EDITORIAL

Improving Clinical Trials in Dentistry

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The randomized controlled clinical trial (RCT) is generally considered the gold standard of scientific human clinical investigation. RCTs that are properly designed, powered, and reported have led to important advancements in the biomedical sciences for the improvement of patient care and assurance of safety. Given the major limitations in extrapolating preclinical animal modeling to the replication of human diseases, RCTs and other human clinical investigations are more important than ever in the development of new clinical therapies for our patients (Hamburg 2011). These medical advances led by RCTs have blossomed into important innovations in patient care over the years with new drugs, devices, and biologics for the promotion of oral health. For the entry of transformative therapeutics to the clinical arena, the diligent adherence to good clinical practice (GCP) and best practices builds confidence in practitioners, patient advocates, and patients who rely on quality clinical trials. A challenge for dentistry has been the very slow adoption of clinical trial registration and quality metrics reporting compared with our medical colleagues. There have been several calls to action, and it is clear that dentistry is now on

the right path toward improvements in registration and reporting.

In this month's issue of the *Journal of Dental Research* (JDR), Smail-Faugeron and coworkers provide a thorough and enlightening assessment of leading journals in dentistry. They report that less than 25% of all RCTs are registered on an international public access database registry (Smail-Faugeron et al. 2015). This situation has also been shown in overall low adherence of trial registration and quality reporting in other areas of the oral health sciences (Faggion and Giannakopoulos 2012). Compared with several years ago, this is a significant improvement, but editors' groups in dentistry recognize that we need to be diligent to strive toward 100% clinical trial registration with increasing standards for publication. It has been clearly demonstrated that there are rewards of clinical trial registration to patients and health care providers alike (Laine et al. 2007; Pihlstrom 2012; Ioannidis et al. 2014). It is now accepted practice for governmental regulatory agencies, ethical boards, and clinical research organizations to require registration given the known benefits to the clinical research community. Clinical trial registration is not only of value to the reporting of RCTs but is also of usefulness in the verification of end points identified a priori for large-scale epidemiological studies (Giannobile 2014). As such, it is recommended

that studies be both registered and in compliance with the Consolidated Standards of Reporting Trials (CONSORT; www.consort-statement.org). The STROBE statement (STrengthening the Reporting of OBservational studies in Epidemiology; www.strobe-statement.org) is of great value in the reporting of epidemiological and observational studies and is required for these studies submitted to the JDR. The journal has required CONSORT and STROBE compliance for a number of years now, and our editorial office assists authors with questions they may have on adherence to these guidelines.

The International Committee of Medical Journal Editors (ICMJE) placed a stake in the ground over 10 years ago to make the important stance to phase in the clinical trial registration to benefit patient safety by reporting a priori the clinical trial end points (De Angelis et al. 2004). Three years ago, the JDR announced that we were going to phase in requirements of clinical trial registration as well (Giannobile 2012). Effective at this writing, all studies submitted to the JDR require a priori clinical trial registration prior to study initiation after 2014. We will no longer review RCTs that do not have a priori clinical trial registration. Fortunately, the large majority of our papers already adhere to the ICMJE guidelines and are consistent with leading medical and dental journals as the industry standard.

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Careful assessments of clinical trial registration have clearly proven that the registration process works well as an effective and financially viable methodology that can ensure the standards are met for quality reporting of clinical trials (McFadden et al. 2014). It is now up to us as active investigators, teachers, and mentors to extend this concept as standard practice in dental medicine.

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