Health Technology Assessment and private health insurance in Brazil: a scoping review and document analysis

Avaliação de Tecnologias em Saúde na saúde suplementar brasileira: revisão de escopo e análise documental

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ABSTRACT Health Technology Assessment (HTA) supports public policies on technology management in several countries. In Brazil, the institutionalization of HTA began in 2000 at the Ministry of Health, and had the participation of the National Regulatory Agency for Private Health Insurance (ANS). However, the public and the private systems have taken different paths. Different HTA processes can generate rework, inefficiency and increase inequities between the public and the private sectors. The objective of this research was to identify the duality between those two sectors regarding the current models of HTA implemented in the country. A scoping review of the literature was carried out from 2000 to 2019, in the Medline, Scopus, Web of Science and Lilacs databases. ANS documents were also analyzed, relating to the HTA process in private health insurance sector. The literature review found a shortage of articles on the topic, while the document analysis allowed to draw a timeline with the main milestones related to the Agency's HTA process. It was concluded that the national coordination of an HTA model is desired, aiming at increasing the transparency of the institutions, the greater credibility of their decisions, greater efficiency of the process, and providing greater equity.

KEYWORDS Technology assessment, biomedical. Public policy. Supplemental health. Unified Health System.

RESUMO *A Avaliação de Tecnologias em Saúde (ATS) respalda políticas públicas na gestão de tecnologias em diversos países. No Brasil, a institucionalização da ATS se iniciou em 2000, no Ministério da Saúde, e contou com a participação da Agência Nacional de Saúde Suplementar (ANS). Contudo, o sistema público e a saúde suplementar trilharam diferentes caminhos. Processos distintos de ATS podem gerar retrabalho, ineficiência e aumentar as inequidades entre o público e o privado. O objetivo desta pesquisa foi identificar a dualidade entre o público e o privado relativa aos modelos de ATS implantados no País. Realizou-se uma revisão de escopo da literatura no período de 2000 a 2019 nas bases de dados Medline, Scopus, Web of Science e Lilacs. Também se realizou análise de documentos da ANS relativos ao processo de ATS na saúde suplementar. A revisão da literatura constatou a escassez de artigos sobre o tema, enquanto a análise documental permitiu traçar uma linha do tempo com os principais marcos referentes ao processo de ATS da Agência. Concluiu-se que a coordenação nacional de um modelo de ATS é desejada, visando a aumentar a transparência das instituições, a maior credibilidade das suas decisões, maior eficiência do processo e proporcionar maior equidade.*

PALAVRAS-CHAVE *Avaliação da tecnologia biomédica. Política pública. Saúde suplementar. Sistema Único de Saúde.*

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Introduction

The Brazilian health system was defined by the Federal Constitution of 1988 as unified and universal[1]. Despite the constitutional option for a model inspired by national health systems of universal and public access, there previously existed a significant private sector in the Country[2]. That sector, comprised by a large extent of private hospital service providers and by private health plans and insurance, remained constitutionally free to act in a supplementary way to SUS[1].

The old system legacy, added to political and economic factors, favored the configuration of a health system characterized by a complex relationship between the public and private sectors. That relation will impact the access to health services, the structure of care networks, the sector financing, and in the implementation of public policies[2].

Private health plans and insurance stand out within the private sector, the reason why, in June 2019, both added covered more than twenty percent of the Brazilian population[3]. So as to regulate the sector, the National Regulatory Agency for Private Health Insurance (ANS), an authority at the Ministry of Health (MS), was created by law in 2000 with the purpose of regulating, standardizing and supervising the activities of the private health plan companies[4].

Among ANS' legal competencies, ensuring adequate and quality care coverage for health plan users is one of them. That understanding called[4] the Agency's obligation to periodically prepare and update a list of mandatory minimum coverage medical procedures by the health plan companies in the country.

It is precisely over the process of the 'list of procedure' periodic updating that technologies are incorporated or excluded in the supplementary health sector. Although not defining criteria or methodology for the ANS to comply with that obligation, HTA has been applied as a tool to assist in the decision-making, as disclosed by the Agency[5].

Since its inception, HTA has supported public policies in the field of technology management throughout several countries. According to the International Society for Pharmacoeconomics and Outcomes Research (Ispor), HTA is

> a form of policy research that examines short- and long-term consequences of the application of a health-care technology. Properties assessed include evidence of safety, efficacy, patient-reported outcomes, real world effectiveness, cost and cost-effectiveness as well as social, legal, ethical, and political impacts[6(1)].

That definition emphasizes HTA political orientation, which, unlike health-related researches, aims to produce and communicate broad information on scientific evidence that provides support for policy formulation[7]. It allows managers and policymakers to ground their decisions more safely and effectively, seeking to achieve the best value for the patient and society, in the light of benefits, risks and costs[8].

It is glaring that health systems, in general, have been facing restrictions that challenge their sustainability, mainly because of rising costs and limited resources. In part, those challenges are due to the aging process and the epidemiological transition, which greatly increased spending on medical care. In addition, the accelerated process of technological innovation and the high and growing impact of new technologies on health spending have been blamed as the main reasons for the prominent concern on HTA[9].

In recent decades, HTA has become a mandatory theme in the organization of health systems in various parts of the world. To some extent, also the countries with national systems, financed and administered by the State, as those of a more liberal orientation and predominance of private assistance adopt HTA to support their decisions concerning the incorporation, payment, reimbursement or financing of new technologies in the system[10].

Following this trend, the theme has been discussed in Brazil since the mid-1980s[11], particularly among academics. However, HTA institutional actions were only initiated in the 2000s, following the creation of the Department of Science and Technology (Decit) at the Ministry of Health (MS)[12].

After the publication of the National Policy of Science, Technology and Innovation in Health in 2004, HTA became officially considered an instrument to contribute to the improvement of the State's regulatory capacity[13]. As from that Policy, a committee was organized with the purpose of structuring the flow for the demands of incorporation, exclusion or alteration of new technologies in SUS, originating the Commission for the Incorporation of Technologies (Citec) at the MS in 2006[14]. In addition, another committee was created to outline the National Policy for The Management of Health Technologies (PNGTS), published in 2009.

The PNGTS covers the principles and general guidelines regarding the actions of all actors involved in the institutionalization of health technology assessment and management in Brazil[14]. In addition to tracing HTA guidelines for the public system, it carries out as part of its objectives to guide supplementary health managers in the incorporation of technologies to the sector[14].

It is possible to note, based on documents and information issued by MS, that ANS has been part of the discussion forums on HTA policies and actions in the country since its inception[15]. In addition, the Agency participated and still participates in the collegiate bodies responsible for the analysis and recommendations concerning the Unified Health System (SUS) incorporation of technologies. The participation lasted since the Commission for Incorporation of Technologies at the Ministry of Health (Citec) inception until its replacement by the National Commission for Incorporation of Technologies in SUS (Conitec), created by Law in 2011[16,17].

Despite ANS participation in the actions of the Ministry of Health regarding the implementation of that policy in the country, it is noted that the use of HTA as a decision-making tool in the process of incorporating, changing and excluding technologies took different paths in the SUS and in the supplementary health sector.

Several national scientific publications have addressed the theme HTA in the SUS, most of which describe its trajectory until the creation and implementation of Conitec or by examining the evaluation processes and recommendations of that Commission[18-20]. However, concerning HTA performance in supplementary health, scientific productions are scarce and often addressed to the assessment of specific technologies[21,22]. The literature review did not find studies mapping knowledge on the theme.

Therefore, this study aimed to map HTA implementation in Brazil since the year 2000 – year when Decit/MS and ANS were created –, exploring its performance in the field of supplementary health and identifying the duality between public and private sectors. A deeper knowledge of the process and its challenges may help the formulation of future public policies addressed to incorporate health technologies in the country more efficiently and equitably.

Material and methods

The study was designed on two complementary methods. The first comprised a scoping review of the literature, while the other consisted of an analysis of ANS public documents related to the process of evaluating technologies in the supplementary health sector.

The choice to use the scoping review rests on the fact that it is useful for

> map rapidly the key concepts underpinning a research area and the main sources and types of evidence available and can be undertaken as

> standalone projects, especially where an area is complex or has not been reviewed comprehensively before[23(1292)].

They represent a form of knowledge synthesis, which incorporates several study designs to systematize evidence with the aim to inform practices, programs and policies and to provide guidance for future research priorities[24]. Essentially, they differ from systematic reviews for answering broader research questions, accepting different study designs and for not systematically performing the assessment of the study quality[24].

Its design and carrying out was based on the methodological proposal of Joanna Briggs Institute (JBI), which includes the following phases: definition of the research question; identification of relevant studies; selection of studies; data mapping; and grouping, synthesis and reporting of results[25].

The research-based question was defined by means of the PCC strategy, a mnemonic for Population, Concept and Context[25], where P is the supplementary health; C is HTA implementation; and C is the Brazilian health system. As result, the main question defined for the search and selection of studies was: 'How did HTA policies implementation occur in the Brazilian supplementary health sector?'.

Additionally, aiming to expand the searches and to make their results more responsive to, due to their narrowness as for the Brazilian supplementary health, it was also asked: 'How did HTA policies implementation occur within SUS scope?' or 'How did HTA policies implementation occur within the private health insurance scope when the international literature is concerned?'.

The bibliographic search, outlined with the help of a librarian, was carried out by means of databases Medline (via PubMed), Lilacs (via VHL), Web of Science, and Scopus. The search period lasted from January/2000 to October/2019. It is important to note that the year 2000 was chosen as the initial milestone for being the year of creation of also the Decit/MS as the ANS, which represented HTA institutionalization bodies within SUS and in supplementary health, respectively.

The following English descriptors were chosen following the MeSH (Medical Subject Headings), a dictionary of terms controlled by the U.S. National Library of Medicine to index articles in PubMed, or their synonyms: Technology Assessment, Biomedical; Insurance, Health; and related free terms, combined with Brazil/Brazil*, 'SUS' and 'Unified Health System', adding the use of the Boolean operators AND, OR and NOT. In Portuguese, the research adopted the Descriptors in Health Sciences (DeCS) or their synonyms, being used: *Avaliação de Tecnologias em Saúde; Saúde Suplementar; Agência Nacional de Saúde Suplementar*; and *Sistema Único de Saúde*.

The search strategies applied for each database are described in *table 1*, as are their respective results.

Table 1. Search strategies used in the scoping review, as per database, result, and the final date of 31/10/2019

Database	Final date*	Search strategy**	Result
Medline (via Pubmed)	31/10/2019	((((((((((health technology assessment[Title/Abstract]) OR health technology assessment[MeSH Terms]) OR health assessment[Title/Abstract]) OR health assessment[MeSH Terms]) OR Technology Assessment, Biomedical[Title/Abstract]) OR Technology Assessment, Biomedical[MeSH Terms])))) OR (insurance health[Title/Abstract]) AND ((Brasil OR Brazil)) Filters: Humans, from 2000 – 2019	286
Lilacs (via BVS)	31/10/2019	tw:(ti:("Avaliação de tecnologias em saúde" OR "Avaliação de tecnologias biomédicas" OR "Tecnologia em saúde" OR "Incorporação de tecnologias" OR "tecnologia biomedica") AND ("saúde suplementar" OR "agencia nacional de suplementar" OR "seguros privados de saúde" OR "Sistema único de saúde" OR sus)) AND (db:("LILACS") AND year_cluster:("2000" OR "2001" OR "2002" OR "2003" OR "2004" OR "2005" OR "2006" OR "2007" OR "2008" OR "2009" OR "2010" OR "2011" OR "2012" OR "2013" OR "2014" OR "2015" OR "2016" OR "2017" OR "2018" OR "2019"))	45
Web of Science	31/10/2019	TI= ("health technology assessment" OR "health assessment" OR "Technology Assessment, Biomedical") AND TS=("health insurance Insurance" OR "health private" OR "health insurance" OR SUS OR "Unified health system" OR Brasil* OR Brazil*)	90
Scopus	31/10/2019	(TITLE ("health technology assessment" OR "health assessment" OR "Technology Assessment,Biomedical") AND TITLE-ABS-KEY ("health insurance Insurance" OR "health private" OR "health insurance" OR SUS OR "Unified health system" OR brasil* OR brazil*))	178
Total	**31/10/2019**		**599**

Source: Prepared by the authors.

* Searches were carried out from September 30 to 31/10/2019.

** Strategies were defined with the help of a professional librarian from the Library of the National School of Public Health Sergio Arouca (Ensp) at the Oswaldo Cruz Foundation (Fiocruz).

In a way to complement, a search for cross references was carried out for all the relevant texts identified so to minimize any losses.

The selection of studies was performed by one of the researchers, who relied on the appraisal of and discussion with the second author whenever a doubt appeared. It was carried out in two phases, first sequentially examining titles and abstracts, and then reading the full text as to apply the inclusion and exclusion criteria.

According to the inclusion criteria, studies of any design were accepted addressing the theme related to HTA policies in Brazil that involved ANS, the supplementary health sector or private health insurance or SUS. Only studies in English, Spanish or Portuguese were selected.

Studies on the assessment of specific technologies were excluded, as were those addressing only methodological issues or economic evaluations, and those that did not refer to HTA in the Brazilian context or in the supplementary health or in private health insurance.

The selected studies were organized in an electronic form created in Excel software spreadsheet®, which was also used to retrieve the relevant data. The following information was extracted: author, year of publication, title, origin of the study, objectives, methodology, results and main findings.

The origin of each study in the description of results was classified as 'national' whenever

referring only to the Brazilian context, and as 'international' whenever exclusively covering the private insurance sector of other countries or whenever dealing with HTA assessment in other realities, provided that Brazil was among them.

Results were reported descriptively, employing tables to summarize the study data. The analysis of main findings was later matched up with data retrieved from the national and international literature on the HTA policies' implementation.

The second methodological path undertaken concerned the search, synthesis and descriptive analysis of the public documents available on ANS website. Documents analyzed included the process of preparation, updating and periodic reviewing of the list of mandatory coverage procedures, since it is the process of incorporation, alteration or exclusion of the sector technologies.

Therefore, the following documents were selected: the two laws governing the sector, the Normative Resolution (RN) and that from the collegiate board, as well as reports and technical notes on the subject.

Aiming to complement the document analysis, the information available in minutes of meetings and presentations of technical groups linked to ANS list of procedures was included, as was that one released by the Permanent Healthcare Regulation Committee (Cosaúde), created by the Agency to address issues concerning care regulation[26].

The results of the analysis were reported descriptively, aiming to draw an evolutionary line depicting the process of updating and periodic reviewing of the list of procedures over time. It started at the inception of the sector regulatory framework, Law No. 9656 of 1998[27], and included the last normative published on the subject until December 2019.

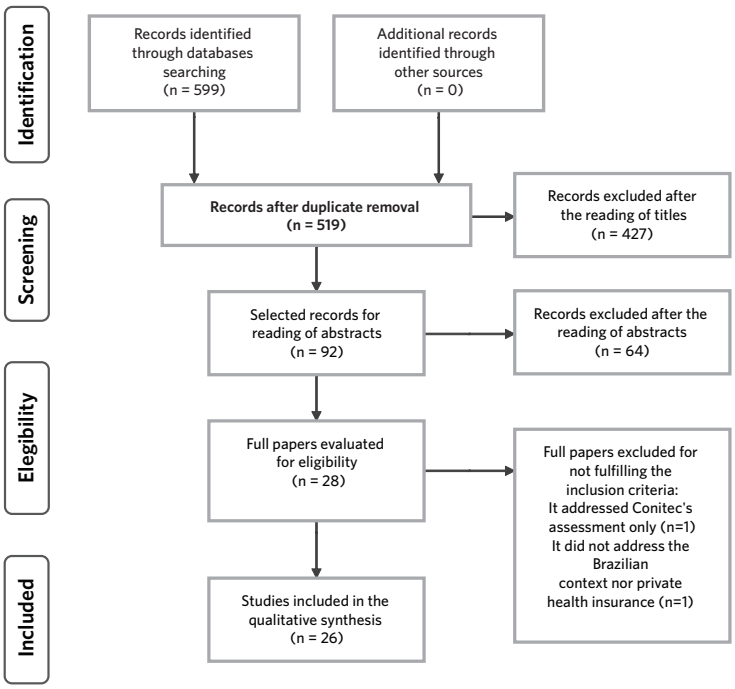
All documents employed in the document analysis are available for public and free access on ANS website. Therefore, the research exempted the Ethics Committee appraisal, since it applied only the literature secondary data and free internet sites.

Results

Scoping review

The search in electronic databases returned 599 records. After removal of duplicates, 519 records remained for title screening, after which 427 records were excluded, leaving 92 papers to be submitted to the abstract screening. Then, the full text of 28 papers was evaluated, 26 of which remained for the final data set. The assessed cross-references were not eligible for inclusion. It is also worth mentioning that no reference was identified in languages other than those defined in the review inclusion criteria (*picture 1*).

Picture 1. Flow Diagram of the paper selection steps



Source: Model adapted from Prisma Flow Diagram, 2009.

Although the searches in the databases included references from the year 2000, the selected studies were all published within the period 2004–2019, among which more than 90% were published as from 2009 (N=24). The latest years concentrated a larger number of studies, as: 2017 (N=4), 2018 (N=3), and 2019 (N=4) (*table 2*).

None of the 26 selected studies addressed exclusively the HTA implementation in the supplementary health. Brazil was the origin of most studies (N=15), among which predominated those whose main objective was to present, describe or inform on HTA trajectory in SUS (N=9). ANS participation in HTA implementation process over the country or the reference to the private sector in that process were addressed in less than half of the studies (N=12).

The national studies were mainly dedicated to reporting on actions coordinated by the MS concerning HTA implementation in the public sector. Many of them depicted a timeline including the main milestones in the trajectory, such as the creation of Decit, Citec and Conitec organizational structures, as well as the publication of national policies that aimed to guide the process throughout the Country[11,12,15,20,28-37].

Among the national studies, Guimarães' work[20] stood out due to addressing HTA in supplementary health more consistently. The author raises specific questions on the private sector, such as the use of new technologies incorporation as a competitive differential between companies operating private health plans. He also mentions some divergences and convergences between different HTA processes in the two sectors[20].

Banta and Almeida[11] emphasized the need to integrate ANS into HTA implementation process in Brazil. They reinforced

the importance of encouraging HTA use by private health plans, reporting that ANS created, in 2005, a task force for technology management in the supplementary health sector, establishing an organizational structure exclusively to that end[11].

Also as per the Brazilian literature, Ali et al.[38] presented a discussion about HTA and its evolution in Brazil, and described some secondary data sources available in the country potentially able to generate evidence on HTA and political decisions[38]. Silva and Elias[39] compared how HTA systems are organized in Brazil and Canada, noting that both are characterized by a wide coverage of the activity scope and by the concentration of activities in national agencies or bodies, despite both carrying out some health system fragmentation, which hinders the coordination of public policies due to the overlap of competencies and the competition between the different entities of the federation[39].

All international studies, except for that of Pericleous and collaborators'[40] published in 2019, evaluated, comparatively and to some extent, HTA experiences in different countries, including Brazil[41-49]. The differences among Latin American countries prevailed, among which Brazil stood out for fast developing HTA programs considered effective[46]. In general, those studies involved only the Brazilian public system, that is, also HTA applied to supplementary health as the private insurance sector were not the object of analysis.

Pericleous's study[40] aimed to examine, by means of literature review and panel of experts, HTA applicability to the public sector as for decision-making of private payers in Canada. Thus, it was similar, at least in part, to the object of this research with regard to the identification of divergences and convergences between HTA application in the public and private sectors. The authors also found scarce publications on the subject in Canada and in the United States. Additionally, the panel of experts concluded that, despite some similarities, there were substantial differences between the two systems, such as demographic issues, health status and other beneficiaries' characteristics that did not favor the adoption of the same kind of assessment for both.

Table 2. Studies comprised by the literature review, as per author, year of publication, title, origin of the study and main results

Author	Year	Title	Origin of study	Main results
Lima, Brito, Andrade (37)	2019	*O processo de incorporação de tecnologias em saúde no Brasil em uma perspectiva internacional* (The process of incorporating health technology in Brazil from an international perspective)	Brazil	The authors reported that, despite the progress, the incorporation of health technologies in Brazil should keep on pursuing continuous improvement.
Pericleous, Amin, Goeree (40)	2019	The value and consequences of using public health technology assessments for private payer decision-making in Canada: one size does not fit all	Canada	The literature review identified few studies meeting the inclusion criteria. The panelists concluded that, despite some similarities, there were substantial differences between the two systems. Most value parameters for the public sector were not applicable to the private one, needing adjustments or revision for their applicability to private payer systems.
Ali, Ichihara, Lopes, et al. (38)	2019	Administrative Data Linkage in Brazil: Potentials for Health Technology Assessment	Brazil	The study emphasized the availability of high-quality data for the adoption in research and policy formulation. This would allow large-scale observational studies to assess the clinical, economic and social impacts of health technologies and social policies, provided the support by specific legislation.

Table 2. (cont.)

Author	Year	Title	Origin of study	Main results
Silva e Elias (39)	2019	*Incorporação de tecnologias nos sistemas de saúde do Canadá e do Brasil: perspectivas para avanços nos processos de avaliação* (Incorporation of technology in health systems in Canada and Brazil: perspectives for progress in assessment processes)	Canada and Brazil	The results revealed that both health systems carry weaknesses, although the Brazilian case exhibited a set of factors such as insufficient resources, impact of judicial decisions, strong dependence on technologies coming from abroad and incipient regional processes and planning in HTA field, which rendered the scenario more complex.
Pichon-Riviere, Soto, Augustovski, et al. (41)	2018	Stakeholder involvement in the health technology assessment process in Latin America	Latin America	The forum participants concluded that the legitimacy of HTA and decision-making processes was identified as one of the main reasons for promoting stakeholder involvement; but certain basic conditions should be met, among them transparency in the HTA process and a clear link between HTA and decision-making.
Pichon-Riviere, Soto, Augustovski, et al. (44)	2018	Health technology assessment for decision making in Latin America: Good practice principles	Latin America	The forum participants identified the principles of good practice to be strengthened by different countries in relation to HTA: transparency in reporting, involvement of relevant stakeholders in the process, mechanisms for appealing decisions, clear priority definition processes and a clear link between HTA results and decision-making.
Banta (42)	2018	Perspective: Some Conclusions from My Life in Health Technology Assessment	International	The author revealed his concerns regarding the narrowness of cost-effectiveness view and little emphasis on ethical, cultural and organizational HTA issues. He also manifested concern about the HTA organisms' independence, and the influence of the health industry.
Oortwijn, Determann, Schiffers, et al. (45)	2017	Towards Integrated Health Technology Assessment for Improving Decision Making in Selected Countries	International	The study identified that monitoring and evaluation of the HTA process were not created in all the countries of the study. He concluded that HTA process implementation is time-consuming and that more transparent and robust processes were needed, among them greater consultation with stakeholders.
Lessa e Ferraz (36)	2017	Health technology assessment: The process in Brazil	Brazil	The study described the opinions of decision makers involved in HTA process in Brazil in 2011. The interviewees indicated that HTA process should be improved to meet their expectations and that the legislation issued that year on the subject beheld some of those concerns, such as the continued acceptance of submissions for assessment of new incorporations, the 180-day deadline for decision-making, and the broadening of the committee to absorb a greater representation of stakeholders.
Lessa, Caccavo, Curtis, et al. (48)	2017	*Fortalecer e implementar a avaliação de tecnologias em saúde e o processo decisório na Região das Américas* (The strengthening and implementing of health technology assessment and the decision-making process in Americas)	Americas	The study concluded that although some countries in the Region have created formal HTA units, there still existed a weak link between HTA process and decision-making.
Rosselli, Quirland-Lazo, Csanádi, et al. (43)	2017	HTA Implementation in Latin American Countries: Comparison of Current and Preferred Status.	Latin America	The authors acknowledged that HTA played a growing important role within Latin American countries, although each country would still need to record its current deployment status and to identify components for improvement. Duplication of effort could be reduced if international collaboration were integrated into HTA national implementation.

Table 2. (cont.)

Author	Year	Title	Origin of study	Main results
Novaes e Soárez (35)	2016	*Organizações de avaliação de tecnologias em saúde (ATS): Dimensões do arcabouço institucional e político* (Health Technology Assessment (HTA) Organisms: Dimensions of the political and institutional framework)	Brazil	The study concluded that technical and political strengthening of HTA process of institutionalization within the national context could add to scientific, technological and innovation policies, effectively impacting on health policies.
Guimarães (20)	2014	*Incorporação tecnológica no SUS: o problema e seus desafios* (Technological incorporation in SUS: the problem and its challenges)	Brazil	The author drawn HTA genealogy and its timeline in Brazil. He discussed the relevance and impact of Law No. 12,401/2011, which regulated integrality in SUS and proposed challenges for deepening HTA actions in Brazil. He also discussed the entry and role of supplementary health under this theme.
Novaes e Elias (34)	2013	*Uso da avaliação de tecnologias em saúde em processos de análise para incorporação de tecnologias no Sistema Único de Saúde no Ministério da Saúde* (Use of health technology assessment under scrutiny for the incorporation of technology in the Unified Health System at the Ministry of Health)	Brazil	The study recognized a methodological and political learning process as for HTA adoption ongoing in that period, showing the need to deepen the analysis of its impact onto SUS.
Oortwijn, Broos, Vondeling, et al. (46)	2013	Mapping of health technology assessment in selected countries	International	The study concluded that HTA mapping in a country could be carried out by focusing on the level of institutionalization and stages of the process, i.e., identification, priority definitions, assessment, appraisal, reporting, dissemination, and implementation in policies and practices. He also acknowledged that although HTA most developed in industrialized countries, there was a growing community in middle-income countries applying HTA.
Kuchenbecker e Polanczyk (33)	2012	Institutionalizing Health Technology Assessment in Brazil: Challenges Ahead	Brazil	The authors concluded that the creation of a national HTA body was an important step not only in terms of HTA development in the country but also in relation to the consolidation of universal access to health care granted by the Brazilian Federal Constitution since SUS creation in 1988.
Silva, Petramale, Elias (12)	2012	*Avanços e desafios da Política Nacional de Gestão de Tecnologias em Saúde* (Advances and challenges of the National Policy on Health Technology Management)	Brazil	The study acknowledged that despite the progresses achieved, Brazil still exhibited a limited tradition in the evidence use for decision-making in health care. It also stressed the constitutional challenge of consolidating a universal health system, bearing comprehensive and equitable care in a context of scarce resources and decentralized decision-making processes.
Ferraz, Soárez, Zucchi (32)	2011	*Avaliação de tecnologias em saúde no Brasil: O que os atores do sistema de saúde pensam a respeito?* (Health Technology Assessment in Brazil: What do the actors of the health system think about it?)	Brazil	The results showed that most respondents considered the HTA process of that period incomplete and unable to meet the needs of the health system. The study also identified a trend towards the development of a decentralized and regionalized process applying separated assessments and decisions as for the public and the private systems.
Silva (31)	2011	*Evaluación De Tecnologías Sanitarias: La Experiencia en el Ministerio de Salud de Brasil* (Health Technology Assessment: the experience in the ministry of health of Brazil)	Brazil	The author considered that challenges persisted towards the achievement of a more effective HTA structure in Brazil, such as the creation of a governmental institution administratively agiler, among other attributes.
Amorim, Ferreira Júnior, Faria, et al. (30)	2011	*Avaliação de tecnologias em saúde: contexto histórico e perspectivas* (Health Technology Assessment: historical context and perspectives)	Brazil	The study stood out for improvements incorporated by the Ministry of Health in HTA process, including the creation of Rebrats and the promulgation of Law No. 12,401/2011, which regulated the incorporation of new technologies within SUS scope.

Table 2. (cont.)

Author	Year	Title	Origin of study	Main results
Oortwijn, Mathijssen, Banta (47)	2010	The role of health technology assessment on pharmaceutical reimbursement in selected middle-income countries	International	The study concluded that increased spending on health care and access to modern technologies strongly boosted HTA in the world. However, HTA developed under unequal pace in middle-income countries provided many of them took advantage of the organizational and methodological experiences of previously created HTA bodies.
Ministério da Saúde (15)	2010	*Consolidação da área de avaliação de tecnologias em saúde no Brasil* (Consolidation of the health technology assessment field in Brazil)	Brazil	The technical report accounted for Rebrats actions of strengthening, approval of the National Policy for Management of Health Technologies, and holding of the HTAi Congress in Rio de Janeiro-Brazil in 2011.
Banta e Almeida (11)	2009	The development of health technology assessment in Brazil	Brazil	The authors acknowledged the need for additional policy changes so to maximize the HTA development impact. They considered desirable that the Brazilian Ministry of Health carried on the development of a HTA national agency.
Banta (49)	2009	Health Technology Assessment in Latin America and the Caribbean	Latin America	The study identified a number of countries under the process of HTA active implementation, such as Brazil, Mexico, Chile and Argentina. Other countries, such as Costa Rica, Colombia, Cuba, Peru, Panama, Paraguay, Trinidad and Tobago and Uruguay, seemed to be following this trend and some others seemed likely to move in that direction in subsequent years.
Ministério da Saúde (29)	2006	*Avaliação de Tecnologias em Saúde: institucionalização das ações no Ministério da Saúde* (Health Technology Assessment: institutionalization of actions within the Ministry of Health)	Brazil	The technical report listed a set of actions implemented by the Ministry of Health: the formal adoption of the Health Technology Assessment; Rebrats and the human resources' training; the Permanent Working Group on Health Technology Assessment (GT-HTA); the technical-operational guidelines; methodological guidelines for studies on HTA and international cooperation, providing the entry of Decit in Inatha.
Krauss-Silva (28)	2004	*Avaliação tecnológica em saúde: questões metodológicas e operacionais* (Health Technology Assessment: methodological and operational issues)	Brazil	The study took in account operational difficulties for the conception and use of technological assessment, for which Brazil depends on data adequacy and availability and on the training of researchers and decision makers.

Source: Prepared by the authors.

HTA: Health Technology Assessment, Rebrats: Brazilian Network of Health Technology Assessment, SUS: Unified Health System, HTAi: Health Technology Assessment International, Decit: Department of Science and Technology, Inatha: International Network of Agencies in Health Technology Assessment.

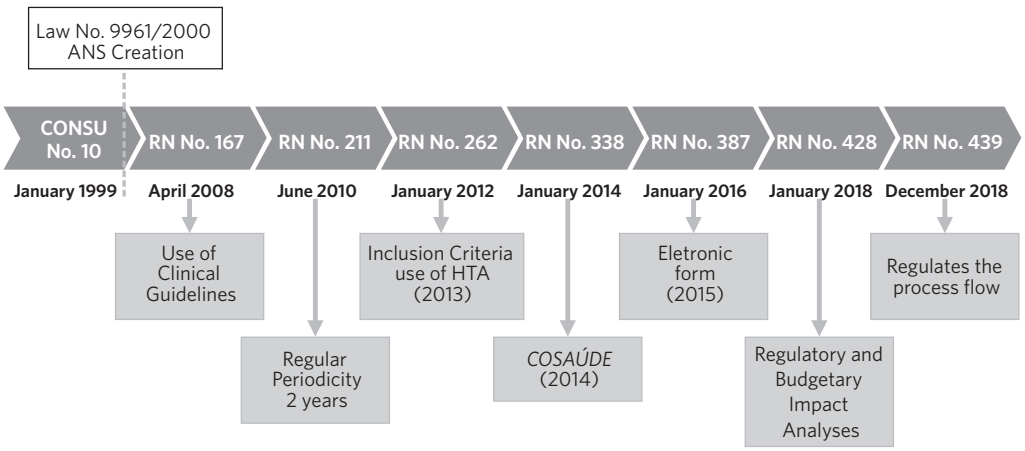
Document analysis

The legal and infra-legal framework that grants ANS the responsibility for the incorporation, alteration and exclusion of technologies as for the supplementary health sector was examined with the objective of extracting information able to identify HTA implementation and use in the Agency's decision-making process.

Law No. 9,656 of 1998, the legal framework that regulated the private health insurance and plan sector[27], and Law No. 9,961 of 2000[4], which created ANS, were analyzed. In addition, all Collegiate Board Resolutions (RDC) and Normative Resolutions (RN) related to the process of preparation and periodic updating of the Agency's list of procedures were examined and summarized in *table 3*, as was the complementary material made available to assist society in public consultations by means its Technical Notes.

Based on the analysis of those documents, it was possible to draw a timeline containing the main regulatory and operational frameworks related to the complex process of periodic review of the Regulatory Agency's list of procedures (*picture 2*).

Picture 2. Timeline of the periodic reviewing process of *ANS* list of procedures, 1999 to 2018



Source: Prepared as from the information available in: http://www.ans.gov.br/index.php/planos-de-saude-e- planos-de-saude-e-operadoras/espaco-do-consumidor/737-rol-de-procedimentos (accessed on 22/01/2019).

ANS: National Regulatory Agency for Private Health Insurance, Consu: Supplementary Health Council Resolution, RN: Normative Resolution, HTA: Health Technology Assessment, Cosaúde: Standing Committee for The Regulation of Health Care.

The first version of the list was created by Private Health Insurance and Plans Council Resolution No. 10 – Consu 10 of 1998 – as part of the deliberations of Law No. 9,656 of 1998 and even before ANS creation. The records related to the methodology adopted in its elaboration were not found on the Agency's website. However, due to the remarkable similarity between the list and the table of procedures of the Brazilian Medical Association (AMB) at the time, it is plausible to assume that the table influenced that construction.

The ANS creation law in 2000 defines, in its article 4, the Agency capacity, including the obligation to elaborate the list of procedures and health events[4]. To this end, the regulator created a discussion forum, attended by several agents of the sector, to discuss the list updating and improvement[50]. In the same year, two Collegiate Board Resolutions (RDC No. 21 and RDC No. 41) were published revising the original list (*table 2*).

During the period 2000–2008, the initial list suffered six revisions. Among them, only those issued in 2004 and 2007 were preceded by public consultation. As from 2008, all RN modifying the list were systematically preceded by public consultation[51] (*table 3*).

Consu No. 10 was revoked in 2008 and a new version of the list was published (RN No. 167), bringing a series of changes and innovations, such as the introduction of clinical and use guidelines for some specific procedures. Those guidelines linked the mandatory coverage to the compliance with requirements grounded on evidence-based medicine, i.e., procedures with clinical or use guidelines would only be covered by health plan companies when these requirements were fulfilled[52].

As from June 2010, the list revisions became regular, being carried out every two years[52]. Additionally, a technical advisory group was created, and composed of the main agents working in the sector, i.e., consumer protection entities, health plan companies, medical professionals and ANS technicians, whose technical discussions preceded the public consultation and were made available on the ANS website[52].

In 2013, a technical note was published by the Agency containing the criteria for including new procedures in the mandatory coverage[5]. Among those criteria, stood out the HTA use, the Evidence-Based Medicine, and the need for economic evaluations. Furthermore, the document refers to Conitec's decisions as one of the key factors in the Agency's decisions[5].

It is important to note that, since the publication of Technical Note No. 26, in February 2013[5], ANS started to use HTA explicitly in its public material as a justification for its decisions regarding the incorporation, alteration or exclusion of new technologies for mandatory coverage in the sector.

In 2014, the Agency created the Cosaúde with the purpose of addressing issues of care regulation, including the mandatory coverage[26]. As a standing committee, it granted greater stability to its members composition, which includes more than thirty institutions working in the supplementary health sector. Since Cosaúde creation, the minutes and meeting presentations became available on the ANS website systematically, easing public access to information related to the list periodic reviewing process[53].

As from 2015, became available on ANS website documents containing more information on the list of procedures so to assist society in the involvement of public consultations. Besides, post-public consultation reports were publicized informing the reasons for also the society demands accepted as for those not accepted by the Agency[54].

Still in 2015, ANS organized the entry flow of demands for changes to the list by means of an electronic form that required technical information about the technology claimed by the plaintiff. The form was only provided for requests coming from Cosaúde members[55].

In 2017, the disclosure of another technical note was added[56] containing, for the first time, a Regulatory Impact Analysis (AIR) as for the new resolution to be published with the list updating. That technical note also included a Budget Impact Analysis (AIO) regarding the proposal for new incorporation of technologies in the sector[56].

Finally, in 2018, ANS developed a norm to regulate the process itself concerning the list of procedures periodic updating, RN No. 439. The norm defined procedures and flows necessary for the list periodic updating. Among others, stood out the standardization of the entry flow and processing of demands for changing the list, as well as the clear definition of the deliberative instances and the broader participation of society[57].

Table 3. Infra-legal documents concerning the periodic reviewing process of the ANS' list of procedures, as per term, theme, carrying out of public consultation, and existence of support material for public consultation, for the period 1998 – 2019

Norm	Term	Theme	Public Consultation (CP)	CP Support Material
Consu No. 10/1998	04/11/1998 to 11/05/2000	Provides for list of procedures preparation	NR	---
RDC No. 21/2000	12/05/2000 to 25/06/2002	Provides for dental list of procedures elaboration	NR	---
RDC No. 41/2000	14/12/2000 to 06/05/2001	Modifies list of procedures	NR	---

Table 3. (cont.)

Norm	Term	Theme	Public Consultation (CP)	CP Support Material
RDC No. 67/2001	07/05/2001 to 28/09/2004	Updates list of procedures	NR	---
RN No. 9/2002	26/06/2002 to 05/07/2007	Updates dental list of procedures	NR	---
RN No. 82/2004	29/09/2004 to 01/04/2008	Provides for the list of procedures and its ratings as for segmentation (MH, AMB, OD, with or without OBS)	CP No. 19	NT No. 16/2004
RN No. 154/2007	06/07/2007 to 06/06/2010	Updates dental list of procedures	CP No. 25	Without NT
RN No. 167/2008	02/04/2008 to 06/06/2010	Updates list of procedures and revokes Consu No. 10	CP No. 27	Without NT
RN No. 211/2010	07/06/2010 to 31/12/2011	Updates list of procedures	CP No. 31	Without NT
RN No. 262/2011	01/01/2012 to 01/01/2014	Updates list of procedures	CP No. 40	Without NT
RN No. 338/2013	02/01/2014 to 01/01/2016	Updates list of procedures	CP No. 53	NT No. 192/ 2013
RN No. 387/2015	02/01/2016 to 01/01/2018	Updates list of procedures	CP No. 59	NT No. 26/2013
RN No. 428/2017	02/01/2018 Effective to date	Updates list of procedures	CP No. 61	NT No. 178/ 2017 and List of procedures Reviewing Report / 2017
RN No. 439/2018	03/12/2018 Effective until publication of this research	Provides for periodic update of the list of procedures process	CP No. 69	NT No. 18 e 19 / 2018

Source: Prepared as from information available in: http://www.ans.gov.br/index.php/planos-de-saude-e-operadoras/espaco-do-consumidor/737-rol-de-procedimentos (accessed on 22/01/2019).

Consu – Supplementary Health Council Resolution, NR – Not carried out, RDC – Collegiate Board Resolutions, RN – Normative Resolution, MH – Hospital doctor, AMB – Outpatient, OD – Dental, OBS – Obstetrics, CP – Public Consultation, NT – Technical Note.

Discussion

The review showed the scarcity of works on HTA implementation and use in Brazilian supplementary health. Also at the international level, the theme is still poorly explored, as indicated by Pericleous and collaborators[40]. Most of the selected studies focused on evaluating HTA implementation in SUS. Only two studies[20,40] addressed critically and explicitly the differences between technology assessments in public and private sectors.

In spite of few exceptions[11,20], studies addressing HTA in supplementary health referred to the sector vaguely and superficially or barely referred to ANS as one of the organisms linked to the Ministry of Health that participated in technical groups and other discussion forums on the subject.

The document analysis revealed an evolution in terms of the organization of the list periodic reviewing process, especially with regard to the participation of society, what generated a greater number of public consultations and institutional transparency, making

available a larger number of documents of public access.

Although more robust, ANS list' process of periodic reviewing, up to the study period, still holds weak relation to the guidelines and directions followed by Conitec concerning the process of evaluating technologies for SUS, thus confirming the dichotomy between the two models. The adoption of an application form for inquiries, the request for the plaintiff technical and scientific opinion, and the carrying out of ANS public consultations are the main similarities between the two processes.

On the other hand, the non-disclosure of HTA reports, the lack of economic assessment, and, particularly, the criteria lack of precision as to the Agency's advising are some of the differences between ANS process and Conitec'.

Coming into force in 2019, the new rule RN No. 439 organizes the list periodic reviewing process, in which some changes tend to increase the congruence between the two processes. Of these changes, stand out the possibility that the society in general require modifications in the list, previously restricted to Cosaúde members; and the possibility that ANS request reports issued by public or private institutions specialized in HTA, similar to what happens in Conitec[58].

Some consideration on the possibility of congruence between HTA public and private processes can be made as from the literature scoping review. Thus, it was evinced in two selected studies[20,40] that one of HTA differences between private and public sectors relies on the incorporation of new technologies, modern and appealing, as a competitive tool among private companies working in the sector. Such difference sustains itself on the fact that companies provide for-profit service both for individuals and other companies; therefore, the client wish is essential[40].

In that regard, Guimarães[20] draws the attention to the change in the behavior of companies working in the Brazilian supplementary health sector concerning the incorporation of new technologies. The author questions that companies often applied uncritical incorporation of new technologies as a marketing tool so to increase their product sales[20]. As from a given moment, the acknowledgement of exponential increase in care expenses questioned such behavior, causing HTA to take part in the speech of private companies' managers as a way of reducing spending[20].

Concurrently, as from 2013, ANS disseminates, by means of a technical note, the use of HTA and economic evaluations as part of the criteria for incorporating new technologies in the sector[5]. Following that logic, it is plausible to assume that health entrepreneurs themselves increased the pressure onto the Regulatory Agency so to strengthen HTA use in the sector adoption of new technologies for mandatory coverage.

As consequence of that inflection, health plan companies started to create their own HTA centers. The Cosaúde meeting minutes started to grant a more technical character to the discussions regarding the incorporation of new technologies in the sector[53]. Consonant with Guimarães' postulate[20], those behavior changes as for the private sector can lead to a congruence between the supplementary health processes of technology incorporation and the SUS.

Comparing the findings of this study with the international literature[39,40,59,60], it is reasonable to consider the need to promote HTA coordination processes in a country. The comparison between the United States (USA) and other European countries, such as Sweden and England, was chosen by Banta[60] so to demonstrate discrepancies between countries not unified towards a national direction and the coordinated functioning of national health systems.

Banta[60] affirms that in the USA, without effective national process coordination, HTA activities are carried out by multiple organizations following various targets, often adopting

different methods and without process transparency. The predominant object is probably cost containment, although other purposes are also mentioned by assessors, such as quality improvement or innovation[60].

In 1997, Seymour Perry and Mae Thamer[59] described earlier the lack of coordination of various HTA instances in the USA, most of them private, i.e., medical centers, hospitals, health insurers, pharmaceutical industry and medical equipment. The authors argue that these private organizations priorities may not necessarily coincide with national priorities as for technology evaluation. Moreover, there is virtually no information exchange or coordination among those groups. Also, the proprietary nature of results among many organizations further limits the availability and usefulness of those evaluations[59].

Regarding those countries carrying out coordinated HTA activity, they tend to implement national health systems and consider convenient and efficient to create HTA programs linked to and supported by the national government[10]. In many cases, the acquisition and access to new technologies are under government control, particularly as for federal health programs[59]. Overall, they seem to exert important influence on their countries' technology management policy.

In Brazil, the HTA system is consisted of a centralized governmental body, Conitec, which is responsible for advising the MS on evaluations and recommendations on SUS' incorporation of technologies at the national level; of limited experiences on HTA very structures at the state level; and of various public and private organizations, such as teaching hospitals, research institutes, among others[39]. Additionally, ANS operates in parallel, adopting HTA as a tool to exercise its legal obligation of updating the list of mandatory coverage procedures in the supplementary sector.

Thus, a fragmented HTA system arises, in which several organizations work at different levels, duplicating efforts and breaking completely the incorporation processes in public and private health sectors. In general, both sectors assess aspects such as effectiveness, safety and budgetary impact, besides promoting, to some extent, the participation of society. However, no comprehensive value-based assessments were identified as per each perspective.

Final considerations

The study aimed to trace HTA history in supplementary health, depicting HTA implementation milestones in SUS and identifying existing dualities between public and private sectors in this process.

HTA implementation throughout the country is part of a broader policy of incentives to science, technology and innovation, aiming to confer rationality to the process of technological incorporation. MS guided the actions towards such implementation, always relying on ANS participation. However, results obtained so far reveal that the Agency and the Conitec/MS work independently and without coordination, applying distinct methodologies to produce their reports and recommendations regarding the inclusion, exclusion or modification of technology use in supplementary health and in SUS.

The disconnection among those findings is noteworthy, as is the country option when defining the PNGTS with the general purpose of

> maximize the health benefits to be obtained with the available resources, ensuring the population's access to effective and safe technologies, under equity conditions[14(15)].

Such Policy should guide all actors involved in the institutionalization of the appraisal and management of health technologies in Brazil.

Besides, the Brazilian Network of Health Technology Assessment (Rebrats) was created in 2008 implying the government cooperation with universities, teaching and research

institutes, among others, of which ANS is part. The use of HTA national network of cooperation should also be aimed at reducing the discrepancies between the evaluations carried out for SUS and supplementary health[15].

As stated by Seymour Perry and Mae Thamer[59], Banta[60] and by Silva and Elias[39], international experiences have suggested that coordinated and standardized HTA processes can bring gains to the evaluation efficiency, reducing redundancies and rework, in addition to improving care supply to the population's health needs. In this sense, as far as the national scope is concerned, both Conitec' and ANS' evaluations are funding by public resources; therefore, their products should revert in favor of the society, either the private health plan beneficiary or SUS' user.

Actually, the evaluation of technologies must necessarily take into account various contextual elements from the public and supplementary sectors, such as economic and structural factors. Thus, different payers may face different priorities and decision-making processes. There are also important differences between the sectors concerning demographic terms, health status and other user characteristics. So, different approaches should be undertaken for assessment of the public sector and the private market[40].

However, the same methodological guidance – standardized HTA reports – joined to greater participation of society, both within SUS and in supplementary health, can offer greater transparency to manager decisions. Increasing transparency of the decision-making process provides greater understanding by the society, allowing the citizen a more consciously demand, besides rendering greater credibility to the process.

Although Brazil has a unified health system, the private sector, especially supplementary health, is quite robust. As a consequence of the dichotomy between the public and private sectors, the implementation of public policies of national scope is hindered, as can be seen by the PNGTS. The national coordination of an HTA model that meets its specificities is desired, for the sake of increasing transparency of the accountable institutions, greater credibility of their decisions, greater efficiency of the process and, especially, to provide greater equity.

Regarding equity, HTA should function as strategy for the consolidation of that principle, favoring a more adequate distribution of resources within the health system, whatever the subsector involved. Equity can be analyzed as a balance between the population to be benefited due to their vulnerabilities and the health needs, regardless of its purchasing power. Better allocation of resources based on health needs provides more equitable supply and distribution of services in both sectors, since those who finance the system are the users themselves, both in the public sector, by means of taxes, and in supplementary health, by means of cash compensation.

Similarly, HTA use can avoid waste and generate greater efficiency in the provision of health services in both sectors, since their products, in addition to identifying the safest and most effective technologies, also inform under which conditions and for which groups of individuals their benefits will be more significant.

It is undeniable the important improvement of HTA implementation in the country since 2000, especially in SUS, which culminated with the Conitec' creation in 2011. As for supplementary health, only in 2013 ANS published a technical note officially creating HTA as a decision-making tool. In 2018, the Agency published a norm defining the list reviewing process, more tuned with SUS patterns.

Neither the literature scoping review nor the document analysis could explicitly evidence the reasons for such discrepancies. However, it can be inferred that commercial, marketing and economic-financial issues involving especially private health plan

companies could explain also the HTA late implementation in the supplementary health as part of the lack of transparency concerning HTA model implemented in ANS.

Few studies investigated the consequences of the lack of alignment between HTA policies in the public and private sectors. New studies under various approaches are essential to a broader understanding of the theme. Therefore, the strengthening of this process is expected due to being essential for the health system sustainability in Brazil.

Collaborators

Lisbôa R (0000-0002-0159-0044)* worked on data conception, planning, collection, analysis, and interpretation; content preparation; text preparation and writing; and approval of the text final version. Caetano R (0000-0003-1480-2453)* worked on the study conception and planning; text preparation and writing; text critical revision; and approval of the text final version. ■

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