The necessity of a public register of clinical trials

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Some recent articles, published simultaneously in several important medical journals such as the New England Journal of Medicine and The Lancet, called the attention to those interested in clinical research [1, 2]. Clinical research is the method of scientific investigation using non-pharmacological or pharmacological therapeutic interventions that involve human beings, analyzing the efficacy and safety of new medications, new surgical techniques or diagnostical investigations. In brief, the articles comment that these journals will demand, starting in September 2005, a prior register of clinical trials in a North American site (www.clinicaltrials.gov) before any articles are accepted for publication. According to the articles, the journals will make this demand in the name of respect and to guarantee access to the information by patients and for public opinion.

With this attitude, the periodicals will also try to reduce the possibility of publication bias, a kind of favoring researches with positive results. In other words, scientific works in which the results confirm the expectations of the researchers or sponsors will have a greater chance of success to have their results published. The interest of the reader may explain the occurrence of bias in publishing, though there are already some initiatives in which the priority is research with negative or unexpected results. The access to www.clinicaltrials.gov is free and the initial page requires an individual or group to register in the name of an institution or company. The registration must be completed in English but it is relatively easy. It is an American initiative, but there are already some Canadian and European centers registered, as well as several pharmaceutical companies and the World Heath Organization (WHO) [3]. The curious point of the process, in our view, is that the short list of the 20 pre-requisites necessary for the registration of a clinical trial are already practically filled in, when, in Brazil, National Commission on Ethics in Research (CONEP) must be consulted about any project. The on-line registration page of CONEP has all or almost all this information and, at least theoretically, it is public. For some time the Commissions on Public Ethics (CEPs) have not accepted any clinical studies that are not registered in CONEP, putting us at the forefront of this initiative. And so why register twice? Can CONEP, in Brazil, be considered an equivalent to the North American register as is the case of Scielo and Medline?

Taking the initiative, the editorial body of the Journal of the Brazilian Medical Association (RAMB), sponsored a discussion on this question and discussed the opinions of several researchers and editors of Brazilian medical journals. The majority of the participants agreed that the register of CONEP should be, at least in part, sufficient. It was suggested that CONEP should be registered in www.clinicaltrials.gov as mother-entity and that all Brazilian randomized clinical studies approved on the site would be registered, similar to the North American National Institutes of Health. Thereby, duplicate registrations might be avoided by researchers but the situation of our clinical studies would be regularized. CONEP is an entity that has excellent international respect and would have no difficulty in being accepted in this role.

It was remembered that the British Medical Journal (BMJ) raised some arguments, including the difficulty of registering in the USA and, for this, was not party to the decision, suggesting that the posture of other journals should also be analysed. It was even discussed whether registration should be necessary for studies published in Brazilian journals. On the other hand, the limitations of the national system were highlighted. Remember that only 227 of the approximately 400 CEPs that exist in Brazil are linked to the National System on Research Ethics (SISNEP). Additionally, if some CEP does not confirm receipt of a project within 30 days after registration in SISNEP the registration number is cancelled. Some fears in relation to the public character were apparent: this type of 'very open' register could be the cause of a loss of originality of the research.

The intention of this editorial is not to establish a

consensus, but to amplify this discussion to the entire Brazilian scientific community. The ideas and concepts discussed here represent the synthesis of several opinions communicated by e-mail or personally. Only with the participation of the entire national scientific community including institutions involved in clinical research including CONEP, National Health Inspection Agency (ANVISA), the Science and Technology Ministry, the Heath Ministry and the World Health Organization (WHO) will it be possible to decide the best way to the precious ideas to develop, as one participant said, 'in the land of Brazilis'.

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Editor da Brazilian Medical Association Journal (Revista da Associação Médica Brasileira - RAMB)

Note of the Editor

Editorial originally published in volume 51 (6) of Revista da Associação Médica Brasileira (RAMB).

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