

Incorporation of technologies in the Unified Health System: the rationalities of the decision-making process of the National Committee for Health Technology Incorporation in the Unified Health System

Incorporação de tecnologias no Sistema Único de Saúde: as racionalidades do processo de decisão da Comissão Nacional de Incorporação de Tecnologias no Sistema Único de Saúde

Kleize Araújo de Oliveira Souza¹, Luis Eugênio Portela Fernandes de Souza²

DOI: 10.1590/0103-110420185204

ABSTRACT This research is aimed at analyzing the decision-making process of the National Committee for Health Technology Incorporation in the Unified Health System regarding the recommendations for the incorporation or not of drugs into this system. This is a study that focused on the analysis of the decisions made in the period from 2010 to 2015. The following data production strategies were used: document analysis, interviews and non-participant observation of plenary meetings. The data analysis revealed three types of rationalities present in the decision-making process of the National Committee for Health Technology Incorporation in the Unified Health System: technical-sanitary rationality, economic rationality, and political rationality. In practice, the solid legislation that guides the evaluation of the demands of technology incorporation in the Unified Health System has determined the predominance of technical-sanitary rationality.

KEYWORDS Biomedical technology. Decision making. Public health.

RESUMO *Esta pesquisa tem como objetivo analisar o processo de decisão da Comissão Nacional de Incorporação de Tecnologias no Sistema Único de Saúde referente às recomendações para incorporação ou não de medicamentos a este sistema. Trata-se de um estudo que teve como foco de análise as decisões tomadas no período de 2010 a 2015. Utilizaram-se como estratégias de produção de dados: análise documental, entrevistas e observação não participante das reuniões do plenário. A análise dos dados evidenciou três tipos de racionalidades presentes no processo de decisão da Comissão Nacional de Incorporação de Tecnologias no Sistema Único de Saúde: a racionalidade técnico-sanitária, a racionalidade econômica e a racionalidade política. Na prática, a sólida legislação que orienta a avaliação das demandas de incorporação de tecnologias no Sistema Único de Saúde determinou o predomínio da racionalidade técnico-sanitária.*

PALAVRAS-CHAVE Tecnologia biomédica. Tomada de decisões. Saúde pública.

¹Universidade Estadual de Feira de Santana (UEFS) – Feira de Santana (BA), Brasil.
Orcid: <http://orcid.org/0000-0002-1224-9140>
kleizearaujo@yahoo.com.br

²Universidade Federal da Bahia (UFBA), Instituto de Saúde Coletiva (ISC) – Salvador (BA), Brasil.
Orcid: <http://orcid.org/0000-0002-3273-8873>
luisaugenio@ufba.br

Introduction

The decision-making process regarding the incorporation of technologies in the health systems is influenced by a number of groups of interest, including physicians, the institutions responsible for providing health services, financial institutions, policy makers and service managers, technology producers, patient organizations, among others, that can play important roles in decision making¹.

Theoretically, this decision-making process for technology incorporation in health must be based on the best scientific evidence produced by studies on Health Technology Assessment (HTA). However, as mentioned by several authors, the technologies that the studies indicate as the most efficient or effective are not always adopted^{2,3}.

Because of the high costs of many of the new technologies, it is critical that the public and private managers in charge of making decisions regarding the incorporation of these technologies get to know what are their benefits, as well as the impacts on service financing and health actions.

In order to regulate the incorporation of the technologies of the Unified Health System (SUS), the Regulation No. 152/Ministry Cabinet/Ministry of Health, January 19, 2006, was issued to define the flow for technology incorporation in the scope of SUS, which was organized based on the actions performed among the Healthcare Assistance Secretariat (SAS), the Secretariat of Science, Technology and Strategic Inputs (SCTIE), the Health Surveillance Secretariat (SVS), the National Regulatory Agency for Private Health Insurance and Plans (ANS) and the Brazilian Health Regulatory Agency (Anvisa), the SAS being responsible for managing the process of technology incorporation and the SCTIE being responsible for evaluating the technologies of interest for the SUS⁴.

The same regulation created the Commission on Technology Incorporation of the Ministry of Health (Citec) with the

purpose of conducting the process of incorporating technologies according to the social needs in health and to SUS management.

Five years later, Citec was replaced by the National Committee for Health Technology Incorporation in the Unified Health System (Conitec), established by the Law No. 12,401 and by the Decree No. 7,646. It is worth mentioning that the fact that it was created by law has conferred legal status to Conitec, unlike Citec. The Decree, on the other hand, mentions the permanent aspect of the committee, which is aimed at helping the Ministry of Health (MS) in the attributions related to the incorporation, exclusion or change by SUS of the health technologies, as well as of the constitution or change of clinical protocols and therapeutic guidelines^{5,6}.

Conitec consists of a Plenary and an Executive Secretariat (SE). The plenary is the body responsible for issuing the reports and conclusive opinions aimed at subsidizing the decisions of the Ministry of Health. It comprises 13 members who have the right to vote, representatives of different bodies and entities, suggested by their officials⁵. Conitec's Executive Secretariat is ruled by one of the units of SCTIE, the Department of Management and Incorporation of Health Technologies (DGITS), created by the Decree No. 7,797, on August 30, 2012, which is in charge of coordinating its activities⁷.

In a document produced by the DGITS about the performance of Conitec, it is possible to see that, in the period between 2012 and 2015, the committee received 459 demands, 259 (56.4%) from the Ministry of Health and the state and municipal secretariats, and 200 (43.6%) from manufacturers, legal bodies, patient organizations and medical societies⁸.

Because of Conitec's competences, its members play an important role in the decision-making process of technology incorporation in SUS, as they are responsible for analyzing information and making relevant decisions related to the modernization and

innovation of the system, the improvement of the quality of life and life expectancy of the population and the financial impact on government coffers.

In this sense, the regulation of the process of incorporating new health technology is a fundamental element in the health assistance systems, either as part of the innovation policy or as a guarantee of the observance of ethical, social or economic aspects involving technology incorporation^{9,10}.

In the context of the decisions made by Conitec, all demands for technology incorporation must show scientific evidence based on efficacy and safety, in addition to studies about economic evaluation and the budget impact from the perspective of SUS^{11,12}.

The need to be guided on scientific evidence and the pressure to meet the deadlines, which are legally set^{5,6}, have encouraged Conitec to search for support institutions, thus developing Conitec's Partner Networks with a greater dissemination of Centers for Health Technology Assessment and various Sentinel System Hospitals, especially in the state of São Paulo¹².

In general, the development of a well-designed legal goal, based on previously defined working processes, was fundamental for controlling Conitec's decision-making process in a standardized and transparent manner, in addition to being legally supported.

This study analyzed Conitec's decision-making process regarding the formulation of the recommendations for incorporating medicines to SUS or not in the period from 2010 to 2015, so as to identify the types of rationality that are predominant.

Conceptual elements

Decision is a choice made among several other alternatives. Making decisions is identifying and selecting a course of action to deal with a specific problem¹³⁻¹⁵.

According to the classical economics

theory, this process of choosing among different alternatives of action is basically guided by rational calculation. The individuals get into situations of having to make decisions with previously known purposes, which determine the value of each one of the possible consequences of action. Based on that, they gather all necessary information, define the set of alternatives and make the 'optimal' decision^{14,15}.

Simon criticized this type of conception of rationality, arguing that the capacity of human beings to gather, understand and retrieve information from the memory and making inferences is limited by incomplete and imperfect information, the complexity of the problem, the limited capacity of processing information, the time available, the preferences, values, and conflicting interests regarding the organizational purposes, as well as by the extremely dynamic environments in which they are. Therefore, he highlighted that rationality is necessarily limited, and one can aspire to a 'satisfactory' decision at the most^{16,17}.

Another important criticism against the rational model of the classical economics theory was made by Lindblom¹⁸, who called the attention to the influence of political interests, related to the accumulation and exercise of power, of those involved in the decision-making process. The political decision model, therefore, emphasizes the action of several social stakeholders, who are aimed at meeting their personal and institutional needs through decision making in the organization.

In the field of health policies, the concomitant presence of different rationalities, which are at the same time complementary and conflicting, thereby influencing the decision-making process, is recognized¹⁹.

Based on the recognition of these rationalities and considering the decision theories, this study adopts the following typology to analyze the decision process related to the incorporation of health technologies:

technical-sanitary rationality, economic rationality, and political rationality.

The first type, the technical sanitary rationality, is close to the concept of reason of the classical economy, which was modified by Simon's criticism. Thus, decisions must be based on the best technical-scientific knowledge available, but one must recognize the impossibility of reaching an optimal decision.

In the concrete case of Conitec, the technical-sanitary rationality is related to the use of clinical, epidemiological, planning and health managing knowledge and, in particular, of the HTA as the conductor of the decision-making process regarding the recommendation of incorporating health technology to SUS or not. More specifically, the decision must be supported by the analysis of the scientific evidence related to the efficacy, accuracy, effectiveness and safety of the technology under evaluation.

The second type, the economic rationality, which is also close to the concept of limited rationality, is related to the concern with the economic-financial sustainability of the health system in the mid- and long-term, and with the budget impact in the short-term.

In the case under investigation, Conitec is aimed at searching for the best information available about the economic impact of the incorporation of a specific technology for the public healthcare system in several time horizons to guide decision making.

The third type, the political rationality, which is close to the political decision model, is related to multiple political interests, which generate conflicts among those involved in the decision-making process. These stakeholders can organize coalitions and political alliances, and the solutions are constantly being negotiated^{17,18}.

In the case of Conitec, the political rationality is related to the recognition of the existence of several interests, which sometimes are conflicting in each decision-making process about the recommendation of the incorporation a particular health

technology or not. It is also related to the strategies adopted by the plenary and by the directors of the committee to deal with the divergences and conflicts.

It is worth mentioning that the concept of health technology adopted in this study is related to the devices, drugs, medical and surgical procedures used in the prevention, diagnosis, treatment, and rehab, including the organizational and support systems where care is offered²⁰.

Methodology

This is a qualitative study of the case of Conitec that is focused on analyzing the decision-making process of recommending the incorporation of biological drugs to SUS or not. It is worth mentioning that this is one of the outcomes of the doctoral thesis entitled 'A influência das ações judiciais na incorporação de medicamentos biológicos ao Sistema Único de Saúde', (The influence of legal actions in the incorporation of biological drugs to the Unified Health System), which was presented at the Graduation Program in Collective Health of the Institute of Collective Health, at the Federal University of Bahia, in 2017.

For data collection, the sources were official documents, semi-structured interviews with the Conitec's members and the non-participant observation in ordinary meetings of the committee.

The documents analyzed were laws, decrees and the internal regulation of Conitec, in addition to meeting minutes and reports recommending the incorporation of technologies.

Thirteen semi-structured interviews were conducted and involved all members of Conitec, including its chairperson and the director of the DGITS.

The non-participant observation of Conitec's ordinary meetings took place between October 2015 and April 2016. More

specifically, the 40th, 42nd and 44th meetings were attended, resulting in a total of 39 hours of observation. To process the empirical material from the documents, interviews, and observation, the technique of theme-based content analysis²¹ was used.

It is worth noting that the study was previously submitted and approved by the Research Ethics Committee of the Federal University of Bahia, under the protocol No. 022/2015, in compliance with the Resolution No. 466/2012.

The decision-making process of Conitec

In the following, the stages of Conitec's decision-making process are described to show the types of rationality that are present or dominant. This description is anchored in the legal and normative definitions that have effectively guided Conitec's behavior in the period analyzed.

PROBLEM IDENTIFICATION AND INFORMATION COMPILATION

In Conitec's decision-making process, the problem is related to the deliberation on the incorporation of a specific technology to SUS or not or, even more, its exclusion from the official distribution lists. It is worth mentioning that, according to article 2 of the Decree No. 7,646/2011⁶, Conitec is aimed at helping the Ministry of Health in the attributions regarding the incorporation, exclusion, and alteration of health technologies, performed by SUS, as well as the constitution or the alteration of clinical protocols and therapeutic guidelines.

The incorporation, the exclusion and the alteration of the health technologies, as well as the constitution or alteration of the clinical protocols and therapeutic guidelines, are preceded by the administrative process, which must be recorded by the interested party at Conitec's Executive Secretariat.

The Executive Secretariat plays an important management role in the process of evaluation of health technologies and the recommendation of their incorporation into SUS or not. Indeed, as mentioned by the interviewee 12, the work in the Executive Secretariat involves receiving the requests and analyzing the conformity to verify if the dossier presented by the plaintiff has the minimum requirements to proceed, because, if it does not satisfy the requirements, it will be denied and returned to the plaintiff. If the demand meets the necessary requirements, the process goes to one of the analysts, who will make a thorough and critical observation of it and add other pieces of evidence, if necessary. Therefore, the degree and the quality of the evidence available, and the degree of reliability of the studies shown, including the economic studies, are evaluated.

Based on the interviews, one can note that the requests received at the DGITS are systematized before they are shown to the plenary members. Therefore, the team of the Executive Secretariat prepares an initial report, which is sent to be analyzed by the members of the plenary before the monthly meeting, so that they can previously know the agenda and the subject matter of the report.

According to the interviewee 10, there is a well-defined working process at Conitec. The plenary members receive the material beforehand. Therefore, who wants and/or needs to has the opportunity to thoroughly analyze all the demands of incorporation. Thus,

[...] the work to approve or not an incorporation is performed in a very technical manner, and we perceive it clearly - and I am extremely critic regarding this aspect - the presentation is not biased in favor of or against approving a particular thing. Undoubtedly, it is a technical report. (Interviewee 10).

The information systematization performed by the Executive Secretariat is of great importance for Conitec's decision

process, as the data survey and information gathering are critical to reducing the uncertainty regarding the situation or problem¹³. Therefore, there is a concern in searching for and analyzing information about the technology that will be evaluated.

We review the document again to see if the plaintiff has written everything or if there are other studies that say the opposite, which can have different results and, therefore, we add information and mention it in the report. (Interviewee 1).

Today, we do not assess anything in terms of management and technology incorporation if we do not have information about scientific evidence on accuracy, safety, effectiveness and economic studies that show the cost-benefit and cost-effectiveness of the technology. (Interviewee 12).

The more the representative is well-informed, the faster things work. They won't ask for deadline extension, they will make a decision right away. (Interviewee 1).

The observation of the meetings at Conitec reinforces what was mentioned in the interviews and read in the documents. Thus, as the plenary members receive the initial report prepared by the Executive Secretariat beforehand, they go to the meetings provided with the information necessary to make a decision. In addition, for each item of the minute, technology assessment studies are shown, including the economic studies, as well as the results of the public consultation.

Therefore, rationality resides in the choice of the most appropriate means to reach specific purposes in order to obtain the best results. However, people only behave rationally according to those aspects regarding the situation that they can perceive or gain knowledge. The other aspects of the situation, which are not perceived or not known by people – although they in fact exist – do not interfere in the decisions. That is, people

make rational decisions only regarding the aspects of the situations that they can perceive and interpret^{13,15}.

It is worth mentioning that, whenever necessary, experts in the topic under discussion are invited to participate in Conitec's meetings, with the purpose of clearing up doubts about the technologies being assessed, as mentioned by one of the interviewees:

[...] In many occasions, it was understood that data were missing or that it was necessary to add more information. Thus, more data are required and the document is sent back to the technical area of Conitec, which can even bring experts to talk about a specific product. (Interviewee 10).

Another important strategy to reduce the level of uncertainty in decision making is the constant training of the team. Therefore, the plenary members are always trained about HTA, because one of the guidelines of the committee is to incorporate technologies according to technical criteria, based on the parameters of efficacy, efficiency and effectiveness that are appropriate for health requirements, as mentioned in the following statements:

The plenary learned, as well as Conitec's team in the beginning. (Interviewee 4).

[...] yeah, there was a learning curve of the team. The team and the plenary were trained on the assessment of economic studies, including the use of evaluation instruments. They [the DGITS] have several partners. (Interviewee 5).

[...] Conitec has always transferred considerable knowledge to us. (Interviewee 10).

The use of the knowledge of the HTA, both by the SE and the plenary members, can help reduce the level of uncertainty of the decision-making process, and it is critical to make decisions about the incorporation of health technologies to SUS or not. These

pieces of knowledge are strongly used in the development stage and in the evaluation of alternatives that are part of the decision-making process.

As can be seen from above, in the first stage of the decision process, the members of Conitec collect and process a great variety of information to characterize the problem. The capacity to collect and process such information to set foundations for the best decision is limited, as it is not possible to have access to all information about a situation and/or a problem. Therefore, Conitec neither has conditions to analyze all situations in depth, nor to search for all alternatives. Thus, as mentioned by Simon, Conitec's members look for the most satisfactory solutions, according to their aims.

Therefore, the characteristics of Conitec's decision-making process that have been shown until now have strong similarities with the rational decision-making model, which was modified by the concept of limited rationality.

DEVELOPMENT AND EVALUATION OF THE ALTERNATIVES

Once the process is analyzed, the decision makers go to the second stage of the decision process, starting to consider the alternatives of plausible actions. In the case of Conitec, scientific studies that demonstrate that the technology in question is, at least, as safe, effective and cost-effective as those available at SUS for the same purpose are analyzed. If necessary, additional studies and complementary research are requested. Therefore, the alternatives are evaluated and compared, in order to choose the most appropriate solution to the problem identified, that is, the favorable recommendation of the incorporation of the new technology into SUS or not. The chosen alternative will be the most satisfactory solution, according to the technical-sanitary criteria.

More specifically,

[...] the proposal of incorporation must have a set of information with the technical characteristics of the proposal itself, either a drug, a product or a laboratory exam. (Interviewee 2).

The factors evaluated in each situation usually are related to efficiency and technology safety. But it's not only that, there is the issue of equity, of the capacity of a healthcare system to adequately provide care a specific number of people. (Interviewee 3).

We use the knowledge from the HTA. (Interviewee 5).

The searches are performed to obtain all the scientific knowledge, that is, the comprehensive literature review, the analysis of the economic models, so that the decision is based on scientific evidence. Therefore, we don't discuss personal opinion, we discuss scientific evidence. (Interviewee 7).

Both the meeting minutes and the reports about incorporation show the results of the studies presented by the plaintiffs, by the DGTIS team, or by the experts invited to clear up doubts about the drug under evaluation.

As in the first stage, in which there is a concern about gathering all information available to analyze a situation, in the second phase, the search for more scientific knowledge on the technology in question will be the foundation to choose among the decision alternatives; in this case, the recommendation of technology incorporation or not.

It is worth mentioning that, in addition to searching for and evaluating scientific evidence, in order to maintain the decision-making process clear, all Conitec's recommendations are sent to public consultation, which was verified in the meeting minutes analyzed, in the incorporation reports issued by the committee and in the interviewees' statements, as well as in the observations.

Although the consultations can also take

place in the first stage of the decision-making process, as a strategy of seeking for more information to help describe the problem, they are more useful and more used in this second stage as a strategy to deepen the assessment of the alternatives available.

The public consultation is important because it gives voice to those who are not directly included in the decision-making process: the users of the public healthcare system and their families, healthcare providers, healthcare institutions, education institutions, companies, medical societies and non-governmental organizations. In effect, there are points of views on specific technologies that are inherent in the users that use them, in the healthcare providers who prescribe and administer them, for example, and which may not be present in the reports sent to Conitec.

Therefore, one can note that, before making a decision, Conitec analyzes carefully the existing alternatives, considering the consequences of each one of them. Besides, it also considers the consequences of incorporating a specific biological drug data or not for patients that will use it, for the health system, the country, and the society. It is really a complex process that involves several technical, ethical, economic and social aspects, and that can be influenced by several factors and stakeholders, within or outside the organization.

Therefore, it is possible to see that, also in this phase, the decision-making process at Conitec can be compared to that of the rational decision model, in the version of limited rationality, as the members of Conitec are aware of the limits of scientific evidence.

[...] as far as science is concerned, an exhaustive search is performed, but sometimes some issues that may not have been considered before appear in the studies evaluated. I believe that the information that we have about technology is not always complete. (Interviewee 3).

Obviously, there are situations that involve conflict of interests of all types. The economic conflicts, which are represented by those who produce technology, dispute the equivalent market of technologies. Therefore, the members of Conitec must be mature enough to always sustain the interest of the population above personal interests. And when I say personal, I don't mean that of the members of Conitec, but of the subjects, of the conflicting interests. (Interviewee 7).

DECISION IMPLEMENTATION AND MONITORING

The third stage of Conitec's decision-making process is related to the decision implementation and monitoring, which starts with the presentation of the report on the recommendation of the technology discussed. This report shows data on the disease, the technology, the analysis of the evidence shown by the plaintiff, the discussion of scientific evidence found by the committee, the analysis of the budget impact, as well as the data on public consultation and Conitec's final deliberations.

After the report is completed, the process is sent by the Executive Secretary to the SCTIE for a final decision. The SCTIE can request for public hearing before making a decision, according to the relevance of the topic.

In case there is a public hearing, the secretary can request that Conitec's plenary, under priority regimen, make suggestions and contributions. If there is a requirement of constitution or change of clinical protocol or therapeutic guideline, the secretary must submit the report to the person in charge of the program or action in the Secretariat, according to the subject matter⁶.

Finally, the decision act of SCTIE's secretary about the order in the management requirement is published in the Federal Official Journal. The Minister of Health can confirm, modify, cancel or revoke totally or partially the decision appealed until 30 days. The deadline can be

extended upon expressed justification for the same period of time.

The Decree No. 7,646/2011⁶ also states that, based on the publication of the decision to incorporate technology in health, or on the clinical protocol and the therapeutic guideline, the technical areas will have the maximum deadline of 180 days to make the technology offer effective by SUS.

Regarding the decision monitoring, as per Conitec's Balance Sheet of the 2012-2014 period²², in 2013, the technologies incorporated in SUS started to be monitored. This monitoring activity involved building a database with relevant information to follow these technologies, selecting the indicators to evaluate the offer and the production of specific reports, which must comprise information about technology, decision, deadlines for an offer, logistics, financing, acquisition, budget impact and consumption.

Finally, the database, the reports and the indicators that allow monitoring and evaluating the process of incorporating technologies in SUS and make it possible to produce strategic information to subsidize Conitec in future assessments and recommendations of incorporation²² are clear indications that the decision process of Conitec is also based on the technical-sanitary rationality in this third stage. This rationality is similar to the rational decision model.

Undoubtedly, it is important that the decision of recommending the incorporation of health technology or not is based on the technical-sanitary rationality, as Conitec's main purpose is to ultimately contribute to the improvement of the quality of life of people who depend on the public health system. Therefore, it is necessary to think of incorporating technologies that take into account the epidemiological profile of the population and that are really safe and effective for those who will use them.

In addition, decision making is necessarily influenced by economic rationality, as the decision must take into account the

sustainability of the public health system. Thus, in addition to being safe and effective, health technology must have a cost-effectiveness relationship greater than the alternatives that are already offered by SUS.

Nevertheless, it is worth mentioning that the economic aspects are considered less important than the technical-sanitary ones, as shown in the following statements:

Of course, the issue of the budget impact and the possibility of financial aid by SUS have to be taken into account, but this is not crucial for a recommendation. We have never refrained from incorporating something thinking that it would be just a matter of budget, this was never the limitation. (Interviewee 13).

The analysis of Conitec is not the analysis of the budget available. In theory, Conitec is not in charge of incorporating technology or not in its analysis because of the existence or non-existence of the budget availability. This would be the responsibility of the federal manager of SUS. (Interviewee 2).

Although the technical-sanitary and economic aspects are crucial for Conitec's decisions, they are not the only elements taken into account at the moment of definition regarding a recommendation about the incorporation of a certain technology or not.

In effect, when the interviewees were asked about other aspects that could influence Conitec's decision process, some of them admitted that there are conflicts of interest and that the plenary members should know how to deal with that so that they do not have undue influence on the decision-making process.

Everybody has influence, everybody has their conflict of interest, so this has to be balanced in decision making. Like I said before: the scientific evidence, the clinical relevance, is the most important thing because the personal interests, the interests of each one involved... This is legitimate.

Everyone has their own, and in the plenary, we have to balance that to oppose to the evidence that is available. (Interviewee 6).

What is evident in this statement is that Conitec's members are aware that the decision process can have influence on private interests.

This type of influence is part of the decision-making process and, in a certain way, different interests aimed at a common good, in theory, affects Conitec's choices.

It is worth mentioning that those involved in the incorporation of new technologies – the manufacturers, the companies that import goods or distributors have aggressive strategies of marketing/lobbies together with the doctors and/or the public to promote the use and dissemination of new technologies.

According to the interviewee 3, the process of technology incorporation, without disregarding the technical-assistant aspect, involves a game of service and product sale for the Ministry of Health. Therefore, every company that has a product that may be interesting for SUS will try to influence the decision process. Thus, the persuasion of the academy, the scientific publications and the group of patients and all possible channels is used to convince of the necessity of using a new technology. In the game of power, the company can even create a new needs in health.

So, it's basically a two-side game: one is selling and the other is buying a service, a product, a technology. (Interviewee 3).

The creation of new needs in health is discussed, for example, in the field of collective health, in which some authors emphasize the existence of a predominant approach to health needs, as if they were synonymous with the technology needs or health services¹⁷. Others say that this confusion leads to an implicit understanding that health needs are necessarily met by health services, reinforcing the expansion of good, service and procedure consumption²³.

According to interviewee 7, the industry of health technologies is one of the greatest and most profitable industries, so the conflicts are huge. Therefore, to participate in the committee responsible for making decisions related to the incorporation of technologies, the members must know the limits between good and bad use, the waste of money and the real value of a technology.

According to other interviewees, the fact that Conitec is heterogeneous makes the decision process more balanced.

Therefore, these interests, this correlation of powers, and the plurality of the plenary help balance these influences. (Interviewee 8).

In all human relationships, there will always be ideological or personal issues that will influence specific situations. The important thing is to see all points of view within the same place. If you have this, the conflicts of interest are over, which is the case here. (Interviewee 10).

The design of Conitec has incorporated a little bit this social representation. The presence of these people brings another dimension, and this does not refer to the vote itself, but to the content of the discussion that is held in Conitec's plenary. (Interviewee 2).

There is a certain balance among the stakeholders and the people prepared to identify eventual bias or to search for additional information that supports your statement and decision. There is a really important balance here. (Interviewee 11).

The diversity of subjects that are part of the committee may seem to act as an element that facilitates Conitec's decision-making process. According to the interviewees, it is exactly the diversity that balances and guarantees the safety to the members of the plenary, as several issues can be considered based on the statements and opinions of the various players involved in the decision, and this can also be observed in the meetings.

Another element that can minimize the conflict of interest of the several stakeholders and, therefore, legitimate the work performed at Conitec is the transparency with which the actions are carried out (required by the Law No. 12,401/2011 and by the Decree No. 7,646/2011)^{6,7}. Thus, the entire process of incorporating technology to health can be accessed by the people, and there is public consultation before the final decision.

In fact, the political rationality, as can be seen, is an important element in the context of the decision-making process at Conitec, considering that, although its members adopt a limited decision-making rationality model, based on the technical-sanitary and economic rationalities, they face certain correlations of power, which usually have to do with different interests that are part of the process of technology incorporation in the Unified Health System.

Conclusions

The analysis of the decision-making process developed by Conitec allowed us to identify three types of rationality used by its members: the technical-sanitary rationality and the economic rationality, which are supported by the normative instruments that

regulate the process of health technology incorporation to SUS, and the political rationality, which was evidenced in the statements of the interviewees.

Finally, the analysis of the specific legislation, the meeting minutes, the documents produced by Conitec, the interviews and the observation reports allowed us to conclude that the decision-making process at Conitec can be considered coherent with the rational decision model, which was modified by the limited rationality and the political decision model.

In practice, the solid legislation that guides the evaluation of the demands of incorporation in SUS – and Conitec's strict observance in the period analyzed – has determined the predominance of the technical-sanitary rationality of Conitec's decision-making process.

Collaborators

Souza KAO has substantially contributed to the conception, analysis planning, and data interpretation, participating in the draft production and in the approval of the final version of the article. Souza LEPF has contributed to the conception and planning of the article, critical review and approval of the final version of the article. ■

References

1. Scheffer MC. Aids, tecnologia e acesso sustentável a medicamentos: a incorporação dos anti-retrovirais no Sistema Único de Saúde [tese]. São Paulo: Universidade de São Paulo, Faculdade de Medicina; 2008. 255 f.
2. Cowan J, Berkowitz D. Technology Assessment at work: Part I – Principles and a case study. *Physician Executive*. 1996; 22:5-9.
3. Davison SN. Technological Cancer: It's causes and treatment. *Health Care Forum J* 1995; 52-58.
4. Brasil. Ministério da Saúde. Portaria nº 152/GM/MS de 19 de janeiro de 2006. Institui o fluxo para incorporação de tecnologias no âmbito do Sistema Único de Saúde. *Diário Oficial da União*. 19 Jan 2006.
5. Brasil. Ministério da Saúde. Lei nº 12.401, de 28 de abril de 2011. Dispõe sobre a assistência terapêutica e a incorporação de tecnologia em saúde no âmbito do Sistema Único de Saúde – SUS. *Diário Oficial da União*. 28 Abr 2011.
6. Brasil. Ministério da Saúde. 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. *Diário Oficial da União*. 21 Dez 2011.
7. Brasil. Ministério da Saúde, Portaria GM/MS nº 2.009/2012 que aprova o Regimento Interno da Comissão Nacional de Incorporação de Tecnologias no SUS. *Diário Oficial da União*. 13 Set 2012.
8. Brasil. Ministério da Saúde. Secretaria de Ciência, Tecnologia e Insumos Estratégicos. Portaria nº 27. Aprova o fluxo de trabalho para elaboração e atualização dos Protocolos Clínicos e Diretrizes Terapêuticas no âmbito da Comissão Nacional de Incorporação de Tecnologias no Sistema Único de Saúde. *Diário Oficial da União*. 12 Jun 2015.
9. Viana ALD, Silva HP, Elias PEM. Economia política da saúde: introduzindo o debate. *Divulg. Saúde debate*. 2007; (37):7-20.
10. Guimarães R. Incorporação tecnológica no SUS: o problema e seus desafios. *Ciênc Saúde Colet*. [internet]. 2014; 19(12):4899-4908.
11. Laranjeira FO, Petramale CA. A avaliação econômica em saúde na tomada de decisão: a experiência da Conitec. *BIS, Bol. Inst. Saúde* [internet]. 2013 maio; 14(2):165-170.
12. Evelinda T, Martins PN, Zanberlan AG et al. Experiência da Rede Paulista de ATS na parceria com a Conitec. *Rev. Eletrôn. Gestão Saúde*. 2015; 6(4):3297-3312.
13. Chiavenato I. *Administração em novos tempos*. 2. ed. Rio de Janeiro: Campus; 1999.
14. Chiavenato I. *Introdução à Teoria Geral da Administração*. 8. ed. São Paulo: Makron; 2011.
15. Eynshardt KM, Zbaracki MJ. Strategic Decision Making. *Strategic Management J*. 1992; 13(esp):17-37.
16. Simon HA. *Comportamento Administrativo. Estudo dos Processos Decisórios nas Organizações Administrativas*. Rio de Janeiro: FGV; 1979.
17. Mota FCP, Vasconcelos IFG. Os processos decisórios nas organizações e o modelo Carnegie. IN: Mota FCP, Vasconcelos IFG. *Teoria Geral da Administração*. 3. ed. São Paulo: Pioneira Thomson Learning; 2006. p. 95-121.
18. Lindblom CE. *O Processo de Decisão Política*. Brasília, DF: UNB; 1981.
19. Paim JS, Almeida Filho N. Análise da situação de saúde: o que são necessidades e problemas de saúde? In: Paim JS, Almeida Filho N. *Saúde Coletiva*:

- Teoria e Prática. 1. ed. Rio de Janeiro: Medbook; 2014. p. 29-40.
20. Organization for Economic Co-operation and Development. Health technologies and decision making. Paris: OECD; 2005.
21. Bardin L. Análise de conteúdo. Lisboa: Edições 70; 2011.
22. Brasil. Ministério da Saúde. Comissão Nacional de Incorporação de Tecnologias no SUS. Balanço Conitec 2012-2014. Brasília, DF: MS; 2014.
23. Campos CMS, Bataiero MO. Necessidade de saúde: uma análise da produção científica brasileira de 1990 a 2004. Interface. 2007; 11(23):605-618.

Received on 07/09/2018

Final version on 09/18/2018

Conflict of interest: non-existent

Financial support: The Brazilian National Council for Scientific and Technological Development (CNPq) and the Ministry of Health (Chamada MCTI / CNPq / CT-Saúde / MS / SCTIE / Decit No. 41/2013)