The appearance of ghost writers was more common when the byline was decided by an individual author (52.8%) than by a group of authors (41.6%), but the difference was not statistically significant ($\chi^2 = 0.11$, $P > .05$).

Conclusions The rates of ghost writers and honorary authors reported by authors who publish in the *Chinese Medical Journal* are similar to rates previously reported among US general medical journals for ghost authors and honorary authors. Many Chinese authors may be unaware of the authorship criteria defined by ICMJE.

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Prevalence of Honorary and Ghost Authorship in 6 General Medical Journals, 2009

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Objective Given the increased awareness of authorship responsibility and inappropriate authorship, and following new policies of some medical journals to publish individual author contributions, this study was conducted to assess the prevalence of honorary and ghost authors in 6 leading general medical journals in 2008 and compare this to the prevalence reported by authors of articles published in 1996.

Design Online survey of corresponding authors of 900 research articles, review articles, and editorial/opinion articles published in 6 general medical journals in 2008 (*Annals of Internal Medicine*, *JAMA*, *Lancet*, *Nature Medicine*, *New England Journal of Medicine*, and *PLoS Medicine*, selected according to Institute for Scientific Information Journal Citation Report ranking in general medicine category). Based on previously reported prevalence rates of 19% of articles with honorary authorship, 9% with ghost authorship, and 2% with both honorary and ghost authorship, the sample size was determined with α at 0.05 and 80% power to detect a 10% difference between prevalence rates in 1996 and 2008. We will also analyze rates of inappropriate authorship according to article types and other characteristics and compare rates for those journals that publish authorship contributions vs those that do not.

Results A total of 630 (70%) corresponding authors responded to the survey. Included in the final data set were 230 (37%) research articles, 136 (22%) reviews, and 264 (42%) editorials. Preliminary analyses show 132 (26%) articles with honorary authors (range by journal: 16%-39%), 49 (8%) with ghost authors (range by journal: 2%-11%), and 15 (2%) had evidence of both (numbers of respondents to specific survey questions vary), compared to 19%, 11%, and 2% in 1996, respectively. The prevalence of honorary authors was highest in *Nature Medicine* (39%) and lowest in *New England Journal of Medicine* (16%); $P = .006$. The prevalence of ghost authors was highest in *New England Journal of Medicine* (11%) and lowest in *Nature Medicine* (2%). Honorary authors were reported for 31% of original research reports, 24% of reviews, and 22% of editorials. Ghosts were more prevalent in research articles (12%) vs reviews (6%) and editorials (5%); $P = .019$. No significant differences were found between journals requiring author contribution disclosures and those that do not. Further analyses will explore article and author characteristics.

Conclusion The prevalence of honorary and ghost authors has not changed significantly since 1996 and thus is still a concern.

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Ghost Writing: How Some Journals Aided and Abetted the Marketing of a Drug

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Objectives To describe the processes by which a pharmaceutical company planned journal publications. To examine variation in policies regarding ghostwriting among the targeted scientific journals.

Design We conducted a retrospective review of over 1000 internal industry documents concerning the gabapentin (Neurontin) case from the University of California, San Francisco, Drug Industry Document Archive, dated 1996-1999. We searched PubMed and Google Scholar (for gray literature) for articles planned for publication. We selected a set of articles resulting from grants that Parke-Davis gave to Medical Education Systems (MES) in 1996-1997 to publish 24 scientific articles and letters to the editor on gabapentin in peer-reviewed journals with prestigious "guest authors." We searched Web sites of and contacted all journals to which these articles were submitted for their former and current policies regarding conflict of interest, ghost authorship, adherence to standards of the International Committee of Medical Journal Editors (ICMJE), independent disclosure verification procedures, and reasons for rejecting the manuscript, if applicable. We also contacted ICMJE to determine if these journals followed the Uniform Requirements for Manuscripts Submitted to Biomedical Journals (as updated in 1997).

Results Eleven proposed articles were eventually published in 7 of the 24 journals originally targeted. None of these articles disclosed participation of Parke-Davis or MES in authorship. Only 2 articles disclosed funding by Parke-Davis or MES. Nine articles were apparently published in alternative journals, 4 of them in supplement issues. Currently all of these journals have policies requiring disclosure of conflicts of interest, but in a majority of cases ghost authorship is not addressed. Information on disclosure verification is sparse.

Conclusions Scientific journals have varied in their effectiveness in requiring and verifying full disclosure of conflicts of interest and authorship. Uniform standards must be implemented across all journals, so that companies wishing to conceal this information do not have an outlet to publish in journals with weaker policies. These standards should extend to journal supplements and letters to the editor.

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Peer Review

The Natural History of Peer Reviewers: The Decay of Quality

Michael Callaham

Objective Commonly used methods of training and screening journal peer reviewers have been shown not to improve the quality of reviews. Does individual reviewer performance change over time, and in what ways?

Design All reviews for *Annals of Emergency Medicine* from 1994 through 2008 were rated and assessed. We used linear mixed effect models to analyze the rating changes over time, calculating actual and predicted intercept and slope for each reviewer, using the xtmixed routine in Stata (ver 10; StataCorp, College Station, TX) and controlling for editor and manuscript. The hypothesis was that individual reviewer performance changes over time.

Results All completed reviews (14,808) by 1498 reviewers were rated on a validated 5-point scale by 84 editors. Reviewers (academic clinicians and clinical researchers) had served the journal a mean of 71.8 months (minimum of 2 months [159 reviewers, 11% of the total], maximum of 175 months) completing a mean of 13.4 reviews each (range, 1-100) with an average quality score of 3.6. The average score of the pool did not change during the study period, indicating changes in its application did not occur. Reviewers with persistent unsatisfactory scores were removed from regular reviewing. Those with only 1 review (429 reviewers, 29% of the total) could not demonstrate a trend, so were excluded from the analysis. Individual reviewers deteriorated over time at a mean rate of -0.0402 review points per year (95% confidence interval [CI], -0.04733 to -0.0330), but this was masked by the increased quality of new recruits (0.022 points/year). A very small proportion of reviewers improved at 0.05 points/year or better ($<1\%$ of the total), and a much larger group grew worse at the same rate (32% of the total). Even 47 senior reviewers selected for consistent quality and volume grew worse at the rate of -0.023 points per year.

Conclusions Reviewers who improved over time or deteriorated were identified, which could lead to identifying characteristics of their demographics or experience that could predict future performance. However, the majority of reviewers deteriorated over time, although at a very gradual rate.

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Does a Mentoring Program for New Peer Reviewers Improve Their Review Quality? A Randomized Controlled Trial

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Objective Traditional methods of peer reviewer training and selection have been shown to be ineffective. We instituted a mentoring program, pairing senior reviewers (selected for high quality) and new reviewers on the same manuscripts, to see if this intervention would improve quality as measured by editors' validated quality scores of all reviews.

Design Over a 2-year period, all new reviewers were randomly assigned to a control group or an intervention group by blinded technique. The intervention group was invited by e-mail to join our mentoring program and asked to communicate with their assigned senior reviewer mentor (by e-mail or phone) each time they were assigned a manuscript. Mentors were volunteers chosen for consistent timeliness and quality over years. Mentors and mentees (who were paired by topic during the study) were also notified each time either was assigned a manuscript to review; both groups (and editors) were blinded as to the study intervention. The content and

amount of communication were left to the mentor and mentee. After 3 reviews, mentees were surveyed regarding their experience. We calculated reviewer-specific and average trend lines for both groups, accommodating for lack of independence of ratings using SAS Proc MIXED models (ver 9.1, SAS Institute, Cary, NC) with a random intercepts and slopes correlation structures. We tested for longitudinal differences in the average trends differences between the 2 groups during the study period.

Results A total of 17 mentees, 15 controls, and 16 mentors completed 194 reviews. Both mentees and control group reviewers received the same number of invitations, but mentees accepted and completed more reviews than control group reviewers (109 vs 84), and mentee mean scores were higher than control group scores when controlling for within reviewer trends and variations in volume and group trend effects (3.81 vs 3.24; difference: -0.56 [95% confidence interval, -1.048 to -0.078], $P = .027$). Satisfaction was not assessed since it has previously been shown not to predict performance, but participants were surveyed for their suggestions.

Conclusion A simple system of pairing newly recruited peer reviewers with volunteer reviewer mentors chosen for consistent quality over time resulted in slightly more reviews accepted and higher review scores.

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Surveys of Current Status in Biomedical Science Grant Review: Funding Organizations and Grant Reviewers' Perspectives

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Objective To describe current status of biomedical grant review and to seek views on developing uniform requirements for the format and peer review of grant proposals.

Design Online survey to convenience sample of 57 international public and private grant-giving organizations. Nine of these sent an online survey via e-mail to a random sample of grant reviewers.

Results Of the grant organizations, 28 (49%) from 19 countries responded. Organizations reported as "frequent/very frequent" (and with deterioration over the past 5 years) these problems: declined review requests (54%), late reports (36%), administrative burden (21%), difficulty finding new reviewers (14%), and reviewers not following guidelines (14%). Half reported providing decisions to back to reviewers; 29% gave feedback on usefulness of reviews, and 46% rationed requests to reviewers. Of responding organizations, 57% supported the idea of uniform requirements for grant review, and 61% supported a uniform format of proposals. Of the 371 grant reviewers, 229 (62%) responded from 22 countries. Of these, 48% had reviewed for at least 10 years; 47% said their institutions encouraged grant review, yet only 7% were given protected time, and 75% received no academic recognition for grant review. Reviewers rated as "extremely/very important"

the following in deciding to review: 51% supporting external fairness, 48% relevance of topic, 46% professional duty, 43% keeping up to date, and 41% avoiding suppression of innovation. Sixteen percent reported that guidance was very clear; 85% reported not having been trained in grant review, and 63% reported that they would like training. For more than half, lack of recognition and pay were never barriers to reviewing.

Conclusions Funders reported a growing workload that is getting more difficult to peer review. About two-thirds of grant organizations supported development of uniform requirements for the format and peer review of proposals. Just under half of grant reviewers take part for the good of science and professional development, but many lack academic and practical support and clear guidance. Given these findings, we propose that work starts on developing uniform requirements for grant review.

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Data Sharing and Conflicts of Interest

Reproducible Research: Biomedical Researchers' Willingness to Share Information to Enable Others to Reproduce Their Results

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Objective "Reproducible research" is a model for communicating research that promotes transparency of methods used to collect, analyze, and present data. It allows independent scientists to reproduce results using the original investigators' same procedures and data and requires a level of transparency seldom sought or achieved in biomedical research. While the full reproducible research model involves more than data sharing, some form of sharing is a basic requirement. This report describes the willingness of biomedical researchers to share their study materials with others.

Design Authors of research articles published in *Annals of Internal Medicine* in 2008 were asked whether and under what conditions they would make available to others their protocols, statistical code, and data. We will ask researchers who stated that they would make materials available to report the number of requests received.

Results Of 72 articles, authors of 13% stated that protocol was available without conditions, 58% with conditions, and 17% not available. Statistical code was available without conditions for 3%, with conditions for 60%, and unavailable for 24%. Data were available without condition for 4%, with conditions for 57%, and unavailable for 38%. Most authors who said materials were available required interested parties to contact them first and many stated specific conditions for sharing these materials. Authors provided no statement about protocol, statistical code, and data availability for 13%, 14%, and 1%, respectively. **TABLE 1** shows reported availability of study materials by study characteristics.

Table 1. Reported Availability of Study Protocol, Statistical Code, and Data by Study Characteristics (N = 72)

		Protocol Available, No. (%)	Code Available, No. (%)	Data Available, No. (%)
Overall, No. (%)		50/63 (79)	45/62 (73)	44/71 (62)
Design	Decision/cost analysis, 6 (8%)	4/5 (80)	3/5 (60)	3/6 (50)
	Observational, 50 (70%)	33/43 (77)	33/42 (79)	32/49 (65)
	Randomized trials, 16 (22%)	13/15 (87)	9/15 (60)	9/16 (56)
Funding	Industry, 14 (19%)	9/12 (75)	10/12 (83)	9/14 (64)
	Nonindustry, 58 (81%)	41/51 (80)	35/50 (70)	35/57 (61)
Author Affiliation	Industry, 10 (14%)	6/8 (75)	5/8 (63)	6/10 (60)
	Nonindustry, 62 (86%)	44/55 (80)	40/54 (74)	38/61 (62)
Conflicts	None disclosed, 35 (49%)	28/32 (88)	24/32 (75)	24/35 (69)
	Conflicts disclosed, 37 (51%)	22/31 (71)	21/30 (70)	20/36 (56)

Conclusions While the majority of authors stated that they would make study materials available to others, most would do so only if others contacted them and attached requirements to the sharing of this information. Researchers were most willing to fully share their protocols and least willing to share data. Information on a larger sample and frequency of requests for materials will be available for presentation in September 2009.

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Investigator Experiences With Financial Conflicts of Interest in Clinical Trials

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Objective To determine the extent to which investigators follow best practices to mitigate financial conflicts of interests in conducting clinical trials. We hypothesized that nonindustry-funded trials may engage in best practices more often than those with commercial funding.

Design E-mail survey of 1109 investigators from Canadian trial sites listed in 2 international trial registries in November 2006. We asked investigators about their experiences with trials conducted from 2001 to 2006. The main outcome was the frequency of 11 best practices, as defined by expert consensus and the literature, to mitigate financial conflicts of interest in trial preparation, conduct, and dissemination stratified by funding source (industry vs non-industry), and type of regulation (externally vs self-regulated).

Results A total of 844 investigators responded (76%), and 732 provided information for analysis. Fifty-five percent had been investigators on both industry- and nonindustry-funded trials. Overall, 41 (6%) investigators experienced best practices in all of their trials. The 3 externally regulated best practices (trial registration, institutional review of signed contracts and budgets) were more or equally likely to be followed in the industry relative to the nonindustry funding environment. Self-regulated practices (contracts had no restrictive confidentiality clauses; sponsor did not own the study data; investigator had access to data from all sites; investigator controlled final decisions regarding study design, analysis, interpretation, and manuscript content) were more frequently followed in nonindustry- than industry-funded trials ($P < .001$). Overall, 269 (37%) investigators reported having personally experienced ($n = 85$) or witnessed ($n = 236$) a financial conflict of interest; more than 70% of these situations related to industry-funded trials.

Conclusions Few investigators report always following best practices to mitigate financial conflict of interest in their clinical trials experience. Compliance was higher when best practices were externally regulated and trials were not industry funded.

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Acknowledgment of Company Support in Research Publications From Investigator-Sponsored Studies

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Objective Many pharmaceutical and medical device companies provide support for independent research through investigator-sponsored study (ISS) programs (also known as investigator-initiated studies). Typically, a company's role in ISS projects is limited to providing funding and/or products, with minimal technical input. The investigator initiates and conducts the study and is responsible for complying with all regulations applicable to both investigators and sponsors. The International Committee of Medical Journal Editors (ICMJE) guidelines state that financial and material support should be acknowledged in published research. Our objective was to examine the frequency of acknowledgment in recent publications arising from a medical device company's ISS program.

Design Publications (2004 through 2008) traceable to ISS agreements were identified by searching company files, institutional Web sites, and the PubMed database. Each publication was examined by 2 or 3 reviewers for eligibility. Publications not addressing the principal goals of the ISS were excluded. Eligible articles were examined for acknowledgment of company support.

Results Our preliminary search identified 55 publications (from 20 peer-reviewed medical journals) arising from 18 ISSs. Several ISSs

generated multiple publications. Disclosure of company support was found in 31 of the 55 (56%) publications. Acknowledgment was found in 10 of the 14 publications (71%) from ISSs that received company monetary support versus 21 of 41 (51%) of publications from ISSs that received product (a diagnostic device) only. Notably, all of the publications without disclosure came from 6 ISSs; 12 of the 18 (66%) ISSs did acknowledge company support in their publications.

Conclusions Publications from one-third of the ISSs we evaluated did not acknowledge company support. Authors may fail to acknowledge support when the company provides product (a diagnostic device) because it is rarely the intervention under study. Acknowledgments may also be missing due to journal practices or author preferences. All organizations providing support should be acknowledged regardless of the level or type of support provided. Opportunities exist for authors, editors, and industry to improve the transparency of ISS publications.

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Commercial Relationships, Funding, and Full Publication of Randomized Controlled Trials Initially Reported in Conference Abstracts

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Background In 1998, the Association for Research in Vision and Ophthalmology (ARVO) started requiring disclosure of author commercial relationships in meeting abstracts.

Objective To explore a possible association between commercial conflicts of interest and publication of randomized controlled trials (RCTs) initially presented as ARVO conference abstracts.

Design We identified RCTs presented as ARVO abstracts in years 2001-2003 and extracted data from each abstract, including "author commercial interest" (as defined by ARVO), study funding, and direction of results of primary outcome. Commercial relationships and funding sources were not mutually exclusive. Using PubMed (latest search March 2009) and direct author contact, we identified full reports associated with included abstracts. We will present 2001-2003 data and will also explore the effect of additional author and study characteristics.

Results We identified 151 abstract reports, of which 130 reported results for the primary outcome. Sixty-nine abstract reports (53%) had been published in full. Commercial relationships were reported as commercial institutional research support, 23 (18%); personal financial interest, 32 (25%); and no commercial relationship, 86 (66%). Full publication of abstracts with authors having commercial institutional support was 65% (15/23, 95% confidence interval [CI], 46%-85%), for those disclosing personal financial interests was 63% (20/32, 95% CI, 46%-79%), and for those reporting no commercial relationships was 49% (42/86, 95% CI, 38%-59%). **TABLE 2** shows publication rates according to commercial relationship categories and results for the primary outcome. Abstracts noting commercial relationships had a higher full publication rate

when the primary outcome result favored the experimental group. Among those studies with results favoring the control group (n = 11), no study disclosed commercial relationships.

Table 2. Publication Rates According to Commercial Relationship Categories

Author commercial relationship ^b	Direction of Results for Primary Outcome (N = 196; 2001 abstracts with primary outcome stated) ^a			
	No. disclosing ^c	Experimental better, No. (% published)	No difference, No. (% published)	Control better, No. (% published)
Commercial institutional research support	23	16 (69)	7 (57)	0
Personal financial interest	32	22 (64)	10 (60)	0
No commercial relationship	86	46 (50)	29 (45)	11 (55)

^aDirection of the difference between the experimental and comparison group for the primary outcome or main study results

^bAuthor commercial relationship categories not mutually exclusive

^cNumber of abstracts disclosing relationship

Results Of the 410 invited reviewers, 50% completed the survey. The following percentage of respondents believe it to be likely or very likely that: a company expects the presentation of medical content given by a member of a speakers bureau to be consistent with the company’s marketing message, > 80%; that a typical consultant to a company would be reluctant to jeopardize their relationship with the company, > 70%; that sponsorship of research influences an author’s judgment, > 90%. Seventy-five percent disagree or strongly disagree that authors have unlimited access to the company data without restrictions on publication. Seventy-four percent report that they would read an article more or much more carefully if the author serves on speakers bureau, 80% if the author is a consultant, and 85% if the author owns stock. The majority of respondents, however, report that their recommendation for publication is unchanged if the lead author falls into any of these categories.

Conclusion The majority of peer-reviewer respondents believe that financial ties to industry influence authors; nevertheless, most also believe that their recommendation of articles authored by physicians in these conflicted roles remains unchanged.

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Conclusions Our preliminary data suggest that studies disclosing commercial relationships show higher publication rates, with results favoring the experimental group, compared with studies reporting no commercial relationship. Further research is needed to explore this association.

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Editorial Training, Decisions, Policies, and Ethics

Background, Training, and Familiarity With Ethical Standards of Editors of Major Medical Journals

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Objective To characterize the current demographics, training, experience, and familiarity with scientific publication ethics of editors of medical journals, expanding on a similar survey of journals in the 1994 Science Citation Index.

Design The 2007 Journal Citation Reports database was used to determine the journals containing the top 50% of total citations within each of 44 medical specialty categories. Category keywords were used to select only journals that a physician might use in making clinical decisions. An electronic survey was sent to the editors in chief of 190 journals (representing 5 million total citations), requesting information about demographics, training, and editorial duties. We included hypothetical scenarios about plagiarism, authorship, conflicts of interest, and peer review to test editorial knowledge.

Results Surveys have been received from 93 editors for a 49% response rate. Respondents to date include editors in 38 of the 44 medical topic categories, whose journals were cited 2.86 million times in the past year. 92% (81) of respondents were male, 81% (58) participated in some degree of patient care, and 79% (71) spent less than 50% of their work time doing editorial duties. Although 86% (78) of respondents were “confident” or “very confident” in their knowledge of scientific publication ethics when they began the survey, this number dropped to 71% (65) by the end. Performance on the editorial scenarios was poor; correct answers were given by 18% (14) to the question on plagiarism,

Perceptions and Integration of Conflict of Interest Disclosures Among Peer Reviewers

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Objective We investigate how peer reviewers’ understanding of key terms in conflict of interest (COI) statements varies in relation to their demographics and reviewer performance and how peer reviewers believe their understanding influences their assessment of articles.

Design We conducted an online survey with questions in the following categories: COI knowledge, perception of COI disclosures, personal information, and integration of COI statements into article assessment. A random sample of 146 core reviewers and 264 specialist reviewers for *Annals of Emergency Medicine* were invited to participate. Survey responses were linked to performance data in the journal files and coded for confidentiality. We provide descriptive statistics of survey responses and examine the relationship of reviewers’ demographics and performance scores with their knowledge of the activities of serving as a consultant or on a speakers bureau and their reported means of integrating that knowledge in article assessments.

30% (27) to authorship, 15% (14) to conflicts of interest, and 16% (15) to peer review. Forty-nine percent (44) believed that additional training in scientific publication ethics would significantly enhance their skills as an editor.

Conclusion Despite high confidence levels among editors in chief of medical journals participating in this survey, there is still a need as well as a demand for further education in scientific publication ethics.

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A Qualitative Study of Editorial Decisions About Publication of Randomized Trials at Major Biomedical Journals

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Objective To understand the decision-making process of journal editors when deciding whether to publish randomized controlled trials (RCTs).

Design Qualitative study of editorial meeting discussions of randomized trials submitted for publication at 3 major biomedical journals (*BMJ*, *Lancet*, and *Annals of Internal Medicine*) during 2003-2004. A total of 50 RCTs were submitted to the journals of which 13 were accepted and 37 rejected. Editorial meetings consisted of editors, statisticians, and, often, invited experts or consultants. Attendees varied among the journals and among meetings. We audio-recorded all editorial meetings in which these manuscripts were discussed. Audiotapes were transcribed and transcripts were analyzed using grounded theory. Thirteen RCTs accepted for publication were compared to a random sample of 13 RCTs rejected after peer review, stratified by journal. We identified commonly expressed themes and whether they were favorable toward publication or critical of the manuscript.

Results Ten recurrent themes emerged including methods, writing (the need for more information, clarification, or explanation to interpret methods and results or issues with presentation and style), results, editor discussions for improving the manuscript (eg, revising analyses, reporting data, implications of the findings), discussion of peer review comments, novelty, whether the manuscript would change clinical practice, conflicts of interest, readership, and author characteristics. For accepted manuscripts, approximately 54% of the comments were critical and 46% were favorable. For rejected trials, approximately 75% of the comments were critical and 25% were favorable. The frequency of themes discussed differed between accepted and rejected manuscripts (TABLE 3).

Conclusions Discussion of the trial reports' methods, results, and writing dominated the editorial meetings. For trials that were accepted, editors also devoted a large proportion of the discussion to suggestions for improving the manuscript and communicating its key messages. The peer review process resulted in constructive suggestions for changing the reporting of accepted trials.

Table 3. Proportion of Themes Discussed During Editorial Meetings for Accepted and Rejected Manuscripts

Theme	Accepted Manuscripts (674 Comments)	Rejected Manuscripts (296 Comments)
	Frequency No. (%)	Frequency No. (%)
Methods	154 (22.8)	91 (30.7)
Writing	116 (17.2)	25 (8.4)
Results	115 (17.1)	72 (24.3)
Editorial suggestions for improvement	75 (11.1)	7 (2.4)
Reviewer comments discussed	72 (10.7)	29 (9.8)
Novel	71 (10.5)	34 (11.5)
Change practice	47 (7.0)	27 (9.1)
Conflicts of interest	14 (2.1)	1 (0.3)
Readership	5 (0.7)	6 (2.0)
Author characteristics	5 (0.7)	4 (1.4)

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Editorial Policies of Pediatric Journals: A Survey of Instructions for Authors

Joerg J. Meerpohl,^{1,2} Robert F. Wolff,^{1,3} Charlotte M. Niemeyer,² Gerd Antes,¹ and Erik von Elm⁴

Objective The continued discussion about ethics and quality of biomedical publishing has led to recommendations for submitting authors. However, it is unclear to what extent these recommendations have been implemented in specialty journals. We studied whether aspects of good publication practice were implemented in the author instructions of pediatric journals.

Design In the Institute for Scientific Information Journal Citation Report (JCR) 2007, we identified all journals (n = 78) in the subject category "pediatrics" and included those publishing original research articles (n = 69). We accessed the online instructions for authors and extracted information regarding endorsement of the International Committee of Medical Journal Editors (ICMJE) Uniform Requirements for Manuscripts Submitted to Biomedical Journals and of 5 major reporting guidelines including CONSORT and STROBE, disclosure of conflicts of interest (COIs), and trial registration. Two investigators collected data independently.

Results The ICMJE Uniform Requirements were mentioned in author instructions of 38 of the 69 journals (55%). Endorsement of reporting guidelines was low with CONSORT being referred to most frequently (14 journals, 20%). Each of the other 4 reporting guidelines was mentioned in less than 10% of the author instructions. Fifty-four (78%) journals explicitly required authors to disclose COIs, and 16 (23%) either recommended or required trial registration. The odds of endorsing the ICMJE Uniform Requirements increased by 2.25 (95% confidence interval [CI], 1.17-4.34) per additional impact factor point. Similarly, the odds increased by 2.32 (95% CI, 0.95-5.70) for requiring disclosure of COIs and by 3.66 (95% CI, 1.74-7.71) for requiring trial registration.

Conclusions According to the author instructions of journals serving the pediatric research community, several recommendations for publication practice are not yet fully implemented. The more widespread endorsement of ICMJE Uniform Requirements and major reporting guidelines could improve the transparency and completeness of pediatric research publications. Many pediatric journals do not have editorial policies regarding trial registration. Disclosure of COIs at the time of manuscript submission should be mandatory.

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Was *JAMA*'s Requirement for Independent Statistical Analysis Associated With a Change in the Number of Industry-Funded Studies It Published?

Elizabeth Wager,^{1,2} Rahul Mhaskar,³ Stephanie Warburton,³ and Benjamin Djulbegovic³

Objective To determine whether the number of industry-funded trials published by *JAMA* changed after the July 2005 requirement for independent statistical analysis.

Design Retrospective before-and-after study. Two investigators independently coded all RCTs published in *JAMA* from July 1, 2002, to June 30, 2008, (ie, 3 years before and after the policy). They were not blinded to publication date. RCTs were classified as "Industry" if they had any commercial funding or support. Discrepancies were resolved by discussion or further analysis. RCTs published in *Lancet* and *New England Journal of Medicine (NEJM)* during the same period provided the control.

Results The total number of RCTs and the proportion with commercial funding decreased significantly in *JAMA* after July 2005. In contrast, *NEJM* published more RCTs, but funding did not change significantly, while *Lancet* published the same number of RCTs, but the proportion of industry RCTs rose nonsignificantly in the same periods. Alternative categorization of funding sources distinguishing total industry funding (IF) from support (IS) (ie, supplying materials only) or joint industry/noncommercial funding (J) produced a less clear pattern but IF+J studies decreased significantly in *JAMA* while IS studies (and IF+IS studies) increased significantly in *NEJM*, and IF studies increased significantly in *Lancet* (TABLE 4).

Conclusions *JAMA*'s requirement for independent statistical analysis for industry-funded studies was associated with a change in the pattern of RCTs published. We cannot tell whether the policy affected the number of RCTs submitted, the acceptance rate, or both. The decrease in RCTs and commercial studies was not seen in the control journals.

Table 4. Number of Industry-Funded Trials Published by *JAMA* Before and After the Requirement for Independent Statistical Analysis

	JAMA		NEJM		Lancet	
	Before	After	Before	After	Before	After
All papers	677	637	697	673	530	529
RCTs (%)	26.3	20.9	37.1	42.2	37.5	39.7
P value	.021		.056		.47	
Industry (%) ^a	60.1	47.3	53.3	58.9	49.2	57.6
P value	.026		.195		.090	

^aStudies with commercial funding

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What Ethical Issues Do Journal Editors Bring to COPE?

Sabine Kleinert¹ and Elizabeth Wager^{2,3}

Objective The Committee on Publication Ethics (COPE) has provided a forum for journal editors to discuss troubling cases since 1997. The keywords assigned to cases were checked and recategorized in 2008 to ensure consistency of use. We analyzed the cases discussed at COPE to identify possible topic trends. In particular, we wondered whether the introduction of the COPE flowcharts in 2006 might be associated with a reduction in the number of straightforward cases.

Design Analysis of cases on the COPE Web site from 1997 to 2008 according to their keywords (which are assigned by COPE).

Results The database comprises 354 cases. The number of cases presented to COPE each year ranges from 15 to 42 but with no clear time trend (eg, there were fewer cases in 2008 than 2007). COPE membership increased steadily from 1997 to 2006 and then more dramatically during 2007 and 2008. The only categories of cases that appeared to increase were plagiarism (perhaps due to increased awareness) and unethical editorial decisions (which has increased since COPE published its code of conduct, perhaps because editors are questioning their practices more). We found no evidence that the flowcharts had reduced the number of straightforward cases submitted. See TABLE 5.

Table 5. COPE Cases by Category, 1997-2008

Category	97-99	00-02	03-05	06-08
Unethical editorial decisions	3	3	10	11
Plagiarism	4	6	11	13
Authorship	17	23	9	18
Data fabrication and falsification	9	4	3	7
Unethical research	32	40	41	38
Other	11	13	6	22
Total	76	89	80	109

Conclusion While the numbers in each category are small, and therefore do not warrant statistical analysis and should be interpreted with caution, apart from plagiarism and unethical editorial decisions, which appear to have increased, we observed no clear patterns in the types of problems presenting to COPE since 1997.

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