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Perspectivas

Perspectives of Pharmacoeconomics to improve access to the Brazilian Public Health System

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The Brazilian health care model was proposed to meet the entire Brazilian population, organized for equity and comprehensive care, ensuring the participation of society. This complex model has structured the country's Public Health System (PHS). Currently, the PHS is undergoing changes and facing difficulties, amidst which we highlight here those related to administrative and financial aspects. One of the important points of PHS financial matters is that the state allocated funds have not been sufficient to maintain adequate access to health and quality of care[1].

Regarding the financial situation concerning the PHS, the decision-making processes have gained strength to rationalize access to health care and maintain quality. It is noteworthy that the Brazilian context of health care decision making relates to two main types of decisions: pricing of new medications or procedures and incorporation of technologies into the PHS. It is of broad interest for the PHS to incorporate effective therapeutic alternatives for the treatment of diseases. Thus, it is possible to reduce rising expenses with the judicialization of health, a process aimed at ensuring access and occurs outside the health system management budgets, affecting health planning for the PHS. In this sense, pharmacoeconomics has been an efficient method for implementing health technologies for reducing costs and improving quality access to the PHS, because it is able to promote the power of decisions, rationalization of expenditures, and supports the best judicial decision[1,2].

The implementation of pharmacoeconomics for health technology assessment (HTA) emerged in Brazil in order to rationalize the incorporation of new drugs into the health system. The Ministry of Health created the coordination of the Department of Health Care in 2006 to provide for the rational incorporation of flow technologies into the PHS, standardized by Order n. 152/2006 and n. 3323/2006. Prospectively, a specific administrative body was created for such activity, the Coordination of Technology Incorporation Committee - *CITEC* was transferred in 2008 under Order n. 2587/2008, to the Secretariat of Science, Technology and Strategic Inputs *SCTIE*.

In 2011, Law 12.401 established a committee for the implementation of pharmacoeconomics in the PHS, creating the National Commission on Technology - *CONITEC*, which replaced *CITEC* [3].

According to the diagnosis made by the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) in the Latin American Conference in 2011, Brazil was ahead of most Latin American countries in the implementation phase of pharmacoeconomic guideline, while in Chile and Mexico the guideline was being developed and, in other countries it was under consideration. In the ISPOR conference in 2015 in Santiago Chile, there were 427 presentations at the event, an increase of 20.7 %, which shows the expansion of this issue in Latin America, following the international expansion of this area (Figure 1).

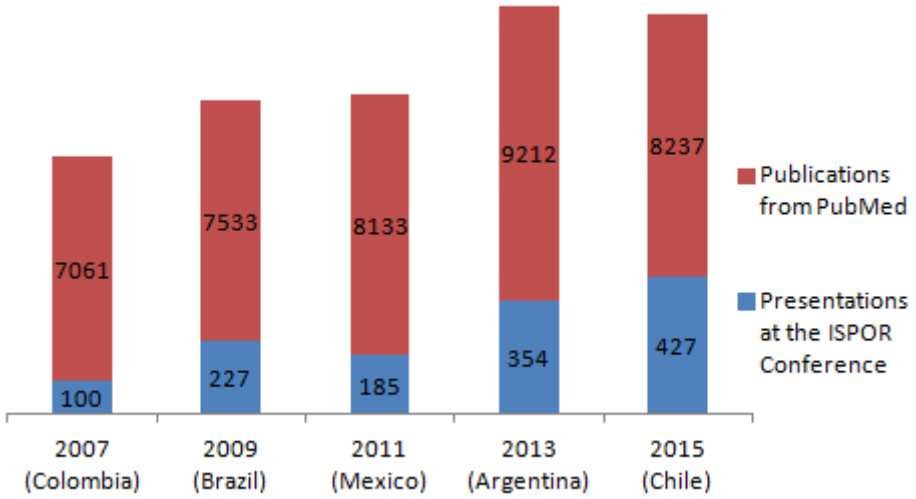

Figure 1. Scientific evolution of pharmacoeconomics highlighting Latin America, measured by number of scientific presentations at the ISPOR Conference. Legend: A) the x axis is "year (country)", Colombia, Brazil, Mexico, Argentina, Chile were host countries of the ISPOR Latin America conference. B) The search of articles from PubMed was performed as follows: descriptors used and search form - ("Economics, Pharmaceutical") OR ("Costs and Cost Analysis") OR ("Cost-Effectiveness Evaluation") OR ("Cost-Benefit Analysis"). The filter used for the search is two sequence years presented in the graph, which includes the year prior to, and of the ISPOR conference.

Created in 2008, the Brazilian Network for Health Technology Assessment - *REBRATS* played an important role in highlighting Brazil in Latin America, because it has been responsible for the production and dissemination of studies and priority research in the HTA field. Therefore, it has main role in the standardization of methodologies, validation studies, professional training and development of mechanisms for monitoring the technological horizon. However, the evaluation of health technologies for expanding access to the PHS with quality, has presented some difficulties[1,3]. Four points can be highlighted regarding the difficulties of the quality of pharmacoeconomic studies in Brazil and their collaboration for the health quality access in the PHS (Figure 2) [3,4,5,6].

Figure 2. Aspects related to quality of pharmacoeconomic studies in Brazil that have impaired to the quality of health access in the PHS.

Health data systems in Brazil have large backlogs or failures. Underreporting and being no linked databases are among the main problems. Although, there have been efforts by the Ministry of Health to create a integrated health database, this process is still slow and has some gaps. The initiative of some research groups to create data platforms that unify the records of the same patient will be very good for the robustness of pharmacoeconomic studies in Brazil [5].

As discussed in the Brazilian session of the ISPOR - V conference of Latin America, the parameters for cost thresholds in Latin America are not well defined. These countries have taken as reference the value of three times the Gross Domestic Product *per capita* as the limit for investments. Thus, this threshold only can be considered robust for very expensive diseases and countries with a stable economy. However, a universal health system from a country with an unstable economy generates a vague limit for investment in health[3].

The pharmaceutical industry certainly plays an important role in aggravation of this problem, making the rational use of drugs (RUD) more difficult. The RUD begins with decision-making in health planning and culminates in the user's system. It is noteworthy that the power of influence of the industry is not restricted only to production of basic scientific evidence, but also in evidence synthesis and understanding of security. This compromises the evaluation of the effectiveness, utility, and projected benefit, which influences the formulation of guidelines for clinical practice, health education professionals in the practice of health care, and in decisions in health[6].

The aforementioned difficulties have contributed with biases in pharmacoeconomic analysis, such as clinical comparisons, choice of comparator indicators, modeling issues and calculation errors concerning medication costs. This has led to misinterpretation of results, corroborating for the uncertainty or failure in the decision-making process. Additionally, this problem has been

aggravated by often not declared or masked conflicts of interest [4].

These issues have contributed to make the access to health even more difficult and to hamper the PHS financial health. It is necessary to identify and solve these issues in order to develop a wide and consolidated network of clinical protocols and guidelines grounded in pharmacoeconomic studies. Hence, it will be possible to overcome health system failures, make the judicialization process a predictable instrument to improve access to health, provide support to rational drug use, and make access to health less costly to the PHS.

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