

Pharmaceutical care as a strategy to improve the safety and effectiveness of patients' pharmacotherapy at a pharmacy school: a practical proposal

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Several patients experience at least one drug-related problem and Pharmaceutical Care can change this reality. This work describes a model for structuring the pharmaceutical care service at a pharmacy training unit of the Brazilian Public Health System based on pharmacotherapy follow-up program of Parkinson's disease patients' results. From the follow-up results (phase 1), a Therapy Management Scheme was designed (phase 2). Of the 57 patients followed-up, 30 presented at least one drug-related problem and 42% were non-adherent to treatment, which supported the need of pharmacotherapy management. The Pharmacotherapy Management Scheme was proposed as a pharmaceutical care service model, which presents 6 steps: first, the pharmacist fills out the dispensing form and assesses patient's pharmacotherapy, if there is a suspect problem, he is invited to the follow-up (steps 1 and 2) and they agree the first appointment. After that, pharmacist studies the patient's case (study phase, steps 3 and 4). At the second meeting, the pharmacist proposes the intervention needed, and at the third, assesses the intervention results and new problems (steps 5 and 6, respectively). The process ends when all therapeutics outcomes are reached. This practical model can significantly contributed to the development and organization of pharmaceutical care services.

Uniterms: Pharmaceutical care. Pharmacotherapy follow-up. Community pharmacy. Patients/safety. Parkinson's disease/treatment.

Muitos pacientes vivenciam pelo menos um problema relacionado ao medicamento e à atenção farmacêutica pode mudar este fato. Este trabalho descreve um modelo para estruturar o serviço de atenção farmacêutica numa farmácia escola do Sistema Único de Saúde brasileiro baseado nos resultados de um programa de seguimento farmacoterapêutico de pacientes com Doença de Parkinson. A partir dos resultados do seguimento, um esquema de gerenciamento da farmacoterapia foi desenhado. Dos 57 pacientes acompanhados, 30 apresentaram um problema relacionado ao medicamento e 42% não aderiram ao tratamento, o que reforça a necessidade de gerenciar a farmacoterapia. O esquema proposto apresenta 6 passos: primeiro, o farmacêutico preenche o formulário de dispensação e avalia a farmacoterapia do paciente; caso haja suspeita de um problema, ele é convidado a participar do seguimento farmacoterapêutico (passos 1 e 2) e marcam a primeira consulta. Após esta, o farmacêutico estuda o caso (fase de estudo, passos 3 e 4). Na segunda consulta, o farmacêutico propõe as intervenções necessárias e, na terceira, avalia seus resultados e novos problemas (passos 5 e 6, respectivamente). O processo termina quando todos os objetivos terapêuticos são alcançados. Este modelo de prática pode contribuir significativamente para o desenvolvimento e organização de serviços de atenção farmacêutica.

Unitermos: Atenção farmacêutica. Seguimento farmacoterapêutico. Farmácia comunitária. Pacientes/segurança. Doença de Parkinson/tratamento

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INTRODUCTION

Pharmaceutical Care (PC), described as “the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve patient’s quality of life” (Hepler, Strand, 1990), has been applied in many different clinical fields to manage and improve treatment outcomes using a follow-up method (Chisholm-Burns *et al.*, 2008; de Lyra *et al.*, 2007; Lee, Grace, Taylor, 2006; Koshman *et al.*, 2008). The Brazilian Consensus in Pharmaceutical Care, which was created in 2002, had considered Pharmacotherapy Follow-up (PF) as one of the Pharmaceutical Care components, defined as a professional practice in which the pharmacist is responsible for patient medication needs. This is carried out by means of detection, prevention and solution of a Drug Related Problem (DRP) and implies a continuous, systemized and documented commitment on behalf of the pharmacist, in collaboration with the patient and other healthcare professionals, with the objective of reaching concrete results that improve the patient’s quality of life (Pan American Health Organization, 2002; Grupo de Consenso, 2001). Furthermore, Brazilian Resolution number 44 of the National Agency of Sanitary Vigilance (ANVISA), an agency which monitors and advocates for good pharmaceutical practice, regulated PC as one of the pharmaceutical services that can be carried out in community pharmacies (Brasil, 2009a).

Parkinson’s disease (PD) is a chronic neurodegenerative disease that usually causes severe disability after 10 to 15 years. Its social and financial impact is high, particularly among the elderly, with a prevalence of 1% of the population older than 60 (Martin, Dawson, Dawson, 2011). It is estimated that the annual global cost of antiparkinsonian drugs is around 11 billion US dollars, and it is about 3 to 4 times more expensive for patients in advanced stages of the disease (Bialecka *et al.*, 2008). Furthermore, these patients are polymedicated and normally present multi-morbidity, increasing the risk of experiencing problems related to medicines (Schröder *et al.*, 2011).

These patients normally have a complex pharmacotherapy, as they need to take a number of different medicines several times per day, thus, non-adherence and drug-drug interactions are common DRP (Obreli-Neto *et al.*, 2012). Furthermore, as the disease worsens the number of doses taken per day increases in order to maintain control over the physical symptoms. Moreover, the probability of the occurrence of either an Adverse Drug Reaction (ADR) or treatment resistance increases. On the other hand, non-motor symptoms (such

as depression, hallucinations, etc) have an important impact on quality of life and on treatment compliance and effectiveness (Chaudhuri, Schapira, 2009). All these factors indicate the need for follow-up for these patients.

Pharmaceutical assistance policy and clinical and patient-centered care are part of the undergraduate curriculum of the Faculty of Pharmacy of the Federal University of Santa Catarina and, in order to put this knowledge into practice, the Pharmacy Training Unit has developed a partnership with the local city government. The Training Unit (called Pharmacy School UFSC/PMF) is part of the Brazilian Public Health System (SUS) and medicines - selected from a drugs list based on guidelines and therapeutics protocols for chronic diseases so as to guarantee the most complete treatment coverage through the rational use of medicines known as “specialized component” of the National Pharmaceutical Assistance Policy - are dispensed monthly without direct cost to the patients (Brasil, 2007, 2009b). A median of 7000 patients are assisted per month and, among these, 170 are suffering from Parkinson’s disease.

Thus, our objective was to propose a practical model for structuring the pharmaceutical care service at a pharmacy training unit based on the results derived from a previous experience of a pharmacotherapy follow-up program of Parkinson’s disease patients.

PATIENTS AND METHODS

The present study was performed in two phases described as follow:

Phase 1

Study design and clinical setting

This study is a description of a pharmacotherapy follow-up of Parkinson’s disease patients carried out at the School of Pharmacy UFSC/PMF, which is a pharmacy training unit of the university.

Previous Pharmacotherapy Follow-up

Patients were enrolled in the follow-up between May and August of 2011 when they came to receive their antiparkinsonian treatment and included after accepting and signing the informed consent form. They had an appointment once a month with the pharmacist for a period of 4 months or until the DRPs were solved, however only the data from the first interview was used in this study. Follow-up data were statistically analyzed by ANOVA using SPSS version 15. The study was approved by the

Ethical Committee in Human Research of the Federal University of Santa Catarina.

Follow-up method

The Dáder pharmacotherapy follow-up method was adapted to this study (GIAF-UGR, 2005a). This involves a structured clinical questionnaire based on information retrieval about patient's health problems and pharmacotherapy. The questionnaire is applied at the first appointment and allows the clinical pharmacist to evaluate the patient's clinical history and identify DRPs, formulate an individualized and adequate action plan for the patient and put in place pharmacotherapy interventions that may be required. The method design is continuous and documented, thus, the pharmacist performs successive interviews during a period of time with each patient and archives all clinical, pharmacological and demographic information. At the second meeting, the pharmacist can review the treatment and apply the intervention and at the third meeting he/she can evaluate the intervention results and the necessity of continuing the follow-up. All information was recorded in a specific database for this study. DRPs were classified according to the Third Consensus of Granada in DRP (Consensus Committee, 2007).

Adherence measurement

To evaluate treatment adherence, the Morisky-Green-Levine validated adherence questionnaire was applied (Morisky, Green, Levine, 1986).

PD severity

Hoehn & Yahr stage scale (H&Y) was used to assess disease severity (Hoehn, Yahr, 1967).

Quality of life measurement

Quality of life was evaluated using the Parkinson's Disease Questionnaire (PDQ39) (Souza, 2007). As there is no validated range score to interpret the PDQ39 (0 is considered the best and 100 the worst) (Peto, Jenkinson, Fitzpatrick, 2001) the global score in this study was divided into two categories: scores ≤ 50 and scores >50 , the lower the value under 50, the better the quality of life.

Phase 2

Pharmaceutical care service model

As a proposal to put in practice the pharmaceutical care service, a pharmacotherapy management scheme to manage patient's pharmacotherapy was designed based on previous pharmacotherapy follow-up results.

RESULTS

Phase 1

Previous pharmacotherapy follow-up of PD patients

Fifty seven patients were followed-up, 54.4% men, mean age of 71.4 ± 9 years old, 61.4% did not have a caregiver and 61.4% were married. Regarding schooling, 67% (38) had studied at least eight years (including graduates) and 12.3% (7) were illiterate. The mean diagnostic age was 6.4 ± 4 years and the majority of them (53%) presented stage 1 on the Hoehn & Yahr stage scale, followed by 32% on stage 2.

The first appointment with the pharmacist lasted about 33 ± 10 minutes. The main issues reported by patients were: lack of information about disease progression, prognosis and antiparkinsonian medication, drug interaction, nausea, the occurrence of nightmares and hallucinations, difficulties in complying with treatment regimen and depression.

The results from the pharmacotherapeutic history recorded are described as follows:

Medication and Drug Related Problems

The average dosage of antiparkinsonian and concomitant drugs taken per day are listed in Table I. In addition to Parkinson's disease the majority of patients presented other chronic health problems treated with medication, such as hypertension (38.6%) and hypertension plus diabetes mellitus (15.8%). Regarding DRPs, 30 patients (52.6%) presented at least one and amongst these, 26 (45.6%) had ADRs due to levodopa combinations (levodopa/carbidopa or levodopa/benserazide). The most cited DRPs were ADRs, hallucinations and constipation.

Adherence

From these patients, 42% were non-adherent to their treatment. The treatment regimen and ADRs were the main causes for this. PDQ 39 scores, duration of disease, age, PD severity and patient schooling did not present statistical association with adherence. Table I contains these results in detail.

Quality of life

The quality of life of Parkinson's patients is strongly affected by motor and non-motor signs and symptoms. These patients presented a global score on the PDQ39 of 39.2 ± 19.3 , which is considered good. Older patients (15, median age of 76.7 years) presented a worse score ($>50\%$) than the others ($p=0.005$). Regarding the subscales, bodily discomfort presented the worst ranking with a mean of

TABLE I - Patients baseline study data (n=57)

Age (years, mean±SD)	71.4±9
Gender (male/female, %)	54.4/45.6
Schooling (%)	Illiterate – 12.3 Just read and write – 3.5 Incomplete elementary school – 17.5 Complete elementary school – 14 Incomplete high school – 1.8 Complete high school – 28.1 Graduate – 22.8
Retired (%)	80
Duration of disease (years, mean±SD)	6.44±4
Caregiver (Yes, %)	38.6
Parkinson Disease medication (mean±SD)	2.3±0.7
Concomitant medication (mean±SD)	4.7±3
H&Y stage (%)	1 – 52.6 2 – 31.6 3 – 8.8 4 – 5.3 5 – 1.8
PDQ39 total scale (%)	≤50 – 68.4 >50 – 31.6
Moriski-Green-Levine (%)	NA – 42
DRP (%)	1 – 52.6 2 – 8.8 None – 38.6
ADR (%)	Yes – 45.6

51.6±25.3, followed by mobility problems (48.4±3) and daily activities (47.5±28.5). Patients reported social stigma and social support as the factors that least affected them (19.5±25 and 19.2±23, respectively). Total PDQ39 score in communication, bodily discomfort, daily activities and mobility were affected by PD severity ($p=0.02$, 0.021, 0.03, 0.001 and 0.005, respectively), as stage 1 patients presented a better score compared with stage 2 or above patients. Apart from these results, the total score and subscales were related to the duration of the disease ($p<0.001$ for all).

PHASE 2: PHARMACEUTICAL CARE SERVICE PROPOSAL

As part of the improvement of the quality of patient-centered care services, during the follow-up, a scheme of Pharmacotherapy management was developed to support the implementation of the Pharmaceutical Care service at the pharmacy. This scheme was designed taking into account both the service and patients' needs

and specificities. This service began with treatment dispensation (which included the pharmacist actions regarding the analysis of the prescription, patient counseling and medicine provision), evaluation of patients' follow-up needs (by filling out the dispensation form every three months, as not all patients presented a DRP) and the follow-up itself (individualized and specialized care). This whole process was called the Pharmacotherapy management scheme and comprises 6 steps: first, when patients come to the pharmacy to collect their treatment, the pharmacist asks some questions evaluating their pharmacotherapy and fills out the dispensing form, and if he/she notices that patients have a need, he/she invites them to participate in the pharmacotherapy follow-up (steps 1 and 2); then, they agree on the first appointment (first interview). After the first meeting, the pharmacist studies the patient's case and identifies DRPs (the study phase, steps 3 and 4). At the second meeting, the pharmacist proposes an intervention to the patient or to the physician, and at the third the pharmacist evaluates if the intervention was effective and if there are any new

problems (steps 5 and 6, respectively). If there are any new problems, the pharmacist arranges a new appointment with the patient and the process starts again until all DRPs are solved and therapeutic outcomes reached (see Figure 1).

DISCUSSION

Because Parkinson's disease is a neurodegenerative disease it includes, besides the classical symptoms,

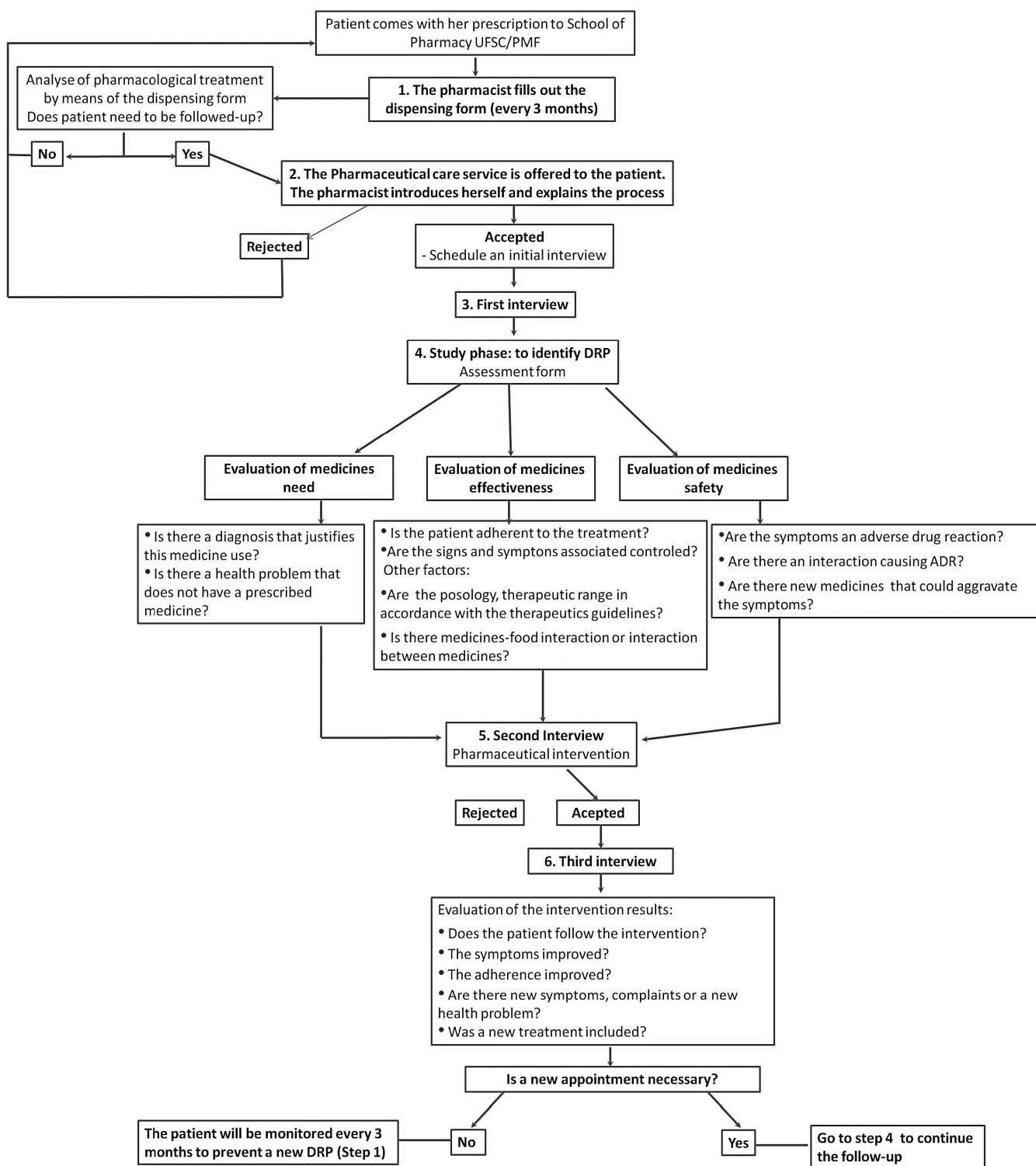


FIGURE 1 - Pharmacotherapy management scheme.

psychosocial and non-motor problems which can strongly affect these patients' quality of life (Tedrus, Fonseca, Kange, 2010). Thus, these patients require more attention from health professionals to ensure the correct and safe use and the adherence of medicines to attain desired clinical outcomes. In this study, PD patients' data were used to demonstrate the importance of specialized care (follow-up) for any person with a chronic disease and to support the development of pharmaceutical care service by designing a pharmacotherapy management scheme.

It has already been shown that pharmacotherapy follow-up programs can improve adherence, decrease adverse effects and generate better clinical outcomes as well as promote the rational use of medicines (de Lyra *et al.*, 2007; Lee, Grace, Taylor, 2006; Viktil, Blix, 2008). However, in Brazil, this service is still in development (de Castro, Correr, 2007; Pan American Health Organization, 2002; Pereira, Freitas, 2008) and pharmacists who work in schools of pharmacy have the responsibility to share their knowledge and contribute to the development of this area, the results of which should improve patient's health and the public health system itself, in relation to the cost-effectiveness of treatments provided. Furthermore, the development of a pharmacotherapy management scheme is necessary to provide appropriate training and knowledge to pharmacists, and to encourage the development of a PF guide, as is the case for other chronic health problems (Sabater-Hernández, 2011; GIAF-UGR, 2005b; GIAF-UGR, 2009).

The results of Phase 1 revealed a PD population with similar demographic characteristics to the epidemiology data previously reported (Davis, Edin, Allen, 2010) and describe the need for individualized care due to poly medication and DRPs presented. Complex treatment posology and ADRs are likely reasons for the large number of DRPs, as well as a delayed perception of improvement in clinical symptoms.

Problems related to non-adherence appear to be the most common DRP among patients with chronic diseases and are related to the increasing costs of healthcare services (Grosset D, European PD Therapy Compliance Study Group, 2010; WHO, 2003; Stuart *et al.*, 2011). The present results agree with these data, showing that 42% of the patients studied did not adhere to their pharmacological treatment. Non-adherence could be responsible for the ineffectiveness of medication leading to misconceptions on the part of physicians when prescribing a drug regimen and dose titration and, sometimes, leading to the prescription of a new medication that increases costs. Furthermore, the majority of these patients are poly medicated, have suffered an ADR, a fact that could accentuate non-adherence. It is

important to note that differently to other studies, non-adherence in this group was not associated to PDQ 39 scores, duration of disease, age, PD severity and schooling (Grosset, Reid, Grosset, 2005).

Non-adherence can arise from prescriber-patient communication, thus a good communication between them is important to attain clinical objectives and avoid misunderstandings. However, sometimes this is not the case. To manage patients' treatments, physicians assume that they are adherent and make decisions based on this; on the other hand, sometimes patients do not understand the information and the reason for taking so many medicines, and the consultation time is insufficient for effective communication (Grosset D, European PD Therapy Compliance Study Group, 2010). Furthermore, patients' experience with medication and their routine have to be taken into account in decision-making and in order to prevent new DRPs, that is, making patients active in their treatment (Shoemaker, 2011; Hibbard, 2004). As an example of it, this study revealed that some patients reported that symptoms alerted them to the need to take the next dose (referring to dyskinesia, shaking, etc) and as a result, they did not forget to take their medication. However, patient did not tell their specialist about it. Thus, sometimes patients and physicians need a support to achieve the desired clinical outcome, and here comes the clinical pharmacist's role, reviewing if patients have sufficient understanding, knowledge and skills to follow their pharmacotherapeutic regimens and, monitoring plans and providing education in partnership with other healthcare professionals (American Society of Health-System Pharmacists, 1997; Wilson *et al.*, 2011).

Regarding quality of life, is already known that it is an important factor for PD patients and their families. As in other studies, these patients had negative perceptions in relation to bodily discomfort, mobility and carrying out daily activities (Tedrus, Fonseca, Kange, 2010; Carod-Artal, Vargas, Martinez-Martin, 2007), as they reported difficulties in performing everyday activities, such as brushing teeth. As the disease progresses, it is expected that its severity and duration further affect quality of life (Welsh, 2008), as reported by these patients and it can influence in desired treatment adherence and clinical outcomes.

All above justify the implementation of the practice of Pharmaceutical care at the Pharmacy School and supports the pharmacotherapy management scheme proposed in phase 2 of this study. However, to make this a well-based service, clinical pharmacist must have in mind that PC is focused on a patient-centered approach and the intervention plan is based on shared decision-

making between patients and pharmacists, as well as patient education. If patients do not feel comfortable and do not trust their pharmacist, the process fails. For this reason, patient-pharmacist communication has to be based on trust and empathy, allowing patients to be active and make decisions in a collaborative way in relation to their treatment, in order to meet their needs and wishes (McKinstry *et al.* 2006; Légaré *et al.*, 2010).

Furthermore, the consolidation of PC at SUS through PF turns the pharmacist into a healthcare provider, establishing a link between the patients and pharmacists, stimulating user responsibility for their health and, finally, enabling a multidisciplinary care team to improve patients' quality of life (Brasil, 1998). According to the present results, pharmacists would have a better view of these patients' needs and wishes, thus their work would be more focused on these aspects. The pharmaceutical management scheme proposed in this study will enable patients to be screened when they go to the pharmacy to collect their medication, identifying DRPs and the need for follow-up in a practical manner without interrupt the routine (Pawloski, Cusick, Amborn, 2012). Furthermore, by evaluating whether the prescription is appropriate and by assessing effectiveness, safety and adherence, medication use can be optimized and unnecessary healthcare spending can be avoided.

CONCLUSION

This model proposed for structuring the pharmaceutical care service in the Pharmacy school showed to be a practical and effective pharmacotherapy management strategy, once all patients will benefit significantly through an improvement in their clinical outcomes by increasing patient safety and treatment effectiveness.

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We confirm all patient/personal identifiers have been removed or disguised so the patient/person(s) described are not identifiable and cannot be identified by analyzing the details of these cases. All authors declare no conflict of interest.

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