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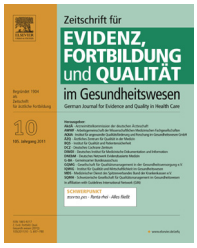

How health economic evaluation (HEE) contributes to decision-making in public health care: the case of Brazil

Wie die Kosten-Nutzen-Bewertung zur Entscheidungsfindung im öffentlichen Gesundheitssektor beiträgt: am Beispiel Brasiliens

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Summary The universal access to a health care system for the Brazilian population was established in 1990. Brazil is a country with no tradition in the production and use of health economic evaluation (HEE) to guide decision making in the public health system. It is only within last two decades that HEEs using a microeconomic approach have appeared in the academic field. On a national level, HEE and Health Technology Assessment (HTA), in a wider sense, were first taken into account in 2003. Two policies deserve to be mentioned – (i) the regulation of medicines in the Brazilian market, and (ii) science, technology and innovation policy. The latter required the fostering of applied research to encourage the application of methods which employ systematic reviews and economic analyses of cost-effectiveness to guide the incorporation of technologies in the Brazilian health care system. The Ministry of Health has initiated the process of incorporating these new technologies on a federal level during the last ten years. In spite of the improvement of HEE methods at Brazilian universities and research institutes, these abilities have not yet reached the governmental bodies. In Brazil, the main challenge lies in the production, interpretation and application of HEE to all technologies within the access scheme(s), and there is limited capacity building. Setting priorities can be the solution for Brazil to be able to perform HEE for relevant technologies within the access scheme(s) while the universal coverage system struggles with a triple burden of disease.

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SCHLÜSSELWÖRTER
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Zusammenfassung 1990 wurde der Zugang zu einer allgemeinen Gesundheitsversorgung für alle Brasilanerinnen und Brasilianer gesetzlich eingeführt. Dabei hatte Brasilien keine Tradition, auf die es bei der Durchführung und Nutzung von Kosten-Nutzen-Bewertungen in der Entscheidungsfindung im öffentlichen Gesundheitswesen zurückgreifen konnte. Kosten-Nutzen-Bewertungen haben erst in den letzten zwei Jahrzehnten Einzug in den akademischen Bereich gehalten. Im staatlichen Sektor hat man 2003 begonnen, gesundheitsökonomische Evaluation und *Health Technology Assessment* (HTA) im weiteren Sinne zu berücksichtigen. Insbesondere zwei Maßnahmen sind zu erwähnen: 1) Regulierung von Arzneimitteln im brasilianischen Markt und 2) die übergreifende Forschungs- und Technologiepolitik. Letztere hat dazu geführt, dass die Forschung zur Anwendung von systematischen Übersichtsarbeiten und Kosten-Nutzen-Bewertungen intensiviert wurde, um auf deren Grundlage Entscheidungen über die Erstattung im brasilianischen Gesundheitssystem zu fällen. In den letzten 10 Jahren hat auch das Gesundheitsministerium darauf hingewirkt, HTA und insbesondere Kosten-Nutzen-Bewertungen im Erstattungsprozess auf nationaler Ebene zu etablieren. Obwohl man sich an den Universitäten und Forschungsinstituten verstärkt mit den Methoden der Kosten-Nutzen-Bewertung beschäftigt, mangelt es in den Behörden und eigentlichen Zentren der Entscheidungsfindung an Experten auf diesem Gebiet. Daher liegt die große Herausforderung darin, trotz der nicht vorhandenen personellen Ausstattung Kosten-Nutzen-Bewertungen zu erstellen, zu verstehen und für Entscheidungen in der öffentlichen Gesundheitsversorgung anzuwenden. Hilfreich dafür kann es sein, Kosten-Nutzen-Bewertungen für die wirklich im System relevanten Gesundheitstechnologien prioritär durchzuführen, denn angesichts der Krankheitslast kämpft das System mit der finanziellen Nachhaltigkeit.

Health care in Brazil

In Brazil, the national health legislation was enacted in 1998. According to the Federal Constitution, the country has the duty of guaranteeing the right to health. This goal is to be reached through social and economic policies, actions for the promotion of health, prevention of diseases and delivery of health care. In 1990, with the creation of the Unified Health System (Sistema Único de Saúde, SUS), the universal access to a health care system for the Brazilian population was established.

The SUS structure of administration is characterized by shared financingon the federal level, the 27 states, and the 5.565 municipalities. Financial sources are taxes and social security contributions. This system covers about 90% of the Brazilian population. Public spending amounts to 41.6% of health care expenses; 58.4% comes from private source [1,2]. The share of the health care sector in thefederal budget has remained fixed, withtotal health care spending representing 8.4% ofthe Gross Domestic Product, equaling to 837 dollars per capita in 2008.

Demands on health care systems are increasing as population grows, science advances and public expectations of health care and quality of life increases [3]. These factors are keys to the growth of the industrial sector and the responsibility ofoffering access to relevant innovations directed to the triple burden of diseases in Brazil [4], characterized by chronic and degenerative diseases (66.3%), communicable disease(23.5%), and injuries (10.2%). While fulfillingthe duty of promoting universal and equal health coverage, Brazil, at the same time, is subject to the dilemma oflimited financial resources, makingrationality inregulatory terms necessary. Brazil, however, is a country without a tradition of production and implementation of health economic evaluation (HEE) to guide decision making in the public health care system.

Health Technology Assessment and Health Economic Evaluation in Brazil: The Broad Picture

In the government sector, Health TechnologyAssessment (HTA) and HEE were first officially legislated ten years ago (2003). Two policies deserve to be mentioned — (i) regulation of medicines in the Brazilian market, and (ii) science, technology and innovation policy [5—7].

The first policy, called the pharmaceutical sector economic market regulation, was passed as Brazilian Federal Law number 10.742. Thisfederal law, in which drug prices were fixed and yearly price adjustments wereestablished, was created as a regulation policy for the pharmaceutical sector. It also called for the creation of the Chamber of Medicines MarketRegulation (Câmara de Regulação do Mercado de Medicamentos, CMED) by theGovernment Council. This Chamber is responsible for the price regulation of medicines in the Brazilian market with the goal of settingmaximum reimbursement prices for new drugs after a benefit assessment has taken place. The evaluation is performed by the National Agency of Sanitary Vigilance (Agência Nacional de Vigilância Sanitária, ANVISA), the Brazilian equivalent of the EMA, and is based on a comparison between the efficacy of a new drug and the current gold standard for the therapy. The assessment includes an appraisal of the literature and aprice comparison with other countries. If the new chemical entity provides an additional benefit for the treatment, the new drug is classified in Category I, and a premium price is allowed which is limited to the lowest price in developed countries. If there is no added improvement, the drug is classified in Category II, and the price is limited to the price of the comparator used from the Brazilian health system [8].

The second policy required fostering applied research to encourage the application of such methodological tools

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as systematic reviews and economic analyses of cost-effectiveness to guide the incorporation of medicines and procedures in the Brazilian health system [9]. In the last decade, the Ministry of Health started the process for the incorporation, exclusion or alteration of new technologies on a federal level of the public health (care) system [10]. Launched in 2009, the National Policy of Health Technology Management is integrated into the above mentioned process. The objective of this policy is to "maximize the health benefits obtained with available resources, assuring population access to safe and effective technologies, with in equity conditions" [10,11]. Such initiatives were objects of discussion and analysis in literature [12], pointing to the fast development of HTA actions in the last years and culminating with the creation of the Brazilian Network for Health Technology Evaluation (Rede Brasileira de Avaliação de Tecnologias em Saúde, REBRATS) [13]. The technology incorporation flow was adopted into the SUS, with an internal Commission for Health Technology Incorporation (Comissão de Incorporação de Tecnologias do Ministério da Saúde, CITEC), that was created in 2006.

The institutionalization of the technologies incorporation process at SUS: Establishing CONITEC in 2011

Important changes relating to healthcare guidelines and the incorporation of health technologies in the public health care system were introduced by the Brazilian Federal Law 12.401/2011. Among them, the commission's new denomination needs to be pointed out, which was called National Commission for Technology Incorporation at SUS (Comissão Nacional de Incorporação de Tecnologias no SUS, CONITEC) [14]. CONITEC officially replaced CITEC. Thus, the law and the accompanying decree 7.646 delineated key changes aimed at improving decision-making and access to medicines, including the expansion of the commission: Society representatives, health care professionals, state and municipal managers were now included [15].

All new technologies that are to be incorporated in the reimbursement list within the public health system (SUS) need to go through an HTA undertaken by CONITEC. Applications for an HTA can be submitted by manufacturers, public health bodies and other stakeholders after a drug receives market authorization from ANVISA and has its maximum price set by CMED, the federal drug pricing body.

From the perspective of the submittant, in this case industries, professionals and scientific societies as well as SUS state and municipal level managers, among others, a request for a technology to be incorporated in the reimbursement schemecan be made. Some changes regarding this process might be highlighted. The first was theestablishment of a 180 day deadline for the analysis and release of a report on the requested incorporation. This deadline, if needed, may be extended for another 90 days. The second modification, should the applicant consider this to be necessary, was the right of appealing to the superior administrative sector of the Ministry of Health to contest the commission's decision. The third modification was the establishment of a deadline for the implementation of a technology into the healthcare services after a decision by the commission. In order toensure transparency, all reports generated by the commission are subject to public consultation. This is done to collect external suggestions.

Based on the decree which regulates that technology coverage needs to be financed to provide universal population access, it can be inferred that HEE was principally introduced to warrantthe sustainability of the health care system in Brazil. Over the past few years, through expanded federal financing, the government has made a significant effort to improve limited and unequal access to healthcare technologies, these principally being drugs. To enable government bodies in the health system to allocate resources to the technologies as requested by the manufacturer, the HEE is part of the incorporation proposal submitted to CONITEC. CONITEC analyses and recommends technologies which will be included in the universal coverage scheme: i) national scheme of healthcare services organized to offer services of primary, outpatient and inpatient care, of urgency and emergency, psychosocial care and (health) surveillance of neglected infectious diseases, chronically degenerative diseases and injuries; ii) national scheme of essential medicines and assistance protocols regarding various illnesses and aggravations, especially those which require high cost medicines [15]. From the outset, CONITEC targets a well-defined patient population and identifies potential subgroups that benefit more from the treatment. CONITEC therefore addresses budget impact concerns and increases the likelihood of a positive recommendation for a proposal.

While supporting the process of a coverage decision regarding medicines and health care procedures, the regulatory aspects as well as an efficient technology management seem to be the objective of a HEE application. In general, a HEE presents a part of the analysis criteria which might lead to the incorporation of technologies in the public system. The following requirements need to be part of the incorporation requests: [15] a) scientific evidence demonstrating that the technology on the list and designated for the treatment of a medical indication is at least as effective and safe as the one already available under SUS b) a comparative study of economic evaluation with current available technologies in SUS and c) in the case of medicines, a price set by the Chamber of Medicines Market Regulation.

The criteria used by CONITEC [15] in the production of reports and regarding the incorporation of a technology in SUS include: a) a broad and systematic search of published and non-published studies; b) critical appraisal of best available evidence considering the clinically relevant outcomes; c) population health needs and priorities of health policy; d) characterization of market and choice of comparable therapeutic alternatives; e) evaluation of logistics and structure necessary to implement the new technology and evaluation of the SUS assistance protocol; f) evaluation of the cost-effectiveness study submitted by the applicant and a budget impact analysis from the perspective of the public (health care) system.

In the analysis process and in the release of reports, CONITEC has been instructed to take the population's health care needs as well as aspects related to system sustainability, i.e. technology transference and national production, into consideration. Relevant results are considered a priority, i.e. reduction in hospitalizations, absenteeism from

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work, surgery or laboratory procedures. The analysis of the benefits for the Brazilian population in the long term perspective involves the costs and the potential of technological innovation for the healthcare services. This analysis presents anaggregated value for the system [16].

Boceprevir and telaprevir are two of the most prominent examples of innovative technologies with a positive HEE. The Secretariat of Health Assistance, within the Ministry of Health, requested an HTA of both drugs for hepatitis C patients with advanced hepatic fibrosis (only for a subpopulation with genotype 1). CONITEC assessed HTAs from international agencies, supporting the cost-effectiveness of boceprevir and telaprevir. CONITEC also analyzed international prices. In its budget impact analysis, CONITEC first evaluated the drug cost for treating the target patient population with alternatives available in the public system, considering the disease progression and retreatment rate. The budget impact model did not quantify indirect costs, but CONITEC mentioned a potential for direct cost savings in the HTA report (eg. the reduction of length of hospital stay).

Methods for Health Economic Evaluation and its Current Challenges: A threshold and a tariff for the QALY

A HEE application commences with the presentation of cost-effectiveness studies as well as budget impact studies by the technology applicant, there by comparing benefit and costs in relation to the technology already covered by SUS. The methodology used inthe referred studies was standardized by REBRATS [17], which offers a manual accessible on its website. The standard methods for economic analysis require a basic structure which presents a comparison with the comparator in use at SUS, costs incurred, an analysis from the perspective of the public system, as well as an analysis of sustainability from a societal perspective. The structure elements of the HEE frameworkare as follows (see Figure 1) [17].

The official Brazilian recommendation regarding uncertainty is: (a) identification of parameters of questioning; (b) choosing a plausible range of varying factors related to uncertainty and (c) presentation of different results obtained from the selected parameter variation.

The lack of the definition of a cost-effectiveness threshold as a parameter for the incorporation of a technology in the decision making process in the Brazilian health care system is a controversial issue. Official documents mention the World Health Organization (WHO) using the threshold of three times the Gross Domestic Product (GDP) *per capita* [18]. The discussion about a threshold mainly revolves around the feasibility and relevance of establishing these standards for a decentralized system of health care services. In such a system, complex management structures need to promote equity and need to attend to a triple burden of diseases. This is not possible when only one of these aspects is used in decision making, however, a further development of the incorporation process is needed [19].

Other questions relate to outcomes which incorporate some kind of quality of life aspects, the QALY for instance, which depends on a national utility measurement. Today,

- Background, justification and objectives: Should be guided by a structured question (intervention and strategies under comparison, target population), which determines the scope of the economic analysis and the appropriate type: cost-effectiveness, cost-utility, cost-benefit or cost minimisation analysis.
- Health System context: Should include a context analysis of the public health care
- Analysis Perspective: Preferably should be conducted using public health care perspective
- Alternatives/Technologies in comparison: The intervention should be compared to usual health care or with the standard treatment for the indication.
- Time horizon: Should be based on the natural course of the disease
- Discount rate: 5% by year for costs and intervention effects
- Health outcomes: Effectiveness measurements should be estimate based in a single study with real data or literature review). Measures and quantification of outcomes based in preferences as Quality Adjusted Life Years and utilities should explicit the standards used for reference, the justification of the selection and method employed, and the stages undertaken to measure preferences.
- Estimate of resources spent and costs: estimates based in a single study or modeling techniques. Direct, indirect, medical, and non-medical costs should be included based on the perspective selected.
- Monetary unit used, date and rate of cambial exchange (if applied)
- Modeling methods: model assumptions should be reported (values, intervals, references and distribution of probabilities to all model parameters. These parameters should be based on official informations or peer reviewed public publications.
- Cost estimative and incremental effectiveness: Should be reported in the incremental cost-effectiveness ratio (ICER). Each component should be separately reported in detail.
- Sensitivity Analysis: Should be included effect of uncertainties in sampling or in computer modeling, parameters variation in discount rates and in analysis perspective. Can use deterministic or probabilistic methods and scenario analysis. These choices should be justified.
- Heterogeneity characterization: Should be used in case of subgroup analysis
- Main findings, limitation, capacity of generalizing results should be reported.
- Declaration of financing sources and interest conflicts should be reported.

Figure 1 Framework for HEE, Brazil, 2009 [17].
Source:
[17] Secretaria de Ciência TeIE, (Brazilian Network for Health Technology Assessment). Diretrizes Metodológicas Estudos de Avaliação Econômica de Tecnologias em Saúde (Economic Evaluation for Health Technologies) [online]. 2009. Available: http://200.214.130.94/rebrats/publicacoes/AVALIACAOECONOMICA.pdf, accessed: 05.03.2014.

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CONITEC prioritizes quantitative outcomes such as gains in life expectancy and a reduction of morbid events. In Brazil, there are no utility measurements for the majority of diseases. Research financed by public resources to define utility values for the Brazilian population is underway. It is expected that the definition of these values will allow the adoption of quality of life aspects in the process of decision making by regulatory bodies and health policy makers.

Nevertheless, CONITEC and REBRATS are working with the Ministry of Health to introduce a cost per QALY threshold in their decision-making process. However, discussions are still at an early stage [19,20].

Critical appraisal of the introduction of CONITEC and the HEE method

The introduction of CONITEC and the resulting changes in the assessment process have improved the assessment of health technologies in Brazil, primarily because it has become more transparent. There has been a significant change in the role of the HEE method in Brazil. Based on the new rule, the HEE approach became mandatory. Now, all new technologies require a positive recommendation from CONITEC to be funded from the Brazilian public healthcare system. The new HTA process is significantly more transparent than that of the former commission, since it is regulated by a federal law that requires assessments of technologies to be publicly disclosed. CONITEC was created with the aim of developing a faster, more efficient and transparent committee, which would be using strict cost-effectiveness criteria and budget impact analysis [21].

While the reforms have resulted in a more open and transparent process, concerns still exist regarding the potential for conflict of interests, the methods of prioritization and the whole evaluation process. First, CONITEC is part of the Ministry of Health, which means that the assessments are conducted by parties with a vested interest in the outcome. Second, it is still not clear how CONITEC prioritises the assessments that they choose to review and evidence suggests that most of the reviews were commissioned by the SUS or other public stakeholders [22].

CONITEC typically considers clinical outcomes first, so positive coverage decisions are usually driven by a strong proven therapeutic improvement as compared to publically available health technologies and a perceived high unmet need in the indication. CONITEC prioritizes technologies that clearly demonstrate large efficacy improvements (see Figure 2) [23]. In order to broaden the physicians' treatment spectrum and to stimulate price competition, CONITEC mayalso cover already publicly fundedtechnologies with similar efficacy in indications. In general, CONITEC uses a similar approach as CITEC. However, the updated guidelines, which present a range of possible methodologies, are not clear on which is the preferred methodology. It is also unclear how the system deals with uncertainty. According to CONITEC guidelines, molecules (that is new drugs) should be compared with products used to treat the same indication, which are funded by the SUS. Indirect costs can be considered when undertaking HTA [22].

In view of the given budget constraints, budget impact is themost important economic consideration for CONITEC.

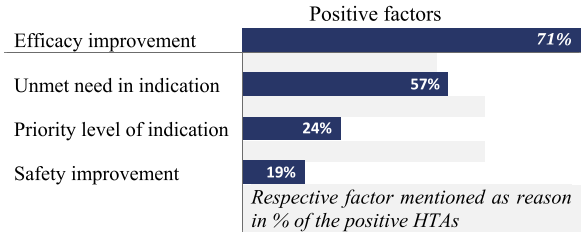

Figure 2 Clinical factors driving CONITEC decisions [23]
Source:
[23] Genenz K, Dominguez A, Alencar R. Unlocking the Key to Public Funding in Brazil [online]. 01.06.2013. Available: http://www.pharmexec.com/pharmexec/article/articleDetail.jsp?id=816162&sk=&date=&pageID=4, accessed: 27.08.2014.

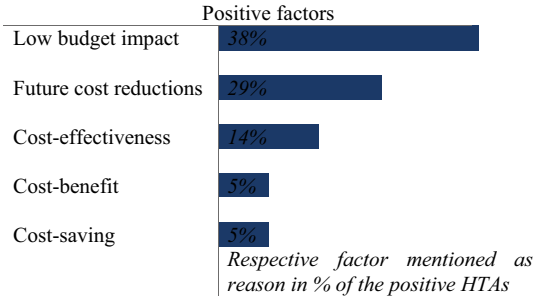

Figure 3 Economic factors driving CONITEC decisions [23]
Source:
[23] Genenz K, Dominguez A, Alencar R. Unlocking the Key to Public Funding in Brazil [online]. 01.06.2013. Available: http://www.pharmexec.com/pharmexec/article/articleDetail.jsp?id=816162&sk=&date=&pageID=4, accessed: 27.08.2014.

Budget impact needs to beassessed by a pharmacoeconomic model and needs to detail allcosts incurred by the technology in the public healthcaresystem. Cost-effectivenessfrom the perspective of the public healthcare systemwas also a relevant driver for an approval (and inclusion in the universal coverage scheme)(see Figure 3) [23].

As well as making the completed appraisals publicly available (which was notpreviously the case), CONITEC established a process of public consultation wherestakeholders are invited to comment on the assessments. It also introduced a reassessmentprocess, which can start as late as 30 days after the publication of the results. The above representsignificant improvements [22].

Since its establishment in March 2012 and until the end of February 2013, CONITEC produced 32 appraisal reports, covering 48 health technologies (of which 85 percent were drugs) across 26 therapeutic indications. Furthermore, 71 percent of the evaluated technologies received a positive funding recommendation. CONITEC is open to recommending innovative technologies. This is supported by the fact that 59 percent of the drugs with a positive appraisal are still on-patent [23].

In addition, gaining support from key stakeholders within the Ministry of Health to advocate for the funding of a new drug significantly increases the likelihood of apositive appraisal. None of the appraisals requested by the Ministry of Health were rejected, while most of the rejected appraisals are from pharmaceutical companies. Most of the

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appraisals requested by departments within the Ministry of Health were for drugs presenting large efficacy gains in therapeutic areas with a small patientpopulation and a high perceived unmet need [24].

Capacity building in the past and future: A major challenge for HEE in Brazil

Some studies published show that HEE production which was financed with public resources was carried out by universities and research institutes in Brazil [10]. From 2004 to 2011 health economic analyses represented 10% of a total of 513 studies which obtained research grants from the Ministry of Health within the scope of Brazilian Network for HTA (REBRATS), butthey did not necessarily lead to the decisions of the incorporation commission.

Another article [25] demonstrated that, between 2008 and 2010, only twelve economic analyses were produced to evaluate a total of 103 technologies submitted to the Ministry of Health. Most of the analyses included the production of short reviews (62) with a focus on efficacy and safety.

Systematic review [26] identified 192 studies of HTA made in Brazil and published between 1990 and 2012 in indexed periodicals (see Table 1) [17]. 90% of the studies were publically financed and 35% had a focus on HEE. These myriad studies reflect the production of universities and research institutes, but did not represent the submissions directly to CONITEC. Manufacturers and other proponents are responsible for formulating the HEE and then engaging universities or consultants. CONITEC takes the responsibility of assessing the information based on the guidelines for HEE.

In spite of the investment in the creation of a HEE culture in Brazil, cultural and structural limitations have been observed. The stakeholders involved are limited, the industry or manufacturer, in particular, is not officially represented in the CONITEC and the participation of patients takes place through the National Health Council (Conselho Nacional de Saúde, CNS) which deals with SUS macroeconomic control.

Facing the size of the country and the complex management of the SUS, HEE initiated at federal level and crucial to the formulation of health policies was disseminated to the federal states and larger municipalities. The implementation of a health economics nucleus with a focus on monitoring purchasing prices and the public budget at the level of federal states has been stimulated since 2004 [27]. The lack of human resources with skills and competence in HEE presents a bottleneck for capacity building in economic analysis in this area, both in terms of government staff and in terms of companies located in Brazil. The lack of a permanent staff in departments at the federal and municipal level, combined with the frequent turnover of decision-level personnel at least every four years hampers the continuity of HEE actions at government level.

The lack of quality information is another obstacle restraining the implementation of HEE. In general, data reflects the population's demand for the services offered. These demands are depicted by statistics produced by public health care services at SUS. Such data therefore reflects access to the system but not necessarily the part of the population which needs health care. It does not include those who have an illness, but do not have access to the official health care system.

Table 1 Characteristics of Brazilian ATS Studies, 1990-2012 [17].

Variables	Frequency
Type of study	n = 192
Cost-effectiveness	67 (35%)
Technical-scientific opinion	37 (19%)
Cost of illness	32 (17%)
Systematic Review and meta-analysis	24 (12%)
Systematic Review	7(4%)
Cost-minimization	7 (4%)
Cost-benefit	5 (2%)
Others	13 (7%)
Evaluated Technology	
Medicines	86 (45%)
Devices and equipment	29(15%)
Biological Products	21 (11%)
Health Programs	38(20%)
Management and organization Systems	3(2%)
Institution Responsible for the Study	
Public University Institution	99(52%)
Public Research Institution	62(32%)
Private Research Institution	14(7%)
Institutions in Collaboration	10(5%)
Pharma Industry	3(2%)
Not Informed	4(2%)
Database where the study was published	
REBRATS (1)	78(41%)
Pubmed	42(22%)
Jornal Brasileiro de Economia da Saúde	36(19%)
Centre for Reviews and Dissemination	14(7%)
SCIELO database	13(6%)
Cochrane Library	5(3%)
EMBASE	4(2%)
Study Financing	
Public	90(47%)
Private	35(18%)
Public and Private	1(1%)
Not informed	66(34%)
Indexed Periodic	
Yes	88(46%)
Public Access to database where the study was published	
Yes	172(90%)

Source:
[25] Decimoni TC, Leandro R, Soarez P. D C. Systematic review of economic evaluation of health technologies developed in Brazil from 1980—2013. The Netherlands: Amsterdam; 2014 (ISPOR 17th Annual European Congress to be held 8—12 November 2014 at the Amsterdam RAI.). URL: http://www.ispor.org/Event/ProgramList/2014Amsterdam?type=Poster&sess=II.

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Conclusions

Overall, the 2011 law has brought a substantial improvement over the previous approach, where appraisals were not publicly disclosed and there were no clear timeline for a review and making decision after a positive recommendation. The majority of improvements within the Brazilian HTA are associated with the process by which HTA is undertaken, mainly through improving the transparency of the system [22]. Since the implementation of the REBRATS the system has seen significant improvements in the capacity building for HTA [27]. It is still too early, however, to assess the full impact of CONITEC, though the relationship between an HTA recommendation and a pricing and reimbursement decision applied in the public health care system in Brazil appears to be clearer. The Ministry of Health uses the CONITEC assessments to determine the discounts requested by manufacturers [23].

Although there has been (the aforementioned) progress in the Brazilian HTA system, there is still room for improvement, specifically in terms of the prioritisation criteria and a more explicit and transparent process for how the HEE dealswith uncertainty parameters [23]. The influence of HEE studies in decision-making at the level of municipal establishment of local health care infrastructure is also rather limited, but the use of budget impact analysis as played a major role in the public health care system [27]. In spite of the improvement of HEE methods at Brazilian universities and research institutes, these abilities have not yet reached the governmental bodies. The main challenges for CONITEC are in the fields of producing, interpreting and applying HEE to all technologies within the access schemes. Setting priorities can be the solution for Brazil to be able to perform HEE for relevant technologies within the access scheme(s) while the universal coverage system struggles with a triple burden of disease.

Conflict of interest

The authors did not receive financing to the elaboration this paperwork.

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