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Impacto econômico das incorporações de tecnologias em saúde no SUS: uma análise de relatórios da Conitec no período de 2017 a 2022*

Economic impact of incorporating health technologies into the SUS: an analysis of Conitec reports from 2017 to 2022

Impacto económico de la incorporación de tecnologías sanitarias en el SUS: análisis de los informes de Conitec de 2017 a 2022

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RESUMO

Objetivo: analisar o potencial impacto econômico das decisões da Conitec no período de 2017 a 2022. **Método:** estudo descritivo e exploratório a partir dos Relatórios de Recomendação da CONITEC (2017 – 2022). **Resultados:** Foram identificadas 328 demandas apresentadas a Conitec. 53,9% foram feitas ou pelo Ministério da Saúde e suas Secretarias, ou por órgãos e instituições púbicas. Medicamentos foram as tecnologias mais demandadas 76,3%. **Conclusão:** demandadas no período de 2017 a 2022 resultaram em impacto orçamentário com potencial para gerar economia e salvar recursos para a sociedade brasileira.

Descritores: Impacto orçamentário, Avaliação de tecnologias em saúde, Sistema único de saúde, Economia da saúde.

ABSTRACT

Objective: to analyze the potential economic impact of CONITEC decisions from 2017 to 2022. **Methods:** descriptive and exploratory study based on CONITEC Recommendation Reports (2017 - 2022). **Results:** 328 demands submitted to Conitec were identified. 53.9% were made either by the Ministry of Health and its Secretariats, or by public bodies and institutions. Medicines were the most demanded technology, 76.3%. **Conclusion:** only the set of technologies with a favorable opinion for incorporation into the SUS, requested between 2017 and 2022, resulted in a budgetary impact with the potential to generate savings and save resources for Brazilian society.

Descriptors: Budgetary impact, Health technology assessment, Single health system, Health economics.

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RESUMEN

Objetivo: analizar el impacto económico potencial de las decisiones del CONITEC de 2017 a 2022. **Métodos:** estudio descriptivo y exploratorio basado en los Informes de Recomendación del CONITEC (2017 - 2022). **Resultados:** se identificaron 328 demandas presentadas al Conitec. El 53,9% fueron realizadas por el Ministerio de Salud y sus Secretarías, o por organismos e instituciones públicas. Los medicamentos fueron la tecnología más demandada, 76,3%. **Conclusión:** sólo el conjunto de tecnologías con dictamen favorable para incorporación en el SUS, solicitadas entre 2017 y 2022, resultó en impacto presupuestario con potencial de generar economía y ahorrar recursos para la sociedad brasileña.

Descriptores: Impacto presupuestario, Evaluación de tecnologías sanitarias, Sistema único de salud, Economía de la salud

INTRODUCTION

Over the last three decades, Brazil has built and consolidated the largest public and universal health system in the world. The Sistema Único de Saúde (Brazilian Unified Health System), or SUS, has undoubtedly represented a huge step forward in terms of social policies in the country, creating, providing and expanding access to health services to an increasing number of people with previously unmet needs, resulting in an improvement in the Brazilian population's health indicators and the efficiency of the services offered (GRAGNOLATI et al, 2013).

In order for the principles of the SUS to be guaranteed, the Ministry of Health has to make decisions that involve, among other things, the incorporation of health technologies aimed at the prevention, diagnosis and treatment of diseases, in a context of scarce resources, increased demand and alternatives available on the market, further increasing uncertainty as to what should or should not be incorporated into the health system.

Created by Law No. 12.401 of April 28, 2011 and regulated by Decree No. 7.646 of December 21, 201, the National Commission for the Incorporation of Tecnologias no Sistema Único de Saúde (CONITEC) is a permanent collegiate body whose purpose is to advise the Ministry of Health on decisions regarding the incorporation, exclusion or alteration of health technologies, as well as the drafting or alteration of clinical protocols and therapeutic guidelines in the SUS. These decisions are based on criteria of efficacy, safety, cost-effectiveness and budgetary impact, and the body is responsible for the entire process of incorporating technologies into the SUS (NOVAES et al, 2020).

CONITEC follows a technology incorporation flow, where it receives, analyzes, submits to public consultations and deliberates on requests made by various applicants within 180 days, which can be extended for another 90 days. Requesters can be private companies, public bodies such as the Ministry of Health (MoH), patient associations and other organizations. The technologies registered can be medicines, health products or medical procedures and the requests must meet a series of criteria proposed by the Commission.

The incorporation of industrialized products has been the main cause of cost increases in the SUS, with medicines being the technologies that contribute most to this. In 2022, Conitec received and analyzed 87 requests. In the first eight months of 2023 alone, there were 39 (Conitec, 2023). It is estimated that annual spending on the purchase of health products and technologies in Brazil could exceed R$20 billion (GUIMARÃES et al, 2019).

Although from the patient's perspective, the benefits provided by technological innovations in healthcare are priceless, the resources available for investment in health policies are finite. The incorporation of a drug for the treatment of cancer, for example, may make it impossible to meet the demand of other groups of patients.

For this reason, from the perspective of health economics, new technologies are analyzed from the point of view of their costs and benefits, considering that investing resources in certain technologies may result in a lack of budget for others, thus introducing the concept of opportunity cost in the management of health resources and in the decision-making process regarding the incorporation of health technologies into the SUS (TOMA, 2012).

In addition to the safety and efficacy/effectiveness of the alternatives under evaluation in the decision-making process, decision-making is also influenced by economic aspects, since it is necessary to consider the sustainability of the public health system. Therefore, the Ministry of Health needs to take into account the social impact of the alternatives being analyzed in the process of incorporating health technologies into the SUS.

Previous studies have suggested that economic factors have been the most important factors guiding Conitec's decisions, although it is not known how much the results of budget impact analyses have influenced these decisions (ELIAS et al, 2014; YUBA et al, 2018).

OBJECTIVE

To analyze the potential economic impact of Conitec's decisions, based on an analysis of the recommendation reports from 2017 to 2022.

METHODOLOGY

This is a descriptive and exploratory study whose source of information was CONITEC's Recommendation Reports, available for consultation on its website (http://conitec.gov.br/), from which information on the demands for incorporating health technologies into the SUS was extracted. The reports were chosen as the empirical material for analysis because they are the product of the entire flow of recommendations for incorporating a technology into the SUS.

The time horizon of the analysis was six years, covering the period from 2017 to 2022. This period was selected because it is relatively broad, six years, covering the pre-pandemic period (2017 to 2019) and the pandemic period (2020 to 2022).

Data was read and extracted from all the final recommendation reports related to requests for the incorporation of medicines, equipment, procedures or supplies publicly available on CONITEC's website, published between February 2017 and March 2022.

Requests for appraisal and approval of Protocolos Clínicos e Diretrizes Terapêuticas (Clinical Protocols and Therapeutic Guidelines) (PCDT) were not considered, although they are also considered health technologies.

The variables of interest were: year of publication of the report, technology requested, pharmacological class, indication for use, budgetary impact, time horizon and Conitec's final recommendation. All the information extracted from the recommendation reports was organized for later analysis in an Excel spreadsheet version 2023.

To estimate the economic impact of the demands, the budget impact for the first year of the time horizon of the analysis defined in the Reports was considered. In the absence of this information, the arithmetic mean of the budget impact for the years analyzed was extracted.

In order to estimate the overall economic impact of all the technologies demanded during the analysis period, the sum (balance between technologies whose budgetary impact saves resources and those that increase costs) of the values referring to the budgetary impact

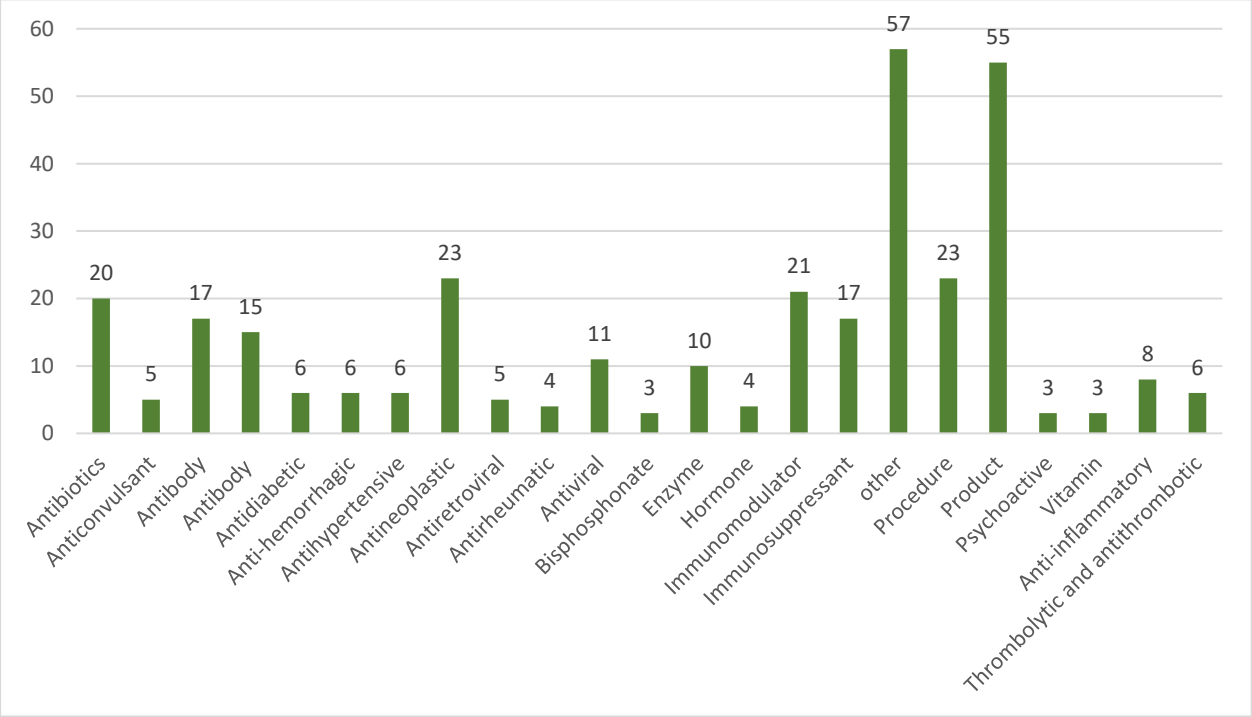
of each of the technologies, stratified by year of demand, type of technologies demanded, with a favorable and unfavorable opinion on incorporation, was carried out.

RESULTS

The results of this study identified 328 requests submitted to Conitec between 2017 and 2022. Of this total, 53.9% (n. 177) were made either by the Ministry of Health and its Secretariats, or by public bodies and institutions.

Medicines were the most demanded technologies in the period, accounting for 76.3% (n. 250) of the demands. Antineoplastics accounted for 9.2% (n. 23) of the total medicines demanded, followed by immunomodulators with 8.4% (n. 21) and antibiotics with 8% (n. 20) (Figure 1).

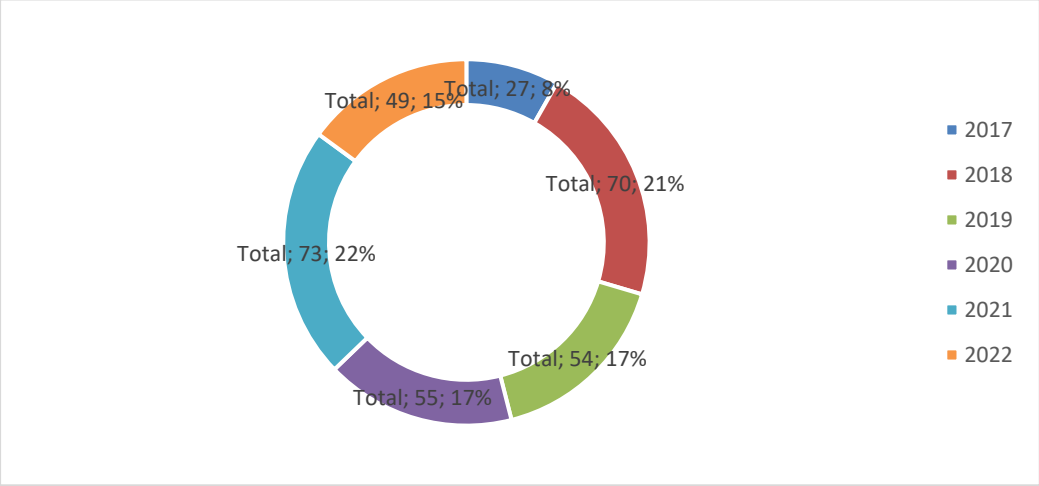
Figure 1 - Distribution of technologies requested by Conitec between 2017 and 2022.



Source: Prepared by the authors.
Note: The "Other" group includes groups of medicines with less than three demands.

The years 2018 and 2021 received the most requests, totaling 70 (21%) and 73 (22%) requests for incorporation, respectively. With only 27 (8%) requests, 2017 was the year with the lowest number of technologies requested in the pre-pandemic period. In relation to the pandemic period, the lowest demand was observed in 2022, with 49 requests (15%) (Figure 2).

Figure 2 - Total number of technologies requested by Conitec between 2027 and 2022.



Source: Authors' own elaboration.

Of all the technologies requested, 60.67% (n. 199) obtained a final opinion in favor of incorporation. The highest proportion was observed among internal requests (24.69% vs. 11.28%). Medicines accounted for 57% (n. 62) of the requests with a favorable opinion for incorporation.

In 2017, 81% (n. 22) of the requests received a favorable opinion. The lowest proportion of favorable opinions was recorded in 2022 (48%), well below the average of 63%.

Among the claims with a favorable opinion, the economic impact over five years was R$ -30,510,250,297.86. As the impact was negative, incorporating these technologies into the SUS has the potential to result in savings for society. If we consider only the years 2021 and 2022, the economic impact was R$ -37,395,122,575.52 (Table 1).

Table 1 - Estimated average annual budget impact of incorporating health technologies with a Conitec opinion favorable to incorporation.

Year	Economic Impact
2017	R$ 497.973.503,96
2018	R$ 3.150.182,978,64
2019	R$ 1.701.012,319,46
2020	R$ 1.535.703,475,60
2021	-R$ 26.905.627,362,40
2022	-R$ 10.489.495,213,12
Total	-R$ 30.510.250.297,86

Source: Authors' own elaboration.

The impact over five years of the technologies with an unfavorable opinion on incorporation was R$ 215,428,681,888.49, thus representing an increase in costs for the SUS.

Table 2 - Estimated average annual budget impact of incorporating health technologies with an unfavorable Conitec opinion.

Year	Economic Impact
2017	R$ 306.414.140,14
2018	R$ 3.720.020.382,80
2019	R$ 44.378.112.232,62
2020	R$ 145.852.364.261,35
2021	R$ 19.662.142.664,96
2022	R$ 1.509.628.206,62
Total	R$ 215.428.681.888,49

Source: Authors' own elaboration.

DISCUSSION

The field of HTA research is continually advancing economic models to guide the right decisions in health care, and the Ministry of Health, through Conitec, has managed to use the results of this research to inform its decisions.

Although the Covid-19 pandemic has reaffirmed the importance of the SUS, it has also shown us a series of weaknesses that we need to overcome in order to meet other important demands, such as ultra-rare diseases and, of course, neoplasms, whose technologies involved in diagnosis, follow-up and treatment demand high costs.

In this sense, expanding the capacity to produce HTA studies is imperative, not least to help meet the demands for incorporation of health technologies at Conitec.

Although occasional teaching and research activities in HTA have been underway since the late 1980s in some university institutions, it is only in the last decade that these activities have become more widely contemplated in Brazil, particularly within the Ministry of Health (BANTA. 2009; NOVAES. 1991; SILVA. 1992).

With the development of health economics as a discipline, many analytical tools were gradually incorporated into HTA and are currently fundamental to the process of managing and evaluating new technologies (SOÁREZ, 2012).

Health economic evaluations have therefore become important management tools that can help managers in the decision-making process regarding the allocation of public resources (SHIELDS and ELVIDGE, 2020).

In a health technology assessment, in addition to cost-utility analysis (CUA) or cost-effectiveness analysis (CEA), budget impact analysis is recommended, which is an extremely useful type of partial analysis in HTA (BRASIL, 2014b; BERTRAM et al., 2016; SHIELDS; ELVIDGE, 2020).

In the present study, we relied on the results of budget impact analyses (BIA) available in the recommendation reports of the National Commission for the Incorporation of Health Technologies (CONITEC), to analyze the potential for saving resources of the technologies demanded or generating costs for society.

Budget impact analyses estimate the potential shift in financial expenditure, providing managers with a global perspective of the cost or saving of resources for the health system, within a timeframe that is generally limited to five years (WATKINS; DANIELSON, 2014; BRASIL, 2012a; FERREIRA-DA-SILVA et al., 2012).

The difficulties imposed on SUS by the severity of the COVID-19 pandemic involved, in addition to political and societal pressures, pressures from the industry itself, which, taking advantage of a time of high demand and low supply of medicines, equipment and supplies around the world, further inflated their prices.

During this period, although there was a slight drop in requests for the incorporation of health technologies, they continued to be submitted to Conitec, in addition to demands aimed at meeting health needs specifically related to Covid-19, which put great pressure on the health system in Brazil.

With the development of vaccines against COVID-19 and the first registrations in Brazil, there was even more pressure for the SUS to make the first doses available to the population, even before Conitec made a statement to this effect.

It is a fact that there was a complete subjugation of the HTA-related institutions, built up over the decades of implementation of the SUS. Vaccines should be evaluated and approved by the commission, based on scientific evidence of the safety, efficacy, effectiveness and cost-effectiveness of those recommended, as established in current legislation (BRASIL, 2011a; 2011b).

During the pandemic period (2020 to 2022), although in relation to vaccines the Ministry of Health did not inform its decisions based on Conitec's recommendations, perhaps due to the exceptional and extreme urgency that the situation required, and it was therefore

not possible for the Commission to analyze and express its opinions specifically in relation to vaccines, all the other decisions did so, as determined by Brazilian legislation.

With regard to the applicants for incorporation requests to Conitec, the Ministry of Health itself was the party that submitted the most requests (53%) of all those submitted. These findings are not surprising, considering that the MoH secretariats are responsible for proposing and updating Protocolos Clínicos e Diretrizes Terapêuticas (Clinical Protocols and Therapeutic Guidelines) (PCDT) and that proposing and updating them will necessarily require the evaluation of certain technologies, usually medicines.

However, considering that it is the pharmaceutical and health products industries that seem to have the greatest interest in having their technologies incorporated into the SUS, the fact that they were not responsible for the largest number of demands in the period may come as a surprise to many.

Medicines have continued to be the most demanded technologies since the beginning of Conitec's activities. These health technologies had already been identified in another study as the category of technologies with the greatest demand for incorporation into the SUS (CAETANO et al., 2017).

The analysis of the budgetary impact of the favorable and unfavorable recommendations for the incorporation of health technologies into the SUS, produced by Conitec between 2017 and 2022, showed that the eventual incorporation of technologies that obtained an unfavorable opinion would imply an increase in costs for society that could add up to R$ 215,428,681,888.49 over five years.

In none of the years analyzed was it possible to observe a negative budgetary impact among the technologies with an unfavorable opinion for incorporation, unlike what was observed among those with a favorable opinion, in the years 2021 and 2022, the budgetary impacts resulted in resource savings.

Elias et al (2014) showed that CONITEC usually prioritizes clinical criteria (such as efficacy) and that recommendations in favor of incorporation are often defined by clinical criteria or therapeutic impact, when compared to other criteria. However, in relation to economic considerations, the budget impact criterion is the one that appears most frequently in these same recommendations, although in a much smaller percentage than the therapeutic impact ones.

The budget impact as an economic criterion even seems to have a greater influence on decisions, given that, among the technologies with a favorable opinion, the budget impact analysis, considering the period of analysis, seems to have the potential to result in resource savings in the order of R$ 30,510,250,297.86.

In a context of progressively rising costs in the health sector, explicit approaches to prioritizing and allocating resources have become increasingly critical. The use of cost-effectiveness thresholds, although already defined by Conitec, does not seem to be the only economic criterion capable of influencing the Commission's decisions.

Despite the importance of budget impact analyses in Conitec's decision-making processes, Yuba et al (2018) reported that only 19.8% of the recommendation reports published between 2012 and 2016 on Conitec's website included a full economic evaluation, despite the emphasis placed on the importance of these studies by the commission's internal regulations, which establish them as mandatory for all requests for the incorporation of technologies.

Therefore, the main contribution of this study is to present the results of the budget impact analysis of the requests submitted to Conitec and the extent to which this decision criterion can impact on health costs in the SUS given the growing demand for the incorporation of health technologies in Brazil. It is worth noting that the aim of this study was not to assess the weights of this or other criteria and the value attributed to the performance of the technologies in the outcome of the decisions made.

The results found need to be interpreted and used with caution, as no more in-depth analysis was carried out, much less of the decision-making processes and the technologies demanded, in order to better understand how the results of the budget impact analysis, stratified by technology demanded, could explain the results found.

CONCLUSION

This study identified that only the set of technologies with a favorable opinion for incorporation into the SUS, demanded between 2017 and 2022, resulted in a budgetary impact with the potential to generate savings and save resources for Brazilian society.

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