

## Health technology assessment in Brazil – an international perspective

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**Abstract** *Given the financial impact of the adoption of new health technologies in health systems, choosing what technology should be introduced and when poses a major challenge for health managers. The health technology assessment (HTA) process should therefore be underpinned by transparent and objective criteria. The objective of this study was to analyze HTA processes in Brazil, overseen by the National Commission for the Incorporation of Health Technology (CONITEC), and to compare these processes with those in countries considered to be at the forefront of this field: Australia, Canada, and the United Kingdom. The following categories were used for the comparative analysis: program structure, definition and selection of topics, evidence review, use of HTA in decision making, program products and dissemination, and transparency. The findings show that there are more similarities than differences between these countries' processes and the CONITEC processes. The main differences identified were: composition of committees, entitlement to appeal, program evaluation, and timeframes for the implementation of recommendations/decisions. Despite making major strides in recent years, Brazil should continue to promote continuous improvement of its HTA process.*

**Key words** *Health investment, Technological development, Health technology assessment, Unified Health System*

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## Introduction

The challenges of allocating finite health care resources have spurred countries with public health systems to consolidate their health technology assessment (HTA) programs. Currently, countries such as Australia, Canada, and the United Kingdom (UK) are at the forefront when it comes to HTA processes<sup>1</sup>.

The primary aim of HTA is to inform the decision-making process concerning the incorporation of new technologies in order to prevent the adoption of technologies that are of doubtful value for the health system<sup>2</sup> and ensure publicly accountable decision-making<sup>3</sup>.

Law 12.401/2011<sup>4</sup> was a milestone in the context of the *Unified Health System* (SUS), Brazil's public health system, because it lays out the criteria and timeframes for the HTA process and established the National Commission for the Incorporation of Health Technology (CONITEC). The latter plays an advisory role to the Ministry of Health relative to decisions about the introduction, exclusion, or alteration of new pharmaceuticals, products, and procedures, as well as the elaboration or review of clinical protocols and treatment guidelines (CPTG).

The HTA process in Brazil has evolved considerably in recent years. However, it still requires improvements and has been identified as a research priority. This is due to rising healthcare costs, growth in life expectancy, an increase in knowledge of the health-disease process, and the continual acceleration of the rate of technological progress, creating pressure for the adoption of innovative technology, which needs to be assessed to ensure safety and clinical effectiveness.

HTA programs should be constantly analyzed and consolidated to ensure the development of effective, sustainable, and transparent processes in the SUS. With this in mind, this article outlines the history of HTA in Brazil and compares current processes in the country to those of countries at the forefront of this field.

## Method

A descriptive study was conducted drawing on a literature review and document analysis of the HTA process in Brazil, Australia, Canada, and the UK.

The following documents were analyzed in relation to HTA processes in Brazil: (1) recent legislation concerning HTA in the SUS<sup>4-6</sup>; (2) the

electronic form used to submit an assessment request to CONITEC (FormsUS)<sup>7</sup>.

In relation to the other countries, searches were conducted of the following databases: Medline/PubMed, Scopus, and Web of Science. The searches were conducted between March and May 2014 and updated in December 2016, using the following descriptors: *Incorporation AND Technologies, health AND technology AND assessment, health AND technology AND assessment AND program, health AND technology AND evaluation, Canada AND Australia AND United AND Kingdom AND Brazil AND HTA*. The literature review focused on documents concerning the countries selected for study. In addition to the aforementioned review, a document search was conducted of the following websites: [www.health.gov.au/hta](http://www.health.gov.au/hta); [www.cadth.ca](http://www.cadth.ca); and [www.nice.org.uk](http://www.nice.org.uk).

A comparative analysis was performed using a methodology proposed by the Center for Evidence-based Policy<sup>8</sup>, a collaboration of academic and governmental entities created in 2003 with the purpose of producing evidence to help address health policy challenges.

The comparative framework<sup>8</sup>, adopted to facilitate comparison with other studies, was designed to respond two questions about HTA: (1) what are the components of a public health resource allocation program, using HTA as a model; and (2) what are the objectives of each component of the program or process. Based on this framework and using the information obtained from the aforementioned review process, the components were organized into six broad domains, as shown in Chart 1.

Australia, Canada, and the UK were chosen because of the long history of HTA in these countries, the prominent role they have played in developing best practices in universal healthcare settings, and the availability of information on programs and processes in English. Programs with limited or no information on the evaluation of HTA processes and those where information was not available in English were excluded.

For the purposes of the study and to enable comparison with the literature, the concept of "technology" in the context of HTA was broadened to encompass procedures, medical services, and the organization and delivery of health, disease prevention, and health promotion services<sup>8</sup>.

HTA in the countries selected for this study is conducted by the following government and arms-length bodies: Australia - the Medical Services Advisory Committee (MSAC); Canada - the

**Chart 1.** Framework for the comparative analysis of HTA processes.

Domain	Component
I. Program structure	(1) Program purpose (2) Governance and organization (3) Scope (4) Key factors analyzed (5) Stakeholder involvement (6) Target audience
II. Definition and Selection of Topics	(1) Topic definition (2) Topic refinement (3) Topic selection
III. Evidence Synthesis	(1) Entities conducting reviews (2) Review methods
IV. Use of HTA in Decision-making (Incorporation)	(1) Decision making bodies (2) Decision making process and criteria (incorporation) (3) Appeal process
V. Program Products and Dissemination	(1) HTA products (2) Implementation (3) Timeframe for implementing guidance after its publication (4) HTA program evaluation
VI. Transparency	(1) Public documents

Canadian Agency for Drugs and Technology in Health (CADTH); the UK– the National Institute for Health and Clinical Excellence (NICE).

## Results

Charts 2 to 5 present a summary comparison of the main features of HTA processes in each country by HTA program component.

### Australia

Australia's HTA program dates back to the 1980s. Australia was the first country to introduce cost-effectiveness as a requirement for incorporating new pharmaceuticals into its public health system<sup>9</sup>.

In Australia, HTA and the incorporation of new technologies are interlinked. State health departments, hospitals, and regional health services all have HTA committees that oversee the incorporation of new technology<sup>9</sup>.

The aim of Australia's HTA program is to advise the Minister of Health and Aging. There are three advisory committees, each with distinct roles: the Prosthesis List Advisory Committee (PLAC), Pharmaceutical Benefits Advisory Committee (PBAC), and Medical Service Advisory Committee (MSAC).

The PLAC issues recommendations to the Minister of Health and Aging as to which prostheses should be included in the Prosthesis List and the respective minimum benefits to be paid. The PLAC is not required to assess the cost-effectiveness of prosthesis before making a recommendation of listing or as the basis for determining the benefit to be paid<sup>10</sup>.

The PBAC is responsible for pharmaceuticals. Manufacturers are required to submit a detailed HTA report to the PBAC after receiving safety approval from the Therapeutic Goods Administration<sup>9</sup>. Specialist organizations issue a confidential expert opinion to the PBAC based on a critical analysis of the HTA reports. Since documentation is considered a trade secret, only an executive summary of the decision of the PBAC is published. In addition to manufacturers, assessment requests may be submitted by medical bodies, health professionals, and private individuals and their representatives<sup>10</sup>.

The PBAC publishes guidelines inform stakeholders of what should be taken into consideration in deciding whether a pharmaceutical should be subsidized and provide guidance on the submission and decision process and the preparation of submissions<sup>10</sup>.

To be included on the list of the Pharmaceutical Benefits Scheme, which provides funding for the majority of pharmaceuticals purchased in the

**Chart 2.** Components of the HTA processes in Australia, Canada, UK, and Brazil – program structure.

Program Structure				
Component	Australia (MSAC)	Canada (CADTH)	UK (NICE)	Brazil (CONITEC)
Program purpose	Advisory role in relation to evidence and policy	Advisory role only in relation to evidence	Advisory role in relation to evidence and policy	Advisory role in relation to evidence and policy
Governance and organization	Government agency	Independent, nonprofit agency	Government agency	Government commission
	Medical Services Advisory Committee, Protocol Advisory Sub-Committee, Evaluation Sub-committee	Drug Policy Advisory Committee, Canadian Drug Expert Committee, COMPUS Expert Review Committee, in addition to specialist panels for specific projects	Four technology assessment standing committees	SE/CONITEC, Plenary, Technical Sub-Commission for the Assessment of CPTG, Technical Sub-Commission for Updating the RENAME and FTN; and Technical Sub-Commission for Updating RENASES
Scope	Products (including vaccines), diagnostic tests (including pathology), medical devices, surgically implanted prostheses, medical procedures and services, surgical interventions, and public health interventions. Pharmaceuticals: responsibility of the PBAC Prostheses: responsibility of the PLAC	Pharmaceuticals, medical devices, medical procedures and health system used in health maintenance, treatment, and promotion	Pharmaceutical products, medical devices, diagnostic techniques, surgical procedures, treatment technologies, and health promotion activities	Pharmaceuticals, products and procedures (vaccines, in vitro diagnostic products, equipment, technical procedures, organizational, information, and educational, and support systems, care programs and protocols)
Key factors analyzed	Safety, clinical effectiveness, and cost-effectiveness	Efficacy, effectiveness, cost-effectiveness, and impact on service	Clinical effectiveness and cost-effectiveness	Efficacy, accuracy, effectiveness, safety, cost-effectiveness, and budgetary impact

it continues

country's pharmacies, the manufacturer must also: submit an application to the Pharmaceutical Benefits Pricing Authority; negotiate pricing with the Ministry of Health; undergo an availability and quality assessment; and receive government approval<sup>1</sup>. Factors such as clinical relevance, cost-effectiveness, the severity of the disease, and the budgetary impact of the new drug are likely to influence PBAC recommendations<sup>11</sup>. Depending on the annual cost of incorporation,

the pharmaceuticals may require additional approval from the following bodies: the Department of Treasury and Finance, for new drugs with a budgetary impact greater than \$5 million; and the Cabinet, for new drugs with a budgetary impact greater than \$10 million<sup>1,10</sup>.

The MSAC advises the Minister of Health and Aging on new and emerging medical services and technologies. Although the committee conducts its own assessments, it is able to delegate

**Chart 2.** Components of the HTA processes in Australia, Canada, UK, and Brazil – program structure.

Program Structure				
Component	Australia (MSAC)	Canada (CADTH)	UK (NICE)	Brazil (CONITEC)
Stakeholder involvement	The MSAC sub-committees include clinical specialists and consumer representatives. Topic definition and selection: open to all applicants for public funding Research protocol: work with applicant/industry and input from the public Evidence review: applicants can give their opinion MSAC pre-assessment report: applicants can give their opinion (public consultation)	Topic definition: open to the public, topics refined with the proponent Evidence review: information requested from manufacturers, authors of reports, and other specialist Implementation: Knowledge Transfer Program centered on relaying the research to decision makers	Stakeholders are involved in every stage of the HTA process Consultants invited to present statements and participate in the HTA process (including, for example, national patient groups, industry, health professionals, and Department of Health) Commentator organizations are also invited to participate in the HTA process	Topic definition: not restrictions on the type of applicant Plenary of CONITEC includes representatives of the CFM, CNS, CONASS, CONASEMS, ANS, ANVISA, as well as the Ministry of Health CONITEC may invite external specialists to assist, collaborate in meetings, or provide technical inputs and/or sign technical cooperation agreements Stakeholders can provide input during the public consultation process and/or public hearing Applicants may appeal against decisions/recommendations published in the official gazette
Target audience	Australia's Department of Health and Aging, health professionals, hospitals, and consumers	Territorial, provincial, and federal health ministries, including drug plans, regional health authorities, and hospitals and clinics	NHS, doctors, patients and carers (England and Wales)	SUS, health professionals, and industry

Source: Authors' elaboration based on Brasil<sup>4</sup>, Ministério da Saúde (Brasil)<sup>6</sup>, CONITEC<sup>7</sup>, Pinson et al.<sup>8</sup>.

Notes: ANS (National Agency for Supplementary Health); ANVISA (National Health Surveillance Agency); HTA (Health technology assessment); CADTH (Canadian Agency for Drugs and Technology in Health); CFM (Federal Medical Council); CNS (National Health Council); CONASEMS (National Council of Municipal Health Departments); CONASS (National Council of State Health Secretaries); CONITEC (National Commission for the Incorporation of Health Technology); FTN (Brazil's national formulary); MSAC (Medical Service Advisory Committee); NHS (National Health System); NICE (National Institute for Health and Clinical Excellence); PBAC (Pharmaceutical Benefits Advisory Committee); CPTG (clinical protocols and treatment guidelines); PLAC (Prosthesis List Advisory Committee); RENAME (National List of Essential Medicines); RENASES (National List of Health Actions and Services); SE/CONITEC (Executive Secretary of CONITEC); SUS (Unified Health System, Brazil's national health system).

other specific bodies<sup>9</sup>. The stages of the MSAC process are summarized in the Implementation Process Framework Version 1.0 (Australian Government, 2016)<sup>12</sup>.

Neither the PBAC nor the MSAC use an explicit decision threshold as constituting ac-

ceptable cost-effectiveness of incorporating technology. The role of economic evaluation in decision-making in Australia remains part of the process and not the ultimate goal<sup>10</sup>.

On average, MSAC and PBAC HTAs have taken 13 and six months to complete, respectively<sup>10</sup>.

**Chart 3.** Components of the HTA processes in Australia, Canada, UK, and Brazil – definition and selection of topics and evidence synthesis.

<b>Definition and Selection of Topics and Evidence Synthesis</b>				
<b>Component</b>	<b>Australia (MSAC)</b>	<b>Canada (CADTH)</b>	<b>the UK (NICE)</b>	<b>Brazil (CONITEC)</b>
Topic definition	Open to the public	Open to the public	Open to the public	Open to the public (no restrictions identified)
Topic refinement	Works with nominating author to refine topic and develop search protocol	Works with nominating author to refine topic and develop search protocol; conducts preliminary literature assessment	Internal project group refines topic, develops search protocol, and conducts preliminary literature assessment	SE/CONITEC refines topic and conducts preliminary literature assessment. May be conducted by an external group at the request of CONITEC
Topic selection	Department of Health and Ageing determines whether proposed service for review is clinically relevant professional service	Topics approved and prioritized by Advisory Committees and Board of Directors based on six core criteria (disease burden, potential clinical impact, available alternatives, potential budget impact, potential economic impact, and available evidence)	UK Department of Health refers technologies for HTA based on prioritization criteria (disease load; impact on health resources; clinical and political importance; whether there is significant inappropriate variation in the use of the technology across the country; factors that potentially affect the timely determination of guidance or guidelines (timeframes); likelihood of the guidance having an impact on policy, quality of life, and reduction of access disparities)	Use of prioritization criteria by CONITEC to select topics for review was not identified.
Entities conducting reviews of evidence	External contractors	Combined internal project group and external contractor	Independent academic centers	Combined internal project group, with the possibility of external contractors
Evidence review methods	Systematic review (full systematic literature review and modeled economic evaluation)	Systematic review	Systematic review	Systematic review or PTC developed in accordance with the latest edition of the Ministry of Health's Methodological Guidelines for the Elaboration of PTC / economic evaluation study (cost-effectiveness, cost-minimization, cost-utility, or cost-benefit) in the context of the SUS in accordance with the latest edition of the Ministry of Health's Methodological Guidelines for Economic Evaluation of Health Technology Studies

Source: Authors' elaboration based on Brasil<sup>4</sup>, Ministério da Saúde (Brasil)<sup>6</sup>, CONITEC<sup>7</sup>, Pinson *et al.*<sup>8</sup>.

Notes: HTA (health technology assessment); CADTH (Canadian Agency for Drugs and Technology in Health); CONITEC (National Commission for the Incorporation of Health Technology); MSAC (Medical Service Advisory Committee); NICE (National Institute for Health and Clinical Excellence); PTC (Parecer Técnico-Científico or Expert Report); SUS (Unified Health System, Brazil's national health system).

**Chart 4.** Components of the HTA processes in Australia, Canada, UK, and Brazil – use of HTA in decision-making (incorporation).

Use of HTA in Decision-Making (Incorporation)				
Component	Australia (MSAC)	Canada (CADTH)	the UK (NICE)	Brazil (CONITEC)
Decision Making Bodies	Australian Department of Health and Ageing	Federal, provincial, and territorial health ministries	NICE	Secretary of the SCTIE
Decision Making Process and Criteria (incorporation)	MSAC advises the Department of Health and Ageing with respect to strength of evidence and public coverage recommendations	CADTH advises regarding the strength of evidence supporting coverage of drugs and health care technologies	Appraisal Committee issues the final appraisal determination. NICE distributes the determination to NHS in England and Wales	CONITEC advises/ makes r the Secretary of the SCTIE as to whether the technology should be incorporated into the SUS
Appeal process	No appeal process identified	No appeal process identified	15 business days for consultees to appeal	10 days starting from the date of publication in the official gazette

Source: Authors' elaboration based on Brasil<sup>4</sup>, Ministério da Saúde (Brasil)<sup>6</sup>, CONITEC<sup>7</sup>, Pinson et al.<sup>8</sup>.

Notes: CADTH (Canadian Agency for Drugs and Technology in Health); CONITEC (National Commission for the Incorporation of Health Technology); MSAC (Medical Service Advisory Committee); NHS (National Health System); NICE (National Institute for Health and Clinical Excellence); SCTIE (Ministry of Health's Secretariat of Science, Technology, and Strategic Inputs); SUS (Unified Health System, Brazil's national health system).

## Canada

Canada has a publicly funded, decentralized national health-care system<sup>13,14</sup> comprised of separate provincial and territorial health insurance plans<sup>14</sup>. Each plan determines how best to organize, manage, and deliver health care within their jurisdictions<sup>14</sup>, following the recommendations of the federal government<sup>9</sup>. The role of the federal government includes premarket approval of technology and price regulation, when applicable<sup>14</sup>.

The first HTA program was introduced in Canada in 1988 and included actions at both national and local level<sup>13,14</sup>. HTA was aimed at informing decisions on the adoption and withdrawal of health technologies, health insurance plan coverage, patient referral to other jurisdictions, and the development of specific programs<sup>9,13</sup>.

Although universities and other organizations have made a valuable contribution to HTA in Canada, this activity has been carried out in the main by government-funded programs with permanent assessment staff<sup>13</sup>.

HTA in Canada focuses on clinical effectiveness and economic aspects, with few reports considering ethical and social issues<sup>9,13</sup>. Owing to the decentralized nature of Canada's health system, HTA decisions are not implemented nationally<sup>13</sup>.

The Canadian Agency for Drugs and Technology in Health (CADTH) provides evidence-based information on the clinical and economic implications of pharmaceuticals and other health technologies (including devices, procedures, and systems) for the 13 provincial and territorial health insurance plans<sup>14</sup>. The CADTH is a nonprofit independent body that also assesses potential technology for future use<sup>9</sup>. In line with the increasing demand for assessment, there has been a growth in the number of local HTA initiatives in hospitals, local health authorities, and province across the country<sup>14</sup>. There is limited duplication of activities across HTA programs, which generally tailor analysis to the local context<sup>9</sup>. The stages of the CADTH process are briefly outlined in Health Technology Assessment and Optimal Use: Medical Devices; Diagnostic Tests; Medical, Surgical, and Dental Procedures. Version 1.0 (Canadian Agency for Drugs and Technologies in Health, 2015)<sup>15</sup>.

The HTA process in Canada does not have clearly defined timeframes. Certain local initiatives suggest that it takes between two to three months from the submission of the assessment request to the issuing of the assessment report<sup>14</sup>.

Information on the use of incremental cost-effectiveness ratio (RCEI) thresholds by decision-makers as a criteria representing acceptable cost-effectiveness was not identified<sup>14</sup>.

**Chart 5.** Components of HTA processes in Australia, Canada, UK, and Brazil – program products, dissemination and transparency.

<b>Program Products, Dissemination and Transparency</b>				
<b>Component</b>	<b>Australia (MSAC)</b>	<b>Canada (CADTH)</b>	<b>the UK (NICE)</b>	<b>Brazil (CONITEC)</b>
HTA products	Technology Assessments; Public Summaries	Technology Reports; Technology Overviews; Health Technology Update Issues in Emerging Health Technologies; Emerging Drug List	Focused (single issue or technology); Large-scale (multiple technologies or diseases)	Report of Recommendations; CPTG; RENAME; FTN; RENASES
Implementation	HTA reports available on website (in English)	HTA reports available on website (in English); knowledge transfer specialist (KTS)	HTA reports available on website (in English); development of implementation tools; costing and audit support	Report of Recommendations and CPTG CONITEC available on website (in Portuguese)
Timeframe for implementing guidance after its publication	Information not identified	Information not identified	90 days	180 days
HTA Program Evaluation	Internal evaluation conducted in 2010	Internal and external evaluation conducted in 2010	Internal evaluation conducted in 2008	Information not identified
Public documents	Following information available on MSAC's website: list of applications in progress, draft protocols, and final assessment reports, and public summary documents, and information on meetings (dates, agendas, minutes)	The HTA products provide a detailed, reproducible, and transparent description. All reports and other products are publicly accessible	HTA process documents and guidance is published on NICE's website	CONITEC publishes the following information on its website: list of technology undergoing assessment, draft reports submitted to public consultations, inputs to public consultations, final assessment reports (with decisions and recommendations regarding incorporation), CPTG RENASES, RENAME, information on meetings (dates, agendas, minutes)

Source: Authors' elaboration based on Brasil<sup>4</sup>, Ministério da Saúde (Brasil)<sup>6</sup>, CONITEC<sup>7</sup>, Pinson et al.<sup>8</sup>.

Notes: HTA (health technology assessment); CADTH (Canadian Agency for Drugs and Technology in Health); CONITEC (National Commission for the Incorporation of Health Technology); FTN (Brazil's national formulary); MSAC (Medical Service Advisory Committee); NICE (National Institute for Health and Clinical Excellence); CPTG (clinical protocols and treatment guidelines); RENAME (National List of Essential Medicines); RENASES (National List of Health Actions and Services).

### United Kingdom

The UK's HTA Program dates back to the 1990s. Through widescale consultation, this in-

dependent government-funded research program, aims to identify the research priorities of the National Health System (NHS) and its patients<sup>9</sup>. NHS committees and civil society repre-



sentatives classify demands in order of priority based on criteria such as disease burden, intervention effectiveness, cost-effectiveness, budgetary impact, and assessment timescale<sup>9</sup>.

The profile of the program was raised with the establishment of the National Institute for Clinical Excellence in 1999, which was renamed the National Institute for Health and Clinical Excellence (NICE) in 2005. The difference between the two is that the latter not only conducts HTAs, but results are used in developing guidance for the NHS on the use of health technologies<sup>16</sup>. Such has been the impact of NICE that its activities have been confused with HTA<sup>16</sup>.

NICE's role is not to determine whether a particular technology should be adopted in the NHS. Rather, the organization is charged with advising the bodies responsible for public policy formulation<sup>9</sup>. As well as a website, the Institute has its own journal (*Health Technology Assessment*) in which the majority of the results of HTAs are published. Research includes evidence synthesis, when there is wide body of evidence, and clinical studies to fill identified gaps<sup>9</sup>.

NICE commissions an independent academic center or centers to prepare assessment reports for consideration by the technology appraisal committee, an independent entity made up of members from the NHS, patient organizations, academia, and industry<sup>16</sup>.

NICE's HTA recommendations are reviewed every three years or when new data emerges and are adopted only in England and Wales<sup>9</sup>.

Since the guidance issued by NICE to the NHS is intended to reflect the views of health professionals and patients, the pressure brought to bear by the pharmaceutical industry, patients' associations, political groups, and professional societies, among others, is minimized<sup>9,16</sup>.

New technology recommended for adoption by NICE should be made available by local health authorities within three months<sup>9</sup>.

The success of HTA in the UK is attributed to the independence of the institutions involved, quality of the work, and involvement of patients and health professionals alike<sup>9</sup>. Weaknesses include difficulties in detecting failed technology, lack of information about allocation of resources for the adoption of new technology, and the length of time of the assessment process<sup>9</sup>. With respect to the latter, multiple technology appraisals take 54 weeks, while single technology appraisals require 39 weeks<sup>16</sup>.

Though aware of the criticism surrounding the use of quality-adjusted life years as the

measure of health gain, NICE uses this indicator to calculate the RCEI<sup>16</sup>. The upper and lower thresholds adopted by NICE are £20 000 and £30 000, respectively<sup>16</sup>. As from 2014, it was expected that the decision on whether to adopt new pharmaceuticals would be taken based on the value-based pricing<sup>17</sup>. This method incorporates other constructs into the QALY-based cost calculation, using a multi-criteria approach.

## Brazil

The first formal event in Brazil dedicated to HTA took place in 1983 in the form of an international seminar promoted by the government and Pan American Health Organization<sup>18</sup>. On this occasion, discussions were centered around issues such as efficacy, cost-effectiveness, and technology transfer.

With the creation of the Department of Science and Technology (DECIT) within the Ministry of Health and other initiatives, at the beginning of the 2000s HTA became the center of interest of national government institutions. These other initiatives include: the establishment of the Science, Technology and Innovation Council (CCTI) within the Ministry of Health and Permanent Working Group on Health Technology Assessment (GT ATS), coordinated by the DECIT, both in 2003; and the coming into force of the National Policy on Science, Technology, and Innovation in Health and creation of a commission to elaborate a proposal for the National Policy on Health Technology Management (PNGTS), both in 2005.

Although Brazil has been taking part in international discussions surrounding HTA since the 1980s, it was only in 2006 that the country joined the International Network of Agencies for Health Technology Assessment (INAHTA), via the DECIT<sup>18</sup>.

In 2006, the technology incorporation process had yet to be regulated. This situation changed with the establishment of the Commission for Technology Incorporation (CITEC)<sup>19,20</sup> attached to the Ministry of Health, whose mission was to oversee the technology incorporation process<sup>19</sup>. Timeframes for the appraisal process, issuing of decisions and recommendations, and adoption of new technologies by the SUS were not defined and public consultation on appraisals and the participation of civil society representatives in the Commission were not mandatory<sup>21</sup>.

The construction of the PNGTS, created in 2009 by Ministerial Order 2.690<sup>22</sup> published by

the Ministry of Health in 2010<sup>23</sup>, was guided by some important issues<sup>23</sup>: (i) the expansion of the health–industrial complex; (ii) the fact that the importation by developing countries of diagnostic and therapeutic methods designed in developed countries generally occurred without any assessment of expected effects and without considering the epidemiological characteristics and health infrastructure of the importing countries; (iii) the incipient nature of monitoring of the results and impacts of new technologies; (iv) the launch and diffusion of new technologies that have an impact on the health system and consequent pressure to adopt these technologies despite a lack of knowledge on their effectiveness and estimate of the financial resources necessary for their adoption. The general aim of the PNGTS is assure access to effective, safe technology thereby guaranteeing health gains, subject to available resources<sup>23</sup>.

The PNGTS<sup>22</sup> provides that the DECIT shall be responsible for the national coordination of HTA. Support to generate and synthesize scientific evidence relevant to HTA is provided by the Brazilian Health Technology Assessment Network (REBRATS). Established in 2011 by Ministerial Order 2.915<sup>24</sup>, REBRATS is “a network of collaborating centers and teaching and research institutions geared towards the generation and synthesis of scientific evidence in the field of health technology assessment (HTA) in Brazil and worldwide”.

In 2011, Law 8.080 was altered by Law 12.401, which added a provision on therapeutic care and the incorporation of health technology in the SUS<sup>4</sup>. The main innovations introduced by this Law were: (i) the appraisal of applications based on evidence showing the effectiveness and safety of the technology and on system impact studies; (ii) the adoption of technology based on CPTG; (iii) the guarantee of public participation through representatives of the National Health Council (NHC); (iv) the establishment of timeframes for the assessment process, issuing guidance for the adoption, exclusion, or alteration of technology (180 days, extendable for another 90 days, starting from the date that receipt of submission is confirmed); (v) mandatory public consultation and public hearing for relevant cases before decision-making. However, Law 12.401 did not manage to put into practice the principle of comprehensiveness, one of the guiding principles of the SUS, given that “in the absence of coordinated actions, the incorporation of technology, *per se*, has little impact on the improvement of access”<sup>24,25</sup>.

Law 12.401<sup>4</sup> lays out criteria and timeframes for the incorporation of new health technology and created CONITEC. According to Decree 7.646<sup>5</sup>, the aim of CONITEC is to “advise the Ministry of Health on the incorporation, exclusion, or alteration of health technologies by the SUS, as well as on the constitution or alteration of clinical protocols and treatment guidelines”. CONITEC brought major advances over the CITEC, which it replaced<sup>26</sup>. Thus, the processes previously overseen by the CITEC (incorporation, subsequent assessments, and abandonment)<sup>1</sup> are currently the responsibility of CONITEC.

HTA is conducted in the following stages: (1) initiation of an administrative process containing the health technology incorporation, exclusion, or alteration request; (2) documentation compliance check; (3) report issued by the Commission Plenary; (4) public consultation; (5) final decision/recommendations issued by the Ministry of Health’s Secretariat of Science, Technology, and Strategic Inputs (SCTIE), which may be preceded by a public hearing; (6) publication of the decision/recommendations in the *Diário Oficial da União*, the government’s official gazette. The technology should be made available in the SUS within 180 days after the publication of the decision/clinical protocol and treatment guidelines<sup>5</sup>.

In 2012, Decree 7.797 (repealed by Decree 8.065)<sup>27</sup> created the Department of Health Technology Management and Incorporation (DG-ITS), whose role involves the monitoring and evaluation of the HTA process and providing support to the CONITEC.

It is also important to highlight the role Brazil’s health surveillance agency ANVISA plays in the technology life-cycle. Created at the end of the 1990s, it plays a role in both the health and economic spheres<sup>1</sup>. With respect to the former, it issues product licenses based on an appraisal of effectiveness, safety, and quality. With regard to the economic sphere, ANVISA is the Executive Secretary of the Drug Market Regulation Chamber (CMED), through which it undertakes economic appraisals to define the price of the pharmaceuticals that enter the domestic market. The price regulation follows a number of criteria, including<sup>18</sup>: the epidemiological characteristics of the disease, health and safety, budgetary impact, and the results of economic assessment. ANVISA used to be a member of the GT HTA<sup>18</sup> and is a member of the Plenary of CONITEC.

It is also worth mentioning the National List of Essential Medicines (RENAME), periodically updated since the 1990s, and the creation of the

Multidisciplinary Technical Commission for Updating the National List of Essential Medicines (COMARE) in 2005. Updating the RENAME is currently one of the responsibilities of CONITEC's Technical Subcommittee for Updating Rename and the National Formulary<sup>6</sup>. In addition, CONITEC is an advisor on the Technical Subcommittee for the Assessment of CPTG and Technical Subcommittee for Updating the National List of Health Actions and Services (RENASES).

Under current legislation, the DECIT is charged with the national coordination and implementation of HTA, while REBRATS is responsible for generating and synthesizing scientific evidence. CONITEC, whose Executive Secretary (SE/CONITEC) is currently the DGITS, is currently responsible for technology incorporation, exclusion, and alteration activities. The roles and responsibilities of the DECIT and DGITS are laid out by Decree 8.065<sup>27</sup>.

It is important to note that, while in other countries HTA is conducted by government or arms-length agencies, in Brazil it is undertaken by a government commission whose executive secretary is a department of the SCTIE.

## Discussion

The health technology incorporation process and HTA programs are not uniform across the countries. Differences occur in relation to decision-making authority, the scope of evidence reviews, length of time that programs have been in place/experience, and program components<sup>8</sup>.

The findings show that the motivation behind the implementation of HTA programs is pretty much the same across countries. HTA programs across the world have arisen to contribute to resource allocation processes to assure the introduction of cost-effective technology to health systems. HTA programs date back around 35 years, with the majority being established in the last 20-25 years<sup>28</sup>. Brazil is one of the developing countries that have a well-established HTA program<sup>29</sup>.

Australia, Canada, and the UK have internationally recognized HTA programs<sup>1,30</sup>. Given that the health systems and economies of these countries differ significantly from those of Brazil, the components of their incorporation processes were not expected to be totally identical to those of Brazil's CONITEC processes. However, despite the fact that the regulatory framework for HTA

in Brazil was established less than ten years ago (CITEC and subsequently CONITEC), there are more similarities than differences between these countries' processes and the CONITEC processes. This is illustrated by the fact that current legislation fits all the criteria/components<sup>8</sup> considered important for structuring a HTA program.

The main differences identified include the entitlement to appeal in certain cases (in Brazil and the UK<sup>31</sup>), program assessment (absent in Brazil), topic selection (absent in Brazil), and timeframes for implementing guidance after its publication (in Brazil and the UK). In both Brazil and the UK, stakeholders are entitled to appeal against final decisions/recommendations. No information was identified on appeals processes in the other countries.

Unlike other countries, in the case of CONITEC, no explicit mention was found of program assessment to enhance HTA. In this respect, a sequential reading of the minutes of meetings of the Plenary of CONITEC between January 2012 and August 2014 show a constant concern with improving the work process<sup>32</sup>. For example, CONITEC introduced information technology tools to streamline the HTA process. With respect to communication, a report documenting the activities and output of the Plenary and hierarchically superior levels was produced. The Plenary also discussed matters relating to its area of responsibility with a view to promoting more interactive, enlightened, and robust technical discussions.

A search of CONITEC's website conducted on 30 September 2016 shows that the Commission promotes continuous improvement, including the following initiatives: (a) installation of a new computer system that permits the electronic management of HTA and technology incorporation processes in the SUS (e-GITS); (b) introduction of a form for bodies/institutions not attached to the SUS, individual, and other bodies/institutions with the SUS; (c) publication of the minutes of Plenary meetings and reports written in simple language, so that society can present considerations/comments regarding public hearings; (d) creation of a direct channel with the National Justice Council via email to respond questions raised by magistrates regarding the adoption of pharmaceuticals, products, or procedures by the SUS; (e) efforts to enhance communication between CONITEC and society aimed at promoting capacity building and public participation in HTA through the production of a monthly bulletin summarizing submissions and recommenda-

tions and overview of activities and results for the period 2012 to 2014; (f) publication of the guide *Entendendo a incorporação de tecnologias em saúde – como se envolver* (Understanding health technology incorporation – how to get involved) in a special edition of the electronic magazine *Revista Eletrônica Gestão e Saúde*, produced by the University of Brasília, dedicated to CONITEC; (g) creation of the program CONITEC in Evidence, with presentations on matters of interest via videoconference on a fortnightly basis.

Unlike the other countries, CONITEC does not use prioritization criteria to select topics for review. This important aspect of HTA programs helps ensure transparency. The main groups of criteria are<sup>8</sup>: technology alternatives; budgetary impact; clinical impact; controversial nature of proposed technology; disease burden; economic impact; ethical, legal, and psychosocial implications; availability and relevance of evidence; level of interest (from government, health professionals, and patients); timeliness of review; and variation in rate of use.

Timeframes for implementing guidance after its publication are defined in Brazil and the UK. These timeframes help ensure the effective monitoring of the implementation of HTA decisions/recommendations.

Another difference is the composition of the committees. While the Plenary of CONITEC is made up of representatives of ministry of health secretariats, regulatory agencies, and other entities, in the other countries studied representation is prioritized considering the technical expertise necessary for conducting the HTA, regardless of institutional links. That is why the independence of the appraisals undertaken by CONITEC is questioned<sup>30</sup>, given that the majority of the members of the Plenary are subordinated to the

Ministry of Health. Autonomy has been shown to be a desirable feature of HTA programs<sup>28</sup>, both in terms of budget and hierarchy.

It is important to note that differences concerning HTA and decision-making regarding the incorporation of technology influenced by the structure of the health system were not explored by this study. For example, although Brazil and Canada both have a federal system of government and publically funded health systems, in the former HTA assessment and decision-making is centralized, while in the latter assessment it is conducted by the federal government and decision-making is decentralized. A study undertaken with health professionals working in both the public and private sector<sup>33</sup> showed that the majority of individuals believed that the assessment process should be centralized but that the decision to incorporate healthcare technologies should be decentralized. The latter was justified by the country's regional differences in terms of population, needs, and priorities<sup>33</sup>.

Finally, it is important to stress that the purpose of this review was to undertake a comparative analysis of the HTA models adopted by each country and therefore an assessment of how the processes work in practice is beyond the scope of this study.

The structure and functioning of CONITEC and the relevant bodies in the other countries is similar and it is clear that Brazil has made major strides in improving its fledgling HTA process. Further research on the HTA process in Brazil could provide important insights to inform measures to enhance access to quality healthcare and at the same time help address the challenge of soaring healthcare costs, upholding the principle of equity in the public health system and improving efficiency.

## Collaborators

SGG Lima: literature review; data collection, analysis, and interpretation; drafting of the content of the article; revision of the content of the article; approval of the final version to be submitted. C Brito and CJC Andrade: data analysis and interpretation; critical review of the content of the article; approval of the final version to be submitted.

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