

Temporal trends in social security benefits for female breast cancer in Brazil

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Abstract *The aim of this study was to assess temporal trends in disability benefits for breast cancer awarded to women by Brazil's National Social Security Institute. We conducted a time-series analysis of disability benefit incidence rates between 2007 and 2018 using joinpoint regression and data from the Unified Benefits Information System (SUIBE) and open access social security system database. The age-adjusted incidence rate increased by 6.7% per year between 2015 and 2018 after a period of stability between 2007 and 2014. The number of benefits granted to women aged 20-49 increased, on average, by 3.4% per year, showing a marked rise from 2015 to 2018 (10.4% per year). The findings highlight that breast cancer is an important cause of sick leave among female workers and that the incidence of the disease is growing in younger economically active women, reinforcing the importance of early referral to the Social Security Professional Rehabilitation Program to help workers return to work and readapt to working life.*

Key words *Breast cancer, Social Security, Benefits*

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Introduction

The incidence of malignant neoplasms has grown around the world and these types of tumors are one of the leading causes of death among the general population¹. The increase in incidence is a result of population aging and growth and changes in the prevalence and distribution of the main risk factors, many of which are associated with socioeconomic development^{2,3}. Evidence shows that the rise in incidence of malignant neoplasms in emerging economies is related to urban lifestyles⁴⁻⁶. Set in this context, breast cancer was the most common cancer and leading cause of death among women globally in 2020⁷. In Brazil, the breast cancer incidence rate increased by 40.0% between 1990 and 2017⁸.

Taking time off work for breast cancer treatment and difficulties returning to work after treatment due to the physical and emotional consequences of the disease have repercussions for health and social security systems, including costs associated with the approach to breast cancer and long-term complications, and indirect costs related to absenteeism and reduced ability to work⁹⁻¹³. Indeed, breast cancer is one of the leading causes of sick leave for malignant neoplasms among women, underlining the importance of social security benefits in cases where time away from work is needed to undergo treatment¹⁴⁻¹⁶.

In addition, other conditions associated with breast cancer or treatment may also lead to absenteeism, such as mental disorders, cardiovascular and inflammatory diseases, upper limb lymphoedema, and non-specific symptoms like fatigue, pain, and insomnia¹⁷⁻¹⁹. Work factors, such as high psychological or physical job demands, can also have a negative impact on return to work²⁰.

In Brazil, since its creation in 1990, the National Social Security Institute (INSS) has been responsible for providing social security coverage for citizens affiliated to the General Social Security Regime (RGPS)²¹, which had more than 82 million participants in 2018²². One of the various benefits provided by the INSS is temporary social security disability assistance, which is awarded in cases of non-work related illness or accidents²³.

It is expected that the rising incidence of breast cancer in Brazil is reflected in the number of benefits awarded by the INSS. However, little research has been conducted to determine the impact of sick leave due to the disease on Brazil's social security system. The aim of this study was

to describe temporal trends in temporary disability benefits awarded by the INSS to women with breast cancer by age group.

Methods

Type of study and data sources

We conducted a time series analysis of temporary disability benefits awarded by the INSS to women with breast cancer in Brazil between 2007 and 2018.

We used data from the Unified Benefits Information System (SUIBE), developed by the Social Security Information and Technology Company (DATAPREV)²⁴. Access to the system is restricted, requiring a username and password, which was provided by the INSS in response to a formal request made to the agency.

We also used the open access social security system database, which provides a range of information on Brazil's social security system, such as benefit statements and information on the contributing population, management and financial reports, and information on worker health²².

Study population and variables

The study population was women aged 20 years and over who received temporary disability benefits for breast cancer between 2007 and 2018. This period was selected based on the availability of benefit and contributor data in the databases used by the study, as the open data for the period prior to 2007 does not include the number of contributors stratified by sex.

The analysis included only benefits recorded in the SUIBE using the relevant code from the International Statistical Classification of Diseases and Related Health Problems: 10th Revision (ICD-10)²⁵. Benefits without codes accounted for 3.1% of the total number of benefits awarded during the period and were excluded from the analysis.

The data collected from the SUIBE was systematized using a flowchart to select the variables of interest (Figure 1). This system uses the term used before the introduction of Presidential Decree 10,410 (June 30th, 2020), which changed the name of the assistance provided by the INSS from "sickness benefit" to "temporary disability benefit"²³.

We extracted the number of social security sickness benefits awarded to women for all health

problems, malignant neoplasms (ICD-10 C00 to C97), and breast cancer (ICD-10 C50 to C50.9) stratified into five-year age groups. These groups were then regrouped into ten-year age groups. We also extracted the mean duration of breast cancer benefits. The data were extracted separately for each year of the study period.

The number of female contributors to the RGPS by age group and calendar year was obtained from the open social security database²².

The outcome variable was the temporary disability benefit incidence rate, calculated as follows:

$$\frac{\text{Number of benefits for breast cancer by age group and year}}{\text{Number of female contributors to the RGPS from the same age group and year}} \times 100,000$$

Age-specific rates were also calculated. To control for the effect of changes in the age composition of the Brazilian population over the period, we adjusted the crude rates for age using direct standardization and the Segi standard population modified by Doll *et al.*²⁶.

Data analysis

The Annual Percentage Change (APC) in benefit incidence rates was calculated using an age-based joinpoint regression model, where the independent variable was calendar year. This method identifies trend change points over time, testing whether the observed temporal trends are best explained by single or multiple line segments. Based on the definition of the best model, APCs are calculated for each segment, making it possible to describe and quantify trends and test for statistical significance.

Average Annual Percentage Change (AAPC) was used as a summary measure of the trend over the study period, computed as a weighted average of the APCs from the joinpoint model, with the weights equal to the length of the APC interval. We calculated 95% confidence intervals (95%CI) for the APCs and AAPC. The following options were selected: homoscedasticity; log transformation of the dependent variable; and fit a correlated errors model based on the data. The trend analyses were performed using one-year periods and the results were presented in tables and a segmented regression graph.

Excel (Microsoft Office Home and Student 2019) was used for data entry and the segment-

ed regression analysis was performed using the Joinpoint Regression Program version 4.9.0.0²⁷.

The study protocol was approved by the Federal University of Juiz de Fora Human Research Ethics Committee (approval No. 4.388.945, November 10th, 2020).

Results

The INSS awarded 812,670 temporary disability benefits to women aged 20 years and over in 2007, 10,517 (1.3%) of which were for breast cancer, compared to 1,134,075 and 23,246 (2.0%), respectively, in 2018. Breast cancer accounted for 1.7% (standard deviation ± 0.3) of all temporary disability benefits awarded to women between 2007 and 2018, totaling 16,350 ($\pm 4,224.9$) benefits per year and representing an increase of 21.0% over the study period. Among malignant neoplasms, it was the most frequent, representing 42.9% (± 1.1) of benefits per year between 2007 and 2018.

The number of female contributors to the RGPS increased by 55.2% over the study period, from 19,038,253 in 2007 to 29,550,806 in 2018. The 20-39 year age group represented the largest share of contributors (59.8%), followed by the 40-59 year (36.2%) and 60 years and over (4.0%) groups, as shown in Table 1. The 20-29 year age group showed the smallest percentage increase in number of contributors over the period (17.6%), while the 60-69 and 70 years and over groups showed the highest percentage increase (182.8% and 151.2%, respectively), despite accounting for, on average, only 4.0% (± 0.8) of contributors.

Breast cancer was the most frequent cause of temporary disability benefits for malignant neoplasms over the study period (42.9% ± 1.1), followed by cervical cancer (10.4% ± 0.5), colorectal cancer (6.8% ± 0.4), thyroid cancer (6.2% ± 0.6), and ovarian cancer (3.4% ± 0.1).

The 40-59 year age group accounted for 73.9% (± 1.0) of the benefits for breast cancer awarded to women, with an increase of 116.7% over the period, while the 20-39 year and 60 years and over groups represented 18.9% (± 0.5) and 7.2% (± 0.6), respectively, with an increase of 126.9% and 152.3%, respectively (Table 2).

The age-adjusted temporary disability benefit incidence rate increased 6.7% per year (95%CI 1.0;12.8) between 2015 and 2018, after a period of stability between 2007 and 2015 (Graph 1).

The 20-29 year age group showed the highest average annual percentage increase (4.9%;

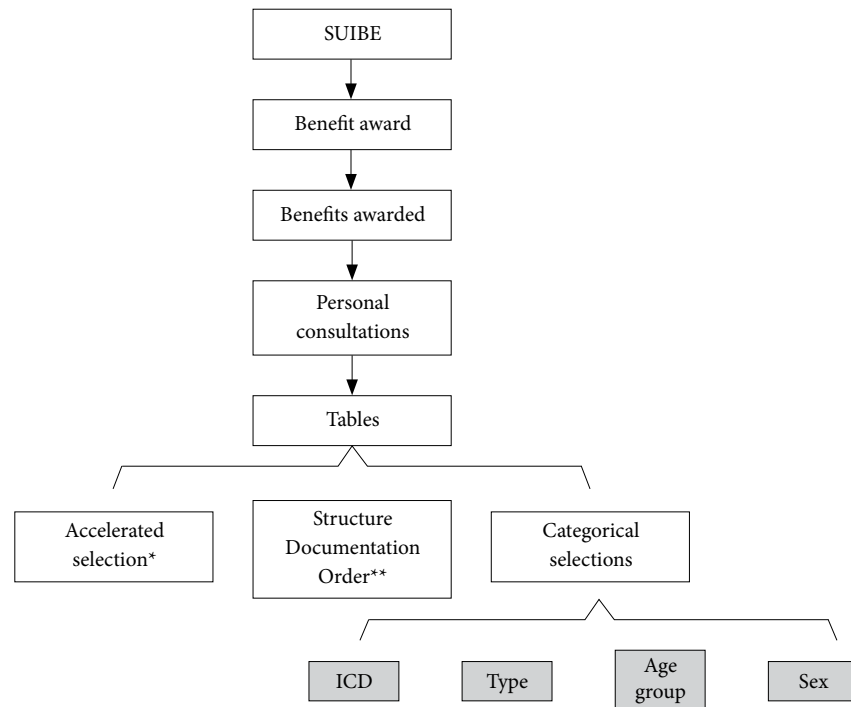


Figure 1. Flowchart showing the strategy adopted to select the study variables from the Unified Benefit Information System (SUIBE).

*Allows you to select months and Years. **Allows you to create tables determining variables for lines, columns, and content.

Source: Authors (2021); SUIBE²⁴.

95%CI 2.3;7.5), followed by the 30-39 year (4.4%; 95%CI 2.8;6.1) and 40-49 year (2.1%; 95%CI 0.7;3.5) groups. After an initial period of stability, from 2013 onwards the annual percentage increase in the 20-29 year group was 11.1% (95%CI 5.7;16.7). The annual percentage increase in the 30-39 year group was 11.9% (95%CI 4.8;19.4) between 2015 and 2018, which was considerably higher than in the period up to 2015 (1.8%; 95%CI 0.7;2.9). In the 40-49 year group, the annual increase was 7.6% (95%CI 1.8;13.7) from 2015, while rates among the older age groups (50 years and over) were stable throughout the entire study period (Table 3).

The average duration of benefits was lowest among women aged 70 years and over (between 128.8 and 176.9 days). The duration of benefits awarded to women from the other age groups ranged between 159.8 and 319.2 days, as follows: 20-29 years: between 181.0 and 319.2 days; 30-39 years: between 176.2 and 313.8 days; 40-49 years: between 169.3 and 300.5 days; 50-59 years:

between 168.2 and 296.0 days; and 60-69 years: between 159.8 and 295.2 days.

Discussion

The findings of this study show that breast cancer is an important cause of sick leave among women contributing to the RGPS. Breast cancer was the leading cause of temporary disability benefits for malignant neoplasms among women, with incidence increasing between 2015 and 2018, after a period of stability between 2007 and 2015. Breast cancer was the leading cause of long-term social security disability benefits for malignant neoplasms awarded to men and women by the Mexican Institute of Social Security between 2006 and 2012, followed by brain and bowel cancer¹⁶. Breast cancer was the leading cause of sick leave for malignant neoplasms among female workers in Japan between 2012 and 2014, followed by cancer of the genital organs and digestive system¹⁴.

Table 1. Absolute and relative frequencies of female contributors to the General Social Security Regime (RGPS) aged 20 years and over between 2007 and 2018 by age group.

Years	Total number of contributors	Age group (years)					
		20-29	30-39	40-49	50-59	60-69	≥70
		n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
2007	19,038,253	6,459,620 (33.9)	5,580,591 (29.4)	4,207,167 (22.1)	2,231,940 (11.7)	495,127 (2.6)	63,808 (0.3)
2008	20,971,724	7,201,942 (34.3)	6,080,050 (29.1)	4,561,748 (21.8)	2,498,352 (11.9)	560,200 (2.6)	69,432 (0.3)
2009	21,732,981	7,117,680 (32.7)	6,381,460 (29.4)	4,800,895 (22.1)	2,742,098 (12.6)	616,263 (2.8)	74,585 (0.3)
2010	23,793,865	7,780,854 (32.6)	7,011,427 (29.5)	5,191,431 (21.9)	3,041,001 (12.8)	689,125 (2.9)	80,027 (0.3)
2011	25,561,628	8,065,631 (31.5)	7,627,019 (29.9)	5,612,878 (22.0)	3,383,926 (13.2)	784,310 (3.0)	87,864 (0.3)
2012	27,428,311	8,415,086 (30.6)	8,239,298 (30.1)	6,028,687 (22.0)	3,747,364 (13.6)	900,066 (3.2)	97,810 (0.4)
2013	29,377,757	8,974,646 (30.5)	8,818,198 (30.1)	6,374,594 (21.7)	4,095,614 (13.9)	1,006,650 (3.4)	108,055 (0.4)
2014	29,061,138	8,496,648 (29.1)	8,729,677 (30.1)	6,370,008 (22.0)	4,261,424 (14.7)	1,087,949 (3.7)	115,432 (0.4)
2015	30,352,794	8,669,918 (28.5)	9,103,512 (30.1)	6,686,512 (22.1)	4,564,718 (15.0)	1,201,554 (3.9)	126,580 (0.4)
2016	29,545,363	8,065,045 (27.2)	8,903,031 (30.2)	6,614,513 (22.4)	4,577,015 (15.5)	1,254,845 (4.2)	130,914 (0.4)
2017	29,064,674	7,662,642 (26.3)	8,756,037 (30.2)	6,550,819 (22.6)	4,621,933 (15.9)	1,332,707 (4.6)	140,536 (0.5)
2018	29,550,806	7,597,544 (25.6)	8,911,117 (30.2)	6,749,822 (22.9)	4,731,962 (16.0)	1,400,085 (4.7)	160,276 (0.5)
μ	26,289,941	7,875,605 (30.0)	7,845,118 (29.8)	5,812,423 (22.1)	3,708,112 (14.1)	944,073 (3.6)	104,610 (0.4)

N: number of contributors; (%): percentage of contributors; μ: mean.

Source: Authors (2021); Statistical data - Social Security and INSS²².

The second leading cause of temporary disability benefits for malignant neoplasms among women was cervical cancer, pointing to a high level of social vulnerability among the study population. Studies have shown that cervical cancer incidence and mortality rates are higher among groups with low sociodemographic index values and in areas with a low level of urbanization, due to deficiencies in diagnosis and treatment²⁸. As a result, these groups are more likely to have a poor prognosis for professional rehabilitation.

Colorectal cancer was the third leading cause of temporary disability benefits for malignant neoplasms among women. In this regard, economic development and industrialization in urban centers is associated with higher prevalence

of physical inactivity and obesity, which are risk factors for colorectal cancer³.

The number of women contributing to the RGPS rose by 55.2% between 2007 and 2018. The workforce participation of women aged 20 to 59 years in Brazil increased by 96.6% between 2007 and 2018²⁹, while female contributors to the RGPS in the same age group rose by 51.5%. This difference suggests that a large contingent of women have no social security protection, possibly leading to an increase in applications for other types of benefit that do not require social security contributions in cases of inability to work³⁰.

The increase in annual breast cancer benefit incidence rates was highest in the 20-29 and 30-39 year age groups, followed by the 40-49 year

Table 2. Absolute and relative frequencies of incidence rates of temporary disability benefits for breast cancer awarded to women aged 20 years and over between 2007 and 2018 by age group.

Year	Total*	Age group (years)											
		20-29		30-39		40-49		50-59		60-69		≥70	
		n	(%)	n	(%)	n	(%)	n	(%)	n	(%)	n	(%)
		i		i		i		i		i		i	
2007	10,517	241	(2.3)	1,764	(16.8)	4,537	(43.1)	3,279	(31.2)	630	(6.0)	66	(0.6)
		3.7		31.6		107.8		146.9		127.2		103.4	
2008	11,608	266	(2.3)	1,840	(15.8)	4,931	(42.5)	3,859	(33.2)	654	(5.6)	58	(0.5)
		3.7		30.3		108.1		154.5		116.7		83.5	
2009	11,904	251	(2.1)	1,953	(16.4)	5,065	(42.5)	3,852	(32.4)	731	(6.1)	52	(0.4)
		3.5		30.6		105.5		140.5		118.6		69.7	
2010	12,864	297	(2.3)	2,100	(16.3)	5,457	(42.4)	4,133	(32.1)	812	(6.3)	65	(0.5)
		3.8		30.0		105.1		135.9		117.8		81.2	
2011	14,618	310	(2.1)	2,438	(16.7)	5,915	(40.5)	4,883	(33.4)	1,004	(6.9)	68	(0.5)
		3.8		32.0		105.4		144.3		128.0		77.4	
2012	15,941	299	(1.9)	2,701	(16.9)	6,441	(40.4)	5,369	(33.7)	1,071	(6.7)	60	(0.4)
		3.6		32.8		106.8		143.3		119.0		61.3	
2013	17,547	327	(1.9)	2,885	(16.4)	7,000	(39.9)	6,098	(34.7)	1,155	(6.6)	82	(0.5)
		3.6		32.7		109.8		148.9		114.7		75.9	
2014	18,763	374	(2.0)	3,163	(16.9)	7,383	(39.3)	6,467	(34.5)	1,302	(6.9)	74	(0.4)
		4.4		36.2		115.9		151.8		119.7		64.1	
2015	16,500	336	(2.0)	2,823	(17.1)	6,377	(38.6)	5,680	(34.4)	1,207	(7.3)	77	(0.5)
		3.9		31.0		95.4		124.4		100.5		60.8	
2016	21,469	453	(2.1)	3,718	(17.3)	8,163	(38.0)	7,405	(34.5)	1,625	(7.6)	105	(0.5)
		5.6		41.8		123.4		161.8		129.5		80.2	
2017	21,220	457	(2.1)	3,760	(17.7)	8,080	(38.1)	7,268	(34.2)	1,541	(7.3)	114	(0.5)
		6.0		42.9		123.3		157.3		115.6		81.1	
2018	23,246	422	(1.8)	4,127	(17.7)	8,923	(38.4)	8,018	(34.5)	1,656	(7.1)	100	(0.4)
		5.6		46.3		132.2		169.4		118.3		62.4	
μ	16,350	336.1	(2.1)	2,772.7	(16.8)	6,522.7	(40.3)	5,525.9	(33.6)	1,115.7	(6.7)	76.7	(0.5)

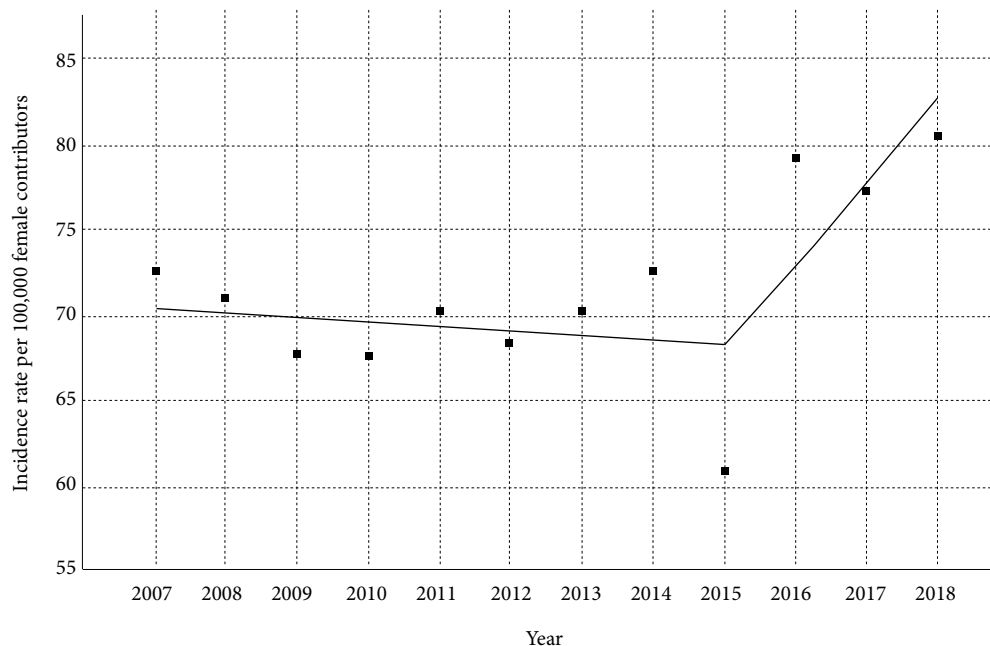
*Total number of temporary disability benefits. N: total number of benefits; (%): percentage of benefits; i: benefit incidence rate per 100,000 female contributors; μ: mean.

Source: Authors (2021); SUIBE²⁴.

group. Age-specific benefit incidence rates were similar to the breast cancer incidence rates in the general female population. The 20-49 and 50 years and over groups accounted for 30.4% (± 2.0) and 69.6% (± 4.4) of benefit incidence, respectively, between 2007 and 2018, compared to 33.1% (± 1.3) and 66.8% (± 1.7), respectively, of breast cancer incidence during the same period³¹.

The incidence of breast cancer benefits increased between 2015 and 2018 in the overall

group and among women aged 30-49 years. In the 20-29 year group, incidence increased from 2013 onwards. Despite accounting for only one-third of breast cancer benefits, the annual percentage increase in benefits among the 20-49 year age group over the period was 3.4%, with this increase being more pronounced between 2015 and 2018 (10.4% per year). This age group accounts for an important share of the economically active female population in Brazil, corre-



Graph 1. Observed and estimated jointpoint regression values for age-adjusted rates of incidence of temporary disability benefits awarded for breast cancer to women between 2007 and 2018.

Points: observed values; continuous lines: estimated values; APC: annual percentage change; AAPC: average annual percentage change; 95%CI: 95% confidence interval. 2007-2015: APC=-0.4 (95%CI: -1.3;0.5); 2015-2018: APC=6.7* (95%CI: 1.0;12.8). AAPC=1.5* (95%CI: 0.1;2.9). *Significant (p<0.05).

Source: Authors (2021).

Table 3. Annual percentage change in incidence rates of temporary disability benefits for breast cancer awarded to women between 2007 and 2018.

Age group/year	APC%	(95%CI)	Trend	AAPC%	(95%CI)	Trend
20-29 years				4.9	(2.3;7.5)*	Upward
2007-2013	0.1	(-3.5;3.7)	Stable			
2013-2018	11.1	(5.7;16.7)*	Upward			
30-39 years				4.4	(2.8;6.1)*	Upward
2007-2015	1.8	(0.7;2.9)*	Upward			
2015-2018	11.9	(4.8;19.4)*	Upward			
40-49 years				2.1	(0.7;3.5)*	Upward
2007-2015	0.1	(-0.8;1.0)	Stable			
2015-2018	7.6	(1.8;13.7)*	Upward			
50-59 years				0.8	(-0.4;1.9)	Stable
2007-2018	0.8	(-0.4;1.9)	Stable			
60-69 years				-0.4	(-1.2;0.3)	Stable
2007-2018	-0.4	(-1.2;0.3)	Stable			
70 years and over				-2.0	(-4.1;0.2)	Stable
2007-2018	-2.0	(-4.1;0.2)	Stable			

APC: annual percentage change; AAPC: average annual percentage change (2007 to 2018); 95%CI: 95% confidence interval. *Significant (p<0.05).

Source: Authors (2021).

sponding to 79.5% of women between 2007 and 2018²⁹, highlighting the potential impact of the disease on work. In addition, women diagnosed with the disease before age 35 are more likely to receive disability benefits for up to 10 years after breast cancer diagnosis, possibly due to more aggressive breast cancer subtypes and treatments³². The prevalence of advanced stage breast cancer diagnosis is higher in women aged between 20 and 49 years³³ and advanced stage cancer is associated with a higher risk of sick leave¹⁹.

The increase in age-adjusted disability benefit incidence rates from 2015 may be the result of policies to expand cancer screening on Brazil's public health system. Created in 2013, Brazil's national cancer prevention and control policy includes actions to promote the early detection of cancer through screening and diagnosis and the monitoring and control of the quality of mammograms³⁴. In 2015, the government published the new Guidelines for the Early Detection of Breast Cancer in Brazil, updating scientific evidence and emphasizing the role played by primary care centers in promoting mammogram screening³⁵. According to data from the Cancer Information System (SISCAN), the number of histopathological breast examinations resulting in breast cancer diagnosis increased from 4,441 in 2014 to 10,376 in 2018³⁶.

We did not identify any changes in the systems or rules for granting benefits that could explain the increase in breast cancer benefit incidence rates from 2015. The only year that showed a reduction in the number of benefits awarded was 2015, possibly due to the INSS physician strike between September and November of the same year. This in turn may have contributed to an increase in benefits in 2016, but not to the increase maintained up to 2018.

The mean duration of temporary disability benefits awarded for breast cancer between 2007 and 2018 ranged between 128.8 and 319.2 days. The duration of benefits or leave³⁷ reported by a study investigating sick leave due to breast cancer was lower than that found by the present study. The findings of another study showed an association between duration and type of treatment, ranging from 19.0 days in women undergoing surgery and radiotherapy and 68.6 days in those undergoing surgery, chemotherapy, and radiotherapy³⁸. The duration of benefits over the study period was smaller among women aged 70 years and over. This is probably due to the presence of comorbidities and greater impact on ability to work, meaning that the transition to a

pension for permanent disability or death may be quicker. In this regard, the higher frequency of related conditions in older patients can lead to an increase in the risk of death or limit neoplasm treatment options³⁹. A study with workers in Spain also showed that the duration of benefits for various diseases, especially neoplasms, was smaller among individuals aged 65 years and over⁴⁰.

Study limitations include the fact that it was not possible to identify whether the same woman received more than one benefit over the period, as the database only provides aggregate data. This means that the data includes different benefits received by the same woman in the same year. We were also unable to characterize the outcomes of the benefits, for example when benefits are stopped because the individual is fit for work, referral for professional rehabilitation, and pension for permanent disability or death. In addition, the open social security database does not provide information on the number of female contributors to the RGPS stratified by region, meaning that it was not possible to perform a regional analysis of benefit incidence rates. Another limitation is that the SUIBE does not include data on the benefit's secondary ICD diagnosis code, preventing the identification of comorbidities or selection of benefits for other conditions where breast cancer is a related condition. Despite the inherent limitations of secondary data, the information on breast cancer and other malignant neoplasms contained in the SUIBE are more reliable than that on other diseases. This is because the INSS physician must pay special attention to make sure the correct ICD code is selected when conducting a medical exam for social security, as benefits for malignant neoplasms are exempt from income tax and have a grace period. Finally, we did not use worker occupation and economic activity variables because they were described generically in the databases, meaning it was not possible to provide an adequate breakdown of occupations among the study population.

This pioneering nationwide study of social security benefits awarded by the INSS to women with breast cancer emphasizes the importance of using the SUIBE to determine the impact of health problems on Brazil's social security system. In addition, it presents a systematic approach to data extraction that could serve as a guide for similar studies using this little-used database.

The findings of this study confirm that breast cancer is the leading cause of sick leave for malignant neoplasms among women in Brazil. It is im-

portant to highlight that the financial burden of breast cancer and its impact on work at national level does not override the psychosocial consequences for quality of life and independence of women affected by the disease⁹. The results also show that the incidence of breast cancer is growing in younger economically active women, in which the impact of the disease on ability to work

is potentially more pronounced, resulting in a progressive increase in the number of benefits awarded. An important program in this regard is the Social Security Professional Rehabilitation Program, which is a key tool for ensuring early referral of patients for assessment in order to help workers return to work and readapt to working life as quickly as possible⁴¹.

Collaborations

FA Girardi conceived the study, managed the data collection, performed the statistical analysis and drafted the manuscript. MC Nogueira conceived the study, performed the statistical analysis and participated in data interpretation and supervision. MT Bustamante-Teixeira participated in data interpretation and manuscript discussion and supervision. MR Guerra conceived the study, participated in data interpretation and coordination of the study.

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