In Brazil, visible Health Technology Assessment (HTA) processes have been in place since 2000 (1). This was carried out by the Secretariat of Health Care Provision (SAS, Secretaria de Atenção à Saúde) of the Brazilian Ministry of Health (MS, Ministério da Saúde) and followed by the Department of Science and Technology (DECIT, Departamento de Ciência e Tecnologia) under the auspices of the Secretariat of Science, Technology and Strategic Inputs (SCTIE, Secretaria de Ciência, Tecnologia e Insumos Estratégicos). A decade later, Law 12.401 of December 2011 established an institutional framework for HTA and National Clinical Guidelines via the creation of the National Committee for Incorporation of Technologies (CONITEC, Comissão Nacional de Incorporação de Tecnologias) in the Unified Health System (SUS, Sistema Único de Saúde). As part of SCTIE, CONITEC succeeds the former Commission for Incorporation of Technologies (CITEC, Comissão de Incorporação de Tecnologias) established in 2006 and supports a more rational decision-making process at both clinical and policy levels (1) in line with priorities identified by the Ministry of Health.

Current HTA Framework in Brazil

CONITEC consists of an Executive Secretariat and 13 members. Of the latter, 7 members emanate from different secretariats of the Ministry of Health, representing the same composition as CITEC. However, six other members are now part of CONITEC: the National Council of Municipal Health Secretaries (CONASEMS, Conselho Nacional de Secretarias Municipais de Saúde); the National Council of State Health Secretaries (CONASS, Conselho Nacional de Secretários de Saúde); the National Health Council (CNS, Conselho Nacional de Saúde); the National Agency of Supplementary Health (ANS, Agência Nacional de Saúde Suplementar); the National Health Surveillance Agency (ANVISA, Agência Nacional de Vigilância Sanitária); and the Federal Council of Medicine (CFM, Conselho Federal de Medicina).

This composition reflects the complex multifaceted governance structure of the Brazilian public-funded national health care system which provides universal access to all Brazilian citizens to free health care at primary, secondary, and tertiary levels. Decision-making processes involve social control of public policies by means of the CNS, 27 State Councils, more than 5000 Municipality Councils, in addition to the Tripartite Committee at the federal level and the bipartite committees in each of the states.

The mission of CONITEC is to make recommendations on the incorporation, alteration, or exclusion of health technologies in the National Medicines List (RENAME, Relação Nacional de Medicamentos Essenciais) and the National List of Health Actions and Services (RENASES, Relação Nacional de Ações e Serviços de Saúde), as well as for the update of Clinical Practice Guidelines and Therapeutic Directives (PCDT, Protocolos Clínicos e Diretrizes Terapêuticas). These recommendations are made in line with societal, health, and management needs of the SUS with an evidence-based approach. (2) With the introduction of CONITEC, all requests for coverage of technologies need to present scientific evidence regarding efficacy and safety, in the form of systematic reviews or technical-scientific advice, as well as health economic evaluation and budget-impact studies. (2) On average, CONITEC convenes during two-day sessions on a monthly basis. The full list of recommendations is regularly updated on the CONITEC website.

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In parallel, DECIT has continued to be involved in health research, HTA studies, training dissemination and management of the Brazilian Network for Health Technology Assessment (REBRATS, Rede Brasileira de Avaliação de Tecnologias em Saúde). The creation and influence of the Institute for Health Technology Assessment (IATS, Instituto de Avaliação de Tecnologias em Saúde), a national institute of science and technology promoted by the National Council for Scientific and Technological Development (CNPq, Conselho Nacional de Desenvolvimento Científico e Tecnológico) composed of several national institutions and research groups, has been beneficial to a variety of health care facilities and decision makers.
IATS supports the development of health care strategies by evaluating the incorporation of economic, ethical, and public health consequences of new technologies by public and private health care providers in Brazil. Last but not least, the Brazilian Chapter of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) has acted as an educational resource in Brazil by translating Health Economics and Outcomes Research (HEOR) concepts into Brazilian Portuguese and by encouraging the adoption of Consolidated Health Economic Evaluation Reporting Standards (CHEERS Checklist) (3) into the recently published pharmacoeconomic guidelines by the Ministry of Health (4).

Two year assessment of CONITEC’s activity (2012-2013)

We analyzed publicly available CONITEC recommendations on the incorporation of pharmaceutical drugs and vaccines for 2012 and 2013. Medical devices, diagnostics and procedures were excluded from the study since they only represented a fourth of CONITEC reports for the given period. One third of all requests emanated from a department pertaining to the MoH and 56 percent from pharmaceutical manufacturers. For the latter, only one fourth received a positive response for drug incorporation, while this was the case for the large majority of MoH claims, as shown in Figure 1.

Figure 1. Breakdown of CONITEC recommendations per claimant request in percent, between 2012 and 2013

Most drugs and vaccines that obtained a positive recommendation were later included in RENAME. This may suggest a clear alignment between CONITEC’s work agenda and evidence-based public health priorities, further illuminating how HTA sustains rational decision making within the Brazilian SUS.

Almost half of drugs and vaccines that obtained a positive recommendation belonged to the class of antineoplastic and immune modulating agents, followed by anti-infective for systemic use and respiratory drugs. This could be linked to the fact that over the same period, the Brazilian government placed strong focus on access to oncology treatments, which is illustrated by a national policy for the prevention and control of cancer in 2013, published by means of an Ordinance in May of 2013.

There were several reasons for rejecting a drug for incorporation. Among them were the lack of further results related to its safety and efficacy, counter-evidence identified by means of a systematic literature review, and the existence of a therapeutic alternative available in the SUS with lower cost of treatment. CONITEC also frequently cross-referenced HTA conducted by other agencies, such as the National Institute for Health and Clinical Excellence (NICE) in the United Kingdom; the Canadian Agency for Drugs and Technologies in Health (CADTH); and the Australian Pharmaceutical Benefits Advisory Committee (PBAC), as a justification for rejecting a drug.

Perspectives on HTA development in Brazil

Kuchenbecker and Polanczyk (2012) highlighted that “the SUS has been incorporating new interventions and technologies in a context of chronic underinvestment” which has led to right-to-health litigations for “high-cost medications that sometimes have unproven and/or even debatable benefits. In this context, “HTA will certainly contribute toward better decision making in Brazil, by enhancing its transparency and accountability.”(5) Indeed, the introduction of CONITEC represents a step towards more transparency and societal participation in the process of HTA. This is proven not only by the consistent online availability of CONITEC reports, but also the existence and effective use of the public consultation procedure, meaning that the civil society’s perspective is considered in CONITEC’s recommendations. However, the role of civil society in other appraisal committees, such as in Germany, Australia, Sweden, Scotland, and England still seem to be stronger.

As of today, CONITEC, as its name indicates, is still a Committee, following priorities identified by the government, and by 7 out of 13 members composed of MoH representatives. CONITEC is not yet an independent agency, as if, for instance the French National Authority for Health (HAS, Haute Autorité de Santé).
Another important issue to take into consideration is that the HTA trend in Brazil should not only be measured at the national level. Indeed, important initiatives have emerged at the state level, such as the HTA Network of the São Paulo state.

Last but not least, HTA processes are embedded in the complex governance structure of the SUS. This raises the question whether political and economic dimensions do not outweigh technical and scientific contributions gained in the HTA process, through networks and initiatives, such as REBRATS or IATS. Their potential benefit would be much more important if the decentralization process of the SUS would had been more effective since its creation 25 years ago.

**Conclusion**

HTA implementation in Brazil has been a stepwise and concerted process, involving a wide range of actors and continuously building on societal consensus. A strong network between several universities and the Ministry of Health has been established in the creation of national guidelines for high-cost medicines as well as in the IATS initiative. The Brazilian experience shows that a unified HTA commission can be created in a federal state despite various regional contexts and an important number of administrative entities.

With the creation of CONITEC, the relationship and link between HTA and evidence-based policy has become stronger. A larger question that is valid both for Brazil and for other emerging countries is to know whether the use of HTA has led to improved access to quality medicines for the patients, which is the goal that HTA should ultimately serve. A comprehensive national database would be helpful to better estimate such impact.

**References**


