To Integrity and Beyond

At its annual meeting in October 2010, the editorial board of Pediatrics discussed a number of substantive issues related to the integrity of the scientific content of the journal. Topics included better identification of potential conflicts of interest, criteria for authorship, clinical trials registration, and clarifying our policies regarding industry-sponsored studies. As readers might imagine, these topics generated lively discussion. The editorial board ultimately reached consensus on each of these subjects, and this commentary describes the results of our deliberations.

REPORTING POTENTIAL CONFLICTS OF INTEREST

The trust that our readers have in the scientific content of the journal rests in part on their confidence that any potential conflict of interest has been openly declared. The Institute of Medicine in its 2009 report defined a potential conflict of interest as “a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest.” It is important to understand that declaring a potential conflict does not imply that judgment has been influenced, only that the conditions exist under which it could be perceived to have been. Reviewers and readers may make their own assessments of whether judgment has been influenced. A potential secondary interest may be financial or nonfinancial and may be directly or indirectly related to the submitted manuscript. A directly related financial interest, for example, would exist if the author were an employee of the sponsoring commercial entity. A nonfinancial secondary interest might include “the desire for professional advancement, recognition for personal achievement, and favors to friends and family or to students and colleagues.” Secondary interests that are not related to the submitted work (eg, a consultancy in an unrelated field) do not create a potential conflict and, thus, do not need to be reported. However, if an author is not sure how a potential conflict might be perceived, erring on the side of disclosure is prudent.

Because peer-reviewed medical journals require authors to disclose potential conflicts of interest, a uniform way to report this information would be of great value and a true time-saver to those who submit manuscripts to a variety of publications. After several years of testing and revision, the International Committee of Medical Journal Editors (ICMJE), a group of 11 medical journal editors who establish policies and guidelines for their own journals and for others to adopt as they wish, finalized in July 2010 a standard conflict-of-interest reporting form. The form can be saved on a personal computer so that minimal revision is required each time a conflict-of-interest form is requested by a participating journal. Readers can peruse the form at www.icmje.org to gain a better understanding of the types of questions now being asked in regard to potential conflicts of interest. The Journal of the American Medical Association, New England Journal of Medicine, Annals of Internal Medicine, British Medical Journal, and the Canadian

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ABBREVIATION

ICMJE—International Committee of Medical Journal Editors

Opinions expressed in these commentaries are those of the author and not necessarily those of the American Academy of Pediatrics or its Committees.

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Medical Association Journal, among others, already use this form. Conversations with some of our fellow pediatric peer-reviewed journal editors (including those for the Journal of Pediatrics, Archives of Pediatric and Adolescent Medicine, the British journal Archives of Disease in Childhood, and Clinical Pediatrics) suggest widespread enthusiasm for adopting the use of this form. As of this month, we will require that authors submitting manuscripts to Pediatrics use the ICMJE form to report potential conflicts of interest. Members of our editorial board have filed their forms, to be updated as needed, and we are working on the logistics of having reviewers use this form to declare their potential conflicts.

AUTHORSHIP AND CONTRIBUTORSHIP

Authorship of scientific articles is the currency of academic medicine and, as such, is highly valued. Perhaps because it is so highly valued, the specific criteria for authorship are sometimes adhered to loosely. Pediatrics follows widely accepted guidelines (well summarized by the ICMJE) for authorship, as described in our author guidelines (www.pediatrics.org/misc/Author_Instructions_2010.pdf).

To qualify as an author, a person must meet all 3 of the following criteria: (1) make a substantial contribution to the intellectual content of the manuscript; (2) either draft or critically review the manuscript; and (3) approve the submitted version of the manuscript. A person's intellectual contribution could involve the conception and design of the study, the acquisition of data (although data collection alone does not qualify a person for authorship), or analysis and interpretation of the data. Ethical standards demand the inclusion as an author of every person who has made these contributions and the exclusion from authorship of those who have not. People who have made significant contributions (such as data collectors, medical writers or editors, or supportive bosses) but do not qualify for authorship should, with their permission, be acknowledged.

For some time, our online instructions to authors have included the requirement for a statement outlining the contributions of each author. As of this month, we will ask that each author, on the same form on which copyright is transferred to the journal, also sign an attestation regarding his or her specific contributions to the work. The lead author will be asked to attest that all persons who qualify as authors have been included and will also attest that those who are acknowledged have given permission for that acknowledgment.

REGISTRATION OF CLINICAL TRIALS

The likelihood that the results of a clinical trial will be published has long been noted to be related to the strength and direction of the results of the study. Consequently, sometimes authors opt not to submit, and some journals may opt not to publish, “negative” studies, which results in a bias in favor of interventions among published studies. Unfortunately, studies with results that were unfavorable to industry sponsors were also, at times, not submitted, because the sponsor controlled the decisions regarding which, if any, results to publish; clearly, publishing results most favorable to their products was in their own, and their shareholders’, best interests. Registries for clinical trials were created to address the problem of suppression of results, with the intent that the existence of all trials would be public knowledge, and selective reporting of only positive results would be discouraged. The most commonly used registry in the United States (www.clinicaltrials.gov) is sponsored by the federal government, but approved registries exist all over the world. In 2005, the ICMJE announced that its member journals would only publish clinical trials that were registered in an approved clinical trial registry before the start of the trial and, in 2007, updated its statement to broaden the scope of included clinical trials. Pediatrics has supported the ICMJE policy but has not yet been as formal in broadening this scope as we now propose to be.

The ICMJE definition of a clinical trial is “any research project that prospectively assigns human subjects to intervention or concurrent comparison or control groups to study the cause-and-effect relationship between a medical intervention and a health outcome. Medical interventions include drugs, surgical procedures, devices, behavioral treatments, process-of-care changes, and the like.” The outcomes must be “health outcomes” (eg, mortality, morbidity, quality of life). Thus, most medical education trials, and trials in which the outcome is a measure of knowledge or of health care provider behavior, do not require registration, although registration of all trials is encouraged. Also, note that a study need not be randomized to be considered a clinical trial; the key is that the exposure is under the control of the investigator.

Our editorial board has endorsed a policy of adherence to the 2007 ICMJE rules for registration of clinical trials. Commercial sponsors, who interact with the US Food and Drug Administration, have been well aware of this policy since its inception, and effective immediately, studies with commercial sponsorship will be required to show that the trial was registered before enrollment of the first patient. Because many investigators who do not perform sponsored research have not been aware of the requirements for trial registration, trials that are not commercially sponsored and in which
registration may not have occurred until after the first patient was enrolled will be considered on a case-by-case basis by the editors for the next 2 years. Thereafter, all clinical trials submitted to Pediatrics will be subject to the same rules. A list of approved registries in other countries can be found on the ICMJE Web site (www.icmje.org/faq_clinical.html).

SPONSORED STUDIES

In the wake of the publicity surrounding data that were both misrepresented and suppressed in the pharmaceutical company–sponsored rosiglitazone trials,3 several journals now require that, for sponsored studies, the lead non–pharmaceutical company author attest that he or she had full access to all data and takes responsibility for their integrity. Some journals (eg, the Journal of the American Medical Association) require that, for industry-sponsored clinical trials, the data must be reanalyzed by an independent, academic institution at the sponsor’s expense. Effective immediately, on the same form on which they attest to their own contributions to the submitted work, authors will find a statement, to which the lead author must attest, that he or she had full access to all of the data used in the study and that he or she takes full responsibility for the integrity of the data and the data analyses. The statement further specifies that the data for all submissions, including those that are industry-sponsored, will be made available to the editors for examination if so requested.

Although the new policies discussed above are driven by the actions of a small minority of investigators, we believe that implementation of these policies will further strengthen the integrity of the information that we share monthly with our readers in Pediatrics. We are confident that every enhancement of the validity and reliability of the information we publish will lead to better health outcomes for our patients, which is what we strive to accomplish with each and every issue of Pediatrics.

REFERENCES

3. DeAngelis CD, Fontanarosa PB. Ensuring integrity in industry-sponsored research: primum non nocere, revisited. JAMA. 2010;303(12):1196–1198