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Patient navigation: fighting for the rights of breast cancer patients in Brazil

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ABSTRACT

Introduction: The content of this article deals with the experience of the navigation program for patients in a breast cancer diagnosis center of the State Health Department of Rio de Janeiro. The objective was to show how the patient navigation program can allow the proper application of the 60-day Law, being a topic of interest for the planning and evaluation of actions to control this cancer in Brazil. **Methodology:** The patient navigator accompanied women from the Unified Health System (*Sistema Único de Saúde* — SUS) with a diagnosis of breast cancer to start treatment at a specialized center within 60 days. Information on the clinical characteristics of the patients, clinical dates and barriers encountered were collected. Univariate logistic regression was used to assess factors associated with starting treatment within 60 days. **Results:** From January to July 2020, 301 breast biopsies were performed, 126 (42%) of breast cancer. The mean age was 54 years (26–88). 75% of the lesions were diagnosed in advanced stages (IIB to IV). The mean time to start treatment was 39 days (11–108). The main barriers found were: fear (93%), difficulty in communicating with the medical team (81%), uncoordinated health care (37%). Being treated outside the city of Rio de Janeiro (RJ) was the main factor associated with treatment within 60 days (79.5% ***vs***. 20.5%, $p < 0.001$). **Conclusion:** The integration of the patient browser into work processes contributed to compliance with the 60-day Law in 86% of cases. In the context of a complex and fragmented healthcare system for a population in a situation of socioeconomic vulnerability, the patient navigation program proves to be a tool to increase the rate of law enforcement in Brazil.

KEYWORDS: breast neoplasms; patient navigation; barriers to access of health services; patient rights.

INTRODUCTION

Although there is a trajectory of actions for the prevention and control of breast cancer (BC) in Brazil, the scenario of its high incidence, diagnosis at an advanced stage, and high mortality continues to be constant due to barriers regarding access to health care[1]. The estimate for the 2020-2022 triennium is of about 66,280 new cases per year, with an incidence of 61.61 per 100,000 inhabitants[2]. The crude death rate was 15.4 per 100,000 inhabitants, with 16,069 deaths in 2016. There was an increase of 33.6% in the mortality rate from BC in the period from 1980 to 2016[2].

Approximately 75% of Brazilians are covered exclusively by the Unified Health System (*Sistema Único de Saúde* — SUS), and although progress toward universal health coverage has been made across the country, large disparities that affect cancer care remain[3]. Women treated in SUS have more advanced disease and worse disease-free and overall survival when compared to women treated in private health care facilities (which can be partially attributed to longer delays and advanced stages in diagnosis)[3].

The average time for diagnosis is up to 31 days in the private health care system, with 18% of cases diagnosed in stages III and IV, while in SUS the average is 93 days, and in some cases it can reach up to 180 days, with 40% of cases diagnosed in these advanced stages[4]. In addition, the average age of BC diagnosis in Brazil is 53 years, and 30% to 40% of women are under 50 years of age. This significant portion of women is outside the Ministry of Health's screening recommendation and has more aggressive and faster growing tumors (HER-2 positive and triple negative subtypes)[4,5].

Providing quality cancer care to all patients presents numerous challenges, including difficulties in coordination of and access to care. It is "a community-based service delivery intervention designed to promote access to timely diagnosis and treatment of cancer and other chronic diseases, removing barriers to care"[6]. Patient navigation has been frequently proposed

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and implemented to face the challenges of access to cancer care in high-income countries[7]. There are still few studies on patient navigation interventions in cancer treatment in low- and middle-income countries in Asia, South America, and Africa, but all suggest that the provision of navigation services can improve access to cancer care in these countries[7]. All barriers to accessing healthcare resources affect health, overall survival, and mortality rates, which is why a patient navigation program (PNP) is so important. This can ensure that patients receive the help they need on the cancer journey in low- and middle-income countries, particularly in areas where access to health care is fragmented and health systems may be fragile and underfunded[8].

Recognizing the negative impact of the delay in cancer diagnosis and treatment, in 2012 the Brazilian government issued Law No. 12.732/12 of the Ministry of Health, or the 60-day Law (*Lei dos 60 Dias*). This law establishes that treatment for any type of cancer for patients in the public health system must start within 60 days of the definitive diagnosis[9]. In a recent initiative in Rio de Janeiro (RJ), the effectiveness of patient navigation in the public health system from a diagnostic center was proven through an increase in the rate of compliance with the 60-day Law from 10% to 52%[10]. This study showed the main factors that contribute to compliance with the Law in Rio de Janeiro[11]:

- improvement in the structure and processes of diagnostic services (histopathological report with the identification of the molecular subtype, delivery of the report in a medical consultation, direct insertion into the system regulation, performance of staging exams);
- patient navigator acting on the main barriers (fear and fatalistic thoughts and uncoordinated health care);
- treatment outside the capital of Rio de Janeiro.

The content of this article deals with the experience of navigating patients in a BC diagnosis center of the State Health Department of Rio de Janeiro within a womens's hospital, *Hospital da Mulher Heloneida Studart* (HM), in the city of São João de Meriti (RJ). This diagnostic center serves mainly the Baixada Fluminense (part of the population in Metropolitan Health Region I)[12]. The objective was to offer those interested in the topic, especially managers and health professionals, subsidies to understand, plan and evaluate the actions to control this cancer throughout the continuum of care in which patient navigation intends to allow the proper application of the 60-day Law .

The PNP at HM aims to help women diagnosed with BC start treatment at a specialized center within 60 days. Its target population is women from the SUS with a diagnosis of BC, who need to start treatment at a specialized center. Its main goals are:

- To be successful if at least 70% of women start treatment within 60 days of histopathological confirmation
- To use the results to inform hospitals and health policy makers about the positive results of patient navigation.

METHODS

This is an intervention in a diagnostic service in which a social worker was trained to be a patient navigator (PN) with the responsibility of monitoring patients recruited from the day of the breast biopsy at the HM Imaging Center to the start of treatment at the Reference Center determined by the regulation of the State Health Department of Rio de Janeiro. Inclusion criteria were: women with a diagnosis of BC over 18 years old and attending a public service for consultation regarding a confirmed BC. Exclusion criteria were: no personal documents; patients with private health care insurance; investigation or diagnosis of second primary tumor; patients in the terminal phase of some other disease (prognosis of survival of less than 6 months); uncontrolled comorbidities; history of drug abuse or alcoholism; patients suffering from major psychotic disorders or uncontrolled psychiatric disorders; mentally handicapped patients; incarcerated patients; loss of follow-up.

Contact with the patient took place at least once a week by phone, e-mail, text message or in person. After three consecutive unsuccessful contacts with the patient, navigation was interrupted, this being called loss to follow-up.

Information was collected on the patients' clinical characteristics, clinical dates, barriers encountered, a satisfaction questionnaire, and the Functional Assessment of Cancer Therapy — Breast[13] questionnaire was applied, which includes a list of statements that other patients with BC judged to be important. Descriptive analysis of population characteristics was performed using measures of central tendency and dispersion (continuous variables) and measures of absolute and relative frequency (categorical variables). To assess factors associated with starting treatment within 60 days, a univariate logistic regression was performed.

RESULTS

From January to July 2020, 301 breast biopsies were performed, with 126 (42%) positive cases for malignancy. Twenty-three patients were excluded (6 died before the biopsy result, 7 were not located, and 10 had private health insurance). Table 1 shows the clinical characteristics of the 103 patients enrolled in the PNP of HM and of the 85 patients followed up to the start of treatment after additional exclusions (14 due to loss of follow-up, 3 due to investigation of a second primary tumor, and 1 due to uncontrolled comorbidities).

Mean age was 54 years (26–88 years). Forty percent of patients were under 50 years of age, and 84% reside in *Baixada Fluminense*. Seventy-five percent of the lesions were diagnosed at an advanced stage (clinical stage IIB to IV). As for the biological profile, 59% were classified as luminal, 21% as HER-2 positive, and 20% as triple negative. Women under 50 years of age were more frequently diagnosed at an advanced stage than women over 50 years (81% *vs.* 77%, p = 0.655). HER-2 and triple negative

Table 1. Clinical and treatment characteristics of women with breast cancer (n = 103).

Characteristics	n	%
Age range, in years		
< 50	42	40
≥ 50	61	60
Municipality of residence		
Belford Roxo	12	12
Cabo Frio	05	5
Duque de Caxias	07	7
Japeri	01	1
Mesquita	05	5
Nilópolis	07	7
Nova Iguaçu	25	24
Rio de Janeiro	19	18
São João de Meriti	22	21
Clinical staging at diagnosis		
in situ	00	0
I	03	3
IIA	23	22
IIB	29	28
IIIA	03	3
IIIB	36	35
IIIC	01	1
IV	08	8
Clinical staging at diagnosis		
Initial	26	25
Advanced	77	75
Histological type		
Invasive ductal carcinoma	89	86
Invasive lobular carcinoma	10	10
Ductal carcinoma *in situ*	03	3
Invasive papillary carcinoma	01	1
Grade		
1	06	6
2	78	76
3	19	18
Biological profile		
Luminal A	25	25
Luminal B	35	34
HER-2 positive	22	21
Triple negative	21	20
Family history for breast cancer		
Yes	29	28
No	74	72
Related death		
Yes	01	1
No	102	99
Additional exclusions		
Loss of follow-up	14	14
Second primary tumor	03	3
Uncontrolled comorbidities	01	1
Type of initial treatment*		
Surgery	16	19
Chemotherapy	64	75
Hormone therapy	5	6
Location of referral center for initial treatment*		
Duque de Caxias	28	33
Nova Iguaçu	26	31
Rio de Janeiro	24	28
Cabo Frio	06	7
Espírito Santo	01	1

Initial staging = *in situ* to IIA, advanced = IIB to IV; Family history for breast cancer = at least one first-degree relative diagnosed with: breast cancer before age 50; bilateral breast cancer or ovarian cancer in any age group; women with a family history of male breast cancer; women with a histopathological diagnosis of proliferative breast lesion with atypia or lobular neoplasm *in situ*; women with a personal history of breast cancer; *after additional exclusions n=85.

subtypes were also more frequent in young women (22% and 32% *vs.* 21% and 17%, p=0.197). Twenty-eight percent of patients had a family history of BC. In the 9-month follow-up, 1 death related to BC was observed.

The mean times of the main clinical dates were: 59 days (3–179 days) between the mammography report and the biopsy; 20 days (15–30 days) between the biopsy and the histopathological report; 8 days (0–18 days) between the histopathological report and insertion into the regulatory system (SER/RJ); 32 days (0–90 days) between insertion in the regulation and the first consultation with a breast cancer specialist at the referral center. Eighty-one percent of patients started treatment with systemic therapy, and 66% started treatment in Baixada Fluminense (*Instituto Oncológico de Nova Iguaçu, Hospital Geral de Nova Iguaçu* and *Hospital Jardim Amália de Duque de Caxias*).

The average time to start treatment was 39 days (11–108 days), with an 86% compliance rate. Figure 1 shows the number of cases (%) of BC, according to the time to start treatment.

Table 2 shows the factors associated with treatment within 60 days. Patients who were referred for initial treatment outside the municipality of Rio de Janeiro (Baixada Fluminense, Cabo Frio, and Espírito Santo) were more likely to be treated within 60 days when compared to patients referred for treatment in the municipality of Rio de Janeiro (79.5% x 20.5%, p < 0.001).

The main barriers reported by patients are shown in Figure 2. Fear and fatalistic thoughts were reported by 93% of patients (fear of breast removal, hair loss, chemotherapy side effects, and death and suicidal thoughts). There was a suicide attempt in which the patient reported that, given the possibility of imminent death, she preferred to take her own life as soon as possible. The other barriers identified are attributed to the health system, such as difficulty in communicating with the health team (81%), uncoordinated health care (37%), waiting to start treatment (25%), and the need to redo staging exams (14%).

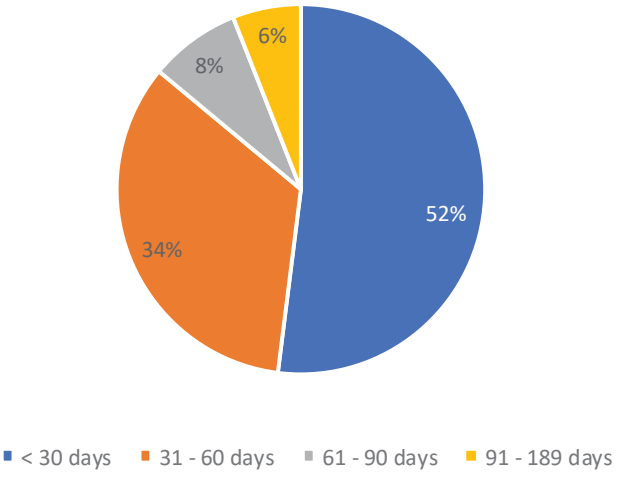


Figure 1. Number of cases (%) of breast cancer according to time to start treatment.

Patients' experience was assessed throughout the entire navigation process. With a score of 1 as a very poor experience and a score of 10 as an excellent experience, patients gave scores of 10, 9, and 8 to their overall experience (95%, 1%, and 4%, respectively). This characterized an excellent performance of the PNP.

Figure 3 shows the patient perception survey with the number (%) of agreement regarding the PN's relationship and services. Gratitude and nurturing and welcoming reception were the prevalent feelings among the patients, as shown by some statements: "I appreciate the reception with a lot of empathy, clearing up doubts, clarifying what was confusing in my head, offering psychological support"; "This awareness and support work is very important in a place that would only be for the delivery of test results"; "Despite the diagnosis, I feel welcomed and confident in the success of my treatment".

Figure 4 shows the responses to the Functional Assessment of Cancer Therapy-Breast questionnaire. This is a multidimensional questionnaire already well validated and used internationally as an instrument to measure quality of life in patients with BC.

Table 2. Factors associated with treatment within 60 days.

Characteristics	Time to start treatment ≤ 60 days (%)	p-value*
Age range (years)		
< 50	42 (57.5)	0.626
≥ 50	31 (42.5)	
Place of residence		
Baixada Fluminense	61 (84)	0.624
Cabo Frio	04 (5)	
Rio de Janeiro	08 (11)	
Clinical staging at diagnosis		
Initial	14 (19)	0.266
Advanced	59 (81)	
Biological profile		
Luminal	42 (57.5)	0.567
HER-2 positive	15 (20.5)	
Triple negative	16 (22)	
Type of initial treatment		
Surgery	11 (19)	0.837
Systemic	59 (81)	
Location of referral center for initial treatment		
Outside the municipality of Rio de Janeiro	58 (79.5)	<0.001
Municipality of Rio de Janeiro	15 (20.5)	

*Pearson's χ^2.

DISCUSSION

To achieve the goals of the PNP at the HM, changes in work processes were necessary, from scheduling the breast biopsy to the start of treatment. The central pillar was to recognize the importance of understanding patients' experiences regarding patient-centered care[14]. The PNP performance was considered excellent by the patients, and the feeling of gratitude and positive experience prevailed.

Cancer is a disease that significantly affects people's lives, both patients and their families. It entails changes in the routine, from the initial commotion in search of an understanding of the diagnosis, after the first symptoms, through the performing of confirmation tests, referral to a specialist, the various visits to care facilities, the costs involved, the interruption of occupational activities, the concern with subsistence, the waiting time for the start of treatment, fears in the face of uncertainty regarding the response to the proposed treatment and, above all, the stigma associated with the diagnosis[15].

The help of the navigator was important to reduce the barriers encountered by patients. The solutions found include: explaining the health system, educating patients about the diagnosis and medical procedures, and showing the importance of attending appointments and taking exams (educational barrier); providing more details about the treatment of the disease and referring patients to support groups or individual psychological support (emotional barrier); explaining about the diagnosis and treatment and advising patients about not being alone in this process and communicating the individual needs of each patient with

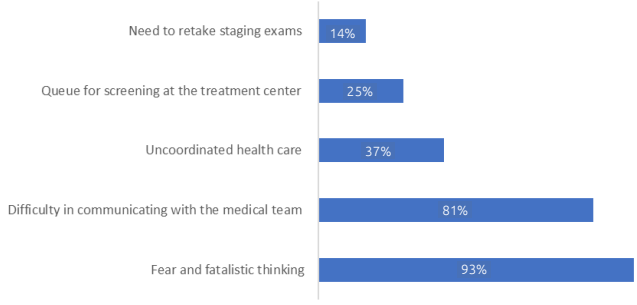


Figure 2. Proportion of barriers reported by patients to start treatment.

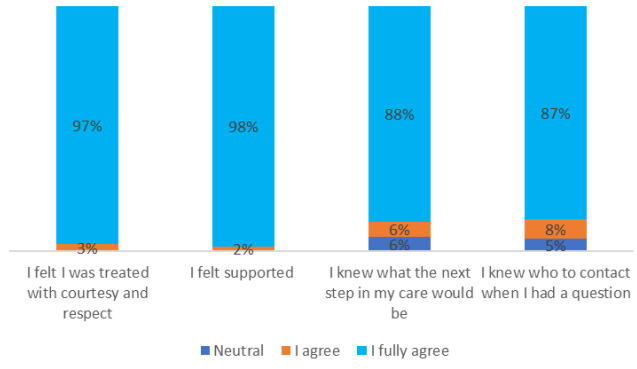


Figure 3. Patient perception survey.

the medical staff (cultural barrier); coordinating appointments for treatment services and ensuring that the tests needed to start treatment are available to doctors (health system barrier)[10].

Historically, cancer is perceived as an intractable and devastating disease, with an outcome directly associated with death. This fact is particularly relevant and can be a source of stress and anxiety for patients[15]. In this study, 52% of patients were stressed with the disease and 72% were concerned that other family members would one day have the same disease. Hence the importance of focusing and listening to patients, seeking to understand the senses and meanings they attribute to experiencing this illness[15].

Seventy-six percent of the patients said they felt little, more or less or not sexually attractive, and 58% managed to feel little, more or less like a woman. It is a process that can be experienced with intense psychological distress in view of the expectations of bodily changes, modification of self-image, impairment of functionality and independence that arise as effects resulting from the indicated treatment, which may involve surgery, chemotherapy, radiotherapy, among other indications. The prevalent issues raised by oncology patients point to the fact that the diagnosis of cancer stimulates emotions and entails a degree of uncertainty and insecurity that include the struggle for dignity and a marked fear for their lifetime[16].

The main barrier reported by patients was fear and fatalistic thoughts (93%), as seen in the pioneer study in *Rio Imagem* in 2018[10] and of Latino populations in the United States[17]. In this sense, the feeling of hope must be encouraged to be part of the patients' trajectory. Despite the fears associated with the disease, it is very important to highlight the current chances of curing and controlling the disease. Maintaining a sense of hope contributes to engaging in possible achievements and positive experiences, despite the changes brought about by the illness. Keeping the routine planning, focusing on achievable activities, preserving the sense of spiritual and/or religious connection, and practicing relaxation activities can contribute to a more hopeful perspective on the scenario that can be disorganizing[18].

In addition, correct, transparent information, transmitted by respectful and careful communication that must be carried out by the health team, facilitates the understanding of the reality of the disease, helping patients in the search for adequate treatment and favoring a more active posture in the process, whilst the lack of information can lead patients to misunderstand their disease, leading them to seek unconventional therapies, often reinforced by the stigma and consequent prejudice against cancer. It is very important that patients find a safe space for care, and the health team involved must be able to offer an active and empathetic approach to emotional issues[18].

Seventy-five percent of the patients had advanced disease at diagnosis, 40% of the patients were considered young, that is, under 50 years of age, and 28% of the patients had a family history of BC, indicating the importance of expanding patient navigation for primary health care[19]. All patients with family risk reported that they were never instructed about the risks of the disease and how to protect their family members (change in lifestyle, screening for high-risk population, genetic counseling, genetic testing, and prophylactic interventions).

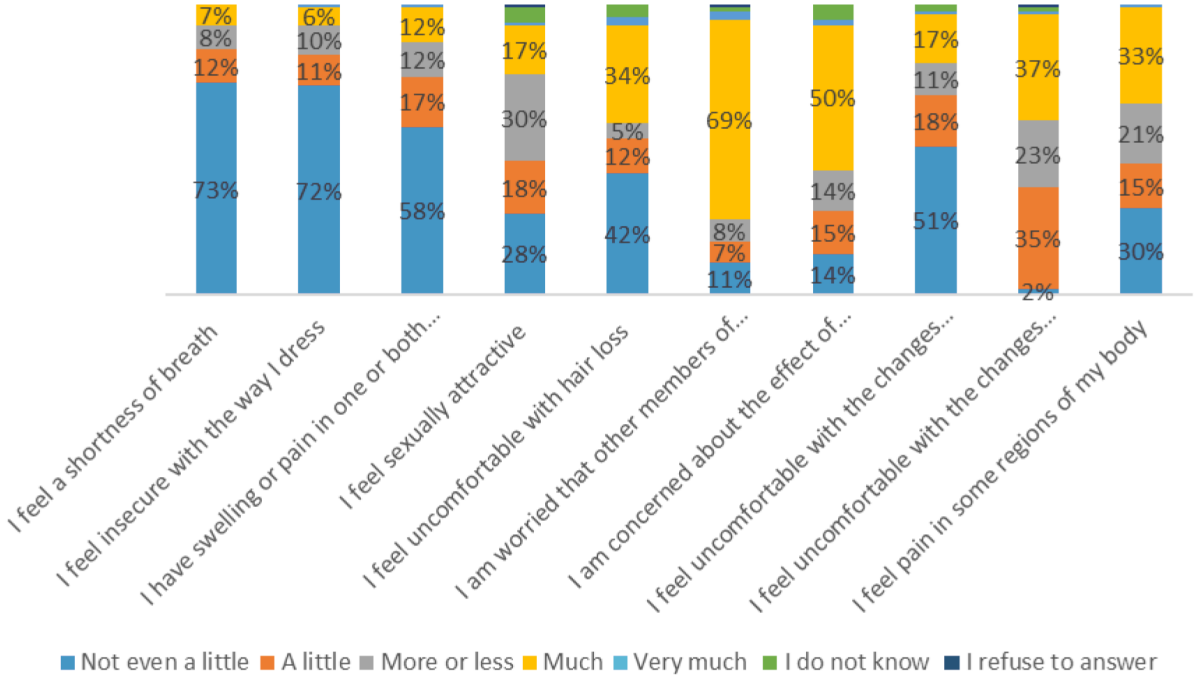


Figure 4. Responses to the Functional Assessment of Cancer Therapy-Breast questionnaire.

Effective actions in the management of care and acting on the main barriers to early detection of BC can favor adherence to personalized mammographic screening, timely investigation, and access to treatment. The PN experience in the Andaraí community, in the municipality of Rio de Janeiro, showed an increase in the tracking rate from 14% to 84%, and 100% of the lesions in 2018 were diagnosed in initial staging[19].

The compliance rate with the 60-day Law was 86%. Medical records and active search of patients diagnosed in HM in 2019 show that the rate of compliance with the law was 27% (Sandra Gioia, HM, personal information, 2020). Thus, the introduction of PN was important to increase compliance with the law, reaching the level considered desirable (above 70%). PN intervention favored the journey of the patients, who, in their majority, needed neoadjuvant chemotherapy and were referred for treatment at the reference centers in Nova Iguaçu (RJ) and Duque de Caxias (RJ) via regulation. And patients with indication for surgical treatment were referred to the General Hospital of Nova Iguaçu. These services do not have waiting lines to start treatment, as seen in services in the city of Rio de Janeiro, which worsened during the COVID-19 pandemic.

Only 20.5% of patients treated in the city of Rio de Janeiro were able to comply with the law, due to the scarcity of places to start treatment. According to a 2017 report by the State Plan for Oncology Care of the State Health Department of Rio de Janeiro, there is a deficit of 14 units in oncology in Rio de Janeiro, 11 of which are in Metropolitan Region I[12]. Most states had a worse rate of compliance with the 60-day Law for cases of BC diagnosed in an out-of-hospital environment, with Rio de Janeiro having the worst performance in all of Brazil (6%)[20]. Compliance with the 60-day law in oncology is an acquired right, and all Brazilians must strive to ensure that it is properly complied with in accordance with current ethics. Given the inability to comply with the law in Rio de Janeiro, the PNP appears as a promising intervention to reverse this situation. And decision-making intends to be within ethical limits and its dilemmas, especially in the approach to the common good, which is based on the connections of all involved, particularly for those who are considered vulnerable[21].

Data observed in the real world with the intervention of navigation show the importance of disseminating good results to the medical community and the population. It is expected that the PNP with BC will become a public health policy in Brazil with exclusive browsers for its area of performance in continuous care[1]. It is also necessary to develop the school and the digital platform for patient navigation to create work organizations based on arrangements of people (health professionals), work processes, and digital technologies to deliver health care with value for the patient, that is, delivering the best outcomes for the patient at a lower cost.

CONCLUSIONS

The introduction of the PNP for BC was considered successful, with an 86% compliance rate for the 60-day Law, but with reservations about the difficulty of complying with the law in the municipality of Rio de Janeiro due to the shortage of human resources and medical supplies.

In the Brazilian context, the PNP can represent an opportunity to properly implement the existing legislation and, as such, it would have a great potential to favor the functioning of the health system in a health care network.

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AUTHORS' CONTRIBUTIONS

S.G.: Formal Analysis, Project administration, Validation, Writing — original draft, Writing — review & editing.

L.B.: Supervision.

M.R.: Data curation.

P.G.: Conceptualization, Methodology, Resources, Funding acquisition, Investigation, Writing — review & editing.

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