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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.

The Complex Governance of Brazil's National Health Care System

Brazil has a much-decentralized public-funded national health care system. As stated earlier, the SUS shares political and managerial responsibilities among the national (Brazilian MOH), state, and municipality levels. As a federative republic, Brazil is divided into 27 states and 5564 cities. The states and municipalities have administrative and legal autonomy within the SUS. There are health councils at the national level (i.e., the National Health Council), the state level, and in all the cities around the country. These health councils represent permanent bodies whose responsibilities include analyzing health plans and management reports drafted by each respective government level. This means that, according to the governance of the SUS, different existing bodies may have overlapping roles within the HTA perspective. As a result, for a given health program to be implemented, it must be evaluated and approved by the local, state, and national health councils on a complex and perhaps unique decision-making process that may be the most decentralized worldwide. Besides the existing health councils, there are other administrative bodies in the SUS: the Tripartite Committee at the federal level and the bipartite committees in each of the states. The tripartite and the 27 bipartite committees by their turn represent intergovernmental bodies aiming to promote negotiations and agreements at policymaking. All these existing bodies and the respective involved stakeholders have been working to promote the processes of setting up and structuring the multiple health care networks within the SUS. These processes involve coordination, regulation, setting the competencies and responsibilities, and the development of integration mechanisms between each level of care. For example, local-level health authorities (i.e., municipalities and state-level departments) may legislate in health in a complementary way concerning the national SUS legislation. Within this complex political and administrative structure, the institutionalization of HTA may assume two different but complementary perspectives. On the one side, assuming that the goal of HTA is to provide policymakers with information on policy alternatives [12], HTA may emerge as a potential policy tool in the processes of promoting synergy and integration among different managerial levels and stakeholders. On the other side, the institutionalization of HTA shall require new and additional approaches to foster the integration of the different existing bodies that make part of the governance of the SUS.

These challenges also include promoting and supporting strategies for coordination and enhancing the synergy between the multiple stakeholders in a context of shared responsibilities between the public and private health care sectors (see Fig. 1). Accordingly, the involvement of other existing bodies within the SUS governance, as well as health care workers and patients' involvement, represents initiatives that are complementary to the mandate of CONITEC. In addition, there are several initiatives related to HTA implementation that are not attributable to CONITEC itself, including the development of care pathways, health economic evaluations, as well as promoting patient involvement and monitoring and evaluation of HTA. It remains to be defined how these other mechanisms of integration and governance will be implemented vis-à-vis the institutionalization of HTA through CONITEC.

It seems that one of the biggest challenging issues for HTA development in Brazil is to institutionalize the assessments performed by CONITEC in the context of the complex governance of the SUS and its related decision-making processes. In his "anthropological inquiry," Gertner [5] perceived that the lack of harmonization of HTA practices in Brazil may compromise contextual factor considerations that are crucial for institutionalizing HTA. Within this scenario, maybe a "network governance" approach could be a useful approach. Considering Jones et al.'s [13] proposed definition of "network governance" as the involvement of a "select, persistent, and structured set of autonomous" organizations (including the nonprofit ones) that are "engaged in creating products or services based on implicit and open-ended contracts to adapt the environmental contingencies and to coordinate and safeguard exchanges," these "network governance" approaches may be useful in this dynamic and complex scenario where different stakeholders' interests shall be taken into account. Such a "network governance" approach may provide comprehensive mechanisms of analysis of the HTA framework in a public-private health care system, as well as improve the synergy among other existing HTA bodies.

The diversity of the contributions of the stakeholders in HTA development is also a matter of debate after the decision of the Brazilian MOH to centralize the evaluations of health technologies. The participation of the associations of health care workers and the bargaining power of the rising Brazilian middle class may also play an important role in HTA institutionalization.

Strengthening HTA to Foster the Decision-Making Process

The existing difficulties and barriers related to HTA development in low- and middle-income countries have been demonstrated elsewhere [14,15]. Indeed, the limited impact of economic evaluation in health care resource allocation has already been documented [15]. On the other side, there is no doubt about the relevance of conducting HTA in a particular setting where this tool may contribute to enhance the transparency and accountability of the decision-making process, especially in the context

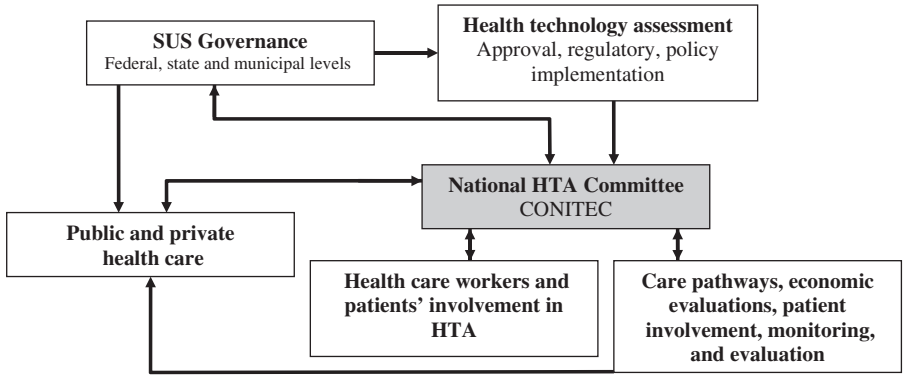

Fig. 1 – Promoting HTA coordination among multiple stakeholders. CONITEC, *Comissão Nacional de Incorporação de Tecnologias no Sistema Único de Saúde*; HTA, health technology assessment; SUS, Sistema Único de Saúde.

of underinvestment, which is the case of SUS. The benefits of HTA also involve promoting more explicit mechanisms of priority setting and resource allocation. Once again, it is necessary to identify the existing decision context-related barriers in middle-income countries. These include lack of understanding of HTA approaches and methodologies, the rising social expectations in health care [14], and the complexity of the governance of the national health care systems as is the case in Brazil.

Evidence-based health policy implementation is mainly driven by processes of decision making that are centered on the justification of the decisions where reliable scientific evidence and the local context matter. In other words, the implementation of evidence-based public health depends not only on the availability of reliable information but also on the existence of mechanisms of decision making that use this information in an effective way. Dobrow et al. [16] have conceived a conceptual framework for evidence-based decision making focusing on how context has an impact on what constitutes the available evidence for making choices and for resource allocation and how that evidence is utilized. According to the proposed framework, there are two distinct orientations to what constitutes evidence, one "philosophical-normative" and the other "practical-operational" [16]. The first represents that available evidence has an inherent value to justify decision making (i.e., what constitutes the validity and reliability of a breast cancer screening strategy). The second relies on the context dependency of the decision-making process (i.e., despite the availability of reliable evidence toward breast cancer screening, what are the political and economic aspects that may influence the decision of implementing this strategy). Assume that many others factors may contribute to a decision outcome rather than the quality of the available evidence itself. These two contexts represent different relationships between evidence and context [16,17] that exert a substantial influence on the processes of HTA development and institutionalization.

To date, few studies have analyzed the impact of HTA on strengthening the quality of decision making. Furthermore, few studies addressed the impact of HTA in low- and middle-income countries.

Brazil has produced few analytical studies assessing its decision-making processes within the SUS and its related complex governance. For example, how do the several aforementioned existing bodies within the governance of the SUS may improve decision-making process? To what extent these existing bodies are accountable? The complex governance of the SUS may represent an obstacle to strengthening decision making? May the institutionalization of HTA have a favorable impact toward more transparent and accountable decisions in the governance of the SUS? Thus, the process of strengthening the mechanisms to foster HTA development should include in-depth studies on how Brazilian decision makers operate and how the HTA approaches may help to enhance the evidence-based oriented decision making.

Conclusions

In the present article, we addressed some of the main challenges of HTA institutionalization in Brazil vis-à-vis the creation of its new HTA national body (CONITEC) enforced by Federal Law 12401, which established a new framework for HTA in Brazil in December 2011. The law came into force recently, after a 6-month period of implementation. CONITEC represents the centralization of HTA in the very decentralized governance of the SUS. Briefly, the main challenges to the institutionalization of HTA in Brazil include the following:

- The institutionalization of HTA may have its impact attenuated in the context of underinvestment of the SUS over the last 15 years as well as the still remaining inequities and limitations to universal access to health care.
- Current efforts to educate health care professionals to perform HTA are very important, but additional initiatives to stimulate their permanence within the SUS are crucial.
- The institutionalization of HTA shall require new and additional approaches to foster the integration of the different existing bodies that make part of the complex governance of the SUS. These include initiatives that are complementary to CONITEC's mandate as well as innovative network governance approaches and promoting more transparent and accountable decision making.
- There is an urgent need for studies assessing the impact of HTA on strengthening the quality of decision making in low- and middle-income countries as a mechanism to foster rational resource allocation. In the same way, further studies are needed to better understand what are the main drivers, challenges, and obstacles to implement evidence-based policymaking from a public health perspective.

Brazil has experienced remarkable progress in health over the past two decades. These advances are related to the reorganization of its national health system and to the changes in the economy that promoted substantial income distribution. Completing the reform of the Brazilian national health care system and the development of HTA agenda are inextricably linked processes. The barriers for HTA institutionalization in Brazil can be largely attenuated if this approach could be used to promote transparency and accountability to the decision-making process and thus to promote equity. Regarding that, the creation of CONITEC represents an important step not only in terms of the development of HTA but also regarding the consolidation of the health care reform and the sustainability of the SUS. There is an urgent need to promote broader approaches assessing the complexity of the governance of the SUS and thus strengthening the process of HTA utilization within the decision-making process.

As the new HTA body in Brazil, and considering the complex governance of the SUS, CONITEC will face big challenges that certainly go beyond its mandate. First, as it was stated before, HTA is now centralized at CONITEC in a context of a much-decentralized national health care system that still needs to clarify and to define state and municipality levels of operational responsibilities. Second, the institutionalization of HTA relies on a broader process of policymaking within an agenda that includes inequalities, unbalanced mechanisms of financing primary and hospital care, and substantial heterogeneity in the provision of services in different regions across the country. Decades of underperforming primary health care services and a very centralized hospital-centered medicine still remain to be reversed. In such a context, HTA will certainly contribute toward better decision making in Brazil.

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