Editorial

Works in the field of tuberculosis study published in the Brazilian Journal of Pulmonology between 2004 and 2011: types of articles, study models, level of scientific evidence, and social impact

Publicações na área de tisiologia no Jornal Brasileiro de Pneumologia entre 2004 e 2011: tipos de artigos, modelos de estudo, grau de evidência científica e impacto social

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The prospects for advances in tuberculosis (TB) research over the coming decade are paralleled only by the discovery of *Mycobacterium tuberculosis* by Robert Koch in 1882, as well as by the discovery of the first effective anti-TB drug, streptomycin, by Selman Waksman in 1943. The explosion of scientific and technological development over the last two decades, together with the recognition that the global TB epidemic has become a serious worldwide problem, has led to a reallocation of financial resources and efforts with the purpose of addressing critical points in the field of TB. Of the 13 original articles in the current issue of the Brazilian Journal of Pulmonology (BJP), 4 are related to TB.[1-4] The subject of TB has once more been given weight in medical schools and institutions of higher learning in the field of health care. In addition, there is growing interest on the part of specialized journals in disseminating scientific production in the field of TB. In 2006, the Stop TB initiative declared the promotion and dissemination of TB research an important component of TB control.[5] There is now a consensus, among public policy makers and researchers alike, that multidisciplinary research, combining the areas of primary care, clinical practice, and operations, should be a worldwide priority.[6] Such research should include a broad spectrum of activities, not only those designed to meet local demands and improve the performance of TB control programs but also those focusing on international policies. In this scenario, the development of new technologies should be linked to their assessment and to the impact that their use will have on the health care system.[7,8] At the national level, TB control programs should prioritize operational research projects involving various partnerships in order to identify local or regional problems and to devise appropriate solutions. At the international level, a robust evidence base (including the use

of systematic reviews, as well as assessment of the level of scientific evidence and of the impact of the use of new technologies) has become increasingly necessary for guiding the formulation (or reformulation) of health care policies.[9,10]

An environment that is conducive to research is essential for achieving the potential for improving TB control programs at all levels. All protagonists should be aware of the benefits of building research capacity through collaboration among public/private health care systems, the academic community (research institutions and local universities), and civil society, by means of nongovernmental organizations (NGOs) engaging in advocacy/assistance, together with research associations, such as the *Rede Brasileira de Pesquisas em Tuberculose* (Rede TB, Brazilian Tuberculosis Research Network), religious institutions, professional associations, such as the Brazilian Thoracic Association, and industry (domestic or foreign).

This editorial provides readers with an analysis of the 144 articles published in the field of tuberculosis study in the BJP between January of 2004 and May of 2011. The articles were categorized by type (original article, case report, opinion, letter, and editorial) on the basis of a classification described elsewhere.[11] Studies using qualitative variables were selected. Original articles were classified by type of study (survey, questionnaire, observational, intervention, and basic research). In order to assess the level of scientific evidence, we used a system developed by the GRADE Working Group.[9] This system classifies the level of scientific evidence on the basis of the ability of a study to avoid systematic errors or bias, as follows: level 1—clinical trials and systematic reviews/meta-analyses of clinical trials; level 2—observation cohort and case-control studies; level 3—descriptive studies, whether analytical or not, with no comparison

group; and level 4—case studies or expert opinions. We assessed social impact only for the articles classified as level 1 or 2, and the scores ranged from 0 to 10, a score of 10 indicating the greatest social impact. We used a modified version of the criterion proposed by Cecilio,[12] and we assessed the following items: geographic coverage; inclusion of an at-risk population or inclusion of aspects related to equity; impact on epidemiological markers; socioeconomic consequences for patients and for the health care system; economic and financial capacity of the TB control program to incorporate new technologies; and national/international implications. In order to identify partnerships, we evaluated the participation of authors and institutions affiliated with the academic community, public/private health care systems, NGOs, the Rede TB, and domestic or foreign industry, as well as the reporting of funding sources (required by the BJP since September of 2008), in all articles.

Of the 144 articles published during the study period, 110 (76.4%) were original articles (75 were descriptive studies and 35 were analytical descriptive studies), 8 were letters to the editor, 8 were viewpoints or interpretive summaries, 9 were case reports, and 9 were editorials. Regarding the type of study, the original articles were classified as follows: survey (n = 52); questionnaire study (n = 23); basic research study (n = 11); observational, retrospective cohort study (n = 5); observational, prospective cohort study (n = 5); observational, case-control study (n = 5); observational, cross-sectional study (n = 1); intervention study (n = 4, of which 1 was a pragmatic trial); mathematical model (n = 1); and article for the dissemination of regulations and guidelines (n = 3). There was only one article in which a qualitative method was used. Using the GRADE system, we found that only 18 (12.4%) of the 144 articles assessed were classified as level 1 or 2 (3 and 15 articles, respectively), whereas 94 (65.4%) and 32 (22.2%), respectively, were classified as level 3 or 4. The analysis of authors and partnerships revealed the following, in decreasing order of frequency: 97 articles (67.4%) from the academic community; 32 articles (22.2%) from the academic community and public/private health care systems; and 3 articles (1.4%) from the academic community, public/private health care systems, and civil society. No article mentioned domestic or foreign industry. The participation of the Rede TB was observed in 88

articles (61%). In 3 (16.7%) of the 18 articles providing the highest level of scientific evidence, the social impact score was equal to or greater than 7, whereas it was 4 or 5 in 11 other articles (61%).

In the last seven and a half years, 823 articles were published in the BJP, 144 (17.4%) of which addressed the subject of TB. Of the 59 articles on TB published since September of 2008, only 15 (25%) reported the funding sources. These data strongly suggest the need for reflection on the part of all actors and protagonists in the field of tuberculosis research in Brazil. In all of the years studied, the participation of authors from the academic community was found to be greater than was that of those from the public health care system, and there were few articles providing a high level of scientific evidence; even those providing such evidence were classified as having little social impact. It is expected that as of June of 2012, when the first impact factor for the BJP will be issued, there will be a growing trend to publish articles providing a higher level of scientific evidence. As previously reported in a similar analysis including the entire scientific production in the field of TB in Brazil between 1986 and 2006, the following problems persist: scientific production remains the domain of the academic community, which responds to the demands of the *Coordenação de Aperfeiçoamento de Pessoal de Nível Superior* (CAPES, Office for the Advancement of Higher Education); there is no participation by the private health care system, which is typically associated with explanatory (phases I, II, or III) clinical trials; and scientific production involving assessment of the impact of new technologies is poor. During the period studied, only one pragmatic clinical trial was published in the JBP. [13] Only after two decades of systematic reviews and meta-analyses was it was realized that the outcomes assessed in most clinical trials do not answer the key questions involved in the decision of whether or not to incorporate the technology into the health care system; such studies involve specific populations that are unrepresentative of the general population and, in general, do not include cost-effectiveness evaluations.[14] Therefore, explanatory clinical trials, conducted at clinical research centers, seek to answer questions of effectiveness—whether and how an intervention works—in order to register a product or procedure with regulatory agencies such as the *Agência Nacional de Vigilância Sanitária* (ANVISA, Brazilian National Health Oversight

Agency) and the Food and Drug Administration. Pragmatic trials are conducted to support decision making in the health care area and, to that end, are carried out under conditions that are very close to those under which health care facilities routinely work. Pragmatic trials also involve patients who are very similar to those who will need treatment in the future.

In view of the aforementioned facts, it is imperative that funds be earmarked for the support of studies providing a higher level of scientific evidence, presenting real clinical relevance, and having a major social impact. In Brazil, an emerging country on the international stage, a coordinated movement involving joint efforts among applied basic research, clinical research, and operational research will occur only if this allocation of funds is, in fact, prioritized by the academic community, as well as by the departments and agencies of the Brazilian National Ministry of Health (the Department of Health Surveillance; the Health Care Department/Division of Primary Health Care; the Department for the Management of Work and Education in Health; the National Health Agency; and ANVISA), federal funding agencies (the Brazilian National Council for Scientific and Technological Development; CAPES; the Financing Agency for Studies and Projects; and the Department of Science, Technology and Strategic Resources), state research foundations, and civil society.

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