

Technical Report

**Hepatitis C in Brazil:
Overview and challenges
in the light of the
COVID-19 pandemic**



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Hepatitis C in Brazil: Overview and challenges in the light of the COVID-19 pandemic



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Executive Summary

- ▶ We present a descriptive analysis of the official data on hepatitis C to provide an overview of the situation and support epidemiological scenarios in Brazil.
- ▶ In 2017, Brazil was one of several countries that pledged to eliminate viral hepatitis. In the following year, Brazil expanded hepatitis treatment criteria with the aim of ensuring universal access to treatment for all individuals living with infections caused by the hepatitis C virus in the country.
- ▶ Until 2019, it was possible to identify a downward trend in some hepatitis C indicators in Brazil. Thanks to national action planning and the outcomes of this planning, the country is in a good position to meet the targets envisaged in the Plan for the Elimination of Hepatitis C in Brazil.
- ▶ The COVID-19 pandemic has had a direct impact on the diagnosis and treatment of HCV, and changes have been made to diagnosis and treatment processes.
- ▶ In 2020, the annual dispensing rate for HCV therapy in Brazil fell by more than 50% in comparison with 2019, which most likely reflects the consequences of the COVID-19 pandemic on HCV control in Brazil.
- ▶ Municipal authorities should incorporate actions aiming at the implementation of new primary care guidelines into their municipal health programmes to ensure that HCV patients receive the right treatment and to fulfil the commitment to achieve the targets established in the Plan for the Elimination of Hepatitis C in Brazil

Introduction

The year 2020 was marked by the global public health challenge and the various social dynamics arising from the COVID-19 pandemic, as well as the complexity of handling, controlling and preventing infection and the new disease. However, despite the ongoing pandemic, the awarding of the Nobel Prize in Physiology or Medicine to Harvey Alter, Michael Horton and Charles Rice for their discovery of the hepatitis C virus, approximately 30 years after their work was published¹, shone a spotlight on the importance of the global goal to eliminate infection by the hepatitis C virus (HCV) as a major public health problem (as recently redefined by WHO)².

In this article, we aim to present a descriptive analysis of the official data on hepatitis C to provide an overview of the situation and support epidemiological scenarios regarding the disease in Brazil. We also seek to contextualise HCV diagnosis and treatment in relation to the targets set in the plan for the elimination of viral hepatitis and the changes in the care provided to hepatitis C patients as a result of the COVID-19 pandemic.

The results presented here reflect the action taken by Brazil to tackle the HCV epidemic and could provide a basis for action to be taken by municipal, state and federal authorities. This study

1 *The Nobel Prize in Physiology or Medicine 2020. NobelPrize.org. Nobel Media AB 2021. Wed. 3 Feb 2021. <https://www.nobelprize.org/prizes/medicine/2020/summary/>*

2 *Available at https://www.who.int/hepatitis/news-events/07_towards-elimination-Dr-Gottfried-Hirschall.pdf?ua=1. Accessed on 04/02/2021.*

has been financed by the Newton Fund Institutional Links project, a partnership between the Getúlio Vargas Foundation (FGV), the Oswaldo Cruz Foundation (Fiocruz) and the London School of Economics (LSE) and aims to analyse Brazil's response to the hepatitis C epidemic.

The plan to eliminate viral hepatitis as a public health problem by 2030, as launched by the World Health Organisation (WHO) in 2016, proposes short-, medium- and long-term actions and targets. Brazil has led the way in the achievement of these targets and was one of several countries that pledged to eliminate viral hepatitis at the World Hepatitis Summit (WHS) in Brazil in 2017. At the opening session of that event, Ricardo Barros, the then-Minister for Health, confirmed that Brazil was working to treat and cure all 660,000 Brazilians infected with HCV in that year. Mr Barros also pledged at the event to expand access to direct-acting antivirals (DAA), allowing treatment to be extended to all eligible cases rather than only the most seriously ill patients (WHS 2017), thereby following the successful example set in the pioneering strategy adopted to control HIV in Brazil (Fonseca et al., 2019).

2017 also saw the adoption of the Plan for the Elimination of Hepatitis C in Brazil by the Tripartite Interagency Commission (Comissão Intergestora Tripartite, CIT). This plan proposed various actions, including: (1) estimating the number of cases of hepatitis nationwide on the basis of epidemiological data; (2) proposing targets for the numbers of cases to be tested, diagnosed and treated to achieve the target set (in accordance with WHO guidance); and (3) assessing the funds needed to achieve the desired targets (Ministry of Health 2018 – Plan for the Elimination of Hepatitis C in Brazil).

The Ministry of Health worked with the Pan American Health Organization (PAHO) and the Center for Disease Analysis (CDA) to develop a mathematical model to estimate the number of HCV cases in Brazil. The prevalence of viral cases requiring treatment for HCV was estimated at approximately 0.7% of individuals aged

between 15 and 69 years in Brazil in 2016 (Benzaken et al., 2018, 2019). The Ministry of Health used this estimate to set annual testing and treatment targets. The targets set for 2020 were the following: to test 15,384,000 individuals in the general population; conduct 40,000 new diagnostic tests; and treat 50,000 people to reduce hepatitis C-associated mortality by 65% in Brazil by 2030 (Ministry of Health 2018 – Plan for the Elimination of Hepatitis C in Brazil).

In 2018, the Ministry of Health also launched the Clinical Protocol and Treatment Guidelines for Hepatitis C and Coinfections (Protocolo Clínico e Diretrizes Terapêuticas para Hepatite C e Coinfecções, PCDT), which expanded the treatment methods available to ensure universal access to treatment for all individuals infected with hepatitis C virus in Brazil (Ministry of Health 2018 – PCDT).

Data and method

This technical report is based on a descriptive analysis and study of official open-access data on hepatitis C in Brazil supplied by the Chronic Diseases and Sexually Transmitted Infections Division (DCCI) of the Department for Health Surveillance (SVS) of the Brazilian Ministry of Health as well as state and municipal health departments.

To carry out this study, we collected official public data from Brazil's Disease Information Reporting System (Sistema de Informação de Agravos de Notificação, SINAN) and Mortality Information System (Sistema de Informação de Mortalidade, SIM), which was processed and provided by the DCCI via the dashboard for indicators and basic data on hepatitis in Brazilian municipalities³ and the viral hepatitis monitoring dashboard⁴. We also examined

³ Available at <http://indicadoreshepatites.aids.gov.br/>. Accessed on 22/01/2021.

⁴ Available at <http://www.aids.gov.br/pt-br/publico-geral/hv/monitoramento>. Accessed on 22/01/2021.

data published in the 2020 viral hepatitis epidemiological bulletin, which includes data reported up to 31/12/2019. We did not use SINAN data provided via the National Health System Information Department (DATASUS) tabulated via TabNet since these data have not been updated since mid-2019⁵.

The raw data and standardised epidemiological indicators are presented in graphs and tables with explanatory comments. The results presented refer to Brazil and its five macroregions.

Results and discussion

In Brazil, epidemiological surveillance of hepatitis C is carried out through the reporting and monitoring of suspected HCV cases recorded in SINAN. All confirmed cases and outbreaks must be reported and recorded using the viral hepatitis investigation form⁶.

The mandatory reporting of diseases was enshrined in Brazilian legislation through Act 6259 of 30 October 1975. SINAN was gradually rolled out from 1993 (Brazil, 2007), and from 1996 all cases of viral hepatitis had to be reported via SINAN. However, in 1998, viral hepatitis was removed from the list of diseases subject to mandatory reporting: the recording of cases was deemed to contribute little towards epidemiological surveillance as the different types of viral hepatitis present different characteristics, including different forms of transmission and distribution in the population. Despite this, the reporting of hepatitis B cases remained mandatory (Teixeria et al, 1998). Hepatitis C was then re-added to the list in 1999 under Order 1461/1999.

5 Available at http://tabnet2.datasus.gov.br/cgi/dhdat.exe?ETL_hepa/ETL_hepatfbr.def (last updated 07/08/2019) and <http://tabnet.datasus.gov.br/cgi/deftohtm.exe?sinannet/cnv/hepabr.def> (last updated on 30/01/2019). Accessed on 22/01/2021

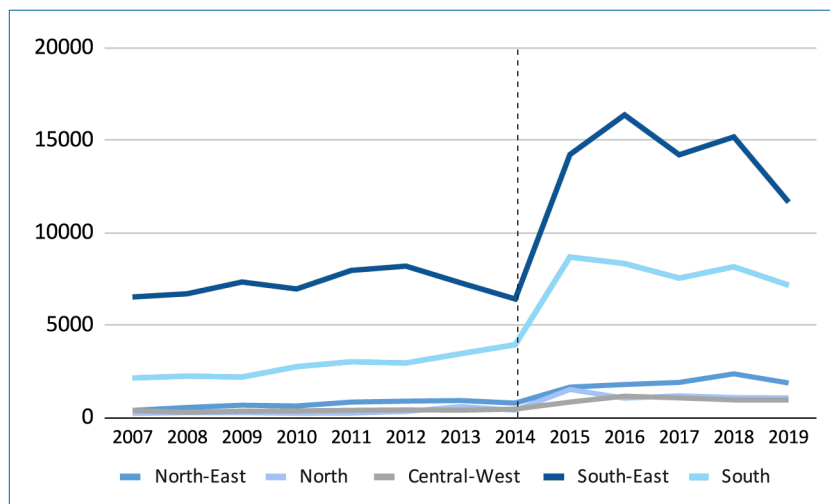
6 Available at http://portalsinan.saude.gov.br/images/documentos/Agravos/Hepatites_Virais/Ficha_Hepatites_Virais.pdf. Accessed on 22/01/2020

In 2002, hepatitis gained greater visibility within the Ministry of Health with the creation of the National Programme for the Prevention and Control of Viral Hepatitis, which led to improvements in the management of care for individuals living with viral hepatitis: for instance, epidemiological and care information systems began to be used to monitor the progression of the disease and health indicators were developed to assess the epidemiological situation concerning the disease in Brazil.

To understand and analyse the official data available, the criteria used for case definition must be taken into account. Until 2014, only individuals testing positive for HCV antibodies and HCV RNA were considered to be HCV cases. However, from 2015, in the light of new WHO guidance on the elimination of hepatitis C as a public health problem, the criteria were modified and an HCV case was defined as any individual testing positive for HCV antibodies or HCV RNA. Case detection sensitivity improved with the expansion of the criteria, with a direct impact on official national statistics. Figures 1 and 2 show that the HCV case detection rate rose in all macroregions of Brazil from 2015. The adoption of more flexible criteria obviously means that the possibility of an increase in false positives, however modest (given the high specificity of these tests), cannot be ruled out.

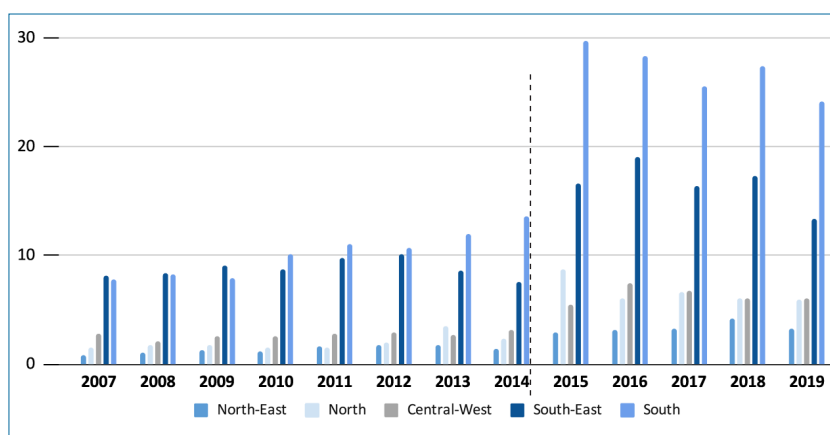
Importantly, the 2015 update to the WHO guidelines on the elimination of hepatitis C introduced treatment with direct antiviral agents (DAAs), with the consideration that if the capacity to treat increases, the definition of who needs to be treated also expands.

Figure 1.
Number of HCV cases¹ by year reported and macroregion of Brazil (2007-2019)



Source: MS/SVS/DCCI (Chronic Diseases and Sexually Transmitted Infections Division, Department for Health Surveillance, Brazilian Ministry of Health). Notes: (1) Data current as at 31/12/2019. Available at <http://indicadoreshepatites.aids.gov.br/>. Accessed on 22/01/2021. Cases in 2007-2014 testing positive for HCV antibodies and HCV RNA; cases in 2015-2019 testing positive for HCV antibodies or HCV RNA. The dashed line indicates the change in case definition.

Figure 2.
Detection rate (per 100k inhabitants) of HCV cases¹ by year reported (2007-2019) and macroregion of Brazil (2007-2019)



Source: MS/SVS/DCCI (Chronic Diseases and Sexually Transmitted Infections Division, Department for Health Surveillance, Brazilian Ministry of Health). Notes: (1) Data current as at 31/12/2019. Available at <http://indicadoreshepatites.aids.gov.br/>. Accessed on 22/01/2021. Cases in 2007-2014 testing positive for HCV antibodies and HCV RNA; cases in 2015-2019 testing positive for HCV antibodies or HCV RNA. The dashed line indicates the change in case definition.

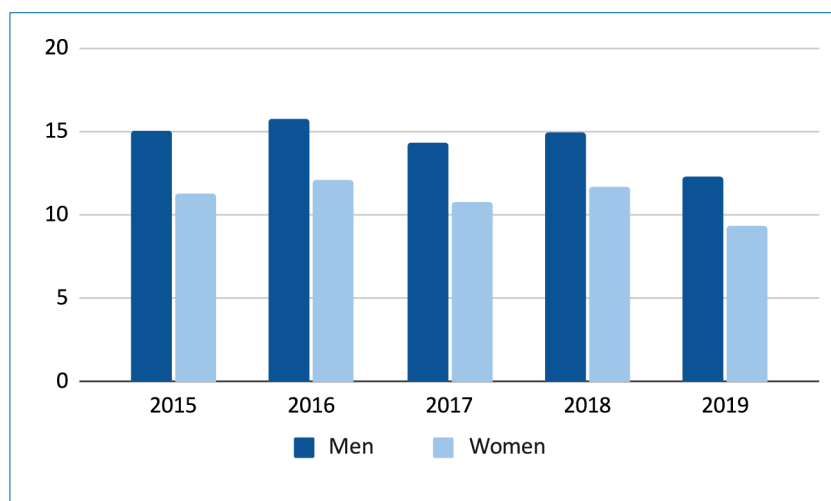
From 2015 to 2019, the case detection rate per 100,000 inhabitants in Brazil remained relatively stable, with 13.2 cases per 100,000 inhabitants in 2015 and 13.3 cases per 100,000 inhabitants in 2018. The detection rate for new cases was lower in 2019 (10.8 cases per 100,000 inhabitants); however, the 2019 data are still considered to be preliminary and are subject to change.

In 2019, the detection rate observed in the North region fell from 8.7 cases per 100,000 inhabitants in 2015 to 5.9 cases per 100,000 inhabitants. There was also a slight decline in the detection rate in the South and South-East regions from 29.7 and 16.6 cases per 100,000 inhabitants in 2015 to 23.9 and 13.2 cases per 100,000 inhabitants in 2019 respectively. Detection rates rose in both the North-East and Central-West regions (see Figure 2).

The South and South-East regions have the highest numbers: in 2019, 18,834 cases were reported in these two regions, representing around 80% of all cases detected in Brazil. The highest case detection rates per 100,000 inhabitants were also reported in these two regions (24.1 in the South and 13.3 in the South-East region, see Figures 1 and 2).

The number of confirmed cases and the case detection rate in Brazil is also higher in men than in women, a difference that has remained stable in recent years. Between 2015 and 2019, the ratio was approximately 1.3:1.0 men to women. In 2019, the case detection rate per 100,000 inhabitants was 12.3 among men and 9.4 among women (see Figure 3).

Figure 3.
Case detection rate per 100,000 inhabitants by year reported (Brazil 2015-2019).¹



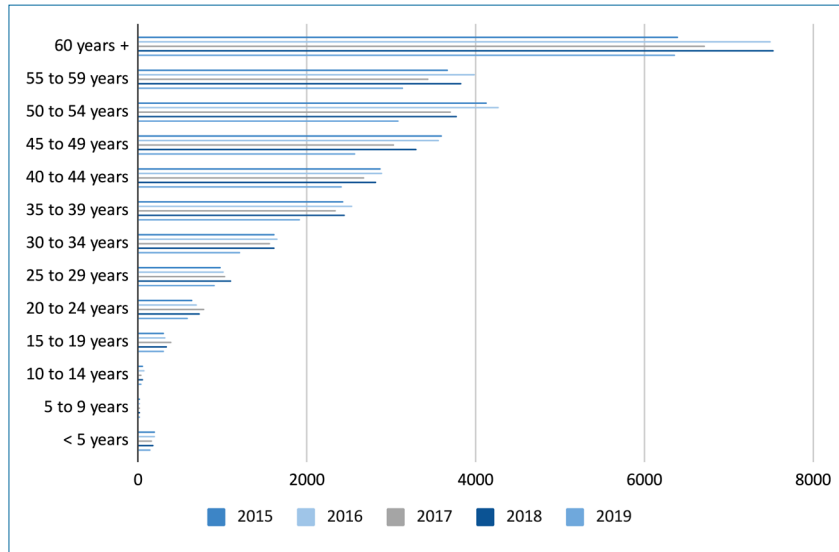
Source: MS/SVS/DCCI (Chronic Diseases and Sexually Transmitted Infections Division, Department for Health Surveillance, Brazilian Ministry of Health). Notes: (1) Data current as at 31/12/2019. Available at <http://indicadoreshepatites.aids.gov.br/>. Accessed on 22/01/2021. Cases in 2015-2019 testing positive for HCV antibodies or HCV RNA.

The highest numbers of cases and rates were also reported in the oldest cohorts. Between 2015 and 2019, the 55-59 age group had the highest case detection rate per 100,000 inhabitants, ranging from 37.5 to 28.5 over that period. In all years in the time period observed, the highest absolute number of recorded cases was observed in the 60+ age group, with 7,500 new cases reported in 2015 and 6,366 cases reported in 2019 (see Figures 4 and 5).

Analysis of the data by age group is essential not only because HCV exposure time is cumulative and long-lasting (i.e. there is normally an interval between the initial infection and the onset of symptoms that may last decades), but because in Brazil's case, there is also the issue of blood bank and blood product monitoring. Mandatory HCV screening only began in the 1990s (Brazil, 2005), meaning the oldest age cohorts have been exposed to additional risk.

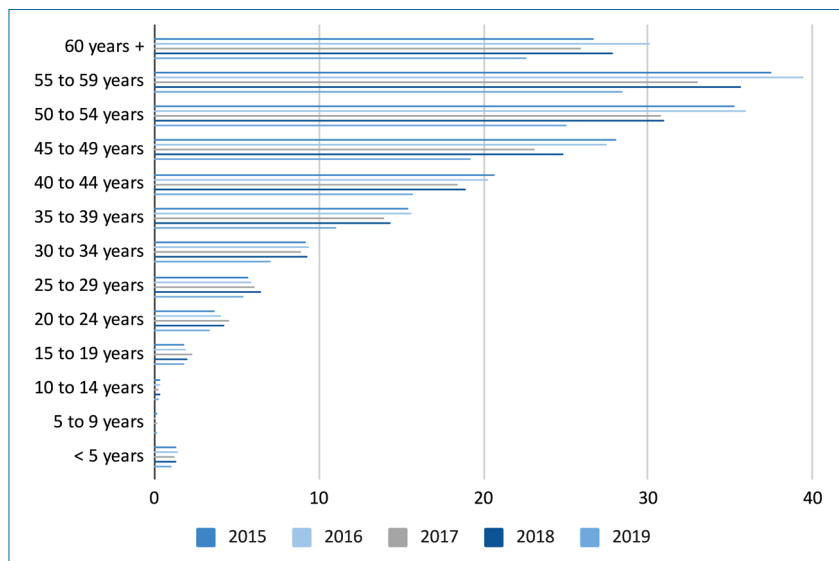
Estimates of the prevalence of HCV worldwide vary considerably given the heterogeneity of populations living in different continents and countries (Polaris Observatory, 2017; Han et al., 2019). In general, the prevalence of infection is higher in low- and middle-income countries and lower in developed countries. High-risk behaviours in certain populations and unsafe injection practices are among the major causes of HCV infection worldwide (Lanini et al, 2016). A more in-depth and specific analysis is therefore needed to compare Brazil's rates with global rates and rates in other countries.

Figure 4.
Number of confirmed
HCV cases¹ by age group
and year reported (Brazil
2015-2019)



Source: MS/SVS/DCCI (Chronic Diseases and Sexually Transmitted Infections Division, Department for Health Surveillance, Brazilian Ministry of Health). Notes: (1) Data current as at 31/12/2019. Available at <http://indicadoreshepatites.aids.gov.br/>. Accessed on 22/01/2021. Cases in 2015-2019 testing positive for HCV antibodies or HCV RNA.

Figure 5.
Case detection rate per
100,000 inhabitants by age
group and year reported
(Brazil 2015-2019)

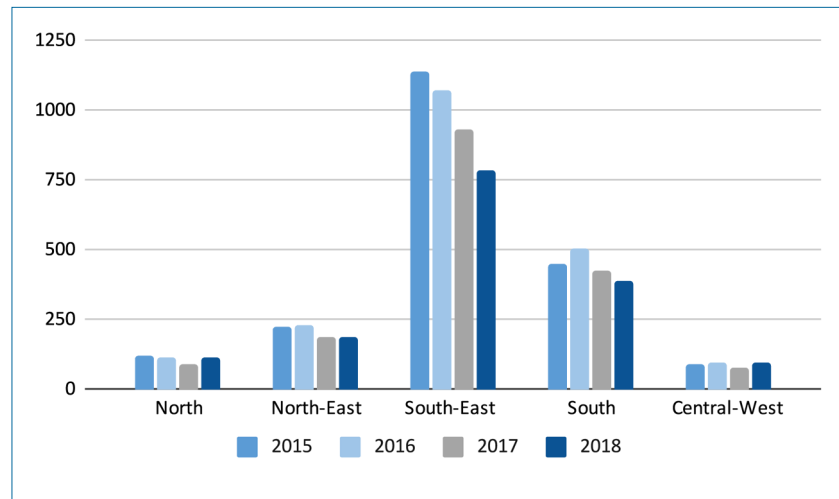


Source: MS/SVS/DCCI (Chronic Diseases and Sexually Transmitted Infections Division, Department for Health Surveillance, Brazilian Ministry of Health). Notes: (1) Data current as at 31/12/2019. Available at <http://indicadoreshepatites.aids.gov.br/>. Accessed on 22/01/2021. Cases in 2015-2019 testing positive for HCV antibodies or HCV RNA.

HCV-associated deaths in Brazil follow the same trend as cases and are concentrated in the South-East and South regions. The highest absolute numbers and the highest death rates are also reported in these regions. In 2015, 1142 deaths caused by HCV were reported in the South-East region. This indicator has declined in recent years, with 788 deaths from HCV recorded in this region in 2019.

The death rate per 100,000 inhabitants was higher in the South region, ranging from 1.5 deaths per 100,000 inhabitants in 2015 to 1.3 deaths per 100,000 inhabitants in 2019. A downward trend was also observed in the number of deaths, especially in the South-East region. However, in the North and Central-West regions the number of deaths appeared to remain stable during the period observed (see Figure 6).

Figure 6.
Number of deaths caused by Hepatitis C¹ by region of residence and year of occurrence (Brazil 2015 to 2018)



Source: SIM/MS (Mortality Information System, Brazilian Ministry of Health).
Note (1): Death from hepatitis C: root cause B17.1 (acute hepatitis C) or B18.2 (chronic viral hepatitis C).

On examining the most recent official open-access statistics on HCV in Brazil presented here, a downward trend can be identified in some of the specific indicators relating to this disease. Thanks to national action planning and the outcomes of this planning, by 2019 the country was in a good position to meet the targets envisaged in the Plan for the Elimination of Hepatitis C in Brazil. However, the national results reflect the overall situation and there may be differences in the indicators for smaller geographical areas such as macroregions, states and municipalities. Analyses focusing on specific areas should therefore be conducted to identify any differences and the possible reasons for those differences.

In 2019, the annual treatment target for Brazil was close to being achieved; however, this figure fell by more than 50% in 2020, most probably as a result of the impact of the COVID-19 pandemic on HCV control in the country (Table 1).

Table 1.
Targets for diagnoses, treatments dispensed and people treated per year envisaged in the Plan for the Elimination of Hepatitis C in Brazil and actual figures (Brazil 2019-2020).

	2020 target	2020 actual	2019 actual
New diagnoses/year	40,000	no info	22,747
Treatment given/year	50,000	19,496 ²	48,304 ¹
People treated/year		16,874 ⁴	36,658 ³

Source: Information panel on Hepatitis B and C treatment. Available at <http://www.aids.gov.br/pt-br/publico-geral/hv/monitoramento>. Accessed on 22/01/2021. Plan for the Elimination of Hepatitis C in Brazil. Available at <http://www.aids.gov.br/pt-br/pub/2019/plano-para-eliminacao-da-hepatite-c-no-brasil>. Accessed on 22/01/2021. Notes: (1). In 2019, 2482 treatment courses were sent to states to create strategic stockpiles. (2) In 2020, 4158 treatment courses were sent to states. (3) Data referring to people treated between 01/01/2019 and 31/12/2019. (3) Data referring to people treated between 01/01/2020 and 31/10/2020.

The COVID-19 pandemic has had a direct impact on the diagnosis and treatment of HCV. In March 2020, the Ministry of Health issued Circular no. 14/2020⁷, which authorised the sharing of equipment belonging to the national HIV and viral hepatitis viral load network with the SARS-CoV-2 response to support the Public Health Laboratories Division during the public health emergency caused by the COVID-19 pandemic.

Memo no. 16/2020⁸, issued soon after in April 2020, provided new guidelines regarding the processing of the genotype tests needed to determine treatment and explained that the process was being affected by disruption to the air and road networks in Brazil.

In early December of that year, the Ministry of Health issued Information Note no. 22/2020⁹, which declared that sample collection for HCV genotype tests would be suspended, making treatment definition more difficult since the results of those

7 Available at <http://www.aids.gov.br/pt-br/legislacao/oficio-circular-no-142020cgistdccisvms>. Accessed on 22/01/2021

8 Available at <http://www.aids.gov.br/pt-br/legislacao/oficio-circular-no-162020cgistdccisvms>. Accessed on 22/01/2021

9 Available at <https://www.cosemssc.org.br/informe-sobre-a-suspensao-da-coleta-das-amstras-para-os-exames-de-genopagem-do-hiv-e-da-genopagem-do-hcv/>. Accessed on 22/01/2020.

tests are used to select the clinical protocol to be followed. The Ministry of Health explained in the Information Note that the tests were suspended as a consequence of delays in the public tender process. This time, the official treatment guidelines were amended in order to define a new treatment protocol that would be valid for medical prescriptions until 28/02/2021 (Information Note no. 24/2020/MS)¹⁰.

In spite of the negative effects of the COVID-19 pandemic, which had a direct impact on the diagnosis and treatment of HCV in Brazil, 2020 saw major progress in care for patients with viral hepatitis. Order no. 1537/MS of 12 June 2020 incorporated the treatment of patients with viral hepatitis into primary health care¹¹. As a result, in addition to the actions concerning health promotion, prevention, screening and diagnosis that already form part of their work, the primary care sector will also be responsible for treating patients with HCV. Medicines to treat HCV have therefore been included in the Strategic Component of Pharmaceutical Care. This means that, while the federal authorities are still responsible for acquiring and distributing medicines, dispensing is now the responsibility of the programme in partnership with state health departments.

¹⁰ Available at http://www.aids.gov.br/system/tdf/legislacao/2020/-notas_informativas/nota_informativa_no_24.2020.dcci_.pdf?file=1&type=node&id=67466&force=1. Accessed on 22/01/2021.

¹¹ Level I: Family Health Strategy Teams, health centres or clinics and testing and advice centres duly supplied with Level II equipment for specialist referrals and counter-referrals where necessary.

Conclusions

Brazil held municipal elections in 2020 and new mayors have taken office in 2021 in time for the development of four-year municipal health plans for the period 2022-2025. These municipal health plans are developed in the first year of each administration and implemented from the second year until the first year of the following administration. As a general rule, municipal health plans should incorporate general guidelines for state and federal health policies and should be aligned with the multiyear plan and the municipal targets programme.

If Brazil is to get back on track towards the elimination of HCV as a public health problem, municipal authorities should incorporate actions aiming at the implementation of new primary care guidelines into their municipal health programmes to ensure that HCV patients receive the right treatment and to fulfil the commitment to achieve the targets established in the Plan for the Elimination of Hepatitis C in Brazil. Furthermore, as states and municipalities now have the autonomy to structure their administrative and care network and can therefore define the scope of viral hepatitis services in their territory, coordination across health regions and municipalities is urgently needed to avoid the unequal provision of care to viral hepatitis patients.

The year 2021 started with a rise in the number of COVID-19 cases and deaths in Brazil (O Globo, 2021). Primary care services have been overloaded thanks to the need for action during the COVID-19 pandemic. At this time of crisis, the authorities must focus on allocating adequate resources to the care of HCV patients and planning actions to achieve hepatitis C prevention and control objectives and targets.

“The technical content in this article is the exclusive responsibility of the authors and does not necessarily reflect the opinions of the institutions linked to the researchers or the project.

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