

Pharmaceutical Service for Multiple Sclerosis Carriers in Brazil: A State Model

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Abstract

The Specialized Component of Pharmaceutical Care is the Brazilian Unified Health System strategy that aims to ensure comprehensive drug treatment at an outpatient level and improve access to high complexity, high cost treatments, such as multiple sclerosis. Given the diversity of treatments available and the differences in financing and dispensing in different countries, the objective of this study was to present the workings of the model of care for patients with multiple sclerosis through the public health system in Brazil in the state of Mato Grosso do Sul. In Campo Grande, the registration and dispensation of drugs for the treatment of multiple sclerosis is the responsibility of the Pharmacy School Professor Ana Maria Cervantes Baraza of the Federal University of Mato Grosso do Sul. In this center, all patients receive pharmaceutical advice on the administration of injectable drugs and oral medications; the storage, preservation, and transportation of refrigerated drugs; and information on the disease and management of adverse reactions. Clinical pharmacy services are also available to patients in a pharmaceutical office, ensuring patient privacy and comfort and enabling the creation of a bond with the pharmacist. The model of care provided by the Pharmacy School allows for the development of pharmaceutical services, encourages the rational use of medicines, and emphasizes the importance of self-care, adherence to therapy, and the co-responsibility of patients and their families.

Keywords: drugs from the specialized component of pharmaceutical care, guidelines, multiple sclerosis, pharmaceutical services, public health

1. Introduction

The first protocol for the treatment of multiple sclerosis (MS) in Brazil was published in 2001 and was guided by interferon- β 1a and 1b and glatiramer acetate 20 mg (Brasil, 2001). Its first update was in 2010, when natalizumab 300 mg was added for treatment after therapeutic failure with interferon- β and glatiramer (Brasil, 2010). In 2013, the literature was updated again and the clinical management of patients with John Cummings virus using natalizumab was included (Brasil, 2013). In 2015, fingolimod 0.5 mg was added as a new treatment (Brasil, 2015) for use after natalizumab 300 mg therapeutic failure, and in 2018, teriflunomide 14 mg was incorporated as the first-choice drug, along with dimethyl fumarate 120 and 240 mg (Maia Diniz et al., 2018). Following therapeutic failure with first-choice drugs, fingolimod 0.5 mg was permitted as the second- or third-choice treatment. Treatment with natalizumab 300 mg required therapeutic failure or contraindication to fingolimod 0.5 mg (Brasil, 2018).

Given the diversity of treatments available and the differences in financing and dispensing in different countries, the objective of this study was to present the workings of the pharmaceutical care model in Brazil to MS patients through the public health system in the state of Mato Grosso do Sul.

1.1 The Public Health System in Brazil and The Specialized Component of Pharmaceutical Assistance

In the early 1990s, the Unified Health System (SUS) was implemented based on the principles established in the

Brazilian Federal Constitution. (Oliveira et al., 2016). Within the field of action of the SUS is the implementation of comprehensive therapeutic care actions (including pharmaceutical) and the formulation of the National Medicines Policy (NMP) that aims to ensure the safety, effectiveness, and quality of medicines and to promote the rational use of and access to medicines that are considered essential. Medicines and other health technologies are at the heart of the health system as they contribute to disease prevention and health care (Vasconcelos, Chaves, Azeredo, & Silva, 2017).

The reformulation of pharmaceutical care by the NMP allowed for the promotion of access to medicines due to the increased availability of medicines in the SUS. The decentralization of drug management was also implemented, which defined the responsibilities for the financing, procurement, and distribution of medicines and reorganized and divided pharmaceutical assistance into three components: basic, specialized, and strategic (Vasconcelos et al., 2017).

Within the scope of the NMP, the Specialized Component of Pharmaceutical Assistance (SCPA) is a wing of the SUS that aims to ensure comprehensive drug treatment at an outpatient level, overcoming the barriers that were effectively preventing access to this health technology, especially within high complexity treatment with risks of refractoriness and especially high cost (Brasil, 2010a; Brasil, 2009).

The SCPA has shared funding and mostly concentrates on the incorporation and dispensation of new monopoly medicines (subject to patent protection). These medicines are costly, which is the reason for the weight of this component in total public spending on medicines. The Ministry of Health spent about \$500 million reais in 2003, and in 2015, this figure jumped to \$6 billion reais (an increase of almost 1,200%).

The Ministry of Health has established technical-administrative and managerial guidelines for priority clinical situations based on their prevalence, complexity, or financial impact on public health, which are the best scientific evidence available for the proper use of these technologies in health. These guidelines form the Clinical Protocols and Therapeutic Guidelines (CPTG) that provide information on the diagnosis and treatment of diseases covered by the SCPA (Brasil, 2010b).

The SCPA is followed in pharmacies throughout Brazil called “poles,” which process the application of medicines through patient registration, evaluation, renewal, and dispensing of drugs (Brasil, 2010a). Structuring, technical management, and administrative requirements, including minimum requirements required and provided (Brasil, 1999), must be in place, guiding the effectiveness of SCPA for the proper organization of pharmaceutical care (Brasil, 2003).

The CPTG contains diagnostic criteria, disease treatment algorithm, and mechanisms for the clinical monitoring and supervising of possible adverse drug effects (Godman et al., 2014). With regard to dispensing professionals, this document recommends and provides guidance on the implementation of services focused on the practice of pharmaceutical care. It proposes the direct interaction of the pharmacist with the user, aiming at rational pharmacotherapy and obtaining definite and measurable results that lead to an improvement in the quality of life (Brasil, 2010b; Brasil, 2010a; Brasil, 1999; Marin, Luiza, Osório-de-Castro, Machado-dos-Santos, 2003; Ivama et al. 2002). Regarding the activities of pharmacists and the practice of pharmacotherapeutic monitoring, the CPTG suggests a need for change in the philosophical, organizational, and functional approach that increases the level of responsibility of the pharmaceutical profession (Picon & Beltrame, 2002).

1.2 Pharmaceutical Service for Multiple Sclerosis Carriers

In Campo Grande in the state of Mato Grosso do Sul, the responsibility for registering patients and dispensing medications for the treatment of MS rests with the Prof. Ana Maria Cervantes Baraza Pharmacy School of the Federal University of Mato Grosso do Sul.

The Pharmacy School began operating in September 2014. The building has 247.7 m², with ample space for patient care, including a pharmaceutical office, classroom, laboratory for handling pharmaceutical products, meeting room, room for teachers and pharmacists, and a drug storage room with a high-performance refrigeration chamber.

Currently, the Pharmacy School treats about 600 patients per month, of whom approximately 150 are carriers of MS, with the remainder being carriers of systemic sclerosis, amyotrophic lateral sclerosis, asthma, and chronic obstructive pulmonary disease. The dispensed medicines are part of SCPA and they are made available by the State Department of Health (SES), through a Cooperation Agreement signed between SES and UFMS. The team is composed of a teaching coordinator and four pharmacists, without rotation, which has helped achieve the recent progress.

In the center, all patients receive pharmaceutical advice regarding the administration of injectable and oral medications, the storage and transportation of refrigerated medications, and information about their diseases and how to manage adverse reactions. For the dispensation of the drugs, monthly scheduling is performed, and in the last week of the month, patients who did not attend are contacted by phone to avoid treatment interruptions.

The guidelines linked to the educational process provide information on the treatments and the procedure for preparing and administering immunomodulators so that the treatments can be performed at home by the patients themselves. All the information and support provide patients with greater autonomy in taking the decision to adhere to their treatment.

In addition to the guidelines and educational process, clinical pharmaceutical services are offered to patients whose care is provided in a Pharmacy School room structured exclusively for this purpose. This involves setting up a pharmaceutical office, ensuring the patient's privacy and comfort, and allowing for the creation of a bond with the pharmacist. The services offered are pharmacotherapy review, health problem management, and pharmacotherapeutic follow-up, among others.

The care process applied by the pharmacist during consultations consists of 1) inviting patients, 2) initial clinical interview, 3) pharmaceutical evaluation, 4) care plan and pharmaceutical interventions, and 5) PCDT monitoring for MS treatment. Returns follow the same design, respecting each patient's individual clinical needs.

The patient guidelines emphasize that patients themselves are responsible for self-care and are co-responsible for their treatment. Therefore, difficulties, such as in the parenteral application of immunomodulators or problems performing activities related to self-care due to physical limitations or memory deficit surrounding this guideline, are discussed with the pharmacist. The families of patients are trained to assist in the adequate support and treatment of the family member and contribute to the rehabilitation of the patient and improvement of their quality of life.

The UFMS Pharmacy School has a multi-professional support network for patients, and there is collaboration between prescribing professionals, pharmacists, nurses, physiotherapists, and nutritionists. Referrals between these professionals follow the reference and counter-reference model.

The unpredictability of the course of MS, the progression of disability, and the impact of symptoms on patients and families negatively affects the quality of life (Pakdaman et al., 2017). Therefore, health professionals must aim to improve quality of life by focusing on the prevention of disease and rehabilitation and engaging in health promotion (Biernacki et al., 2019). The Pharmacy School provides collaborative services to promote the health of MS sufferers, which are essential for the rehabilitation and social adaptation of this group of patients. (Bosworth et al., 2017)

2. Conclusion

The Pharmacy School's model of care has enabled the development of a pharmaceutical service for patients with MS which focuses on the patient rather than on medications. The success of the Pharmacy School can be a template for implementing similar services.

Given the importance of patient counseling, the services provided act as a strategy for fostering the rational use of medicines, which is firmly supported by the pharmacist's work with the patient, family members, and the healthcare team. It is necessary to propose lifestyle changes in a compensatory and motivational way. These interventions are systematically performed in consultations to enable patients to face their daily difficulties and feel more positive about following their treatments. Pharmacotherapeutic follow-ups and scheduling, actively searching for overdue patients, and monthly drug dispensation strengthen the bond between patients and pharmacists, which contributes to treatment adherence.

The standardization of the pharmacotherapeutic follow-up process is fundamental to obtaining indicators and concrete clinical, humanistic, and economic outcomes, which must be continuously evaluated for service improvement.

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Competing Interests Statement

The authors declare that there are no competing or potential conflicts of interest.

References

- Biernacki, T., Sandi, D., Kincses, Z. T., Füvesi, J., Rózsa, C., Mátyás, K., Vécsei, L., & Bencsik, K. (2019). Contributing factors to health-related quality of life in multiple sclerosis. *Brain and behavior*, 9(12), e01466. <https://doi.org/10.1002/brb3.1466>
- Bosworth, H. B., Fortmann, S. P., Kuntz, J., Zullig, L. L., Mendys, P., Safford, M., Phansalkar, S., Wang, T., & Rumpitz, M. H. (2017). Recommendations for Providers on Person-Centered Approaches to Assess and Improve Medication Adherence. *Journal of general internal medicine*, 32(1), 93-100. <https://doi.org/10.1007/s11606-016-3851-7>
- Brasil. (1999). Resolução ANVISA nº 328 de 22 de julho de 1999 .Dispõe sobre requisitos exigidos para a dispensação de produtos de interesse à saúde em farmácias e drogarias. Diário Oficial da União. Retrieved from http://portal.anvisa.gov.br/documents/10181/2718376/RES_328_1999_COMP.pdf/ead78ff5-7923-4273-9c7c-e61ecdcc2448?version=1.0
- Brasil. (2001). Ministério da Saúde (MS). Portaria nº 97, de 22 de março de 2001. Aprova o Protocolo Clínico e Diretrizes Terapêuticas da Esclerose Múltipla. Diário Oficial da União.
- Brasil. (2009). Ministério da Saúde (MS). Portaria GM/MS nº 2981 de 26 de novembro de 2009. Aprova o Componente Especializado da Assistência Farmacêutica. Diário Oficial da União. Retrieved from http://bvsms.saude.gov.br/bvs/saudelegis/gm/2009/prt2981_26_11_2009_rep.html
- Brasil. (2010). Ministério da Saúde (MS). Portaria nº 493, de 23 de setembro de 2010, Aprova o Protocolo Clínico e Diretrizes Terapêuticas da Esclerose Múltipla. Diário Oficial da União. Retrieved from http://bvsms.saude.gov.br/bvs/saudelegis/sas/2010/prt0493_23_09_2010.html
- Brasil. (2010a) Ministério da Saúde. Secretaria de Ciência, Tecnologia e Insumos Estratégicos. Departamento de Assistência Farmacêutica e Insumos Estratégicos. Da excepcionalidade às linhas de cuidado: o componente especializado da Assistência Farmacêutica. Brasília, DF. Retrieved from <https://www.saude.gov.br/images/pdf/2020/May/28/Livro-1---Da-excepcionalidade---s-linhas-de-cuidado---o-Componente-Especializado-da-Assist--ncia-Farmac--utica.pdf>
- Brasil. (2010b). Ministério da Saúde (MS). Protocolos Clínicos e Diretrizes Terapêuticas. Brasília: MS. Retrieved from <http://bvsms.saude.gov.br/sistema-unico-de-saude-3/2-uncategorised/2281-protocolos-clinicos-diretrizes-terapeuticas-e-linhas-de-cuidado>
- Brasil. (2013) Ministério da Saúde (MS). Portaria nº 1.323, de 25 de novembro de 2013. Aprova o Protocolo Clínico e Diretrizes Terapêuticas da Esclerose Múltipla. Diário Oficial da União. Retrieved from http://bvsms.saude.gov.br/bvs/saudelegis/sas/2013/prt1323_25_11_2013.html
- Brasil. (2015) Ministério da Saúde (MS). Portaria nº 391, de 05 de maio de 2015a. Aprova o Protocolo Clínico e Diretrizes Terapêuticas da Esclerose Múltipla. Diário Oficial da União. Retrieved from <http://www.saude.gov.br/images/pdf/2015/julho/02/RETIFICA---O-ANEXO-PT-391-DE-5-5-2015---PAR-A-PUBLICA---O-NO-SITE.pdf>
- Brasil. (2018) Ministério da Saúde (MS). Portaria SAS/SCTIE/MS nº 10 de 02 de abril de 2018. Aprova o Protocolo Clínico e Diretrizes Terapêuticas da Esclerose Múltipla. Diário Oficial da União Brasil 2018. Retrieved from https://www.in.gov.br/materia/-/asset_publisher/Kujrw0TZC2Mb/content/id/9579435/do1-2018-04-09-portaria-conjunta-n-10-de-2-de-abril-de-2018-9579431
- Godman, B., Acurcio, F. A., Guerra Júnior, A. A., Alvarez-Madrado, S., Faridah Aryani, M. Y., et al. (2014) Initiatives among Authorities to Improve the Quality and Efficiency of Prescribing and the Implications. *J Pharma Care Health Sys*, 1, 113. <https://doi.org/10.4172/jpchs.1000113>
- Ivama, A. M., Noblat, L., Castro, M. S., Oliveira, N. V. B. V., Jaramillo, N. M., & Rech, N. (2002). *Consenso Brasileiro de Atenção Farmacêutica: Proposta*. Brasília: Organização Pan-Americana da Saúde.
- Maia Diniz, I., Guerra, A. A. J., Lovato Pires de, L. L., Souza, K. M., Godman, B., et al. (2018) The long-term costs for treating multiple sclerosis in a 16-year retrospective cohort study in Brazil. *PLOS ONE*, 13(6), e0199446. <https://doi.org/10.1371/journal.pone.0199446>
- Marin, N., Luiza, V. L., Osório-de-Castro, C. G. S., & Machado-dos-Santos, S., organizadores (2003). *Assistência Farmacêutica para gerentes municipais*. Brasília: Organização Pan-Americana de Saúde.

- Oliveira, L. R. de, & Passador, C. S. (2016). The Brazilian Unified National Health System Proposal Of a Cost-effectiveness Evaluation Model. *BAR - Revista da Administração Brasileira*, 13(2), e140120. Epub 25 de julho de 2016. <https://doi.org/10.1590/1807-7692bar2016140120>
- Pakdaman, H., Amini Harandi, A., Gharagozli, K., Abbasi, M., Tabassi, A., Ashrafi, F., Ghaffarpor, M., Sharifi, S., Delavar Kasmae, H., Assarzaghan, F., Arabahmadi, M., & Behnam, B. (2017). Health-related quality of life in patients with relapsing-remitting multiple sclerosis treated with subcutaneous interferon β -1a in Iran. *The International journal of neuroscience*, 127(6), 501-507. <https://doi.org/10.1080/00207454.2016.1198793>
- Picon, P. D., & Beltrame, A. (2002). *Protocolos Clínicos e Diretrizes Terapêuticas*. Retrieved from <http://dtr2001.saude.gov.br/sas/dsra/protocolos/index.htm>
- Vasconcelos, D. M., Chaves, G. C., Azeredo, T. B., & Silva, R. M. (2017). National Medicines Policy in retrospective: a review of (almost) 20 years of implementation. *Ciência & saúde coletiva*, 22(8), 2609-2614. <https://doi.org/10.1590/1413-81232017228.02432017>

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