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Special Report

Maintaining the Trust of Physicians and the Public in the Medical Literature: Report of a Task Force on Scientific Publishing of Clinical Trials

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ABSTRACT: In 2006, the American Society of Bone and Mineral Research and the *Journal of Bone and Mineral Research* convened a task force to consider whether and how to change our editorial policies to assure complete and unbiased reporting of clinical trials. We invited editors of journals that publish research on osteoporosis and disorders of bone and mineral metabolism and presidents of related societies to participate. The task force was charged to consider whether journals should (1) adopt the Principles for Protecting Integrity in the Conduct and Reporting of Clinical Trials published in 2006 by the American Association of Medical Colleges (AAMC) and should (2) require authors and sponsors of industry-funded clinical trials to provide a jointly signed letter that states that the authors had full access to all the data and analyses on which the manuscript was based. The AAMC Principles recommend that multicenter trials should designate a Lead Investigator, Steering Committee, and Publication and Analysis (P&A) Committee, which should consist of a majority of academic investigators who are not sponsor employees. The P&A Committee should have the right to access any data generated during a study and to conduct its own statistical analyses. A majority of task force members voted to support the AAMC Principles, to require a letter jointly signed by academic investigators and industry sponsor stating that the authors had access to the data on which the submission was based, and to recommend adoption of these requirements to their respective societies and journals. Broad-based adoption of the AAMC Principles and requirement of a jointly signed attestation of data access by journals that publish clinical trials in diseases of bone and mineral metabolism should improve the position of academic clinical investigators in their interactions with industry and other funding sources.
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Key words: clinical trials, industry, conflict of interest, American Association of Medical Colleges Guidelines, RAND methodology

BACKGROUND

In the last two decades, industry support of biomedical research in the United States has grown tremendously.[1] Pharmaceutical companies provide ~70% of the funding for clinical trials that test the efficacy and safety of new drugs, whereas federal government support of such efforts has declined.[2,3] In most cases, industry support of clinical trials has benefited public health. However, legitimate concerns about industry funding of clinical trials include the potential that such funding will bias the published literature and may lead to flawed recommendations for clinical management of patients.

Academic clinical investigators and industry sponsors share a common objective to design and conduct rigorous clinical trials of high scientific quality and to develop and test safer, more effective drugs to treat disease. However, industry sponsors have additional goals not shared by academic investigators, authors, reviewers, readers, and the lay public, most notably the successful marketing of drugs within an increasingly competitive landscape of therapeutic alternatives. To achieve this goal, a company may design studies to detect relatively trivial differences between drugs, differences that may be exploited for marketing purposes,[4] or pose research questions in such a way as to maximize the likelihood that the study outcome will favor their product.[5] Recent evidence indicates that investigators with ties to drug companies are more likely to report results favorable to those companies[2] and that studies sponsored by industry are significantly more likely to report proindustry conclusions.[6–9] In addition, there is also the potential for negative publication bias, because studies that do not support the sponsor's agent may never be published.

The Food and Drug Administration (FDA) and other international governmental organizations require large, lengthy, multicenter, phase III clinical trials to establish safety and efficacy and grant approval for new drugs.[10] These trials are intensely scrutinized; FDA scientists review the datasets and may perform their own analyses. However, several high profile examples indicate that scientific and ethical lapses still occur.[11–13] Of even greater concern, phase IV posthoc or ancillary studies are not typically subject to the same degree of oversight unless the sponsor intends to seek a new approval from the FDA. Thus, there

exists greater potential for scientific and ethical lapses, of importance because results of such trials may have substantial influence on prescribing practices and may increase the costs of health care.

ROLE OF MEDICAL JOURNALS IN DISSEMINATING RESULTS OF CLINICAL TRIALS

Many journals have strict guidelines for reporting of clinical trials. The most widely used are the Uniform Requirements for Manuscripts Submitted to Medical Journals, developed by the International Committee of Medical Journal Editors (ICMJE).[14] These guidelines include listing financial and personal conflicts of interest for all authors and describing the role of the sponsor in the study design, the collection, analysis, and interpretation of data, writing of the report, and the decision to submit the report for publication. The journal editor may also request that all authors of a study funded by a sponsor with a proprietary or financial interest in the outcome, sign such declarations as "I had full access to all of the data in this study" and "I take full responsibility for the integrity of the data and the accuracy of the data analysis." In 2001, the *Journal of the American Medical Association* (*JAMA*) adopted additional requirements for reporting results of industry-sponsored clinical trials[15] and now requires that an independent scientist, such as a biostatistician at an academic center, conduct data analyses for industry-sponsored studies to validate the analyses reported in a manuscript.

In January 2006, the Association of American Medical Colleges (AAMC) published "Principles for Protecting the Integrity in the Conduct and Reporting of Clinical Trials." This document recommends principles that should apply to all clinical research conducted in academic institutions, regardless of source of funding.[16] The AAMC Principles also promote much greater involvement of academic investigators in the analysis of the data from industry-sponsored clinical trials. The goals are to promote the responsibility and accountability of principal investigators and lead authors and protect the credibility of academic research.

ASBMR TASK FORCE ON SCIENTIFIC PUBLISHING OF INDUSTRY-SUPPORTED CLINICAL TRIALS

In 2006, the American Society for Bone and Mineral Research (ASBMR) convened a Task Force on Scientific Publishing of Industry-Supported Clinical Trials. The goal was to review regulations currently in place in the *JBMR* and to benchmark our conflict of interest and data access policies against other journals. We also wished to ensure that we were following best editorial practices to assure complete and unbiased reporting of research from industry-sponsored clinical trials. We invited presidents of societies interested in bone and mineral research and editors of journals (vide infra) that publish research on osteoporosis and disorders of bone and mineral metabolism to participate. The Task Force members reviewed policies from a range of journals and other background materials and then met by conference call to discuss whether participating medical journals should adopt the AAMC Principles for Protecting Integrity in the Conduct and Reporting of Clinical Trials[16] and require the authors and sponsors of industry-funded clinical trials to include with manuscript submissions a jointly signed letter, which states that the authors had full access to all the data and analyses on which the manuscript was based.

AAMC PRINCIPLES FOR PROTECTING INTEGRITY IN THE CONDUCT AND REPORTING OF CLINICAL TRIALS

The AAMC Principles consist of 22 recommendations that address several different aspects of conducting and reporting clinical trials. These include publication and public availability of research results, registration, organization, and administration of the study, publication by individual authors of subsets of the data, and authorship. Important recommendations include the following:

1. Academic researchers and their institutions should ensure that positive, negative, and null study findings are always published in a timely fashion, preferably in peer-reviewed journals, and failing this, are listed on an accessible online repository.
2. Clinical trials should be registered in a public, nonprofit, international registry before the first participant's enrollment, and data should be regularly updated to include links to all published reports resulting from that trial.
3. All multicenter trials should designate a Lead Investigator, a Steering Committee that represents all investigators, and a Publication and Analysis Committee. These committees should consist of a majority of academic investigators who are not sponsor employees.
4. The Publication and Analysis Committee (or principal investigator of single site studies), through a qualified expert of its choosing, should have the right to access any data generated during a study that are necessary to ensure its integrity and validity and should have the right to conduct its own statistical analyses of the data.
5. Academic investigators and institutions should adhere to the ICMJE standards of authorship and should not permit ghost or guest authorship of manuscripts. Manuscripts submitted for publication should be accompanied by the protocol and prespecified analysis plan.

The RAND Corporation/University of California Los Angeles (RAND/UCLA) Appropriateness Method (RAM)[17] was developed to synthesize expert opinion on health care topics and is a mechanism for reaching formal agreement on scientific and medical issues. The Task Force used a modified RAM to assess the degree of consensus among Task Force Members on each of the 22 recommendations. Task Force members were provided a ranking document to review individually before the teleconference (Table 1) that listed each guideline separately and separated complex guidelines into subrecommendations. We included one additional question for consideration ("Should journals require that authors and industry sponsors of clinical trials

TABLE 1. ASBMR TASK FORCE ON SCIENTIFIC PUBLISHING OF INDUSTRY SUPPORTED CLINICAL TRIALS: RESPONSES TO AAMC GUIDELINES

Rating scale: 1 = strongly disagree; 5 = uncertain; 9 = strongly agree

	AAMC principles for protecting integrity in the conduct and reporting of clinical trials	*Degree of agreement*								
	Publications and public availability of research results									
1	Researchers and their institutions have an ethical obligation when conducting human research to seek to make the results available publicly.	1	2	3	4	5	6	7	8	9
2	Contracts between sponsors and institutions for conducting clinical trials should require a good faith effort to publish the results of such trials in a peer reviewed journal in a timely fashion.	1	2	3	4	5	6	7	8	9
3	Contracts for clinical trials should contain a commitment of adequate funding to cover the full costs of the analysis defined in the protocol and the costs associated with publishing the results. This principle applies even when the study is terminated for any reason prior to meeting its pre-specified objectives.	1	2	3	4	5	6	7	8	9
4	All trials meeting the ICMJE requirements for registration should make their results publicly available, by means of a link to any peer reviewed publications and by posting the results in an online accessible repository, within 18 months of submission of a manuscript for publication.	1	2	3	4	5	6	7	8	9
5	After publication of the results, the sponsor, the investigators, and their institutions should adopt a model for public sharing of the data underlying publications similar to that of NIH, which permits exceptions for confidential or proprietary information.	1	2	3	4	5	6	7	8	9
	Registration of clinical trials									
6	Within 21 days of initiating enrollment of participants, any clinical trial covered by these principles should be fully registered pursuant to the ICMJE requirements for registration. Registration must include the assignment of a unique identifying number to each clinical trial.	1	2	3	4	5	6	7	8	9
7	Registration should be accomplished either in clinicaltrials.gov or in another public, non-profit, international registry and should include all the elements required by that registry.	1	2	3	4	5	6	7	8	9
8	Insofar as is feasible, trial registration data should be regularly updated to include a link to all published reports associated with the study.	1	2	3	4	5	6	7	8	9
	Lead investigator and steering committee									
9	A multisite clinical trial, at the outset, should identify a lead or principal investigator and a steering committee to represent the full body of investigators.	1	2	3	4	5	6	7	8	9
	Publication and analysis committee									
10	a. A multisite clinical trial, at the outset, should establish a publication and analysis committee (P&A committee).	1	2	3	4	5	6	7	8	9
	b. It is essential that the P&A committee be independent of the sponsor's control, have access to the full set of data, understand and implement the pre-specified analysis plan, and have the resources and skills to both interpret that analysis and perform additional analysis if required.	1	2	3	4	5	6	7	8	9
	c. In order to prevent any appearance of undue influence by the sponsor, the P&A committee should contain a majority of participating, non-sponsor-employed investigators, with appropriate skills in analysis and interpretation of clinical trials.	1	2	3	4	5	6	7	8	9
	d. The P&A committee and the steering committee may have the same membership.	1	2	3	4	5	6	7	8	9
11	The P&A committee in multisite clinical trials (or the principal investigator of single site studies), through a qualified expert of its choosing, preferably a member of that committee, should have the right to access any data generated during the study that the committee deems necessary to ensure the integrity and validity of the study and its full reporting.	1	2	3	4	5	6	7	8	9
12	a. The P&A committee in multisite clinical trials (or the principal investigator of single site studies), should require that the sponsor of the study perform its analysis of trial data in a defined period of time.	1	2	3	4	5	6	7	8	9
	b. The committee (or PI) should be able to conduct its own analysis through an expert selected by it, to the extent it deems this necessary.	1	2	3	4	5	6	7	8	9
13	The sponsor should share with the P&A committee all analyses called for by the study that the sponsor conducts of any biological materials it receives during the course of the study.	1	2	3	4	5	6	7	8	9
14	The P&A committee or PI should make a good faith effort to disseminate the results of the study through peer reviewed mechanisms.	1	2	3	4	5	6	7	8	9

TABLE 1. CONTINUED

	Rating scale: 1 = strongly disagree; 5 = uncertain; 9 = strongly agree									
	AAMC principles for protecting integrity in the conduct and reporting of clinical trials	*Degree of agreement*								
	Individual publication									
15	a. Site-specific publications in multisite trials have an unavoidable potential for bias. Because they are almost never part of the original analytic plan, they are often misleading, and should be strongly discouraged.	1	2	3	4	5	6	7	8	9
	b. However, to respect an academic institution's commitment to academic freedom, site-specific analyses should nonetheless be permitted with conditions.	1	2	3	4	5	6	7	8	9
	c. Accordingly, an individual site investigator in a multisite trial should be free to analyze and publish data from the individual site, consistent with sound principles of science and analysis, but only after review and comment by the P&A committee and only after publication of the study as a whole, or, in the absence of acceptance of the full publication, within 2 years from the specified end points or earlier termination of the study.	1	2	3	4	5	6	7	8	9
	Authorship									
16	a. Ghost or guest authorship is unacceptable.	1	2	3	4	5	6	7	8	9
	b. Authorship implies independent, substantial, and fully disclosed participation in the study and in the preparation of the manuscript.	1	2	3	4	5	6	7	8	9
	c. It is acceptable for employees of the sponsor to participate in drafting and publication activity, but only if their roles are fully disclosed.	1	2	3	4	5	6	7	8	9
17	Institutions conducting trials should adopt as policy the standards of authorship defined by the ICMJE.	1	2	3	4	5	6	7	8	9
18	Where applicable, investigators should use the CONSORT principles as guidance for publication of trial results.	1	2	3	4	5	6	7	8	9
19	Investigators should fully disclose, and journals should publish, the existence of all relevant financial interests, including consultancies of any investigator, in all communications of trial results.	1	2	3	4	5	6	7	8	9
20	a. Any manuscript submitted for publication should accurately disclose the roles of each author in conducting the study and preparing the manuscript.	1	2	3	4	5	6	7	8	9
	b. Such information should also be disclosed in any public presentation of study results, to the extent practicable.	1	2	3	4	5	6	7	8	9
21	Manuscripts submitted for publication should disclose all previous publications involving the same protocol or database.	1	2	3	4	5	6	7	8	9
22	Manuscripts submitted for publication should be accompanied by the protocol and pre-specified analysis plan and all dated amendments to them, and any deviations to the pre-specified plan should be identified and discussed.	1	2	3	4	5	6	7	8	9

submitted for publication send with the submission a jointly signed letter that the authors either held and analyzed all the data or had full access to and reviewed all of the data and analyses upon which the submission is based?").

Task Force members considered each statement and ranked it according to whether they agreed (ranking it 7, 8, or 9), disagreed (ranking it 1, 2, or 3), or were uncertain or neutral (ranking it 5, 6, or 7). A statistician prepared a summary document with the lowest, highest, and median ranking for each statement and the number of Task Force members who agreed, disagreed, and were uncertain/neutral on each question. If two or more individuals disagreed, the statement was ranked as nonconsensus, even if the median ranking was in the agree range, that is, between 7 and 9. The Task Force met by conference call in May 2006 to review the results.

There was remarkable consensus on each of the Principles. Although some statements in the Publications and Public Availability of Research section are beyond the scope of most journal procedures, there was unanimous agreement that results of human research should be made available publicly (median score, 9), that contracts between sponsors and institutions should require a good faith effort to publish results in a timely fashion (median score, 9), and that said contracts should include adequate funding for costs of analyses and publishing (median score, 9). There was also agreement that all trials meeting ICMJE requirements for registration should make results publicly available within 18 mo of completion (median score, 8), and the majority agreed that sponsors and investigators should adopt a model for public data sharing (median score, 8). In the Registration of Clinical Trials section, there was unanimous support for registration of trials and monthly updates of links to any peer-reviewed publications resulting from the trial (median score, 8 for both).

In the Lead Investigator and Steering Committee section, there was agreement that multicenter trials should identify at the outset a Lead Investigator and Steering Committee (median score, 9).

In the Publications and Analysis (P&A) Committee section, the AAMC guidelines go beyond the requirements of the ICMJE and support a greater role for academic inves-

tigators in the analyses than is often typical in industry-supported studies. The majority agreed that a P&A Committee should be formed (median score, 8.5) that is independent of the sponsor (median score, 8.5), has access to the full dataset (median score, 8), and includes a majority of non–sponsor-used academic investigators with the skills necessary to implement the analysis plan and analyze and interpret clinical trials (median score, 8). Two Task Force members disagreed with the statement that the P&A Committee could have the same membership as the Steering Committee, although overlap was considered permissible. Therefore, although the median score was 8, consensus was not reached on that point. In addition, Task Force members strongly supported the rights of the P&A Committee or a designated member to access data generated by the study (median score, 8), conduct their own analyses (median score, 8), access the results of analyses of biological materials, and publish results of the study (median score, 9). Finally, because individual investigators cannot determine whether they have been given access to all the relevant data, the sponsor should be required to provide a clear and unambiguous declaration to this effect.

The section entitled Individual Publication engendered some disagreement. Site-specific publications are those that do not include the entire study population but instead are based on separate studies or analysis of a subset of participants that were enrolled at one particular study site. The AAMC states that site-specific publications of multicenter trials have an unavoidable potential for bias, should be discouraged, and should be permitted only under defined circumstances. Some members voiced concern about limiting site-specific publications, noting that, although site-specific publication of primary endpoints are seldom justified, other endpoints, such as effects on particular racial or social groups, may only be assessed at certain sites and thus be worthy of separate publication. Although task force members did not support universal prohibition (median score, 6; with three task force members ranking this statement between 1 and 3 or disagree), they agreed that site-specific publications should be under the jurisdiction of the P&A Committee (median score, 7.5).

In the Authorship section, Task Force members agreed that ghost/guest authorship is unacceptable (median score, 9), on the stated implications and requirements of authorship (median score, 9), that it is acceptable for sponsor employees to participate in drafting manuscripts if their roles are disclosed (median score 8), that journals should adopt ICMJE standards for authorship (median score, 7), use CONSORT (Consolidated Standards of Reporting of Trials) principles[18,19] to guide publication of trials (median score, 8), and that authors should disclose all relevant financial interests (median score, 9). Two Task Force members felt that it would be impractical for a journal editorial office to review the protocol and analysis plans for all clinical trials; therefore, consensus was not reached on this point, although the median score was 8.

Finally, Task Force members agreed strongly that journals should require a jointly signed letter attesting that academic investigators had access to all the data on which a manuscript was based (median score, 9).

At the conclusion of the call, a majority of the ASBMR Task Force members voted to support the AAMC Principles with the exception of the few points on which consensus was not reached and to support the requirement of a letter jointly signed by academic investigators and industry sponsor stating that the authors had access to the data on which the submission was based. A majority agreed to recommend adoption of these requirements to their respective societies and journals. At the time of this publication, the ASBMR and the *JBMR*, the International Osteoporosis Foundation, the National Osteoporosis Foundation and their journal *Osteoporosis International* (*OI*), the International Bone and Mineral Society and its journal *Bone,* the European Calcified Tissue Society and its journal *Calcified Tissue International* (*CTI*), and the International Society For Clinical Densitometry and its journal *Journal of Clinical Densitometry* (*JCD*) and the American Association of Clinical Endocrinologists and its journal *Endocrine Practice* have voted to adopt the AAMC principles and to require a jointly signed letter. The *JBMR* has already implemented these changes in editorial policy and has incorporated them into their Instructions to Authors. The New England Journal of Medicine is a member of the ICMJE that declined to endorse the AAMC principles in January 2006 but will reconsider them at their next meeting in 2008. The Endocrine Society and the *Journal of Endocrinology and Metabolism* have declined to endorse at this point.

IMPLICATIONS OF THE ASBMR TASK FORCE RECOMMENDATIONS

The *JBMR* and other journals that participated in the Task Force, excepting the *New England Journal of Medicine*, do not attract major phase II and III studies supervised by regulatory agencies. Rather, they attract phase IV "marketing" studies and posthoc analyses that are not supervised by the FDA, yet have great potential to influence prescribing practices and patient care. There are powerful incentives for investigators who believe that they have not been allowed access to all relevant data by an industry sponsor not to "rock the boat." Most often the incentives are financial, particularly in this era of flat federal funding for biomedical research and for clinical trials in particular. Investigators not only risk withdrawal of funding but also future opportunities for research supported by that sponsor. On the other hand, the likelihood of a clinical trial being published in a highly regarded journal may be greater when it has been conducted in an academic medical center and includes academic investigators as authors. Despite the importance of these publications to industry, in our view, there is an imbalance of power because the financial support provided by industry to the investigator may outweigh the credibility given to industry research by publications that include academicians as authors. Adoption of the AAMC Guidelines would help to rectify this imbalance of power by providing better leverage to academic investigators in dealing with industry sponsors.

SUMMARY

The American Society for Bone and Mineral Research (ASBMR) convened this Task Force to review and improve *JBMR* editorial policies so that future reports of research from industry-sponsored clinical trials would be as complete and unbiased as possible. Representatives of societies and journals that participated in the ASBMR Task Force voted to adopt the AAMC Principles for Protecting Integrity in the Conduct and Reporting of Clinical Trials[16] and to require a statement attesting full access to the data and analyses on which the manuscript was based. The *JBMR*, *OI, Bone, JCD, CTI,* and *Endocrine Practice* have voted to adopt the AAMC principles and to require a jointly signed letter. The *JBMR* has incorporated these changes in editorial policy into the Instructions to Authors.

The AAMC document articulates an idealistic set of principles on how best to conduct and report clinical trials. They advocate the organizational structure of a multicenter clinical trial—whether supported by industry or another mechanism—include a Lead Investigator, Steering Committee, and Publications and Analysis Committee comprised of a majority of investigators who are not industry employees, with the requisite expertise in analysis and interpretation of clinical trials. If, in the future, journals refused to publish studies that were not organized in this manner, there would be greater leverage for investigators in their dealings with industry and their efforts to obtain full access to research data (if such access is not provided to them). The integrity of the research and of the academic and industry investigators who conduct clinical trials would be enhanced.

Finally, however, we acknowledge that enforcing such policies is difficult and that journals are ultimately dependent on the integrity of submitting authors. The endorsement of the AAMC Principles by *JBMR*, *Osteoporosis International, Bone, Journal of Clinical Densitometry, Calcified Tissue International*, and *Endocrine Practice* will have a positive impact on the quality of clinical trials reported in these journals. This may not be the only step that should or will be taken. However, we believe it is a step in the right direction. The Task Force strongly recommends that all scientific journals present a united front in support of these Principles. Although there will be exceptions in their application, a case-by-case approach to such exceptions would be strengthened if the baseline from which variance is sought is grounded in the idealism of the AAMC Principles.

ASBMR TASK FORCE ON SCIENTIFIC PUBLISHING OF INDUSTRY-SUPPORTED CLINICAL TRIALS*

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*Not all organizations represented on the Task Force have formally endorsed the AAMC Principles.

ORGANIZATIONS AND JOURNALS ENDORSING THE AAMC PRINCIPLES FOR PROTECTING THE INTEGRITY IN THE CONDUCT AND REPORTING OF CLINICAL TRIALS

American Association of Clinical Endocrinologists
American College of Epidemiology
American College of Neuropsychopharmacology
American Heart Association
American Medical Association
American Pediatric Society
American Society for Bone and Mineral Research
Association of Medical School Pediatrics Department Chairs
Bone
Calcified Tissue International
Endocrine Practice
Federation of American Societies for Experimental Biology
International Society for Clinical Densitometry
International Bone and Mineral Society
Journal of Bone and Mineral Research
Journal of Clinical Densitometry
National Osteoporosis Foundation
Osteoporosis International
Society for General Internal Medicine
Society for Pediatric Research
The BlueCrossBlueShield Association and every (38) BCBS Plan in the United States
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