

Open access, transparency, and quality of information in clinical trials

Various initiatives in the last decade have attempted to guarantee both open access to data and transparency of information in clinical trials and led to the creation of the International Clinical Trials Registry Platform by the WHO in 2007. According to the revision of the *Declaration of Helsinki* in 2008 (Article 30), authors, editors, and publishers have ethical obligations concerning the publication of the results of clinical trials, publishing or otherwise making publicly available all negative, inconclusive, and positive results, as well as funding sources, institutional affiliations, and conflicts of interest. In Latin America, three measures have called for the registration and publication, in Portuguese, of information on clinical trials conducted in Brazil: (1) a recommendation by the Latin American and Caribbean Center on Health Sciences Information (BIREME) to editors of scientific journals in the health field that are indexed in the Scientific Electronic Library Online (SciELO) and LILACS (Latin American and Caribbean Literature on Health Sciences Information); (2) the creation of the Brazilian Clinical Trials Registry (ReBEC); and (3) a specific ruling by the National Health Surveillance Agency (ANVISA; RDC n. 36 of June 27, 2012). The commitment to publication of results on all subjects enrolled in clinical trials is based on the notions of altruism and the common public good, efforts to reduce publication bias and unnecessary duplication of research efforts, and greater added value from clinical trial results by providing a reliable and unbiased source of information for systematic reviews, meta-analyses, and evidence-based guidelines. Despite such efforts, the article by Reveiz et al. (p. 1095-100), published in this issue, shows that: journals' adherence to the recommendation by BIREME is limited to two-thirds of publications, only 20% of articles report the registration of randomized clinical trials, and fewer than 7% of trials are registered prospectively, i.e., prior to recruitment of the first study subject. In instructions to authors, only 13% of journals mention the use of CONSORT (Consolidated Standards of Reporting Trials) in data reporting on randomized controlled clinical trials. This shows that commitment to registration of clinical trials and quality of information reported in articles depend on the restrictions imposed by journals during article submissions. Action by regulatory and funding agencies, namely by conditioning study approval and funding on prospective registration of the clinical trial, can potentially improve this situation. Reveiz et al. emphasize that journal editors and publishers should join with regulatory and funding agencies, federal government offices, and international and nongovernmental organizations to establish mechanisms for promoting and expanding access to information from clinical trials through their registration and the use of specific guidelines to improve the quality of data reporting. The position by Guido Rasi, Executive Director of the European Medicines Agency, in the workshop entitled *Access to Clinical-Trial Data and Transparency* (http://www.ema.europa.eu/docs/en_GB/document_library/Report/2012/12/WC500135841.pdf), emphasizing the agency's commitment to the publication of clinical trial data after conclusion of the market authorization process, summarizes the current stage of the discussion on open access to data and information from clinical trials: "*Today represents the first step in delivering our vision. We are not here to decide if we will publish clinical-trial data, only how. We need to do this in order to rebuild trust and confidence in the whole system*".

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