


The effectiveness of public health actions and services in Brazil: The indispensability of defining economic limits

 <https://doi.org/10.56238/colleinternhealthscienv1-137>

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ABSTRACT

This research aimed to demonstrate the need to set a cost-effectiveness threshold for access to health. Health was discussed as a fundamental right, but not an absolute one due to the existence of limits that must be built considering the essentiality of

the right and the scarcity of resources. The issues of the cost of the right to health and the scarcity of available resources was addressed to highlight the need for a cost-effectiveness threshold in Brazil. The themes were approached from the theoretical references of Stephen Holmes and Cass Sunstein to demonstrate that fundamental rights, including health, always demand positive actions from the State and, consequently, involve costs that can't be ignored. The research is conducted at the interface between human rights and legal economics. As a methodological process, documentary research related to data and bibliographic research is used. The study allowed the interpretation that there are historical, systemic and economic limits to access to health. Finally, there is a need to define a cost-effectiveness threshold in the SUS.

Keywords: Access to health, Health technology, Thresholds, Cost-effectiveness.

1 INTRODUCTION

The realization of fundamental rights is directly linked to the financial resources available for this purpose. Holmes and Sunstein address this issue when dealing with the theory of the costs of rights¹, especially when they point out that fundamental rights always demand positive actions by the state and, consequently, involve costs that cannot be ignored.

Introducing the topic of costs into discussions dealing with fundamental rights, such as the right to health, conveys the impression of potential affront to the preservation of rights, for while the costs of rights are almost an incontrovertible truth, few face the reality that the fact that a certain cost is inherent in a given right forces us to forgo something to acquire or secure it (HOLMES et al., 2019, p. 13).

¹ HOLMES et al., 2019.

Facing the reality of the costs of rights is in no way an affront to the preservation of rights or to the commitment to the protection of fundamental rights, but only in knowing the various aspects involved in the guarantee of rights.

As a rule, rights are disseminated only for their positive aspects, without any approach to points that may sound negative, such as their costs, making it difficult to face the issue dispassionately. In this sense:

The universal desire to present rights as a good thing, without any caveats, may help explain why an approach that does not take into account cost is viewed sympathetically by all sides of the debate. Indeed, we can even speak, in this context, of a cultural taboo - founded, perhaps, on realist concerns - against 'costing' the guarantee of rights. The premise that our most fundamental rights can be enjoyed at no cost, though widespread, is patently false (HOLMES et al., 2019, p. 13).

The great dilemma involved in the cost of rights is the finiteness of public resources. When we project rights on an ideal level we associate them with total comprehensiveness and complete effectiveness, but this idealization is very distant from the reality in which rights are applied. Reality is much more complex and limiting than the ideal world.

In addressing the budget cap on social service departments in the United States, Holmes and Sunstein (2019, p. 88) state:

(...) who are given very limited funds to deal with potentially endless problems (...). Because of the hard budget constraints, certain potential victims of maltreatment become actual victims, and the state will have done little to prevent this from happening. This situation is deplorable, but in an imperfect world where resources are limited, it is also inevitable. To take rights seriously. One must take the scarcity of resources seriously.

The scarcity of resources is what separates the ideal plane in which rights are conceived from the real plane in which they are realized. This separation arises from the confrontation of the costs inherent in rights with the limitation of available resources, which is not properly considered when discussing fundamental rights.

As a logical consequence of the fact that rights cost resources and that resources are limited, it can be stated that there is no absolute right. Using syllogistic reasoning, where the major premise is that rights cost resources and the minor premise is that resources are limited, one arrives at the conclusion that rights are limited.

The limitation of rights means that they only receive state protection up to a certain point established, in part, by budgetary decisions that deal with the allocation of scarce public resources. Therefore, the concept that rights are inviolable is merely a rhetorical flourish, because nothing that costs money is absolute. Rights are limited and this limitation varies according to the fluctuation of the amount of available resources, so that when the amount of available resources decreases, the range of a given right will diminish and, on the contrary, when the availability of resources increases, it will expand. For this

reason politics is the main sphere for the debate of what limit one wants to set for certain rights (HOLMES et al., 2019, p. 77/78 and 98).

The realization that rights are limited because of the scarcity of resources necessarily leads to a discussion about the efficient allocation of these resources for the protection of certain rights.

One cannot agree with the interpretation that scarcity is a justification for the non-protection of fundamental rights, but, on the other hand, it sounds reasonable to defend the idea that, if there is a minimum protection of fundamental rights, the measurement of the maximum limit of protection should be determined by the availability of existing public resources. In the words of Holmes and Sunstein (2019, p. 103), "the question should always be 'Protected to what extent?', and never 'Protected or not protected?'"

Whenever it comes to the allocation of public resources to guarantee or implement rights, one must first decide about which rights, groups, and recipients have the best claim to make use of public resources in given circumstances (HOLMES et al., 2019, p. 103).

From this perspective, it can be said that the debate over the resources required to realize fundamental rights is directly linked to the notion of public policy choices and the associated idea of scarcity when confronting the needs presented with the resources available to meet them. This is because needs tend to infinity while the possibilities of fulfillment are limited due to the available resources. These choices are up to the administrator, who, by necessarily deciding to meet certain needs, will leave others unmet. In a context of limited and insufficient resources to meet all needs or all of them, difficult choices must be made to decide which interests should be addressed and to what extent (MORAES, 2018, p. 43).

Thus, beyond budget-related issues, attention to the cost of entitlements also raises discussion of basic philosophical issues related to distributive justice and democratic accountability (HOLMES et al., 2019, p. 106).

When one understands this dimension associated with the scarcity of available resources, one has the real perception that the economic concept of opportunity cost also applies to rights and their realization. In other words, if resources are limited and insufficient to meet all demands, the application of resources for a certain purpose eliminates the possibility of committing the same resources to another purpose.

The opportunity cost as defined imposes on public managers the need to make decisions that have in their essence the idea of prioritizing demands when it is impossible to meet all of them. These are the so-called tragic choices. Tragic because, necessarily, only some demands will be contemplated with certain state benefits to the detriment of others.

In this sense, Holmes and Sunstein (2019, p. 190) well point out that:

To take into account the cost of rights, therefore, is to think more or less like a government authority asking itself how to allocate limited resources intelligently, always in view of a wide range of public goods. Legal rights have an 'opportunity cost': when they are imposed, other valuable goods (including other rights) have to be set aside, because the resources consumed in imposing the rights are scarce.

As a result, the decision that determines the allocation of resources becomes relevant and is seen as defining the priorities of society in the realization of rights and, for this very reason, should reflect the desires of society rather than private interests.

Besides the indispensable issues of transparency and monitoring of funds spent in order to avoid misappropriation of public resources, it is also necessary to address issues of equity and distributive justice so that not only the expenses are compatible with the services provided, reducing the margin for deviation, but also that these expenditures meet the priorities established by most of society and not only by a particular group.

Not for another reason, Holmes and Sunstein (2019, p. 192) point out that:

The cost of rights does not merely raise questions of democratic transparency and accountability in the process of resource allocation; it also unexpectedly introduces us to the very heart of moral theory by proposing questions of equity and distributive justice. When rights are qualified as public investments, this encourages rights theorists to pay attention to the question whether the imposition of those same rights is being not only valuable and prudent, but also justly distributed. This is a question of whether the money spent on the protection of rights (as conceived and implemented at a given time) benefits society as a whole, or at least the majority of its members, and not just groups endowed with special political influence.

The recognition that every right has its cost is a basic premise for discussing, pointing out, and finding solutions to protect rights more efficiently (HOLMES et al., 2019, p. 194). As a general premise, it also applies to discussions regarding the right to health. This theory has great potential to be used in the discussion of setting limits for access to health, as well as in the problematization of issues related to the economy that were not widespread in the legal field until then, allowing a deepening in the theme addressed.

It is impossible to think of a more efficient protection of the right to health without considering the costs involved and other aspects related to them. The effectiveness of public health actions and services in Brazil is linked to the necessary understanding of the existence of costs associated with the guarantee of universal access and equal and integral treatment, as well as the systemic structuring of the Unified Health System (SUS).

The realization of the fundamental right to health and the costs inherent to it should be studied under the prism of the indispensability of financial resources to ensure rights in the modern state. Added to this is the fact that the resources of states derive from taxes and are, by nature, finite.

At this point, it is essential to highlight that other aspects related to the finiteness of public resources related to health are part of this discussion, such as governance and management of SUS and interests of the various actors involved in the process, however, will not be addressed in this work because it is understood that these discussions, although healthy at any time of development of the theme, are more effective when a maximum spending limit is already defined and, consequently, the recurrent expansion of the spending ceiling is removed from the analysis, which forces the discussion to address issues related to the best use of public money for health.

In this sense, the finiteness of public resources as a parameter that limits spending should be considered when the issue of guaranteeing a fundamental right is put under discussion, not as a way to prevent its exercise, but as a way to establish the maximum limit that the State should spend to meet this demand and reinforce the non-existence of an absolute right.

Based on the grounds developed here that rights cost and resources are limited, and that the issue in this sphere should be the extent of protection, is it not time to begin to understand that the pendulum of protection of the right to health cannot swing to either extreme, but should be settled in an economically feasible middle ground that ensures reasonable health protection in a way that effectively covers everyone in a universal, equal and integral manner?

The answer to this question does not seem to be the most complex point of the intended solution. The complexity lies in the subsequent step of defining the parameters for establishing the desired middle ground. This definition implies making the difficult decision of allocating public resources for a certain purpose within the health area, knowing that with it other potential destinations will not be met.

Putting these aspects into perspective, one cannot only consider the minimum amount constitutionally provided for commitment in the area of health, but also the maximum limit that society is willing to spend on this right, not forgetting the scarcity of resources and the opportunity cost that imposes the impossibility of using resources that were intended for this purpose in another right.

When the right to health is analyzed from this point of view, public policy decisions are complex and must involve many aspects that are often unrelated to the analyses made by those who are not aware of all the aspects involved.

Clarifying the various aspects present in the realization of the right to health is of vital importance to deepen the public debate. When we talk about diverse aspects, we seek to highlight the importance of discussing the maximum limit that society is willing to pay or even able to afford for the realization of this right.

It is not enough to discuss the minimum value that should be used in the realization of the right to health or even simply quantify the cost of health technologies, it is necessary to discuss the threshold of willingness to pay, without which the other discussions, although important, do not cover the totality of the issues involved in the theme.

It is as if the existence of the costs of the right to health is recognized, but the finiteness and scarcity of the available resources is denied. Although this way of approaching the issue sounds illogical, this is how the right to health is treated when a willingness-to-pay threshold is not discussed.

In addressing the issue of the cost of rights, Holmes and Sunstein (2019, p. 194) pointed out that public deliberation should involve some necessary questioning to consider all aspects involved in the realization of a right from a cost perspective. As a general recommendation, it also holds true for the right to health:

Public deliberation should therefore focus on the following questions. (1) How much do we want to spend on each right? (2) What is the best package of rights, given that the resources used to protect one right will no longer be available to protect the others? (3) What are the best formats for providing maximum rights protection at minimum cost? (4) Do rights, as currently defined and imposed, redistribute wealth in a publicly justifiable way?

The answers to these questions provide valuable elements for defining the path to be followed in the difficult quest for the realization of rights, considering not only the theoretical level, but also the practical difficulties of the reality of finitude and scarcity of resources.

When this approach is transposed to the field of health, the use of cost rationalization techniques is verified, such as the health economic evaluation Cost-Effectiveness Evaluation (CEA) and Budgetary Impact Evaluation (BIA), as a way to, at the same time, try to satisfy as much as possible of the right to health, without, however, disregarding the financial viability of the Unified Health System, reconciling the existing duality: infinite or unlimited human needs with the scarce resources of society (SANTOS, Vânia Cristina Canuto, 2010, p. 13).

It is important to emphasize at this point that it is not simply a matter of tax collection, but of defining limits. Even if collection increases, the human aspirations are still unattainable. The best treatment, the best medicine, the best health professional available is everyone's desire, but it is unattainable in a universal, egalitarian and integral way, because the costs associated with them are extremely high and are constantly renewed in a relationship impossible to be equated with a simple increase in tax collection.

The main point of this observation is the need to define the limits to be adopted by the State in the realization of rights. Should all human needs be contemplated by the State? And to what extent? The tragic choice lies in the answer to these questions.

In the words of Paula (2012, p. 191): "It is necessary to conceive a prior rational choice about the limits of state action in the provision of the health service". In the same sense, Moraes (2018, p. 44) states that "The scarcity in the face of demands leads, therefore, to the need to design public policies, which imply choices about what will be contemplated by them and what will not".

When clear limits are established, an apt reference is created to guide all public policy related to health and, consequently, to guarantee the development of the SUS in all its integrity and in compliance with its governing principles.

On the contrary, the system is distorted and has its scope restricted when a medicine, treatment or procedure is granted whose cost-effectiveness analysis has been negative, because it will require the withdrawal of resources from the established public health policy. That is, it will be necessary to withdraw resources from another destination to absorb the extra cost (MORAES, B. T., 2018, p. 46-47).

Understanding the issue of the fundamental right to health from this perspective changes the approach to dealing with the topic, because it introduces the idea that the constitutionally enshrined right to health is so important that it should effectively fulfill its constitutional purpose of equally covering all

who need it at all levels of complexity, and not just prioritizing certain citizens to the detriment of the collectivity.

This supplants the widespread understanding - mistaken in my opinion - that including the economic-budget analysis in the right to health limits its potential access².

The approach proposed here is so concerned with the universal, equal, and integral access to the right to health that it fears that the individual approach in prioritizing treatment not provided for in the SUS will lead to the complete annihilation of the system for lack of financial capacity to meet the infinite yearnings of human needs.

In the precise words of Moraes (2018, p. 47): "It is inferred from this that to ignore the economic impact that a given technology entails on SUS is to contribute to the non-attainment of the objectives inscribed in the Constitution itself regarding the comprehensiveness of public health provision."

One cannot simply close one's eyes to the costs inherent to the realization of the right to health as if this were not a complicating factor that must be faced when one talks about the subject in order to live disassociated from the limitations imposed by reality.

Only with an adequate consideration of the fundamental duties and the costs of rights, can we achieve a state in which the ideas of freedom and solidarity do not exclude each other, but rather complement each other. That is, a state of freedom at a moderate price (NABAIS, 2007).

Thus, this work is justified by the social impact of the theme, whether from the point of view of the citizen who wants to see his claim assured, or from the point of view of the State that intends to establish a reasonable criterion for managing its demands with respect to economic/budgetary planning, as well as to contribute to a deeper discussion on the theme of access to health, focusing the discussion under the prism of the limits, without moving from the minimum guarantee of access to health.

2 THE ECONOMIC-BUDGETARY LIMITS TO ACCESS TO HEALTH CARE AND THE WILLINGNESS-TO-PAY (WTP) THRESHOLD

Understanding that the realization of the right to health requires public resources and that, therefore, the costs involved in the inclusion of a given technology among Public Health Actions and Services (PHAS) must integrate the technical analyses required for this evaluation is an important step regarding one of the economic aspects of the right to health, but it is not enough.

As previously discussed, linked to the concept of cost of rights is the idea of finitude and scarcity of available resources to meet this cost. In other words, cost is only one of the economic dimensions of the right to health; the other dimension is the finiteness and scarcity of resources.

² See NOVAES, H. M. D. and SOÁREZ, P. C. de, 2020, p. 7.

It is not enough simply to quantify the costs if we do not define the real capacity of the State to bear these costs and to what extent. The real importance of studying costs is not in their measurement per se, but in the possibility that they will be absorbed by the State's costing capacity.

More than defining the exact cost of HPS, it is important to know if this cost fits within the State's ability to bear it. Therefore, in addition to defining the cost, it is important to establish limits so that the State can absorb all the costs within its capacity and availability to spend resources.

It is not enough to know precisely the cost of a health technology if it does not correlate with the state budget limit available to pay for this expense. Otherwise, we would have only a monetary or monetizable reference without any concern about the reflection of this value in the State's capacity to cope with this cost.

Similarly, if we establish only a budgetary threshold without any concern about the individual cost of each health technology to be introduced through HPAI in the SUS, we would have only a reference to the ability to pay for a particular HPAI from a global view of state revenues and expenses, without caring about the high cost of drugs that are not paid for in the same proportion as the gain in quality of life, which in itself makes them not cost-effective.

Finding this maximum viable limit demands an effort in the search for parameters that allow us to face the reality of limited resources without adopting extremist preconceived positions, either on the side of defending the right to any and all available health treatment, or on the side of the impossibility of extending available treatment due to lack of resources.

The search for a parameter serves both to curb the impulse of those who wish to implement health treatments to the maximum extent, without any analysis of economic feasibility, and also to make more flexible the insurmountable obstacle imposed by those who intend to use economic issues as the only ones to be considered in this analysis.

Thus, a middle ground is reached that is able to temper the two extremes and reach the best possible solution for the implementation of the right to health in its maximum degree and with respect for the managing principles of the SUS.

This middle ground can be understood in the following terms: not all wishes will be achieved, but many will be implemented. Thus, what this study seeks is to find the intersection between possible solutions and economically achievable ones.

To achieve this scope, it is important that the economic analysis in its various models and the budget impact analysis not only be treated individually within the study of new health technologies presented to the National Commission for the Incorporation of Technologies into SUS (CONITEC), but also to establish the need for a conjugated, expanded, and global analysis of these data in comparison with the other data on the value of the total budget allocated to health or even with the threshold of disposition delete.

The finite resources materialized in the budget constraint prevents the public health system from making available to all all the technologies offered. Contextualizing this approach, Santos (2010, p. 34) states:

The challenge for health systems in the coming decade is to identify the optimal allocation of available resources to maximize health. Health research will continue to produce a significant increase in alternatives for detection, prevention, and treatment of disease. However, budgetary constraints will not allow health care systems to offer all of these interventions to everyone. This fact is already recognized by many decision makers in many countries, but the response to the challenge is still heterogeneous.

The question is how to make this point more and more explicit and to contribute so that viable solutions emerge from the discussions about the theme to face this situation in the best possible way.

Currently in Brazil, the economic-budgetary aspects are studied by contrasting a current paradigm technology or scenario against the technology to be incorporated in an attempt to find the incremental cost-effectiveness ratio to be defined as the economic value of cost increase per unit of effectiveness evaluation measure.

However, this cost increase is not confronted with any ceiling parameter capable of reflecting the finite state budget resources. At least, not in a standardized or explicit way.

The cost-effectiveness and budgetary impact analyses (CBA and OIA) in the form in which they are adopted in Brazil study a given technology in comparison with another new technology to assess its cost and effectiveness gain per individual during his or her lifetime or a scenario in force with another one that includes the technology under study to assess the economic-budgetary impact within a system for a certain predetermined period of time. Because they have different comparative parameters and objectives, the mentioned analyses should be understood as complementary and not exclusive (FERREIRA-DA-SILVA et al, 2012, p. 1223-1224 and COSTA et al., 2019, p. 74).

The outcome of ACE and AIO is expressed, respectively, by a measure called the incremental cost-effectiveness ratio (ICER) that reflects the cost per health outcome gained (unit of effectiveness), usually *quality-adjusted life years* (QUALY), or by a measure called the incremental budget impact ratio that reflects the cost difference between the scenario with the introduction of the new treatment and the reference scenario of current therapeutic practices (PINTO et al, 2016, p. 58-59 and FERREIRA-DA-SILVA et al, 2012, p. 1225).

At this point, it is important to point out that in research carried out by Yuba for his doctoral thesis, the conclusion was reached that:

After 5 years of CONITEC's operation (2012-2016), it is observed that there is a difficulty in developing economic evaluation studies. This difficulty, especially contextualized for Brazil, comes from the lack of available data, both economic and clinical. Additionally, the members of the plenary demonstrate difficulty in dealing with economic data, as they consider scientific evidence only clinical data. A possible explanation is the training of most of them in the health area, which provides the legitimization of clinical data, and the lack of knowledge in the economic area, generating

difficulties in understanding this type of information; they expressed a lot of mistrust in this type of information because they believe there are many uncertainties involved" (YUBA, p. 112).

This shows how much we still need to advance, because the difficulties are enormous even in what we have already established today (requirement for economic studies), which is aggravated when it goes deeper to no longer simply gauging costs, but also setting limits.

It is interesting to note that the ACE and AIO results represent a value that gains importance when compared to some reference parameter. Otherwise it is nothing more than a simple result resulting from an equation in which all fields were properly filled. This reference parameter that adds value to the equation's result is called a threshold.

In addressing the incremental cost-effectiveness ratio Yuba (2018, p. 5) rightly pointed out:

The RCEI value alone is not enough to help managers decide whether the costs and consequences of the technology would be the best way to allocate resources: this decision will depend on how much society is willing to pay for the additional health gain, which is the value of the cost-effectiveness threshold (LCE).

Within this perspective, the absence of a clear and defined cost-effectiveness threshold prevents cost-utility analysis from being used as an adequate tool for decision making, since it lacks a systematic and universally recognizable decision criterion. In other words, it is possible to quantify the cost, but it is not possible to assess whether this quantified cost is within parameters established as capable of being absorbed by the resources available to the State.

Bringing this idea into a more visual context, it can be stated that the value society is willing to pay for an additional health gain is the benchmark for the choice of new intervention and can be represented within a Cartesian plane by a diagonal line passing through the intersection of the principal axes, where the (x) axis represents the effectiveness scale and the (y) axis represents the cost scale. All interventions that lie to the right of the threshold are cost-effective.

From this perspective, the ACE and AIO represent studies capable of providing raw values that find improved applicability when compared to the benchmark contained in the willingness-to-pay threshold.

Although it highlights very well the importance of having a defined cost-effectiveness threshold, even for the EIA to gain relevance and achieve its primary objective, in Brazil there is no defined threshold to use as a ceiling parameter.

In addressing the issue in its Economic Evaluation Guideline (2014), the Ministry of Health made the point that:

The final product of complete economic evaluation studies is the estimation of a CER of a new technology alternative in relation to the standard alternative. In theory, this value could be compared to a threshold value of willingness to pay, which could contribute to the decision of whether or not to incorporate the new technology. However, the organizations that produce and evaluate health economic studies in Brazil still do not have accumulated experience that would allow them to adopt

a single threshold value for the willingness to pay from which the incorporation of a given technology would be considered cost-effective.

Not having accumulated experience does not change or refute the reality of the finiteness of available public resources. The best way to provide the experience necessary to establish a threshold is to discuss the possibility of it being widely and consciously introduced.

In a reality of finite resources, it is essential that the threshold of cost-effectiveness or willingness-to-pay be present through a limit capable of reflecting the maximum possible value to be committed to a given technology.

The *threshold* can be defined as a numerical reference applicable to the incremental cost-effectiveness ratio (ICER) capable of establishing the limit for a technology to be considered cost-effective (PINTO et al, 2016, p. 58-59).

In other words, "it can also be understood as the maximum value that society can or is willing to pay to obtain a QALY or a year of life with a new health technology" (SANTOS, 2010, p. 56).

Therefore, threshold is a reference for the cost-effect relation of an intervention to be considered acceptable in a given health system studied. A true limit that should guide the inclusion of new technologies in the Unified Health System - SUS.

The importance of this benchmark is in serving as a comparative parameter to assess the cost per effectiveness gain provided by a given new technology in relation to what society can or is willing to pay for each increment in quality-adjusted quality of life or other standard of effectiveness measurement.

Defining, understanding, and highlighting the relevance of the threshold concept is not the most arduous task in this issue, but rather establishing the cut-off point to be adopted as the threshold. That is to say, the neuralgic point of the theme is less to recognize the need for a threshold and more to fix what is the threshold that should be adopted.

The introduction of economic analysis as a necessary element for the evaluation of new health technologies inevitably leads to the existence of a threshold, either express or implicit. Facing this inevitability and thinking of uniformity and transparency, it would be better to establish a well-defined threshold expressed and known to all.

Based on all the rationale developed in this paper, especially linking the threshold to the theoretical element involved in the cost of rights related to scarcity and finitude, the value to be adopted as the threshold should come from the understanding of: a) health costs, whether individualized per citizen or collectively considered, whether segmented by disease, procedure and treatment or globally encompassing all public health actions and services, whether by federative entity or by the federation; as well as; b) the value society assigns to this right.

In this sense (Ministry of Health - Methodological guidelines: Economic Evaluation Guideline, 2014, p. 83):

Despite the criticisms, the adoption of a LDP assists the goal of maximizing the social gain of the system. Ideally, the value of the threshold should come from studies on value in health and from a global understanding of society on the subject. In this sense, it is important to highlight the role of academia in seeking evidence to support decision making regarding a threshold, but it should also be noted that there are problems in waiting for complete answers only after instituting definitions regarding adoption, non-adoption, investment and disinvestment in health. Finally, in a system that begins to consider economic analysis, thresholds will exist, whether they are apparent or not; the formal adoption of a threshold promotes uniformity in decisions about which technologies will be adopted.

The difficulty in establishing the threshold value does not stem solely and exclusively from the resistance of having a value that can serve as a parameter for comparing the economic data obtained, but also from the complexity involved in establishing this threshold value.

Many of the points involved in the studies for setting a threshold are not watertight, and their change can directly reflect on the value set as a threshold, bringing with it an aggravating factor for setting a threshold value.

Among the various aspects that can influence the value of the threshold, PINTO and others (2016, p. 59) highlight some. The first of them is the budget defined for the health sector, whose expansion would tend to increase the value of the threshold. However, he considers that this relationship is complex and that the budget increase does not necessarily represent an increase in the value available for new incorporations, and may only be an increase in infrastructure, personnel, and activities.

Another factor is the efficient use of incorporated technologies and the disincorporation of inefficient technologies. The former would tend to reduce the threshold value, while the latter would open up scope for increasing the threshold parameter.

Finally, they point out that, in theory, the threshold could be affected by changes produced as a result of other areas, such as basic education. Likewise, an increase in life expectancy and a decrease in the risk of disease can influence the threshold value.

To try to encompass the various aspects potentially involved in defining a representative threshold value, there are several modalities used for establishing a threshold.

At this point, it is important to point out that in Brazil there is no defined value parameter regarding how much society is willing to pay for a quality-adjusted life year (QALY) provided by a new technology. That is, there is no definition of the cost-effectiveness threshold in Brazil. This fact does not prevent efforts to quantify and define this limit.

Furthermore, it is important to emphasize that the economic and budgetary impact analysis in opposition to the reference value known as the cost-effectiveness threshold, although they may lead to a decision not to incorporate a given technology and, consequently, not to provide it to the population universally, does not necessarily have this sole purpose. Many times these studies are used by the countries

as a subsidy to negotiate price adequacy and conditions with the pharmaceutical industry. This is also an important role of having the threshold well defined.

Therefore, for an analysis that appreciates the various aspects involved in the realization of the right to health, the quantification of costs is an important and decisive step, since it makes it possible to clarify the potential amount of resources that will be committed, but it is not enough.

It is also necessary to discuss the aspect of finiteness and scarcity of resources, which is materialized with the definition of a willingness-to-pay threshold. The first step of measuring costs in the realization of the right to health is already well established in our legal system, the second, however, still lacks further study, discussions, and definitions. In the following topics we intend to contribute to the development of the theme by facing complex and difficult issues, but essential to find the best way forward.

3 THE THRESHOLD PROPOSED BY THE WORLD HEALTH ORGANIZATION (WHO) AND INTERNATIONAL EXAMPLES

The theoretical concept of threshold as a numerical reference capable of reflecting the maximum possible value to be committed to a given technology in order for it to be considered cost-effective due to the benefits provided in terms of gain of QALYs or years of life adds to the economic studies of law the important marker of finitude and scarcity of resources.

However, the concept itself is not able to generate practical repercussions without clearly defining the value of the numerical reference. In different terms, it would be like saying that the threshold is a limit that should be used to measure the cost-effectiveness ratio, without defining what this limit would be. Conceptually, the definition is unambiguous, but for practical purposes it is of little use.

The difficulty of the practical use of this concept without the definition of a reference value is easily proven when one transposes the values found in economic analysis studies to the Cartesian plane represented by the effectiveness and cost axes. In this situation, the threshold is represented by a diagonal line that reflects the intersection of cost-effectiveness considered adequate in relation to a previously defined value for each gain obtained.

In the absence of a defined reference value, there is no way to transpose the threshold diagonal to this Cartesian plane. Since there is no threshold diagonal, the constant values of the effectiveness and cost axes are only points that represent the cost oscillation to obtain a certain effectiveness, without it being possible to infer whether the technologies are cost-effective in difficult situations that involve gaining effectiveness with increased cost or losing effectiveness with decreased cost.

Of course, for the technologies that represent cost reduction with increased effectiveness or cost increase with decreased effectiveness the solution is easy, those are considered cost-effective and those are not. But even so, this would only serve to compare an existing technology with a new one, but it could not be adopted for new technologies without another existing one. The difficulty lies in the limiting situations.

When defining a concept as a limiter, it is important to establish the reference value attached to this definition that is capable of enabling its quantification, regardless of the unit of measurement to be used.

For Woods and others (2016, p. 929/930) estimating the cost-effectiveness threshold of health spending (also called by them opportunity cost) is a crucial aspect of any health resource allocation decision.

To reach this conclusion, the authors develop the reasoning that cost-effectiveness analysis seeks to identify which interventions offer health gains in relation to their costs that are high enough to warrant their adoption. To this end, they argue that it is necessary to define the cost per QALY gained or DALY avoided for the intervention to be considered cost-effective.

They argue that all countries face constraints in the resources available for health care to the extent that funding one intervention means that others are unavailable for funding, and that therefore the value of the reward for the decision to fund an intervention should play a central role in that decision. Because of this, they define opportunity cost of a resource commitment as "the health lost because those 'other' interventions that are available to the health care system cannot be delivered" (WOODS et al., 2016, p. 929/930).

They maintain that the cost-effectiveness threshold should describe the amount of money that, if removed from the health care system, will result in generating one less unit of health, or in other words, the cost of generating health in the current system. Thus, if the incremental cost-effectiveness ratio of a given intervention is less than the cost-effectiveness threshold it means that the allocation of resources for that purpose will increase the health of the population, because one QALY is lost in the overall health system considered so that more than one QALY is gained from the new intervention, so that the net effect on health will be positive and such intervention can be considered cost-effective. When the opposite occurs, the benefits of the intervention are insufficient compared to its costs and, consequently, the intervention will not be considered cost-effective (WOODS *et al.*, 2016, p. 929-930).

Establishing this reference value is not a simple, easy, or even uncritical task, but the difficulty, complexity, and subjection to criticism cannot be an insurmountable impediment to discussion on the subject. Some reference values are suggested and adopted internationally in countries with health systems similar to the Brazilian one.

The World Health Organization's (WHO) Commission on Macroeconomics and Health issued a recommendation in 2002 to adopt a threshold for willingness-to-pay based on the cost of DALYs avoided compared to the country's Gross Domestic Product (GDP).

The technology that has an incremental cost-effectiveness ratio lower than one times *per capita* GDP is considered very cost-effective and those that have a value between one and three *per capita* GDP are considered cost-effective. Above the value of three GDP *per capita* the technology is considered not cost-effective (Ministério da Saúde-Diretrizes metodológicas: Economic Evaluation Guideline, 2014, p. 83/85; VANNI et al, 2010, p. 2545-2546; SANTOS, 2010, p. 60 and PINTO et al, 2016, p. 59-60).

A first point about the WHO recommendation is that the threshold parameter is the disability-adjusted life year (DALY), which is different from the QALY normally used to calculate the incremental cost-effectiveness ratio.

Although the parameters are different (DALY x QALY), often the estimate established by WHO of up to three times GDP *per capita per* DALY is also used with RCEI calculated in monetary unit per QALY (Ministry of Health - Methodological guidelines: Economic Evaluation Guideline, 2014, p. 83/85).

Another point to be observed is the use of the limit of three GDPs *per capita* as a parameter for defining cost-effective technology. The setting of the limit is not supported by robust elements capable of demonstrating the calculations made and costs considered for the establishment of the benchmark. Its adoption is justified simply based on the direct and indirect benefits that this setting is able to bring to national economies (SANTOS, Vânia Cristina Canuto, 2010, p. 58-61).

A point of criticism of the WHO recommendation is that some countries with high GDP *per capita* allocate a small proportion of their budget to health (PINTO et al, 2016, p. 59-60). However, as mentioned above, this WHO recommendation is intended for low-income countries, which is why the mentioned criticism deserves, by intellectual loyalty duty, at least this contextualization so that it does not sound unreasonable.

Applying the WHO recommendation for the Brazilian public health system and considering the *per capita* GDP disclosed by the IBGE (Brazilian Institute of Geography and Statistics) in 2018 (the last *per capita* GDP value disclosed)³, we would have the reference values between R\$ 33.593.82 (thirty-three thousand, five hundred and ninety-three reais and eighty-two cents), corresponding to one GDP *per capita* and R\$ 100,781.46 (one hundred thousand, seven hundred and eighty-one reais and forty-six cents), corresponding to three GDPs *per capita per* QALY or DALY added.

Although subject to criticism, this parameter recommended by the WHO offers a benchmark that can serve as a starting point for more in-depth and specific studies by the countries, especially considering the peculiarities of their health system and their budgetary capacity.

The WHO recommendation is not the only existing threshold reference. Some countries adopt their own thresholds fixed in monetary values, such as the United States of America, the United Kingdom, Australia, Canada, and New Zealand.

The United States uses a threshold of 50,000.00 US\$ (fifty thousand US dollars) per QALY or per year of life earned. The origin of this value is nebulous and a literature review evidenced no citation of source or method of calculation in the first article that mentions it as arising from a dialysis program. However, among those that mention it, reference is still made to the analysis of the dialysis procedure in chronic renal patients. There is currently guidance to avoid cost-effectiveness analyses that use QALYs or

3 Available at: <https://www.ibge.gov.br/explica/pib.php>. Accessed on 08/18/2021.

any other form of weighting for quality of life or disability in the United States (SANTOS, 2010, p. 20-21; Ministry of Health, Methodological Guidelines: Economic Evaluation Guideline, 2014, p. 83/85).

In the UK, the threshold is set at a value range of £20,000.00 to £30,000.00 (twenty to thirty thousand pounds sterling) per QALY gained. This threshold range was assessed by retrospective analysis of the recommendations of the *National Institute for Health and Clinical Excellence* (NICE), the British body responsible for the development of HTA. The cost-effectiveness threshold adopted by the UK is not the only criterion used to support the agency's decisions, and, therefore, there is no policy of automatic adoption or refusal of technologies based only on RCEI, so much so that several drugs were introduced without observing this parameter. Similarly, NICE recognizes higher thresholds for specific cases such as palliative care and end-of-life. Finally, it is important to highlight that the discussion about the appropriateness of the values established as thresholds is ongoing (Ministério da Saúde, Diretrizes metodológicas: Economic Evaluation Guideline, 2014, p. 83/85; YUBA, 2018, p. 5; SANTOS, 2010, p. 20-21 and LIMA et al, 2019, p. 1717).

Although the cited threshold range can be extrapolated, it is interesting to note that this punctual and specific elongation does not escape the control of the State or a detailed analysis to verify its viability. As Santos (2010, p. 76-82) mentions when quoting Raftery (2006):

(') when the cost per QALY is above £20,000 (£29,000; US\$37,000), the judgement about the acceptability of the technology for the use of NHS resources has to be more explicit about factors such as the range of uncertainty about the calculation, the innovative nature of the technology, the particular characteristics of the condition and population that will receive the technology, and where to appropriate the benefits and costs to society more widely. Above an incremental cost-effectiveness ratio of £30,000/QALY, funding the technology will depend on these factors being extremely strong.

Within this perspective, some examples of drugs that exceeded the established threshold range are cited (SANTOS, 2010, p. 76-82). By the end of 2005 the highest cost per QALY that NICE accepted was £39,000.00 (thirty-nine thousand pounds sterling) (range £35,000.00-£43,000.00) for the drug riluzole for the treatment of amyotrophic lateral sclerosis. It is also interesting to mention the case of beta interferon and glatiramer acetate used for the treatment of multiple sclerosis. At first these drugs were deemed non-cost-effective by NICE because they had an incremental cost ratio per QALY of £35,000.00-£104,000.00 (thirty-five thousand to one hundred and four thousand pounds sterling) (estimated average £70,000.00). However, rather than simply discarding treatment, risk sharing was proposed by the government with the cost-effectiveness threshold at £36,000 so that eligible patients would have their clinical progress monitored to achieve the target cost-effectiveness, with the possibility of reduction for patients whose progress fell below the target. This measure demonstrates the rigorous attention and control with which NICE treats the issue of the cost-effectiveness threshold, always with the finite resources in mind.

On the other hand, researchers from the University of York (CLAXTON et al, 2015), starting from the premise of inexistence of empirical estimates the cost-effectiveness threshold and adopting the

opportunity cost approach based on empirical data questioned the range of values established as threshold for the United Kingdom (between £20,000.00 and £30,000.00 (twenty thirty thousand pounds sterling) per QALY gained by estimating the threshold value at £12,946.00 (twelve thousand, nine hundred and forty-six pounds sterling) per QALY gained.

This study, although it has brought important empirical data base, did not lead to changes in the use of cost-effectiveness threshold adopted by NICE (YUBA, Tania Y., p. 5). In contrast, it brought a new perspective to the discussion on the theme by bringing the threshold closer to real data and broadening horizons on the calculation form for defining a threshold more consistent with reality.

Supported by this value, another study was developed (WOODS *et al.*, 2016) aiming to establish thresholds for low- and middle-income countries based on the opportunity cost and using *per capita* income variables adjusted by purchasing power and elasticity linked to the statistical value of life. The result contrasts with the values recommended by the WHO, suggesting that thresholds of 1 to 3 GDPs *per capita* for low- and middle-income countries is quite high.

Australia and New Zealand set thresholds based on values of previous decisions on incorporation and rejection of technologies. Adopting this criterion, Australia set the threshold at AU\$69,000 (sixty-nine thousand Australian dollars) per QALY gained, and New Zealand set the threshold at NZ\$20,000.00 (twenty thousand New Zealand dollars). Canada, when applying this method, found quite discrepant values when considering cost-effective technologies. Some technologies perceived as cost-effective showed higher values than those perceived as not cost-effective. This is reflected in the greater extent of the threshold range adopted by Canada, ranging from CAN\$20,000.00 to CAN\$100,000.00 (twenty to one hundred thousand Canadian dollars) per QALY gained (Ministry of Health - Methodological Guidelines: Economic Evaluation Guideline, 2014, p. 83/85). There are authors who claim that there is no evidence on the adoption and values of proposed cost-effectiveness thresholds for Canadian decision makers" (LIMA, Sandra Gonçalves Gomes et al, 2019, p. 1717).

In relation to Australia, it is also interesting to highlight the existence of other layers of spending control linked to budget forecasting. The recommendations for incorporation of the Pharmaceutical Benefits Advisory Committee (PBAC), the Australian body that recommends the incorporation of new health technologies, are all evaluated by the government and approved by the Ministry of Finance and Administration when the annual cost of introduction exceeds 5 million Australian dollars, or by the Council of Ministers when it exceeds 10 million Australian dollars per year. Otherwise, a public funding forecast is prepared for the implementation of the new health technology (SANTOS, Vânia Cristina Canuto, 2010, p. 64 and 67).

Although the cost-effectiveness thresholds presented above are adopted (implicitly or explicitly) by some countries, they do not reflect a concrete, empirical evaluation based on opportunity cost within a system with limited resources. They are closer to estimates of individuals' willingness to pay to improve

their own health, without considering the finitude and scarcity of resources. The definition of these threshold values, therefore, is disassociated from the concept of finite resources within a health care system.

This observation has been well worked out by WOODS and others (2016, p. 930) when they state that cost-effectiveness thresholds have generally not been defined to reflect the amount of money that would displace a QALY of the value of health care investment within a system and are not based on the assessment of health opportunity cost resulting from resource constraints. Thus, using these limits when assessing the value of individual interventions in the context of existing spending limits is not consistent with improving population health because they do not reflect the opportunity costs that are imposed on health care systems. In this sense Woods and others (2016, p. 932-934) state:

Policymakers in all countries, whether classified as high-, middle-, or low-income, face difficult decisions about how to allocate scarce health care resources. CEA [*Cost-Effectiveness Analysis*] provides a means by which to compare the costs and health gains of interventions with a basis for informing investment decisions. For CEA [*Cost-Effectiveness Analysis*] results to align with improved population health, the health gains from recommended interventions must exceed the health lost when resources are committed to those interventions. The CETs [*cost-effectiveness thresholds*] should therefore reflect our best estimates of the opportunity cost of health spending (k) rather than the consumption value of health (v).

To exemplify the disconnect of the thresholds adopted today with the opportunity cost in a given health care system, the authors applied their methodologies for some countries and the result was cost-effectiveness thresholds with the value of \$3 to \$116 (1% -51% of GDP per capita), \$44 to \$518 (4% -51% of GDP per capita), \$422 to \$67 (11% - 51% of GDP per capita), and \$4,485 to \$8,018 (33%-59% of GDP per capita) for Malawi, Cambodia, El Salvador, and Kazakhstan, respectively. For Luxembourg (the country with the highest per capita income in the world), the estimated threshold value was \$43,092 to \$143,342 (39% -129% of GDP per capita). For the United States, a cost-effectiveness threshold was estimated in the range of \$24,283 to \$40,112 per QALY, a far cry from the conventionally applied value (WOODS, B. *et al.*, 2016, p. 932).

As a conclusion, the authors understand that there is a need for more empirical evidence for decision makers' understanding of opportunity cost and that their studies should be taken as a first attempt to inform about the importance of this key issue in setting thresholds. They also state that the evidence suggests that the thresholds used so far are too high and should not be used to inform resource allocation decisions (WOODS, B. *et al.*, 2016, p. 934).

Finally, it is interesting to note that although the establishment of threshold parameters can be improved, its necessity is patent, since "if the NHS or any system in the world provided everything that everyone wanted, it would consume almost the entire gross domestic product of the country leaving nothing for any other type of public or even private expenditure" (SANTOS, 2010, p. 83). Therefore, although challenging, the issue must be addressed in order to enable the granting of the right to health in its maximum degree within the conditions of the states.

4 THE ABSENCE OF A THRESHOLD IN BRAZIL AND THE FEDERAL SENATE BILL N. 415/15

Having created this solid theoretical basis on the issue of the cost-effectiveness threshold for the incorporation of new technologies in the public health system, the Brazilian case will be dealt with, addressing the current situation in Brazil and the proposal contained in the Federal Senate Bill 415/15.

There is currently no legal establishment of a defined cost-effectiveness threshold in Brazil, although economic evaluation is a requirement for the approval of the incorporation of technologies into the SUS under Law No. 12,401/11 that amended Law No. 8,080/90 at least since 2011 (PINTO et al, 2016, p. 59).

The provision for economic evaluation as a requirement for health technology analysis seeks to make explicit that health technologies, in addition to technical-scientific issues, have an important economic aspect embodied in the costs and the scarcity of available resources that must always be considered.

In this sense is the reasoning of Pinto and others (2016, p. 58) when stating:

The scenario of finite resources, enhanced by an expressive supply of new technologies for health systems in general, and in particular for the Brazilian Unified Health System (SUS), requires the manager to make incorporation decisions based on multiple criteria, including economic evaluations.

However, to establish the need for economic evaluation without defining the threshold range, as repeatedly defended in this study, is the same as admitting the existence of costs in the right to health without admitting that the available resources are scarce, which should always be avoided under the penalty of seeing the economic issue through only one prism, instead of the two that it has.

Considering the current normative scenario in Brazil that imposes the submission of economic studies and that these studies without a threshold reference lose much of their validity and relevance, some recommendations are necessary to avoid that the normative provisions are not merely formal.

Based on this assumption, the methodological guidelines on economic evaluation of the Ministry of Health after stating that in Brazil there is still no threshold of willingness to pay or methodology chosen for its determination, recommend (Ministério da Saúde - Diretrizes metodológicas: Economic Evaluation Guideline, 2014, p. 85) that:

a) studies are conducted to evaluate the feasibility of using threshold ranges for the health system in Brazil; b) each case will be analyzed in its specificity and budgetary availability of the decision maker, but trying to maintain some homogeneity in the incorporation of technologies; and c) that the economic analyses presented include in the acceptability curves wide ranges of analysis, but including the value of one to three times the *per capita* gross domestic product of the country *per* QALY.

By admitting the inexistence of a threshold, but recommending studies to evaluate the use of threshold ranges for the Brazilian health system, with the added alert of the need for homogeneity in decisions to incorporate new technologies and that the economic analyses include in the acceptability curves the ranges from one to three times the Brazilian *per capita* GDP *per* QALY, the Ministry of Health signals three important points: a) the recognition of the current situation lacking a concrete threshold in Brazil; b) the importance of thresholds, and; c) the need for efforts to be made in the search to establish a threshold consistent with the Brazilian Unified Health System.

Although Brazil does not yet have a definition of the cost-effectiveness threshold established and adopted as a representative standard of the amount that society is willing to pay more for a new technology to gain one year of quality life, there are already studies that seek to fill this gap and point to directions to be followed to establish a reference value.

An important study in this regard is the dissertation by Corah Prado, who used a simple rule of three to verify the value of the threshold range to be adopted by Brazil if it maintained the same proportion of *per capita* spending in the U.S. and the UK in relation to the threshold established by them. To reach the result, the author presented the thresholds data in these countries (US\$ 50,000.00/QALY) and the *per capita* spending on health, comparing it with the *per capita* spending on health in Brazil. As a conclusion, she verified that on average, public per capita spending in Brazil is 7.5 times lower than in the two countries when using the dollar adjusted by purchasing power parity and 14.7 times lower if the comparison is made by dollar, at the average exchange rate. Thus, by a simple rule of three he proposed that the threshold range of cost-effectiveness in Brazil should be the same and set between US\$ 3,383 to 6,663 per QALY earned (SANTOS, Vânia Cristina Canuto, 2010, p. 60).

Of course, this reasoning does not necessarily include the peculiarities of Brazil and its public health system, but it does clean up a little the uncritical transposition to Brazil of criteria adopted by other countries, clearly demonstrating that the local reality of each country is different and will only be represented in the cost-effectiveness threshold if it is present in the elements of the equation for fixing the threshold. This is the same principle present in the WHO recommendation when it adopted the *per capita* GDP as an element to calculate the threshold.

It is worth recording for documentation purposes, without any binding character or definition of cost-effectiveness threshold parameter, that the Ordinance of the Health Care Secretariat (SAS) of the Ministry of Health No. 458, dated May 21, 2012, signed by the then Secretary, Dr. Helvécio Miranda Magalhães Júnior, when approving the Diagnostic and Therapeutic Guidelines - Epithelial Malignant Ovarian Neoplasm, mentions circumstantially that, despite the existence of controversy related to the topic, traditionally, in the evaluation of cost-effectiveness, the incremental cost-effectiveness ratio of less than \$50,000 per year of life saved is used. This superficial mention should not be understood as being able to establish a definition on the subject.

The first legal initiative to address the issue of the value of the cost-effectiveness threshold for the Brazilian single health system is the Federal Senate Bill 415/15, which in its original proposal addresses, among other objectives, the mandatory definition in regulations and the disclosure of the cost-effectiveness indicator or parameter used in the analysis of requests for incorporation of technology and others.

To this end, the bill renames the sole paragraph of art. 19-O of Law 8.080/90 to §1, and includes two more paragraphs. What is of interest for the purposes of this work is the second paragraph, which establishes that "The cost-effectiveness indicator or parameter used in the analysis foreseen in § 1 will be defined in regulation and widely disseminated".

Senator Cássio Cunha Lima's project, from 2015, justifies the inclusion of the paragraph on the grounds that the sole paragraph of art. 19-O of Law 880/90 imposes the need for cost-effectiveness evaluation for the incorporation of new health technologies by SUS and that the legislation or infralegal normative acts have not yet established the parameters or cost-effectiveness indicators to be used.

It also argues that it is not clear "the legal basis according to which Conitec analyzes the cost-effectiveness of a medical procedure, nor what is the threshold adopted to consider that a procedure is cost-effective, a gap that sometimes allows the adoption, by the public administration, of low-quality technical discretion.

The project had its original text modified by Amendment No. 9 presented by Senator Fernando Bezerra Coelho, which, due to the urgency imposed by the covid-19 pandemic, was sent directly to the Plenary. The substitute eliminated the amendment to art. 19-O and added the third paragraph to art. 19-Q of Law No. 8.080/90 with the following wording "The methodologies used in the economic evaluation referred to in item II of § 2 of this article will be set out in regulation and widely disseminated, including with regard to indicators and cost-effectiveness parameters used in combination with other criteria.

In his opinion, senator Fernando Bezerra Coelho highlighted "that the regulation of technological incorporation is essential for the proper functioning of public health systems", as well as emphasized the need for conjugation with other criteria.

The substitute's wording, by establishing that the methodologies employed in the economic evaluation will be set forth in regulations and widely disclosed, including with regard to the cost-effectiveness indicators and parameters used in combination with other criteria, opts to leave the subject matter to infralegal technical deliberations that have greater knowledge and practical experience on the subject, making possible not only the election of criteria that are more consistent with reality, but also allowing greater ease for alteration, improvement, and modification of the fixed criteria. It also makes it possible that the cost-effectiveness threshold is not the only criterion to be considered when choosing the incorporation or not of a health technology to SUS.

On 04/27/2021, the project was approved by the Federal Senate Plenary in the terms of the substitute. On 04/29/2021 it was sent to the House of Representatives, where it was renamed PL no.

1.6313/2021. In the House of Representatives it was approved by the Social Security and Family Commission and by the Constitution and Justice Commission. In March 2022, the bill was sanctioned under No. 14.313/22, adding § 3º to article 19-Q, of Law No. 8.080/91, in the following terms: "The methodologies employed in the economic evaluation referred to in item II of § 2 of this article shall be provided in regulations and widely disclosed, including with regard to the cost-effectiveness indicators and parameters used in combination with other criteria."

The delay in the project's passage through Congress and, later, in the expedition of the regulation, demonstrates the absence of consensus in the Legislative Branch and, reflexively, in society in general about the theme in question, but it does not prevent the discussion from deepening and maturing the idea of the indispensability of defining an economic-budgetary threshold of cost-effectiveness to be adopted by the Brazilian Unified Health System.

5 CONCLUSION

For the Brazilian Unified Health System (SUS) to effectively materialize the constitutional guarantee of health as a right of all and a duty of the State, guaranteed through universal and equal access within its own system that allows comprehensive care and that, at the same time, is economically healthy and budget viable, it is essential to discuss the need to define a cost-effectiveness threshold.

Tying the effectiveness of the constitutionally consecrated Unified Health System to the economic aspect of the right reinforces the understanding that all rights have a cost associated with their guarantee/implementation/grant (HOLMES et al, 2000).

When dealing with the cost of rights from a public sector perspective, two aspects must necessarily be addressed. The first is that the State must spend resources to ensure the enshrined right, and the second, directly related to the first, is that the resources available to the State are finite and limited, and must be used in the best possible way to ensure the maximum possible effectiveness per monetary unit applied.

Only with an adequate consideration of the fundamental duties and the costs of rights, can we achieve a state in which the ideas of freedom and solidarity do not exclude each other, but rather complement each other. That is, a state of freedom at a moderate price (NABAIS, 2007).

In reality, we are facing situations in which the resources available for application in HPAs are not sufficient to meet all demands, and their allocation must go through conscious, albeit difficult, decisions to choose HPAs that result in better health gains for the general population per monetary unit allocated, always properly assessing the opportunity cost.

When the right to health is faced through this realistic prism, the need to implement tools capable of enabling greater rationalization of health care becomes pressing.

However, although the legislative change that introduced the need for cost-effectiveness assessment of new technologies that intend to be incorporated into the SUS dates back to 2011 (Law No. 12,401/11),

in Brazil we still do not have a definition on a cost-effectiveness threshold, either expressly or even implicitly. Similarly, it is not possible to infer the threshold from the analyses of the technologies analyzed by CONITEC that presented calculation of the incremental cost-effectiveness ratio (PRADO, 2015, p. 3142).

The legislative change brought by Law 12,401/11 to Law 8,080/90 equated CONITEC's procedure for analyzing health technologies to that performed by the best agencies in various countries around the world by introducing the requirement for a cost-effectiveness study in the evaluation. In doing so, it imposed the need "to work with a cut-off value, which indicates which technologies can be sustained by the system. Without this, how to know if a given incremental cost-effectiveness ratio represents gains in health and efficient use of financial resources?" (PRADO, 2015, p. 3142).

As mentioned in the present work, in Brazil "there is still no research dedicated to the theme of value in health and LDP consolidated, nor a methodology chosen for determining such a threshold" (Ministério da Saúde - Diretrizes metodológicas: Economic Evaluation Guideline, p. 83/85).

The main reason for the delay in advancing this issue stems from a distorted and simplistic view of the cost-effectiveness threshold, held by both the medical community and the general public, that its adoption has the sole and exclusive purpose of limiting health spending due to the budgetary constraints in Brazil.

To defend this view is to neglect that the state's resources are limited and that the best way to face this limitation is to optimize the allocation of the resources that are available in order to transform them into the greatest gain for the health of the population with their efficient allocation.

When facing reality from this perspective, one realizes that by highlighting the importance of the cost-effectiveness threshold, the opposite of what the predominant view preaches is being intended: to make available technologies that add value to treatments already incorporated into the SUS and that enable effective gains for the health of the population facing an inexorable scenario of scarce resources (PRADO, 2015, p. 3145).

The reality of resource scarcity is so present and real that although there is no cost-effectiveness threshold defined yet for Brazil, the majority recommends adopting the criterion proposed by the WHO that if the new technology costs up to 3 GDPs *per capita per DALY* added it is considered cost-effective (VANNI et al, 2010, p. 2545-2546 and SANTOS, 2010, p. 60).

The use of the threshold recommended by the WHO in the absence of a cost-effectiveness limit set by Brazil clearly demonstrates the indispensability of adopting a cost-effectiveness threshold, even if it has not been established based on its own criteria and consistent with the reality faced by the country.

Facing the issue from this point of view is to recognize the other side of the cost of law theory, that is, scarcity and limitation of resources, and to try to find the best possible solution so that the limitation is not faced only by the downside of preventing the increase of new health technologies, but also serves to

optimize the gain in health with the expenses incurred in the allocation of resources. This is the real reason for the indispensability of setting a cost-effectiveness threshold.

From this perspective that the establishment of a cost-effectiveness threshold is indispensable, better than adopting a generic threshold based on a measure of health benefit not adopted in our cost-effectiveness assessments (DALYs) is to try to build a threshold consistent with the parameters used here and with the practical reality and the national economic and budgetary limits.

The establishment of a cost-effectiveness threshold in Brazil would provide some advantages to SUS compared to the system of economic analysis devoid of a defined threshold as it currently occurs.

The main one is to establish a parameter capable of aiding and facilitating the interpretation of economic evaluations in decision making and scientific research. Another would be to offer support for incorporation decisions and also for the prioritization of health investments. A third would be to clarify the opportunity cost. This would also help the Judiciary in the decision making for health technology supply in a more critical way and considering the RCEI in comparison with the threshold, avoiding that SUS management bodies pay a high cost for technologies without established evidence and that SUS is burdened in an anarchic way and disregarding principles and concepts dear to the system (PINTO et al, 2016, p. 60).

Threshold setting also has the potential to contribute to economic analyses to encourage and prioritize the more efficient and effective use of health budget resources in Brazil, so that increasingly the same amount of allocated resources entails a greater gain in health benefits for the population (PINTO et al, 2016, p. 60).

It is also interesting to highlight the possibility of making the parameter used to establish the cost-effectiveness limit known to society in order to expose it to criticism, so that it can be refined and improved and, over time, gain solid foundations and solid value.

Considering that the definition of a threshold is not yet a consensus in Brazil and that in order for the change in the current scenario to occur it is necessary to go step by step, the establishment of a threshold consistent with the reality faced by Brazil should observe, both under the aspect of the principles that govern the right to health and the cost of this right, the new technologies available and the scarcity of resources, some parameters capable of harmoniously accommodating the various nuances involved.

The idea of value parameters is understood in the need for the threshold to encompass several situations that have complex variables and that may fluctuate due to specific situations that could lead to their exclusion if a single value were adopted. Not to mention that it allows different situations to receive different treatments in line with the principle of equality of material goods.

In this sense Prado (2015, p. 3144) argues that "probably should be adopted not a single value of LCE, but a range that considers different important variables, but mainly access to new technologies, by citizens in all regions of the country.

Beyond the range, the LCE should not be adopted as the sole and rigid criterion. Apparently, there is a trend to work with a threshold that allows other criteria to be taken into consideration when analyzing the incorporation of new technologies by SUS, adopting a soft LCE, as it became known, instead of a hard LCE. (PRADO, 2015, p. 3144).

Another important conceptual aspect in the view of some authors is that it should be contained in the definition of threshold the possibility of periodic review/reassessment of the value of the LCE. (2015, p. 3139):

The revision of the LCE can occur in two ways: a) revision of the nominal values, for example, thresholds fixed in predefined monetary values; b) revision of the parameters of the indexer value, for example, thresholds fixed in *per capita* GDP or any other economic indicator. This second case has the peculiarity of enabling the ordinary revision that occurs with the indexer calculation update and also the extraordinary revision to modify the nominal value of the indexer used.

Regular re-evaluation of the LCE value ensures that it is appropriate to changes in efficiency, cost, and budget that occur over time and are natural in a market economy such as the Brazilian one. These variables can fluctuate up and down in order to increase or decrease the value of the LCE.

Finally, the cost-effectiveness threshold should conceptually observe the possibility of acting on two fronts: incorporation of new technologies and disincorporation of old technologies. The main function of the threshold is, without a doubt, to serve as a parameter for the cost-effectiveness analysis of a technology that intends to be incorporated into the Brazilian National Health System, but the rebound effect of its main function is to also serve as a parameter for the cost-effectiveness analysis of technologies already incorporated into the SUS and, consequently, to subsidize the elimination of technologies included in the list of HPS, but already obsolete, expensive, and not very effective compared to the existing new technologies.

In this way, the materialization of the constitutional guarantee of the right to health as a right of all and a duty of the State, ensured by means of universal and equal access within the SUS necessarily involves discussing the cost of rights and the scarcity of available resources and, consequently, the indispensability of defining a cost-effectiveness threshold capable of enabling the achievement of increasingly better results in benefits to the population's health with the limited amount of resources available, providing greater efficiency in the application of each monetary unit spent in relation to the health result obtained.

Only a clear definition of the cost-effectiveness threshold makes it possible to measure the efficiency of the resources allocated to health. Otherwise, we will continue allocating a high percentage of the national budget to health without being able to verify the efficiency of this allocation, submitting ourselves to the risk of collapsing or even annihilating our health system.

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