Organized by: ABIMED — TECNOLOGIA. SAÚDE. VIDA.

Elaborated by: LCA

TECHNOLOGICAL INNOVATIONS IN THE HEALTHCARE INDUSTRY

Impacts on medical-hospital costs and social welfare

May 2023

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SUMMARY

EXECUTIVE SUMMARY

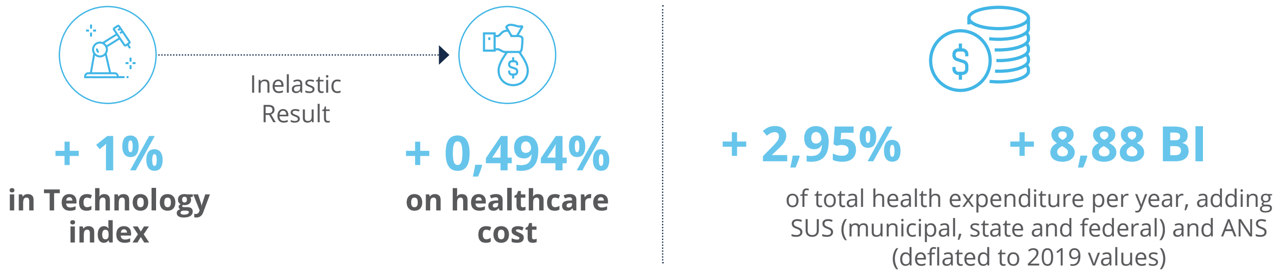
The present work aims to quantify the impact of technology on medical-hospital costs and measure the gains in terms of social well-being arising from technological growth. These same relationships are also evaluated through case studies of three medical technologies.

The increase in medical technology has a positive impact on population well-being, counterbalancing the increase in health costs.

The increase in health costs continues to increase in several countries, with holds a relevant issue not only in Brazil, but also all over the world. Between 2008 and 2019, in Brazil, **the Medical Technology Index raised in 117% (annual average of 5.7%)**.

From the application of econometrics methods, it was estimated that the medical technology index has a positive impact on healthcare costs. **A 1% increase in the index positively impacts health cost *per capita* by 0.494%**. This means that the increase of medical technology caused a growth in health expenditure of R$ 8.88 billion, on an annual average, between 2009 and 2019 (ANS + SUS), in a total of R$ 97.68 billion .

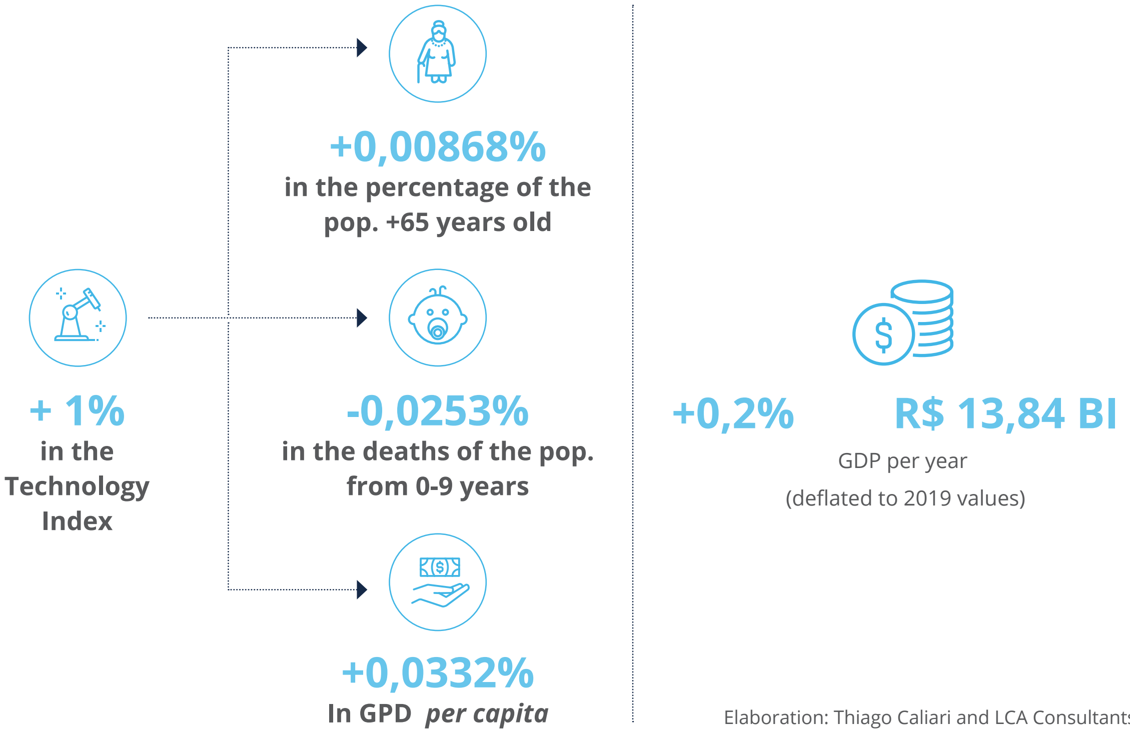
Figure 1: Impact of medical technology on healthcare costs



Elaboração: Thiago Caliari e LCA Consultores.

In terms of well-being, on the other hand, there is a **1% increase in the technology index, increasing the proportion of the population over 65 by 0.00868%, reducing child mortality by 0.0253% and increasing GDP *per capita* by 0.332%**. In monetary terms, the increase in medical technology promoted a GDP increase of R$ 13.84 billion, on an annual average, between 2009 and 2019, totaling R$ 152.24 billion .

Figure 2: Impact of medical technology on well-being



Elaboration: Thiago Caliari and LCA Consultants.

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Despite the fact that medical technology promotes higher health care costs, the social welfare gains produced by the introduction of new technologies are of great importance in promoting increased efficiency in the prevention and treatment of disease.

The adoption of medical technologies in health systems can combine the economy with financial resources with the increase in the quality of life of the population.

The production, dissemination, incorporation and use of technologies in health systems depends on the technical, economic and social characteristics of different countries. In this context, health technology assessment (HTA) is a relevant tool to assist in decision-making on the use or not of medical technologies by health systems.

The present study evaluated health technologies, especially their cost-effectiveness, through the approach of three case studies:

1. CDI: implantable cardioverter-defibrillators;
2. PET: positron emission tomography;
3. Hip prostheses: total hip arthroplasty (THA).

The three case studies showed that innovations in the field of medical equipment can represent efficient alternatives for the management of prevalent diseases in the areas of cardiology, diagnostic imaging, and orthopedics.

In the case of cardioverter-defibrillators (ICDs), in general, it is concluded that there is an improvement in the symptoms and survival of the patients. Among the findings, the gain in years of life **stands out**, 1.52 years, compared to optimized medical therapy. In the comparison between treatment with defibrillators and treatment with pacemakers, **higher survival is observed** (8.11 vs. 7.12 respectively) and **quality-adjusted life year (QALY)**, 1.47, in patients of different classes of heart failure. There are still **lower rates of hospitalization, hospital remediation, and generator replacement** in patients with quadripolar devices when compared to patients treated with bipolar devices.

The use of positron emission tomography (PET) in patients with non-small cell lung cancer is more **accurate** (94% vs. 86%), more effective for correct staging **(60% vs. 40%)**, and more effective diagnosis **for assessing tumor resectability (84% vs. 70%)** compared with computed tomography, as well as a lower rate of **unnecessary surgeries** (19% versus 47%).

On the other hand, with the use of hip prostheses, **there are lower in-hospital mortality for early THA** compared to late THA (7.4% versus 16.9%); **lower expenses in early** THA (R$ 3,626.00 vs. R$ 5,622.3), compared to late THA; **higher gains of QALYs for hybrid prostheses** (5.38 to 11.90), in comparison to cemented prostheses (5.22 to 11.69).

Figure 3: Summary of the main results found in the health case studies.

Cardioverter defibrillators Implantable (CDI)

- Gains in life year (1.52 years) compared to optimized treatment with medication;
- Survival gain (8.11 vs 7.12 and QALY (1.47) compared to pacemaker treatment;
- Lower rates of hospitalization, rehospitalization, and replacement of generator in the comparison of treatments with quadripolar devices in relation to bipolar.

Emission tomography positron (PET)

In patients with non-small cell lung cancer and compared to computed tomography:

- Improved accuracy (94% vs 86%);
- Increased diagnostic effectiveness for correct staging (60% vs 40%);
- Increased diagnostic effectiveness assessment for tumor resectability (84% vs 70%)
- Lower rate of unnecessary surgeries (19% VS 47%).

Hip Prostheses (THA)

In comparison between early THA versus late THA:

- Lower in-hospital mortality (7,4% vs 16,9%)
- Lower expenses (R$3.626,00 vs. R$5.622,3)
- In comparison of hybrid prostheses in relation to cemented prostheses:
- Biggest QALY gains, from 5.38 to 11.9

Elaborated by: Silvia Kobayashi, Alessandro Campolina and LCA Consultants.

The positive impacts of technological innovations in the health sector are undeniable. The intensive use of Artificial intelligence, Internet of Things, Big Data, robots, 3D printing, and many other advances have been increasingly essential in both the prevention and diagnosis, treatment, and rehabilitation of diseases, resulting in positive effects such as better quality of life, longevity, access to quality services for the population, besides social well-being.

Sponsored by ABIMED – Brazilian Association of the Health Technology Industry, and elaborated by LCA Consultants, together with some external consultants, the present work aims to shed light on the two spheres of medical technology – cost and social welfare – in order to contribute with the discussions about its importance in the socioeconomic conditions of the country and in decision-making about using the medical technology or not using such technologies by the health systems.

This paper also presents three case studies, based on a solid methodological approach in the areas of cardiology, diagnostic imaging and orthopedics, which reveals the importance of the methods of economic evaluation in health in selecting the most efficient alternatives among the current technological innovations.

In summary, it is an important reference to prove that medical technology holds positive and unequivocal effects on the well-being of the population and generates positive effects for the economy of our country.

Fernando Silveira Filho
CEO of ABIMED

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ABOUT ABIMED

ABIMED – Brazilian Association of the Health Technology Industry brings together companies that represent about 65% of the medical equipment and devices market in Brazil, companies with a diversity of sizes and origin of capital. The purpose of the entity is to continuously contribute to the expansion of the population's access to advanced health technologies, aiming at people's quality of life and longevity.

Our main mission is to represent the health product technology industry by proposing policies that ensure a favorable environment for innovation and competitiveness of members in local and global markets, as well as contribute to the development of the health sector in the country. The vision is to be the reference association in the health products sector, as an ethical, and innovative institution that promotes the population's access to technology, based on three core values: Integrity, Respect and Inclusion.

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INTRODUCTION

The rise in the price indices of medical and hospital equipment is a frequent issue in vogue in the governmental and private spheres. There are several factors that put pressure on costs along the complex production chain of health services. The high costs of innovations pose significant financing challenges that must be carefully assessed when making decisions about resource allocation. The observation of the relationship between technology and health expenditures is widely discussed in the health economics literature, but it suffers from difficulties in measuring.

In conjunction with the potential increase in costs, the use of technologies also has an impact on social well-being and, consequently, on the overall productivity of the economy. The intensive use of solutions that encompass technological advances is essential in both the prevention and treatment of diseases. The effects on increasing the quality of life and longevity of the population reflect the positive impacts of innovations.

In this context, the Brazilian Association of the Health Technology Industry (ABIMED) asked LCA Consultants, with external consultants[1], to make a study to evaluate the relationship between medical technology in these two spheres – cost and social welfare –, through two approaches. The first seeks to establish the relationships between the intensity of technology use and medical costs and health benefits in an aggregated way, while the second strategy seeks to establish these relationships based on case studies.

The first approach, from Section 2, will quantitatively elucidate both the relationships between medical technology and health costs, as well as its relationship with social well-being. Models were elaborated, supported by the review of specialized sectoral literature, based on the application of statistical tools - Econometric. We sought to establish, in quantitative terms, the influence of technology on the evolution of medical and hospital costs, i.e., to what extent the use of technologies contributes to the so-called medical inflation. To capture the effect on well-being, models were created based on the variables of life expectancy, infant mortality, and GDP per capita.

In order to establish a measure capable of representing the technological issue, the strategy adopted was the construction of a technology index given by the sum of some types of equipment divided by the number of inhabitants. The control variables to separate the effect that is sought to be measured – the technological issue – from other effects that interfere with the medical cost were also used,

such as frequency of use of medical procedures, age profile, price factor, macroeconomic and demographic effects, among others.

In the second approach, developed in Section 3, case studies are presented, with analysis of specific procedures with representativeness in ambulatorial/hospital costs, in order to estimate the impact of technological evolution in terms of cost and well-being on these specific treatments. From the contextualization of the demographic and epidemiological transition of contemporary society and its implications for the ongoing technological transition in health systems, 3 technologies were identified for structuring the case studies – implantable cardioverter defibrillators (ICD), positron emission tomography (PET) scans and hip prostheses.

The development of the analyses was based on the presentation of the technologies, a bibliographic review of economic evaluations and identification of the resources necessary for the implementation of the technology, with discussion of the use of economic evaluation studies for the identification of cost drivers and cost-effectiveness analysis of the selected technologies in the Brazilian context.

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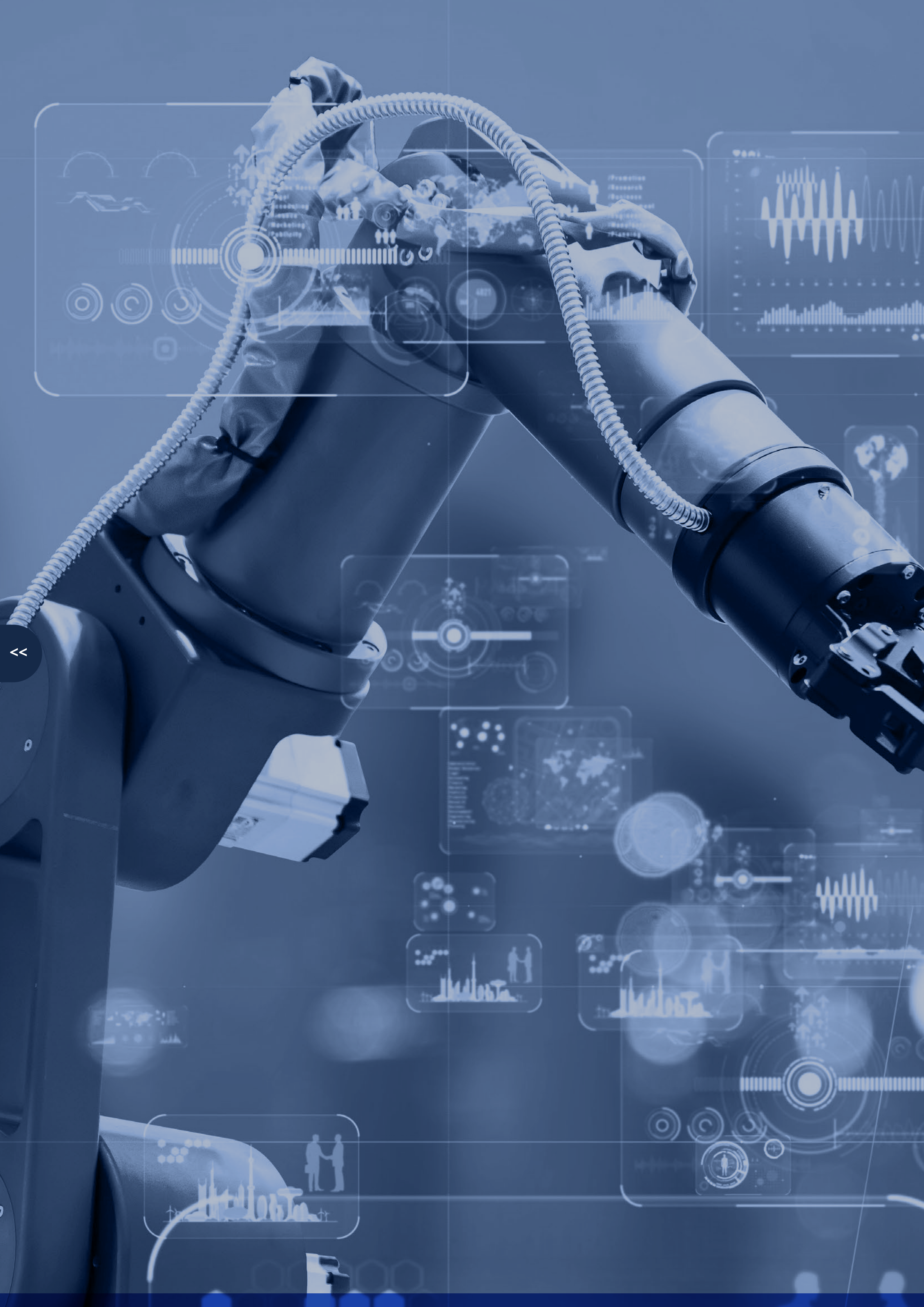
1. Silvia Takanohashi Kobayashi, Alessandro Campolina e Thiago Caliari.

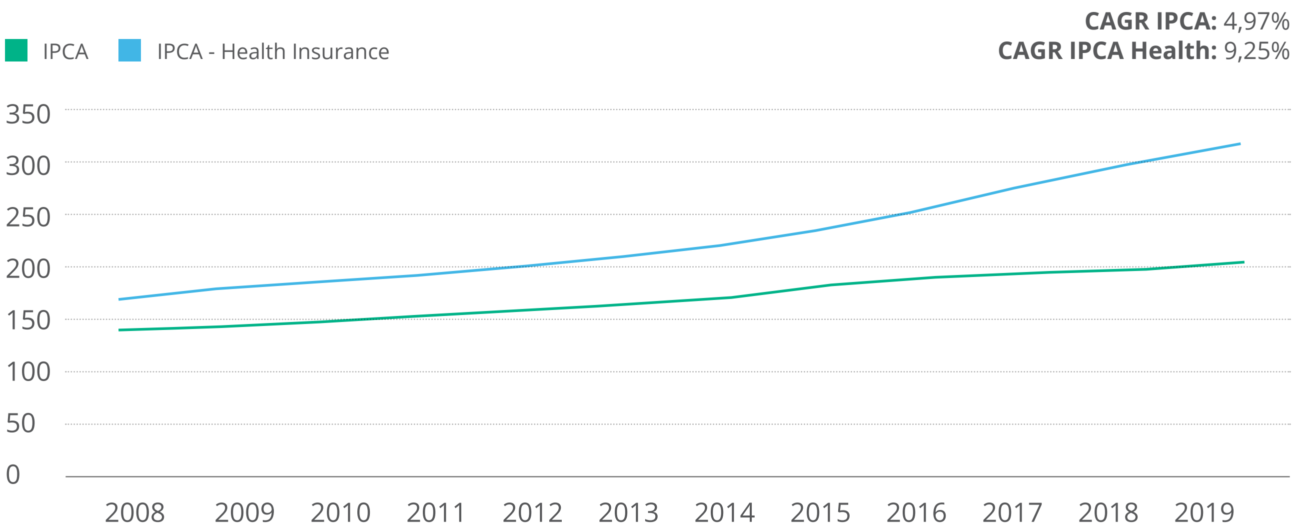


ANALYSIS OF THE RELATIONSHIP BETWEEN INTENSITY OF TECHNOLOGY USE AND HEALTH COSTS AND BENEFITS

Elaborated by: **Thiago Caliari** and **LCA Consultants**

The reduction of health costs is a phenomenon that can be observed globally. Its evolution consistently outpaces general inflation, with a difference between these global average rates each year[2]. The Brazilian case is not different from the rest of the world. Between 2008 and 2019, the period considered, in the present study, the variation of the Extended Consumer Price Index (IPCA) was 84% (CAGR[3] of 4.97%), while the item "health plans" of the IPCA – called medical inflation – recorded a variation of 190% for the same period (CAGR of 9.25%).

Chart 1: Medical inflation and IPCA, base 100 (2008=100)



Source: IBGE. Elaborated by: Thiago Caliari and LCA Consultants.

The sectoral literature has pointed to several factors to explain this behavior. The aging of the population and, consequently, the increased relevance of the elderly population in the composition of the portfolios of beneficiaries of health plans increase the risk of accidents, putting pressure on costs. The higher incidence of chronic diseases[4] that require continuous and expensive treatments also impacts costs. The sedentary lifestyle and other bad habits of the population not only lead to an above-average use of health services, but also favor the development of chronic conditions, increasing the risk of future accidents. The inefficient use of medical services, resulting from agency problems intrinsic to the organization of the sector, is another variable that contributes to the upward trend in medical costs.

In addition to these characteristics, the incorporation of new technologies in medicine has also been pointed out as a factor in increasing costs. Contrary to what usually occurs in the vast majority of markets, where technology is associated with cost reduction, in health it can result in both cost increases, derived from the need to train human resources, the need to update regulatory and certification instruments,

2. AON PLC. Global Healthcare Cost Trends, 2021. Available at: https://img.response.aonunited. com/Web/ AonUnited/%7Bf169b530-39a0-4182-8c4d- a435fe8a801c%7D_2021-MedicalTrend-DRAFT_pt-BR.pdf

3. Compound Annual Growth Rate (CAGR) is a metric, commonly used in the financial market, that indicates the annual growth rate of a variable if it varied steadily and in a compound manner over a given period.

4. PAHO. WHO reveals leading causes of death and disability worldwide between 2000 and 2019, 2020. Available at: https://www.paho.org/ en/news/9-12-2020-who-reveals-main-causes-death-and-disability-around-the-world-between-2000-e

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and investments in the physical infrastructure as well as cost reduction, associated with greater precision in treatments, acceleration of recovery, among others.

In addition, as it is a sector of high technological intensity, it involves the use of equipment with high acquisition and operating costs, but which has been contributing to the improvement of social well-being through the improvement of diagnostic and treatment techniques. Technological advances in health are a central element in explaining the significant drop in mortality from various diseases and the consequent increase in longevity.

Given the relevance of the technology factor, it will be discussed in detail in this study, under two direct objectives:

1. To evaluate the relationship between sectoral technological innovations – embedded in the evolution of hospital equipment – and the variation in health costs, with a view to understanding the impact of such innovations on the increase in the cost of supply in the sector (economic logic),

2. To evaluate the relationship between technological innovations and the social well-being provided by health services, observing the importance of technological development in the medico-sanitary logic.

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DELIMITATION OF THE MAIN VARIABLES FOR THE STUDY

Health costs in Brazil

Studies that analyze the determinants of health costs have been based on ad-hoc *rationality* or availability of data (Wilson, 1999)[5] and have the common characteristic that the standard dependent variable observed is per capita health expenditure, with some variations: real, nominal or disaggregated value in terms of health costs of the resource, with emphasis on the former. The studies have varied cuts, being at the macro level (emphasis on the country level, but also being observed studies with more disaggregated regional cuts) or meso level (studies at the level of analysis of the establishment – hospital – and the patient). The increased availability of data has allowed these studies to use more robust econometric models, especially panel data models.

Although the main objective of this study is to assess impacts within the scope of the total health market, the need to proceed with statistical analyses with a higher level of disaggregation limits the possibility of analyzing the private health market. This is due to the availability of data on the platform of the National Supplementary Health Agency (ANS); It does not provide disaggregated information on the basis of comparison necessary for the generation and guarantee of econometric models with a reasonable number of variables, and variables that are aligned with those used in the relevant literature.

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The Variation in Hospital Medical Cost (VCMH), an index prepared by the Institute for Supplementary Health Studies (IESS), as well as the item called health, which is part of the IPCA, would be alternative proxy variables for the analysis of medical cost, but the lack of openness to different geographical levels of these indices makes their use unfeasible, since working with aggregated data at the national level impairs the robustness of the model. It would also be possible to use a comparative analysis of per capita health expenditure in several countries based on information from the World Bank, but this alternative also brings relevant restrictions. The international comparison would limit the analysis of the specificities of health expenditure in Brazil, in addition to the fact that there is an undesirable level of aggregation for the technology proxy variables. Thus, the study will be based on data made available by the public health sector, accessible on the DATASUS platform. The data, in theory, refer to municipal, state and federal public Health expenditure, at the outpatient and hospital levels. The reality, however, is different, because the information from the states and municipalities is often not fed on the site, so that the bulk of the amounts made available are the Union's transfers. In addition, in some municipalities the management format is different, in the form of management contracts, and in such

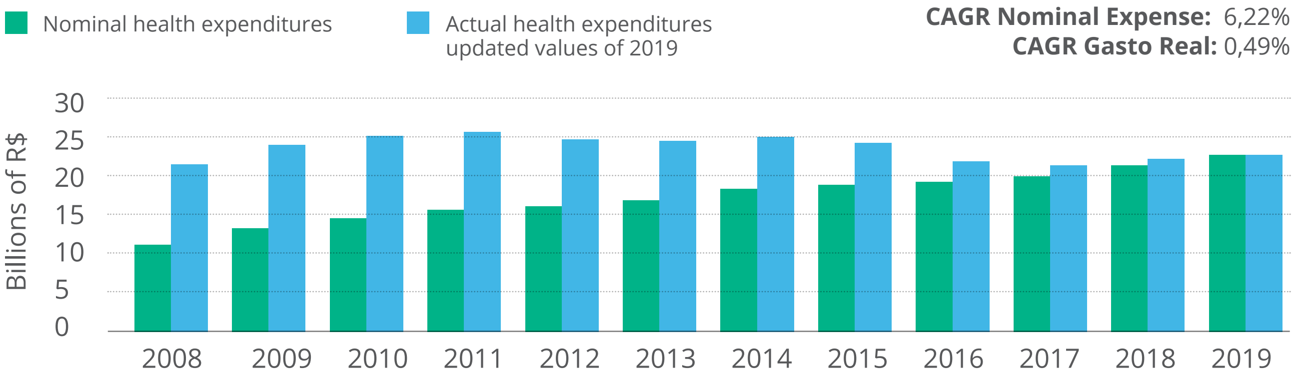
5. Wilson, R. M. (1999). Medical care expenditures and GDP growth in OECD nations. American Association of Behavioral and Social Sciences Journal, 2, 159–171.

6. An association between IPEA, MS and Fiocruz has attempted to carry out statistical surveys of total health expenditures based on the OECD (System Health Account – SHA) measurement, but the accounts that have been made available in recent work are aggregated. There are nuances that need to be discussed and remedied. Aggregated data are available at: Ministry of Health (BR). Health accounts from the perspective of international accounting: SHA account for Brazil, 2015 a 2019. 2022. Available at: https://www.ipea.gov.br/portal /images/ stories/PDFs/livros/ livros/220202_livro_contas_de_saude.pdf May 2nd 2022.

cases the information on the Union's transfers may not be present. Despite all this complexity, variability and bias of the data, DATASUS is the best information that can be had on SUS expenditures, and this is the variable that researchers in the sector have used[6].

Information on public Health expenditure is open at different geographic levels, making it possible to expand the sampling of the models and bringing robustness to the estimates. Graph 2 below shows the evolution of these values. Between 2008 and 2019, public Health expenditure in nominal values increased by 106% (CAGR of 6.22%), and in real values (deflated by the IPCA) the variable grew by 6% (CAGR of 0.49%).

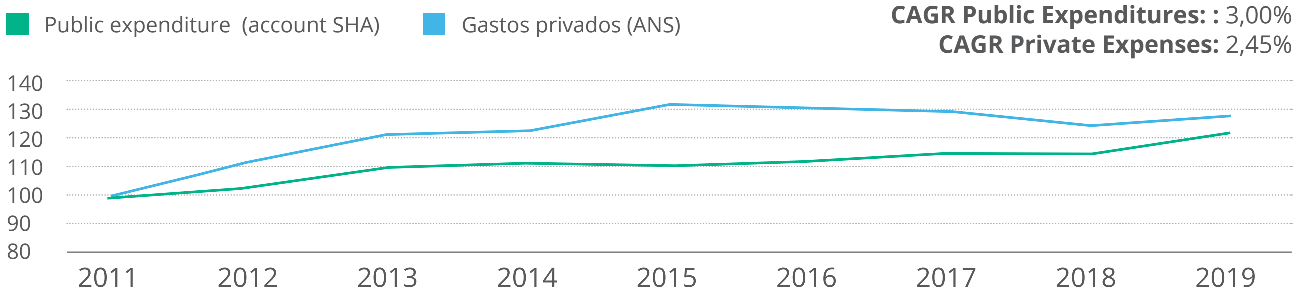
Graph 2: Evolution of public Health expenditure, in nominal values and updated values for 2019, billions of R$, 2008 to 2019



Note: Deflated values for 2019 by IPCA (IBGE). Source: DATASUS and IBGE.
Elaborated by: Thiago Caliari and LCA Consultants. Note: values deflated by the IPCA 2019.

It is appropriate here to justify the support of the base to be used. It is known that the best option would be to observe the relationship between medical inflation and technology through the evolution of private health expenditures because this is the economic locus where market forces present themselves. Measurement from the perspective of the public system, on the other hand, can incorporate a standard of regulation with greater control by the State, which has budget constraints and public policy decisions impacting the definition of prices. The approach via public expenditures, however, does not seem to be a strong limitation for the study because, when observing the evolution of the average expenditure of public and private health procedures, illustrated in Graph 3 below, both are on an upward trajectory in the period, with a correlation of 0.82.

Graph 3: Evolution of real private and public Health expenditure (average cost of hospital and outpatient procedures), from 2011 to 2019 (2011=100)



Source: ANS and IBGE. Elaborated by: Thiago Caliari and LCA Consultants.

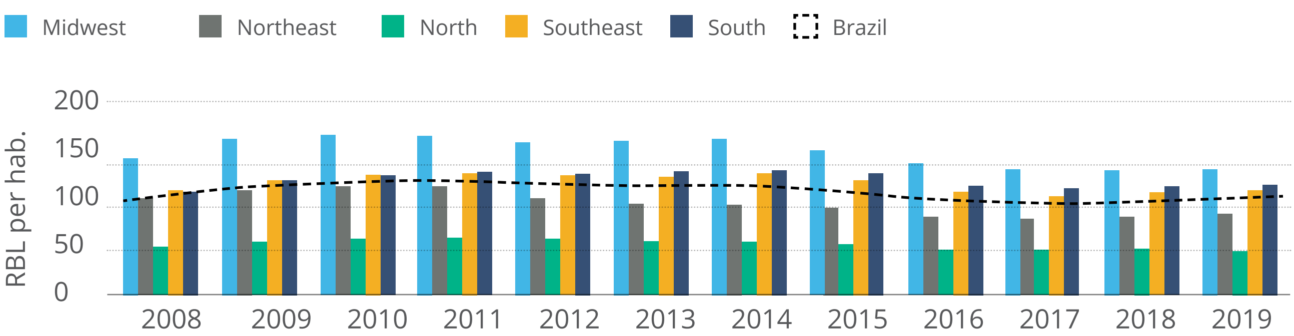
It is also important to explain the geographical cut-off to be established in the analysis, and this definition is based on the dynamics of SUS care itself. The system presents a decentralized care strategy, defining the municipality as the federative entity to which the provision of health services was assigned, with the Union and the states being responsible for the technical and financial provision for the exercise of the functions (Caliari et al., 2009)[7]. There is, therefore, an important expenditure constraint imposed on the supply side. The expenses of each municipality depend, to a large extent, on the transfers of the Union through the SUS, and such transfer is heterogeneous and dependent on the level of complexity of the services provided. Through the health macro-regions, distinct standards of care are established by level of complexity in a broad geographic area, which observe the criteria of (i) regional conformation with the necessary scale for the sustainability of high-complexity services, and (ii) territorial contiguity, aiming to provide regional cohesion as well as to provide the organization, planning and regulation of health services in the territory. This highlights the need to observe the best relationship between supply and demand at the different levels of service and, consequently, the importance of economies of scale in more complex services (characterized by lower demand and higher costs).

In this format, the definition of geographic boundaries for health regions is complex and may also vary over time, depending on the evolution of the mandate and regional characteristics. A strategy widely used in SUS analyses is the adoption of the micro-regions of the Brazilian Institute of Geography and Statistics (IBGE) as a proxy for health regions, and this is precisely the geographical framework established in this study.

To construct the variable per capita expenditure, the sum of SUS outpatient and hospital expenditures was divided by the population of each micro-region. The data were deflated by the IPCA to 2019 values, in order to expunge the trend of standard prices for the entire society. Graph 4 below shows the evolution of this index. Real health expenditure per capita grew 15.5% between 2008 and 2011. After that, it started to show a declining trajectory, accumulating a drop of 16.4% from 2011 to 2019. In the entire period, the indicator decreased by 3.6% (CAGR of -0,31%)[8]

Graph 4: Evolution of public Health expenditure *per capita*, by micro-region, in R$ per inhabitant. (updated for 2019), 2008 to 2019

CAGR Brazil: -0,31%



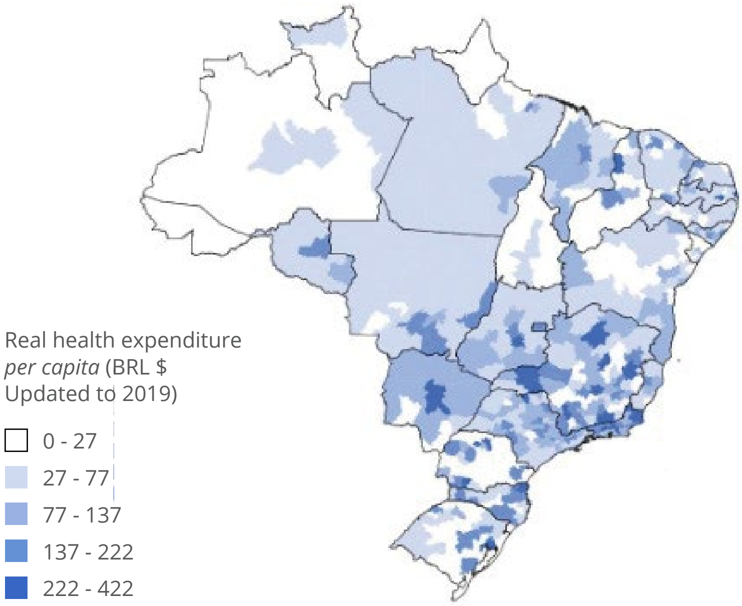
Source: DATASUS. Elaborated by: Thiago Caliari and LCA Consultants.

7. Caliari, T; et. al. Far from the parties and close to the federation: an evaluation of municipal expenditures on public health. Economic Research and Planning, v. 39, n. 3, p. 466-496, dec. 2009. Available at: <http://repositorio.ipea.gov.br/handle/11058/5111>

8. CAGR values segmented by macro-region: (i) Midwest: -0.65%; (ii) Northeast: - 1.36%; (iii) North: -0.72%; (iv) Southeast: 0.11%; (v) South: 0,54%.

The microregional distribution of per capita expenditure in 2019 is depicted in Figure 4. It is possible to observe the regional differences resulting from the SUS management format elucidated above.

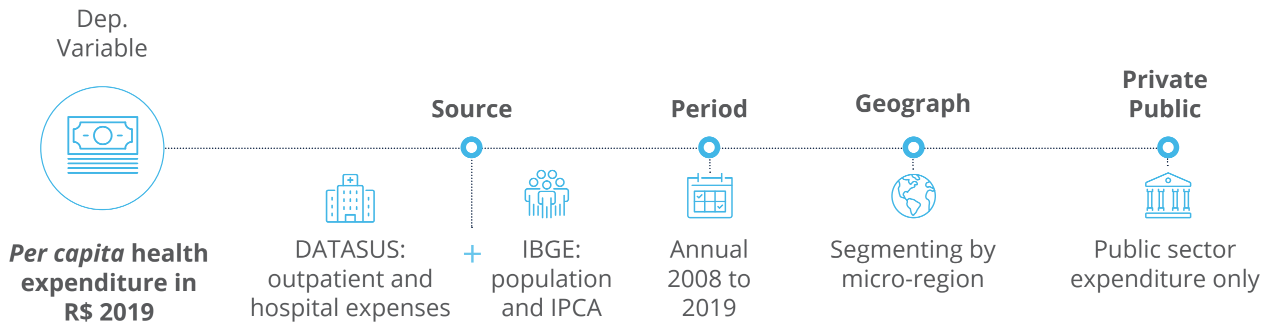
Figure 4: Amount of public Health expenditure per capita by micro-region, 2019 (R$ /inhabitants)



Source: DATASUS and IBGE. Elaborated by: Thiago Caliari and LCA Consultants.

The summary of the variable used to represent the cost of health care is shown in Figure 5.

Figure 5: Summary of the health cost variable (public expenditures)



Elaborated by: Thiago Caliari and LCA Consultants.

Health technology in Brazil

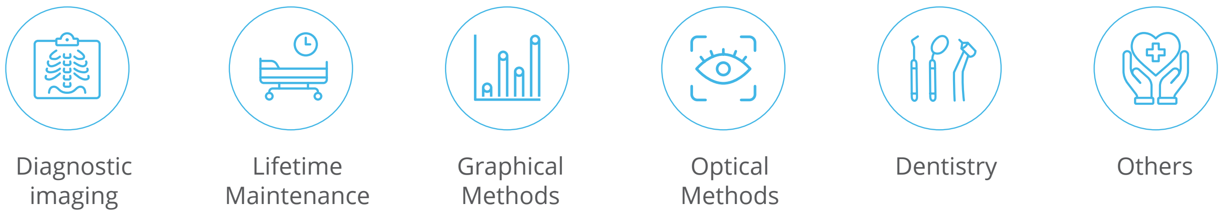
To analyze the relationship with health costs, and later with social well-being, it is necessary to adopt a way of measuring the evolution of technology in health. Usually used as an observation of control[9], a Medical Technology is present in the sectoral literature that evaluates the determinants of healthcare costs and well-being. Some works create specific variables, such as Willemé and Dumont.

9. Often measured by observing the time trend (residual approach) or some aggregate proxy of Technology (R&D expenditure, patents). All the researched works can be found in the annex I.

(2014)[10], which use the number of new drugs and medical equipment approved, and You and Okunade (2016)[11], who propose a technology index given by the sum of some types of equipment[12] divided by the number of inhabitants.

The definition of the technology variable used in the present study is close to the strategy adopted in the study by You and Okunade (2016)[11], based on the construction of a Medical Technology Index for Brazil consisting of the sum of the number of medical equipment used in public and private health divided by the population, using data provided by DATASUS. The index includes major medical equipment: machines for diagnosis (mammography machines, electrocardiographs, endoscopes, etc.), for life maintenance and hospitalization (respirators, incubators, defibrillators, etc.), and for treatment procedures (phototherapy equipment, hemodialysis equipment, etc.). The types of equipment are shown in Figure 6[13].

Figure 6: Types of medical equipment included in the Medical Technology[14]



Elaborated by: Thiago Caliari and LCA Consultants.

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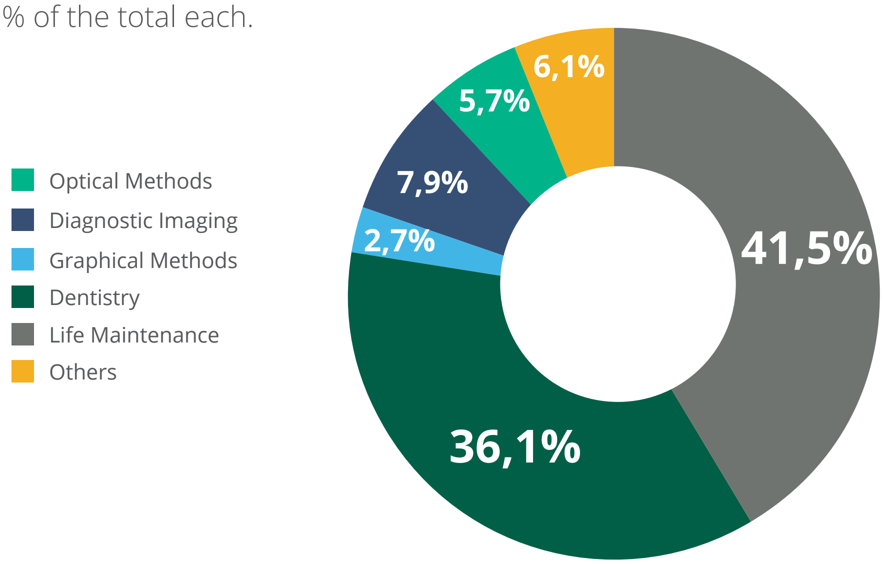
As shown in Graph 5, life maintenance and dental equipment are the most numerous[15], together representing more than 77% of the total, while the other types represent between 3% and 8% of the total each.

Graphic 5: Composition of Medical equipment in Brazil, by number of equipment, 2019

Note: Not considering audiology and infra equipment. Source: DATASUS. Elaborated by: Thiago Caliari and LCA Consultants.



10. Willemé, P; Dumont, M. Machines that go 'ping': medical technology and health expenditures in oecd countries. Health Economics, v. 24, n. 8, p. 1027-1041. 2014.

11. Okunade, A; You, X. Income and Technology as Drivers of Australian Healthcare Expenditures.Health Economics. v. 26, n. 7, p. 853-862. 2016.

12. Considering computed tomography, magnetic resonance imaging, lithotripters and radiotherapy equipment.

13. The complete list of equipment considered in the Medical Technology Index and the detailed methodology for its preparation are presented in Annex II of the Statistical Approach.

14. Audiology equipment, which is only available for data from 2011 onwards, and infrastructure equipment, which is related to the basic hospital structure, are not included.

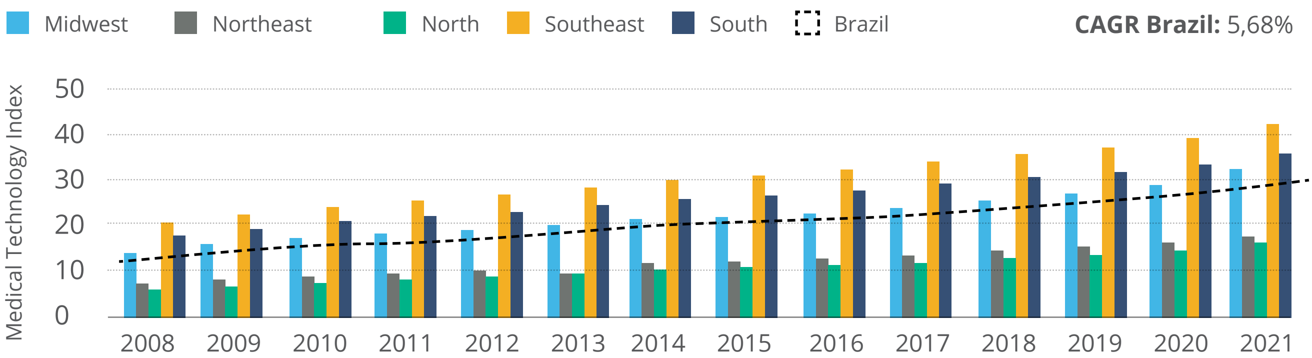
15. Considering the types of equipment covered by the Medical Technology Index, in 2019, Brazil had 1.75 million pieces of equipment.

The different types of equipment were aggregated into a single index using the PCA (Principal Component Analysis) method. This method aims to reduce a set of variables that are correlated with each other into an optimized component that represents all of them and preserves the variability of the initial data sample. The technical advantage of this method is the reduction of the size of the data with minimal loss of information, solving the problem of multicollinearity16 that would be caused by the strong correlation between the original variables17. Moreover, equipment very representative in number, such as dental and life-sustaining equipment, do not bias the results.

Subsequently, the values were standardized, using the maximum and minimum values of the created variable, so that the index varies between 0 and 100.

Between 2008 and 2019, there was a linear and uniform growth of the index in the five macro-regions of Brazil. Considering the national average, the index grew 117% (CAGR of 5.68%), as shown in Chart 6.

Chart 6: Evolution of the Medical Technology Index, between 0 and 100, by regions, 2008 to 2021.



NOTE: the index after standardization varies between 0 and 100 for each microregion, and they represent the minimum and maximum values respectively of the variable obtained by the PCA method. Source: DATASUS. Elaboration: Thiago Caliari and LCA Consultants.

16. Collinearity occurs when two or more (multicollinearity) variables have a high correlation. This causes estimators to often become statistically insignificant because it is not possible to separate the effects of the correlated variables on the dependent variable.

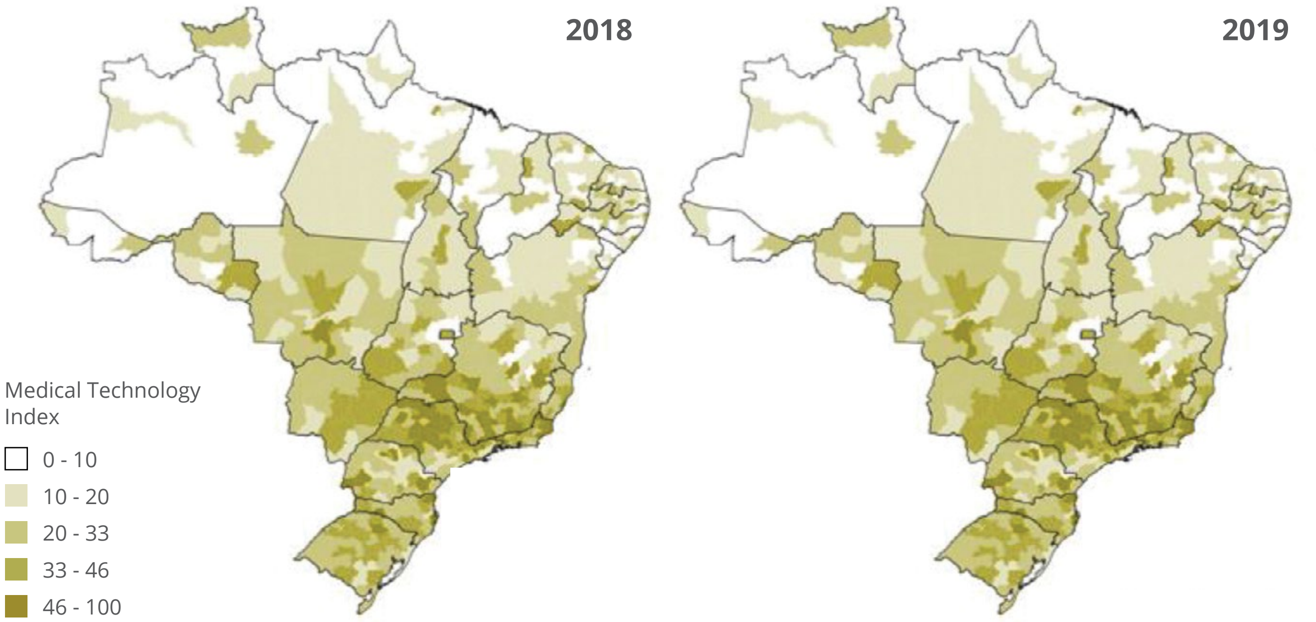
17. The mean correlation between the variables was 0.67, and in none of the cases was it lower than *0.58.

18. CAGR values segmented by region: (i) Midwest: 6.11%; (ii) Northeast: 6.57%; (iii) North: 7.48%; (iv) Southeast: 5.21%; (v) South: 5.17%

As shown in Figure 7, some micro-regions stand out for presenting higher Medical Technology Index values, in line with the distribution of public Health expenditure *per capita*. The South, Southeast and Midwest regions concentrate the micro-regions with a higher Medical Technology Index compared to the North and Northeast regions.

In the period analyzed, there was an increase in the Medical Technology Index in most of the country's micro-regions. Despite this, as also shown in the previous graph, regional inequalities were maintained, indicating intrinsic characteristics in the care provided by health services in each location.

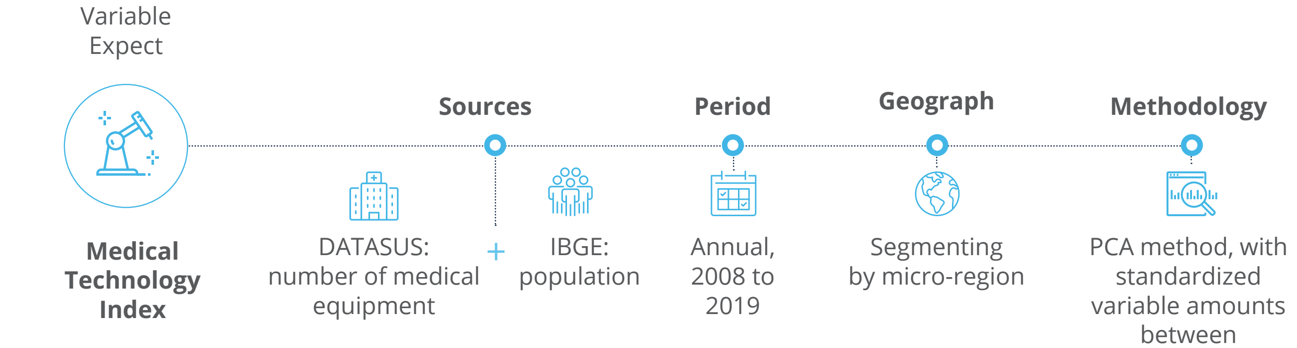
Figure 7: Medical Technology Index by microregion, between 0 and 100, 2008 and 2019



NOTE: the index after standardization varies between 0 and 100 for each microregion, and they represent the minimum and maximum values respectively of the variable obtained by the PCA method. Source: DATASUS, and IBGE. Elaborated by: Thiago Caliari and LCA Consultants.

Figure 8 consolidates the main information of the variable used to represent medical technology.

Figure 8: Summary of the medical technology variable



Elaborated by: Thiago Caliari and LCA Consultores.

19. Agha, L. The effects of health information technology on the costs and quality of medical care. Journal of Health Economics, v. 34, p. 19-30. mar, 2014.

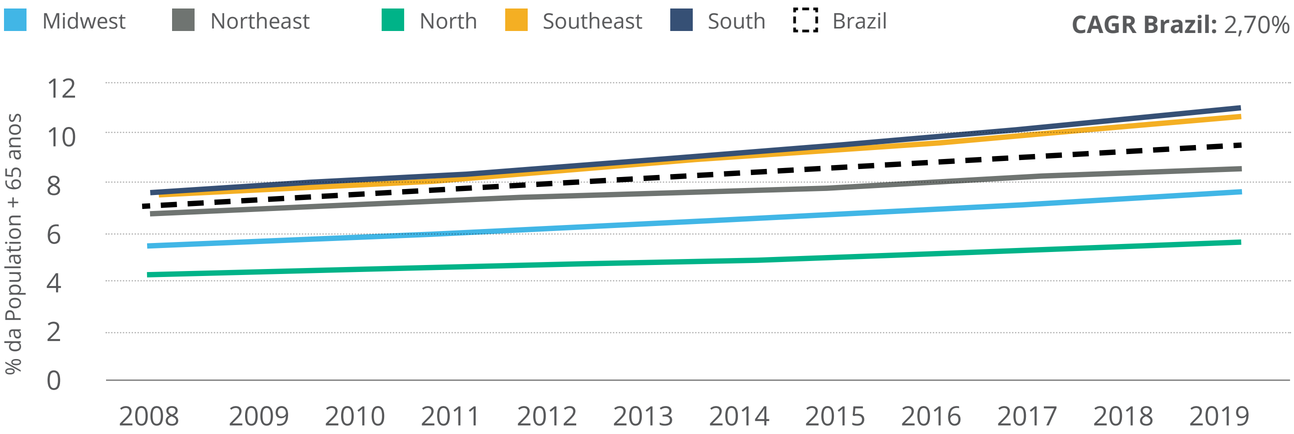
20. CAGR values segmented by macro-region: (i) Centro-Oeste: 3,00%; (ii) Northeast: 2,06%; (iii) North: 2,34%; (iv) Southeast: 2,91%; (v) South: 3,25%.

Representative of well-beingr

Three metrics are suggested to estimate the relationship between medical technology and social well-being: life expectancy, infant mortality, and GDP per capita. The use of these indicators is supported by the literature consulted, since most of the articles used income characteristics (GDP *per capita* and GDP per worker) as a dependent variable, while some authors, such as Agha (2014)[19], also use mortality indicators as a way to measure well-being.

The life expectancy was calculated based on the Percentage of +65 years old Population. As shown in Graph 7, between 2008 and 2019 there was a population aging trend in all macro regions of the country. During this period, the percentage of the Brazilian population over 65 years of age grew by 38% (CAGR of 2.70%).

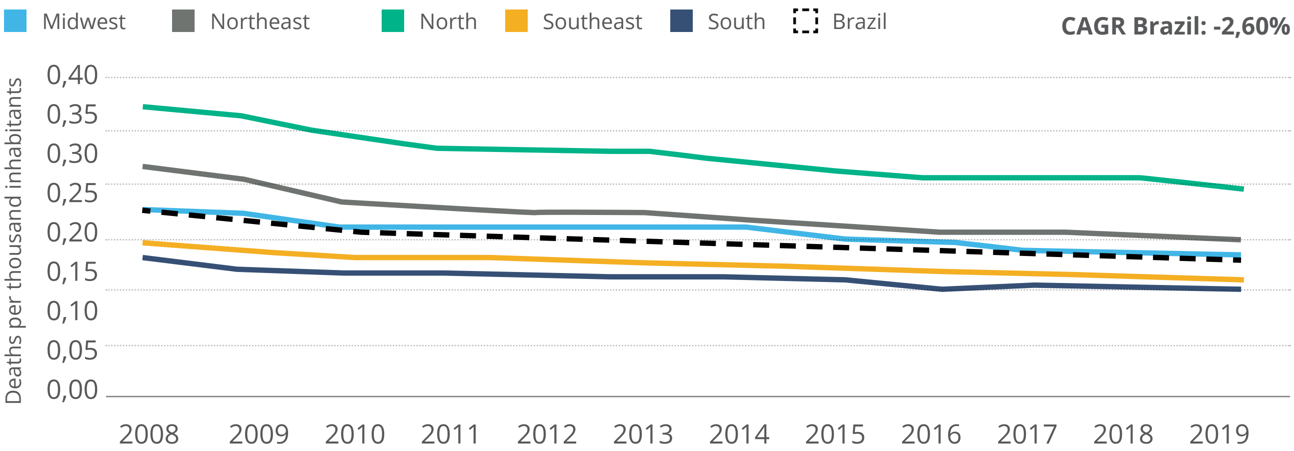
Graph 7: Percentage of the population over 65 years of age by macro-region, 2008 to 2019[20]



Source: DATASUS. Elaborated by: Thiago Caliari and LCA Consultants.

Infant mortality was measured by the number of deaths per hundred thousand inhabitants among the population aged 0 to 9 years. Between 2008 and 2019, the indicator fell by 27% in Brazil (CAGR of -2.60%), which also denotes gains in terms of well-being.

Graph 8: Death of pop. 0-9 years old per 1000 hab., 2008 to 2019[21]



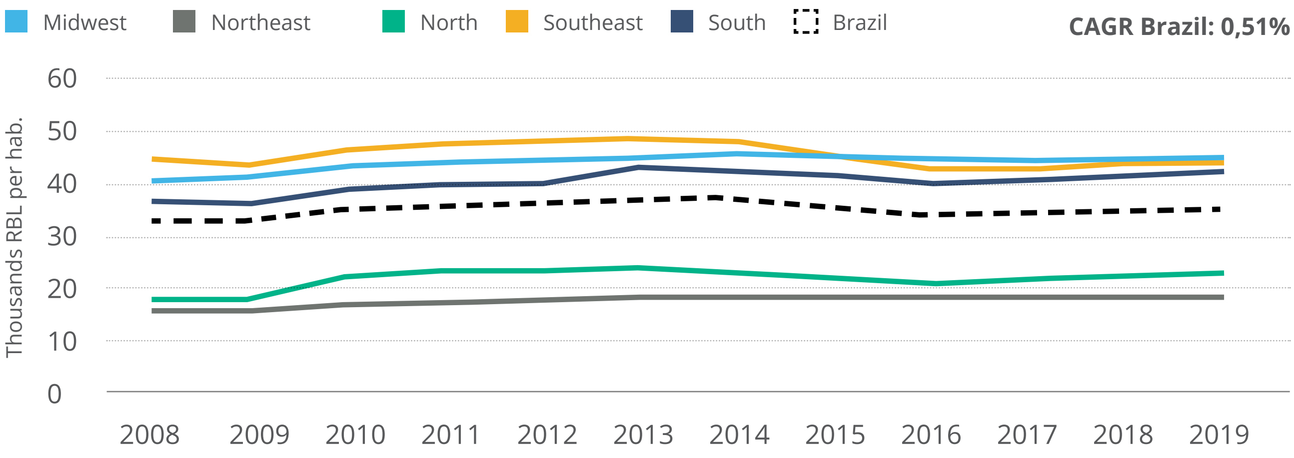
Source: DATASUS. Elaborated by: Thiago Caliari and LCA Consultants.

21. CAGR values segmented by region: (i) Midwest: -2.31%; (ii) Northeast: -3.16%; (iii) North: -2.80%; (iv) Southeast: -2.26%; (v) -2.13%.

<<

Finally, the GDP *per capita* real[22] Brazilian growth of 6.3% in the period (CAGR of 0,51%).

Graph 9: Real GDP per capita by macro-region (BRL thousand in 2019), 2008 to 2019[23]



Source: IPEADATA. Elaborated by: Thiago Caliari and LCA Consultants

The analysis by micro-region, presented in Figure 9, indicates the existence of strong regional inequalities for all indicators: the micro-regions of the North and Northeast rate than the micro-regions located in the South, Southeast and Midwest.

22. Deflated by the IPCA.
23. CAGR values segmented by region: (i) Midwest: 0.76%; (ii) Northeast: 1.38%; (iii) North: 2.09%; (iv) Southeast: -0.11%; (v) South: 1.15%.

Figure 9: Microregional distribution of social welfare variables, 2019

Life expectancy (% of population over 65 years of age)

- 2 - 5
- 5 - 8
- 8 - 11
- 11 - 14
- 14 - 19

Infant mortality (Deaths of the population aged 0-9 years per 1000 inhabitants)

- 0 - 0,18
- 0,18 - 0,27
- 0,27 - 0,38
- 0,38 - 0,58
- 0,58 - 0,85

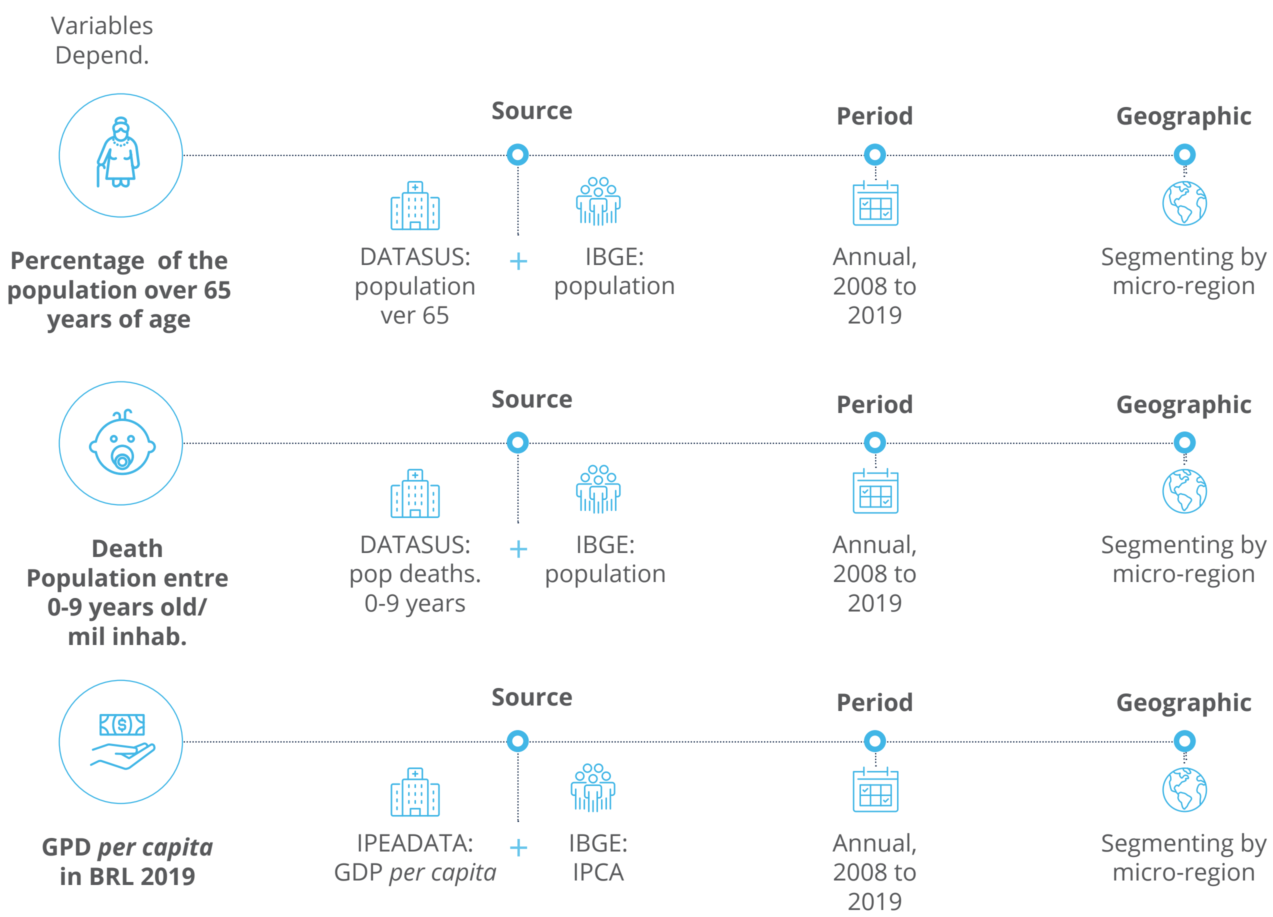
GPD per capita (BRL updated for 2019)

- 4.000 - 19.158
- 19.158 - 33.596
- 33.596 - 52.691
- 52.691 - 109.245
- 109.245 - 183.000

Source: DATASUS, IBGE, IPEADATA. Elaborated by: Thiago Caliari and LCA Consultants.

The variables used as a proxy for well-being are summarized in Figure 10 .

Figure 10: Summary of well-being variables



Elaborated by: Thiago Caliari and LCA Consultants.

ECONOMETRIC ANALYSIS OF THE RELATIONSHIP BETWEEN MEDICAL TECHNOLOGY AND HEALTHCARE COSTS

The literature on the subject uses different statistical formats to measure the determinants of health costs. However, most of the articles consulted have a common structure of equations:

$$\textit{Health Cost} = f\ (\textit{Resources, Regional Specificities}) \quad (1)$$

The dependent variable – health cost – is usually described as a function of the resources used in health (called resource variables, typically capital and labor) and the specific characteristics of each region (called control variables).

The model developed in this study to capture the relationship between medical technology and health costs uses the real public expenditure on health per capita as a dependent variable (or explained variable), the Medical Technology Index and the number of physicians per capita as resource variables relating, respectively, to the factors capital and labor employed in health. In addition, it includes demographic variables (population and percentage of the population over 65 years of age), income (GDP per capita) and private health (number of beneficiaries of medical care per thousand inhabitants) as regional control variables[24]. Also included in the model is a variable control of a vector of unobserved characteristics of each federative region, in addition to the idiosyncratic error term.

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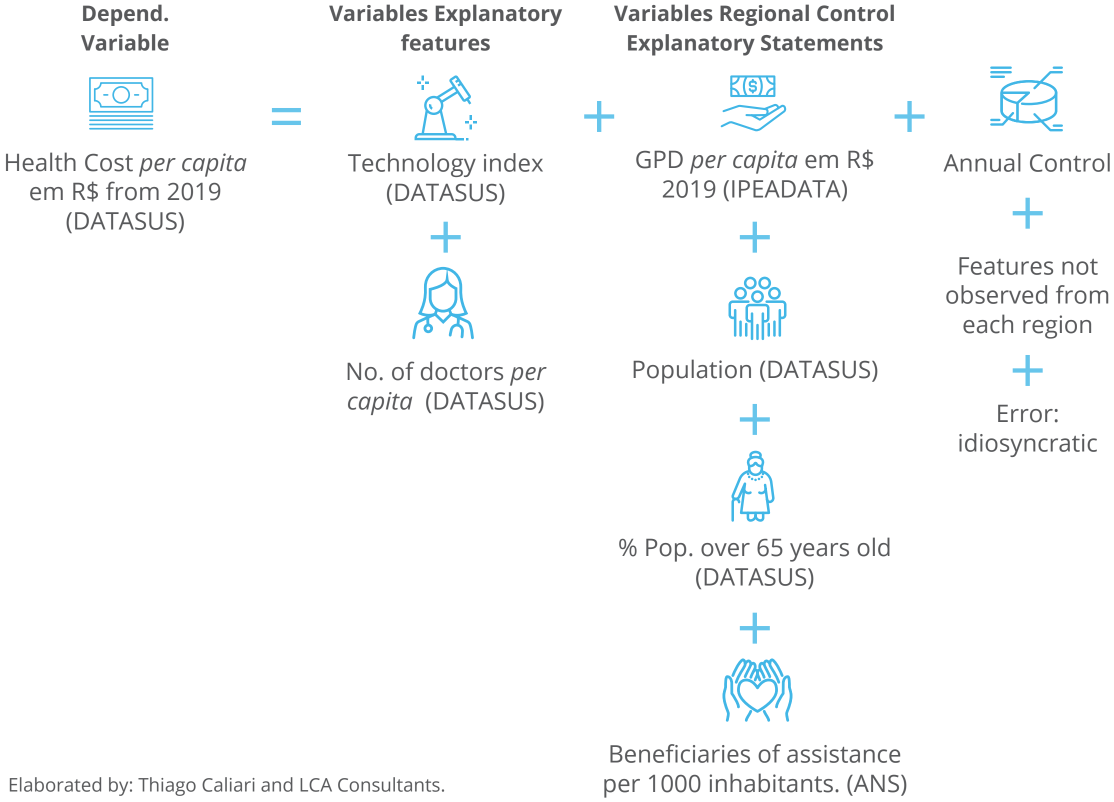
24. The full description of the variables of the econometric models is presented in Annex III.

Figure 11: Model for analyzing the relationship between medical technology and health care cost



Elaborated by: Thiago Caliari and LCA Consultants.

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Regressions use panel data, i.e., they follow the evolution of the same sample (cross-sectional dimension) over time (temporal dimension). As a result, the number of observations inserted in the model is increased, which increases its informational capacity and reduces the risk of problems with collinearity, which could get difficult

for the estimation of the parameters of the equation (Wooldridge, 2002)[27]. The micro-regions of the IBGE represent the cross-sectional dimension of the data, so that each of the 558 micro-regions of Brazil constitutes an observation of the sample.

This geographic segmentation, in addition to increasing the number of observations in the model, is a very common expedient in analyses related to the SUS, since this division of the IBGE is typically used as a proxy for the health regions in which the Brazilian Unified Health System is based.

Due to the availability of data, the time frame analyzed is the period 2008-2019. DATASUS makes outpatient and hospital expenditures available only from 2008 onwards, while GDP information at the micro-region level is only available until 2019. All variables were transformed into natural logarithms according to the standard specification of empirical models observed in the specialized literature (usually called log-log models[25]). In this type of model, the coefficients (β's) can be interpreted as elasticities, i.e., in which a variation of 1% in the explanatory variable i implies a variation of βi% in the dependent variable. Model specifications are summarized in Table 1.

Table 2: Summary of Econometric Model Specifications

Model Specifications	
Panel Method GLS[26]	Regressions performed with panel data, combining data from different locations in different observation periods. Generalized least squares method used (GLS)
Regional Areas	550 Microregions in Brazil (IBGE)[28]
Periodicity	Annual, between 2008 and 2019
Log-log	All Variables are transformed into a natural logarithm, and can be interpreted as elasticities
Progressive Models	Explanatory variables are progressively included to assess the robustness of the specification and explanatory variables.

The results of the regressions on medical technology and health care cost are described in Table 2. The per capita GPD (Ln_GPD BW) had a significant impact[29] on the cost of health care only in the first regression – which did not even include the variable of medical technology. The Population of the micro-region (Ln_Population), on the other hand, had a positive and highly significant impact on all models. These results are consistent with the

25. Models with the log-linear specification are presented in Annex IV.

26. In order to establish the best specification for the models to be estimated, a series of tests were performed. The Hausman specification test led to the rejection of the null hypothesis, which indicates that the assumption that the unobserved characteristics of each region are fixed over time is the most appropriate. In addition, tests for the presence of autocorrelation (Wooldridge, 2002) and heteroscedasticity (modified Wald test) did not allow the rejection of the null hypothesis, which led to the adoption of the generalized least squares (GLS) method as the estimator of all models. Finally, in order to test the robustness of the selected variables, the model was estimated five times, with the successive increment of control variables. The latest model, with all the Variables, it was what provided the best fit.

27. WOOLDRIDGE, J. M. Econometric Analysis of Cross Section and Panel Data. Cambridge: MIT Press, 2002.

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literature and with the dynamics of SUS financing, which privileges population aspects over economic factors.

The number of health care beneficiaries ((*Ln_Assist. med*), as indicated in the bibliography, it had a positive and highly significant effect, as well as the number of doctors per capita (*Ln_Doctors*) – which was also expected. On the other hand, the Percentage of the population over 65 years old ($Ln_{Pop}65+$) did not have a statistically significant impact on health costs, a result that, although counterintuitive, is supported by the literature (Chun-Yu et al., 2014)[30].

Table 2: ***Log-log*** **models in GLS panel of the dependent variable of health expenditure**

Variáveis	(1)	(2)	(3)	(4)	(5)
Ln_GPD PC	0.374***	0.0756	0.0311	0.0191	-0.149
Ln_population	0.556***	0.457***	0.403***	0.401***	0.356***
Ln_Technology		**0.714*** **	**0.579*** **	**0.586*** **	**0.494*** **
Ln_Doctors			0.259***	0.263***	0.121*
Ln_pop +65				-0.0425	0.0153
Ln_med. Assis.					0.272***
Constant	-6.962***	-4.787***	-3.290***	-3.268***	-0.0453
Observations	6,179	6,178	6,178	6,178	6,178
Microregions	550	550	550	550	550
Region Control	SIM	SIM	SIM	SIM	SIM
Year Control	SIM	SIM	SIM	SIM	SIM
Wald (chi2)	1107.23	1399.35	1368.06	1366.83	1416.21
Prob > chi2	0.0000	0.0000	0.0000	0.0000	0.0000

Notes: *** p<0.01, ** p<0.05, * p<0.10. Elaborated by: Thiago Caliari and LCA Consultants.

Finally, and the central point of the analysis, as highlighted in Figure 12, Medical Technology (*Ln_Technology*) presented positive and statistically significant coefficients, consistent with expectations. In the best-fit model, which includes all Variables (model 5), its impact was 0.494. Effects of this magnitude indicate that the variable of interest has an inelastic result for the variable dependent, i.e., Increases of a certain magnitude in the technological index (1%, for example) cause less-than-proportional increases in health expenditure (from 0,494%).

This result is in line with the literature, since all studies indicate that there is a general net impact of increased health costs with the increase in medical technology. It is also important in that it shows that an increase in medical technology increases health care costs less than proportionately.

28. Brazil has a total of 558 Microregions, but some of the Variables (explanatory or dependent) were not present in any year of the analysis in 8 Microregions.

29. In econometrics, an explanatory variable is said to be significant (or significant) if it is possible to reject the hypothesis that its impact is statistically equal to zero (called the null hypothesis). This is the same as saying that this variable has a causal effect on the explained variable. The null hypothesis is confirmed or rejected by performing statistical tests on the regression results.

30. Chun-Yu H.; et. al. Unbalanced growth and health care expenditure.
Economics of transition and institutional change, v. 22, n. 4, p. 739-758. Out, 2014.

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Figure 12: Impact of medical technology on health expenditure

Elaborated by: Thiago Caliari and LCA Consultants.

Based on the estimated results, it is possible to calculate the impact of medical technology on healthcare costs in monetary terms.

As indicated in Equation 2, the Percentage impact of medical technology on health expenditure, in a given year, is equivalent to the estimated coefficient (0.494) multiplied by the Percentage variation of the index in that period. Based on this result, the impact in R$ is obtained by multiplying the percentage impact by the annual health expenditure of the previous period, adding the SUS expenditures at the municipal, state and federal levels (SHA account)[31] and private expenditures obtained in the ANS (equation 4).

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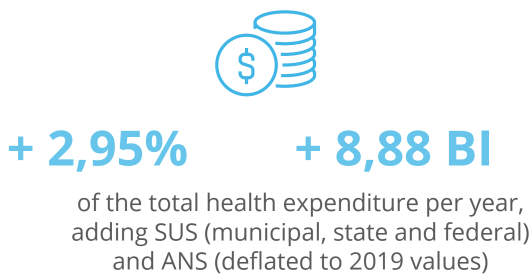
*Impact % = Ln_Technology (0,494) * Var. % Annual Index* (2)

*Impact R$ = Impact % * annual expenditure (t-1) (SUS est/mum + SUS fed + ANS)* (3)

Figure 13 shows the average annual impact, Percentage and in R$, of medical technology on health expenditure in the analysis period. Medical technology produced, on average, an increase of 2.95% per year in health expenditures, which is equivalent, in real terms, to R$ 8.88 billion in additional expenditures every year. It is worth noting that these values result from the strong expansion of the Medical Technology Index, which, among 2008 and 2019, raised by 117%. The following section will address the impact of this technological increment on well-being.

Figure 13: Monetary impact of medical technology on total health costs.

Elaborated by: Thiago Caliari and LCA Consultants.



31. Based in the values of hospital and outpatient care available at: (i) Ministry of Health (BR). Health accounts from the perspective of international accounting: SHA account for Brazil, 2015 to 2019. 2022. Available at: https://www.ipea.gov.br/por tal/images/stories/ PDFs/livros/livros/220202_ livro_contas_de_saude.pdf May 2nd 2022 and Ministry of Health (BR). SUS accounts from the perspective of international accounting. Brazil, 2010-2014. 2018. Available at: https://bvsms.saude.gov.br/bvs/publicacoes/contas_SUS_perspectiva_contabilidade_ internacional_2010_2014.pdf.

ECONOMETRIC ANALYSIS OF THE RELATIONSHIP BETWEEN MEDICAL TECHNOLOGY AND SOCIAL WELFARE

As in the estimation of the impact of Technology on the costs of social welfare, although the literature uses different statistical formats to measure the determinants of social welfare, it is possible to verify a common structure of equations in most of the articles consulted:

Well-being = ƒ (Resources, Regional specificities) (4)

Analogous to the case of the impact on costs, the dependent variable – well-being – is usually described as a function of the resources used in health (called resource variables, typically capital and labor) and the specific characteristics of each region (called control variables). Three models of well-being were constructed under this structure, using different dependent variables, namely: life expectancy, infant mortality, and GPD *per capita*.

It should be noted that, in all three cases, the specification used is exactly the same of the model in the previous section, i.e., *log-log* models, estimated by the generalized least squares method (GLS), and using panel data from 550 Microregions in Brazil between the years 2008 and 2019.

In the life expectancy model, the Percentage of the Population over 65 years represents the dependent variable. The Medical Technology Index (*Ln_Technology*) and the number of doctors per capita (*Ln_Doctors*) correspond, respectively, to the resource variables related to the capital and labor factors employed in health. The GPD per capita (*Ln GPD* per capita *real*), the Population of the micro-region (*Ln_Population*) and the number of Health care beneficiaries per thousand inhabitants (*Ln_Health care*) are the regional control variables. A common procedure in panel data analysis, the model also includes a temporal control variable, a regional control variable, in addition to the idiosyncratic error term.

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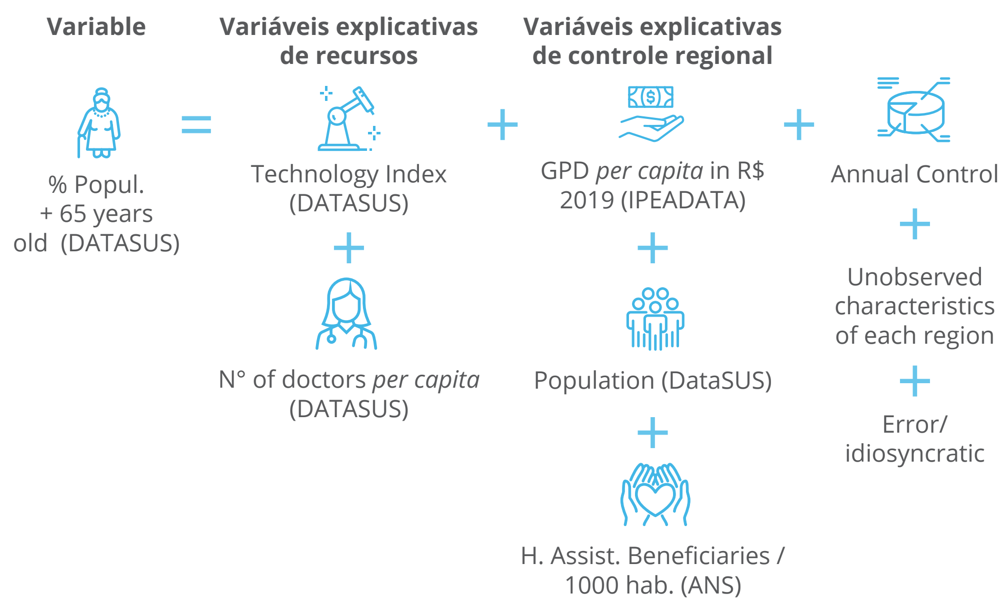
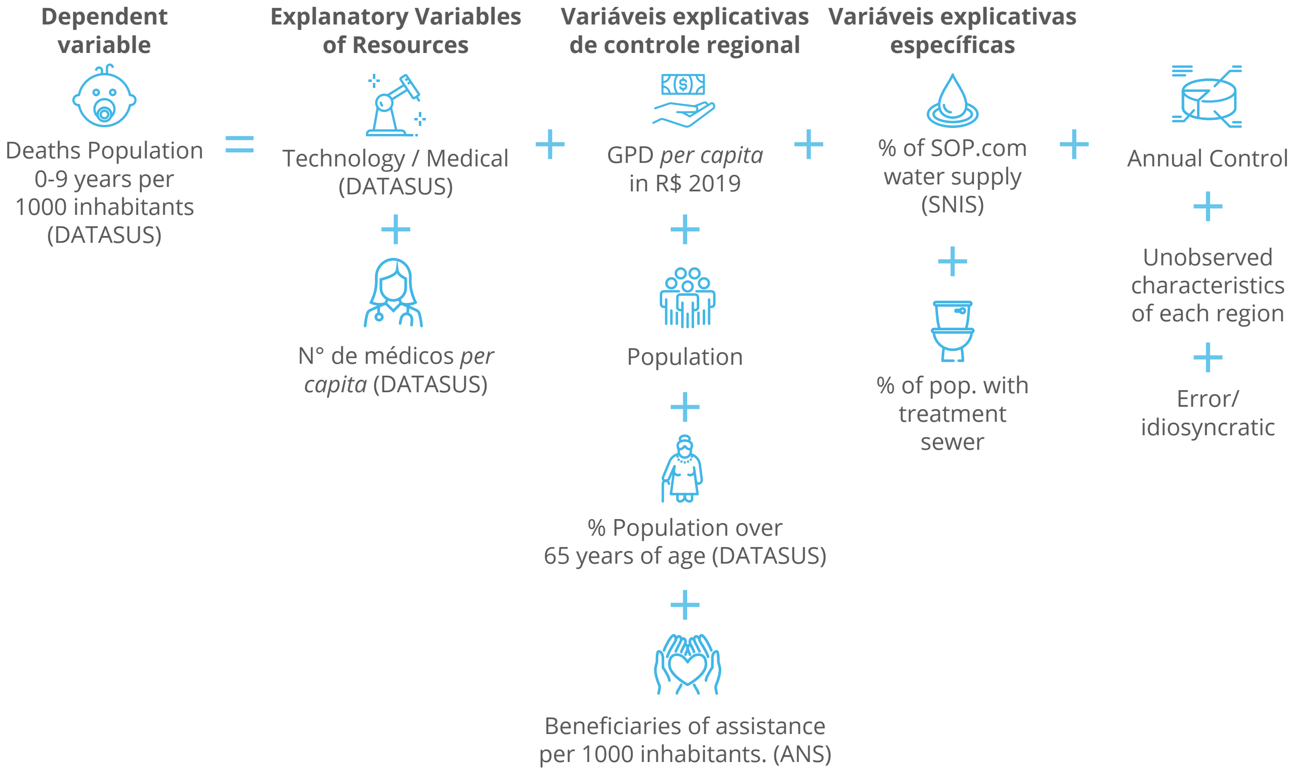
Figure 14: Well-being model with Life expectancy as a variable dependent



Elaborated by: Thiago Caliari and LCA Consultants.

The infant mortality model uses all the explanatory, resource, and regional control variables provided in the life expectancy model. It also includes the percentage of the population over 65 years of age (*Ln Pop 65+*) as a regional control variable, in addition to the percentage of the population with water supply (*Ln_Water*) and sewage (*Ln_Sewage*) as specific explanatory variables. This adjustment is necessary because the economic literature suggests that sanitation has a highly relevant impact on infant mortality, so that the non-inclusion of these controls could generate biased and inefficient estimators.

Figure 15: Well-being model with infant mortality as the dependent variable



Elaborated by: Thiago Caliari and LCA Consultants.

The per capita GPD model differs from the others only in the specific explanatory variables, which are also suggested by the economic literature and were included in the model with the objective of bringing greater robustness to the estimates obtained. In this sense, it adds to the model which includes the number of companies per capita (*Ln physical capital*), the number of employees per capita (Ln human capital), the number of employees with degrees per capita (*Ln_Graduated*) and the length of time they remain in the job (*Ln_Experience*).

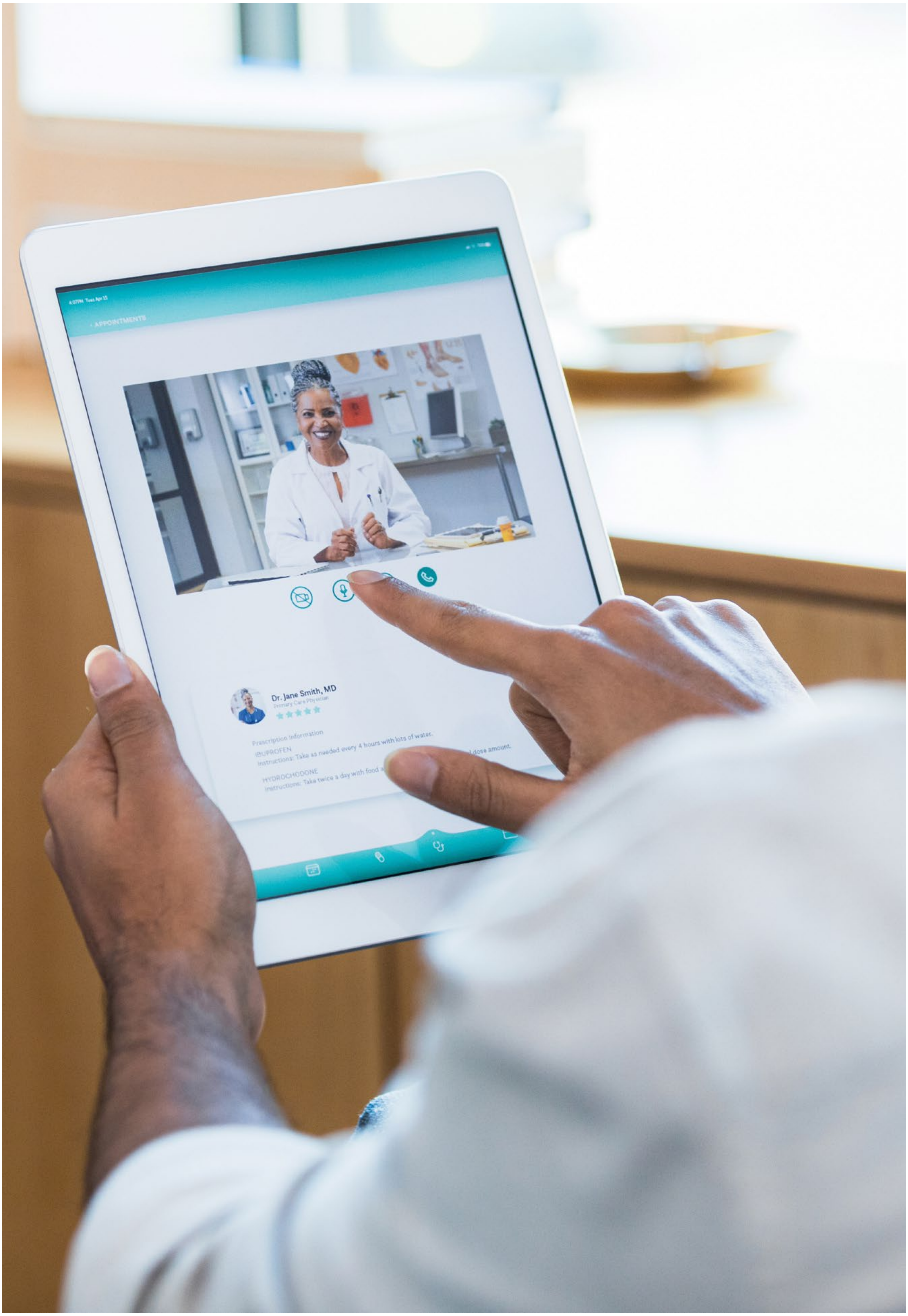

Dr. Jane Smith, MD

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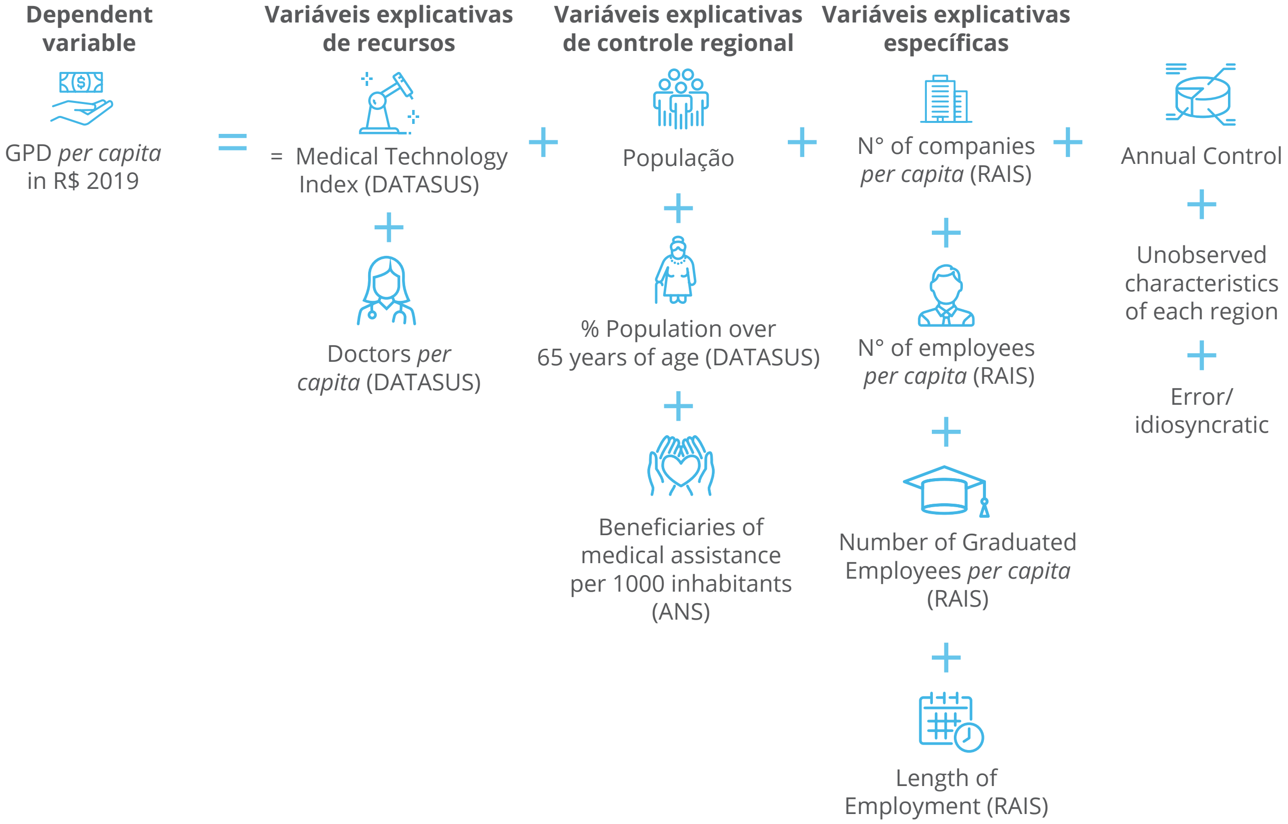
Figure 16: Well-being model with per capita GPD as the dependent variable



Elaborated by: Thiago Caliari and LCA Consultants.

Table 3 shows the results of the three welfare models, considering the complete specifications[32]. The results obtained for almost all variables were consistent with expectations[33].

32. The models using specifications with progressive inclusion of explanatory variables and the log-linear models, performed as robustness tests, are presented in Annex IV of the work.

33. In the infant mortality model, however, the controls of water and sewage coverage appear to have a positive and significant impact on the dependent variable, which, in addition to being counterintuitive, confronts the evidence found in the literature. This result can be explained by the fact that there is no sanitation information for many Brazilian municipalities, which imposed relevant limitations on the treatment of these databases. Even so, the log-linear models, provided in the appendix, show that this result did not impact the robustness of the estimates associated with the other variables.

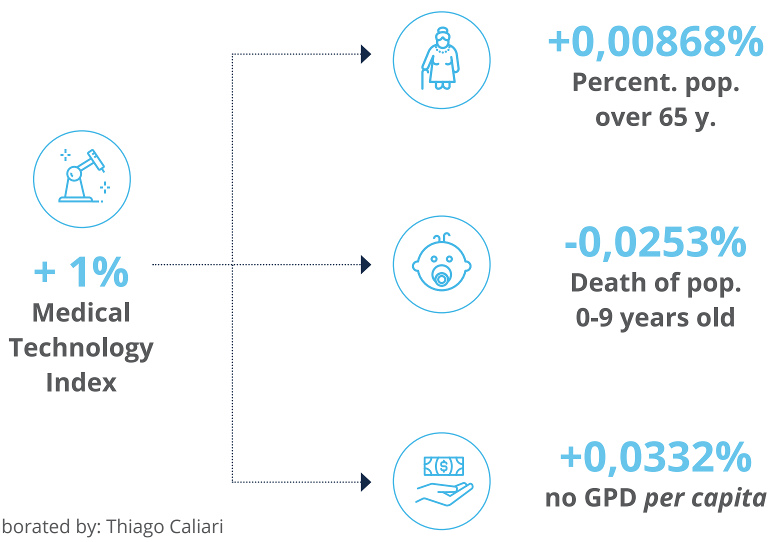
Table 3: *Log-log* models in GLS panel of Social Welfare Variables

Variables	Life expectancy	Infant mortality	GPD *per capita*
Ln_GPD *per capita* real	-0.0150***	-0.0730***	
Ln_population	-0.0447***	0.0291***	
Ln_sewage		0.0303***	
Ln_water		0.0399**	
Ln_Technology	**0.00868*** **	**-0.0253** **	**0.0332*** **
Ln_Doctors	0.00584***	-0.0197	0.0532***
Ln_pop +65		-0.507***	-0.327***
Ln_Health care	-0.00187	-0.0352***	0.136***
Ln_Physical Capital (companies)			0.0493***
Ln_Human capital (employees)			0.314***
Ln_graduates			-0.00980
Ln_experience (Length of Employm.)			-0.0711***
Constant	-1.819***	-2.548***	10.70***
Observations	6,695	6,469	6,681
Microregions	558	540	557
Region Control	SIM	SIM	SIM
Year Control	SIM	SIM	SIM
Wald (chi2)	66526.31	6938.75	42491.11
Prob > chi2	0.0000	0.0000	0.0000

Notes: *** p<0.01, ** p<0.05, * p<0.10. Own elaboration from various sources.

As shown in Figure 17, the results of the impact of Technology on well-being are consistent with expectations; the increased use of medical equipment has a positive and significant impact on the three Variables of well-being. A 1% increase in the Medical Technology Index increases the Percentage of the Population over 65 by 0.00868%; reduces infant mortality by 0.0253%; and increases GPD *per capita* by 0.0332%.

Figure 17: Impact of Medical Technology on Social Welfare Variables



Elaborated by: Thiago Caliari and LCA Consultants.

Estimated results of GPD per capita allow us to calculate the impact in monetary terms of medical technology on well-being.

The impact of the Percentage of medical technology on the GPD *per capita*, in a given year, is equivalent to the estimated coefficient (0.0332) multiplied by the Percentage change of the GPD per capita in that period. With this result, the impact in R$ is obtained by multiplying the Percentage impact by the actual total GPD of the previous period (equation 6).

$$\textit{Impact \%} = Ln_{\textit{actual GPD per capita}} (0{,}0332) * \textit{Var. \% annual actual GPD pc} \quad (5)$$

$$\textit{R\$ Impact} = \textit{\% Impact} * \textit{Total GPD real}_{t-1} \quad (6)$$

The average annual impact of medical technology on per capita GPD was an increase of 0.2% in real GPD, which is equivalent in real terms to R$ 13.84 billion more income for the country, on average, each year, as shown in Figure 18.

Figure 18: Monetary impact of medical technology on or GPD *per capita*

Elaborated by: Thiago Caliari and LCA Consultants.

+0,2% **R$ 13,84 BILLION**

of GPD per year
(deflated to 2019 values)

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Further considerations on the impact of Technology on social well-being

In addition to monetary comparisons, qualitative observations and impact on long-term economic development should be of interest to civil society.

One of these impacts is in relation to the life expectancy of the population: as can be demonstrated, medical technology has a positive relationship with the Percentage of Population over 65 years. This is an important aspect that is consistent with the specialized literature. Wong et al. (2012)[34] conducted a specific study on the subject, demonstrating that the probability of using health care increases over time for all ages, with a special impact on the elderly. In general, they state that older adults can benefit more from technology through increased quality of life and, emphatically, point out that increasing the likelihood of older adults benefiting from technology is as important as increasing the quality of technology.

In addition, by having a positive relationship with life expectancy, medical technology can increase the long-term productivity of the economy. Literature empírica econômica aponta a relevância do aumento da expectativa de vida no aumento da produtividade nos últimos séculos nos EUA e Europa (COSTA; STECKEL, 1995[34]; FOGEL, 1990[36], 1994[37]; STECKEL, 2001[38]). Barro and Sala-i-Martin (1995)[39] identified that the increase in life expectancy by 13 years increases the growth rate of GPD per capita by 1.4% per year. Bloom and

Canning (2000)[40] cite three possible mechanisms of impact of increased life expectancy on productivity:

1. Individuals with longer life expectancies may choose to invest more in education and receive higher returns on their investments;
2. With longer life expectancy, individuals may be motivated to save more for retirement, resulting in greater accumulation of physical capital;
3. A healthier workforce can be more productive because workers have more physical and mental energy and reduce absences from work.

The reduction in infant mortality also tends to have a positive impact on the future flow of GPD and, therefore, the possibilities for economic development. The literature usually points to periods of transition in this process, associated with the different income level of the countries. In countries with a lower level of development, the 'demographic explosion' (also called 'demographic gift') caused by declining mortality tends to increase the participation of the population in the economy: it increases future expenditure on goods and services, the labor force, future household savings, taxes, among other important components of GPD (KIRIGIA et al., 2015[41]; WHO, 2009[42]). Bloom and Williamson (1998)[43] estimate that demographic gift impacted between 1.4% and 1.9% the growth of GPD per capita in East Asia between 1965 and 1990. Kirigia et al. (2015)[39] seek to measure the future loss in GPD in African countries due to infant mortality in the region in 2013, reaching the discounted value of USD 150 billion (in purchasing power parity).

Over time, as society acquires a higher level of development, social adaptation to the lower mortality rate leads to a reduction in fertility, as it reduces the need for more children to guarantee future economic capacity, causing society to go through a period of demographic transition (BLOOM; WILLIAMSON, 1998)[41]. This lower fecundity associated with new social and consumption patterns, encourages parents to increase investment in the formation of human capital and in the transmission of skills and knowledge to each child (WHO, 2009, p.36)[40]. This tends to result in better quality of work (BLOOM; CANNING, 2000)[38], leading to a state of sustainable

34. Wong, A.; et. al. Medical innovation and age-specific trends in health care utilization: Findings and implications. Social Science & Medicine, v. 74, p. 263-272. 2012.

35. Costa, D.; Steckel, R. Long term trends in health, welfare, and economic growth in the United States. NBER Historical Paper, n. 76. Nov, 1995.

36. Fogel, R. The conquest of high mortality and hunger in Europe and America: timing and mechanics. NBER Historical Paper, n. 16. Set, 1990.

37. Fogel, R. Economic Growth, Population Theory, and Physiology: The Bearing of Long-Term Processes on the Making of Economic Policy. The American Economic Review, v. 84, n. 3, p. 369-395. Jun, 1994.

38. Steckel, R. Health Indicators of the Standard of Living. Indicators, v. 1, n. 1, p. 139-159. 2002.

39. Bloom, D.; Canning, D. The health and wealth of nations. Science's Compass, v. 287, p. 1207- 1209. Fev, 2000.

40. BARRO, R.; SALA-I-MARTIN, X. Economic Growth. New York, NY, USA: McGrawHill, Inc., 1995.

41. Kirigia, J.; et. al. Health Indicators of the Standard of Living. BMC Public Health, v. 15, p. 1103. 2015.

42. Health Indicators of the Standard of Living. Department of Health Systems Financing Health Systems and Services. World Health Organization. 2009.

43. Bloom, D.; Williamson, J. The World Bank Economic Review, v. 12, n. 3, p. 419-455. Set, 1998.

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development with a higher standard of income for the population (BLOOM; WILLIAMSON, 1998)[41].

Still, it is possible to observe a net positive impact in monetary terms of health technology. Considering the measured impact on the total sum of outpatient and hospital expenditures (an increase of R$ 8.88 billion considering the public system – municipal, state and federal – and private – Health care) and, at the same time, the impact measured on the GPD per capita, a positive result of benefits is obtained, which add up to approximately R$ 4.96 billion per year between 2009 and 2019. totaling R$ 54 billion (in 2019 values).

The statistical measurement strategies developed at this stage of the study corroborate the results of the academic and professional literature researched and presented in the previous sections: medical technology has an effect on the increase in health care costs, but, on the other hand, it also has effects on the increase in health cost of the Population's well-being, measured through different indicators. The magnitude of these impacts is also close to that found in the literature, although this comparison should be made sparingly given the different techniques used, the indicators considered, the geographic area and the period of analysis. In short, it is understood that the models have statistical relevance and can help discussions about the importance of medical technology in the socioeconomic conditions of Brazil.

Figure 19 summarizes the main points of the analysis using the aggregate approach.

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Figure 19: Summary of the aggregate approach

Between 2008 and 2019**, the Medical Technology Index grew by 117%, CAGR of 5.68%**

The Medical Technology Index has a positive impact on the cost of healthcare. A 1% increase in the index positively impacts **per capita health expenditure by 0.5%**

The increase in medical technology caused an increase in health expenditure of R$ 8.88 billion, on an annual average, between 2009 and 2019 (ANS + SUS), totaling R$ 97.68 billion in the period

Medical technology also impacts social welfare. The 1% increase in the index increases the proportion of the Population 65+ by 0.001%, reduces infant mortality by 0.025% and increases per capita GPD by 0.33%

The increase in medical technology promoted an increase in GPD of R$13.84 billion, in the annual average, between 2009 and 2019, totaling R$152.24 billion

Elaborated by: Thiago Caliari and LCA Consultants.


MEDICAL
CARE
HEALTH

>>


ANALIZING_FUNCTIONS
TARGET IDENTIFICATION
77
34
30
98
45
60
X8
REACTOR01
REACTOR02
x65
DATA TRANSFER CODE

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CASE STUDIES

Elaborated by: **Silvia Kobayashi, Alessandro Campolina** and **LCA Consultants**

As he last decades have witnessed intense processes of transformation and technological innovation in the area of health, with changes in the diagnostic and therapeutic processes, in the way health services are organized, and in health costs and expenditures (Novaes, 2006)[44].

The production, dissemination, incorporation and use of technologies in health systems depends on the technical and political characteristics of health systems, determined by the social and economic policies of different countries. Faced with the important economic, ethical, and social implications related to the intensive incorporation of medical technologies into health systems, governments have increasingly been called upon to manage scarce resources strategically, investing in services that deliver the best health outcomes at a cost to be financed. In this context, health technology assessment (HTA) has been constituted as an auxiliary instrument in the different decision-making processes related to the use of health technology and technology.

In this context, health technology assessment (HTA) has been constituted as an auxiliary instrument in the different decision-making processes related to the use of health technology and technolog medical and non-medical logia in health care (Novaes, 2006)[45].

In this sense, this section of the study sought to contextualize the application of disruptive medical equipment – implantable cardioverter defibrillators (ICDs), positron emission tomography (PET) scans and hip prostheses – and to assess the cost of effectiveness and recommendation of incorporation of these technologies, in order to assess their potential impact on the sustainability of health systems. To this end, case studies on this equipment were constructed, based on a broad review of the scientific literature. 97 scientific articles and 19 HTA reports carried out in the Brazilian context were selected for full reading and data extraction for the elaboration of case studies of the technologies of interest.

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ANALYSIS STRATEGY: METHODOLOGY AND SELECTION OF STUDIES

This section begins with the presentation of the cost-effectiveness analysis of health evaluations enshrined in literature and institutionalized in health systems around the world and details the methodology of the case studies. Then, for each case chosen, the technology is presented, the disease in which its application is most common, and the analysis of the documents that evaluate its cost effectiveness. Finally, the main results found in the study of each technology are presented.

44. Novaes, H.M. From production to evaluation of health systems technologies: challenges for the 21st century. Rev. Saude Publica. 2006;40 Spec no.:133-40.

45. Idem à nota 44.

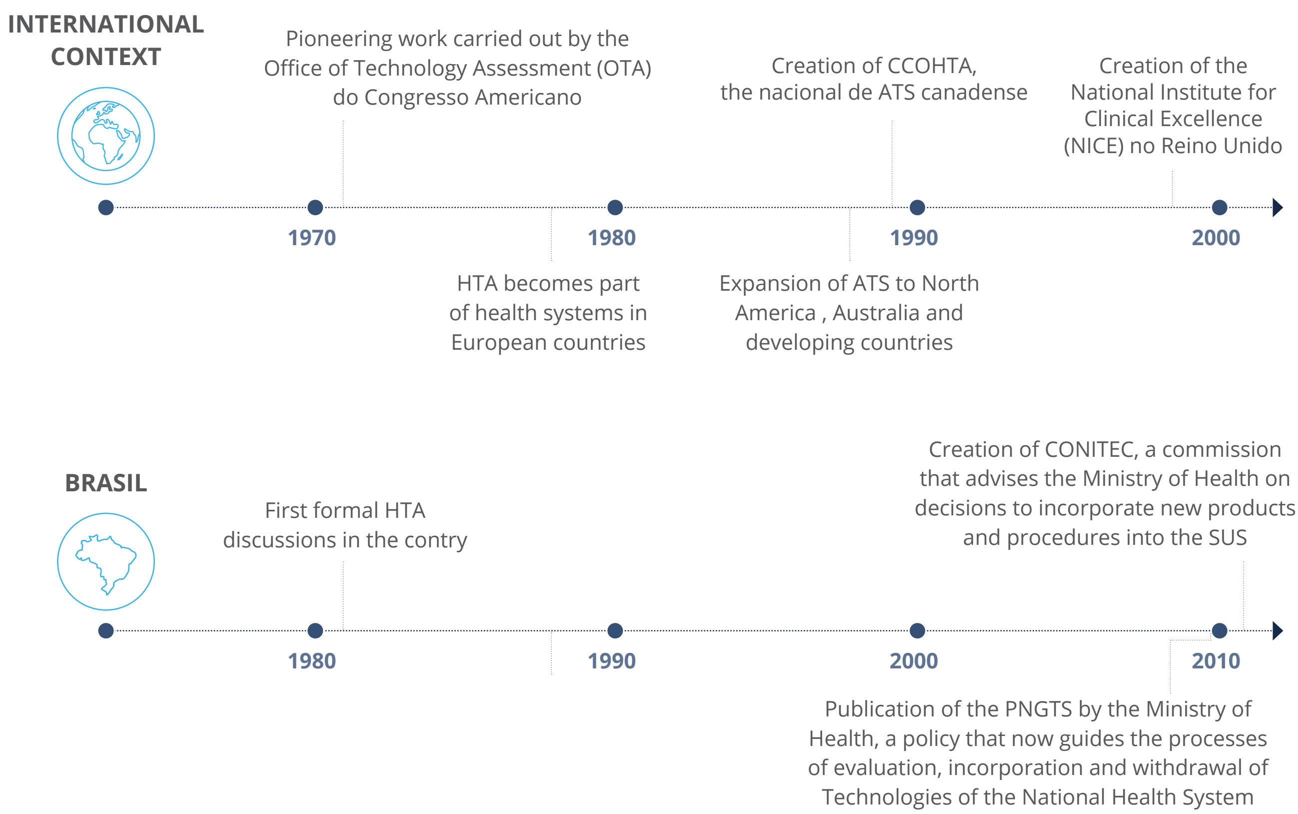
Cost-effectiveness analysis in health technology assessments

Health Technology Assessment (HTA) has been defined as:

> *A multidisciplinary field of policy analysis, which studies the clinical, social, ethical, and economic implications of the development, diffusion, and use of health technologies (INAHTA, 2022)[46].*

A better understanding of the scope and potential of HTA can contribute to better equity and access to health services, greater efficiency in resource allocation, improved effectiveness and quality of services, and greater financial sustainability of the health system. The figure below details the evolution of HTA adoption internationally and nationally[47].

Figure 20: Evolution of HTA institutionalization



Elaborated by: Silvia Kobayashi, Alessandro Campolina and LCA Consultants.

46. International Network of Agencies for Health Technoogy Assessment. HTA Tools and Resources 2022. Disponível em: <https://www.inahta.org/hta-tools-resources>

47. A figura foi construída com base em múltiplas fontes. Para a evolução da ATS nos países europeus, consultar:

O'Donnell, J.C.; Pham, S.V.; Pashos, C.L; Miller, D.W.; Smith, M.D. Health technology assessment: l essons learned from around the world--an overview. Value Health. 2009;12 Suppl 2: S1-5.

For the cases of Australia and North American countries, see: Cleemput, I. et al. Threshold values for cost-effectiveness in health care. Brussels: Belgian Health Care Knowledge Centre (KCE), 2008.

For discussions and seminars on the introduction of HTA in Brazil during the 1980s, see: Department Department of Science and Technology, Secretariat of Science, Technology and Strategic Inputs, Ministry of Health Consolidation in the area of health technology assessment in Brazil. Rev. Public Health, 2010; 44(2):381-3;

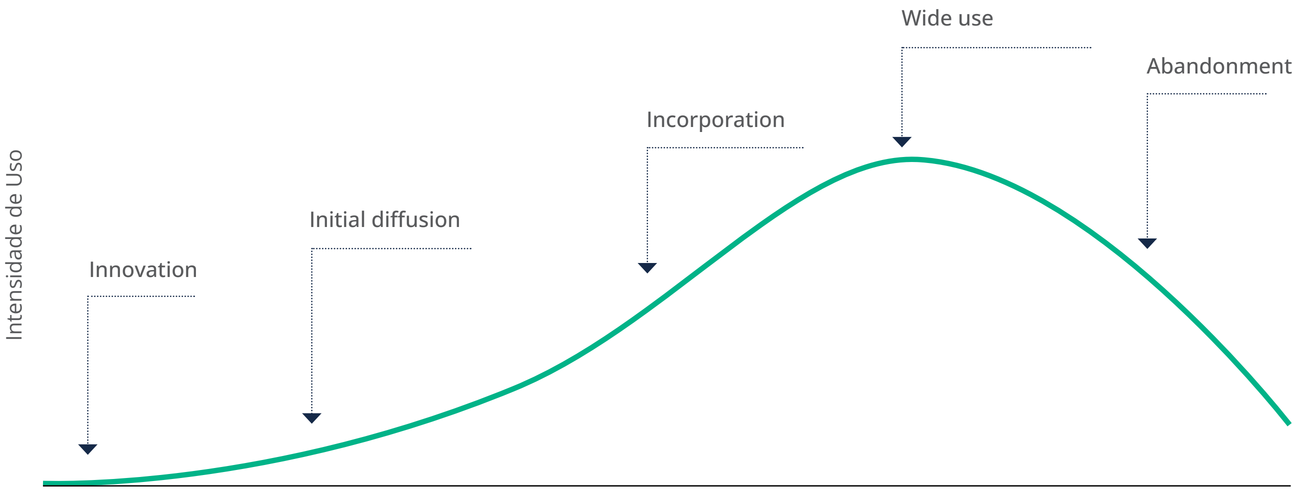
The precision of HTA processes depends on a broad and shared understanding of the concept of health technology. In a broad perspective, health technologies could be considered "all forms of knowledge that can be applied to the solution or reduction of the health problems of individuals or populations". Therefore, health technologies comprise items in addition to medicines, equipment and procedures used in health care.

The evaluation of a technology can be carried out at any stage of its life cycle – innovation, initial diffusion, incorporation, wide use and abandonment (Banta e Luce, 1993)[48].

The life cycle of health technologies is strictly related to price. In the early stages of the introduction of innovation in the market, technological appropriation tools by the innovative firm (usually patents) generate barriers to entry for other competitors and high market power, allowing for high prices. Throughout the process, either with the fall of the patent or with the increase in access to information and technology of competing companies, greater competition is generated and consequent loss of prices[49].

In the stage of wide use, with the consolidation of the use of Technologies in health systems, more factors can reduce their prices, such as the reduction of costs due to economies of scale and the greater number of professionals who have overcome the learning barrier.

Figure 21: Life cycle of health technologies



Source: Adapted de Banta H, Luce B. Introduction. Health Care Technology and Its Assessment: An International Perspective. Oxford University Press, 1993. New York, NY. P. 1-5. Elaborated by: Silvia Kobayashi, Alessandro Campolina and LCA Consultants.

Contó, M.; Bonan, L.F.S. Arcabouço legal da incorporação e acesso a dispositivos médicos no Brasil: estrutura, tipos de avaliação e oportunidades para avanços. Jornal Brasileiro de Economia de Saúde, 2020;12(3): 213-25.

For the implementation of the National Policy for Health Technology Management (PNGTS), see: Ministry of Health. Department of Science and Technology and Strategic Inputs. Department of Science and Technology. National Policy on Health Technology Management. Brasilia DF2010. p. 48.

Finally, for the creation of CONITEC, consult: Department of Science and Technology, Secretariat of Science, Technology and Strategic Inputs, Ministry of Health Consolidation of the area of health technology assessment in Brazil. R. Public Health, 2010;44(2):381-3;

Ministry of Health. Secretariat of Science, Technology and Strategic Inputs. Department of Science and Technology. National Policy on Health Technology Management. Brasília DF2010. p. 48.

48. Banta, H.; Luce, B. Introduction. Health Care Technology and Its Assessment: An International Perspective. Oxford University Press, 1993. New York, NY. p. 1-5.

49. Malerba, F., Orsenigo, L. (1995) Schumpeterian patterns of innovation. Cambridge Journal of Economics, 19(1), pp. 47-65.

The methodologies used in HTA studies are based on the appropriate and legitimate use of scientific and technical knowledge, as an objective analysis, aimed at maximizing benefits for patients, with respect to conflicts of interest. HTA has been compared to a bridge that attempts to unite the world of research with the world where decision-making takes place (Drummond et. al., 1993)[50], ensuring the transfer of knowledge through the collection, analysis and synthesis of research results in a systematic and reproducible manner. The scope of HTA studies comprises a set of properties, attributes, and impacts of technologies: technical properties; clinical safety/adverse effects; efficiency; utility; age; economic impacts; social, legal, ethical, and/or political impacts (Yancy et. al., 2013; Battista, 1996)[51,52].

In this process, when a new technology-based procedure is recognized by health care providers as significant and sufficiently safe, evaluations begin on the convenience of incorporating this procedure into the set of services regularly offered to patients (Jena e Philipson, 2008)[53].

Health economic evaluations (AES) are one of the types of HTA studies able to support these technology reimbursement decisions by health systems, since they perform the comparative analysis between two or more alternative interventions, comparing costs and results obtained.

- They are defined as formal analytical techniques to compare different proposed action alternatives, taking into account both positive and negative health costs and consequences (Drummond et al., 2005)[54];

- They weigh the costs of the resources applied and the health consequences achieved , including waste from the use of a given technology in populations in which it is not cost-effective[55], in order to assist in decisions about the prioritization of interventions and the allocation of resources;

- They often involve information synthesis studies (such as systematic reviews and meta-analyses) to obtain the best estimates of health outcomes and the elaboration of Clinical guidelines that guide the use of the technologies evaluated;

- They require multidisciplinary knowledge, and may involve professionals from disciplines such as epidemiology, statistics, clinical research, health administration, and economics.

50. Drummond, M.; Sculpher, M.; Torrance, G. O'Brien, B.; Stoddart, G. Methods for the Economic Evaluation of Health Care Programmes. Oxford Medical Publications, 2005. V. 3, p. 379.

51. Yancy, C.W.; Jessup, M.; Bozkurt, B. et al. 2013 ACCF/AHA guideline for the management of heart failure. A report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. 2013;62(16): p. 147–239.

52. Battista, R. Towards a paradigm for technology assessment. In: Peckham, M.; Smith, R. editors. The scientific basis of health services. London: BMJ Publishing Group; 1996.

53. Jena, A.B.; Philipson, T.J. Cost-effectiveness analysis and innovation. J Health Econ. 2008;27(5):1224-36.

54. Drummond, M.; Sculpher, M., Torrance, G.; O'Brien, B.; Stoddart, G. Methods for the Economic Evaluation of Health Care Programmes. Third ed: Oxford Medical Publications; 2005. 379 p.

55. Waste occurs when a technology regulated by health surveillance agencies is applied to populations in which no previous economic evaluations have been carried out, characterizing a situation similar to the off-label use of drugs (use of a drug in situations in which its indication has not been approved). In this situation, a production is characterized by in excess, see that the health service produces more than what is necessary to meet customer demand.

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There are four main methodologies of complete SES of health programs, according to Drummond et al. (2005)[56]:

- Cost-Minimization Analysis (ACM))
- Cost-effectiveness analysis (ACE))
- Cost-utility analysis (ACU)
- Cost-benefit analysis (ACB)

Overall, economic assessments can provide governments and private payers with an important means of allocating scarce health resources based on the costs and effectiveness of available medical technologies.

There is a growing emphasis on the use of such analyses to guide the adoption of new technologies and manage their long-term impact on health care expenditures (Drummond et al., 2005)[57]. The emergence of new studies may demonstrate additional benefits of technologies in dimensions of health not initially evaluated and long-term benefits that only become evident with studies with longer population follow-up.

In addition, as previously seen, the cost impact of a given technology needs to be monitored over time, as its wide use in the health system can make it more cost-effective, either by reducing costs resulting from the expiration of patents and the emergence of competing alternatives, or by obtaining economies of scale and learning from professional teams.

In practice, it is common **to refer to both an ECA or ACU as a study of "cost".**

to- effectiveness", these being the studies that have guided political decisions, with the adoption of cost-effectiveness thresholds, which dictate that a given technology will be incorporated .

Seeking to make the analyses more objective and quantitative, the studies are based on the concept of quality of life adjusted for quality of life (QALY).

COST/QALY: incremental cost per quality-adjusted year of life, i.e., the additional cost required to gain an additional year of healthy life. Thus, the new technology is recommended when the QALY provided by it is below a certain pre-defined threshold (Drummond et al., 2005)[58].

After calculating the costs and effectiveness of the strategies, they should be ordered, starting with the cheapest to the most expensive. After being sorted according to costs, incremental cost-effectiveness ratios (ICER) are calculated.

56. Ibid . 54.

57. Ibid 54. In addition to these 4 types, there are also cost-consequence analyses (ACC) which, despite being less robust than the other types of complete evaluations, can provide important support for decision-making.

ICER: dividing the difference in the costs of the alternatives by the difference in their effectiveness, according to the equation below.

$$ICER = \frac{Cost\ A - Cost\ B}{Consequence\ A - Consequence\ B} \qquad (5)$$

The ICER expresses a summary of the results of a comparative evaluation of different health care strategies, the main result being an ESA. In the case of economic analyses with multiple options, the ICER is usually calculated in relation to the strategy with the immediately cheapest cost, i.e., the standard procedure is not to calculate the ICER of each strategy always using the cheapest strategy as a basis for comparison. This is due to the way in which ICER is interpreted according to willingness-to-pay threshold values, as discussed below (Drummond et al., 2005)[59].

It is important to note that the interpretation of the results of an ESA should be made in light of a pre-established willingness-to-pay (LDP) threshold.

LDP: To understand this concept, it is necessary to remember the concept of opportunity cost and accept that the objective of a health system is to maximize the benefit provided within a given budget constraint. Thus, establishing the value of a technology requires a consideration of whether the additional health benefit gained from the use of this technology exceeds the health losses with other treatments that will be shifted to investment in the new technology in question, depending on its additional costs.

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58. Ibid 54.

59. Ibid 54.

This comparison is adequately represented by the comparison of ICER with an LDP, which should represent the least cost-effective alternative ever incorporated into the health system (Drummond et al., 2005)[60].

Different countries have values of LDP specific to their contexts, as shown in Table 4 below. In Brazil, there is a broad discussion underway, but so far there is no LDP value proposed by the Federal Government for the incorporation of technologies in the health system.

Table 4: Willingness-to-Pay Threshold in different countries

Country	LDP/QALY gain (local currency)	LDP/QALY gain (em US$)
United Kingdom (NICE, 2013))[61]	£20.000-£30.000	US$22.758-US$34.137
Australia (Cleemput et al., 2008) [62]	AU$69.900	US$ 45.222
New Zealand (Cleemput, et al., 2008) [63]	NZ$20.000	US$ 11.862
Canada (Cleemput et al., 2008) [64]	CAN$20.000 e $100.000	US$ 14.838 e US$ 74.189
Netherlands (Cleemput et al., 2008) [65]	€80.000	US$ 79.657
United States (Bridges et al., 2010)[66]	US$50.000	US$ 50.000
Brazil	In definition	In definition

Note: Reference date for exchange rates between national currencies and the dollar: 04/11/2022. The rates used for each country/currency were: United Kingdom 0.8788 £ / US$; Australia 1.5457 AU$/US$; New Zealand 1.6861 NZ$/US$; Canada 1.3479 CAN$ / US$; Netherlands €1.0043 / US$. Elaboration: Silvia Kobayashi, Alessandro Campolina and LCA Consultants.

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In any case, assessing whether the ICER attributed to a given technology is below the LDP established in different contexts can be an indication of its value for the health system and allow the identification of innovations that have been presented as good alternatives for the allocation of scarce resources.

Object of analysis and survey of studies

In order to construct case studies on disruptive medical equipment, a survey of information was carried out, based on a broad review of scientific literature and a consultation of the CONITEC and UNIMED-RS databases, in order to collect relevant data on the clinical and economic aspects of 3 types of technologies:

- Implantable cardioverter defibrillators (ICDs)
- Positron emission tomography (PET) scans
- Hip prostheses.

60. Ibid 52.

61. National Institute for Health and Clinical Excellence (NICE). Guide to the methods of technology appraisal. 2013. Disponível em:<http://www.nice.org.uk/article/PMG9/chapter/Foreword>.

62. Cleemput, I. et al. Threshold values for cost-effectiveness in health care. Brussels: Belgian Health Care Knowledge Centre (KCE), 2008.

63. Ibid 60.

64. Ibid 60.

65. Ibid 60.

66. Bridges, J. F.; Onukwugha, E.; Mullins, C. D. Health care rationing by proxy: cost-effectiveness analysis and the misuse of the $50,000 threshold in the US. Pharmacoeconomics, Pennsylvania, v. 28, n. 3, p. 175-184, 2010.

For the choice of the 3 cases, the most representative specialties of the survey of national technical opinions (CONITEC, UNIMED-RS) and the respective Technologies evaluated were considered. In addition, the increase in the prevalence of heart diseases, neoplasms and injuries due to falls associated with population aging was also considered.

The methodological details of this survey are attached at the end of this document. In total, 1731 scientific articles were collected in the MEDLINE, EMBASE and LILACS databases; Of which, after the selection process, 97 were highlighted for full reading and data extraction for the elaboration of the case studies. In addition, 19 HTA reports were surveyed in Brazil, based on the CONITEC and UNIMED-RS databases. Of the total number of documents analyzed, 93 are international (80%) and 23 are national (20%). 41 of the documents (42.3%) are from Europe, 32 (33%) are from the United States and 8 (8.2%) are from Brazil.

- **CDI:** 61, of which 57 were scientific articles and 4 were reports.
- **PET:** 36, of which 26 were articles and 10 were reports.
- **Hip prostheses:** 19, of which 14 were scientific articles and 5 were reports.

From the selection of studies, the following stand out: (i) the participation of articles that considered the technology cost-effective according to the methodology described above or reports that recommended inclusion in the health system; (ii) the most interesting applications and results of the studies in terms of effectiveness; (iii) the calculation of the savings/benefit generated by each technology.

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STUDY 1: IMPLANTABLE CARDIOVERTER-DEFIBRILLATORS (ICD)

Technology Description

Implantable cardioverter-defibrillators (ICDs) are devices that enable the monitoring of the heart rhythm and are capable of generating an electric shock with the aim of restoring the normal heart rhythm. They consist of a pulse generator, approximately 30-40 cm^3 (similar to a pacemaker), weighing less than 80 g, and one or more electrodes.

These devices consist of three main parts:

- **Defibrillator:** a small metal box containing a microprocessor, circuitry, and a battery.

- **Electrodes:** wires that carry electrical energy from the defibrillator to the heart and relay information about the heart's electricity to the defibrillator.

- **External programmer:** specialized computer to monitor and adjust instructions to the device.

At first, these devices were implanted through the transthoracic route, requiring thoracotomy surgery and general anesthesia. Currently, the generators are positioned in the anterior thoracic region and connected to the cardiac chambers by electrodes through the transvenous route (without the need for surgery), under local anesthesia.

In recent years, there has been a great improvement in ICD technology, particularly related to size reduction and implant technique, enabling a smaller incision and more physiological responses, increasing patient comfort.

Another improvement was the development of the ability to record intracardiac electrocardiograms, allowing the monitoring of each episode of ICD activation; enabling the necessary corrections in the programming of the defibrillator in a quick manner. Another important development was the reduction in the defibrillation threshold and adaptive frequency. The most recent devices are able to detect and trigger stimuli according to the various situations of arrhythmias, in a modified way. These devices have an approximate durability of 5 to 8 years, which has been gradually expanded with advances in technology. The battery life is about 6 to 7 years, depending on the number of electrical shots required for each patient (Bryant, 2005)[67].

Most commonly addressed OER/disease

The main diseases indicated for the use of ICDs are arrhythmias and cardiac insufficiency. Data from DATASUS showed that in 2021 there were 163,407 hospitalizations for heart failure, with 22,024 deaths (mortality rate of 13.48). The average length of stay of these hospitalizations was 7.8 days and the total cost to the SUS was R$330.98 million.

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Table 5: Statistics on heart failure in Brazil, 2018 to 2021

Insuficiência Cardíaca	2018	2019	2020	2021
Hospitalizations	200.833	199.844	169.693	163.407
Deaths	22.337	22.806	20.546	22.024
Mortality rate (%)	11,12	11,41	12,11	13,48
Average length of stay (days)	7,7	7,7	7,5	7,8
Total amount (R$ million)	406,50	403,73	353,33	330,98

Note: total values include expenses with hospital procedures deflated for 2021 by the IPCA (IBGE). Source: Ministry of Health – SUS Hospital Information System (SIH/SUS). Elaboration: Silvia Kobayashi, Alessandro Campolina and LCA Consultants.

For conduction disorders and cardiac arrhythmia, there were 60,231 hospitalizations in 2021, with 9,293 deaths (mortality rate 15.43). The average length of stay of these hospitalizations was 4.4 days and the total amount for SUS was R$ 279.16 million.

67. Bryant, J.; Brodin, H.; Loveman, E.; Payne, E.; Clegg, A. The clinical and cost-effectiveness of implantable cardioverter defibrillators: A systematic review. Health Technol Assess. V. 43, p. 9- 36. Disponível em: < https://www.embase.com/search results?subaction=viewrecord&id=L41535991&from=export>

Table 6: Statistics on arrhythmia in the Brazil, 2018 - 2021

Arrhythmia	2018	2019	2020	2021
Hospitalizations	64.760	69.673	60.362	60.231
Deaths	7.174	8.308	8.670	9.293
Mortality Rate (%)	11,08	11,92	14,36	15,43
Average Length of Stay (days)	4,8	4,7	4,4	4,4
Total (R$ million)	335,83	347,89	294,66	279,16

Note: Total amounts include expenses with deflated hospital procedures for 2021 by the IPCA (IBGE). Source: Ministry of Heath – SUS Hospital Information Center (SIH/SUS). Elaborated by: Silvia Kobayashi, Alessandro Campolina and LCA Consultants.

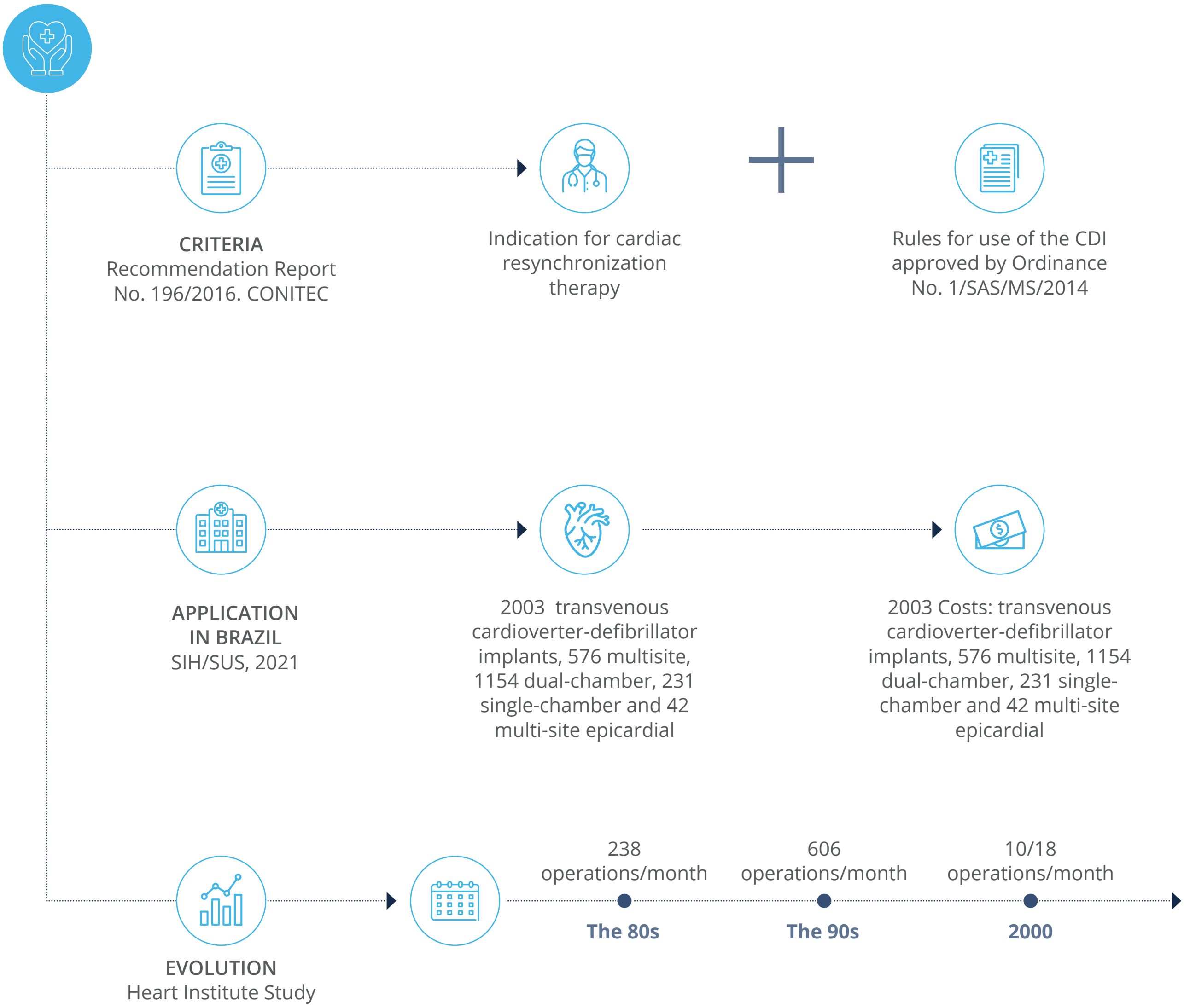
CONITEC, which advises the Ministry of Health, published it in the report of Recommendation No. 196 of January 2016 Implantable Defibrillator Diverter – Resynchronizer: Should be used in patients and, in addition to the clear indication of cardiac resynchronization therapy, fulfills the criteria for the use of the CDI approved in 2014[68].

Since the first ICD implantation in 1980, more than 240,000 have been implanted around the world. In Brazil, the number of cardiac device implants has increased over the years. A study by the Heart Institute accounted for an average of 238 operations/ month in the 1980s, increasing to 606 operations/month in the 1990s (growth of 155%), and 1,018 operations/month in the 2000s (increase of 68.0% in relation to the 1990s, p < 0.001 between the periods analyzed). At the Institute, these operations accounted for 27.5% of all cardiovascular surgeries (Yancy et al., 2013)[69].

68. The ordinance updates, in its annex, the protocol for the use of the ICD in health establishments accredited by the SUS. Recommendation Report. Ministry of Health. Protocol of Use Implantable cardiac pacemakers and resynchronizers nº 196 January/2016. 2016.

69. Ibid 51.

Figure 22: Application of CDI in Brazil



Elaborated by: Silvia Kobayashi, Alessandro Campolina and LCA Consultants.

According to data from the Hospital Information System of the SUS (SIH/SUS) of the Ministry of Health, in 2021, the following were carried out:

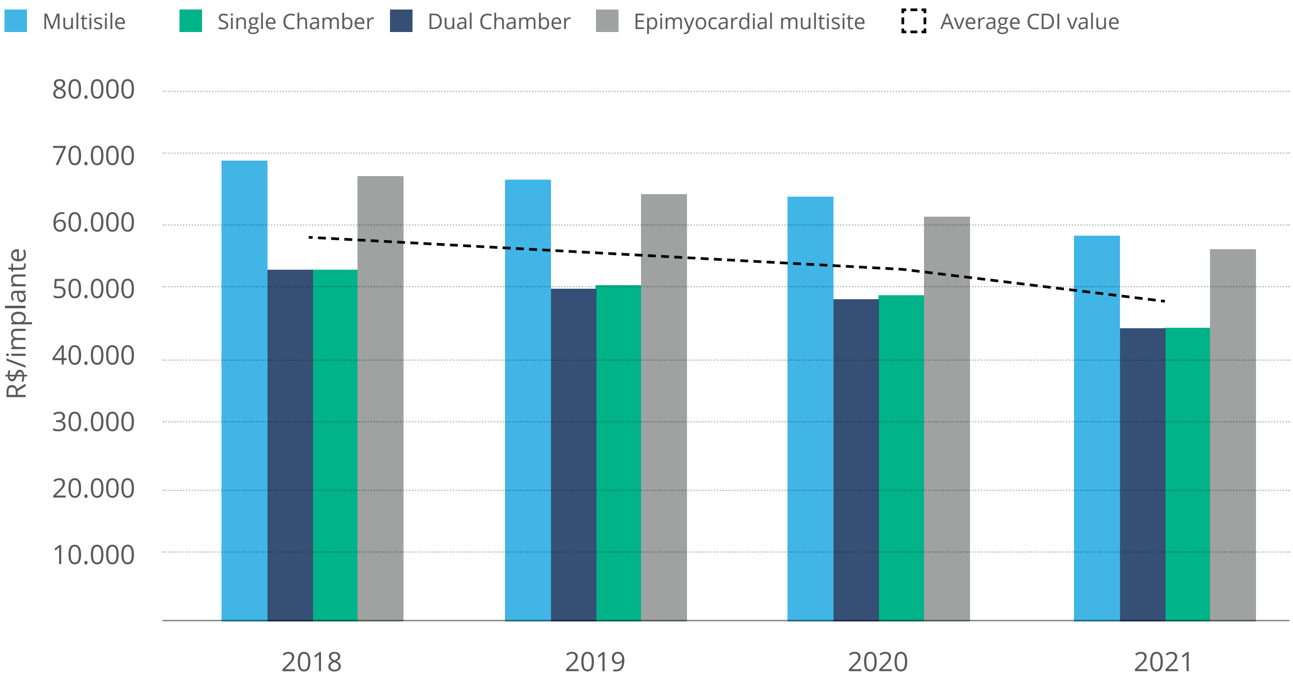
2003 implants of transvenous cardioverter-defibrillators, being:

- 576 multisite;
- 1154 dual-chamber;
- 231 single-chamber;
- 42 epicardial multisite.

The total amount spent by SUS was R$ 97.13 million. Despite the increase in ICD implants in recent years, there has been a reduction in the value per implant, with a drop of R$ 9 thousand in the average value in the period, with the highest in Multisite (R$ 12.7 thousand). Graph 10 illustrates this evolution.

Chart 10: Value per transvenous ICD implant in R$ (updated for 2021), 2018 to 2021[70]

CAGR Average value CDI: -4,26%



Note: total values deflated for 2021 by the IPCA (IBGE). Source: Ministry of Health – Information System SUS Hospital Hospitals (SIH/SUS). Elaborated by: Silvia Kobayashi, Alessandro Campolina and LCA Consultants.

Cost-effectiveness analysis and highlights in the selected articles/reports

A total of 61 documents were included in the bibliographic survey for CDI, of which 57 were scientific articles and 4 were reports.

- Of the 57 articles analyzed on cardioverter-defibrillators, 32 (56%) analyses evaluated ICD, and 8 (14%) evaluated cardiac resynchronization therapy with defibrillator (CRT-D). Another 35 (61.4%) compared the main technology with drug therapy (MD), and 5 (9%) with pacemaker cardiac resynchronization therapy (CRT-P). Variations of cardiac resynchronization therapy and drug therapy were also used as comparators.

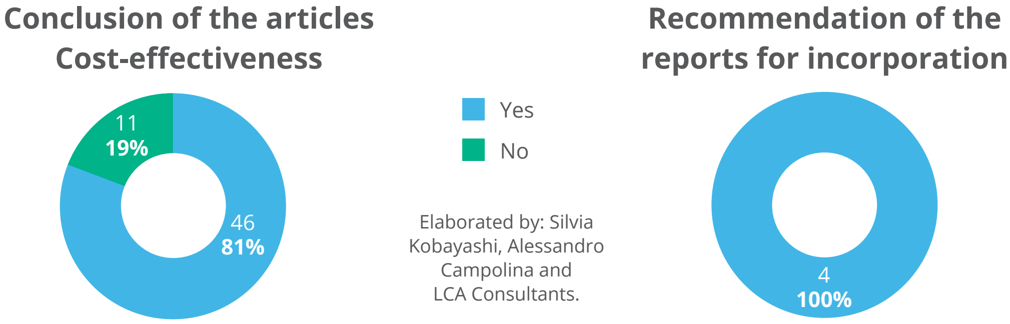
- 45 (79%) studies use ACU for economic evaluation and 9 (16) ACE.

- 46 (81%) studies concluded that the evaluated technology is cost-effective (ICER < LDP). The 4 reports recommended the incorporation of the technology evaluated;

- Cardiac resynchronization therapy (CRT) has been observed to improve symptoms and survival in patients with heart failure (gain of 52 years of life in class III HF, when compared to medical therapy).

70. GAGR segmented by implant type: (i) Multisite: -4.52%; (ii) Dual Chamber: -4.43%; (iii) Single Chamber: -4.60%; (iv) Epimyocardial Multisite: -4.62%.

Graph 11: Conclusion of the documents on cost-effectiveness and incorporation of the CDI



Therefore, such as CONITEC, the National Institute for Health and Clinical Excellence of the United Kingdom – NICE (NICE, 2000)[71], recommends the routine use of ICDs, and highlights the following categories:

1. Secondary prevention of patients who present, in the absence of treatable causes: (i) cardiac arrest due to ventricular tachycardia (VT) or ventricular fibrillation; (ii) spontaneous and persistent ventricular tachycardia, leading to syncope or significant hemodynamic compromise; (iii) persistent ventricular tachycardia, without syncope/ cardiac arrest, with reduced ejection fraction (< 35%), and not less than Functional Class III in the Classification of Heart Failure.

2. Primary prevention for patients who do not have a previous episode of cardiac arrest or ventricular tachycardia with: (i) history of myocardial infarction, VT not consistent with Holter monitoring (24-hour electrocardiogram), VT provoked by electrophysiological tests, and left ventricular dysfunction with ejection fraction less than 35%, and not less than Functional Class III in the Heart Failure Classification; (ii) family history of high risk of sudden cardiac death, including long QT syndrome, hypertrophic cardiomyopathy, Brugada syndrome, arrhythmogenic right ventricular dysplasia, and corrected tetralogy of Fallot.

71. National Institute for Clinical Excellence. Guidance on the use of implantable cardioverter defibrillators for arrhythmias. NICE. 2000

Heart failure (HF) is a clinical syndrome characterized by symptoms (shortness of breath and fatigue) and signs (fluid retention) caused by incapacity of ventricles eject blood appropriately (Pazos-Lopez P. et. al., 2011)[72]. The risk of developing HF is approximately 20% among patients over the age of 40, and more than 650,000 new cases are diagnosed annually in the United States. Considering that HF patients generate more than one million hospital Hospitalizations per year and have a short-term risk of rehospitalization of 25%, the American Heart Association (AHA) has estimated that 8 million Americans will have HF by 2030 (Cleemput, I. et al., 2008)[73]. Given its prevalence, HF represents an economic burden. Significative aspect not only for individual patients, but for the healthcare system as a whole. Projections suggest that by 2030, the total cost of HF treatment will be US$ 69.7 billion (Cleemput, I. et al., 2008)[74].

Cardiac resynchronization therapy (CRT) improves symptoms and survival in patients with HF. The American College of Cardiology Foundation (ACCF) Guidelines for the management of HF make recommendations for the use of CRT and implantable cardioverter defibrillator (ICD) for patients with HF, conditioned to specific clinical characteristics and manifestations (Cleemput et al., 2008)[75].

ICDs are used to deliver therapies, such as defibrillation or anti-tachycardia pacing, to treat life-threatening arrhythmias associated with sudden cardiac death. Modern types of CRT devices combine the functionality of a CRT-P (or pacemaker) and that of an ICD, and are called CRT defibrillators (CRT-D).

Despite improvements in access to the implantation of these devices and the accumulation of user experience in recent decades, approximately 30% of patients do not benefit from their symptoms (Daubert et al., 2012 and Mullens W. et. al., 2009)[74,75]. post-implantation complications may occur, contributing to the reduction of the efficacy of this therapy (Sohal, 2014)[78]. The advancement of technology in this area, with the introduction of devices with multipolar (quadripolar) electrodes, has led to fewer complications (Sperzel et al., 2012)[79].

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72. Pazos-Lopez, P.; Peteiro-Vazquez, J.; Carcıa-Campos, A et al. The causes, consequences, and treatment of left or right heart failure. Vasc Health Risk Manag. 2011, v. 7, p. 237–254.

73. CLEEMPUT, I. et al. Threshold values for cost-effectiveness in health care. Brussels: Belgian Health Care Knowledge Centre (KCE), 2008.

74. Ibid 73.

75. Ibid 73.

76. Daubert, J-C.; Saxon, L., Adamson, P.B. et al. 2012 EHRA/HRS expert consensus statement on cardiac resynchronization therapy in heart failure: implant and follow-up recommendations and management. Europace 2012, v. 14, p. 1236–86.

77. Mullens, W.; Grimm, R.A.; Verga, T. et al. Insights from a cardiac resynchronization optimization clinic as part of a heart failure disease management program. J Am Coll Cardiol, 2009; 53:765– 73.

78. E.g. altos limiares de captura, estimulação do nervo frênico (SNP), deslocamento do eletrodo e infecção. Sohal, M.; Chen, Z.; Sammut, E. et al. New developments in the delivery of cardiac resynchronization therapy: targeted lead placement, multisite and endocardial pacing. Expert Rev Med Devices 2014; 11: 295–304.

Forleo, G.B.; Mantica, M.; Di Biase, L. et al. Clinical and procedural outcome of patients implanted with a quadripolar left ventricular lead: early results of a prospective multicenter study. Heart Rhythm 2012; 9: 1822–8.

Biffi, M.; Exner, D.V.; Crossley, G.H. et al. Occurrence of phrenic nerve stimulation in cardiac resynchronization therapy patients: the role of left ventricular lead type and placement site. Europace 2013; 15: 77–82.

Gras, D.; Böcker, D.; Lunati, M. et al. Implantation of cardiac resynchronization therapy systems in the CARE-HF trial: procedural success rate and safety. Europace 2007; 9: 516–22.

79. Through the reprogramming of the most proximal pole, the presence of lower sustained capture thresholds and greater ease of delivery. Sperzel J, Dänschel W, Gutleben K-J, et al. First prospective, multicenter clinical experience with a novel left ventricular quadripolar lead. Europace 2012 ; 14: 365–72.

More modern devices, such as CRT-D, reduce mortality even in less severe patients, such as those with HF class II of the New York Heart Association (NYHA) classification, when compared to the ICD alone, showing the potential to expand the indication of these therapies to a very large number of patients.

However, the high costs of HF devices have led to concerns that the widespread implementation of CRT, especially ICD devices, could significantly burden health budgets, especially in the case of low- and middle-income countries with large populations, such as Brazil.

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Improvements in cardiac resynchronization therapy, with or without ICDs, have been investigated in several countries to assess the cost-effectiveness of new equipment for patients with symptomatic heart failure.

In the United States, a cost-effectiveness analysis (Shah et al. 2020)[80] was conducted to assess in which subgroup of patients the implantation of ICD, CRT-P, and CRT-D devices would be cost-effective. The results of the analyses showed that:

1. The variation in the main estimates of the parameters of the economic analysis model had a minimal impact on the results of the model;
2. For sensitivity analyses where costs ranged by 200%, the CRT-D device remained the most preferred treatment option. cost-effective in 10 of the 16 subgroups;
3. The largest contributor to the total costs of treated patients was hospitalizations;
4. All devices (ICD, TRC-P, and TRC-D) led to cost savings when compared to optimized drug treatment;
5. Greater survival gains for CRT-D over a 2-year time horizon were observed, compared with drug treatment.

80. Shah, D.; Lu, X.; Palu, V.F.; Tsintzos, S.I.; May, D.M. Cost-effectiveness analysis of implantable cardiac devices in patients with systolic heart failure: a US perspective using real world data. Journal of Medical Economics 2020; 23(7): 690–697.

In another study (Behar et al., 2017)[81], also aimed at investigating the value of innovations in defibrillator therapies, the authors analyzed the costs of long-term use of health services, in terms of hospitalizations that occurred in the 5-year follow-up period, to investigate whether the higher purchase price of quadripolar devices (relative to bipolar devices) was offset by expected decreases in costs resulting from a reduction of hospitalizations. It was observed that:

1. Patients in the quadripolar group had a lower prevalence of ischemic heart disease and a lower number of hospitalizations (51 of 309 patients with quadripolar vs. 75 out of 287 patients with bipolar device; p = 0.003[82]);

2. The estimated ICER in a probabilistic model was £3,835 (US$ 4.364[83]). In the sensitivity analysis, quadripolar TRC-D had a 97% probability of being cost-effective on a £20,000 (US$22,578) LDP earned and 99.3% probability of being cost-effective on a £30,000 LDP ($34,137) per QALY earned.

3. Lower absolute number of hospitalizations in patients with quadripolar CRT-D systems, mainly due to the reduction in rehospitalizations due to HF and generator changes;

4. It is concluded that if quadripolar TRC-D systems were purchased for up to £932 (US$ 1,061) more than bipolar systems, they would generate a cost saving over a period of 5 years after accounting for all expenses and that an additional purchase price of £933 to £2,400 (US$ 1,062 to US$ 2,730), of the quadripolar systems in comparison With bipolar systems, it would still represent a cost-effective option.

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81. Behar, J.M. et al. Cost-Effectiveness Analysis of Quadripolar Versus Bipolar Left Ventricular Leads for Cardiac Resynchronization Defibrillator Therapy in a Large, Multicenter UK Registry. JACC Clinical Electrophysiology 2017; 3 (2):107-16.

82. The authors performed statistical tests that indicate the statistical validity of the result.

83. All conversions from Sterling Pound to US Dollars considered the exchange rate recorded on 04/11/2022: 0.788 Pounds/US$

Another study (Gold et al., 2017)[84] investigated the ICER of early CRT implantation in patients with mild HF[85]. In this study, it was observed that:

1. The TRC-D offered an average benefit in all simulations of 1.47 QALYs over the CRT-P (8.10 vs. 6.63, respectively) at an additional average cost of $63,454 ($111,203 vs. $47,749, respectively), resulting in an ICER of $43,678/QALY gained;
2. Although combined biventricular pacing and defibrillation (CRT-D) devices are more expensive than biventricular pacemakers (CRT-P), no simulation resulted in ICER exceeding the US$50,000/QALY earned LDP of the US;
3. It is concluded that their results supported the reimbursement of CRT-D even in patients with a lower level of severity compared to CRT-P[86].

In Brazil, a study was conducted to evaluate the cost-effectiveness of ICD in patients with HF from the perspective of the SUS (Ribeiro et al., 2010)[87] which found that:

1. ICD therapy was more expensive but more effective when compared to conventional therapy, generating an ICER of US$ 50,345 per QALY gained.
2. ICER would be below the LPD for Brazil, recommended by the WHO[88] only if the implantation of the ICD and the cost of the generator were reduced by 50%, but technological evolution could contribute to this cost reduction, since that the estimates would be close to a cost-effective value if the frequency of replacement of generators increased to 7-year intervals at that time.
3. In sensitivity analyses performed in the study, all other parameters did not substantially decrease the ICERs to more favorable limits.

In another study from Brazil (Bertold et al., 2013)[89]:

1. the ICER of CRT compared to drug treatment was R$ 15,723 per QALY gained.

84. Gold, M.R.; Padhiar, A.; Mealing, S.; Sidhu, M.K.; Tsintizos, S.I.; Abraham, W.T. Economic Value and Cost-Effectiveness of Cardiac Resynchronization Therapy Among Patients with Mild Heart Failure. JACC Heart Failure 2017; 5(3): 204-12.

85. Até então, a TRC tinha se mostrado custo-efetiva nas classes funcionais III/IV da classificação da New York Heart Association (NYHA). Sendo menos estudada na IC classe II. Entretanto, vários estudos já demonstravam que pacientes com IC leve (classe funcional II da NYHA) se beneficiam da TRC. A classificação NYHA (New York Heart Association), é uma classificação funcional usada para predizer o prognóstico e a sobrevida de pacientes com Insuficiência Cardíaca (IC). Classe I – ausência de sintomas: não apresenta sintomas e consegue realizar as atividades diárias sem se sentir cansado ou com falta de ar; Classe II – sintomas ligeiros: sente- se bem em repouso, mas a atividade moderada causa cansaço ou falta de ar; Classe III – sintomas moderados: sente-se bem em repouso, mas mesmo uma atividade física reduzida causa cansaço ou falta de ar; Classe IV – sintomas graves: não consegue realizar nenhuma atividade física sem desconforto e tem alguns sintomas em repouso.

86. Idem.

87. Ribeiro, R.A. et al. Cost-Effectiveness of Implantable Cardioverter-Defibrillators in Brazil: Primary Prevention Analysis in the Public Sector. Value in Health 2010; 13 (2) 160-8.

88. LDP de três vezes o Produto Interno Bruto *per Capita* do país – R$ 31.689 para o Brasil.

89. Bertoldi, E.G.; Rohde, L.E.; Zimerman, L.I.; Pimentel, M.; Polanczyk, C.A. Cost-effectiveness of cardiac resynchronization therapy in patients with heart failure: The perspective of a middle- income country's public health system. International Journal of Cardiology 2013; 163: 309–315.

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2. For CRT combined with implantable cardioverter-defibrillator (CRT-D), ICER was R$ 36,940/QALY gained, compared to ICD alone, and R$ 84,345/QALY gained when compared to CRT alone.

3. Sensitivity analyses showed that the model was generally robust. The authors concluded that upgrading to CRT-D has an ICER above the WHO LPD, but that for ICD-eligible patients, upgrading to CRT-D would be marginally cost-effective.

In a more recent study on the Brazilian case, the cost-effectiveness of ICD therapy compared to drug therapy in SUS patients was evaluated (Wherry et al., 2021)[90]:

1. The estimated ICER for the use of ICDs in the context of primary care was R$ 21,156 per QALY gained;

2. The results of the sensitivity analyses were consistent with those of the base case;

3. The authors concluded that, considering an LDP of R$ 105,723 adopted for the study (equivalent to 3x the Brazilian GPD per capita , according to WHO recommendations), the intervention with CDI would be considered cost-effective in this Brazilian population.

In the context of the Brazilian supplementary health of UNIMED (Technical Chamber of Evidence-Based Medicine) members, 2 reports were published: one recommending the selection of pacemakers in 2006 and the other recommending cardiac resynchronization (2005 with update in 2012). Both evaluated the indications based on data from the international literature, without economic evaluations. In summary, they concluded that:

1. Bicameral pacemakers reduce the incidence of atrial fibrillation, improve physical capacity, and improve quality of life scores;

2. There is a tendency towards a reduction in the development of heart failure;

3. There is a benefit in reducing mortality and hospitalization rates for HF patients who met specific clinical criteria.

In the context of the SUS, in 2016 CONITEC published a report on the ICD use protocol, with recommendations for the different types of devices, without economic evaluations. In 2017, it issued an opinion with the analysis of a study prepared by a remote monitoring system company, which pleaded for the incorporation of his system by SUS, in which he demonstrated a result of R$ 2,599.00 per year of life gained. CONITEC pointed out an important limitation of this study, since it assumed that the technology would generate a significant reduction in mortality – and considered that in scenarios

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90. From a study called 1.5 Primary Prevention. Wherry, K.; Holbrook, R.; Higuera, L.; Fujiiv, Rodriguez, D.A. Cost- Effectiveness Analysis of Implantable Cardioverter Defibrillator Therapy for Primary Prevention Patients with Additional Risk Factors in Brazil. International Journal of Cardiovascular Sciences; 2021. DOI: https://doi.org/10.36660/ijcs.20200016.

without a reduction in mortality due to the device, there would be an incredible cost in 10 years between R$ 5,636 and R$ 9,023. The agency also criticized the calculation of the incremental budget impact, pointing out that the proposed numbers for the target population would be underestimated.

Initially, they recommended an unfavorable opinion on the incorporation of Technology, suggesting that the transfer values for the acquisition of the devices already allowed the inclusion of remote monitoring. In addition, the incorporation of the company's specific system could limit access or represent a market reserve. After conducting a public consultation, which raised contributions from the Population in general and considering that the company proposed the inclusion of remote monitoring in the reimbursement amounts already practiced by the Ministry of Health, without linking the device brand, the agency modified its deliberation and the final recommendation was unanimous in approving the incorporation of Technology into the SUS.

Table 7: Summary table of the main results of the studies evaluated in IDUs

Methodology	Country	Results
ACU	USA	TRC-D was cost-effective in relation to CDI and TRC-P; Hospitalizations were the largest contributors to total costs (Shah D, et al. 2020). CRT-D in patients with mild HF was cost-effective, considering an LPD of US$50,000/QALY earned (Gold MR, et al. 2017)
ACU	United Kingdom	TRC-D (Quadripolar Device) with 99.3% of being cost-effective, being the highest purchase price of these devices (in relation to bipolar patients) was compensated by decreases hospitalization costs (Behar JM, et al. 2017).
ACU	Brazil	CDI was not cost-effective considering an LPD of 31,689/QALY gained, but authors point out that technological evolution could contribute to making this device cost-effective (Ribeiro RA, et al. 2010). TRC-D would be cost-effective for ICD-eligible patients, presenting an ICER of R$36,940/QALY gained, compared to ICD (Bertoldi EG, et al. 2013). ICD would be cost-effective compared to drug treatment, in the context of primary care, with an ICER of R$21,156/QALY earned (Wherry K, et al. 2021).
Reports	Brazil	In the context of supplementary health, HTA reports have concluded that ICD therapy benefits in reducing mortality and hospitalization rates . In the context of the SUS, the final decision of CONITEC was unanimous in recommending the incorporation of CDI Technology.

Elaborated by: Silvia Kobayashi, Alessandro Campolina and LCA Consultants.

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The cross-referencing of information from the scientific literature and HTA recommendations carried out in the Brazilian context showed that the scientific advances made in cardiac resynchronization therapy, especially with the use of ICD devices, have brought benefits to patients with life-threatening heart disease at a cost that has been considered acceptable in different contexts. ICER values below thresholds established for the incorporation of ICR have been observed for the most modern devices and even in less advanced stages of heart failure.

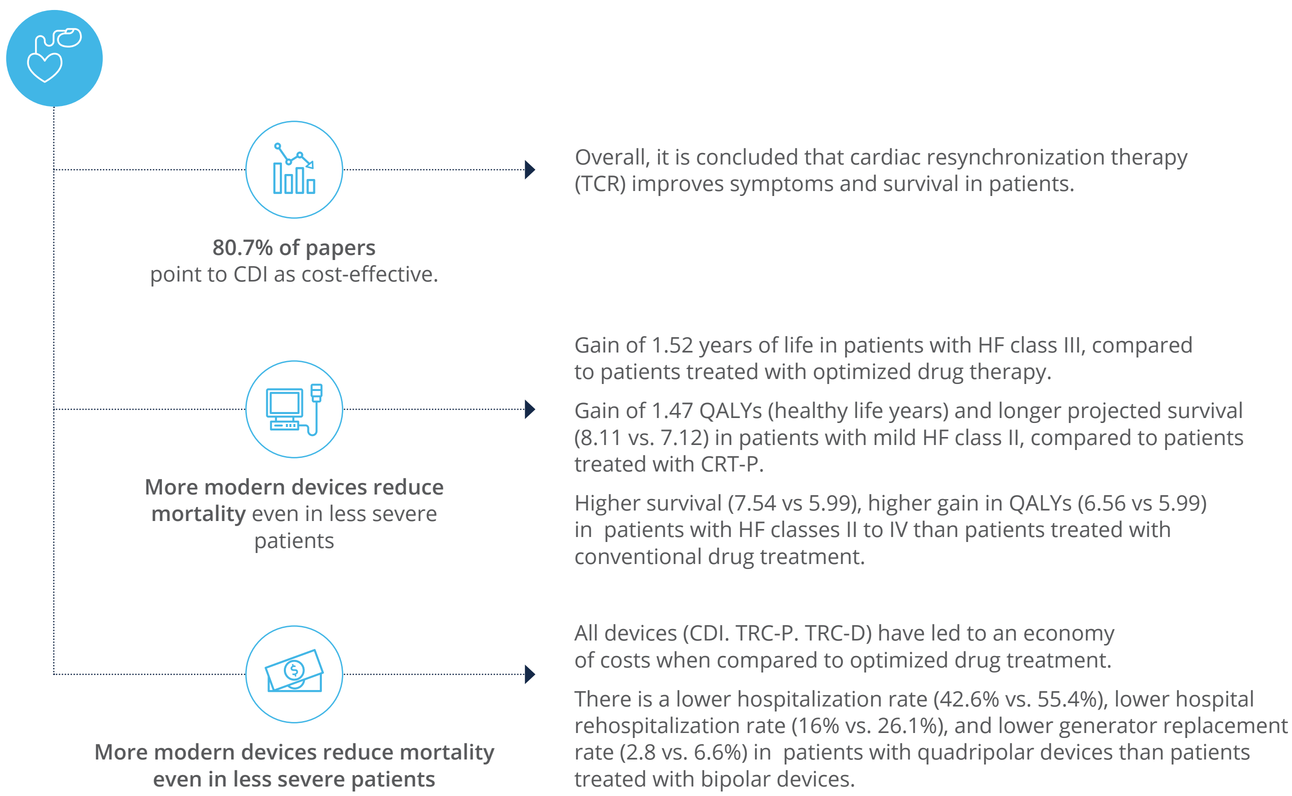
In Brazil, initial studies raised doubts about the efficiency (cost-effectiveness) of ICD devices, but more recent studies, which have followed the evolution of technology in this area, highlight the possibility that these devices represent good options for resource allocation, even in health systems in low- and middle-income countries.

The case of the incorporation of ICDs into the health system reveals how technological advances can make some devices progressively more cost-effective and how these devices currently constitute options that make significant contributions to the long-term well-being of the population affected by heart disease.

Main results

The case of the incorporation of ICDs into the health system reveals how technological advances can make some devices progressively more cost-effective. Figure 23 below summarizes the main results of this study.

Figure 23: Main results in CDI



Elaborated by: Silvia Kobayashi, Alessandro Campolina and LCA Consultants.

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STUDY 2: COMPUTED TOMOGRAPHY POSITRON EMISSION (PET)

Technology Description

PET (Positron Emission Tomography) is an imaging diagnostic technique in the field of nuclear medicine developed in the early 1970s, shortly after computed tomography. It uses radioactive tracers and the principle of coincident detection to measure biochemical processes within tissues. Unlike other imaging technologies that focus predominantly on anatomical definitions of disease—such as X-rays, computed tomography (CT), and magnetic resonance imaging (MRI)—PET evaluates perfusion and metabolic activity in the tissue and can be used as a complement or even substitute for these models. Molina et al., 2008)[91]

91. Molina, J.R.; Yang, P.; Cassivi, S.D. et al. Non-small cell lung cancer: epidemiology, risk factors, treatment, and survivorship. Mayo Clin Proc. 2008; 83: 584–94.

PET can be used to track the deposition of radioactive molecules at certain sites in the body. The most commonly used radiopharmaceutical component is 2-[18F]Fluoro-2-deoxyD-glucose (FDG). FDG is a glucose analogue that accumulates in tissues with high metabolic activity, such as neoplastic tissue. FDG uptake is also increased in benign pathologies, including sites of inflammation, trauma, and infection (Tanoue, 2008)[92].

PET technology is complex and multicomponent, involving the devices that detect the radiation resulting from the decay of the positron (which will give rise to the reconstructed image), as well as the set of equipment related to the production of radionuclides and their subsequent combination with biological elements (cyclotrons and generators, and synthesis units), so that they can function as a radiotracer. There are four dominant designs on the market: (i) full-ring PET scanners, operating in two or three dimensions; (ii) PET CT scanners with partial rotational ring; (iii) modified gamma-cameras for coincident imaging; (iv) gamma-chambers modified with a high-energy collimator for 511 keV photons.

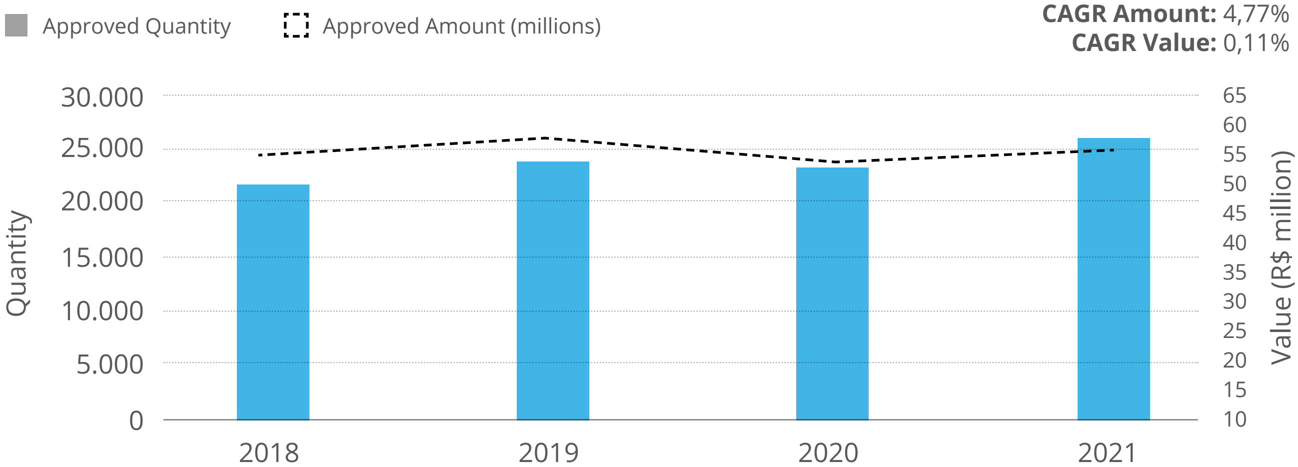
Each of these systems has a different cost/performance ratio. More recently, PET-CT has appeared, and currently, all PET-CT scans commercialized use multi-slice computed tomography (CT) technology, with hybrid equipment that simultaneously records anatomical and functional images in a single examination. The procedure is usually performed on an outpatient basis.

Most Commonly Addressed Area/Disease

The clinical application for the use of PET technology has been indicated predominantly in three major areas: oncology, cardiology and neurology.

In Brazil, data from the Ministry of Health's Outpatient Information System (SIA/SUS) showed that in 2021, 26,011 PET-CT scans were approved, with a total value of R$ 54.81 million.

Chart 12: Number of approved PET-CT scans and total amount spent in R$ million (updated to 2021), 2018 to 2021



Note: deflated values for 2021 by the IPCA (IBGE). Source: Ministry of Health Information System Hospital SUS (SIA/SUS). Elaborated by: Silvia Kobayashi, Alessandro Campolina and LCA Consultants.

92. Tanoue, L.T. Staging of non-small cell lung cancer. Semin Respir Crit Care Med. 2008; 29: 248–60.

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In oncology, the potential indications for the procedure are for differentiating between benign and malignant tumors, defining the extent of the disease, monitoring the therapeutic response, identifying recurrences, and identifying the primary site of the disease.

Worldwide, lung cancer ranks first among men with some type of cancer and third among women. The total number of new cases estimated for this disease in 2018 in the world represented 1.37 million new cases in men and 725 thousand new cases in women, corresponding to an estimated risk of 35.5/100,000 men and 19.2/100,000 women. In Brazil, according to the latest estimate published by the National Cancer Institute for the year 2020 (Brazil/INCA, 2019)[93], the total number of new cases of this neoplasm would be 30,200 cases, corresponding to 7.9% of cancers in men and 5.6% in women. Data from DATASUS showed that in 2021 there were 23,951 hospitalizations for malignant neoplasm of the trachea, bronchi and lungs, with 6,523 deaths (mortality rate of 27.23). The mean length of stay of these hospitalizations was 6.7 days and the value the total cost for SUS was R$ 39.94 million.

Table 8: Lung cancer statistics in Brazil, 2018 to 2021

Lung Cancer	2018	2019	2020	2021
Hospitalizations	24.408	26.266	24.596	23.951
Deaths	6.634	7.049	6.667	6.523
Mortality rate (%)	27,18	26,84	27,11	27,23
Average length of stay (days)	7,6	7,6	6,9	6,7
Total amount (R$ million)	45,28	47,78	43,51	39,94

Note: Total amounts include expenses with deflated hospital procedures for 2021 by the IPCA (IBGE). Source: Ministry of Health - SUS Hospital Information System (SIH/SUS). Elaborated by: Silvia Kobayashi, Alessandro Campolina and LCA Consultants.

As for the clinical aspects, cancers that originate in the lungs are morphologically divided into two main groups: non-small cell cancer (NSCLC) – 75% to 80% of the total –, which has a slower growth and dissemination pattern; and undifferentiated small cell cancers (SCLC) – about 20%.

- **NSCLC:** heterogeneous group composed of three distinct histological types, squamous cell carcinoma, adenocarcinoma and large cell carcinoma, often classified together because, when localized, they have the potential to be cured with surgical resection[94].

- **SCLC:** lymphocytic (oat cell), intermediate, and combined (small cell plus squamous cell carcinoma or adenocarcinoma). Oat cell tumors are a special subtype of cancer characterized by rapid growth, great capacity for dissemination, and early brain invasion.

93. José Alencar Gomes da Silva National Cancer Institute. 2020 estimate: Cancer incidence in Brazil / José Alencar Gomes da Silva National Cancer Institute. – Rio de Janeiro, INCA, 2019.

94. Removal of the tumor by surgical intervention.

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Only about 15% to 20% are diagnosed at an early stage, and symptoms usually occur when the cancer is advanced. The most common manifestation of lung cancer is the solitary pulmonary nodule (SPN), which corresponds to a single lung lesion, usually spherical, revealed by any imaging method, predominantly solid, not accompanied by lesions suggestive of metastases or invasion of neighboring structures, not associated with hilar enlargement or atelectasis, and usually with a diameter of less than 3 to 4 cm (Brazil/INCA, 2004)[95].

When the diagnosis of this cancer is suspected by means of the imaging method, it is necessary to confirm the histological type by means of bronchoscopy with biopsy, percutaneous puncture-biopsy or video-assisted thoracoscopy with biopsy. Tumor stage—that is, the determination of the location and extent of the cancer—as defined by the American Joint Committee on Cancer, is considered the most important prognostic factor. Disease staging procedures are essential to distinguish patients with disease limited to the chest from those who have distant metastases, differentiating the therapeutic strategy to be used and informing the patient's prognosis.

Cost-effectiveness analysis in the selected articles/reports

A total of 36 documents were selected from the bibliographic survey for PET, of which 26 were scientific articles and 10 were reports.

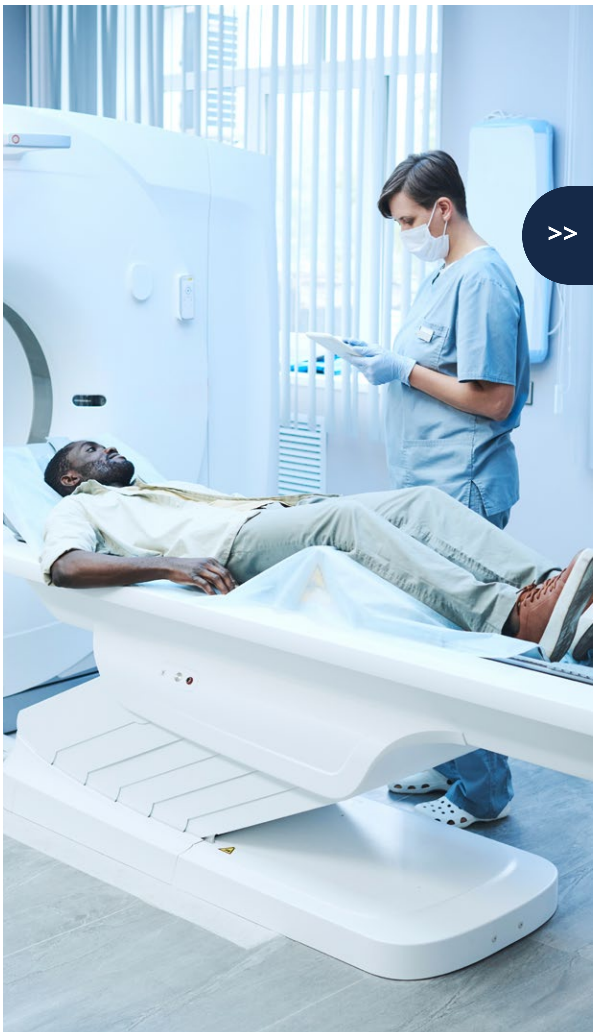
- Of the total number of articles, 18 (69%) evaluated PET, 6 (23%) evaluated PET-CT and 2 (8%) evaluated PET + mediastinoscopy. In addition, 18 (69%) compared the main technology with computed tomography (CT), 2 (8%) with mediastinoscopy, and another 2 (8%) with ultrasound-guided fine-needle aspiration (USG-FNA). The other comparators such as bronchoscopy, SPECT, and computed tomography with dynamic contrast (TC_CD) were also used.

- 12 articles (46%) use ACE for economic evaluation, 7 (27%) use ACU, and 6 (23%) use ACE.

- 22 (85%) concluded that the evaluated technology is cost-effective (ICER < LDP).

- Out of the 10 reports, 6 recommended the incorporation of the Technology evaluated.

The use of PET in oncology shows the following results: a greater number of correctly staged cancer patients, a reduction in the number of unnecessary surgeries, and a gain in QALYs.



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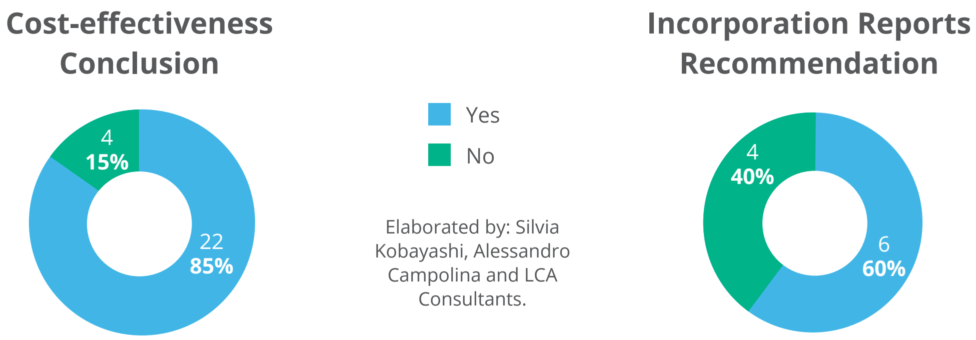
95. Report of Recommendation of the National Commission for the Incorporation of Technologies in the SUS – CONITEC – 107. PET-CT in the Staging of Lung Cancer Non-Small Cells Abril de 2014

Graph 13: Conclusion of documents on cost-effectiveness and incorporation of the CDI



O estadiamento inicial no CPNPC determina o melhor tratamento e é essencial para a Initial staging in NSCLC determines the best treatment and is essential for defining the prognosis. Incorrect staging can lead to inappropriate treatment (unnecessary surgeries in patients with advanced disease), as well as contraindication for curative surgery in patients with potentially curable disease (Van Tinteren et al., 2008)[96].

Patients with limited disease (stages I and II) are candidates for curative surgery followed by adjuvant chemotherapy in patients with stage II NSCLC. Because treatment is predominantly determined by the initial stage of NSCLC, the accuracy of the diagnostic work-up is crucial for appropriate therapeutic planning.

The standard diagnostic investigation of these patients is based on CT imaging, but the addition of PET[97] imaging has greater diagnostic accuracy than CT alone, and can also be economically favorable when implemented in the diagnostic algorithm (Bradbury et al., 2003; Dietlein et al., 2000; Klose et al., 2000; Van Tinteren et al., 2002; Pieterman et al., 2000)[98].

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96. Van Tinteren, H.; Hoekstra, O.S.; Smit, E.F. et al. Effectiveness of positron emission tomography in the preoperative assessment of patients with suspected non-small-cell lung cancer: the PLUS multi-centre randomised trial. Lancet. 2002; 359: 1388–93. Swensen SJ, Brown LR, Colby TV, et al. Lung nodule enhancement at CT: prospective findings. Radiology. 1996; 201: 447–55.

97. Usando o análogo de glicose 18F-FDG, como radiofármaco.

98. Bradbury, I.; Bonell, E.; Boynton, J. et al. Positron Emission Tomography (PET) Imaging in Cancer Management. Health technology assessment report 2. Glasgow: Health Technology Board for Scotland; 2003

[18F]-fluoro-2-deoxy-D-glucose (FDG-PET) positron emission tomography has a consistently important role in noninvasive evaluation of patients in the preoperative period of NSCLC. FDG-PET has high staging accuracy compared to CT and, therefore, has had a great impact on the identification of unresectable disease[99]. The combination of the two imaging procedures provided by hybrid PET-CT scanners was introduced in 2001, combining the advantages of morphological imaging with functional imaging (Beyer et al. 2000; Cerfolio et al., 2004)[100].

In this sense, PET is a recommendation to be considered in patients with NSCLC who receive potentially curative therapy (surgery or radiation therapy). The preoperative evaluation of NSCLC is, therefore, one of the main applications of FDG-PET.

To evaluate the impact of this diagnostic technology on the health system, a study (Kee et al., 2010)[101] aimed to estimate, from the point of view of payers, the ICER of NSCLC staging with integrated PET-CT in relation to CT alone (representing the main diagnostic test routinely performed). In this study, it was observed that:

1. The ICERs per correctly staged patient were US$ 3,508 for PET-CT when compared to CT alone.

2. The incremental cost-effectiveness rates per QALY gain were US$ 79,878 for PET-CT versus CT alone, decreasing to US$ 69,563 when considering the quality-of-life losses presented by patients;

3. With incremental costs of $939 per patient and incremental QALYs of 0.01 per patient for PET-CT compared to CT alone, the ICER of PET-CT was US$ 79,878 per QALY gained;

4. Despite an apparently elevated ICER when a minor surgical morbidity is assumed—i.e., the loss of quality of life due to surgical intervention is decreased—the PET/CT ICER moves below the LDP assumed in the study of US$ 62,780/QALY gained for the United Kingdom (Kee et al., 2010)[102].

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Dietlein, M.; Weber, K.; Gandjour, A. et al. Cost-effectiveness of FDG-PET for the management of potentially operable n on-small cell lung cancer: priority for a PETbased strategy after nodal- negative CT results. Eur J Nucl Med. 2000; 27: 1598–1609. Klose, T.; Leidl, R.; Buchmann, I.; Brambs, H.J.; Reske, S.N. Primary staging of lymphomas: cost- effectiveness of FDG-PET versus computed tomography. Eur J Nucl Med. 2000; 27: 1457–1464. Van Tinteren, H.; Hoekstra, O.S.; Smit, E.F. et al. Effectiveness of positron emission tomography in the preoperative assessment of patients with suspected non-small-cell lung cancer: the PLUS multicentre randomised trial. Lancet. 2002; 359: 1388–1393. Pieterman, R.M.; Van Putten, J.W.; Meuzelaar, J.J. et al. Preoperative staging of non-small cell lung cancer with positron-emission tomography. N Engl J Med. 2000;343: 254–261.

99. A disease in which a surgical procedure to remove the tumor is not possible.

100. Beyer, T.; Townsend, D.W.; Brun, T. et al. A combined PET/CT scanner for clinical oncology. J Nucl Med. 2000; 4: 1369–1379.
Cerfolio, R.J.; Ojha, B.; Bryant, A.S.; Raghuveer, V.; Mountz, J.M.; Bartolucci, A.A. The accuracy of integrated PET-CT compared with dedicated PET alone for the staging of patients with nonsmall cell lung cancer. Ann Thorac Surg. 2004;78: 1017–1023.

101. Kee, F.; Erridge, S.; Bradbury, I.; Cairns, K. The value of positron emission tomography in patients with non-small cell lung cancer. European Journal of Radiology 73 (2010) 50–58.

102. Ibid. 101.

In another study (Schreyögg et al., 2010)[103] conducted in Germany from the perspective of the United Kingdom:

1. The ICERs associated with the decision to opt for a PET strategy over a non-PET strategy for NSCLC patients aged 50, 60, 70 and 80 years were £6,704 (US$7,629), £8,385 (US$9541), £10,636 (US$12,103) and £13,785/QALY earned ($15,686), respectively;

2. For all of these estimates, all figures were well below the LDP of approximately £30,000/QALY earned ($34,137) by the NICE agency.

3. More generally, and reinforcing the implications of the previous study, the impact of quality of life (in terms of the preferences and desires of the patient) in ICER, PET and other diagnostic tests have been investigated less thoroughly than the impact of increased technical accuracy. The authors then suggest that more attention should be paid to patients' preferences.

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In Brazil, a study by Cerci et al. (2012)[104] compared the accuracy and cost-effectiveness of metabolic staging (MS) with FDG-PET in relation to conventional staging (CE) in the initial staging of patients with NSCLC.

1. The initial staging of the 95 patients by CT procedures had a total cost of R$ 114,000, while by FDG-PET the cost was R$ 126,350. The calculated cost of PET-CT would be R$ 193,515 in these same patients;

2. The cost of futile thoracotomy105 in 31 patients in the CS totaled R$ 308,915; in 8 patients in the MS, the sum was R$ 79,720, representing a total saving of R$ 229,195;

3. The authors concluded that, in line with other studies, the results demonstrated the benefits of MS, with a significantly lower percentage of futile thoracotomy relative to the rate by CE (19% versus 47%).

103. Schreyögg, J. et al. Cost-Effectiveness of Hybrid PET/CT for Staging of Non–Small Cell Lung Cancer. The Journal of Nuclear Medicine 2010; 51(11):1668-75.

104. Cerci, J.J. et al. Positron emission tomography with 2-[18F]-fluoro-2-deoxy-D-glucose is cost-effective in patients with non-small cell lung cancer in Brazil. Radiology Bras. 2012; 45(4):198–204.

The same authors, in a study with two hundred and ten patients with newly diagnosed Hodgkin's lymphoma (HL), estimated the ICER of FDG-PET at the initial staging of these patients (Cerci et al., 2011)[106]. Reinforcing the efficiency of this diagnostic method, the results showed that:

1. The ICER of the PET-CT strategy was US$ 16,215 per patient with modified treatment and;
2. The costs of PET-CT at the beginning and end of treatment would increase the total costs of LH staging and treatment top-notch by only 2%.

In 2010, the Technical Board of Evidence-Based Medicine for UNIMED members, in the context of supplementary health, published a favorable opinion on the use of PET in the staging of NSCLC for cases with apparently localized disease and candidates for treatment with surgical resection, due to its greater sensitivity and specificity for the detection of mediastinal metastases, the ability to detect a higher proportion of patients with more advanced stages of the disease and thus avoid a greater number of patients with a greater number of patients. surgeries were unnecessary than among patients undergoing traditional staging. This same opinion, however, contraindicated the use of PET for routine use in the planning of radiotherapy in patients with NSCLC. In the same year, CONITEC also published an unfavorable opinion on the use of PET in the diagnosis, staging and restoration of Small Cell Lung Cancer.

In the context of the SUS, in 2014, CONITEC recommended the incorporation of PET-CT for the clinical staging of potentially resectable non-small cell lung cancer. The report cites an ICER of R$ 14,252.70 per unnecessary surgery avoided in the staging strategy using PET scans in patients with negative CT scan results. The adoption of PET-CT in the staging of NSCLC was considered more accurate, as it eliminates unnecessary surgeries resulting from undiagnosed advanced disease, and is cost-effective with a 90% probability of disbursing the amount of R$ 20,000.00 per avoided surgery. Thus, this incorporation of Technology could have a positive impact on morbidity and mortality and the more efficient use of public resources.

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105. Surgical procedure to open the thoracic cavity that does not generate relevant clinical benefit to the patient.

106. Cerci, J.J. et al. Consistency of FDG-PET Accuracy and Cost-Effectiveness in Initial Staging of Patients with Hodgkin Lymphoma Across Jurisdictions. Clinical Lymphoma, Myeloma & Leukemia 2011; 11 (4): 314-20.

Table 9: Summary table of the main results of the studies evaluated in PET

Methodology	Country	Result
ACU	United Kingdom	Despite a high ICER for oncological staging with PET compared to CT (US$79,878/QALY gained), the technology could be considered cost-effective if lower morbidity related to surgical intervention were assumed (Kee F, et al, 2010).
ACU	Germany	Oncological staging strategy with PET in patients with NSCLC would be cost-effective in different age groups, with ICERs ranging from £6,704 (US$7,629) to £13,785/QALY earned (US$ 15,686), all being below the proposed LDP by NICE (Schreyögg J, et al. 2010).
ACC	Brazil	95 patients with NSCLC evaluated; patients staged with CT had a total cost of R$114,000 and those with FDG-PET had a total cost of R$126,350, and the group staged with FDG-PET had a lower rate of unnecessary surgeries – 19% versus 47% of the group staged with TC (Cerci JJ, et al. 2012).
ACE	Brazil	In 210 patients with Hodgkin's lymphoma evaluated, PET-CT staging showed an estimated ICER of US$16,215 per patient with modified treatment, and the costs of PET-CT would increase the total costs of LH staging and treatment by only 2% (Cerci JJ, et al. 2011).
Reports	Brazil	In the context of Supplementary Health and in the context of the SUS, both the Technical Chamber of Evidence-Based Medicine for UNIMED members and CONITEC recommended the use of PET in the staging of NSCLC for cases with localized disease and candidates for treatment with surgical resection, due to its ability to detect a higher proportion of patients with more advanced stages of illness and thus avoid unnecessary surgeries.

Elaborated by: Silvia Kobayashi, Alessandro Campolina and LCA Consultants.

The case of diagnostic imaging using PET technology shows that the innovation in the nature and quality of acquired images, in the staging process of oncological disease, represents a potential for improving the clinical management of patients with NSCLC; to the extent that it would make it possible to select more accurately the patients who are candidates for surgical procedures and who are not. Avoiding futile surgical procedures represents a great benefit for patients suffering from a debilitating disease such as cancer, but also a possibility to save money for resources that would

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In international and national contexts, some studies suggest that ICERs associated with the use of PET in NSCLC may be below those of LDPs adopted in different health systems. Although the use of PET leads to an increase in the initial costs of performing the diagnostic procedure, this increase can be compensated by reducing the resources used in the management of the oncological disease in the longer term.

Main results

The incorporation of PET-based diagnostic methods illustrates the efficiency of a disruptive technology in modifying the chain of resource utilization in a specific disease. In the case of diagnostic imaging, the study showed that a high-cost technology such as FDG-PET or PET-CT can change the production chain of health services in the area of oncology, leading to cost reductions that can in the end, make this technology cost-effective in different contexts. The figure below summarizes the main findings of the PET study.

Figure 24: Main results in PET

84.6% of the articles indicate PET as cost

HTA studies show that innovation in imaging brought by the PET scan avoids unnecessary surgeries.

Despite the use of PET leading to increased upfront costs. This can be compensated by reducing the resources used in the management of oncological disease in the long term.

Greater diagnostic accuracy and effectiveness in patients

Higher accuracy (94% vs. 86%), higher diagnostic effectiveness for correct staging (60% vs. 40%) and greater diagnostic effectiveness for the evaluation of tumor resectability (84% vs. 70%) for PET-CT compared to CT.

Lower rate of unnecessary surgeries (19% vs. 47%) in the PET staging group compared to the CT staging group. Staging with PET would modify the treatment of 41% of these patients.

In addition to the impact of the use of PET in cases of NSCLC, the higher sensitivity of PET compared to tomography (97.9% vs. 87.3%) in cases of patients with Hodgkin's Lymphoma is also noteworthy.

PET can **change the supply chain of services** in the field of oncology

Incorporation of PET is an example of how a technology can add sufficient therapeutic benefits, to the point of representing a good option for allocating resources in different contexts.

Elaborated by: Silvia Kobayashi, Alessandro Campolina and LCA Consultants.

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The average total expenditure on lung cancer surgeries in Brazil, considering the period from 2018 to 2021, was R$ 11 million per year. Based on this mean value, the difference between the rates of unnecessary surgeries between the groups staged with PET and CT represents approximately R$ 3 million, 28% of the expenditure on this procedure, as shown in Figure 25 below.

Figure 25: Savings with reduction of unnecessary surgeries generated by staging performed with PET

-28%
- R$ 3 million per year

Savings on surgeries unnecessary oncology (deflated to 2021 values)

Note: total values deflated for 2021 by the IPCA (IBGE). Source: Ministry of Health - System of Hospital Information of the SUS (SIH/SUS). Elaborated by: Silvia Kobayashi, Alessandro Campolina and LCA Consultants.

STUDY 3: HIP REPLACEMENTS

Technology Description

Prostheses for total hip arthroplasty (THA) surgeries are made with biocompatible materials such as cobalt, chromium-titanium and high-density polyethylene. There are several types of prostheses and combinations of materials possible in THA, both with regard to the acetabular component and the femoral component (head). Current implants have four main combinations of femoral head and acetabular support surface materials: metal-polyethyleneA (MoP), ceramic-to-polyethylene (CoP), ceramic-to-ceramic (CoC), or metal-to-metal (MoM). Metal-ceramic implants are uncommon and the most widespread in clinical practice are MoP-type implants.

The polyethylene that covers the acetabular component in the CoP and MoP combinations have different compositions and can also be classified as highly cross-linked (a new generation of polyethylene) or not highly cross-linked (including different types of polyethylene). The polymerization of ethylene creates ultra-high molecular weight polyethylene, which is biocompatible and wear-resistant due to its low-friction surface. On the other hand, cross-linked polyethylene is obtained by the process of irradiation of polyethylene with gamma rays, producing "cross-links" in the molecule of the material, and free radicals are removed by increasing the pre-melt temperature (Brazil/Ministry of Health, 2018)[107].

Possible fixation techniques (the method of attaching the material from the bearing surface to the bone) also vary between cemented (when both components are cemented), uncemented (no component is cemented), hybrid (the femoral stem, but not the acetabular dome, is cemented), or reverse hybrid (the acetabular cup, but not the femoral stem, is cemented) (Brazil/Ministry of Health, 2018)[108]. Thus, we

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107. Recommendation Report. Ministry of Health. Ceramic-polyethylene prostheses for total hip arthroplasty in young patients. November/2018. 2018.

108. Ibid. 107.

have: (i) cemented prosthesis: uses bone cement to fix the acetabular component in the pelvis and the femoral part in the femur; (ii) non-cemented prosthesis: its parts (acetabulum and femoral component) are fixed directly to the bone surface, without the use of cement (Central UNIMED-RS, 2012)[109]; (iii) hybrid prosthesis: the acetabular component is fixed to the pelvis by means of screws, and the femoral component is fixed with cement to the femur. On average, a prosthesis lasts around 15 to 20 years (Central UNIMED-RS, 2012)[110].

Most Commonly Addressed Area/Disease

According to Ordinance No. 503, of March 8, 2017, which approves the author's standards in the case of the use of total knee prosthesis and hybrid total hip prosthesis, the Unified Health System (SUS) provides replacement surgery for hybrid total hip prosthesis (where only one of the components is cemented, most commonly the femoral), consisting of a titanium alloy metal acetabular component with fixation and with holes to allow the placement of screws (Brazil/Ministry of Health, 2018)[111].

In recent years, the population of elderly people in Brazil has been growing rapidly, and it is estimated that, in 2030, it will represent 13.44% of the total population. In the 2010 census of the Brazilian Institute of Geography and Statistics (IBGE), the number of elderly people was 20,438,561, representing 11.8% of the population.

The Health, Well-being and Aging (SABE) study, carried out in the city of São Paulo, found that 28.6% of the elderly reported falls, which increased with age. It was observed that 26.2% of these falls occurred in people between 60 and 74 years of age and 36.9% in people over 75 years of age, being more frequent in women (33.0%) than in men (22.3%). The occurrence of falls is an important problem in the elderly, and fractures, particularly those of the femur (cervix or other parts), can lead to various types of complications, including death. In the same study, activity limitations and arthritis/rheumatism/arthrosis (31.7%) were identified as the main factors responsible for this condition. Of these elderly, 62.6% reported having some type of limitation, 22.1% were very limited and 40.5% had little limitation.

The Center for the Study of Aging of the Federal University of São Paulo (UNIFESP) conducted a cohort study to evaluate the factors associated with falls and their recurrences in a population of community-dwelling older adults. Of the 1,415 older adults evaluated, 32.7% reported having suffered a fall in at least one of the surveys and 13.9% said they had suffered falls in both the first and second surveys.

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109. Recommendations of the National Technical Board of Evidence-Based Medicine of the UNIMED System.

Analysis of hip prosthesis implantation studies comparing different coating surface materials (metal, metal-polyethylene, ceramic-ceramic, ceramic-polyethylene). 2012.

110. Ibid 109.

111. Report to Society, n.135. CONITEC, Ministry of Health. Ceramic Prosthetics-Polyethylene for tota hip arthroplasty in young patients. 2018.

Proximal femoral fractures are the leading cause of fall-related death in the elderly, accounting for about 340,000 hospitalizations per year in the United States, at a cost of approximately three billion dollars.

In Brazil, DATASUS data showed that in 2021 there were 114,921 hospitalizations due to femoral fractures, with 3,966 deaths (mortality rate of 3.45). The average length of stay of these hospitalizations was 7 days and the total amount for SUS was R$ 286.25 million.

Table 10: Statistics on femoral fracture in Brazil, 2018 to 2021

Femoral fracture	2018	2019	2020	2021
Hospitalization	103.211	109.189	109.229	114.921
Deaths	3.398	3.603	3.615	3.966
Mortality Rate (%)	3,29	3,30	3,31	3,45
Lenght of Stay (days)	8,1	7,9	7,1	7,0
Total (R$ million)	294,54	307,71	296,06	286,25

Note: total values include expenses with hospital procedures deflated for 2021 by the IPCA (IBGE). Source: Ministry of Health - SUS Hospital Information System (SIH/SUS). Elaborated by: Silvia Kobayashi, Alessandro Campolina and LCA Consultores.

Femoral neck fractures are divided into two groups, considering the displacement of bone fragments, a factor that has repercussions on the choice of surgical treatment to be adopted (Brazil/Ministério da Saúde, 2018)[112]:

1. Non-Deviated Femoral Neck Fractures: the indicated treatment modality consists of performing a preservation procedure, opting for by performing osteosynthesis with the application of extramedullary implants (screws or plate system and sliding screw with fixed angle).

2. Deviated Femoral Neck Fractures: a procedure is indicated partial arthroplasty or total arthroplasty may be performed, depending on the individual characteristics of the elderly person to be treated.

112. CONITEC Recommendation Report, Ministry of Health No. 323. Brazilian guidelines for the treatment of femoral neck fractures in the elderly. No 323. October/2018. 2018.

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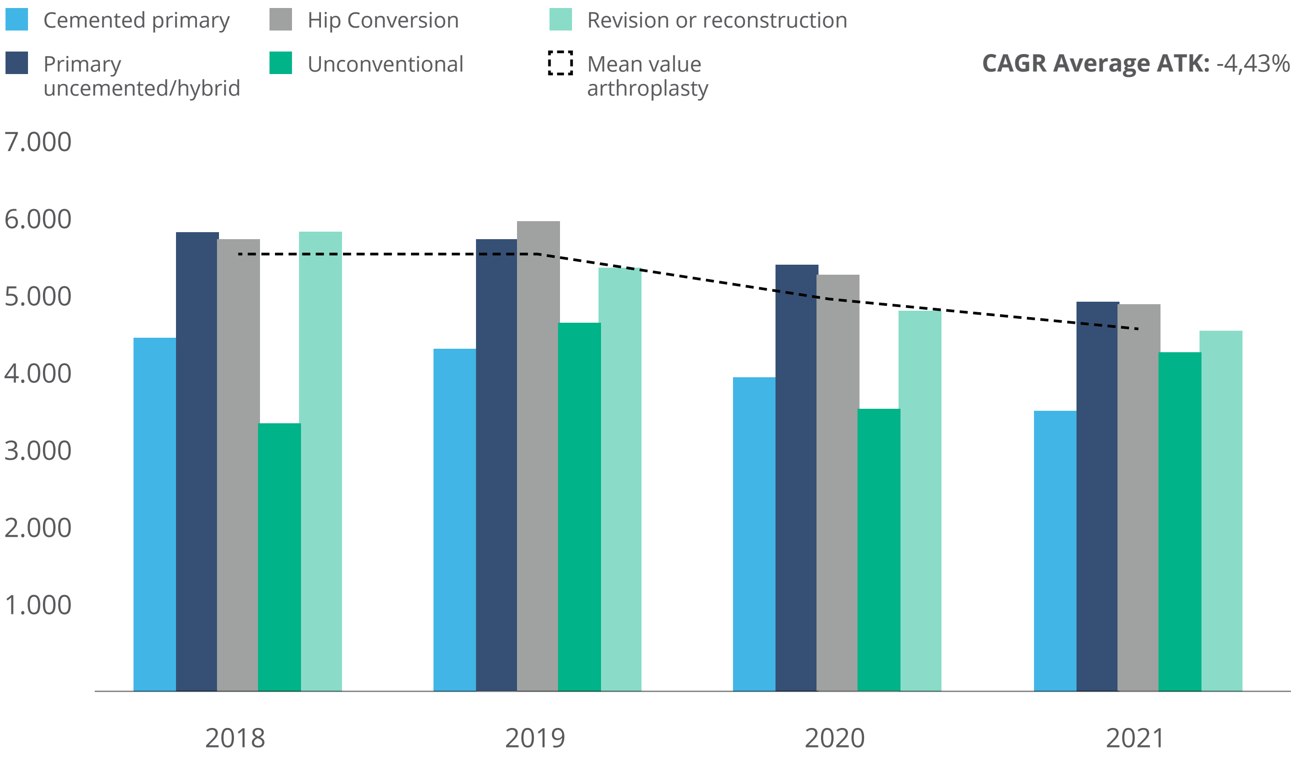
The Total Hip Arthroplasty (THA) is a replacement surgery of the injured hip joint by a mechanical model called a total hip prosthesis with biocompatible materials, which reproduces joint function similar to the original biological model.

There are several reasons why your doctor may recommend hip replacement: hip pain that limits day-to-day activities, such as walking or slouching; hip pain, even at rest, day or night; hip stiffness that limits the ability to move or lift the leg; insufficient pain relief with the use of anti-inflammatories; physical therapy or walking aids. The most common cause of chronic pain and dysfunction in the hip is arthritis, such as: osteoarthritis, rheumatoid arthritis and traumatic arthritis.

It is estimated that more than 300,000 THAs are performed each year in the United States alone and that 2.5 million people currently live with a hip replacement in that country, however there is a constant increase in the number of procedures both due to longer life expectancy and also due to the growth in the use of THA in younger and more active patients.

According to data from the SUS Hospital Information System (SIH/SUS), of the Ministry of Health, in 2021, 12,609 total hip arthroplasties were performed (2,919 cemented primary, 7,779 non-cemented/hybrid primary, 286 hip conversion, 52 non-conventional, and 1,573 revision or reconstruction), totaling R$ 58.85 million spent by SUS.

Chart 14: Value by type of arthroplasty in R$ (updated for 2021), 2018 to 2021[113]



Note: total values deflated for 2021 by the IPCA (IBGE). Source: Ministry of Health – Information System SUS Hospital Hospitals (SIH/SUS). Elaborated by: Silvia Kobayashi, Alessandro Campolina and LCA Consultants.

113. CAGR by type of arthroplasty: (i) Cemented primary: -5.68%; (ii) Cementless/hybrid primary: -4,01%; (iii) Hip conversion: -3.97%; (iv) Unconventional: 6.78%; (v) Revision or reconstruction: -5.76%.

Possible complications of arthroplasty are: cellular reactions to small particles of metal or bone cement that over time generate a bone reaction that can cause osteoporosis, make the prosthesis loose, cause pain or pain bring the bone; infection, which, although rare, when it occurs is serious; dislocation of the prosthesis, which may occur during the first postoperative weeks; and release of the prosthesis.

Despite the benefit obtained by the initial surgery, it is known that artificial articular prostheses have a limited duration, and it is not uncommon for them to present dysfunction after 10 or more years of joint replacement, requiring hip prosthesis revision surgeries (Brazil/Ministry of Health, 2009)[114].

Análise de custo-efetividade nos artigos/relatórios selecionados

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A total of 19 documents were selected in the bibliographic survey for hip prostheses, of which 14 were scientific articles and 5 were Reports.

- 5 (36%) articles evaluated the cementless prosthesis, 3 (21%) evaluated early arthroplasty, and 2 (14%) the hybrid prosthesis. The other studies evaluated prostheses of various materials. There were 6 (43%) articles that compared the main technology with the cemented prosthesis and 3 (21%) with the delayed arthroplasty. The other comparators used were prostheses with different types of materials.

- 10 articles (71%) use ACU for economic analysis, 2 (14%) ACC, 1 (7%) ACE, and 1 (7%) ACB.

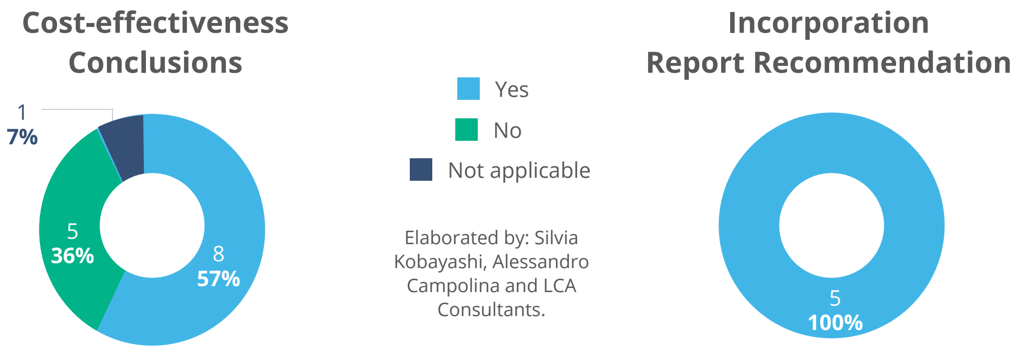
- 8 articles (57%) concluded that the evaluated technology was cost-effective.

- The 5 Reports recommended the incorporation of the Technology evaluated.

The following are observed: (i) reduction in in-hospital mortality with early hip arthroplasty (THA); (ii) reduction of hospitalization costs with early THA; (iii) gain in QA-LYs; (iv) reduction of revision surgery rates; (v) longer life of the prosthesis, and (vi) higher postoperative quality of life.

114. Caliari, Report de Recommendation Ministry of Health. Prosthesis for revision hip arthroplasty with material other than the primary one (acetabular tantalum component for revision hip prosthesis surgery). No 427. February/2019. 2019.

Graph 15: Conclusion of documents on cost-effectiveness and incorporation of Hip Prosthesis



Elaborated by: Silvia Kobayashi, Alessandro Campolina and LCA Consultants.

Proximal femoral fractures are considered an important public health problem and have very serious repercussions for elderly patients, with high morbidity and mortality, a high rate of postoperative disability, and increasing costs for both the family and society (Wei et al., 2001; Cummings et al., 2002)[115].

Total hip replacement is one of the most common surgical procedures. Over the years, a large number of different prosthetic designs have been developed and introduced to the market. Currently, prosthesis brands are often grouped into cemented, non-cemented, and hybrid prostheses.

The first effective hip implants were developed in the 1950s, with a small metal head that articulates with a polyethylene cup fixed with bone cement. They are the cheapest and most prevalent type of hip implant, with a long history of use worldwide (Karrholm et al., 2016; Berry et al., 2002)[116].

However, the polyethylene component wears down with increasing physical activity and loading, resulting in loosening and bone loss over time, which is more common in younger, more active patients, and implant failure requires additional surgery to revise and replace the prosthetic hip implant.

115. Wei, T.S.; Hu, C.H.; Wang, S.H.; Hwang, K.L. Fall characteristics, functional mobility and bone mineral density as risk factors of hip fracture in the community-dwelling ambulatory elderly. Osteoporos Int. 2001;12(12):1050–5.

Cummings, S.R.; Melton, L.J. Epidemiology and outcomes of osteoporotic fractures. Lancet. 2002;359(9319):1761–7.

116. National Joint Registry. 14th Annual Report. Bristol, UK: National Joint Registry for England, Wales, Northern Ireland and the Isle of Man; 2017. Karrholm, J.; Lindahl, H.; Malchau, H.; Mohaddes, M.; Rogmark, C.; Rolfson, O. Swedish Hip Arthroplasty Register: Annual Report 2015. Gothenburg, Sweden: Swedish Hip Arthroplasty Register; 2016.

Australian Orthopedic Association. Hip, Knee and Shoulder Arthroplasty Annual Report 2016.

Sydney, Australia: Australian Orthopedic Association National Joint Replacement Registry; 2017.

Berry, D.J.; Harmsen, W.S.; Cabanela, M.E.; Morrey, B.F. Twenty-five-year survivorship of two thousand consecutive primary Charnley total hip replacements: factors affecting survivorship of acetabular and femoral components. J Bone Joint Surg Am 2002;84-a (2):171e7.

Non-cemented prostheses, although the most expensive, have become the most commonly used type of prosthesis for total hip arthroplasty in countries such as England, Wales, Italy, Australia, Canada and the United States; and hybrid prostheses have progressively grown in popularity (NJR, 2011; CJRR 2009; Graves et al., 2011; Mendenhall, 2004; Stea et al., 2009)[117]. The increased use of cementless components has contributed to doubling the costs of prostheses over the years. Although a study analyzing data from the National Joint Registry for England and Wales, the world's largest orthopedic registry, suggested that cementless dentures may be associated with lower mortality rates than cemented dentures, evidence has been scarce to assess whether the increased costs of cementless components are actually justified by better health outcomes.

Given the variety of implant combinations currently available at widely differing prices and the increasing volume of THA procedures performed worldwide, it is important to consider the ICER of prosthetic implants for different groups of patients undergoing THA surgery.

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117. National Joint Registry for England and Wales. National joint registry, 8th annual report. NJR, 2011.
Hip and knee replacements in Canada—Canadian Joint Replacement Registry (CJRR) 2008- 2009 annual report.
Canadian Institute for Health Information, 2009.

Graves S, Davidson D, de Steiger R, Tomkins A, Ryan P, Griffith L, et al. Australian Orthopaedic Association National Joint Replacement Registry. Annual report. AOA, 2011.

Mendenhall S. Hip and knee implant review. Orthopedic News Network 2004; 14:1-16.

Stea, S.; Bordini, B.; De Clerico, M.; Petropulacos, K.; Toni, A. First hip arthroplasty register in Italy:
55,000 cases and 7 year follow-up. Int Orthop 2009; 33: 339-46

A Brazilian study conducted by Loures et al. (2015a)[118] sought to evaluate the cost-effectiveness of the early surgery strategy for hip fractures in the elderly, the direct costs of the early and late surgery groups showed statistically significant differences:

1. Of the 110 patients studied, 27 were allocated to the "early" group and 83 to the "late" group.
2. In-hospital mortality was higher in the late surgery group (7.4% versus 16.9%);
3. The decision tree, elaborated for the study, showed the dominance of the early surgery strategy in relation to late surgery, with R$ 9,854.34 (US$ 4,387.17) against R$ 26,754.56 (US$ 11,911.03) by QALY earned, respectively;
4. Costs per patient were R$ 3,626.00 (US$ 1,614.28) in the early surgery group versus R$ 5,622.31 (US$ 2,503.03) in the late surgery group ($p < 0.005$), with the daily rate of the infirmary being the item that most contributed to this difference: R$ 794.98 (US$ 353.92) against R$ 1,881.44 (US$ 837.61) ($p < 0.001$);
5. The authors selected cases of hip fracture between January 2008 and September 2012 from SIH-DATASUS and obtained 215,442 paid hospital Hospitalization authorizations in this period, with an average of 45,356 cases of proximal femoral fracture on average per year;
6. It was concluded that instituting early surgery as a routine, i.e., fracture-surgery interval of less than four days, would generate savings of R$ 90,544,636.36 (US$ 40.31 million) in costs, with the potential to save 3,882 lives and produce a surplus of 3,129 QALY per year.

In another study (Loures et al., 2015b)[119], carried out by the same authors, the two strategies were considered:

1. In every thousand patients submitted to the early surgery strategy, Compared to the delayed surgery strategy, 94 lives would be saved.
2. Hospital stay was statistically significant between the two groups, with a mean length of stay of 7.22 days (SD 3.43 days) for patients in the early surgery strategy versus 15.90 days (SD 6.81 days) in those in late surgery.

118. Loures, F.B.; Chaoubah, A.; de Oliveira, V.M.; Almeida, A.M.; Campos, E.M.S.; de Paiva, E.P. Economic analysis of surgical treatment of hip fracture in the elderly. R. Public Health 2015; 49: 12. doi:10.1590/S0034-8910.2015049005172.

119. Loures, F.B.; Chaoubah, A.; Maciela, V.S.; Paivab, E.P.; Salgado, P.P.; Netto, A.C. Cost-effectiveness of surgical treatment of hip fracture in the elderly in Brazil. Rev Bras Orthopedics 2015B; 50(1): 38-42.

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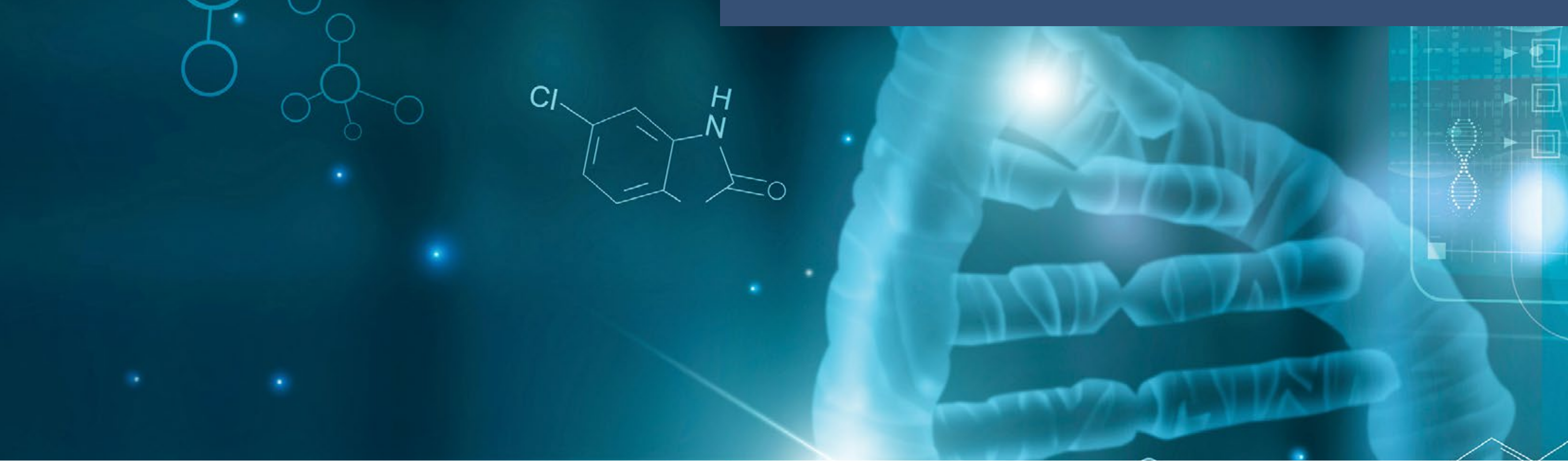

In a study conducted in the United Kingdom (Pennington et al. 2013)[120], the authors sought to estimate the ICER of the three types of prostheses most commonly chosen for total hip replacement (cemented, non-cemented, and hybrid):

1. In men and women aged 70 to 80 years, revision rates at five and 10 years were lower for cemented prostheses and higher for cementless prostheses;
2. Only in 60-year-old men were cementless prostheses competitive in terms of 10-year revision rates;
3. In all subgroups, the initial costs were lower with cemented prostheses and higher with non-cemented prostheses;
4. Hybrid prostheses were highlighted for producing higher expected QALYs at a lower overall cost than cementless prostheses;
5. The ICER for a hybrid prosthesis compared to a cemented prosthesis was around £2,100 ($2,390) per QALY earned for men and £2,500 ($2844) for women;
6. In patients aged 70, which is roughly the average age of those who had undergone a total hip replacement for osteoarthritis, the incremental costs per QALY for hybrid prostheses compared to cemented prostheses were around £2,100 ($2,390) for men and £2,500 ($2,844) for women;
7. In all subgroups, with the exception of women in the age group of 80 years, hybrid prostheses resulted in higher mean quality postoperative life than cementless or cemented prostheses, and were more likely to be the most cost-effective;
8. The study questioned the increased use of cementless prostheses for total hip arthroplasty, reinforcing that cemented prostheses are the cheapest option, but estimated that hybrid prostheses would lead to greater gains in the average postoperative quality of life and would be the alternativemore cost-effective for most patients.

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In a more recent study (Fawsitt et al. 2019)[121], the authors evaluated the cost-effectiveness of 24 types of prostheses, with different combinations of materials and fixation strategies:

1. Cemented metal implants over polyethylene with a small head were the most cost-effective for men and women over 65 years of age, and these findings were robust for the sensitivity analyses performed;

2. Cemented ceramic implants over small-head polyethylene were more cost-effective in men and women younger than 65 years, but these results were more uncertain;

3. In older age categories, the small-head cemented polyethylene-metal implant combination (reference implant) consistently had lower implant costs and longer service life, low revision rates, and QALY gains equal to or greater than all other implant combinations;

4. The authors concluded that they found no evidence that cementless, hybrid, or reverse hybrid implants were the most cost-effective option for any group of patients.

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In 2010, the Technical Board of Evidence-Based Medicine for UNIMED members, in the context of supplementary health, published an opinion with an analysis of the evidence on total hip arthroplasty with cemented versus non-cemented fixation, concluding that there is a trend towards better results, with greater durability of the prosthesis, in the long term (> 10 years of follow-up), in patients who underwent total hip arthroplasty with cemented fixation.

In 2012, it issued an opinion on hip prosthesis implantation comparing different coating surface materials (metal-to-metal, metal-to-polyethylene, ceramic-to-ceramic, ceramic-to-polyethylene). Based on the analysis of 17 randomized clinical trials published from 2006 to 2012, it was concluded that there was no clinical evidence of superiority among the components of hip prosthesis coatings described in the literature: both ceramic, polyethylene and metal coatings showed a good rate of revision-free survival of the prostheses.

120. Pennington, M.; Grieve, R.; Sekhon, J.S.; Gregg, P.; Black, N.; van der Meulen, J.H. Cemented, cementless, and hybrid prostheses for total hip replacement: cost effectiveness analysis. BMJ 2013; 27 (346): f1026. DOI: 10.1136/bmj.f1026.

121. Fawsitt, C.G. et al, Choice of Prosthetic Implant Combinations in Total Hip Replacement: Cost- Effectiveness Analysis Using UK and Swedish Hip Joint Registries Data. Value in Health 2019: 303-21. https://doi.org/10.1016/j.jval.2018.08.013.

In 2018, in the context of the SUS, CONITEC published the Brazilian Guidelines for the treatment of femoral neck fractures in the elderly. Regarding the type of fracture, it recommends:

1. Arthroplasty for displaced femoral neck fractures has better functional results and lower reoperation rates compared to open reduction and internal fixation[122].

2. Total hip arthroplasty is also indicated for elderly patients with deviated femoral neck fractures who show signs of coxarthrosis (hip arthrosis), with community functional demand (those who can perform community activities in addition to domestic activities) and good cognitive capacity (attention, judgment, reasoning, memory, language), as long as there are favorable clinical conditions.

3. As for the type of prosthesis, he recommends unipolar prostheses because they have a lower cost. Although no statistical and clinical difference was found between cemented and non-cemented techniques, it indicates the best option cemented total arthroplasty for the treatment of elderly patients with displaced femoral neck fractures.

That same year, CONITEC published a report on ceramic-polyethylene prostheses for total hip arthroplasty in young patients. A cost-minimization and budget impact analysis were carried out to estimate the economic impact of the incorporation of ceramic-polyethylene prostheses from the perspective of the SUS as a source of payment:

1. The result was an incremental cost per surgery of R$ 2,217.95, with a variation in the sensitivity analysis (depending on the price of the ceramic cephalic component) from R$ 561.52 to R$ 6,936.52 per surgery;

2. The annual budget impact ranged from R$ 649,310.81 in the first year of incorporation to R$ 2,927,541.78 in the tenth year after incorporation;

3. The opinion concluded that the studies indicated a lack of clinical benefit of CoP over MoP in primary THA, both in young patients and in patients in general;

4. The cost-minimization analysis performed, as well as the calculation of the budgetary impact, indicated a relevant economic impact of the incorporation of the ceramic-polyethylene prosthesis in the public health system, although only for the subgroup of young patients (arbitrarily defined as those under 55 years of age). Even so, the Commission unanimously issued a recommendation in favor of the incorporation of ceramic-polyethylene prostheses (ceramic heads associated with polyethylene acetabular components) for patients with indication for primary total hip arthroplasty (THA).

122. Surgery in which the fractured parts are aligned and plates and/or screws are placed.

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Table 11: Summary table of the main results of the studies evaluated on hip prostheses

Methodology	Country	Result
ACU	Brazil	110 patients were studied, 27 underwent early THA and 83 late THA, in-hospital mortality (7.4% vs. 16.9%) and costs per patient (R$3,626.00 vs. R$5,622.31) were lower in those who underwent early THA. The daily rate of the infirmary was the item that contributed most to the difference (Loures FBa, et al. 2015).
ACU	United Kingdom	Considering the 2 strategies, early THA and late THA, the authors showed that the early strategy would save 94 lives for every 1000 patients undergoing surgery (Loures FBb, et al. 2015). Considering cemented, non-cemented and hybrid prostheses, with the exception of women in the age group of 80 years, hybrid prostheses resulted in a higher mean postoperative quality of life and were highlighted for producing greater gains of QALYs at a lower cost (Pennington M, et al. 2013). Comparing 24 types of prostheses, cemented metal implants over small-head polyethylene were the most cost-effective for men and women over 65 years of age. Cemented ceramic implants over polyethylene with a small head were more cost-effective in men and women under the age of 65 (Fawsitt, et al. 2019).
Reports	Brazil	In the context of Supplementary Health, the Technical Board of Evidence-Based Medicine for UNIMED members published an opinion with favorable evidence pointing to greater durability of the prosthesis for patients undergoing THA with cemented fixation. In another opinion, he concluded that there was no clinical evidence of superiority between the components of prosthesis coatings – both coatings with ceramic, polyethylene and metal showed a good rate of revision-free survival of the prostheses. In the context of the SUS, CONITEC published the Brazilian Guidelines for the treatment of femoral neck fractures in the elderly, recommending THA for displaced femoral neck fractures because it presents better functional results and lower reoperation rates. In another opinion, CONITEC indicated a relevant economic impact of the incorporation of the ceramic-polyethylene prosthesis in the public health system, although only for the subgroup of young patients. Even so, it unanimously issued a favorable recommendation the incorporation of the ceramic-polyethylene prosthesis.

Elaborated by: Silvia Kobayashi, Alessandro Campolina and LCA Consultants.

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The case of the incorporation of hip prostheses in health systems reveals how the use of a certain technology can impact health outcomes, while at the same time revealing how methods of economic evaluation in health can be used to support decisions and contribute to more efficient alternatives being selected among current technological innovations.

In the case of Brazil, early access to THA surgery and a technology that modifies the pattern of morbidity and mortality of patients with hip fractures and osteoarthritis can have significant impacts in terms of resource utilization and costs for the health system. Regardless of the cost of the technology itself, Brazilian authors have shown that the rapid performance of hip arthroplasties in cases of fractures can prevent hospitalization costs, making prostheses used in THA cost-effective options.

On the other hand, international studies have shown that economic evaluation studies are important decision-making tools and that the results obtained from the analyses may vary depending on the target population, the context of the health system, and the alternative technologies available for comparisons. Overall, all these results show that the incorporation of hip prostheses is a necessary condition to ensure the well-being of a population in the process of progressive aging and that the selection of available options can be made based on scientific methods, in order to support the allocation of resource-efficient efforts and ensure the sustainability of health systems.

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Main results

The studies analyzed indicate that the incorporation of hip prostheses is a condition needed to ensure the well-being of a progressively ageing population, and that the selection of available options can be made on the basis of scientific methods. The results varied according to the target population, the context of the health system and the alternatives of technology available for comparisons. The figure below summarizes the main results found.

Figure 26: : Main results in hip replacements

57.1% of the articles
indicate THA as cost-effective

Early access to total hip replacement can have significant impacts in terms of resource utilization and costs for the health system, mainly by preventing costs of prolonged hospital stay.

Higher quality of life and lower mortality
in-hospital in-hospital THA in

In general, hybrid prostheses were the ones that obtained the best results in terms of quality of life in the postoperative period, standing out as the ones that produced the greatest gains of QALYs at a lower cost.

In-hospital mortality is lower for early THA when compared to late THA (7.4% versus 16.9%).

In addition, the expenses in early THA are also lower when compared to late THA (R$3,626.00 vs. R$5,622.30), with the daily ward stay being the item that most contributed to this difference.

Early THA can have significant **impacts on resource utilization and costs** for the health system

The incorporation of hip replacements in health systems reveals how the use of a particular technology can impact health outcomes;

It also reveals how the methods of economic evaluation in health can be used so that more efficient alternatives can be selected among the current technological innovations.

Elaborated by: Silvia Kobayashi, Alessandro Campolina and LCA Consultants.

Considering the annual average of ATK expenditure of R$ 77 million between 2018 and 2021 in Brazil, this difference of R$ 3,626.00 against R$ 5,622.30 can result in a reduction of up to R$ 24 million, a saving of 31% in these expenses.

Figure 27: Economics with early THA

-31% OFF
- R$ 24 million/ year

Economy with early THA (deflated to 2021 values)

Note: total values deflated for 2021 by the IPCA (IBGE). Source: Ministry of Health - Information System SUS Hospital Hospitals (SIH/SUS). Elaborated by: Silvia Kobayashi, Alessandro Campolina and LCA Consultants.

BRIEF SUMMARY OF RESULTS

The 3 case studies showed that innovations in the area of medical equipment can represent efficient alternatives for the approach of prevalent health conditions in the areas of cardiology, diagnostic imaging and orthopedics.

In the case of cardiology, the study showed that more modern technologies, such as CRT-D (which associates an implantable defibrillator with cardiac resynchronization therapy), can be cost-effective and have been recommended for incorporation into different health systems.

In the case of diagnostic imaging, the study showed that a high-cost technology such as FDG-PET or PET-CT can change the production chain of health services in the area of oncology, leading to cost reductions that can ultimately make this technology cost-effective in different contexts.

In the case of orthopedics, the study showed that the wide variety of materials and fixation strategies related to existing hip prostheses makes the use of health economic evaluation methods important to assist in the choice of the most cost-effective alternatives, depending on the health system in question.

Overall, the 3 studies showed that different medical equipment can bring clinical benefits and contribute to the well-being of patients, in a workable way for the health system.

Figure 28: Summary of case studies

Cardioverter defibrillators implantable

TCR-D

- **Gain of 1.52 years of life** in patients with HF class II
- **Gain of 1.47 QALYs and higher projected survival (8.11 vs. 7.12)** in patients with mild HF class IICDI

CDI

- **Longer projected survival (6.99 vs. 5.95)** in patients with HF class II and III**. Gain of 1.42 years of life and 1.24 QALYs** in patients with class II and III HF
- **Higher gain in life years saved (11.79 vs. 8.54) and higher gain in QALYs (9.85 vs. 7.15)** when compared with patients treated with conventional drugs

Tomography Positron emission

FOR PATIENTS WITH **NSCLC**

- **Higher accuracy (94% vs. 86%), greater diagnostic effectiveness for correct staging (60% vs. 40%) e Greater diagnostic effectiveness for evaluation of the tumor resectability (84% vs. 70%)**
- **Lower rate of unnecessary surgeries (19% versus 47%)** compared to the staged group with computed tomography

FOR PATIENTS WITH **HODGKIN'S LYMPHOMA**

- **Higher sensitivity of PET** compared to CT **(97,9% vs. 87,3%)**

Hip replacements

SURGERY TIME

- **Lower in-hospital mortality for early THA,** compared to late THA **(7.4% vs. 16.9%)**
- **Lower costs for early THA (R$3,626.00 vs. R$5,622.3)** compared to late THA
- **Early THA would save 94 lives for every 1000 patients** undergoing surgery

TYPES OF PROSTHESES

- **Higher gains of QALYs for hybrid prostheses** (5.38 to 11.90), compared to cemented prostheses (5.22 to 11.69)

Elaborated by: Silvia Kobayashi, Alessandro Campolina e LCA Consultores.

CONCLUSIONS

The relevance of the Technology factor in health motivated this study, which sought to evaluate the relationship between sectoral technological innovations and the variation in health costs; and to evaluate the relationship between technological innovations and the social well-being provided by health services, in view of the importance of technological development in the health logic. These objectives were conducted under two approaches, one aggregated and the other case studies.

The models produced in the first approach explain the impacts of technology on costs and social well-being in quantitative terms. The statistical measurement strategies were shown to be adherent to the results of the academic and professional literature researched, showing that **medical technology, even though it produces an increase in health costs, has positive effects on the well-being of the population, measured by different indicators**.

- A 1% increase in the Medical Technology Index positively impacts expenditure in health per capita by 0.5%.
- In Brazil, in the annual average between 2009 and 2019, the increase in medical technology represented an increase in total health expenditures of R$ 8.9 billion.
- In terms of well-being, the 1% increase in the Medical Technology Index generates: (i) increase of 0.001% in the proportion of the elderly population; (ii) 0.025% reduction in infant mortality; and (iii) increase in GPD *per capita* de 0,33%.
- On an annual average between 2009 and 2019, the expansion of medical technology led to an increase in R$ 13.8 billion in Brazilian GDP.

Such results may help to conduct discussions about the importance of medical technology in the socioeconomic conditions of the country.

On the other hand, the case studies reveal the importance of the methods of economic evaluation in health in the choice of more efficient alternatives among the current technological innovations. **The 3 case studies – ICDs, PET in oncology and hip prostheses – showed that innovations in the area of medical equipment can represent efficient alternatives for the management of health** conditions prevalent in the areas of cardiology, Diagnostic Imaging and Orthopedics.

- The incorporation of the ICD into the health system reveals that technological advances can make some devices progressively more cost-effective and that such equipment is an option that make significant contributions to the long-term well-being of the population affected by heart disease. The use of TCR-D generates a gain of 1.52 years. Of life in patients with class III HF compared to therapy

with the use of optimized medication. In patients with mild HF class II, the use of TCR-D generates a gain of 1.47 QALYs and longer projected survival, 8.11 versus 7.12, compared to to treatment with CRT-P. Treatment with quadripolar devices results in a reduction in hospitalization, rehospitalizations, and generator replacement rates compared to patients treated with bipolar devices.

- PET technology can save the patient from unnecessary oncological surgeries, avoiding up to 28% of procedures and generating resource savings. Compared to CT scans, the procedure is more accurate in the diagnosis of non-small cell lung cancer, 94% versus 86%, greater effectiveness in diagnosing correct staging, 60% vs. 40%, and greater diagnostic efficacy for assessing tumor resectability, 84% vs. 70%.

- Hip replacements are essential to Population's quality of life. Early access to technology, compared to late access, decreases in-hospital mortality, 7.4% against 16.9%, and can have significant impacts on the use of resources and costs for the health system, by reducing treatment costs from R$ 5.622 to R$ 3.626.

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ANNEXES

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STATISTICAL APPROACH

ANNEX I: THEORETICAL REVIEW

There are three levels of standard analysis in the scientific literature that deals with health costs and benefits, each with a specific common methodology: micro, meso, and macro. In the context of Technology studies, these levels refer to the spheres of technological aggregation: research at macro levels seeks to analyze results from indicators with a high level of aggregation, while studies at meso and micro levels have the capacity to work with greater disaggregation, sometimes having specific technologies as their object. Below is a table with details about the Levels Mentioned.

Table 12: Levels of analysis and main methodology of the articles studied

Level/analysis	Main Methodology
Micro	Case Studies on Technological Costs and Benefits procedures, and diseases
Meso	Econometric analyses of the relationship between specific clusters of Technology or technological progress at the provider level (hospital)
Macro	Econometric Analysis with Proxy Variables for Technological Progress

Elaborated by: from a variety of sources.

The studies analyzed for the aggregate approach of the work relate the incorporation of Technology to two main themes: medical costs and social welfare.

Regarding the first topic, the analysis of the impact of Technology is usually a control observation, especially in studies with greater aggregation, often measured through the observation of the temporal trend (residual approach) or some aggregate proxy of Technology (R&D expenditure, patents). In studies with greater disaggregation, however, the variable assumes greater relevance in the analysis, being measured by outcome variables (life expectancy, infant mortality and percentage of elderly), to a lesser extent, or by resource variables (technological indexes, quality of services, number of technologies with regulatory approval), to a greater extent. In the case of medical costs, the variable used in per capita health expenditure. The Table below details the methodologies used.

Table 13: Selected studies on the determinants of health costs

Text	Period	Countries	Methods	Dependent variable	Explanatory	Explanatory Technology
Okunade, Murthy 2002	1960-1997	USA	Time series	Real *per capita* expenditure on health	-	Total R&D expenditure and total health R&D expenditure
Freeman 2003	1966-1998	USA (statewide)	Dashboard data	Real *per capita* expenditure on health	Disposable personal income	Time Trend
Di Matteo 2005	1980-1998	USA and Canada (state/province)	Dashboard data	Real *per capita* expenditure on health	Income, Age, State/ Provincial GPD, Regional D.	Time Trend
Dreger, Reimers 2005	1975-2001	21 countries	MQO e Dashboard com cointegração	Real *per capita* expenditure on health	GPD real *per capita*	Life expectancy, infant mortality and Percentage of elderly
Hartwig 2008	1960-2004	19 countries	Dashboard data	Real *per capita* expenditure on health (difference)	Difference in Growth Rate of nominal wages per employee and productivity / real GPD *per capita* / Total employment	-
Blank, Van Hulst, 2009	1995-2002	Netherlands (hospital)	Dashboard	Variable Cost	1. Production (number of discharges and patients / outpatient clinics) / 2. Resources (wages, capital, office supplies)	Technology Index made up of technology clusters
Bundorf et al 2009	2001 and 2006	USA (patient)	Comparative descriptive statistics	-	-	-
Smith et al 2009	1960-2007	USA (patient)	Growth Analysis, Factor Decomp.	Estimated health expenditure (adjusted prices of health care costs)	GPD *per capita* / Health care /other variables control	Difference-based of health expenditures
Narayan et al 2011	1972-2004	18 countries	Dashboard data	Real *per capita* expenditure on health (real and nominal)	GPD *per capita* / Population over 65 years old	Time Trend
Xu, Saksena, Holly 2011	1995-2008	143 countries	Dashboard data	Real *per capita* health expenditure (total, government and out-of-pocket)	GPD per capita/ government expenditure as a percentage of GPD/demographic structure/disease prevalence/health system characteristics	Time Trend

Hartwig 2011	1980-2005	9 countries	Dashboard data	Nominal *per capita* expenditure on health	GPD *per capita* / Relative price of health care / Population over 65 years of age	Time Trend
Colombier 2012	1965-2007	20 countries	Panelized data fixed effects	Nominal *per capita* expenditure on health	Adjusted Baumol variable / GPD *per capita*	Time Trend
Farag et al 2012	1995-2006	173 countries	Dashboard data	Nominal *per capita* expenditure on health	GPD *per capita* (possible endogeneity: share of agriculture and schooling rate) / Governance variables / Population over 65 years of age / GINI index / number of doctors per 1000 inhabitants	-
Acemoglu et al 2013	1970-1990	USA	OLS e Instrumental variables	Nominal *per capita* expenditure on health	GPD *per capita* (endogeneity: oil price and total oil reserves)	Time Trend
Ho, Li, Zhou 2014	2002-2010	China (province)	Dashboard data	Nominal *per capita* expenditure on health	Salary Difference and GPD *per capita* / GPD per provincial / Population over 65 years of age / provincial government deficit / emission losses water and gas	Quality of health services (Variables factor analysis) of care in hospitals)
Agha 2014	1998-2005	USA (hospital)	Dashboard data	Health expenditure	Hospital Control Variables (investment and status) / Patient control (sex, gender, age, diagnosis)	Information Technology Inclusion Binary Variable
Willemé, Dumont 2014	1981-2012	18 countries	Dashboard data	Nominal *per capita* expenditure on health	GPD *per capita* / percentage of public budget in health expenditures / percentage of out-of-pocket expenditures healthily / age composition / Body	Number of Drugs and Medical Equipment Approved by FDA
Zortuk, Çeken 2015	1995-2011	181	Dashboard data	Nominal *per capita* expenditure on health	GPD *per capita* / Population between 0 and 14 years old / Population over 65 years old / Percentage of public Health expenditure	-
You, Okinade 2016	1971-2011	Australia	Time series	Nominal *per capita* expenditure on health	GPD *per capita*	Technology Index (Medical Equipment)

Elaborated by: Thiago Caliari and LCA Consultants.

In relation to the second topic of interest – social well-being – the analyzed studies use an exogenous growth rate as a proxy for Technology, for the most part, while for Variables of well-being they use mainly Variables of income, with some exceptions, such as the use of a mortality indicator.

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Table 14: Selected studies on the relationship between economic performance/well-being and health variables

Text	Period	Countries	Method	Dependent variable	Explanatory	Text
Knowles, Owen 1995	1960-1985	84 countries	Dashboard data	GPD by worker	Investment rate, education, life expectancy	Exogenous technological growth rate
Knowles, Owen 1997	1960-1985	77 countries	Dashboard data	GPD by worker	Investment rate, education, life expectancy	Exogenous technological growth rate
Rivera, Currais 1999a	1960-1990	24 countries OCDE	*Cross section*	GPD by worker	Investment rate, education, health expenditure, population growth	Exogenous technological growth rate
Rivera, Currais 1999b	1960-1990	24 countries OCDE	*Cross section*	GPD by worker	Investment rate, education, health expenditure, population growth	Exogenous technological growth rate
Bhargava et al 2001	1960-1990	125 countries	Dashboard data	GPD *per capita*	Investment rate, education, health (survival rate, fertility rate), trade opening, leaving.	-
Bloom et al 2001	1960-1990	-	Dashboard data	GPD *per capita*	Investment rate, education, health (life expectancy)	Exogenous by country
Arora 2001	100-125 anos	10 countries	Dashboard data	GPD *per capita*	Life expectancy	-
Bloom et al 2004	1960-1990	-	Dashboard data	GPD by worker	Capital by worker, education, experience, life expectancy	Exogenous technological growth rate
Weil 2007	-	-	-	GPD *per capita*	Survival rate, education, physical capital	-
Wong et al 2012	1981-2009	Netherlands (patient)	Dashboard data	Likelihood of healthcare use by age group	Gender, age, budget, mortality, wages, and interactions between variables	Healthcare Patents
Agha 2014	1998-2005	USA (hospital)	Dashboard data	Mortality and quality indices (readmission, complications, and adverse events to medications)	Hospital control variables (investment and status)/control of patient (sex, gender, age, diagnosis)	Information Technology Inclusion Binary Variable

Elaborated by: Thiago Caliari and LCA Consultants.

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Annex II: Preparation of the Medical Technology Index

The complete list of medical equipment included in the Medical Technology Index is presented in the Table below:

Table 15: Equipment included in the Medical Technology Index

Type of equipment	Equipment considered
Diagnostic imaging	Camera Range Mammography machine with simple control Mammography machine with stereotactic X-ray up to 100 MA X-ray from 100 to 500 MA X-ray over 500 MA Dental x-rays X-ray with fluoroscopy X-ray for bone densitometry X-ray For hemodynamics Computed Tomography Magnetic resonance imaging Color doppler ultrasound Ultrasound Conventional ultrasound Exclusive Mammography Film Processor Computerized Mammography Machine PET/CT
Graphical Methods	Electrocardiograph Electroencephalograph
Dentistry	Dental Equipment Dental Compressor Light Curing Pen High Rotation Pen Low Rotation Pen Amalgamator Prophylaxis device with bicarbonate jet
Lifetime Maintenance	Intra-Aortic Pump/Balloon Infusion Pump Heated Cradle Bilirubinometer Flow Meter

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Type of equipment	Equipment considered
Lifetime Maintenance	Defibrillator Phototherapy Equipment Incubator Temporary pacemaker Monitor de ECG Invasive Pressure Monitor Non- Invasive Pressure Monitor Pulmonary Resuscitator/Ambu Respirator/Ventilator
Optical Methods	Airway Endoscope Urinary Tract Endoscope Digestive Endoscope Optometry Equipment Laparoscope/Video Surgical Microscope Ophthalmic Chair Ophthalmic Spine Refractor Lensometer Projector or Optotype Table Retinoscope Ophthalmoscope Keratometer Applanation tonometer Biomicroscope (slit lamp) Campimeter
Other equipment	Ultrasound/shortwave diathermy apparatus Electrostimulation apparatus Blood products infusion pump Apheresis Equipment Cardiopulmonary bypass equipment Hemodialysis Equipment Bier Oven

Elaborated by: Thiago Caliari and LCA Consultants.

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To form the Medical Technology Index, the Principal Component Analysis (PCA) was performed on the number of average equipment *per capita*, which aims to construct components that are not correlated with each other that retain most of the variability and correlation structure from the original variables, obtained through linear transformations. The result of the analysis is presented in the following table.

Table 16: PCA – Medical Technology Index

Observations: 7,812 | Components 6
Trace: 6 | Rho: 1

Rotation: (non-rotated = main)				
Component	**Self-Value**	**Diference**	**Proportion**	**Cumulative**
Comp1	436.828	384.602	0.728	0.728
Comp2	0.522268	0.07813	0.087	0.815
Comp3	0.444133	0.14078	0.074	0.889
Comp4	0.303348	0.09389	0.051	0.939
Comp5	0.209449	0.05693	0.035	0.974
Comp6	0.152519	-	0.025	1

Autovetors – Components (Main ones)							
Variáveis	**Comp1**	**Comp2**	**Comp3**	**Comp4**	**Comp5**	**Comp6**	**Not Explained**
Image diagn	0.4444	0.1853	0.0627	-0.0456	-0.117	-0.8651	0
Dentistry	0.3838	0.422	0.7381	0.0992	-0.0506	0.3427	0
Life Maint.	0.4137	-0.4943	-0.0498	-0.2089	-0.7033	0.2092	0
Graph. Meth.	0.4148	0.1834	-0.2969	-0.703	0.4082	0.2127	0
Optical Meth.	0.3957	-0.6291	0.155	0.3266	0.5629	-0.0136	0
Other	0.3942	0.3374	-0.5803	0.5861	-0.0752	0.2119	0

Elaborated by: Thiago Caliari and LCA Consultants.

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The cumulative proportion of explanation of component 1 for the set of suggested variables was 78.2%, which corroborates its explanatory relevance. It will be considered the Medical Technology Index. Next, the Medical Technology Index was standardized so that the values were in the range between 0 and 100, using the following equation:

$$\textbf{Standardized Tec Index} = \textbf{100} * \frac{\text{(ind PCA value X − minimum ind PCA value)}}{\text{(maximum value of ind PCA − minimum value of ind PCA)}}$$

Annex III: Variables of two econometric models

The table below details all the variables of the econometric models, as well as the sources of the information.

Table 17: List of dependent and explanatory variables for the suggested models

Model Variable	Variable Name	Description	Sourc
Dependent Variables			
Cost Model and Technology			
c_pc	Health expenditure *per capita*	Sum of hospital and outpatient expenses *per capita*	DATASUS
Wellness Model and Technology			
b_e	Infant mortality	Deaths Population 0-9 years per 1000 population	DATASUS
	Life expectancy	Proxy: Percentage da Population over 65	DATASUS
	GPD *per capita*	Micro-regional GPD *per capita*	Ipeadata
Explanatory Variables			
Resource variables			
Technology	Capital Resources	Medical and hospital equipment *per capita*	DATASUS
Medical	Human resources	Number of Doctors *per capita*	DATASUS
Regional Control Variables			
X, Y	GPD *per capita*	GPD microrregional *per capita*	Ipeadata
	Population	Population /microrregional	DATASUS
	Health care	Beneficiaries / 1000 inhabitants	ANS
	Population +65 years old	Percentage of Population +65 y	DATASUS
Control Variables for Specific Models (Welfare and Technology Models)			
Infant mortality model	Sewage treatment	Percentage of the population with sewage treatment	SNIS
	Water Treatment	Percentage of Population with Water Treatment	SNIS
GPD Model *per capita*	Physical capital	Number of large and medium-sized enterprises *per capita*	RAIS
	Human Capital	Employees *per capita*	RAIS
	Graduated	Number of large and medi-um-sized enterprises *per capita*	RAIS
	Experience	Number of employees with a bachelor’s degree per capita	RAIS

Elaborated by: Thiago Caliari and LCA Consultants.

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Annex IV: Other specifications of econometric models

Table 18: Log-linear models Dashboard data GLS
(logarithm dependent variable of real health expenditures *per capita*)

Variables	(1)	(2)	(3)	(4)	(5)
Ln_GPD *per capita* real	0.374***	0.233***	0.199***	0.214***	0.188***
Ln_population	0.556***	0.452***	0.407***	0.426***	0.409***
Tecnology		0.184***	0.145***	0.139***	0.133***
Doctors			0.196***	0.193***	0.174***
Population +65				2.062	2.274
Health car					0.525
Constant	-6.962***	-4.312***	-3.638***	-4.188***	-3.815***
Observations	6,179	6,179	6,179	6,179	6,179
Microregion	550	550	550	550	550
Region Control	SIM	SIM	SIM	SIM	SIM
Year Control	SIM	SIM	SIM	SIM	SIM
Wald (chi2)	1107.23	1153.22	1165.15	1179.93	1176.50
Prob > chi2	0.0000	0.0000	0.0000	0.0000	0.0000

Notes: *** p < 0.01, ** p < 0.05, * p < 0.10. Elaborated by: from a variety of sources.

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Table 19: Log-linear models' data in GLS panel by federative region
(logarithm dependent variable of real health costs *per capita*)

Variables	(1) Southeast	(2) Sohth	(3) Northeast	(4) Midwest	(5) North
Ln_GPD *per capita* real	0.112	1.903***	0.105	0.437***	0.387***
Ln_population	0.199***	1.122***	0.227***	0.303***	0.836***
Technology	0.0716**	0.195*	0.334***	0.147***	0.307***
Doctors	0.262***	-0.391	0.186	0.539***	-0.897***
Population +65	-5.425*	5.357	0.0966	6.602***	8.274
Health care	0.465	2.218	0.521	-1.951***	-0.366
Constant	0.369	33.29***	0.138	-5.534***	-10.02***
Observations	1,858	892	2,127	616	686
Microrregions	160	90	184	52	64
Year Control	SIM	SIM	SIM	SIM	SIM
Wald (chi2)	173.07	420.18	474.25	785.24	135.50
Prob > chi2	0.0000	0.0000	0.0000	0.0000	0.0000

Notes: *** p < 0.01, ** p < 0.05, * p < 0.10. Elaborated by: from a variety of sources.

Table 20: *Log-log* models data in GLS panel (dependent variable life expectancy)

Variables	(1)	(2)	(3)	(4)
Ln_GPD *per capita* real	-0.00504***	-0.0147***	-0.0150***	-0.0150***
Ln_population	-0.0413***	-0.0440***	-0.0454***	-0.0447***
Ln_Technology		0.00930***	0.00848***	0.00868***
Ln_Doctors			0.00570***	0.00584***
Ln_Health care				-0.00187
Constant	-1.924***	-1.829***	-1.806***	-1.819***
Observations	6,696	6,695	6,695	6,695
Microregions	558	558	558	558
Region Control	SIM	SIM	SIM	SIM
Year Control	SIM	SIM	SIM	SIM
Wald (chi2)	91177.14	66660.03	66858.92	66526.31
Prob > chi2	0.0000	0.0000	0.0000	0.0000

Notes: *** p < 0.01, ** p < 0.05, * p < 0.10. Elaborated by: from a variety of sources.

Table 21: *Log-log* models data in GLS panel (dependent variable infant mortality)

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Variables	(1)	(2)	(3)	(4)	(5)
Ln_GPD *per capita* real	-0.0351***	0.00814	0.0156	-0.0930***	-0.0730***
Ln_population	0.0266***	0.0426***	0.0475***	0.0247***	0.0291***
Ln_sewage	0.00785	0.0134**	0.0114*	0.0317***	0.0303***
Ln_water	-0.107***	-0.0335*	-0.0265	0.0287*	0.0399**
Ln_Technology		-0.129***	-0.109***	-0.0410***	-0.0253**
Ln_Doctors			-0.0376***	-0.0350***	-0.0197
Ln_pop +65				-0.498***	-0.507***
Ln_Health care					-0.0352***
Constant	-1.666***	-1.911***	-2.100***	-2.152***	-2.548***
Observations	6,47	6,469	6,469	6,469	6,469
Microregions	540	540	540	540	540
Region Control	SIM	SIM	SIM	SIM	SIM
Year Control	SIM	SIM	SIM	SIM	SIM
Wald (chi2)	4862.89	5051.31	5078.08	6988.39	6938.75
Prob > chi2	0.0000	0.0000	0.0000	0.0000	0.0000

Notes: *** p < 0.01, ** p < 0.05, * p < 0.10. Elaborated by: from a variety of sources.

Table 22: *Log-log* models data in GLS panel (dependent variable GDP *per capita*)

Variables	(1)	(2)	(3)	(4)	(5)
Ln_Physical Capital	0.0565***	0.0539***	0.0487***	0.0577***	0.0493***
Ln_Human Capital	0.593***	0.554***	0.498***	0.452***	0.314***
Ln_Graduates	-0.00365	-0.00555	-0.0117	-0.00778	-0.00980
Ln_experience	-0.0713***	-0.0783***	-0.107***	-0.0679***	-0.0711***
Ln_Technology		0.0597***	0.0282***	0.0580***	0.0332***
Ln_Doctors				0.101***	0.0532***
Ln_pop +65				-0.366***	-0.327***
Ln_Health care					0.136***
Constant	11.93***	11.68***	11.72***	10.57***	10.70***
Observations	6,682	6,681	6,681	6,681	6,681
Microregions	557	557	557	557	557
Region Control	SIM	SIM	SIM	SIM	SIM
Year Control	SIM	SIM	SIM	SIM	SIM
Wald (chi2)	36457.46	36953.49	37707.19	40951.75	42491.11
Prob > chi2	0.0000	0.0000	0.0000	0.0000	0.0000

Notes: *** p < 0.01, ** p < 0.05, * p < 0.10. Elaborated by: from a variety of sources.

>>

Table 23: Log-linear models given in GLS panel (dependent variables well-being and technology)

Variables	(1) Expectativa de vida	(2) Mortalidade infantil	(3) PIB *per capita*
Ln_GPD *per capita* real	-0.0115***	-0.0562***	
Ln_population	-0.0477***	0.0325***	
Ln_Sewage		0.0306***	
Ln_Water		0.0139	
Technology	0.00747***	-0.00884**	0.00983***
Doctors	0.0142***	-0.00194	0.00807
Pop +65		-6.120***	-2.815***
Health care	-0.0664***	-0.515***	1.391***
Ln_Physical Capital			0.0521***
Ln_Human Capital			0.390***
Ln_Graduated			-0.0158**
Ln_Experience			-0.112***
Constant	-1.799***	-0.869***	11.63***
Observations	6,696	6,47	6,682
Microregions	558	540	557
Region Control	SIM	SIM	SIM
Year Control	SIM	SIM	SIM
Wald (chi2)	66749.08	6509.99	40500.69
Prob > chi2	0.0000	0.0000	0.0000

Notes: *** p < 0.01, ** p < 0.05, * p < 0.10. Elaborated by: from a variety of sources.

METHODOLOGICAL APPROACH CASE STUDIES

Review Question

For this literature review, we used the acronym PICOT to structure our review question. The elements of the acronym indicate who is the target of the intervention (Population), the health technologies being compared (Interventions), who are the comparators (Comparator) and the type of study we are targeting (Type of study). The research question of this review is, therefore: "Innovative devices, such as ICDs, Pet Scans and Hip Prostheses, are efficient (cost-effective) when compared to other devices, according to Economic Evaluations in Health (AES) published in the scientific literature and Brazilian HTA reports?".

Eligibility criteria

Studies were included in the literature review if they met the following eligibility criteria:

Type of participants

Studies involving the population that used any type of health technology in the area of cardiology, orthopedics and nuclear medicine, which are related to indications for ICD, Hip Prosthesis and PET Scan, in the treatment of Heart Failure, Hip Fracture (or Osteoarthritis) and Lung Cancer, respectively, were included.

Type of interventions

We included studies comparing 3 types of health technologies (ICD, Hip Prosthesis and Pet Scan) used for the prevention, diagnosis and treatment of Heart Failure, Hip Fracture (or Osteoarthritis) and Lung Cancer.

Type of studies

Studies involving the concept of ESA were included. Only complete AESs were included, namely: Cost-Effectiveness Analysis (ACE), Cost-Utility Analysis (ACU), Cost-Benefit Analysis (CBA) and Cost-Consequence Analysis (ACC).

Context

Studies involving the context of the health systems where these services are performed, such as hospitals, outpatient clinics, day hospitals, basic health units, etc., were included.

Composition of the review team

The multidisciplinary review team was composed of 2 experienced and expert reviewers in HTA and 1 specialist in information systems (literature retrieval).

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Data Sources & Search Strategy

We searched for studies in the following electronic databases, with no limit on publication date: PubMed, EMBASE, and LILACS. Articles in English or Portuguese were included. We use a combination of free-text terms and controlled vocabulary, which corresponds to the subject descriptor officially registered in each database, whenever possible (MeSH term for PubMed and Emtree in EMBASE). The initial search strategy carried out in PubMed was adapted to the other electronic databases. Studies published only as abstracts were not included as they do not provide detailed information on the methods and results of an AES. The complete search strategy for this review is presented at the end of this appendix, as well as the number of articles retrieved and included in this study.

Selection of studies

The retrieved records were uploaded to the Rayyan systematic review management software (rayyan.qcri.org), which allowed the trials to be triaged by two independent reviewers and conflicts to be identified. Two independent reviewers screened the retrieved records by reading titles and abstracts. In case of insufficient information in the abstract, the registry was included in the second phase. Disagreements among the reviewers were resolved through discussion and consensus.

In the second phase of study selection, two independent reviewers assessed the full publication of potential studies to confirm eligibility. A standardized questionnaire was used to record the reasons for exclusion from the studies. Disagreements between reviewers were resolved through discussion and consensus or arbitration by a third party if necessary.

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Data Extraction

Prior to data extraction, a standardized form was developed to collect variables of interest and a pilot phase was carried out, extracting data from three eligible studies to verify agreement with commonly used terms, train reviewers, and validate the form. Two independent reviewers then extracted data from eligible studies using the standardized form. Disagreements among the reviewers were resolved through discussion and consensus. Specifically, the following variables were collected:

- Article Title Type of Technology
- Nature of the document (Scientific Article / HTA Report) Author
- Year
- Title of Revista Contexto (country of origin)
- Literature (national or international)
- Type of Study (Subtype of Health Economic Evaluation) Technology of Interest
- Comparisons
- Impact on Costs (Utilization of Impacted Resources) Impact on Quality of Life (Impacted Domains) Incremental Cost-Effectiveness Ratio (ICER)
- Notes on the Assessed Items
- Author's Conclusion
- Recommendation (Cost-effective: yes or no)

Evaluation of the Quality of Articles and Reports

Two independent reviewers carried out a critical evaluation of the studies inspired by Good Evaluation Practices of Economic Evaluation Studies in Health[122]. Disagreements among reviewers were also resolved through discussion and consensus. We rated it as "adequately reported," "incompletely reported," or "not reported" for the following domains:

- Defining the decision problem: identify objectives, type of decision, alternatives to be compared;
- Describing the methods for calculating costs and clinical outcomes;
- Estimating and presenting Incremental Cost-Effectiveness Ratios (ICER) to enable conclusions about the efficiency of the technology of interest;
- Dealing with uncertainty: Perform uncertainty analysis to understand the level of robustness of the results;
- Interpreting the results according to a Willingness to Pay Threshold (LDP) referenced by the authors in order to support decision-making.

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Data synthesis

A narrative synthesis of the results, inspired by the guidelines of the European Social Research Council Guidance on the Conduct of Narrative Synthesis in Systematic Reviews[123], was performed. Some studies were selected to discuss the evidence presented, based on the robustness of their methods and considering whether they were conducted in the Brazilian context.

Search Strategy

Search Strategy – Scientific Articles on CDI

("Costs and Cost Analysis" OR "Economics, Hospital" OR "Economics, Medical" OR "Eco- nomics, Nursing" OR "Economics, Pharmaceutical" OR pharmacoeconomic* OR "cost minimization" OR "cost effectiveness" OR "cost benefit" OR "cost utility" OR "cost of illness" OR "cost consequence" OR "health economics"[MeSH Terms]) OR ("Costs and Cost Analysis"[Title/Abstract] OR "Economics, Hospital"[Title/Abstract] OR "Economics, Medical"[Title/Abstract] OR "Economics, Nursing"[Title/Abstract] OR "Economics, Pharmaceutical"[Title/Abstract] OR pharmacoeconomic*[Title/Abstract] OR "cost mitigation"[Title/Abstract] OR "cost effectiveness"[Title/Abstract] OR "cost benefit"[Title/ Abstract] OR "cost utility"[Title/Abstract] OR "cost of illness"[Title/Abstract] OR "cost consequence"[Title/Abstract] OR "health economics"[Title/Abstract])) AND ("Defibrillator Implantable" OR "Implantable Defibrillator" OR "Implantable Defibrillators" OR "Implantable Cardioverter-Defibrillators" OR "Implantable Cardioverter Defibrillator" OR "Cardioverter Defibrillator, Implantable" OR "Cardioverter Defibrillators, Implant-

able" OR "Defibrillator, Implantable Cardioverter" OR "Defibrillators, Implantable Cardioverter" OR "Implantable Cardioverter Defibrillators" OR "Cardioverter-Defibrillators, Implantable" OR "Cardioverter-Defibrillator, Implantable" OR "Implantable Cardioverter Defibrillator")
Adapted for: EMBASE and LILACS.

Search Strategy – Articles on PET Scan

("Costs and Cost Analysis" OR "Economics, Hospital" OR "Economics, Medical" OR "Eco- nomics, Nursing" OR "Economics, Pharmaceutical" OR pharmacoeconomic* OR "cost minimization" OR "cost effectiveness" OR "cost benefit" OR "cost utility" OR "cost of ill- ness" OR "cost consequence" OR "health economics"[MeSH Terms]) OR ("Costs and Cost Analysis"[Title/Abstract] OR "Economics, Hospital"[Title/Abstract] OR "Economics, Medical"[Title/Abstract] OR "Economics, Nursing"[Title/Abstract] OR "Economics, Pharmaceutical"[Title/Abstract] OR pharmacoeconomic*[Title/Abstract] OR "cost minimization"[Title/ Abstract] OR "cost effectiveness"[Title/Abstract] OR "cost benefit"[Title/Abstract] OR "cost utility"[Title/Abstract] OR "cost of illness"[Title/Abstract] OR "cost consequence"[Title/Abstract] OR "health economics"[Title/Abstract])) AND ("Defibrillator, Implantable" OR "Implantable Defibrillator" OR "Implantable Defibrillators" OR "Implantable Cardioverter Defibrillators" OR "Implantable Cardioverter Defibrillator" OR "Cardioverter Defibrillator, Implantable" OR "Cardioverter Defibrillators, Implantable" OR "Defibrillator, Implantable Cardioverter" OR "Defibrillators, Implantable Cardioverter" OR "Implantable Cardioverter Defibrillators" OR "Cardioverter-Defibrillators, Implantable" OR "Cardioverter-Defibrillator, Implantable" OR "Implantable Cardioverter- Defibrillator")
Adapted for: EMBASE and LILACS.

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Search Strategy – Scientific Articles on Hip Prosthesis

("Arthroplasties, Replacement, Hip" OR "Arthroplasty, Hip Replacement" OR "Hip Prosthesis Implantation" OR "Hip Prosthesis Implantations" OR "Implantation, Hip Prosthesis" OR "Prosthesis Implantation, Hip" OR "Hip Replacement Arthroplasty" OR "Replacement Arthroplasties, Hip" OR "Replacement Arthroplasty, Hip" OR "Arthroplasties, Hip Replacement" OR "Hip Replacement Arthroplasties" "Hip Replacement, Total" OR "Total Hip Replacement" OR "Replacement, Total Hip" OR "Total Hip Replacements") AND (("Costs and Cost Analysis" OR "Economics, Hospital" OR "Economics, Medical" OR "Economics, Nursing" OR "Economics, Pharmaceutical" OR pharmacoeconomic* OR "cost minimization" OR "cost effectiveness" OR "cost benefit" OR "cost utility" OR "cost of illness" OR "cost consequence" OR "health economics"[MeSH Terms]) OR ("Costs and Cost Analysis"[Title/Abstract] OR "Economics, Hospital"[Title/Abstract] OR "Economics, Medical"[Title/Abstract] OR "Economics, Nursing"[Title/Abstract] OR "Economics, Pharmaceutical"[Title/Abstract] OR pharmacoeconomic*[Title/Abstract] OR "cost minimization"[Title/Abstract] OR "cost effectiveness"[Title/Abstract] OR "cost benefit"[Title/ Abstract] OR "cost utility"[Title/Abstract] OR "cost of illness"[Title/Abstract] OR "cost consequence"[Title/Abstract] OR "health economics"[Title/Abstract]
Adapted for: EMBASE and LILACS.

Search Strategy at CONITEC – Reports of Recommendations on ICD, Pet Scan and Hip Prosthesis

- Source: https://www.gov.br/conitec/pt-br
- Search period: 2012-2022

Search Strategy in the Technical Chamber of Evidence-Based Medicine – Central UNIMED RS - Reports of Recommendations on ICD, Pet Scan and Hip Prosthesis

- Source: https://www.UNIMED.coop.br/site/web/UNIMEDrs/recomenda%C3%A7%C3%B5es-de-medicina-baseada-em-evid%C3%AAncias
- Search Period: 2005 - 2022

Papers and Reports Included

Table 24: Distribution of scientific papers retrieved by search strategies

	Pubmed	Embase	LILACS	Total
CDI	594	368	8	970
PET	122	144	6	272
Hip Prosthesis	237	243	9	489
Total	953	755	23	1731

Elaborated by: Silvia Kobayashi, Alessandro Campolina and LCA Consultants.

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Figure 29: Flowchart for the inclusion of scientific articles, according to the number of papers collected and evaluation by the reviewers

- **1731** Title, Author, and Citations
- **1258** Reading Abstracts
- **183** Read the full article
- **97** Data Extraction

Elaborated by: Silvia Kobayashi, Alessandro Campolina and LCA Consultants.

Table 25: Distribution of recommendation reports retrieved by the search strategy

	CONITEC	CTMBE Unimed R$
CDI	2	4
PET	3	10
Hip Prosthesis	3	5
Total	8	19

Elaborated by: Silvia Kobayashi, Alessandro Campolina and LCA Consultants.

122. Husereau D, et al. Consolidated Health Economic Evaluation Reporting Standards (CHEERS) 2022 Explanation and Elaboration: A Report of the ISPOR CHEERS II Good Practices Task Force. Value in Health 2022; 25(1):10–31.

123. Popay J, Roberts H, Sowden A, Petticrew M, Arai L, Rodgers M, et al. Guidance on the Conduct of Narrative Synthesis in Systematic Reviews: A product from the ESRC Methods Programme. Lancaster Univ. 2005.

124. Husereau D, et al. Consolidated Health Economic Evaluation Reporting Standards (CHEERS) 2022 Explanation and Elaboration: A Report of the ISPOR CHEERS II Good Practices Task Force. Value in Health 2022; 25(1):10–31.

125. Popay J, Roberts H, Sowden A, Petticrew M, Arai L, Rodgers M, et al. Guidance on the Conduct of Narrative Synthesis in Systematic Reviews: A product from the ESRC Methods Programme. Lancaster Univ. 2005.

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GLOSSARY OF ACRONYMS AND ABBREVIATIONS

ABIMED: Brazilian Association of the Health Technology Industry

ACB: Cost-Benefit Analysis

ACC: Cost-Consequence Analysis

ACCF: American College of Cardiology Foundation

ACE: Cost-Effectiveness Analysis ACM: Cost-Minimization Analysis

ACU: Cost-Utility Analysis

AES: Health Economic Assessments

AHA: American Heart Association

ANS: National Agency for Supplementary Health

AOA: Australian Orthopedic Association

ATQ: Total Hip Arthroplasty

ATS: BMC Health Technology Assessment: BioMed Central Health Services Research BMJ: British Medical Journal

CAGR: Compound Annual Growth Rate

CCOHTA: Canadian Coordination Office for Health Technology Assessment

CDI: Implantable Cardioverter Defibrillators

CONITEC: National Commission for the Incorporation of Technologies in the Unified Health System

CoC: Ceramic-Ceramic

CoP: Ceramic-Polyethylene

CPNPC: Non-Small Cell Lung Cancer

CPPC (SCUD): Small Cell Undifferentiated Cancers

CT: Computed Tomography

EC: Conventional Staging

EHRA: European Heart Rhythm Association

EM: Fluoro-2-deoxy-D-glucose

Fiocruz: Osvaldo Cruz Foundation

GLS: Generalized Least Squares

HRS: Health Research System

HTA: Arterial Hypertension

IBGE: Brazilian Institute of Geography and Statistics

IC: Heart Failure

IESS: Institute for Health Studies

INCA: National Cancer Institute

IPCA: Extended National Consumer Price Index

IPEA: Institute for Applied Economic Research IRM: Magnetic Resonance Imaging

JACC: Journal of the American College of Cardiology

KCE: Belgian Health Care Knowledge Centre

LDP: Willingness-to-Pay Threshold

LH: Hodgkin´s Lymphoma

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LILACS: Latin American and Caribbean Literature in Health Sciences

MEDLINE: Medical Literature Analysis and Retrieval System Online

MoM: Metal-Metal

MoP: Metal-Polyethylene

MQO: Ordinary Least Squares

MS: Ministry of Health

NBER: National Bureau of Economic Research

NICE: National Institute for Health and Care Excellence

NJR: National Joint Registry for England and Wales

NPS: Solitary Pulmonary Nodule

NYHA: New York Heart Association

OCDE: Organization for Economic Co-operation and Development

OMS (WHO): World Health Organization

OPAS: Pan American Health Organization

OTA: Office of Technology Assessment

PAAF: Fine Needle Aspiration Biopsy

PCA: Principal Component Analysis

PET: Positron Emission Tomography

GPD (GDP): Gross Domestic Product

PNGTS: National Policy for Health Technology Management

QALY: Quality-Adjusted Life Year

RAIS: Annual Social Information Report

RCEI: Incremental Cost-Effectiveness Ratios

SABE: Health, Well-Being and Aging

SHA: System of Health Accounts

SAI/SUS: Outpatient Information System of the Unified Heath System

SIH/SUS: Hospital Information System of the Unified Heath System

SNIS: National Sanitation Information System

SPECT: Single Photon Emission Computed Tomography

SUS: Unified Health System

TC-CD: Computed Tomography with Dynamic Contrast

TM: Drug Therapy

TRC (CRT): Cardiac Resynchronization Therapy

TRC-D (CRT-D): Cardiac Resynchronization Therapy Defibrillator

TRC-P (CRT-P): Cardiac Resynchronization Therapy with a Pacemaker

TV (V-tach): Ventricular tachycardia

UNIFESP: Federal University of São Paulo

USG: Ultrasonography

USG-PAAF: Ultrasonography-Guided Fine Needle Aspiration Biopsy

UNIMED: National Union of Medical Cooperatives

VCMH: Variation of Average Hospital Cost

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