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Institutionalizing Health Technology Assessment in Brazil: Challenges Ahead

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ABSTRACT

The evolving process of institutionalizing health technology assessment (HTA) in low- and middle-income countries is not yet fully understood. The present article aims to provide an analysis of some of the most recent changes in the development of HTA in Brazil, as well as the main challenges and potential barriers that may determine the process of institutionalizing HTA in the country vis-à-vis the recent approval of its federal HTA law at the end of 2011. Based on the authors' experience in HTA from an academic research perspective as well as from national and regional/local policymaking implementations, this article also proposes some measures to foster the institutionalization of HTA, for which Brazil would have to overcome three fundamental challenges for decision making: 1) Brazil has to complete an unfinished agenda regarding the implementation of its national Unified Health System (SUS), 2) the complex governance of the SUS has to be thoroughly reassessed, and 3) HTA institutionalization is to be promoted to strengthen decision making. The recent creation of a Brazilian national HTA body represents an important step not only in terms of the development of HTA in the country but also regarding the consolidation of the universal access to health care that is guaranteed by the Brazilian Federal Constitution since the creation of SUS in 1988. There is an urgent need to promote broader approaches to assess the complexity of the governance of the SUS, thus strengthening the process of HTA within the decision-making process.

Keywords: Brazil, developing country, health technology assessment, middle-income country.

Introduction

To date, the process of institutionalization of health technology assessment (HTA) in low- and middle-income countries though evolving is still immature. HTA development entails different aspects such as the existence of HTA bodies with the capacity to identify, prioritize, and appraise new technologies as well as to report, disseminate, and implement the resulting assessments. Studying the development and institutionalization of HTA in some middle-income countries, Oortwijn et al. [1] found a substantial heterogeneity in the experiences of Argentina, Brazil, India, Indonesia, Malaysia, Mexico, and Russia. According to the authors, the current main efforts to institutionalize HTA in those countries are dedicated fundamentally to instruct and train new personnel to perform HTA, which is an important but insufficient step. Furthermore, from the perspective of low- and middle-income countries, the institutionalization of HTA at a national level goes beyond training personnel and depends not only on context-dependent factors (i.e. social, economic, political, and cultural aspects) but also on political commitment, capacity for investment, the development and degree of maturity of the decision-making processes as well as the structure of the national health care systems, among others. These are important aspects to foster the institutionalization of HTA in every country but are crucial determinants from the perspective of low- and middle-income ones.

Brazil is a middle-income country that in 2011 had an estimated population size of 192.4 million inhabitants [2]. The country has a public-funded national health care system, the Sistema Único de Saúde (SUS). The SUS provides universal access to all Brazilian citizens free of charge. Brazil's economy has experienced a relatively recent process of industrialization, which has placed it as the sixth largest economy worldwide, with a 2011 gross domestic product current purchasing power parity of US $2294 [3]. The development of HTA in Brazil has been assessed by others studies [4,5], which described its historical antecedents and previous existing national HTA bodies [4] as well as "an anthropological inquiry" into HTA and technology incorporation in Brazil [5]. The present article provides an analysis aiming to address some of the most recent changes in the development of HTA in Brazil, as well as the main challenges and potential barriers that may determine the process of institutionalization of HTA in the country vis-à-vis the recent approval of its federal HTA law in 2011. Based on the authors' experience in HTA as scholars as

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well as in implementing national and regional policies, the article also proposes some measures to overcome the existing challenges.

To foster the process of institutionalization of HTA, Brazil will have to overcome three main drivers of decision making: 1) Brazil has to finalize the implementation agenda of the SUS, 2) the complex governance of the SUS must be reassessed given that it represents a substantial challenge for the institutionalization of HTA, and 3) HTA institutionalization is to be promoted to strengthen decision making.

Brazil's Unfinished Health Care Reform

In 1988, the Brazilian Constitution established the SUS, under which all citizens were to be granted the right to universal care. The Constitution states that the government must provide all the necessary mechanisms to ensure access to health care, including public funding to enable free access to all medicines. Since then, Brazil has made significant advances in the process of structuring the SUS, resulting in measurably better health conditions for its population. These advances, coupled with the Brazilian economic and social development observed over the last two decades, have resulted in a substantial reduction in the burden of infectious diseases, an increase in life expectancy, and a substantial progress toward the Millennium Development Goals [6], which are the pledge of the Millennium Declaration, a 189-nations' promise to free people from extreme poverty and deprivation until 2015.

With its large emerging economy, in recent years, Brazil has been progressively attracting further interest from international pharmaceutical companies and the medical device industry. The country has become a large consumer market of medications and other health technologies guaranteed by its Constitution. Although the SUS represents an important social advance, it has been clearly underfunded since its creation. With a national health care population coverage estimated at 75%, the SUS has been incorporating new interventions and technologies in a context of chronic underinvestment. Brazil's health care expenditure per capita was estimated at US $921.00 in 2009. This level of investment remains constant over the past 15 years [7]. The persistence of this underinvestment creates a complex paradox. On the one hand, the Brazilian Constitution mandates universal access to health care as a citizen's right and a duty of the state. That means that Brazilian citizens have free health care at primary, secondary, and tertiary levels in a much-decentralized health care system that shares political, legal, and financial responsibilities within the federal, state, and municipal levels. On the other hand, Brazil is an emerging economy with low per capita investment in health, where the increasing demands for new technologies contrast with a clearly underfinanced health care system.

This paradox has contributed substantially to the process of creation of a "judicialisation of the right to health" [8] whereby thousands of lawsuits are started every year to ensure patients' rights to high-cost medications that sometimes have unproven and/or even debatable benefits. Previous existing national HTA approaches and bodies were not able to have an impact on the rising tendency of the "judicialization" of the right to access to health care in Brazil. To some extent, a parallel agenda is being created by law enforcement, increasing inequity and reducing the availability of the already limited resources. Because of this process of "judicialization," the Brazilian Supreme Court held a public hearing in 2009 to discuss access to health care, after which new mechanisms for the development of HTA were implemented. These new mechanisms resulted in December 2011 in the approval of Law 12401, which established a new framework for HTA in Brazil and created a new national HTA body, the *Comissão Nacional de Incorporação de Tecnologias no Sistema Único de Saúde* (CONITEC)—the National Committee for Incorporation of Technologies in the SUS under the auspices of the Brazilian MOH.

CONITEC substituted the existing previous Brazilian national HTA body through a broader and more structured framework of actions and responsibilities. Further, Law 12401 amended Law 8080, the main legislation of the SUS, which establishes its principles and its related operational mechanisms of functioning. Law 12401 states that 1) HTA must address efficacy, effectiveness, safety as well as the impact of implementing technologies; 2) the implementation of new technologies must be integrated with the elaboration of national *clinical protocols* (i.e., critical pathways) and clinical guidelines; 3) the process of HTA is to be centrally performed by the Brazilian MOH with technical advice from CONITEC; 4) the rules of procedures for HTA must also include its maximum period of duration and a mandatory public consultation and an optional public hearing as part of the process; 5) CONITEC is composed of 13 representatives from the following institutions: seven representatives from the Brazilian MOH: the Science, Technology, and Strategic Inputs Secretariat, the Executive Secretariat, the Special Secretariat of Indigenous Health, the Strategic and Participatory Management Secretariat, the Secretariat of Management of Labor and Education in Health, and the Health Surveillance Secretariat; one representative from the national regulatory agency: the Brazilian Health Surveillance (Agência Nacional de Vigilância sanitária); one representative from the national regulatory agency for the private health care sector (Agência Nacional de Saúde); one representative from the National Association of the State Secretaries of Health; one representative from the National Association of the Municipal Secretaries of Health; one representative from the National Health Council; and one representative of the Federal Council of Physicians. The diversity of CONITEC's representatives provides a notion of the complexity of the governance of the SUS and, therefore, for HTA development. This topic will be further discussed hereinafter.

Undoubtedly, the creation of CONITEC represents a substantial step toward the institutionalization of HTA in Brazil and reinforces the importance of HTA in promoting more transparency and accountability in decision-making processes. The potential impact of CONITEC's activities, however, ought to be better understood within the context of the chronic underfunding of the SUS and its unfinished implementation process that is still under way to guarantee universal access to all citizens. In Brazil, as well as in other Latin American countries, the prerequisites for equitable access to health care are far from being met [9]. Socioeconomic and regional inequalities are still unacceptably large in Brazil, and thus represent a substantial challenge to its health care agenda. Within the SUS, the persistence of a large share of services that are contracted out from the private sector results in conflicts and wider disparities [10]. In such a context, the HTA approaches may represent important tools helping to strengthen the decision-making process and thus to promote equity. On the other hand, the impact of HTA development may be largely minimized because of insufficient economic resources and the inequalities that still remain after almost 25 years of the creation of the SUS. As an example of some of the existing disparities in Brazil that resulted in a substantial unbalanced resource distribution, a recent study performed by the MOH showed that the spending per capita on high-cost drugs is substantially higher compared with the overall per-capita spending on health care [11]. The absence of a national structured strategy to educate and retain health care workers within the SUS also represents an important obstacle to the process of institutionalization of HTA. Few human resource policies were implemented at a national level within the SUS over the last 25 years.