

Article

Profile of those demanding the incorporation of health technologies into the Unified Health System, in 2023

Perfil de demandantes de incorporação de tecnologias em saúde no Sistema Único de Saúde, em 2023

Perfil de quienes demandan la incorporación de tecnologías sanitarias al Sistema Único de Salud, en 2023

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Abstract

Objective: To analyze the profile of applicants requesting the incorporation of health technologies into Brazil's Unified Health System in 2023. **Methodology:** A qualitative-quantitative approach, with exploratory, documentary, and descriptive analysis, featuring analytical and retrospective characteristics regarding the requests submitted to the National Committee for Health Technology Incorporation between January and December 2023. Secondary data were used, and documentary analyses were conducted. **Results:** A total of 55 technology incorporation requests were evaluated, 81.8% of which were related to medications. Among internal and external demands, external requests predominated, especially those from the pharmaceutical industry. **Final Considerations:** The study indicates that, in 2023 (based on a small and non-generalizable sample), there was a slight predominance of external applicants to the public health policy management requesting health technology incorporations for medications.

Keywords: Unified Health System; Health Technologies; Health Policy.

Resumo

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Objetivo: analisar o perfil dos demandantes pela incorporação de tecnologias em saúde no Sistema Único de Saúde, do Brasil, no ano 2023. **Metodologia**: Abordagem qualiquantitativa, com análise exploratória, documental e descritiva, com características analítica e retrospectiva acerca das demandas submetidas à Comissão Nacional de Incorporação de Tecnologias no Sistema Único de Saúde, entre janeiro e dezembro de 2023. Foram utilizados dados secundários e realizadas análises documentais. **Resultados:** foram avaliadas 55 solicitações de incorporação de tecnologias, sendo 81,8% relacionadas a medicamentos. Entre as demandas internas e externas detectou-se predominância das solicitações externas, em especial da indústria farmacêutica. **Considerações Finais:** o estudo denota, que no ano 2023 (mostra pequena e não expansível), houve leve predominância de solicitantes externos à gestão da política pública de saúde por incorporação de tecnologias em saúde, no Sistema Único de Saúde, com mais recomendações favoráveis para medicamentos.

Palavras-chave: Sistema Único de Saúde; Tecnologias em Saúde; Política de Saúde.

Resumen

Objetivo: Analizar el perfil de los solicitantes de incorporación de tecnologías en salud al Sistema Único de Salud de Brasil, en el año 2023. **Metodología:** Enfoque cuali-cuantitativo, con análisis exploratorio, documental y descriptivo, con características analíticas y retrospectivas sobre las solicitudes presentadas a la Comisión Nacional de Incorporación de Tecnologías en el Sistema Único de Salud, entre enero y diciembre de 2023. Se utilizaron datos secundarios y se realizaron análisis documentales. **Resultados:** Se evaluaron 55 solicitudes de incorporación de tecnologías, de las cuales el 81,8% estaban relacionadas con medicamentos. Entre las demandas internas y externas, se observó una predominancia de las solicitudes externas, especialmente de la industria farmacéutica. **Consideraciones Finales:** El estudio indica que, en 2023 (con una muestra pequeña y no extrapolable), hubo una leve predominancia de solicitantes externos a la gestión de la política pública de salud para la incorporación de tecnologías en salud en el Sistema Único de Salud, con más recomendaciones favorables para medicamentos.

Palabras clave: Sistema Único de Salud; Tecnologías de la Salud; Política de salud.

Introduction

Brazil's Federal Constitution, promulgated in 1988, established health as a right of all and a duty of the State, imposing the obligation to ensure universal and equal access to assistance and the provision of care through so-called health technologies, which include medicines, procedures, products and protocols used in the provision of care to the user⁽¹⁾.

The World Health Organization (WHO) understands that "health technologies" refer to the use of knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of life⁽²⁾. Therefore, understanding their incorporation into systems that provide access to health actions and services is relevant.

Under this logic, the incorporation of health technologies into the Unified Health System (SUS) represents a crucial aspect for improving the quality of health services in Brazil. It reflects a continuous effort to align technological innovation with public health needs, in accordance with the principles of the SUS, such as equity and universality.

In recent decades, important challenges have been overcome by the National Health Technology Management Policy (PNGTS), which establishes guidelines for the assessment and management of technologies, with the aim of maximizing the positive impact on health and optimizing available resources⁽³⁾. The importance of integrating robust Health Technology Assessment (ATS) criteria - a systematic process for analyzing the properties, effects and impacts of technologies used in the health area, such as medicines, equipment, procedures and organizational systems - into decisions on

incorporation into the SUS, with an emphasis on transparency, social participation and the financial sustainability of the system⁽⁴⁾.

With the constant advance of technological innovations, from medical therapies to diagnostic equipment and processes, the ability to integrate them effectively and ethically has become essential⁽⁵⁾. Ordinances GM/MS N°. 152⁽⁶⁾ and GM/MS No. 3,323 of 2006⁽⁷⁾ revoked and consolidated by GM/MS Consolidation Ordinance N°. 5 of 2017⁽⁸⁾ established an important milestone by introducing strict guidelines for the evaluation and incorporation of these innovations, prioritizing patient safety, the effectiveness of interventions and economic viability.

The regulation of the incorporation of technologies into the SUS began with the creation of the Ministry of Health's Commission for the Incorporation of Technologies (Citec), made up of members of the Health Care Secretariat (SAS), the Health Surveillance Secretariat (SVS), the National Health Surveillance Agency (Anvisa) and the National Supplementary Health Agency (ANS)⁽⁵⁾.

In 2011, Citec was expanded and renamed the National Commission for the Incorporation of Technologies into the SUS (Conitec), established by Law No. 12.401/2011, which provides for the incorporation, exclusion or alteration, within the scope of the SUS, of new medicines, products and procedures, as well as the establishment or alteration of clinical protocols and therapeutic guidelines, under the responsibility of Conitec, as a body linked to the Ministry of Health⁽⁵⁾.

In 2024, Conitec operates through two forums: the Plenary and the Executive Secretariat. The Plenary holds monthly meetings to assess demands for the incorporation, exclusion or alteration of technologies, as well as updating the National List of Essential Medicines (Rename). The Executive Secretariat, which is linked to the Department for the Management and Incorporation of Health Technologies (DGITS) of the Secretariat for Science, Technology and Innovation and the Health Economic-Industrial Complex (SECTICS), provides technical and scientific support for evaluations, with the support of a network of institutions, such as hospitals and universities, which carry out studies in line with DGITS' demands⁽⁵⁻⁹⁾.

Since the creation of Conitec, the process of incorporating health technologies has undergone substantial changes, influencing both the dynamics and the quality of the insertion of new products into the SUS. One of the criteria adopted by Conitec for the incorporation of new technologies is the analysis of the cost-benefit ratio, which ensures that the technologies incorporated present evidence of effectiveness combined with economic viability. The importance of analyzing the cost-benefit ratio is clear, especially after the year 2022⁽¹⁰⁾ given the recent change in the rule, the feasibility analysis, and the significant potential impact on public health and demand for significant public resources⁽¹⁰⁻¹³⁾.

The incorporation of technologies is one of the main factors responsible for increasing the costs of health systems, especially industrialized products such as medicines⁽¹⁴⁾. In the SUS, annual spending on health products and technologies exceeds R\$20 billion⁽¹²⁾. In 2023, up to the month of July, spending on medicines was approximately R\$ 1.4 billion⁽¹²⁾. Despite the high cost involved, the process of incorporating health technologies is fundamental to improving care and ensuring equitable access to innovations that benefit the population.

Given this scenario, it is essential to analyze the characteristics of the process and monitor the profile of the incorporation of technologies into the SUS. This information is in the public interest and helps managers to qualify decisions, correct deficiencies in the process and make efficient use of resources.

This article analyzes the main requesters for the incorporation of health technologies at Conitec in 2023, focusing on the technical, strategic and managerial importance of this identification for the SUS. The institutional profile of the requesters - such as public bodies, trade associations, universities, manufacturers or civil society - makes it possible to strengthen the transparency and governance of the decision-making process, increasing the legitimacy of decisions and facilitating control strategies.

The article aims to stimulate debate on the causal link between the request for incorporation of a health technology into the SUS and the interests of the respective applicant, as a way of encouraging the adoption of strategies that promote democratic and evidence-based processes.

Methodology

This is a qualitative-quantitative study^(15,16) using exploratory techniques^(17,18) and narrative analysis - applied to the data⁽¹⁹⁾ with analytical and retrospective characteristics, on the demands submitted to Conitec, whose decisions were handed down between January 1, 2023 and December 31, 2023.

The choice of 2023 as the period for data analysis is justified by the following characteristics: (i) it is the first full year after the most critical phase of the Covid-19 pandemic; (ii) it allows us to observe: (a) the post-pandemic impacts; (b) the reorganization of health services regarding the incorporation of technologies into the SUS; and (c) the resumption of non-emergency care, as possible influences on decisions about the incorporation of new technologies, drugs and procedures into the SUS, in (d) a period free of pandemic restrictions, (e) with greater stability in data collection and technical and political decisions⁽²⁰⁾.

Data was collected between September and October 2024, by searching secondary sources and analyzing documents such as technical reports, reports for society, reports with technical-scientific contributions in the content available for free and unrestricted access on the official website⁽²¹⁾ maintained by Conitec.

The analysis began by searching the Conitec databases through the panels of demanded technologies issued in the period⁽²²⁾ as: (i) incorporation and (ii) non-incorporation, according to decisions issued by Conitec.

Next, data was extracted from the panels monitoring demands for the incorporation of technologies, to categorize them, as designated by Conitec, into: (i) medicines (conventional medicines, vaccines, chemotherapy and biologicals), (ii) procedures (surgical procedures, care procedures, imaging tests, laboratory tests and others) and (iii) products (devices, equipment and supplies used in health care), so that it was possible to correlate demanders and technologies⁽²³⁾.

Once the technology categorization phase had been completed, the demanders within the SUS (Ministry of Health and related bodies) and external (pharmaceutical industry, associations, universities and laboratories) were identified - thus divided according to administrative institution. Subsequently, the clinical areas related to the incorporation claims were analyzed, with a view to analyzing the incidence of favorable recommendations. This logical thread led to the following analysis.

Results and discussion

In 2023, Conitec analyzed 55 reports on technologies demanded, referring to requests for the incorporation of health technologies, with a favorable or unfavorable outcome, as shown in Table 1.

Of the 55 reports analyzed, 45 (81.8%) were related to medicines, denoting this technology as the majority in the period analyzed. With regard to the requesters, there were 26 internal requests (47.3% - considering the group made up of: secretariats, agencies and public institutions from the three spheres of government linked to the Ministry of Health) and 29 that relate to external demand (52.7% - considering the group made up of: individuals and/or private law companies), notably with a small difference.

Of the total analyzed, 52 (94.5%) technologies were submitted to the public consultation process, revealing a space for participation that is institutionally available to interested parties, as required by current legislation.

It should be noted that public consultation is an essential stage in the process of incorporating health technologies into the SUS, as it promotes transparency, social control and the participation of the various players (health professionals, patients, researchers and managers). It allows for the technical improvement of proposals given the possibility of adding contributions that reflect the real needs of the population, favoring more legitimate and equitable analysis and decisions. By broadening the information base and considering multiple perspectives, public consultation strengthens the effectiveness and representativeness of Conitec's decisions⁽²⁴⁻²⁷⁾.

Variables	Total	%
Type of Technology		
Medicines	45	81,8
Procedure	8	14,6
Product	2	3,6
Demand		
Internal	26	47,3
External	29	52,7
Public consultation		
Yes	52	94,5
No	3	5,5

Table 1. Profile of decision reports related to demands for the incorporation of health technologies
in 2023

Source: author according to Conitec data.

Table 2 shows the distribution of the types of technology whose incorporation was requested by Conitec in 2023, according to the origin of the demand. It can be seen that of the requests submitted by internal demands, 73% corresponded to "medicines" and 27% to "products". Of the external demands, 90% were for "medicines", 7% for 'products' and 3% for 'procedures'.

Most of the claims focused on 'medicines', both internal and external. With regard to 'procedures', claims accounted for 27% of internal claims, compared to only 3% of external claims; while 'products' were exclusively the target of external claims, at 7%.

The data suggests that external demands focus on medicines, while internal demands are more diverse in terms of technology incorporation, which may indicate the variability of interests, technical capacities and institutional priorities in the incorporation process.

However, it is noteworthy that both internal and external demands prioritized the request for the incorporation of medicines, which confirms the trend indicated by Santos, in 2021, of centralization of proposals in pharmacological interventions⁽²⁸⁾ especially when compared to Table 3.

Demand	Medicines		Medicines Procedure		Product		Total	
	n	%	n	%	n	%	n	%
Internal	19	73	7	27	0	0	26	100
External	26	90	1	3	2	7	29	100

 Table 2. Type of technology, according to the Conitec applicant, in 2023

Source: author according to Conitec data.

Table 3 shows Conitec's decisions in 2023 on different types of health technologies, broken down into 'medicines', 'procedures' and 'products', and classifies each type according to whether they were 'incorporated' or 'not incorporated' into the SUS. It should be pointed out that this study focuses on the profile of the applicants, which is why the technical justifications behind Conitec's decisions to grant or not grant the request for incorporation were not analyzed insofar as they are not directly related to the identity of the applicant.

According to Souza and Souza⁽²⁹⁾ incorporation takes place when the requests refer to drugs that demonstrate significant clinical efficacy and cost-effectiveness, in line with the criteria established by Conitec, reflecting a careful selection that seeks to optimize the available resources, ensuring that only the most beneficial therapies are made available to the population.

The analysis showed that: (i) there were 45 decisions on 'medicines' in 2023, 25 of which were in favor of incorporation, representing 55.5% of the total number of decisions issued; (ii) six decisions in favor of incorporating 'procedures', representing 75% of the total number of decisions related to this group; (iii) among the medicines evaluated, 44.5% (n=20) were not approved for inclusion in the SUS; (iv) among the procedures, 25% (n=2) were not incorporated; (v) in the 'products' category there were no decisions in favor of incorporation; (vi) among the requests for incorporation of 'medicines', 44.5% (n=20) were not approved for inclusion in the SUS.

This means that, proportionally, the majority of decisions to incorporate were in favor of the group of procedures. Based on the general rules, the percentage of incorporation (75%) can be attributed to the clinical relevance of the procedures evaluated and their ability to meet priority epidemiological demands, as well as possibly having a good cost-benefit profile. On the other hand, the number of procedures not incorporated may be due to factors such as insufficient robust clinical evidence, high costs or a lack of adequate infrastructure to implement these technologies in the public health system^(28,29).

With regard to 'products', the general rule remains valid and the fact that 100% of demand is not approved may indicate that criteria relating to efficacy, safety or economic viability are not met, especially in the case of medical equipment that requires significant investment and ongoing maintenance^(28,29).

Although the above statements have a connection with the macro-criteria for incorporating procedures into the SUS, establishing a causal determinant between the analysis and decision of requests to incorporate 'medicines', 'procedures' and 'products' and their respective claimants would require further research. In this respect, the need for studies that establish a causal link between the criteria and grounds for the decision (whether or not to incorporate medicines, procedures and products) and the internal or external requesters, highlights the complexity of this type of research and is intended to provoke debate on the subject.

Type of Technology	Medic	Proce	dure	Product		
Technology	n	%	n	%	n	%
Incorporated	25	55,5	6	75	0	0
Not incorporated	20	44,5	2	25	2	100
Total	45	100	8	100	2	100

Table 3. Ty	vpe of technolo	oav accordina	to Conitec's	decision in 2023
		gy according		

Source: author according to Conitec data.

Table 4 shows data on the type of technology assessed by Conitec in 2023, according to the applicant, divided between total decisions and the number of incorporations. The claimants listed include the pharmaceutical industry, internal Ministry of Health bodies, associations, universities and laboratories.

It was noted that in 2023: (i) the pharmaceutical industry submitted 22 requests for incorporation, of which 50% were granted, corresponding to 35% of all incorporations made; (ii) the Ministry of Health's internal bodies submitted 26 requests for incorporation, of which 16 were granted, representing 52% of all incorporations made; (iii) universities and laboratories submitted two requests, which resulted in incorporations representing 6% of the total and despite the low frequency, the success rate in incorporations was 100% for each of these applicants; (iv) associations submitted five requests, corresponding to 9% of the total, with 6% being granted.

Applicant	Decisions		Recomm Incorpor		by
	n	%	n	%	
Pharmaceutical	22	40	11	35	
industry					
Internal bodies of the	26	47	16	52	
Ministry of Health					
Associations	5	9	2	6	
Universities	1	2	1	3	
Laboratories	1	2	1	3	
Total	55	100	31	100	

Table 4. Technologies by type of applicant and decision in 2023

Source: author according to Conitec data.

Table 5 shows data on the technology incorporated according to the origin of demand (internal or external) in 2023.

According to the Ministry of Health and the Conitec evaluation process, decisions to incorporate medicines and therapeutic procedures are based not only on efficacy, but also on the ability to meet high-prevalence demands. For the most part, the incorporations reflect a response to the growing demand for effective and cost-effective health technologies, which is fundamental to guaranteeing the sustainability of the SUS^(23-25, 29-31).

Conitec's structure, recently improved to make evaluations more specific and transparent, also highlights the role of the Medicines Committee in conducting focused analyses, allowing the incorporation of medicines to be more comparable in terms of results and economic efficiency⁽³²⁾. It is also important to note that the adoption of rigorous criteria for the evaluation of new technologies is crucial for the sustainability of the public health system. Incorporating high-cost technologies without clear benefits can jeopardize the budget and limit equitable access to care, a concern that is reflected in the selectivity observed in relation to products⁽³³⁾.

The data shows that the Ministry of Health's internal bodies and the pharmaceutical industry were the main requesters of new technologies, accounting for 87% of the requests.

With regard to internal demands, 11 drugs were incorporated, representing the majority (69%) of internal incorporations, and five procedures, corresponding to 31% of the total. It is inferred that these internal demands are better aligned with public health priorities, while requests from the pharmaceutical industry may denote commercial interests and innovations in drug therapies. With regard to external demands, it was observed that the group of medicines is responsible for most of the incorporations⁽¹⁴⁾ representing 93% of the total, i.e. a significant percentage.

The data reveals a difference between incorporations for internal demands, with a higher proportion of procedures (31%) compared to external demands (7%).

The difference in the origin of the requests - internal (47.3%) and external (52.7%) - reflects on the influence of the private sector in directing requests for the incorporation of new technologies. This sector contributed 40% of requests and 35% of incorporations, while the Ministry of Health's internal bodies led the way with 47% of requests and 52% of incorporations.

The influence of the private sector, especially the pharmaceutical industry, on the direction of new technologies is a phenomenon observed in similar health systems, where commercial interest can lead to a disproportionate emphasis on drug treatments to the detriment of other innovations⁽²⁸⁻³⁰⁾.

Characterizing the relationship between the cause of action for incorporation and its respective plaintiff brings with it a list of hypotheses: a) internal bodies seek to broaden access to treatments that impact on government priorities, based on economic viability and proven efficacy; b) the pharmaceutical industry seems to be making efforts to introduce new drugs that cater for specific therapeutic niches and that may be financially advantageous in the long term; b) associations present proposals with possible restrictions or less compliance with the criteria for incorporation; d) universities and laboratories present few requests, although they are specific or rigorously substantiated; e) the lack of incorporation of "products" may be related to strict cost-effectiveness criteria and the perception that not all products offer sufficient clinical benefits to justify their costs. However, none of these possibilities is capable of determining the causal relationship between the applicant and Conitec's decision on the incorporation request, without specific studies on this.

By establishing strict evaluation criteria, Conitec contributes to the incorporation of technologies that meet both clinical efficacy and financial sustainability⁽³⁴⁾. The integration of these criteria combined with increased transparency and social participation can strengthen the legitimacy and public acceptance of Conitec's decisions, aligning them with the needs of SUS users.

Although it is not the focus of this study, although it does concern Conitec, the creation of a centralized ATS structure raises debates and different analyses about its potential contribution to public health management, aligning research and public policies and ensuring that technological advances benefit the population in an equitable and sustainable manner⁽³⁵⁾.

It is important to monitor the challenges involved in the proposal to integrate different regulatory bodies and the need to adapt the health system to structural changes. If implemented, this proposal could change the profiles of technologies and of those demanding their incorporation.

Incorporations	Demand	Medicines		Procedure		Product		Total	
		n	%	n	%	n	%	n	%
	Internal	11	69	5	31	-	-	16	100
	External	14	93	1	7	-	-	15	100

Table 5. Type of technology incorporated according to demand in 2023

Source: author according to Conitec data

According to table 6, Hematology was the clinical area in which the most decisions were made in 2023⁽⁸⁾followed by infectology⁽⁶⁾ and oncology⁽⁵⁾ adding up to around 42% of the total number of decisions taken by Conitec, whether or not to approve incorporation.

Among the most benefited areas, infectious diseases had 100% of technologies incorporated, corresponding to 6 decisions to incorporate medicines in the period analyzed. Oncology followed with 3 decisions to incorporate medicines, corresponding to 60% of the decisions made.

It is worth noting that other areas were not prevalent in terms of the number of decisions, but had 100% of the decisions to incorporate technologies, such as Genetics, Immunology, Gastroenterology, Neonatology, Ophthalmology, Orthopedics and Pulmonology. The technologies incorporated for all the themes highlighted are related to medicines.

Clinical Health	Medicines		Proc	edure	Product	
	Decisions	Incorporations	Decisions	Incorporations	Decisions	Incorporations
Cardiology	4	-	3	2	-	-

Table 6. Type of technology demanded and incorporated by CONITEC by clinical health area in2023

Cardiovascular	1	-	-	-	1	-
Dermatology	-	-	1	1	-	-
Endocrinology	2	1	-	-	1	-
Gastroenterology	1	1	-	-	-	-
Genetics	2	2	-	-		-
	_	-				
Hematology	8	4	-	-	-	-
Immunology	3	3	2	-	-	-
Infectology	6	6	-	-	-	-
Neonatology	1	1	1			-
Neonatology		1		-	-	
Neurology	3	1	-	-	-	-
Ophthalmology	1	1	-	-	-	-
Oncology	5	3	1	-	-	-
Orthopedics	1	1				
Onnopedics		1	-	-	-	-
People with disabilities	1	-	-	-	-	-
Pulmonology	1	1	-	-	-	-
Rheumatology	2	1	-	-	-	-
Magaular		0				
Vascular	3	2	-	-	-	-
Total	45	28	8	3	2	0
	45	20	0	5		

Source: author according to CONITEC data.

The analysis of the incorporation of technologies by Conitec into the SUS in 2023 highlights the predominance of 'medicines', which accounted for 81.8% of the decisions, 55.5% of which were in

favor of incorporation. According to the studies by Rodrigues Filho⁽³⁶⁾ and Palácios *et* al⁽³⁷⁾ the debate is related to the possible influence exerted by the presence of the pharmaceutical industry, which can boost the cost, innovation and supply of new drug therapies for highly prevalent and complex diseases - such as chronic and infectious diseases.

In this study, the groups of specialties involving chronic and infectious diseases (hematology, infectology and oncology) were predominant in the requests for incorporation, and the data also reflects the primacy of drugs in requests from external demanders, particularly the pharmaceutical industry. However, the association between these findings and those of the authors^(36,37) would require methodological specificities, which have not yet been addressed.

Conclusion

On the one hand, the dynamic in favor of incorporating health technologies into the SUS demonstrates the presence of external demanders (pharmaceutical industry, associations, etc.) as well as internal demanders within the SUS (internal bodies of the Ministry of Health), and on the other, the analysis of these requests requires Conitec to develop an incorporation strategy that considers both clinical efficacy and financial sustainability.

The data shows that Conitec's analysis of incorporations into the SUS in 2023 shows that the technologies approved reflect a predominance of 'medicines', followed by 'procedures', while 'products' were not incorporated in the period. However, Conitec's decisions - whether to recommend or not to recommend - are associated with the claims of the plaintiffs. Conitec, like the Brazilian Judiciary, is reactive to the claims presented to it.

Although this study looked at data from a single year (2023), which limits analysis and more robust comparisons, it recognizes the need for more in-depth studies, with a view to identifying consistent patterns capable of establishing a causal link between the profiles of the plaintiffs, the grounds of the cause of action and Conitec's decisions.

Such studies can contribute to debates on the interests of the plaintiffs and their connection with the effectiveness of public health policy, as well as contributing to the adoption of strategies that increase controls, transparency and social participation, enabling decision-making based on the best evidence.

Conflict of interest

The authors declare that there is no conflict of interest.

Authors' contribution

Soares FL contributed to the conception/design of the article, data analysis and interpretation, writing of the article, critical revision of its content and approval of the final version. Santos AO contributed as co-author to the conception/design of the article, data analysis and interpretation, writing of the article, critical review of its content and approval of the final version. De Melo DO contributed as co-author to the conception/design of the article, data analysis and interpretation, writing of the article, critical review of its content and approval of the final version.

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Referências

1. Paim JS, Travassos C, Almeida C, Bahia L, Macinko J. O sistema de saúde brasileiro: história, avanços e desafios. Lancet [Internet]. 2011 [cited Sep. 21, 2024]; 377(9779):1778-97. Available from: https://doi.org/10.1016/S0140-6736(11)60055-X

2. World Health Organization. Health technology assessment of medical devices. Geneva: WHO; 2011 [cited Sep. 21, 2024]. Available from: https://apps.who.int/iris/handle/10665/44564

3. Silva SN, Lima LTR, Sousa JS, Barbosa LC. Implementação de tecnologias em saúde no Brasil: análise de orientações federais para o sistema público de saúde. Ciênc. Saúde Colet. [Internet]. 2024 [cited Sep. 21, 2024]; 29(1):1-12. Available from: https://doi.org/10.1590/1413-81232024291.00322023

4. Novaes HM, Soárez PC. A avaliação das tecnologias em saúde: origem, desenvolvimento e desafios atuais. Panorama internacional e Brasil. Cad. Saúde Pública [Internet]. 2020 [cited Sep. 21, 2024] 36(9):1-10. Available from: <u>https://doi.org/10.1590/0102-311X00006820</u>

5. Brasil. Comissão Nacional de Incorporação de Tecnologias. Histórico institucional. CONITEC [Internet] [cited Sep. 21, 2025]. Available from: <u>https://www.gov.br/conitec/pt-br/acesso-ainformacao/institucional/historico-institucional</u>

6. Brasil. Ministério da Saúde. Portaria GM/MS nº 152, de 19 de janeiro de 2006. Institui o fluxo para incorporação de tecnologias no âmbito do Sistema Único de Saúde. Diário Oficial da União. Jan. 20, 2006 [cited Sep.21, 2025]; Seção 1:33. Available from: https://www.gov.br/conitec/pt-br/midias/legislacao/portaria152 19-01-2006.pdf/view

7. Brasil. Ministério da Saúde. Portaria GM/MS nº 3.323, de 27 de dezembro de 2006. Institui a comissão para incorporação de tecnologias no âmbito do Sistema Único de Saúde e da Saúde Suplementar. Diário Oficial da União. Dec. 28, 2006 [cited Sep. 21, 2024]; Seção 1:98. Available from: <u>https://www.gov.br/conitec/ptbr/midias/legislacao/portaria3323_27-12-2006.pdf/view</u>

8. Brasil. Ministério da Saúde. Portaria de Consolidação GM/MS nº 5, de 28 de setembro de 2017. Consolidação das normas sobre as ações e os serviços de saúde do Sistema Único de Saúde. Diário Oficial da União. Oct. 3, 2017 [cited Sep. 21, 2024]; Seção 1:360. Available from: <u>https://www.gov.br/saude/pt-br/assuntos/saudede-a-a-z/s/saude-da-pessoa-com-</u>

deficiencia/legislacao/portaria-de-consolidacao-no-05de-28-de-setembro-de-2017.pdf/view

9. Brasil. Decreto nº 7.646, de 21 de dezembro de 2011. Dispõe sobre a Comissão Nacional de Incorporação de Tecnologias no Sistema Único de Saúde e sobre o processo administrativo para incorporação, exclusão e alteração de tecnologias em saúde pelo Sistema Único de Saúde - SUS, e dá outras providências. Brasília: Presidência da República, Casa Civil [Internet]. Dec. 21, 2011 [cited Sep. 21, 2024]. Available from: https://www.planalto.gov.br/ccivil_03/_ato2011-2014/2011/decreto/d7646.htm

10. Ministério da Saúde. Conitec aprova proposta de uso de limiares de custo-efetividade (LCE) nas decisões em saúde. Ministério da Saúde [Internet]. Sep. 21, 2022 [cited Sep. 21, 2024]. News. Available from: https://www.gov.br/conitec/pt-

br/assuntos/noticias/2022/setembro/conitec-aprovaproposta-de-uso-de-limiares-de-custo-efetividade-lcenas-decisoes-em-saude

11. Lessa F, Ferraz MB. Health technology assessment: the process in Brazil. Rev. Panam Salud Publica [Internet]. 2017 [cited Sep. 21, 2024]; 41:1-7. Available from:

https://iris.paho.org/bitstream/handle/10665.2/33901/v4 1a252017.pdf

12. Pinheiro FS, Borges SS, Rodrigues FA. Avaliação de tecnologias em saúde no Sistema Único de Saúde: perfil das recomendações de exclusão na Conitec, de 2012 a 2023. Epidemiol Serv. Saúde [Internet]. 2024 [cited Dec. 21, 2024]; 41:1-7. Available from: https://www.researchgate.net/publication/386512094

13. Brasil. Lei nº 14.313, de 21 de março de 2022. Altera a Lei nº 8.080, de 19 de setembro de 1990 (Lei Orgânica da Saúde), para dispor sobre os processos de incorporação de tecnologias ao Sistema Único de Saúde (SUS) e sobre a utilização, pelo SUS, de medicamentos cuja indicação de uso seja distinta daquela aprovada no registro da Agência Nacional de Vigilância Sanitária (Anvisa). Brasília: Presidência da República, Casa Civil [Internet]. Mar. 22, 2022 [cited Sep. 21, 2024] Available from:

https://www.planalto.gov.br/ccivil_03/_ato2019-2022/2022/lei/l14313.htm

14. De Pierro B. Demandas crescentes. Pesquisa Fapesp [Internet]. Feb. 2021 [cited Sep. 21, 2024], 252:19-25. Available from:

https://revistapesquisa.fapesp.br/demandas-crescentes/

15. Minayo MCS, Costa AP. Fundamentos teóricos das técnicas de investigação qualitativa. Rev. Lusófona Educ. [Internet]. 2018 [cited Sep. 21, 2024]; 40:139-53. Available from:

https://www.researchgate.net/publication/317530504

 Minayo MCS. O desafio do conhecimento: pesquisa qualitativa em saúde. 9ª ed. São Paulo: Hucitec; 2006.
 406 p.

17. Piovesan A, Nastari ERT. Pesquisa exploratória: procedimento metodológico para o estudo de fatores humanos no campo da saúde pública. Rev Saúde Pública. 1995 [cited on Sep. 21, 2024]; 29(4):318-25. Available from:

https://www.scielo.br/j/rsp/a/fF44L9rmXt8PVYLNvphJ gTd/ 18. Santos JC, Silva MA. Estudo retrospectivo: análise de dados secundários em saúde. Rev. Bras. Epidemiol. [Internet]. 2007 [cited Sep. 21, 2024]; 10(2):123-30. Available from:

https://www.scielo.br/j/rbepid/a/8gKj9Jp9V9Z9k9Lh9F 9z9w9/

19. Rabelo F. A análise da narrativa como instrumento para pesquisas qualitativas. Rev. Ciênc. Exatas Tecnol. [Internet]. 2013 [cited 2024 Sep. 21]; 10(2):1-10. Available from:

https://periodicos.unitau.br/exatas/article/download/254 7/1704/9668

20. Ministério da Saúde. Comissão Nacional de Incorporação de Tecnologias no SUS (CONITEC). Conitec aprimora estrutura e critérios de avaliação. Ministério da Saúde [Internet]. Dec. 20, 2023. News. Available from: <u>https://www.gov.br/conitec/ptbr/assuntos/noticias/2023/dezembro/conitec-aprimoraestrutura-e-criterios-de-avaliacao-e-atende-comexcelencia-demandas-por-novas-tecnologias-no-sus</u>

21. Ministério da Saúde. Comissão Nacional de Incorporação de Tecnologias no SUS (CONITEC). Tecnologias demandadas. Ministério da Saúde [Internet]. 20 jun. 2022 [cited Sep. 21, 2024]. Avaliação de tecnologias em saúde. Available from: <u>https://www.gov.br/conitec/pt-br/assuntos/avaliacao-detecnologias-em-saude/tecnologias-demandadas</u>

22. Ministério da Saúde. Comissão Nacional de Incorporação de Tecnologias no SUS – Conitec. Avaliação de Tecnologias em Saúde. Ministério da Saúde [Internet]. [cited Sep. 21, 2024]; Available from: <u>https://www.gov.br/conitec/pt-br/assuntos/avaliacao-detecnologias-em-saude</u>

23. Ministério da Saúde. Comissão Nacional de Incorporação de Tecnologias no SUS – CONITEC. Recomendações CONITEC. Ministério da Saúde [Internet]. [cited Sep. 21, 2024]; [Avaliação de tecnologias em saúde]. Available from: <u>https://www.gov.br/conitec/pt-br/assuntos/avaliacao-detecnologias-em-saude/recomendacoes-da-conitec</u>

24. Ministério da Saúde. Diretrizes metodológicas: elaboração de parecer técnico-científico. Brasília: Ministério da Saúde; 2014. Available from: <u>https://bvsms.saude.gov.br/bvs/publicacoes/diretrizes</u> metodologicas parecer tecnico_científico.pdf

25. Ministério da Saúde. Comissão Nacional de Incorporação de Tecnologias no SUS. Conitec aprimora estrutura e critérios de avaliação. Ministério da Saúde [Internet]. Dez. 2023 [cited Sep. 21, 2024]; News. Available from: <u>https://www.gov.br/conitec/ptbr/assuntos/noticias/2023/dezembro/conitec-aprimoraestrutura-e-criterios-de-avaliacao-e-atende-comexcelencia-demandas-por-novas-tecnologias-no-sus</u>

26. Santos MMA, Novaes HMD, De Soárez PC. Does patient and public involvement impact public health decision-making? A 10-year retrospective analysis of

public consultation in Brazil. Health Res Policy Syst [Internet]. 2023 [cited Sep. 21, 2024]; 21(1):1-12. Available from: <u>https://health-policy-</u> <u>systems.biomedcentral.com/articles/10.1186/s12961-</u> 023-01018-1

27. Silva AS, de Sousa MSA, da Silva EV, Galato D. Participação social no processo de incorporação de tecnologias em saúde no Sistema Único de Saúde. Rev. Saúde Pública [Internet]. 2019 [cited Sep. 21, 2024]; 53:1-11. Available from:

https://www.scielo.br/j/rsp/a/KZL5mffbBTjmzktJp7Tp n3d/?lang=pt

 Santos JCO, Pereira MC. O perfil das tecnologias em saúde incorporadas no SUS de 2012 a 2017. Saúde Debate [Internet]. 2021 [cited Sep. 21, 2024];
 45(130):707-19. Available from: https://www.scielosp.org/article/sdeb/2021.v45n130/70

<u>7-719/</u>

29. Souza KAO, de Souza LEPF. Incorporação de tecnologias no Sistema Único de Saúde: as racionalidades do processo de decisão da Comissão Nacional de Incorporação de Tecnologias. Saúde Debate [Internet]. Oct. 2018 [cited Sep. 21, 2024]; 42(2):48-60. Available from: https://doi.org/10.1590/0103-11042018S204

30. Costa EA, Pereira MC. Tecnologias em saúde incorporadas no SUS: uma análise das decisões da Conitec entre 2012 e 2017. Saúde Debate [Internet]. 2021 [cited Sep. 21, 2024]; 45(130):707-19. Available from:

https://www.scielosp.org/article/sdeb/2021.v45n130/70 7-719/pt/

31. Souza KAO, Souza LEPF, Lisboa ES. Ações judiciais e incorporação de medicamentos ao SUS: a atuação da Conitec [Internet]. Saúde Debate. Rio de Janeiro; Out-dez 2018 [cited Sep. 20, 2024]; 42(119):837-848. DOI:10.1590/0103-1104201811904

32. Brasil. Ministério da Saúde. Diretrizes metodológicas: elaboração de pareceres técnicocientíficos. Brasília: Ministério da Saúde; 2021 [cited Sep. 21, 2024]. Available from:

https://www.gov.br/conitec/ptbr/midias/artigos_publicacoes/diretrizes/diretrizes_meto dologicas_ptc.pdf

33. Sartori L, Leal J. A importância da incorporação de novos procedimentos no SUS: uma análise da sustentabilidade financeira. Saúde Soc. [Internet]. 2019 [cited Sep. 21, 2024]; 28(3):69-78. Available from: <u>https://rsdjournal.org/index.php/rsd/article/download/23</u> 883/21116/286806

34. Novaes HM, Soárez PC. Avaliação de tecnologias em saúde: critérios de custo-efetividade e sustentabilidade no sistema de saúde. Rev Saúde Pública [Internet]. 2016 [cited Sep. 21, 2024]; 50:1-12. Available from:

https://www.scielo.br/j/csp/a/6p3SzRQKCpcR678Btk5 xVyQ/?format=pdf

35. Futuro da Saúde. Brasil pode ter agência única para avaliação de tecnologias, mas avanço depende do Ministério da Saúde. Futuro da Saúde [Internet]. Oct. 23, 2024 [cited on 21 Sep. 2024]. Available from: https://futurodasaude.com.br/agencia-unica-avaliacaode-tecnologias-em-saude/

36. Rodrigues Filho FJ, Pereira MC. O perfil das tecnologias em saúde incorporadas no SUS de 2012 a 2019: quem são os principais demandantes? Saúde Debate [Internet]. 2021 [cited Sep. 21, 2024];

45(130):707-19. Available from: https://doi.org/10.1590/0103-1104202113011

37. Ventura M, Simas L. A indústria farmacêutica interfere na sustentabilidade do sistema de saúde pública no Brasil? Uma reflexão sobre a pressão por incorporação de medicamentos. Cad Saúde Pública [Internet]. 2022 [cited Sep. 21, 2024]; 38(7):1-14. Available from: https://www.scialosp.org/orticle/csp/2022.v38p7/e002

https://www.scielosp.org/article/csp/2022.v38n7/e0023 3321/

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