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A Comparison of Authorship Policies at Top-Ranked Peer-Reviewed Biomedical Journals

In a highly competitive scientific environment, authorship decisions are important. Including authors who do not meet authorship criteria dilutes the merits of other authors and may lead to inappropriate academic advancement and have a corrupting and discouraging influence on research.^{1,2} To ensure the honesty of the scientific process, the International Committee of Medical Journal Editors (ICMJE) defined 3 criteria for authorship eligibility, which, taken together, are indicative of personal effort and accountability.³ More than 500 biomedical journals have requested listing themselves as subscribers to ICMJE Uniform Requirements (URM) for Manuscripts Submitted to Biomedical Journals. However, the prevalence of authorship policies and criteria and authorship definitions vary widely, with many journals having implemented no criteria.

We studied high-impact, peer-reviewed journals to assess these variations.

Methods. We performed a cross-sectional study in 135 peer-reviewed biomedical journals from 35 publishers,

including the 15 top-rated journals in 9 Journal Citation Reports (JCR) medical categories rated according to the 2009 JCR Impact Factor (IF) (eTable 1).⁴ We included English-language journals publishing (1) original research and other types of contents (all-content journals) and (2) all contents except original research (review journals). Guidelines or instructions for authors and manuscript submission available on journal Web sites were reviewed independently by 2 authors (J.M.P. and C.H.) using a standard form (eAppendix) in December 2010.

We coded journal authorship criteria (if any) using 12 criteria largely based on *Archives of Internal Medicine* and *JAMA* authorship criteria as a baseline (eAppendix). Criteria were coded into 8 categories according to compliance with the 3 ICMJE authorship criteria: categories 1 through 6 correspond to criteria 1 to 6 in the eAppendix; category 7, criteria 7 to 10 in the eAppendix; and category 8, none. The eAppendix and eTable 2 show the information collected for each journal.

The number of journals publishing contributorship disclosures was determined by review of 10 randomly selected articles from each journal published between July and December 2010.

We analyzed ICMJE criteria required according to different variables including the 4 publishers with the most journals.

Results. The median IF was 6.1 (interquartile range, 4.4-9.8). No association was observed between the IF and journal requirement of none or 1 or more criteria.

Three criteria were required by 51.4% of all-content journals vs 21.8% of review journals ($P = .005$). There was a significant association between criteria requirement and URM endorsement ($P < .001$): of the 50 journals subscribing to ICMJE requirements, 18% required no criteria, compared with 51.7% of the 85 that did not (**Table**). Each criterion was required by approximately 50% of jour-

Table. Authorship Criteria Requirement According to Region, Type of Contents, ICMJE URM Endorsement, and Publisher^a

Variable	Total (n = 135)	No Criteria (n = 53; 39.3%)	1 or 2 Criteria (n = 22; 16.3%)	3 Criteria (n = 60; 44.4%)	P Value
EO Region					
Europe	73 (54.1)	28 (38.3)	12 (16.4)	33 (45.2)	.99
United States	45 (33.3)	19 (42.2)	7 (15.6)	19 (42.2)	
Both	17 (12.6)	6 (35.3)	3 (17.6)	8 (47.0)	
Type of contents					
Reviews only	32 (23.7)	20 (62.5)	5 (15.6)	7 (21.8)	.005
All contents	103 (76.3)	33 (32.0)	17 (16.5)	53 (51.4)	
ICMJE URM endorsement					
Yes	50 (37.0)	9 (18.0)	7 (14.0)	34 (68.0)	<.001
No	85 (63.0)	44 (51.7)	15 (17.6)	26 (30.6)	
	Total (n = 78)	No Criteria (n = 38; 48.7%)	1 or 2 Criteria (n = 14; 18.0%)	3 Criteria (n = 26; 33.3%)	P Value
Publisher ^b					
Elsevier	40 (51.3)	20 (50.0)	8 (20.0)	12 (30.0)	.008
Wiley-Blackwell	16 (20.5)	6 (37.5)	3 (18.7)	7 (43.8)	
Lippincott W&W	9 (11.5)	2 (22.2)	0	7 (77.8)	
Nature Publishing Group	13 (16.7)	10 (76.9)	3 (23.1)	0	

Abbreviations: EO, editorial office; ICMJE URM, International Committee of Medical Journal Editors Uniform Requirements.

^aData are given as number (percentage) of journals unless otherwise specified.

^bOnly the 4 publishers with the most journals are listed.

nals (eTable 3).

There were significant differences in the number of criteria required between the 4 publishers analyzed ($P = .008$) (Table). Of the 60 journals including 3 criteria, the largest number belonged to infectious diseases ($n = 11$) and medicine (general and internal) ($n = 10$) (eTable 4). There was a significant association between subject category and criteria requirement ($P = .01$). Only 28 (20.7%) of journals, and no review journal, included published contributorship disclosures (eTable 5). There was a significant association between URM endorsement and journal category ($P = .001$) but not between endorsement and journal region (eTable 6).

Comment. Scientific journals themselves, together with ICMJE institutional support, are the prime movers in formulating authorship guidelines and regulations.⁵ This review of top-ranked journals' authorship policies suggests that much work remains to be done and that policies and criteria vary widely. Although there was no significant association between ICMJE criteria requirement and the IF, only 44.4% of journals required all criteria, while 39.3% required none. Worryingly, although the relationship between criteria requirement and URM endorsement was significant, only 68% of ICMJE journals required all criteria and 18% required none.

Journals use different authorship and contribution policies, statements, and forms; place ICMJE or their own authorship criteria in different Web site sections; and require submission of authorship forms at different stages. This results in misunderstanding and confusion and does little to prevent undeserving authorship.⁶ Furthermore, some publishers' Web sites post authorship statements and policies that do not parallel their journals' policies.⁷

It is unclear why 32% of ICMJE journals do not require all 3 criteria: possibly, editors have decided to use their own. In an international survey, 55% of 74 health care editors professed unawareness of ICMJE URM, while 21% were aware but had never used them.⁸

We found significant differences in the number of criteria required by the 4 leading publishers with, strikingly, only 30% of journals from Elsevier, the world's largest biomedical publisher, requiring all criteria (50% requiring none). The significant association between medical category and criteria requirement probably reflects the differences in URM endorsement between categories.

Contributorship statements, required by some journals at manuscript submission or acceptance to guide editorial decision making, do not totally resolve the difficulties inherent in honorary or ghost authorship but appear to have had an impact on some journals.^{6,9} However, only 20.7% of journals, mainly from general and internal medicine, included contributorship statements in published articles, possibly owing to a lack of information on contributorship from the ICMJE and many journals.

No review journal required contributorship disclosures, and only 21.8% required all 3 ICMJE criteria compared with 51.4% of all-content journals. These differences may suggest more-relaxed editorial attitudes by review journals normally containing commissioned articles with fewer authors, making unwarranted authorship less probable. However, ICMJE authorship definitions do not distinguish between

original and nonoriginal research and the Archives and other leading journals publish contributorship statements for clinical, systematic, and narrative reviews.

The study limitations include the cross-sectional design and selection of journals.

Clear authorship criteria are essential to ensure rigorous scientific inquiry and help readers judge which authors are making what types of contributions. Journals not posting authorship statements nor adhering to ICMJE policies are serving science badly because, without their support, the numbers of unmerited authors are unlikely to diminish significantly. Biomedical journals should pursue consensus on authorship definitions more vigorously, ensuring uniform adoption of ICMJE criteria, either current or updated to include quantitative measures, for original articles and reviews.

The ICMJE guidelines should be revised to create a standardized contributorship disclosure form to be published by as many journals as possible. Publishers should avoid duplication of standardized authorship policies and discrepancies with their journals.

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Author Contributions: Dr Bosch had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. *Study concept and design:* Bosch, Pericas, and Hernández. *Acquisition of data:* Bosch, Pericas, and Hernández. *Analysis and interpretation of data:* Bosch, Pericas, Hernández, and Torrents. *Drafting of the manuscript:* Bosch, Pericas, and Hernández. *Critical revision of the manuscript for important intellectual content:* Bosch, Pericas, Hernández, and Torrents. *Statistical analysis:* Torrents. *Administrative, technical, and material support:* Bosch, Pericas, and Hernández. *Study supervision:* Bosch, Pericas, and Hernández.

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Online-Only Material: eTables 1-6 and the eAppendix are available at <http://www.archinternmed.com>.

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Potential Safety Signals and Their Significance

In 2007, President George W. Bush signed into law the Food and Drug Administration Amendments Act (FDAAA) (121 Stat 962). This Act, by adding subsection (k)(5) to section 505 (21 USC §355), directed the Food and Drug Administration (FDA) to “conduct regular, bi-weekly screening of the Adverse Event Reporting System [AERS] database and post a quarterly report on the AERS Website of any new safety information or potential signal of a serious risk identified by AERS within the last quarter.”¹ The AERS contains over 4 million reported adverse events data from 1969 until the pres-

See Invited Commentaries at end of letter

ent and is aimed to maintain the FDA’s postmarketing safety surveillance program for all approved drug and therapeutic biologic products. The content of this database is dependent on the voluntary reporting from both health care professionals and consumers and is mandatory for pharmaceutical manufacturers.² For the purpose of this research letter, *potential safety signals* are potential signals of serious risks and new safety information identified by the FDA through the surveillance of the AERS database. The process of posting potential safety signal quarterly reports generated from AERS started in the first quarter of 2008 by the FDA.³ The FDA indicates that the identified potential safety signals do not denote a causal relationship between the drug and the listed risk. In addition, the FDA emphasizes that prescribers and con-

sumers should not take any action.³ This creates confusion for both health care providers and consumers because a potential safety signal has been identified on the FDA’s Web site, calling into question the meaningfulness of the listed potential safety signal. Should health care professionals and consumers be cautious if a potential safety signal is present on the FDA’s Web site?

Methods. On May 3, 2011, the FDA’s Web site was used to find quarterly reports of potential safety signals from January of 2008 to December of 2010.³ The quarterly reports were used to calculate the number of actual label changes resulting from a potential safety signal. The total number of potential safety signals that resulted in labeling changes was calculated as a percentage. Among those potential safety signals that resulted in a label change, subgroups of the different sections of a label were analyzed, and included the following: Adverse Reactions, Warnings and Precautions, Boxed Warning, Drug Interactions, Dosage and Administration, Contraindications, and Use in Specific Populations. The number of safety signals that resulted in either the addition of a Risk Evaluation Mitigation Strategy (REMS) or voluntary withdrawal of a drug from the US market was also evaluated.

Results. After reviewing 153 potential safety signals released between January of 2008 and December of 2010, a total of 74 (48%) label changes had occurred (**Table**), with 4 REMS implemented and 1 drug withdrawn from the market. Among those potential safety signals that resulted in a label alteration, the most common section adjusted was Warnings and Precautions (62%).

Comment. The initial start of many potential safety signals are driven by the FDA’s use of the AERS database to assess postmarketing adverse reactions. As of May 3, 2011, close to half of all potential safety signals listed on the FDA’s Web site from 2008 to 2010 resulted in labeling changes. Most of these labeling changes resulted in an updated Warnings and Precautions section. This is concerning because the current recommendations to health

Table. Results From Quarterly Reports From January 2008 to December 2010

Result	Quarterly Reports, Year, No. (%)			Total
	2008	2009	2010	
Potential safety signals, No.	60	45	48	153
Label changes	30 (50)	28 (62)	16 (33)	74 (48)^b
Subgroups ^a				
Warnings and Precautions	16 (53)	19 (68)	11 (69)	46 (62)
Adverse Reactions	11 (37)	5 (18)	7 (44)	23 (31)
Drug Interactions	2 (7)	1 (4)	0	3 (4)
Dosage and Administration	1 (3)	1 (4)	0	2 (3)
Boxed Warning	6 (20)	2 (7)	1 (6)	9 (12)
Contraindications	0	1 (4)	1 (6)	2 (2)
Use in Specific Populations	0	0	1 (6)	1 (1)
REMS	2 (7)	2 (7)	0	4 (5)
Withdrawn from market	0	0	1 (6)	1 (1)

Abbreviation: REMS, Risk Evaluation Mitigation Strategy.

^a Calculated from the number of actual label changes.

^b The calculated 48% total label changes includes the 1 drug withdrawn from the market and those drugs with newly implemented REMS.