JHPHS
Journal of Hospital Pharmacy and Health Services

Original Paper

Open Access

Judicial demands and drug supply profile by the Ministry of Health in a public university hospital

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Submitted: 09-03-2025 Resubmitted: 09-05-2025 Accepted: 15-05-2025

Double blind peer review

Abstract

Objective: To characterize the judicial demands and drug supply profile by the Ministry of Health (MS) in an intravenous admixture center (CMIV) of a public university hospital. **Methods:** This was a cross-sectional, descriptive, and retrospective study conducted through the analysis of the CMIV database of the public university hospital from 2012 to 2024 for the legal claims profile and from 2015 to 2024 for the medication supply profile by the MS. **Results:** Over a 13-year period, 860 patients involved in legal claims were treated by the CMIV, ranging from 6 to 286 patients per year. A total of 16,520 doses were prepared, with an average of 1,271 preparations per year. The number of distinct medications involved in legal claims was 58. The most legally demanded medications were Bortezomib, Rituximab, and Cetuximab. Regarding the supply of medications by the MS, over the 10 years analyzed, a total of 824 patients were treated, ranging from 96 to 208 patients per year. A total of 11,600 doses were prepared, with an average of 1,160 preparations per year. These data correspond to the use of only five medications supplied by the MS during the study period: trastuzumab, rituximab, asparaginase, pertuzumab, and dactinomycin. **Conclusion:** The study highlighted the strategic role of CMIV in the provision of judicialized drugs, especially in onco-hematological treatments. It revealed shortcomings in the incorporation of new technologies by the Brazilian Unified Health System (SUS) and the resulting strain on hospital infrastructure. The findings underscore the need for adequate structural resources, trained personnel, and an accessible, integrated database to support more efficient and sustainable public health policies, aimed at reducing judicialization and promoting equitable access to healthcare.

Keywords: health judicialization, antineoplastics, oncology, pharmaceutical assistance.

Perfil de demandas judiciais e de medicamentos fornecidos pelo Ministério da Saúde em um hospital público universitário

Resumo

Objetivo: Caracterizar o perfil de demandas judiciais e de fornecimento de medicamentos pelo Ministério da Saúde (MS) em uma central de misturas intravenosas (CMIV) de um hospital público universitário. **Métodos:** Trata-se de um estudo transversal, de caráter descritivo e retrospectivo, realizado por meio da análise do banco de dados da CMIV de um hospital público universitário. Foram analisados os registros relacionados às demandas judiciais de medicamentos, no período de 2012 a 2024, e os registros de fornecimento de medicamentos pelo MS, no período de 2015 a 2024. **Resultados:** Ao longo de 13 anos, foram atendidos pela CMIV 860 pacientes oriundos de ações judiciais, variando-se de 6 a 286 pacientes por ano. Um total de 16.520 doses foram preparadas, com uma média de 1.271 preparos a cada ano. O número de medicamentos distintos judicializados foi de 58. Os medicamentos mais demandados judicialmente foram Bortezomibe, Rituximabe e Cetuximabe. Em relação ao fornecimento de medicamento pelo MS, em 10 anos analisados, foram atendidos um total de 824 pacientes, variando de 96 a 208 pacientes por ano. Um total de 11.600 doses foram preparadas, com uma média de 1.160 preparos por ano. Esses dados correspondem ao uso de apenas 5 medicamentos fornecidos pelo MS no período do estudo em questão: Trastuzumabe, Rituximabe, Asparaginase, Pertuzumabe e Dactinomicina. **Conclusão:** O estudo evidenciou o papel estratégico da CMIV do hospital universitário no fornecimento de medicamentos judicializados, especialmente em tratamentos onco-hematológicos, revelando falhas na incorporação de tecnologias pelo SUS e a sobrecarga das estruturas hospitalares. Os resultados apontam a necessidade de estrutura adequada, pessoal capacitado e base de dados acessível para subsidiar políticas públicas mais eficientes e sustentáveis, com foco na redução da judicialização e no acesso equitativo à saúde.

Palavras-chave: Judicialização da saúde, antineoplásicos, oncologia, assistência farmacêutica.

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Introduction

The judicialization of health, understood as the pursuit of solutions to issues related to access to healthcare services and supplies through the judiciary, has increasingly become a prominent phenomenon in Brazil[1]. This trend is particularly evident when it comes to access to medications, especially those that are high-cost and not incorporated into public health policies[2]. Judicialization reflects, on one hand, weaknesses in the structuring and implementation of pharmaceutical policies and, on the other, the growing societal demand for innovative and personalized treatments[3]. However, this practice has led to significant impacts on the management of public resources[4].

In the fields of oncology and hematology, this reality becomes even more pronounced. Cancer treatment often involves specific therapies, advanced technologies, and high-cost medications, whose incorporation into the Unified Health System (SUS) can be significantly delayed[5]. Consequently, patients and their families turn to the courts as a means to secure access to these treatments. This judicial pressure on health systems requires agile and efficient responses, while simultaneously challenging the financial and operational sustainability of public institutions[6].

The complexity of onco-hematological treatment, characterized by high-cost therapies and individualized protocols, poses logistical and financial challenges for health systems, especially in a country with continental dimensions and socio-economic disparities like Brazil[7]. In this context, the SUS has sought strategies to ensure universal access to essential medicines, among which is the centralization of purchases of certain antineoplastic drugs by the Ministry of Health (MS). This policy aims to reduce regional disparities, negotiate more competitive prices, and ensure the availability of innovative therapies throughout the national territory[8].

However, implementing this policy requires operational reorganization of High-Complexity Oncology Care Centers (CACON) or High-Complexity Oncology Units (UNACON), which are responsible for coordinating cancer treatment within SUS[9]. These centers must adapt processes such as demand forecasting, inventory control, patient monitoring, and accountability to the MS. These challenges are heightened in public university hospitals, which, in addition to providing healthcare, are also involved in teaching and research activities[10,11]. In this regard, oncology pharmacies play a strategic role, as they are responsible for the safe compounding of chemotherapy drugs, in compliance with Good Compounding Practices (ANVISA Resolution RDC No. 220 of 2004). This requires not only specialized infrastructure, such as clean rooms and biosafety equipment, but also trained professionals in inventory management[12,13] and the use of the Medication Administration System (AME).

In the context of a public university hospital, the Intravenous Admixture Center (CMIV) assumed a strategic role in addressing judicial demands starting in 2012, and in receiving medications supplied by the MS from 2015 onward. It served as the interface between the hospital's oncology and hematology services, the State Department of Health (SES), and the judiciary. As a result, the university hospital in question was recognized as a CACON, and the CMIV began to play a strategic role in supporting oncological treatment, being responsible for storing, compounding, and dispensing medications supplied by the MS and those ordered through legal actions. This role required the implementation of specific procedures, including the use of the AME system provided by the state, management of the medication inventory, and detailed reporting to the relevant authorities[14,15].

The lack of data on the usage profile of court-mandated and MS-supplied medications hampers the planning and management of human and material resources, both for the relevant state agencies involved and for healthcare establishments such as CACON and UNACON. This can result in supply bottlenecks, work overload, or underutilization of resources[16]. Given this context, the objective of this study was to characterize the profile of judicial demands and the supply of medications by the MS in the CMIV of a public university hospital.

Methods

This was a cross-sectional, descriptive, and retrospective study conducted through analysis of the database of the Intravenous Admixture Center (CMIV) of a public university hospital. The study evaluated records related to court-mandated medication demands from 2012 to 2024 and records of medication supplies provided by the Ministry of Health (MS) from 2015 to 2024.

The hospital where the study was conducted is classified as a high-complexity institution and holds the International Accreditation certification from the Joint Commission International (JCI). It has approximately 860 inpatient beds, including intensive care and emergency units, as well as 112 support beds.

The CMIV section is part of the Pharmacy Service and is responsible for the preparation of potentially hazardous drugs, including antineoplastic chemotherapeutics (both parenteral and oral), clinical trial drugs, and other high-cost injectables such as immunosuppressants, antifungals, and antibiotics. It also prepares certain anesthetics and anticoagulants in standardized doses that follow institutional guidelines. These medications are compounded in biological safety cabinets, in properly classified areas, with strict microbiological monitoring that includes testing of surfaces, the environment, and personnel.

The AME system is an online management system provided by the State Health Department (SES), which centralizes information about patients, treatments, medication dispensation, inventory, and other relevant data for specialized pharmaceutical care. It functions as a modern, secure, internet-accessible database, facilitating the management and control of medications provided by the state[17].

All infusions involving medications obtained either through legal action or supplied by the MS were recorded in separate spreadsheets. The origin of the medication was identified using the AME system, which served as the inclusion criterion for the database. Each entry included the following information: date, patient name, patient medical record number, medication name, batch number, number of vials, dose, and stock origin—these were the variables used for compiling results. Two incorrect records were excluded from the analysis.

Data were stored using Microsoft Office Excel® 2016. The functions Filter, Sum, and Percentage were used for analysis, with tabulations of the number of Patients, number of Preparations, number of Medications, and number of Distinct Medications—the latter referring to the count of different medications recorded over the study period. Additionally, the most frequently court-demanded and MS-supplied medications (% relative to the total number of preparations) were compiled, along with the main types of neoplasms that led to judicial medication requests and MS-supplied treatments.

This project was approved by the Research Ethics Committee of the public university hospital under approval number 2022-0271, with the Certificate of Presentation for Ethical Consideration (CAAE) number 60172022.1.0000.5327.

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Results

Over the 13-year study period, a total of 860 patients were treated by the CMIV through court-mandated medication demands, ranging from 6 to 286 patients per year. A total of 16,520 doses were prepared, varying from 34 to 2,429 doses annually, with an average of 1,271 preparations per year. A total of 58 distinct medications were identified as being requested through legal action (Table 1). Therapeutic indication analysis revealed a predominance of drugs used in the management of onco-hematological conditions, in contrast to a minority representation of medications used for rheumatologic, cardiologic, neurologic, and genetic treatments.

Table 1. Number of patients, preparations, and different medications originating from legal actions in an intravenous admixture center of a public university hospital, from 2012 to 2024.

Year	Nº of Patients	Nº of Preparations	Nº of Medications
2012	6	34	1
2013	21	164	2
2014	40	257	3
2015	77	468	8
2016	136	1,085	13
2017	126	1,383	14
2018	117	1,342	23
2019	123	1,098	15
2020	180	2,121	16
2021	221	2,111	27
2022	213	1,898	27
2023	250	2,130	31
2024	286	2,429	34
TOTAL	860	16,520	58

It is noteworthy that the most commonly court-requested medications were Bortezomib (24%), Rituximab (18%), Cetuximab (13%), Azacitidine (12%), Trastuzumab (7%), Pembrolizumab (5%), Nivolumab (4%), Trastuzumab Emtansine (3%), Bevacizumab (2%), and Brentuximab (2%), together accounting for approximately 90% of all preparations during the study period. Accordingly, the main neoplasms associated with court-mandated medication demands were multiple myeloma (26%), non-Hodgkin lymphoma (17%), colorectal cancer (13%), breast cancer (11%), acute myeloid leukemia (12%), melanoma (5%), and Hodgkin lymphoma (2%) (Figure 1). Additionally, a timeline illustrating the number of patients using the most requested court-mandated medications during the study period is shown in Figure 2.

Regarding medications supplied by the Ministry of Health (MS), over the 10-year period analyzed, a total of 824 patients were treated, ranging from 96 to 208 patients per year. A total of 11,600 doses were prepared, ranging from 602 to 1,490 annually, with an average of 1,160 preparations per year (Table 2). The number of distinct medications supplied by the MS ranged from 2 to 4 per year, totaling only 5 medications throughout the study period: Trastuzumab (60%), Rituximab (26%), Asparaginase (6%), Pertuzumab (8%), and Dactinomycin (1%).

Figure 1. Main neoplasms that required court-mandated medications in an intravenous admixture center of a public university hospital, from 2012 to 2024 (% relative to the total number of preparations).

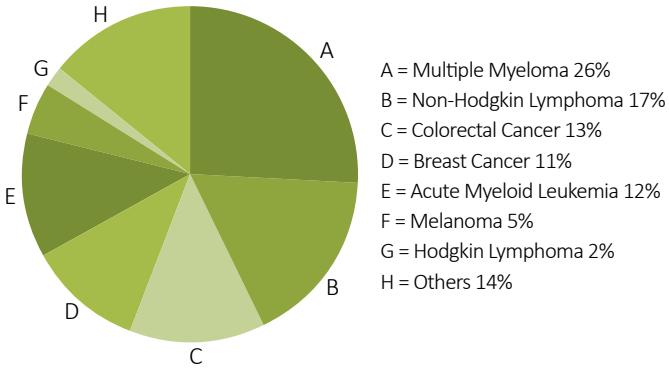


Figure 2. Timeline of the number of patients using the most court-demanded medications in an intravenous admixture center of a public university hospital, from 2012 to 2024.

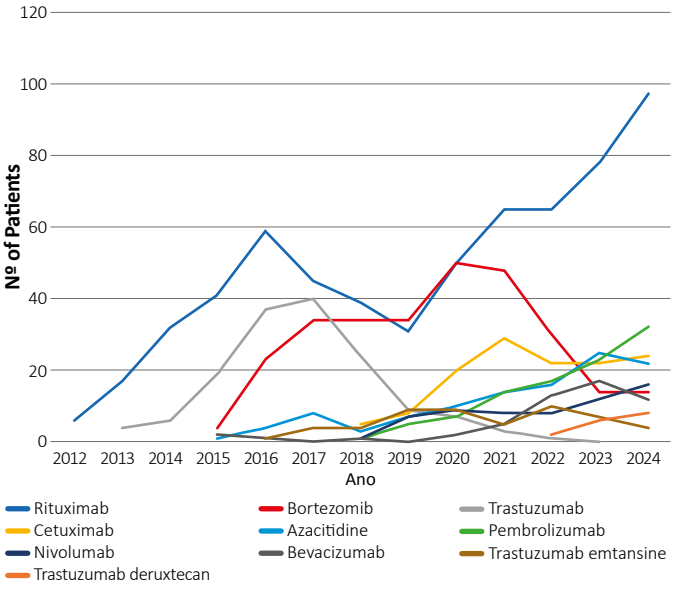
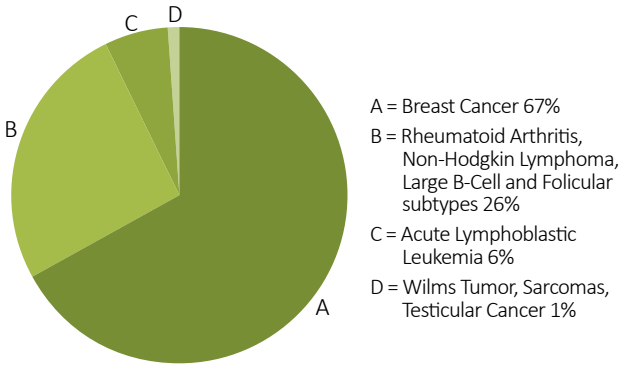


Table 2. Number of patients, preparations, and different medications supplied by the Ministry of Health in an intravenous admixture center of a public university hospital, from 2015 to 2024.

Year	Nº of Patients	Nº of Preparations	Nº of Medications
2015	103	602	2
2016	208	1,556	4
2017	188	1,490	4
2018	146	988	4
2019	126	1,091	3
2020	96	905	4
2021	110	1,146	3
2022	101	1,133	3
2023	114	1,251	3
2024	139	1,438	3
TOTAL	824	11,600	5

Breast cancer was the most commonly treated neoplasm with MS-supplied medications, accounting for 67% of all preparations, followed by the combined group of rheumatoid arthritis, non-Hodgkin lymphoma (including diffuse large B-cell and follicular subtypes) (26%), acute lymphoblastic leukemia (6%), and a group comprising Wilms tumor, sarcomas, and testicular cancer (1%) (Figure 3).

Figure 3. Main neoplasms treated with medications supplied by the Ministry of Health in an intravenous admixture center of a public university hospital, from 2012 to 2024 (% relative to the total number of preparations).



Discussion

The results presented in this study highlight the magnitude of both medication litigation and Ministry of Health (MS) drug supply demands, particularly within the field of onco-hematology, in the context of the CMIV of the analyzed public university hospital. The progressive increase in the number of patients treated annually demonstrates the growing demand for onco-hematological therapies, made possible both through legal actions and via the medication supply provided by the Brazilian Unified Health System (SUS) through the MS. This phenomenon reflects, simultaneously, the evolving epidemiology of cancer[18] and the inherent challenges in pharmaceutical inventory management in contexts of budgetary constraints[16], which are intensified by the high therapeutic complexity and elevated costs associated with antineoplastic drugs[2,6].

The yearly increase in the number of preparations suggests a need for targeted logistical planning, including forecasting of seasonal demand and continuous training of involved teams[19,20]. These findings are consistent with previous studies that identify challenges in compounding management, such as the need for agile recording and monitoring systems to prevent shortages or waste[21]. The total of 16,520 preparations from court-mandated medications, along with the 11,620 from MS-supplied drugs during the study period, reinforces the importance of adequate infrastructure and ongoing training, as well as the strict adherence to Good Compounding Practices and the implementation of quality control protocols (ANVISA Resolution RDC No. 220/2004) —critical aspects in university hospitals that integrate care and professional training[7].

Bortezomib was the most litigated medication throughout the 13-year study period, reflecting both its clinical importance in the treatment of severe diseases such as multiple myeloma and existing gaps in the management and distribution of high-cost medications within SUS. This finding aligns with a study by Cervi et al., which also identified Bortezomib as the most litigated drug in legal cases handled by the oncology department at the Federal University of Pelotas Teaching Hospital (UFPEL) from January 2017 to August 2019[22].

The predominance of drugs such as rituximab, cetuximab, trastuzumab, pembrolizumab, nivolumab, trastuzumab emtansine, bevacizumab, and brentuximab in legal demands is aligned with the global trend in cancer treatment towards targeted therapies, immunotherapies, and antibody-drug conjugates (ADCs)—often associated with high costs and a need for rapid access[19-22]. Regarding the drugs supplied by the MS—trastuzumab, rituximab, asparaginase, pertuzumab, and dactinomycin—these are consistent with therapeutic guidelines for prevalent neoplasms such as breast cancer, lymphomas, leukemias, and sarcomas. This supports the notion that centralized resource management facilitates access to high-cost therapies[8,23-25].

Over the study period, some medications initially acquired through litigation were incorporated into SUS protocols via specific ordinances. Rituximab, for instance, was approved for the treatment of diffuse large B-cell lymphoma and CD20-positive follicular lymphoma under MS/SCTIE Ordinance No. 63/2013. However, rituximab continues to be widely litigated for use in other lymphomas, hematologic diseases, and autoimmune conditions not covered by SUS, thereby maintaining its high litigation rate. Trastuzumab was included in SUS for adjuvant treatment of HER2-positive breast cancer via MS/SAS Ordinance No. 73/2013 and later authorized for palliative care under MS/SCTIE Ordinance No. 29/2017. From 2018 onward, a sustained decline in litigation cases was observed, with no court-mandated preparations recorded from 2024 onwards. Also in 2017, MS/SCTIE Ordinance No. 57/2017 included pertuzumab for use in combination therapy with trastuzumab, aiming for dual HER2 blockade in cases of breast cancer with visceral metastases.

Thus, these medications (rituximab, trastuzumab, and pertuzumab) were made available through centralized procurement and distributed by state health departments to CACONs and UNACONs. In these cases, CMIV's role in inventory control, compounding, reporting to the State, and ensuring rational use remained unchanged, with only the source of the medication shifting. The responsibilities toward the State Health Department (SES) and integration with the AME system remained consistent.

Bortezomib was incorporated into SUS for the treatment of multiple myeloma by MS/SCTIE Ordinance No. 43/2020. In this and other subsequent incorporations of oncology drugs, the federal determination was that each CACON would independently procure the necessary medications using funds from newly established Authorizations for High-Complexity Procedures (APAC). Thus, these drugs were meant to be part of CACONs' inventories and no longer shared with SES. Nevertheless, Bortezomib continued to be supplied by SES to patients with ongoing legal proceedings, indicating possible misuse of judicial mechanisms for a drug already included in the SUS formulary.

Brentuximab was incorporated into SUS only for CD30-positive Hodgkin lymphoma refractory to autologous hematopoietic stem cell transplant, via MS/SCTIE Ordinance No. 12/2019. Nivolumab and pembrolizumab were incorporated through Ordinance No. 23/2020 for advanced melanoma. Trastuzumab emtansine was added through Ordinance No. 98/2022, exclusively for HER2-positive breast cancer with residual disease after adjuvant therapy—implying continued litigation for metastatic cases.

Unfortunately, these medications have remained largely unavailable within SUS in practice, even years after their official incorporation. In this context, CMIV's role in managing such demands underscored the importance of efficient pharmaceutical management, integration with the AME system, and thorough accountability reporting. These elements are critical to ensure patient safety and transparency in public resource usage. Additionally, the study reinforces the need for better coordination among judicial authorities, public agencies, and healthcare institutions to balance the right to access medications with the financial sustainability of the healthcare system[26,27].

Among the study's limitations are its restriction to a single institution and reliance on retrospective data, which may limit the generalizability of the findings[28]. Although all professionals are trained, data entry into CMIV's database depends on human input, which can introduce inconsistencies. Furthermore, certain medications such as rituximab—also used in autoimmune and rheumatologic conditions—have multiple therapeutic indications. It was included in this study due to its overlap with oncologic demand met by SES. The study also did not present cost data due to significant variability across the years. A detailed cost analysis is suggested as a future research direction.

The findings also highlight the importance of public policies that promote evidence-based and rational incorporation of healthcare technologies. CMIV's performance in the university hospital studied shows that even amidst logistical and financial constraints, it is possible to ensure patient safety, medication traceability, and proper reporting through integrated and efficient management[28-30].

Therefore, this study contributes to understanding the profile of legal demands and MS-supplied medications, emphasizing the pivotal role of oncology pharmacy and the urgent need for strategies that support healthcare system sustainability in the face of increasingly complex therapeutic demands.

Conclusion

This study characterized the profile of legal demands and medications supplied by the Ministry of Health (MS) in a CMIV (Centralized Unit for Intravenous Mixtures) of a public university hospital, highlighting the critical role of this unit in liaising with judicial authorities and government agencies. The findings also underscore the need for adequate infrastructure and trained personnel to meet the growing demand, ensuring patient safety and the quality of care provided.

The analysis of CMIV's operations revealed the magnitude of health-related litigation and the impact of centralized drug supply by SUS, particularly in onco-hematologic treatments. The growing demand for high-cost therapies was evident, as was the burden placed on hospital infrastructures tasked with implementing these therapies.

The concentration of lawsuits around a small number of drugs, such as bortezomib, rituximab, and trastuzumab, reveals significant gaps in the effective incorporation of new technologies into SUS and highlights delays in their availability, even after ministerial ordinances are issued. This scenario exposes structural shortcomings in the implementation of public health policies and underscores the urgent need to enhance SUS's capacity to respond to the introduction of new technologies, as well as to strengthen coordination among federal, state, and municipal entities.

The study also highlights the importance of establishing and maintaining a structured, integrated, and accessible database on judicialized medications and those supplied by MS. Such a system would support more effective management, planning, negotiation, and distribution efforts. These measures are essential to reduce reliance on litigation and to promote equitable and timely access to healthcare in Brazil.

Therefore, this study contributes to a better understanding of some of the key challenges to ensuring the right to health in Brazil, while also offering potential pathways for solutions in the field of pharmaceutical assistance. Its findings may inform the development of more rational, efficient, and sustainable policies aligned with SUS principles and aimed at expanding equitable access to health technologies.

Funding

This research did not receive any specific funding for its execution.

Authors' Contributions

CAYW: Study conception and design; CAYW, ECS, RSO, and RCR: Data analysis and interpretation; CAYW, ECS, RSO, and RCR: Manuscript drafting and critical revision of the intellectual content.

Acknowledgments

Intravenous Mixture Center (CMIV) of the Pharmacy Service at the university hospital in Porto Alegre; Supply Coordination Department of the university hospital in Porto Alegre; Health Department of the State of Rio Grande do Sul (SES/RS).

Conflict of Interest Statement

The authors declare no conflicts of interest related to this article.

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