Recentralizing Drug Procurement in a Context of Decentralized Health System: The Case of Hepatitis C Drugs in Brazil

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This paper is a preliminary version of the report on the study over Brazil's response to the hepatitis C epidemic. The authors welcome feedbacks but would like to require their prior consent for this paper dissemination.

Abstract

Brazil has one of the most decentralized health systems in the world, with more than 5,000 municipalities responsible for healthcare provision. This article analyzes the paradoxical process of recentralizing the procurement of hepatitis C drugs in Brazil in the mid-2000s. This recentralization shows an unexpected shift in the health system's organization, which previously gave substantial power to elected state governments to procure and distribute these drugs. We aimed to determine why (and how) the purchasing of interferon was recentralized despite its apparent impact on the decision-making autonomy of regional governments and the weakening of organized regional interests.

This qualitative study analyzed the policy and institutional processes needed to reallocate drug procurement to the central government. It investigated dozens of Ministry of Health ordinances, meeting minutes from the Tripartite Commission (a deliberation body made up of representatives of the three levels of government) and Public Hearings at the National Congress, hundreds of newspaper articles, and interviews with decision-makers.

Decentralization of hepatitis C drugs created unequal access to these drugs across the country. Fragmented public procurement resulted in different prices in different jurisdictions. The frequent shortages of hepatitis C medicines increased litigation against state governments. The treatment supply problem was the genesis of powerful hepatitis

[1] The authors would like to thank São Paulo Research Foundation (FAPESP) for their financial support to carry out this research and the translation of this article. LBA received the undergraduate research scholarship (2018/19737-7, 01/10/2018 - 31/12/2019), the research internship abroad (BEPE), and the Master's degree scholarship (2019/25141-2); EMF received the Young Investigator Grant (15/18604-5, 01/12/2016-30/11/2021, JP-FAPESP); AD is funded by the Coordination for the Improvement of Higher Education Personnel from the Ministry of Education (CAPES) (88887.504139/2020-00). The authors would also like to thank Fundação Getulio Vargas, the Oswaldo Cruz Foundation, the London School of Economics, and the British Council-Newton Fund for their financial support to carry out the research "Brazil's Fight Against Hepatitis C: Surveillance, Control, and Care" (2020-2022)

C patient advocacy in Brazil, which put intense pressure on state governments. In turn, state governments accepted that the Ministry of Health recentralized treatment procurement as a way to avoid blame and expensive court litigations. This process highlighted the importance of coordinating procurement at a national level, which, a few years later, served as a basis for a major recentralization of high-cost drug programs. Recentralization created an important institutional legacy. In 2015, once innovative, high-cost treatment for hepatitis C became available (direct-acting antiviral drugs), the approach to procuring them was based on the existing arrangements created in the earlier process of recentralization (Fonseca, Shadlen & Bastos, 2019).

Decentralization in a healthcare system is usually seen as an apolitical enterprise. Our study enriches the literature by exploring the reallocation of authority (and agency) of a life-saving program in the context of hyper-federalist and decentralized health systems. We also provide insights into the politics of credit and blame, which have shaped much of what we have seen today in the COVID-19 pandemic response in federal countries.

Keywords: hepatitis C, recentralization, drug procurement, federalism, Brazil.

1. Introduction

This article shows a preliminary report of a study over Brazil's response to the hepatitis C epidemic, with emphasis on the recentralization of the procurement for drugs as interferon and pegylated interferon – the latter was a high-cost, innovative drug at the time.

Brazil has one of the most decentralized health systems in the world. More than 5000 municipalities are responsible for providing healthcare services, while the Ministry of Health (MS, acronym in Portuguese) and the state governments are responsible for managing the health policy. This qualitative study analyzes the paradoxical process of recentralizing the procurement of hepatitis C drugs in Brazil between 2006 and 2009. The treatments for hepatitis C at the time were available at the Unified Health System (SUS, acronym in Portuguese) and, despite being funded by the MS, it is the state government's responsibility to acquire hepatitis C treatments. The recentralization of the procurement for hepatitis C drugs demonstrates an unexpected shift to SUS management. This study

aimed to understand how and why the procurement of these drugs was recentralized, despite its apparent impact on the decision-making autonomy of regional governments.

Previous studies have shown the centralizing nature of Brazilian federalism, highlighting the importance of the MS to induce and fund health policies in the country (Arretche, 2002; Marques & Arretche, 2003). These studies have provided substantial evidence regarding the possible recentralizing initiatives by the federal government. MS would be able to recentralize the procurement of drugs as it has (and applies) agenda power and substantial control of financial resources (Arretche, 2002; Monteiro-Neto, 2014). However, the literature still has gaps regarding the positioning and strategies of the state governments toward centralizing initiatives, such as in the case of hepatitis C drugs. As this decision is to be agreed upon by the municipal, state, and federal executives in the Tripartite Commission (CIT), the State Departments of Health would have a chance to stop the recentralizing procurement of drugs if they wanted to.

It would be reasonable that the states chose to keep their responsibility for the procurement of these drugs for various reasons. First, to be in close contact with players in the pharmaceutical industry. In Brazil, governors are elected with support from the pharmaceutical industry, which is one of the main funders of political campaigns (Scheffer & Bahia, 2013; Junqueira & Chaves, 2019; Grupo de Trabalho em Propriedade Intelectual [GTPI], 2014). Thus, governors would lose privileged access and bargaining power with these agents. Second, according to Arretche's (2003) suggestion, with the political and administrative decentralization of SUS, the subnational governments may have articulated interest group coalitions with the pharmaceutical industry. In other words, the decentralization created local political economies that would be hard to revert without a big exogenous shock. Lastly, drug distribution can be a great tool to credit claiming, that is, it would allow the governor to claim the credit of a well-succeeded policy. We observed it in the supply of COVID-19 vaccines in the state of São Paulo (Folha de S. Paulo, 2021). Why did the state governments not oppose the loss of this attribution to the federal government?

This study intends to contribute to the understanding of the recentralizing process of public policies in the Brazilian case. The reconstruction of the gradual process of recentralizing the procurement of hepatitis C drugs allowed us to identify the incentives of players and the conditions that determined this outcome in the context of a decentralized health system with a federal-level resource concentration. The analysis of tangible cases of recentralization is essential to highlight this phenomenon that is

becoming increasingly common, including as a possible reaction to processes prior to the decentralization (Almeida, 2005; Dickcovick, 2006). This study is especially interesting because it suggests the decisions that seemed to reduce the autonomy of regional governments not always are taken against their will. On the contrary, we described a case in which this change was not only accepted but acclaimed by state managers.

The article is organized as follows: in the next section, we describe the methodology used to conduct this research; then, we analyze the hepatitis C pharmaceutical policy path, which we divided into two parts. First, we addressed the moment when responsibilities were divided between federal and state levels, with a short description of the challenges faced in this model. This is important to contextualize the reconstruction of the processes of decision-making that involved the three government levels and resulted in the recentralization of the procurement of hepatitis C drugs to the MS. The second part discusses the process of recentralizing the procurement in the MS, the reaction of the states, and a short report of the results of this path change. Finally, we conclude with the main findings of this research.

2. Methodology

This is a qualitative study based on government documents, media news, and semi-structured interviews with decision-makers of the MS. The documents, which were collected between September 2020 and February 2021, consisted of regulations of the MS; technical notes, reports, and evaluations of the technical areas of MS involved with the fight against hepatitis C; minutes and/or transcriptions of the CTI meetings and of some public hearings at the National Congress. The news was collected from the Dow Jones's platform Factiva during the same period.

The decision-makers, who were interviewed between February and May 2021, were selected from a documental search regarding their involvement with the pharmaceutical management toward hepatitis C and with the process of recentralizing the procurement of hepatitis C treatments between 2006 and 2009. Table 1 shows the data of each interview, each interviewee's position, and the reference which will be used from now on. The interviews occurred via Zoom. Their audios were recorded and transcripted with the participants' consent. Data analysis, including documents and interview transcriptions, was performed via Atlas.ti, Cloud version, a software program that analyzes qualitative data. It was shared with all the team members in this research.

All documents were organized in chronological order to a better understanding of the sequence of events leading to the phenomenon hereby studied. We understand that the attention on the series of events is essential in cases involving negotiations at government levels because it allows us to identify the root of the problems that were affecting the pharmaceutical policies of hepatitis C treatments and the strategies taken for each federative entity related to this challenge.

Table 1– List of decision-makers interviewed

Reference	Interview Date	Position (level)
Interview 1	May 11, 2021	Advisement on viral hepatitis policy management (MS)
Interview 2	May 12, 2021	Management of national programs of diseases (MS)
Interview 3	February 17, 2021	Policy management of viral hepatitis (MS and SES-SP)
Interview 4	February 26, 2021	Policy management of viral hepatitis (MS and SES-SP)
Interview 5	March 30, 2021	Management of pharmaceutic policies (MS)
Interview 6	April 29, 2021	Management of pharmaceutic policies (MS)
Interview 7	April 9, 2021	Policy management of viral hepatitis (MS)
Interview 8	May 18, 2021	Policy management of HIV/Aids, viral hepatitis, and STIs (MS)

MS – Ministry of Health
SES-SP – São Paulo's State Department of Health
Source: elaborated by the authors

3. The pharmaceutical policy's pathway regarding hepatitis C in the Unified Health System

The government documents collected and the interviews with decision-makers allowed us to reconstitute the processes of decision-making at the three government levels that resulted in the recentralization of the procurement of hepatitis C drugs in the MS. The pharmaceutical policy's pathway regarding hepatitis C in Brazil can be divided into two moments: the first one is characterized by the decentralized procurement of treatments; the second, by responsibility recentralization to the MS.

First moment: decentralized procurement of hepatitis C *treatments*

Since 1999, when hepatitis C drugs were included in SUS, hepatitis C drugs have been considered "exceptional drugs", implying that their procurement and dispensation

to patients were responsibilities of state departments of health, but their funding was made by the MS per each procedure concluded. In other words, state departments of health received from MS an amount corresponding to the treatments given to the population, based on a price table determined at the moment of drug inclusion in SUS.[2] Also, only drugs described in the national protocol were funded by MS. This national protocol was elaborated by MS's technical committees and approved by the three government levels in the CTI.

In 2000, the hepatitis C treatment approved by the MS consisted of standard alpha-interferon shots with the antiviral ribavirin. This treatment had a palliative response with an extremely low cure rate and were relatively cheap. Later, pegylated interferon emerged, which differs from the standard interferon due to a chemical process that changes its therapeutic effect, increasing its half-life and stability and decreasing Immunogenicity (Santos, 2019). Then, patients and organizations started to pressure the state departments of health to include this drug. The state managers, in turn, passed on this demand to the MS – responsible for establishing the national protocols – according to the executive summaries of the CIT meetings.[3]

However, the drug could not be included by MS at the time due to a lack of scientific evidence proving its superiority compared to the standard interferon. Nevertheless, some state departments of health, such as São Paulo's, started to offer the drug, mostly due to judicial actions filed by patients (Ministry of Health, 2003; Folha de S. Paulo, 2002). At the time, pegylated interferon was considered a high-cost drug (R$ 1,600.00 a month per patient,[4] or close to U$ 550, considering the exchange rate back then), and the state departments of health that offered the drug had to do it using their own resources.

In 2001, the first article proving that pegylated interferon was superior to standard interferon was published. The study showed higher efficacy of the former against hepatitis C with fewer collateral effects (Mann et al, 2001). According to the decision-makers interviewed, this study enabled the inclusion of the drug in MS's national protocols (Interviews 2-5). After the publication of the new protocol in November 2002, states started to receive financial compensation for this drug.

[2] A policy regulated by the 1999 Ordinances GM/MS no. 531, as of 30 April, no. 1481 as of 28 December and Ordinance SAS/MS no. 409, as of 5 August 1999.
[3] Executive summary of the Tripartite Commission's ordinary meeting on February 20, 2003
[4] Source: Ministerial Ordinance GM/MS 1318, as of 23 July 2002, which determines the price of exceptional drugs for resource allocation by the MS to the state departments of health.

However, even with the inclusion and the federal funding of all hepatitis C drugs available, this shared responsibility arrangement did not reach the expected results, because the state departments of health continued facing difficulties to regularize treatment provision to patients, as we observed in media reports (Folha de S. Paulo, 2000; Gazeta do Povo, 2006), government documents (Ministry of Health, 2002), and interviews (Interviews 1-6). These sources suggest that the main challenge still was the high cost of treatment with pegylated interferon, which, according to the state departments of health, did not match the financial resource sent by the MS.

The decision-makers interviewed stated that these two pharmaceutical companies would sell pegylated interferon[5] to states at higher prices than those fixed in SUS's price table. The MS's documents showed that this difference created "*implicitly* the image of co-funding between the Union and the states since the values passed by MS weren't exactly being followed for procurement" (MS, 2010, p. 69, our emphasis). According to the reports of public hearings at the National Congress and also to the CTI meetings, the states demanded that the MS revised the values allocated and better defined the role of each federal entity in the so-called "co-funding" (MS, 2003; Chamber of Deputies, 2007). Therefore, one can understand that the supply of these drugs relied on the capability of each state to spend its own resources in order to compensate the value discrepancy – most likely generating an interfederative conflict to some degree.

If, on the one hand, the state governments faced difficulties imposed by MS's rules, on the other hand, there was evidence that those state governments which were capable of overcoming these obstacles and regularizing the drug supply would take credit for that, including for being ahead of the MS. This is was the case of São Paulo. In 2006, São Paulo increased the access to pegylated interferon to re-treatment cases – which was included later on in the national protocol. The media reported this fact highlighting the pioneering nature of the state:

> "São Paulo's government has now implemented two norms that increase the access of hepatitis patients to their drugs. Hepatitis C patients that did not entirely heal with the conventional treatment can try a 're-treatment' with pegylated interferon. [...] These two treatments implemented by the State

[5] There were two types of pegylated interferon, the 2a and the 2b, both similar in efficacy according to 2002 PCDT (Clinical Protocol and Therapeutic Guidelines). The 2a version was commercialized by Roche and the 2b by Schering-Plough.

> Department of Health do not belong to the Hepatitis Program of the Ministry of Health." Excerpt of the news from Estado de S. Paulo, published in April 6, 2006.

Yet, besides the blame and credit game between state and federal governments, this anecdote shows another undesirable effect of the decentralized procurement at a regional level: the pronounced inequality of access to treatments between different regions. More populated states and with a higher capability to negotiate with pharmaceutical companies, like São Paulo, could get more discounts on drug prices. However, most of the smaller states had a low administrative and financial capability. Sometimes these smaller states did not even perform testing campaigns to avoid creating a demand for treatments that they would not be able to supply (Interview 1). This corroborates other studies, showing that state governments' capabilities to implement policies vary according to their financial and administrative resources,[6] in spite of their equal formal conditions to access federal resources (Marques & Arretche, 2003; Arretche, 2010).

Thus, the shared arrangement to supply drugs – with funding by MS and procurement by the state departments of health – did not produce the expected effects, that is, to guarantee the regular supply of treatment to patients. Even with the provision of federal resources, the high cost of these drugs impaired procurement, and the different financial and administrative capabilities between states generated substantial access inequality on a national scale. The solution for this problem, agreed upon by all government levels, was to recentralize the procurement of hepatitis C drugs in the MS as described below.

Second moment: the recentralization of the procurement of hepatitis C drugs

The recentralization of the procurement of hepatitis C drugs was a gradual process. It started in 2006, with the procurement centralization of standard interferon in the MS, and ended in 2009, when the other drugs (pegylated interferon and ribavirin) were centralized. This process was conducted by MS and implemented via ministerial ordinances (Table 2) approved by the CTI.

[6] There must be other causes affecting the implementation of these policies by state governments, such as divergent political agendas, demography characteristics, and so on. This study does not approach directly these causes, only those mentioned in the interviews and in the collected documents marked as relevant to the recentralization process.

Table 2 – Ministerial ordinances for the recentralization of the procurement of hepatitis C drugs

Ordinance	Date	Decision
Ordinance GM/MS no. 562	March 16, 2006	It centralizes the procurement of standard interferon and other two exceptional drugs in the Ministry of Health.
Ordinance GM/MS no. 2577	October 27, 2006	Approves the Drugs of Exceptional Dispensing Component (CMDE)
Ordinance GM/MS no. 204	January 2, 2007	It regulates the funding sections of the Unified Health System (SUS), creating the components of Pharmaceutical Assistance: Strategy Component (HIV/Aids and endemics) and Specialized Component (including hepatitis C).
Ordinance GM/MS no. 2981	November 26, 2009	It regulates the Specialized Component of Pharmaceutical Assistance, defining the centralized procurement of standard and pegylated interferon, and ribavirin.

Source: elaborated by the authors

This series of modifications via ministerial ordinances changed the pathway of pharmaceutical management in SUS. The National Policy for Drugs, released in 1998, defined that "[the] major priority of the Ministry of Health is the *full decentralization* of the drug procurement and distribution process" (our emphasis).[7] Then, the switch of responsibility for drug procurement from state governments to MS represents an inflection on this trajectory, from decentralization to recentralization of competencies in healthcare.

Previous studies have shown that the MS inserted in its agenda the reform of the appendix on exceptional drugs after a reorientation in their political agenda. In 2006, MS started to develop policies aimed at the Economical and Industrial Complex of Healthcare (CEIS) (Fonseca & Costa, 2015). Although the decentralization of procurement of hepatitis C drugs would bring consequences to state governments' autonomy, the MS did not find resistance from state managers according to interviewees' statements. On the contrary: "all the states loved it," according to one of the decision-makers (Interview 5). He explained that CTI's decisions are based on unanimity, that is, a mutual agreement among all three government levels. If there is a lack of consensus, propositions are rejected. Yet, "talking about centralizing procurement was always easier than trying to attribute responsibilities, or operational measurements, to other federal entities" (Interview 5).

[7] Ordinance GM/MS no. 3916, as of 30 October 1998, approving the National Policy for Drugs.

For this reason, recentralization on the procurement of specialized drugs, despite representing a reduction in regional governments' autonomy, was welcome by decision-makers: they saw an opportunity to give up a responsibility that could lead to potential blame-generating pressures compared to other opportunities to claim credit. This strategy was identified by Weaver (1986): "politicians are motivated primarily by the desire to avoid blame for unpopular actions rather than seeking to claim credit for popular ones" (Weaver, 1986, p. 371). Regarding hepatitis C treatments, to avoid blame-generation for irregular supply, the governors agreed to reduce their own autonomy in the procurement of these drugs.

This was possible thanks to the centralizing federative institutions in Brazil. SUS divides the responsibility for health actions into the three government levels, but it greatly concentrates financial resources on MS. If, on the one hand, this can reduce subnational governments' autonomy, on the other hand, it allows them to execute blame-avoidance strategies in a scenario with limited resources and regional inequality. Even with federal funding for drugs, the states continued facing difficulties to regularize the supply of hepatitis C drugs. Consequently, when the proposition of recentralization by the MS was presented, they opted to give up this duty. Even São Paulo's government, which could overcome the challenges in the procurement of high-cost drugs – even expanding access to them, as stated in the re-treatment case – ended up agreeing with the recentralization to the detriment of its autonomy and possible opportunities of credit-claiming.

The recentralization of drug procurement had major consequences on the policy against hepatitis C in the country. First, the recentralization increased equality in the distribution of treatments, since drug supply was no longer contingent on the capability of each state (Interviews 5-7; Chaves et al, 2017). Second, studies have suggested that centralized procurement reduced hepatitis C treatment prices, as it increased the bargaining power of MS in negotiations with pharmaceutical companies (Chaves et al, 2017). This experience created an important institutional legacy, serving as an example for the recentralization of the procurement of other high-cost drugs in 2009 (Fonseca & Costa, 2015). Later on, in 2015, in the incorporation of new treatments for hepatitis C – the direct-acting antivirals (DAAs), which are innovative drugs with a healing prognostic of more than 95% –, the approach to centralized procurement was based on the arrangement created previously for pegylated interferon.

4. Conclusion

This case study concluded that state decision-makers, when facing challenges imposed by the procurement of high-cost drugs (pegylated interferon) and the subsequent incapability to regularize treatment supply, opted to reduce their own autonomy and accept the recentralization of responsibility to the MS.

This conclusion partly discards alternative explanations based on "competitive federalism", which indicates that states would never give up on their autonomy, especially in sensitive policies such as the free supply of high-cost drugs, which they could claim credit for successful actions. The findings of this research contributed to the literature on inter-government relationships and Brazilian centralized federalism. It focused on the analysis of strategies and behavior of the regional states, which have received little attention from this academic approach.

[summary and conclusion to follow]

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