

# Breast Cancer: Value-Based Healthcare, Costs and Financing

## Cancro de Mama: Valor em Saúde, Custos e Financiamento



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### ABSTRACT

**Introduction:** Breast cancer is the second most common oncological disease worldwide. To analyse the new disease specific funding programme (breast cancer) implemented at the Francisco Gentil Portuguese Institute of Oncology, Lisbon Center (Instituto Português de Oncologia de Lisboa Francisco Gentil), the actual costs of the patients were examined using activity-based costing as a costing methodology. This study addresses the following question: "How much does it cost to treat breast cancer per 'patient-month' compared to the monthly fixed 'funding envelope'?"

**Materials and Methods:** The study cohort consisted of 807 patients, corresponding to all the patients eligible for the new disease specific funding programme and who were enrolled during the first year of implementation. Activity-based costing was used to calculate the total real costs per stage of disease and per 'patient-month' as well as the deviation from the monthly fixed 'funding envelope'.

**Results:** The total costs were 6.6 M€, whereas the total funding was 5.2 M€ for a total of 5648 'patient-months'. In 2014, the balance difference between the funding obtained and the actual costs was -1.4 €M for the cohort of 807 patients.

**Discussion:** The extreme cases of differences in cost per 'patient-month' compared to the monthly fixed 'funding envelope' were (i) stage 0/Tis, with higher funding at 415.23 € per 'patient-month', and (ii) stage IIIC, with lower funding at 1062.79 € per 'patient-month'.

**Conclusion:** The 'patient-month' cost, regardless of disease stage was 1170.29 €. The median deviation per 'patient-month' was negative (241.21 €) compared to the monthly fixed 'funding envelope' of 929.08 € in the first year. Establishing activity-based costing - funding models will be crucial for the future sustainability of the healthcare sector.

**Keywords:** Breast Neoplasms/economics; Cost-Benefit Analysis; Costs and Cost Analysis; Health Care Costs

### RESUMO

**Introdução:** O cancro de mama é a segunda doença oncológica mais comum no mundo. Com o propósito de estudar o novo financiamento por patologia – cancro de mama – implementado no Instituto Português de Oncologia de Lisboa Francisco Gentil, foram analisados os custos reais dos doentes, através da metodologia de custeio *activity based costing*. Pretendeu-se dar resposta à pergunta de investigação: "Quanto custa tratar o cancro de mama por 'mês\*doente' face ao 'envelope financeiro' fixo mensal?"

**Material e Métodos:** O universo foi constituído por 807 doentes correspondendo a todos os doentes elegíveis no novo programa de financiamento por patologia e entrados ao longo do primeiro ano de implementação. Através do *activity based costing* foram apurados os custos reais totais por estágio da doença e por 'mês\*doente' e o desvio relativamente ao 'envelope financeiro' fixo mensal.

**Resultados:** Total de custos (6,6 M€), total de financiamento (5,2 M€) para um total de 5648 'meses\*doente'. Em 2014, o saldo entre o financiamento obtido e os custos reais, foi negativo em 1,4 M€ para o universo de 807 doentes.

**Discussão:** As situações extremas em termos de custos por 'mês\*doente' face ao 'envelope financeiro' mensal fixo foram: (i) o estágio 0/TIS com financiamento superior em 415,23 € por 'mês\*doente'; (ii) o estágio IIIC com um financiamento inferior em 1062,79 € por 'mês\*doente'.

**Conclusão:** O custo 'mês\*doente', independentemente do estágio da doença, foi de 1170,29 €. O desvio médio 'mês\*doente' foi negativo (241,21 €) face ao 'envelope financeiro' mensal fixo de 929,08 € no primeiro ano. Estabelecer modelos de financiamento com base no *activity based costing* será crucial para a sustentabilidade futura do sector da saúde.

**Palavras-chave:** Análise Custo-Benefício; Custos e Análise de Custo; Custos em Saúde; Neoplasias da Mama/economia

### INTRODUCTION

In a time when healthcare-related costs increasingly correspond to a higher percentage of tax revenues (according to the Ministry of Finance, the 2014 budget of the Portuguese National Health Service [Serviço Nacional de Saúde (SNS)] corresponded to approximately 63% of the Portuguese income tax (*Imposto sobre o Rendimento de Pes-*

*soas Singulares* - IRS) revenue, to 46% of the direct taxes and 22% of the total taxes), the need for new methodologies aimed at the identification of the real costs of diagnosis and treatment of different pathologies has become crucial in order to substantiate future political options regarding healthcare.

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According to the World Health Organization, breast cancer was responsible for 521,000 deaths worldwide in 2012<sup>1</sup> or approximately 6.4% of total cancer-related deaths.

Around 6,000 new patients are still diagnosed per year in Portugal, with a 1% male prevalence.<sup>2</sup>

A 38% increase in the prevalence in women has been found between 2005 and 2007, according to the Portuguese National Oncologic Registry (*Registo Oncológico Nacional*) and, in line with the American Cancer Society, data also showed that one in 35 women diagnosed with breast cancer is in risk of death and that one in 8 is in risk of developing breast cancer over her lifetime.<sup>3</sup>

As this is the most frequent cancer worldwide and with the largest number of eligible patients for the new disease-specific funding programme, it was established that the research question would be: “how much would it cost per ‘patient-month’ to treat breast cancer, compared to a monthly fixed ‘financial envelope’?”

Three specific pathologies – (i) breast, (ii) colorectal and (iii) cervical cancer have been included into the new disease-specific funding programme held by the Portuguese Central Administration of Healthcare Systems (*Administração Central do Sistema de Saúde (ACSS)*) since 2013.

From a total of 1,228 new patients included into the programme with a specific funding by the *Instituto Português de Oncologia de Lisboa* (IPO Lisboa) in 2014, 807 patients (66%) presented with breast cancer.

This study aimed at the assessment of the actual costs per ‘patient-month’ and compared to a monthly fixed ‘financing envelope’ regarding breast cancer, as the largest number of eligible patients according to the criteria of this new funding programme throughout its first year of implementation at the IPO Lisboa (in 2014) presented with this pathology.

A fixed funding of 929.08€ was assigned per patient and per month, regardless of the medical procedure.

‘Patient-month’ was the physical unit used for the study’s domain, allowing for the comparison between funding and the actual costs involved.

Activity-based costing (ABC),<sup>4,5</sup> commonly known as ABC defrayal, has been used and developed at the IPO Lisboa.

Different constraints existed when searching for comparable scientific studies as those found were not clear enough as regards study’s time frame. Studies involving disaggregated costs at different TNM (tumour, node and metastasis) disease stages were also not found.<sup>6</sup> However, a study carried out in the United Kingdom has been found,<sup>7</sup> involving a group of 223 patients with breast cancer over a 15-month period (2010 and 2011), which will be described in conclusions, even though it does not allow for any comparisons.

## MATERIAL AND METHODS

The design of this study was based on the following steps:

1) Study of the group of patients diagnosed with breast

cancer and eligible according to the criteria of the new disease-specific funding programme. Four inclusion criteria were considered: (i) only patients having started therapy at the institution were included (patients having already started therapy elsewhere, as well as those on treatment for a relapse or cancer progression were excluded); (ii) only patients on cancer treatment, i.e. having undergone one of the following therapy modalities (surgery, chemotherapy, radiation therapy or hormone therapy), were included; (iii) all treatments carried out upon patient admission throughout a two-year (730 days) period were included and (iv) all diagnosis and therapy procedures, as well as ancillary tests and any follow-up procedures were included;

2) Study timeline – a total of 807 patients, the whole group of eligible patients for the breast cancer specific funding and included throughout 2014 (January to December) were involved in the study. Funding and costs were calculated according to the period of time between the month in which the patient was eligible to be included into the new disease-specific funding programme and the final month of 2014; for instance, a patient included in the programme in January had 12-month funding and costs and a patient included in May had 8-month funding and costs;

3) Patient stratification according to stage;

4) Analysis of actual costs per ‘patient-month’, taking into consideration the resource expenditure throughout diagnosis and treatment, namely including medical visits, ancillary tests, medication, operating theatre, day-clinic sessions and in-patient episodes;

5) Assessment of the deviation between actual costs per ‘patient-month’ and monthly fixed disease-specific funding.

The analysis of the actual costs of breast cancer is based on the work already developed at the IPO Lisboa from 2008 and aimed at obtaining a cost accounting regarding the activity and resource expenditure in healthcare institutions. This methodology has been promoted by the Portuguese Central Administration of the Health System (*Administração Central do Sistema de Saúde – ACSS*) through pilot studies carried out at different hospitals countrywide, from which the results are still unknown as they have not yet been published.

The ABC defrayal project was launched in 2008 and by 2012 all healthcare activities that were carried out at the IPO Lisboa were automatically defrayed by using the ABC methodology. Different information can be obtained with the ABC defrayal, namely regarding the cost of each day of hospital stay regarding each specialty, each day-clinic session, each medication, test, physiotherapy session, specialty visit or each multidisciplinary team meeting.

An ABC defrayal methodology associated to a Structured Query Language (SQL) database allowed for an automatic identification of the information regarding the costs involved in healthcare activities considering the cost structure, the allocation of time to different occupations and resource expenditure.

This methodology allowed for a knowledge which is unavailable with the traditional accountability systems, as these

are usually based on assessments regarding large cost aggregates. In addition, time and expenditure are usually allocated to homogeneous sections, as for instance operating theatre expenditure, rather than allocated to specific healthcare procedures and activities, without taking into account the composition of the surgical team, the time allocated to a specific surgery, among others, that are considered with the ABC defrayal.

The link between each patient's medical record number (with information on all medical procedures and expenditure) and the database (information on the costs involved in each medical procedure / expenditure [ABC defrayal]) allows for the assessment on the actual costs per 'patient-month'.

The hospital received a monthly fixed amount of 929.08 € per patient throughout 2014, corresponding to the first year of funding for breast cancer, regardless of the disease staging<sup>6,8,9</sup> and subsequently of the resource consumption.

Patients were grouped according to the disease staging, in line with the TNM (Tumour, Nodes, Metastasis) system used by the institution.

A two-stage therapy approach to patients with breast cancer has been used at the IPO Lisboa. The identification of the factors underlying the treatment model is involved in stage I, including clinical factors regarding the patient, tumour location, size, regional and distant spread and pathological factors involving histologic and immunohistochemical markers. Therapy selection (three typologies) is involved in stage II, including a) type of surgery, b) radiation therapy – dose, modality and area and c) medical treatment – chemotherapy, hormone or immunotherapy.

Staging is crucial as this is what therapy planning as well as outcome, therapy assessment and comparability between patient series is based on.

Some patients in whom staging was not possible were grouped into an 'Unclassified' category.

## RESULTS

Approximately 85% of the patients included in the study were aged between 40 and 80 [1% male patients (8 patients)]. These percentages were in line with the international indicators for this pathology and described in the state of the art (Table 1).

A total cost of 6.6 M€ has been found (Table 2).

Patients attended on average 19 outpatient visits and the real costs of these reached a total of 0.3 M€ (Table 3), corresponding to 4.7% of the total value (6.6 M€) in 2014.

A larger number of ancillary tests was obtained in patients with stage IV disease and a correlation between the most advanced stages of the disease and the higher volume of tests seemed to exist.

A 1.7 M€ costs with ancillary tests corresponded to 26% of the total value.

A mean 10.6-day hospital stay per episode has been found in patients with stage IV disease, longer than what was found in patients with other stages of the disease, which was a consequence of the systemic disease that these patients usually present and the subsequent need for medical care.

A mean 2-2.3-day hospital stay per episode has been found in patients with earlier stages (0/Tis and I) of the disease (Table 3), which was explained by the low level of severity when compared to other more advanced stages.

A total of 0.57 M€ regarding in-patient costs corresponded to 8.6% of the total value.

A total of 0.6 M€ regarding the operating theatre costs corresponded to 9.3% of the total value (Table 4), while a 0.1 M€ regarding costs with unscheduled medical appointments has been found, corresponding to 1.7% of total costs.

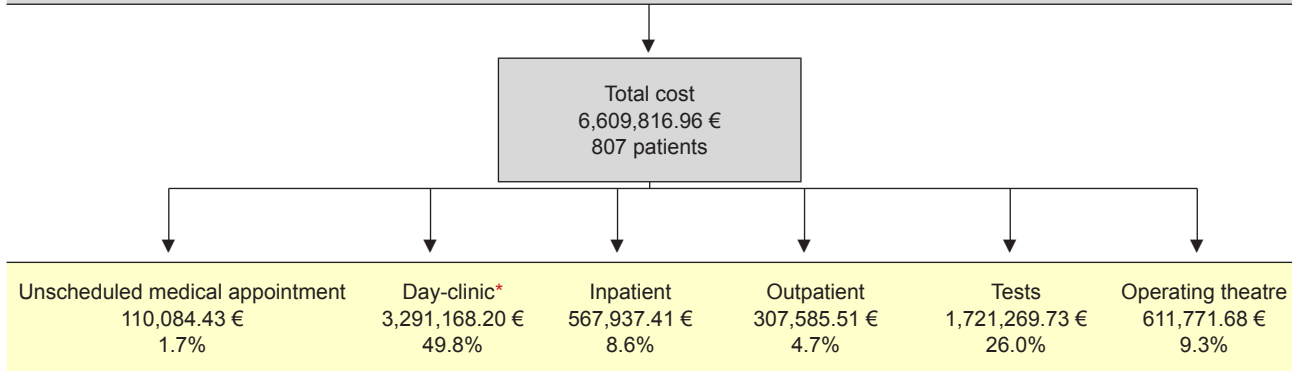
A percentage of 41% of the patients attended day-clinic sessions, mostly patients with stage I, IIA and IIB disease (Table 5); a higher average daily number of sessions per patient was found in patients with stage IIIC and IV disease. A total cost of 0.8 M€ has been found in this area, to which

Table 1 – Characteristics of the study population (807 patients) per age and gender

Age group	Age	%	Female	%	Male	%	Total
[25 ; 30]	25	0.12%	1	100%	0	0%	1
[30 ; 35]	30	1.86%	15	100%	0	0%	15
[35 ; 40]	35	4.09%	33	100%	0	0%	33
[40 ; 45]	40	8.05%	65	100%	0	0%	65
[45 ; 50]	45	11.90%	96	100%	0	0%	96
[50 ; 55]	50	11.28%	91	100%	0	0%	91
[55 ; 60]	55	11.65%	92	97.87%	2	2.13%	94
[60 ; 65]	60	9.91%	80	100%	0	0%	80
[65 ; 70]	65	13.75%	109	98.20%	2	1.80%	111
[70 ; 75]	70	9.05%	73	100%	0	0%	73
[75 ; 80]	75	9.17%	73	98.65%	1	1.35%	74
[80 ; 85]	80	6.07%	46	93.88%	3	6.12%	49
85+	85	3.10%	25	100%	0	0%	25
Total		100%	799	99.01%	8	0.99%	807

**Table 2 – Total costs per breast cancer stage. Year 2014.**

Staging	Female	%	Male	%	Number of patients	Total costs per stage
0	80	100%	0	0%	80	308,309.27 €
I	289	99.31%	2	0.69%	291	1,773,516.72 €
IIA	164	98.80%	2	1.20%	166	1,451,963.33 €
IIB	114	100%	0	0%	114	1,287,937.64 €
IIIA	55	98.21%	1	1.79%	56	626,485.23 €
IIIB	32	94.12%	2	5.88%	34	365,125.06 €
IIIC	19	100%	0	0%	19	304,755.91 €
IV	21	100%	0	0%	21	305,253.52 €
Unclassified	25	96.15%	1	3.85%	26	186,470.28 €
<b>Total</b>	<b>799</b>	<b>99.01%</b>	<b>8</b>	<b>0.99%</b>	<b>807</b>	<b>6,609,816.96 €</b>



\* Including chemotherapy and immunomodulating drugs up to a value of 2,455,284.51 €  
Source: authors' own source

costs with drugs (cytotoxic drugs and immunomodulating drugs) (3.3 M€ in total) were added, corresponding to 50% of the global costs, mainly due to the cost of immunomodulating drugs.

A 6.6 M€ total costs were found for a total 5.2 M€ funding, corresponding to a total 5.648 'patient-months' (Table 6).

**DISCUSSION**

This study allowed for the monitoring of the outcomes through data chronological series regarding the types of

treatment for each disease stage, the associated costs and the construct of outcome indicators, such as: survival rates per disease staging, mean hospital stay per in-patient episode and per disease stage and the relationship between costs and funding.

A total of 5.648 'patient-months' were funded for breast cancer in 2014.

A significant difference has been found between the actual costs and funding through the analysis of the actual costs regarding the patients included into the new disease-specific funding and using the ABC defrayal, with a 1.4 M€

**Table 3 – Costs and outpatient activity, ancillary tests, therapy and inpatient activity**

Total costs = 6,609,816.96 €						
Outpatient = 307,585.51 € (4,7%)			Ancillary tests = 1,721,269.73 € (26%)		Inpatient = 567,937.41 € (8,6%)	
Staging	Mean visits per patient	Total cost of medical visits - ABC**	Mean number of tests per patient	Total costs of tests - ABC**	Mean stay per patient	Total costs of inpatient activity - ABC**
0/Tis	15.3	15,575.12 €	60.1	171,430.04 €	2.3	45,250.31 €
I	16.7	85,397.98 €	82.7	618,088.75 €	2.0	170,200.06 €
IIA	19.4	66,734.53 €	120.5	294,897.02 €	3.7	129,207.08 €
IIB	24.0	56,803.81 €	152.2	297,179.70 €	3.9	112,681.08 €
IIIA	22.4	27,365.18 €	143.0	118,410.62 €	3.6	38,110.07 €
IIIB	19.6	18,450.98 €	147.5	68,951.65 €	4.8	16,372.97 €
IIIC	26.8	12,948.37 €	188.2	57,529.24 €	3.5	13,075.21 €
IV	16.8	13,887.26 €	268.0	46,735.64 €	10.6	14,900.10 €
Unclassified	18.3	10,422.28 €	106.1	48,047.07 €	3.4	28,140.54 €
<b>Total</b>	<b>19.0</b>	<b>307,585.51 €</b>	<b>112.9</b>	<b>1,721,269.73 €</b>	<b>3.1</b>	<b>567,937.41 €</b>

\*\* Activity-based costing  
Source: authors' own sources

Table 4 – Operating theatre costs and activity

Total costs = 6,609,816.96 €						
Operating theatre = 611,771.68 € (9.3%)						
Staging	Number of patients	Number of patients attending operating theatre	Number of episodes	Number of episodes per patient	Total costs with operating theatre - ABC*	Mean costs per episode
0/Tis	80	61	75	1.2	61,001.28 €	813.35 €
I	291	209	203	1.1	220,026.64 €	1,083.88 €
IIA	166	122	155	1.3	135,858.23 €	876.50 €
IIB	114	83	118	1.4	102,454.43 €	868.26 €
IIIA	56	38	50	1.3	44,542.92 €	890.86 €
IIIB	34	15	19	1.3	15,062.70 €	792.77 €
IIIC	19	14	17	1.2	16,397.75 €	964.57 €
IV	21	6	8	1.3	5,059.45 €	632.43 €
Unclassified	26	13	14	1.1	11,368.27 €	812.02 €
Total	807	561	686	1.2	611,771.68 €	891.80 €
Operating theatre costs per patient = 1,091 €						
Operating theatre costs per episode = 892 €						

\* Activity-based costing

Source: authors' own sources

Table 5 – Day-clinic activity and costs

Total costs = 6,609,816.96 €						
Day-clinic = 3,291,168.20 € (49.8%)						
Staging	Number of patients attending DC*	Number of DC* sessions	Mean number of DC* sessions per patient	DC* partial costs ABC**	CT§ and IM§§	DC* total costs (ABC** + drugs)
0/Tis	0	0	0.0	0.00 €	0.00 €	0.00 €
I	70	342	4.9	161,031.81 €	471,480.80 €	632,512.60 €
IIA	88	430	4.9	201,844.45 €	592,797.50 €	794,641.95 €
IIB	68	397	5.8	187,030.58 €	547,303.73 €	734,334.32 €
IIIA	39	209	5.4	98,478.69 €	288,127.15 €	386,605.85 €
IIIB	26	132	5.1	60,813.80 €	181,975.05 €	242,788.85 €
IIIC	16	111	6.9	52,470.26 €	153,024.47 €	205,494.72 €
IV	14	116	8.3	53,415.08 €	159,917.46 €	213,332.55 €
Unclassified	9	44	4.9	20,799.02 €	60,658.35 €	81,457.37 €
Total	330	1781	5.4	835,883.69 €	2,455,284.51 €	3,291,168.20 €

\* DC: Day-clinic; \*\* Activity-based costing; § Chemotherapy; §§ Immunomodulating drugs

Source: authors' own source

negative deviation, i.e. around an average 241.21 € per 'patient-month' compared to a monthly fixed 'funding envelope' of 929.08 €.

The total costs associated to the treatment of patients with stage 0/Tis and I disease showed a positive difference vs. funding.<sup>9</sup> The analysis of patients presenting with other stages showed a negative difference.

The group of patients with stage 0/Tis disease, showing a 415.23€ higher funding per 'patient-month' and those with stage IIIC disease, with a 1,062.79 M€ lower funding per 'patient-month' were the extreme situations in terms of costs per 'patient-month' vs. the monthly fixed 'financial envelope'.

The differences that were found in this study between the actual costs of breast cancer and the funded amount showed a funding gap when compared to the actual costs

of the standard treatment of this disease at the IPO Lisboa and is in line with other studies on underfunded cancer treatment in Portugal.<sup>10</sup>

A total 2.5 M€ spent in cytotoxic and immunomodulating drugs used in day-clinic sessions is worth mentioning. The costs with drugs corresponded to 38% of the global costs (6.6 M€) in 2014 and were probably not considered into the formulation of this disease-specific funding programme. This ratio is in line with other studies on drug expenditure in cancer treatment.<sup>11</sup>

This study has some limitations including (i) the fact that monthly fixed pricing (929.08 €) formulation per patient was not assessed, (ii) the fact that no other studies allowing for comparison were not found and just allowing for a rough approximation to international estimates, i.e. studies on breast pathology are not methodologically nor conceptually

**Table 6** – Patients admitted throughout 2014, months of funding and actual costs per ‘patient-month’

Stage	No. of patients	Total costs – ABC	Funding	Δ funding/ costs	‘Patient-month’	Costs per ‘patient-month’	Δ funding/costs per ‘patient-month’
0	80	308,309.27 €	557,448.00 €	249,138.73 €	600	513.85 €	415.23 €
I	291	1,773,516.72 €	1,856,301.84 €	82,785.12 €	1,998	887.65 €	41.43 €
IIA	166	1,451,963.33 €	1,051,718.56 €	-400,244.77 €	1132	1,282.65 €	-353.57 €
IIB	114	1,287,937.64 €	770,207.32 €	-517,730.32 €	829	1,553.60 €	-624.52 €
IIIA	56	626,485.23 €	353,050.40 €	-273,434.83 €	380	1,648.65 €	-719.57 €
IIIB	34	365,125.06 €	211,830.24 €	-153,294.82 €	228	1,601.43 €	-672.35 €
IIIC	19	304,755.91 €	142,149.24 €	-162,606.67 €	153	1,991.87 €	-1,062.79 €
IV	21	305,253.52 €	174,667.04 €	-130,586.48 €	188	1,623.69 €	-694.61 €
Unclassified	26	186,470.28 €	130,071.20 €	-56,399.08 €	140	1,331.93 €	-402.85 €
<b>Total</b>	<b>807</b>	<b>6,609,816.96 €</b>	<b>5,247,443.84 €</b>	<b>-1,362,373.12 €</b>	<b>5,648</b>	<b>1,170.29 €</b>	<b>-241.21 €</b>

Fonte: própria dos autores

structured in order to allow for an analogy to the present study.

Studies with a disaggregation of costs per TNM staging were also not found, even though a study carried out in the United Kingdom<sup>7</sup> through a 15-month period (2010 and 2011) and involving 223 patients with breast cancer showed an annual total cost of 11,870.83 € per patient, corresponding to a 989.24 € cost per ‘patient-month’, even though disease staging was unknown. Nevertheless, when compared to the value obtained in our study (1,170.29 €) a 181.05 € difference is obtained.<sup>7</sup>

## CONCLUSION

This study was aimed at calling attention to the need for knowing the actual costs per patient, per pathology and breast cancer staging.

As regards breast cancer, the costs per disease staging may be more relevant for the formulation of pricing regarding healthcare than just the costs per pathology with not detail on disease staging.

The ABC methodology which has been used in this study allowed for a new vision and a unique professional and multidisciplinary involvement based on the approximation of medical to management language. This common language makes the decision process and sharing of data, information and knowledge easier, reducing the status quo that has long existed between healthcare and management professionals that hardly had any connections between them due to the lack of knowledge on the terms and concepts used within each scientific area.

The dimensions that were analysed included (i) patient’s eligibility according with the criteria of the new disease-specific funding programme launched in 2014; (ii) the actual costs per ‘patient-month’ and per disease staging, considering the therapy criteria and (iii) the monthly fixed ‘funding envelope’ for breast cancer.

These dimensions were included into the study, allowing for a current analysis on healthcare organisation and on the need for the development of further studies using the ABC methodology, namely for studies on the efficiency of departments,<sup>12</sup> on the quality of healthcare,<sup>13</sup> on funding adequacy

as well as for future monitoring of healthcare outcomes.

The study also allowed for a reflection on the population attending the IPO Lisboa and leading to the conclusion that the population is represented by the whole range of disease stages, in line with the international series, rather than only patients with advanced stage disease, subsequently with poorer outcome, involving higher total costs than those that were found in the study.

The increasing costs in oncology is due to an increasing incidence of cancer over the years<sup>14,15</sup> as well as to new and more expensive therapies already available in the market.

Apart from disease staging, all the innovative therapies must be accommodated into a funding model, in order to be realistic.<sup>16</sup> For example, breast reconstruction is performed at the same time as cancer resection surgery, aimed at improving patient’s self-image and quality of life. However, these innovations should be considered in funding models as a replacement or an alternative to previous standards, as well as their economic impact.

In conclusion, a detailed study on cost assessment using an ABC methodology is crucial for the development of adequate, outcome-oriented funding models,<sup>17</sup> as well as for a sustainable healthcare future.<sup>18</sup>

## HUMAN AND ANIMAL PROTECTION

The authors declare that the followed procedures were according to regulations established by the Ethics and Clinical Research Committee and according to the Helsinki Declaration of the World Medical Association.

## DATA CONFIDENTIALITY

The authors declare that they have followed the protocols of their work centre on the publication of patient data.

## CONFLICTS OF INTEREST

The authors declare that there were no conflicts of interest in writing this manuscript.

## FINANCIAL SUPPORT

The authors declare that there was no financial support in writing this manuscript.

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