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Editorial

Clinical Trial Registration

As editor of Operative Dentistry, one of my driving motivators is a desire to maintain the journal's stature as an upper echelon dental journal. In an ever-changing publishing world, required decisions go far beyond whether or not a given manuscript should be accepted for publication. For instance, our editorial staff considers recommendations made by the International Committee of Medical Journal Editors (ICMJE), an organization that outlines ethical principles and other publication guidelines for authors and editors in the health sciences.

In recent years, the ICMJE has advocated for the registration of all randomized clinical trials in searchable electronic databases available to the public at no cost.[1] Because there is no peer review mechanism associated with the registry, these databases hold information concerning the protocols but exclude the results of the trials. One reason for this suggested policy is the belief that a greater level of transparency will enhance the likelihood that a trial will be completed as planned and therefore increases the reliability of the evidence that the trial provides. A description of the required information for the database is included in the United States Federal Drug Administration Amendments Act of 2007.[2]

As with many such initiatives that touch multiple complex issues, this registry has proven to be controversial largely because it makes public, on a broad scale, the path of investigation that a particular research team is taking. In dentistry, many of these trials involve products that do not have patent protection because of their similarity to other existing products. Utilizing a public registry prospectively, before recruiting subjects, could arguably hinder a potential market advantage for dental manufacturers. Of note, the registry guidelines specifically state that feasibility or pilot studies are not intended to be covered. Rather, only larger efficacy studies that carry more clinical relevance for the public are targeted. On the positive side, registering randomized clinical trials provides an additional level of oversight to the appropriate conduct and reporting of the work. These clinical trials are designed to answer specific questions. Registered trials could assist editors and reviewers in discerning whether the aims of a trial were met or whether, retrospectively, data was manipulated or omitted in order to provide a positive result.[3]

At a recent Chicago meeting of journal editors and other interested parties, several journals (including the Journal of Dental Research, the Journal of the American Dental Association and the Journal of Periodontology) made it known that they have instituted a registration requirement. At least one journal is requiring registration, but not prospectively. But, it was clear that not all journals were excited about moving in this direction.

One hundred seventy-four dental publications are included in the PubMed/Medline's National Library of Medicine Catalog[4] and the American Dental Association holds over 600 journal titles in its library.[5] Each of these publications must make a decision about whether it is important for them to require this registration and I fully expect that there will be some who will opt out. Thus, clinical trial registration will become another factor that differentiates our dental publications. I believe that Operative Dentistry must continue to be a reliable source of the best available evidence for decisions regarding oral health. It seems to me that focusing on a high level of credibility in today's world of multiple information sources would uphold the reputation of this journal for the members of its supporting academies.

Moving forward, authors submitting to Operative Dentistry will be asked to provide registration information that our editors, reviewers, and staff can validate. (This registration will be in addition to the requirement of providing appropriate approval from a human subjects oversight committee given prospectively for any study using human subjects or tissues.) Completion of the registration process is a fairly innocuous task and can happen on any publically accessible database such as NIHClinicalTrials.gov. More specific instructions will be included in the journal's instructions to authors.

It is my hope that clinical trial registration will help keep this journal, and thus our sponsoring

Academies, recognized as desiring to provide optimal care for the people we serve. I am grateful for the many researchers around the world who contribute to our quest for knowledge, no matter whether they work in the private or public sector. I look forward to continuing to publish the best of that work.

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3. Philstrom B (2012) Public registration of clinical trials: good for patients, good for dentists *Journal of the American Dental Association* **143(1)** 9-11.
4. National Center for Biotechnology Information (2013) NLM catalog. Retrieved online April 30, 2013 from http://www.ncbi.nlm.nih.gov/nlmcatalog.
5. American Dental Association (2013) ADA library: current journals. Retrieved online April 30, 2013 from http://webopac.ada.org/eLibSQL04_A60005_Documents/journals-current-external.pdf.

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