Promoting transitions of care, safety, and medication adherence for patients taking fingolimod in community pharmacies

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Introduction

Multiple sclerosis (MS) is a chronic demyelinating disease of the central nervous system, which is commonly associated with an increase in disability. Relapsing-remitting MS (RRMS) is the most frequent form (85-90% of patients) and is characterized by subacute neurological deficits (relapses) followed by partial or complete recovery (remissions).[1] Affecting more than 2.3 million people worldwide, MS is one of the most common neurological disorders causing nontraumatic disability in young adults.[2]

As there is still no cure for MS, current treatments aim to reduce the frequency of relapses and delay the progression of disability. In the last two decades, only injectable disease-modifying therapies (DMTs) were available. Fingolimod was the first oral DMT approved as a first-line treatment for RRMS in Switzerland in 2011. The arrival of oral forms of treatment has offered new prospects for MS patients; this needle-free and more convenient administration has improved patient satisfaction.[3-5] Nevertheless, fingolimod therapy is associated with safety issues (described below),[6] and lifelong drug use for chronic conditions is known to be challenging.[7]

Fingolimod may lead to cardiovascular, ophthalmic, hematologic, hepatic or pulmonary complications. This drug also carries a risk of infections, possible cancer and presumed fetal toxicity. To manage these risks and ensure safe and effective use of fingolimod, stringent pharmacovigilance measures are recommended.[8] A 6-hour medical monitoring at the administration of the first dose at treatment initiation is required, as well as various medical tests prior to and after commencing fingolimod. All patients should be cautioned with regard to symptoms of potential serious adverse fingolimod reactions, and women with childbearing potential should be counseled about the teratogenic risk and the use of effective contraception. These pharmacovigilance measures involve the monitoring of patients by healthcare providers throughout the long-term treatment.

Chronic treatments and adverse effects are known to affect medication adherence.[7,9] Adherence is defined as “the extent to which a person’s behavior – taking medication, following a diet, and/or executing lifestyle changes – corresponds with agreed recommendations from a healthcare provider”.[7] Injectable DMTs are associated with suboptimal adherence.[10] The main barriers reported are the following: needle phobia, adverse effects, depression/cognitive impairment, perceived lack of efficacy, disease progression, and cost.[10-14] Cognitive impairment, which may increase the risk of poor adherence, occurs in 40-65% of MS patients.[15] In addition, patients may struggle with perceiving treatment utility during asymptomatic phases, potentially affecting their motivation, especially if adverse effects are present. Poor DMT adherence is associated with increased risk of relapses for MS patients and negative economic outcomes.[16,17] Studies on oral DMT adherence are rare due to their

recent development. Despite better adherence than injectable DMTs, 28% of fingolimod users discontinued it within the first year.[18,19] Adherence is a dynamic process influenced by various factors; therefore, patient-tailored interventions with a multidisciplinary approach are recommended.[7]

The potential negative consequences related to fingolimod safety issues as well as poor adherence and the risk of severe disease exacerbations upon fingolimod discontinuation[20,21] highlight a need to continually support patients taking this drug. Pharmacists have a strategic position, with the opportunity to provide collaborative services with other healthcare providers to ensure both optimal safety and adherence.[22,23] To address this need, in 2013, the Community Pharmacy of the Center for Primary Care and Public Health (Unisanté), University of Lausanne, Switzerland[a], in collaboration with the Division of Neurology of the Lausanne University Hospital developed and disseminated a pharmacy-based person-centered and integrated care program called the Fingolimod Patient Support Program (F-PSP). This article aims to describe the F-PSP.

Program Description

The F-PSP was launched in 2013 as a specialty pharmacy service carried out in collaboration with other healthcare providers. Patients are free to exit the program at any time, based on a shared decision with the healthcare team. Swiss mandatory health insurance[24] covers the cost of the F-PSP (weekly fees-for-services) and the medication. The F-PSP complements basic pharmacy services[25] with two person-centered interventions, medication adherence support and pharmacovigilance tailored to fingolimod, through pharmacist-led interviews using motivational techniques and the collection of patient-reported outcomes as defined by the FDA[26] (Figure 1). A secure web platform was designed to deliver the program, and a trained pharmacy network was created to disseminate it.

[a]previously named: “Community Pharmacy Center of the Department of Ambulatory Care & Community Medicine”

	Medication adherence support[27]	Pharmacovigilance activity
Aims	**Patient medication adherence monitoring and support**	**Fingolimod patient safety monitoring and support**
Key elements	•Pharmacist-led interviews with motivational approach •Collection of patient-reported outcomes	
	•Monitoring of longitudinal electronic medication adherence •Medication adherence feedback to patient	•Medication reconciliation and use review •Information on the responsible use of fingolimod •Warning of risks •Reminders of recommended medical tests •Tracking and monitoring symptoms, especially those of potential serious adverse fingolimod reactions
Tools (Appendix B)	• Secured web platform with a semi-standardized step-by-step process, including: - Electronic pharmaceutical and health records - EM data uploading system editing a graph drug intake - Clinical decision support system - Safety alarm system - Archiving material support system - Structured report • Electronic monitor	
Inclusion interview with the TCP during the first dose monitoring at the Neurology Division	•Exploration of readiness for treatment initiation •Assessing personal and psychosocial conditions •History of treatment and past medication adherence •Presentation of EM •Setting fingolimod intake schedule according to the patient's preferences and the recommendations for appropriate use	•Medication reconciliation and use review •Information on the management of missed doses within the first two weeks •Addressing active contraception use in women with childbearing potential •Discussion about procedures in case of new co-treatments
Post-1st dose monitoring interview with the NCP within a network pharmacy 2 weeks after fingolimod initiation	•Uploading and validation of electronic adherence data •Presentation and discussion of adherence results since last visit •Exploration of fingolimod adherence barriers / facilitators and supporting medication adherence •Intervention: IMB model[28], patient's psychosocial needs and other moderating factors, and subgoals to address	•Information on possible serious and most common fingolimod adverse events/symptoms •Information on symptoms of potential serious adverse fingolimod reactions to pay attention to •Information on the management of missed doses after the 2nd week •Information on vaccination •Discussion about procedures in case of pregnancy
Follow-up interviews with the NCP within a network pharmacy at 1, 2 and every 3 months after fingolimod initiation		•If needed, medication reconciliation and use review •Tracking of symptoms, especially those of potential serious adverse fingolimod reactions •Reminders of recommended medical tests

Figure 1: Pharmacy-based Fingolimod Patient Support Program (F-PSP)

EM = electronic monitor of medication adherence, IMB model = Information-Motivation-Behavioral Skills model, NCP = network community pharmacist, TCP = transition care pharmacist

The interventions

The medication adherence intervention aims to support and reinforce adherence to chronic treatment, following the practice standards from the interprofessional medication

adherence program (IMAP) as detailed by Lelubre et al.[27] This latter is composed of pharmacist-led motivational interviews based on the Information-Motivation-Behavioral Skills model (Fisher's IMB model)[28] and longitudinal medication adherence monitoring through an electronic monitor (EM – MEMS®SmartCap, Aardex Group, Seraing, Belgium). The EM records and displays each opening on the cap screen, providing daily adherence support to patients. EM data are uploaded at the pharmacy to supply a graph illustrating the patient's drug intake profile, showing both a calendar and a chronology to provide feedback to patients.[27]

The pharmacovigilance activity aims to prevent, detect and address fingolimod safety concerns according to the recommendations published by the health authorities, the Marketing Authorization Holder, and the local University Neurology Division.[8,29,30] The pharmacovigilance activity consists of informing patients on the recommendations regarding fingolimod, reminding patients of the recommended medical tests, and tracking and monitoring symptoms, especially those of potential serious adverse fingolimod reactions.

The secure web platform

A secure web platform (SISPha SA, ofac groupe, Lausanne, Switzerland) was designed to support and structure the pharmacist intervention with a semi-standardized step-by-step process.[31] The platform combines electronic pharmaceutical and medical records, an EM data uploading system, a clinical-decision making support system coupled with a safety alarm system and an archiving material support system, including practical recommendations and training documents (e.g., to conduct interviews or upload EM data). During the interviews, the platform guides the pharmacists and supports their clinical decisions regarding fingolimod therapy management. According to the patient's clinical pathway, it lists key questions to ask, information to transmit and reminders of the recommended medical tests. Moreover, infotips (pop-up windows) provide additional fingolimod clinical information. The safety alarm system warns the pharmacists if two or more recorded symptoms mentioned by the patient could be the consequence of a severe adverse reaction to fingolimod. For example, if a patient complains about vomiting plus dark urine, the platform will display a warning message indicating possible hepatic dysfunction and will recommend a medical consultation. The platform also enables patient-reported outcome data collection. At the end of each interview, the platform issues a structured report including the summary of the patient-pharmacist interaction and the fingolimod adherence graph.

The community pharmacy network

A network of community pharmacies (22 in 2017) was created to disseminate the F-PSP in Western Switzerland. Any community pharmacy is free to join or exit the network at any time. Member pharmacies must subscribe to the platform (annual fees), have a trained staff

member responsible for the F-PSP and have a confidential consultation room. At least one pharmacist per pharmacy should receive a minimum three-day standardized training course (at the pharmacy's own expense) on how to conduct motivational interviews, use the platform, manage patients taking fingolimod, and handle EM (data uploading, refill). The handling of EM, as well as billing the program, can be delegated to pharmacy technicians.

Process, providers and content of interviews

The F-PSP is proposed for each patient initiating fingolimod, except for non-autonomous people under treatment (institutionalized patients or those undergoing home care), and starts once the Neurology Division schedules the first dose of fingolimod. The F-PSP process comprises the following five steps: 1. patient eligibility assessment, 2. F-PSP presentation, 3. patient enrollment, 4. patient transition and 5. long-term F-PSP sustainability (Figure 2).

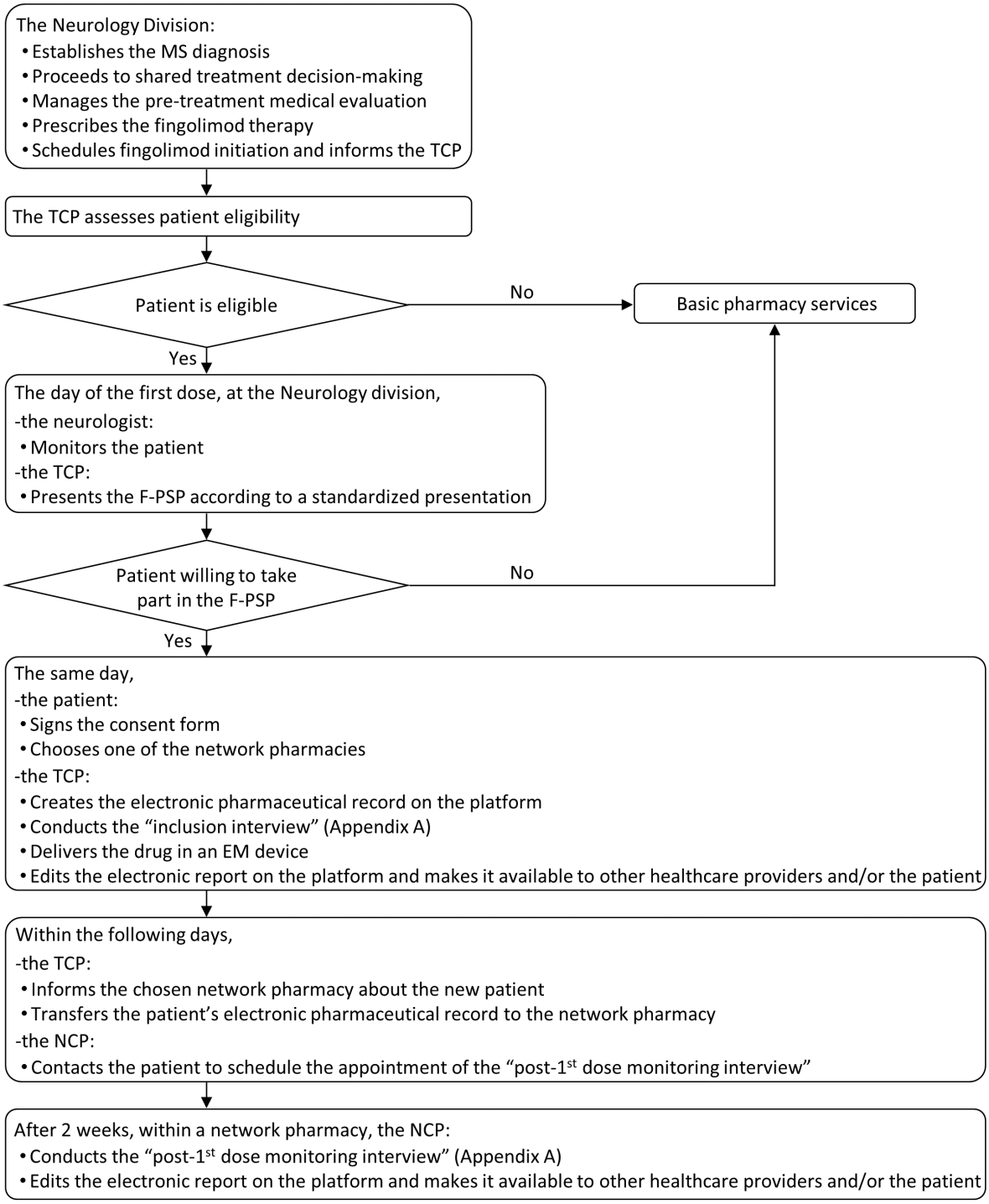

Figure 2: Fingolimod Patient Support Program (F-PSP) Process

EM = electronic monitor of medication adherence; F-PSP = fingolimod Patient Support Program; MS = multiple sclerosis; NCP = network community pharmacist; TCP = transition care pharmacist

A transition care pharmacist (TCP) provides the four first steps. The TCP presents the F-PSP to each eligible patient during the mandatory 6-hour medical monitoring at the Neurology division. Patients willing to take part sign a consent form, which allows the recording of personal data on the web platform, information transmission between pharmacists and the

healthcare team and data use for research. Patients choose one network pharmacy that will deliver the F-PSP over the long-term. They can change pharmacies within the network at any time. Then, the TCP conducts the inclusion interview and coordinates the patient's transition within the chosen network pharmacy. Thereafter, the network community pharmacist (NCP) ensures the long-term sustainability, through a "post-1st dose monitoring interview" and "follow-up interviews".

Patients not taking part in the program receive basic pharmacy services in the community pharmacy of their choice.

The core of the F-PSP consists of the following three types of interviews: an "inclusion interview" conducted by the TCP and a "post-1st dose monitoring interview" and "follow-up interviews", both conducted by the NCP (Figure 1). These are scheduled according to a standardized timeline defined by the fingolimod refill schedule, based on the Swiss package size. However, the frequency of interviews can be increased depending on patients' needs.

At the inclusion interview, the TCP delivers to the patient fingolimod repacked into the EM of medication adherence and gives instructions on the use of the tool. Then, the patient brings the EM to all subsequent interviews. Prior to each interview, the data are uploaded to the web platform, and a pill count is performed to validate the data. At the beginning of each interview, the NCP asks three standardized questions to validate the patient's EM use. Then, the NCP shows, describes and discusses the adherence graph with the patient. The pharmacist conducts the intervention based on this objective overview of fingolimod adherence.[27] The content of each interview is detailed in Figure 1. Finally, in each interview, the pharmacist invites the patient to ask questions, collects patient-reported outcomes and edits the intervention report through the platform. This report is then available to the patient's neurologist, MS nurse, general practitioner and/or other pharmacist to ensure continuity of care.

Program origin and development process

The conceptualization of the F-PSP was a collaborative academic development between the Community Pharmacy of Unisanté and the Lausanne University Hospital Neurology Division. The aims were to ensure responsible use of fingolimod and patient empowerment by promoting medication adherence and patient safety, through a person-centered and integrated care approach. The development of the F-PSP was supported by an unrestricted grant from the marketing authorization holder. At that time, the SISPha® secure web platform was already available in a generic version, used by a network of pharmacies (with a basic training) to manage patients tacking chronic medication. From the existing platform, a specific module tailored to patients taking fingolimod was designed by the Community Pharmacy of Unisanté, in collaboration with SISPha SA. From the existing network, a specific network of

specialized pharmacies was developed. The training of these pharmacies was completed by a specific course on the management of patients taking fingolimod and on the specific fingolimod module of the platform. This course was developed by the Community Pharmacy of Unisanté and the Lausanne University Hospital Neurology Division.

Initial Report

Over the course of four years (October 2013 to October 2017), the F-PSP was presented by the TCP to 125 patients among the 131 who started fingolimod at Lausanne University Hospital Neurology Division. Seventy-three (58.4%) patients (median age [interquartile range (IQR)]: 36.0 [28.0-43.0] years old; female: 63.0%) were willing to join the F-PSP. The main reasons for refusal to join the program were as follows: the geographic location of the network pharmacies, the program was perceived as time-consuming and the patients felt self-confident enough to assume full responsibility for the treatment.

The 73 patients who joined the F-PSP attended it in 12 different network pharmacies. From the launch in 2013 to 2017, NPCs conducted 673 interviews with the patients, representing a median retention time (first-last interview) [IQR] of 581 [210-1054] days and a total of 44,519 patient days. In this interval, 40 patients withdrew from the F-PSP, including 11 due to fingolimod discontinuation.

On average, the TCP presented the F-PSP (including questions and answers regarding the F-PSP and the fingolimod) in 35 minutes [IQR: 30-45min] to patients not joining the F-PSP (n=53). To patients joining the F-PSP, the TCP and pharmacy technician needed 132 minutes [IQR: 116-155 min] to present the program and run the inclusion (interview, report, EM handling).The TCP takes on average 45 minutes [IQR: 31-60 min] to coordinate a patient's transfer to the chosen network pharmacy. The time spent by the NCP was measured in one pharmacy (55 patients) as follows: to run the post-1st dose monitoring interview and the follow-up interviews, the NCP and pharmacy technician take on average 72 minutes [IQR: 56-85 min] and 55 minutes [IQR: 43-70 min], respectively (Table 1).

Table 1 : Median time [IQR] in minutes spent by the TCP, NCP or pharmacy technician to deliver the Fingolimod Patient Support Program (F-PSP)[a]

Variable	Inclusion interviews (TCP) (n=73)	Post-1st dose monitoring interviews (NCP) (n= 50)[b]	Follow-up interviews (NCP) (n=385)[b]
Interview conduction (pharmacist)	65 [56-79][c,d]	30 [23-45]	22 [15-30]

Report writing (pharmacist)	50 [40-60][d]	25 [15-37]	16 [10-25][f]
EM handling (pharmacy technician)	17 [15-20][d]	10 [10-15][f]	14 [10-15][d]
Transfer of patient coordination to the chosen network pharmacy (pharmacist)	45 [31-60][e]	NA	NA

[a]IQR = interquartile range, TCP = transition care pharmacist, NCP = network community pharmacist, F-PSP = Fingolimod Patient Support Program, EM = electronic monitor of medication adherence, NA = not applicable

[b]: data available only for one pharmacy

[c]: time including program presentation

[d] 3 missing values

[e]: n=14

[f]: 1 missing value

Forthcoming articles will present details and in-depth findings on satisfaction and experiences of patients regarding the F-PSP (SATFINO study, an article for which has been submitted[32]), as well as on medication adherence and safety of patients attending the F-PSP (AFINO study, an article for which is currently in preparation).

Discussion

Patients are free to participate in and to exit the program at any time if it does not suit them. The high interest rate and the long retention time show that this program meets patients' needs and that they are satisfied. Hence, the development in community pharmacies of such programs integrating new technologies with clinical information and medication management systems seems promising.

The F-PSP is an advanced model of care responding to the emphasized need to reengineer health systems towards more people-centered and integrated health services.[33,34] Indeed, the interviews are personalized, individualized and adapted to the needs and pace of each patient. The pharmacist supports medication adherence in a holistic manner with a multifaceted approach targeting various case-specific aspects (the patient's physical, mental, emotional and socioeconomic well-being). The pharmacovigilance activity provides comprehensive information (e.g., structured education on fingolimod or answers to any drug-related questions) to the patients to reassure them about any safety concerns. In addition, it provides them with the necessary skills to make effective decisions about their own health, thereby

contributing to the responsible use of fingolimod. Through the interviews and the platform, pharmacists can promote coaching and self-empowerment of patients.

Patients play an active role in the program by using the EM of medication adherence and participating in the individualized interviews. The discussion about the adherence graph in each interview provides visual and objective adherence feedback and strengthens their involvement.

With this model, the continuity of care is sustained through interprofessional collaboration involving neurologists, MS nurses and general practitioners in addition to the pharmacists who lead the F-PSP. Continuity of care is enabled by both the TCP and the NCP. The TCP facilitates the transition from a medical to a pharmacy setting, and the NCP ensures information exchange to other healthcare providers through the interview reports. The constant evolution of demographics, society, health technologies and medicine, as well as the increasing prevalence of chronic diseases in a healthcare system that is still very fragmented, urgently demonstrates the need for such programs.[35]

In addition to supporting individual patients, the systematic longitudinal data collection on the web platform (EM of medication adherence and interview reports) supplies the creation of new knowledge about fingolimod adherence and patient-reported outcomes. Therefore, collecting real-world data should optimize patient management by improving the post-marketing pharmacovigilance monitoring and the level of understanding of the experience of patients taking fingolimod. These data should contribute to ensuring treatment effectiveness. Finally, the implementation and evaluation of innovative models of care support research on health services and therefore help to bridge the gap between practice and research.

The expected benefits of such a service are wide and positive for individuals and their families, healthcare providers and health systems.[34] By ensuring a responsible use of fingolimod through the minimization of drug issues and the empowerment of patients, the F-PSP should improve the health outcomes of patients. Through better collaboration, both patients and professionals can improve their relationships and satisfaction levels. Finally, F-PSP may have a favorable impact on costs by minimizing safety issues and sustaining adherence to fingolimod.[36,37]

Conclusion

The F-PSP is intended to be a generic model of a specialty pharmacy service that is transferrable to any other healthcare context, specialty drug or disease. However, the organization of community pharmacies needs to be reshaped to deliver this type of specialty pharmacy service. In addition, it is necessary to rearrange the roles of healthcare providers

and the use of information and communication technologies. Indeed, the role of the pharmacist needs to be enhanced, as illustrated in the F-PSP by the role of the TCP or NCP in the pharmacy network. Moreover, e-tools, such as the F-PSP web platform, can strengthen the clinical skills and reasoning of pharmacists. This should promote pharmacists' empowerment and contribution to a higher quality of care.

Disclosures

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KEY POINTS:

The Fingolimod Patient Support Program (F-PSP) is a specialty pharmacy service aiming to ensure fingolimod effectiveness by promoting medication adherence and patient safety, through a person-centered and integrated care approach.

This innovative model is intended to be transferrable to any other healthcare context, specialty drug or disease.

The systematic and longitudinal collection of adherence data and patient-reported outcomes supports research on health services and helps to bridge the gap between practice and research.