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Gynecologic cancer in Brazil and the law of sixty days

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Conflict of Interest

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Brazil is a continental country with more than 200 million inhabitants [1]. The main health provider is a public system called Sistema Único de Saúde (SUS). By law, the Brazilian government is obliged to provide, at no cost, all health care for the citizens, including preventive and primary to tertiary healthcare. Cancer is the second most common cause of death in Brazil and, according to the Brazilian National Cancer Institute (INCA), there are expected to be nearly 600,000 new cancer cases in 2017 [2].

Recently, our group presented at the 2017 Society of Gynecologic Oncology meeting some important clinical and demographic variables of gynecological cancers in Brazil that were collected using the National Hospital Registry of Cancer (NHRC) from 2000 to 2014 [3]. Data from 193,000 gynecologic cancer patients were analyzed as follows: 133,751 cervical cancer, 36,645 endometrial cancer, 14,299 ovarian cancer, 6,036 vulvar cancer, and 2,193 vaginal cancer patients. The most notable information was observed at the stage of the initial diagnosis and the amount of time between diagnosis to the first treatment received, which could be surgery, radiotherapy or chemotherapy. These data confirm what oncologists already see on a daily basis in their respective clinics in the public health system: a high proportion of patients being diagnosed with locally advanced disease — for example, only 20% of cervical and vaginal cancer patients and 51% of endometrial cancer patients were diagnosed in International Federation of Gynecology and Obstetrics (FIGO) stage I (compared to 46% of cervical cancer and 67% of endometrial cancer confined to the primary site in American women) [4]; and long intervals between diagnosis and treatment: 36% of the cervical cancer patients and 38% of endometrial cancer patients wait more than 90 days for their first treatment.

Due to the long delays between the diagnosis and the initiation of the cancer treatment, in 2012 the Federal Government decreed the “Law of 60 days” (Federal Law number 12.732/12). This law came into effect in 2013 and regulates the maximum period that a patient with cancer has to wait, in order to initiate his/her treatment, in an attempt to decrease the time between diagnosis and treatment and the consequences thereafter. There were many misinterpretations of the law, due to the fact that it failed to specify whether the interval began from the date in the pathological report or the physician’s knowledge of the result. The law was then changed in the same year, specifying that the count should begin after the physician’s notes in the patient’s medical records (on May 17, 2013, MS/GM Ordinance No. 876/13). However, this was a cause for concern because scheduling a medical appointment can take from several weeks to several months. There was a lot of popular and political pressure with this change and on March 6th, 2014, the Ministry of Health amended an

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Table 1. Time between diagnosis and first treatment comparing years 2009/2012 to 2013/2016

Time between diagnosis and first treatment (day)*	Years		Total [†]
	2009/2012	2013/2016	2009/2016
≤30	15,605 (35.8)	6,712 (34.9)	22,317 (35.5)
31–60	10,366 (23.8)	4,852 (25.3)	15,218 (24.2)
61–90	5,905 (13.5)	3,030 (15.8)	8,935 (14.2)
>90	11,738 (26.9)	4,618 (24.0)	16,356 (26.0)
Total	43,614 (100.0)	19,212 (100.0)	62,826 (100.0)

Values are presented as number (%).

*First treatment can be surgery, chemotherapy, or radiotherapy; [†]Data updated on August 7, 2017.

Administrative Order MS/GM 876/13, with the objective of determining that the maximum period of 60 days to start treatment should begin from the signature of the pathological report.

In order to evaluate whether the “Law of 60 days” changed the patients' access to treatment, we used the NHRC database and compared patients from the years 2009/2012 (group A, n=43,614 patients) and 2013/2016 (group B, n=19,212), an interval covering the 4 years before and after the law came into force (**Table 1**).

In this short follow-up, a minimal change occurred. Considering only the valid data (excluding 28.2% of missing information), in group A, 59.6% of the population initiated treatment according to the law (within 60 days) compared to 60.2% in group B ($p>0.05$). However, at least 26% of the patients in group A, and 24% in group B, started treatment more than 90 days after diagnosis (**Table 1**).

But what barriers could be associated with this unfavorable scenario? Why are patients still waiting in long lines for treatment? There are many factors associated with it. Here we highlight what we believe to be the most important obstacles:

- Delays in scheduling medical appointments: as some reports show, the queues are long for patients who need assistance. In a report, the average waiting time for primary care in public health in Brazil was 15 days, reaching 50.2 days for care at a secondary level (general hospitals) [5]. According to the INCA, there are 288 tertiary cancer centers in the country, most of which are concentrated in the south and southeast regions, and a lack of tertiary cancer centers in the less populated and developed areas [6].
- Shortage of chemotherapeutic agents: The Regional Medical Council of Rio de Janeiro (CREMERJ) and the Public Defender of the Union (DPU) presented on March 2017, a survey conducted between October and November 2016 that pointed to failures of the State in cancer care. There was a shortage of chemotherapeutic agents in 42% of the 19 public hospitals treating oncologic patients. Moreover, they found that this is a recurring problem [7].
- Late pathological and Immunohistochemistry reports: in the same survey conducted in Rio de Janeiro in 2016, the average time was 4 weeks and 8 weeks, respectively, to obtain results from the pathology report and immunohistochemistry [6].
- Shortage of radiotherapy machines and human resources: there is a lack of machines in the public system as well as human resources. In a recent article on the current needs for radiotherapy in the Brazilian public health system, a deficit was shown in 2015 of 255 radiotherapy machines, 387 radiation oncologists, and 546 radiation physicists [8].

- Lack of equipped hospitals: a survey conducted by the Brazilian Federal Council of Medicine (CFM) demonstrated that Brazil had 311,917 inpatient beds in 2015, which is considered to be insufficient by CFM and 7% less than 2011. Concerning intensive care unit (ICU) beds, 86% of the cities in Brazil did not have public ICU beds. The World Health Organization does not establish a rate of hospital beds, but Brazil's number is even lower than the average rate worldwide (2.3 and 2.7/1,000 patients, respectively) [9].

Since many gynecological cancers are related to human papillomavirus (HPV) infection (cervical, vulvar, and vaginal cancers), it would be important to take a step forward to improve preventive strategies, such as cervical screening and vaccination. Indeed, the Brazilian government included in 2017 the HPV vaccine for boys between the ages of 11 and 15 years old and extended the vaccination temporarily for both sexes until the age of 26 years old, for better coverage of the population. Some other important steps should be to improve women's health education, the amount of equipment, radiation oncologists, and perhaps centralization of care.

In summary, we are far from achieving an adequate form of care in gynecologic cancer in Brazil. It may be a potentially short time to evaluate a big difference, specially because there have been some misinterpretations of the law. Despite the best results after the "Law of 60 Days," the difference is minimal before and after the law came into effect and we can still observe long waiting times for the first treatment with a considerable proportion of patients waiting more than 90 days. It seems that a federal law that aims to ensure faster treatment will not work if there is not a deep restructuring of the system. If our government and politicians do not do their homework, giving priority to funding and investments in cancer care, we will not see an impact in the near future and our women may face even longer queues as the incidence of cancer tends to increase.

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