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Article

The clinical pharmacist's role in a high-cost medicine pharmacy: Patient-centered care

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In Brazil, medicine dispensing is a pharmacy service provided within the national health system that allows the pharmacist to interact directly with the patient in order to prevent, detect and solve problems related to pharmacotherapy and health needs. However, it is known that most dispensing services provided in the country are still limited to supplying medications and, at their finest, offering advice on medication utilization. Attempts to change this scenario present new challenges the area of pharmacy, which involve the need for a patient-centered pharmaceutical service model. This paper describes the patient-centered pharmaceutical service of high-cost medicine dispensing performed at a pharmacy linked to the Brazilian Unified Health System. In the model described here, the medicine-dispensing activity is the pharmacist's main field of practice, which consists of identifying patient needs related to health care itself and medication utilization. It also aims to introduce the instrument developed (a Pharmaceutical Care Protocol) that contributed to implementing this clinical service provided by the pharmacist. The protocols guide and qualify the service by providing information that helps in evaluating the effectiveness and safety of treatments and in the preparation of the care plan and can be used as a basis for other services that intend to adopt clinical pharmacy practices.

Keywords: Community pharmaceutical service. Specialized component of pharmaceutical assistance. Brazil.

INTRODUCTION

At the beginning of the first chapter of Jones and Rospond's book *Patient Assessment in Pharmacy Practice* (Jones, 2009), Rhonda Jones tells us a story of a 74 year-old man who, while entering a pharmacy, loses his balance just before asking the pharmacist for a refill of his antihypertensive medications. Jones uses this real-life example to invite us to reflect on the kinds of care that can be offered by a pharmacist. In her view, in a typical drug-centered approach, the pharmacist would be concerned only about the safe provision of drug products, and would have ignored the patient's loss of balance. On the other hand, in a patient-centered approach, the pharmacist would take that opportunity to gather further information about the patient, evaluate the data, and make interventions for the benefit of the patient's health and quality of life.

From this perspective, what can be said about the pharmacy practice in Brazil?

In general, medicine dispensing is still the only pharmacy service in Brazil through which the pharmacist and the patient have the opportunity to interact, which it is the moment risks associated with medication utilization can be prevented (Soares *et al*., 2013; Araújo, Freitas, 2006). However, this practice is usually limited to handing

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the medicine to the patient. At best, the pharmacist would also offer advice on medication utilization, as advocated by the Pan American Health Organization (PAHO) (OPAS, 2011). Although the North American concept of pharmaceutical care has strongly influenced the Brazilian clinical pharmacy movement, medicine dispensing seems to have remained the same for decades. In this sense, Bernardo e Hoepfner (2016) argue that an old Brazilian Law's statement[1] is behind such a limited practice.

Drug dispensing is a comprehensive service that involves professional values and attitudes, giving patients the support they need when they need it. With this meaning, dispensing can be organized with the purpose of qualifying care and may involve specific routines to optimize pharmacotherapy, especially in complex clinical situations (Soares *et al*., 2013; Bernardo, Hoepfner, 2016).

In the Brazilian Unified Health System (SUS), accessibility to medicines has grown in recent years much more than have the pharmacy services provided to patients (Soares *et al*., 2013; Araújo, Freitas, 2006). At the same time, the struggle to adopt the patient-centered approach in the provision of services enables health expansion and solutions (Oliveira *et al*., 2016). In this context, the integration of medicine dispensing with core services may contribute to better therapeutic outcomes (Soares *et al*., 2013; Bernardo, Hoepfner, 2016). This is particularly relevant in the care of patients with chronic diseases that require the use of new technologies and/or high-cost medicines.

In Brazil, high-cost medicines are covered by the Specialized Component of Pharmaceutical Assistance (CEAF, from the Portuguese acronym for Componente Especializado da Assistência Farmacêutica). The CEAF is a governmental strategy aimed at allowing full access to high-cost medicines to ensure the comprehensiveness of treatments, based on the care pathways expressed in the Protocols published by the Ministry of Health. The CEAF is a significant strategy in that it is the only means of access to some medicines, especially those at higher prices (Brasil, 2009).

The purpose of this paper is to describe the patient-centered care service provided at the pharmacy of the Federal University of Santa Catarina (UFSC), which is linked to the Unified Health System and dispenses high-cost medicines covered by the CEAF. Additionally, the paper introduces the instrument (Pharmaceutical Care Protocol) that contributed to the implementation of this service.

DESCRIPTION OF THE FACILITY

The pharmacy in question is responsible for dispensing high-cost medicines used for the treatment of chronic diseases, provided by the public health system free of charge (covered by the CEAF). Approximately 5000 patients are assisted monthly by appointment. Since 2008, the CEAF patients have been assisted through this service thanks to an agreement between the local public health network and the university (UFSC).

In this context, logistics activities are carried out by pharmacists of the municipal government in collaboration with administrative technicians, responsible for inventory and storage control and most of the CEAF-related bureaucratic procedures, in addition to assisting part of the patients.

The physical structure destined to provide the service to the public comprises a reception room and a medicine dispensing area. At the reception room, the staff organizes the flow of the pharmacy and guides patients so that their needs related to access to medicines and other health services are met. The dispensing area has 15 individualized booths, where each patient is assisted with comfort and some privacy.

The patient-centered care service is led by the UFSC's pharmacist team. Patients are also assisted by undergraduate students under the supervision of a pharmacist. Furthermore, the university develops teaching and research activities aimed at improving the pharmaceutical services offered, with emphasis on the needs of the users within the SUS.

DESCRIPTION OF THE CLINICAL SERVICE PROVIDED BY PHARMACISTS

The methodology underlying this patient-centered care service draws on pharmaceutical care theoretical frameworks as a philosophy of practice and orientation

1 According to Brazilian Law 5.991/1973, medicine dispensing is the provision of drugs, medicines, pharmaceutical supplies and related products to the consumer, whether for remuneration or not.

towards a logical process of decision-making, allowing the professional to apply his knowledge in a systematic way in the care of patients (Cipolle *et al*., 2012).

The appointments are held every 20 minutes. This time was established according the number of pharmacists and students available to assist patients daily. The care provided includes patient reception, assistance with medicine prescriptions, clinical assessment, pharmacists' interventions when necessary, and patient care recording.

Patient reception

During informal conversations in the appointments, the pharmacist's attention is focused on the patients' needs, with the aim of understanding their experiences with their medicines, the perception of their health/disease process, and the social and family issues that may influence the clinical outcomes.

Clinical assessment

Clinical assessment is carried out in a comprehensive manner, i.e. the pharmacist/student keeps a watchful eye on the patient's therapeutic needs comprising all health problems rather than solely those that require the use of the medicines from the CEAF.

Help with medication prescriptions

The pharmacist/student systematically checks the patients' knowledge about their disease, treatment goals and how their medicine must be administered. Patients can also be asked about their pharmacotherapeutic and clinical history. Besides patients' and/or caregivers' reports, their medication prescriptions are checked.

Clinical assessment

Medicine dispensing is performed monthly when the treatments are assessed for their effectiveness and safety based on the signs and symptoms reported and laboratory tests presented by the patient or caregiver. Upon suspicion of therapy ineffectiveness, the pharmacist/student initially investigates the utilization process and how the medicine is stored in the patient's house. Then, adherence to therapy and to non-pharmacological treatment is also investigated from the patients' reports regarding how they are using their medicines and following a non-pharmacological approach.

Potential drug-drug and drug-food interactions and patients' reports of adverse events (AE) are considered for drug safety assessment. In order to relate the reported AE to the patients' medicines, the study analyzes the temporal relation between the beginning of the medicine use and the beginning of the clinical picture and its description in the literature. To assist the drug-drug and drug-food interactions analysis, the Medscape software was used.

Pharmacist's interventions when necessary

Interventions directed to patients and/or caregivers include spoken and/or written guidance and printed educational materials such as guidelines for the treatment of constipation or insomnia (sleep hygiene); instructions on the administration of injectables and eye drops; the storage of thermolabile and photosensitive drugs; tables with information on foods high in triglycerides, cholesterol, sugar and protein; control and recording of blood pressure and blood glucose, among others. For patients with adherence difficulties, strategies are developed for medicine organization and for administration at the time prescribed, such as tables with the names of their medicines and their respective administration times, or the use of alarms and reminders. Whenever necessary, and in agreement with the patient, a thorough medicine timetable is organized considering drug-drug and drug-food interactions and respecting the particularities of each medicine. When the treatment scheme needs to be changed, interventions are carried out directly with the prescriber using a referral letter, written based on the best available scientific evidence, with information searched in databases such as Pubmed, Cochrane, Bireme, Micromedex, among others.

Patient care recording

Records on the treatment progress are made using the SOAP note method that organizes the information into subjective data, objective data, assessment, and plan.

The use of this instrument helps with the organization of the patient's history and with the development of clinical reasoning, making possible greater assertiveness of the intervention towards a negative response to a given treatment (Zierler-Brown *et al*., 2007). The SOAP was chosen because it is the method routinely used in the healthcare network of the municipality where the university pharmacy in question is located.

OVERCOMING THE DIFFICULTIES OF THE CEAF'S CLINICAL SERVICE PROVIDED BY PHARMACISTS

In order to instrumentalize and measure the care provided, pharmaceutical care protocols were created. Initially, protocols regarding clinical conditions were developed, comprising the largest number of assisted patients. Of the 80 clinical conditions covered by the CEAF, protocols were created for about 50 of them until 2017. Previously, these protocols were developed, tested and validated as a teaching method for the clinical service provided by the pharmacist (Foppa *et al*., 2019). Later on, they were incorporated into the clinical service routine to guide the care of patients.

These protocols are intended to assist in the clinical service delivered by the pharmacist by objectively providing fundamental information on the diseases covered by the CEAF and the treatments thereof, which is, to a large extent, infrequent in a pharmacist's daily practice. The protocols are prepared in the form of flowcharts that allow the pharmacist/student to systematically evaluate the patient's pharmacotherapy, guide himself/herself in decision-making, and perform interventions when necessary.

The referred protocols are divided into 3 steps: (1) pathophysiology of the disease; (2) first drug-dispensing appointment; and (3) follow-up (assessment of the effectiveness and safety of the treatment). The first step aims to demonstrate, in a summarized way, the main pathophysiological mechanisms of the disease, its most common signs and symptoms, so as to prepare the pharmacist/student to assess the effectiveness and safety of the treatment, and if necessary to instruct the patient, as shown in Figure 1.

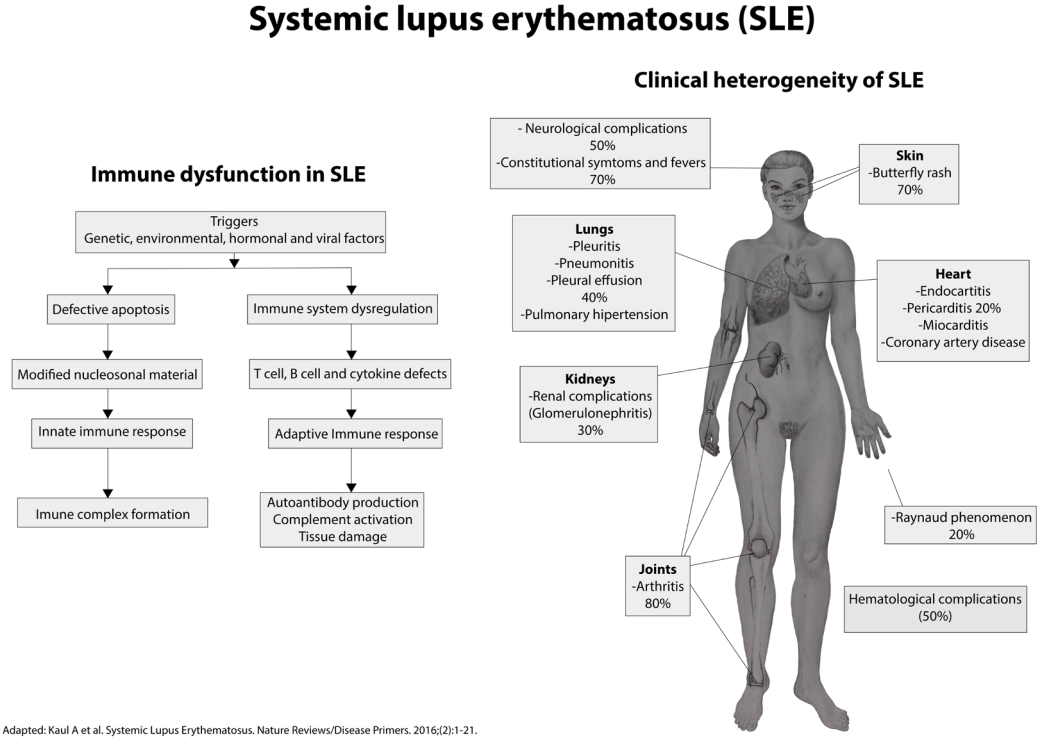

FIGURE 1 – Schematic diagram showing the pathophysiology of Lupus.

The second step refers to the flow of the first medicine-dispensing appointment and contains information about the disease, the medicines used (administration, storage, and particularities) and non-pharmacological orientations related to the treatment, as shown in Figure 2.

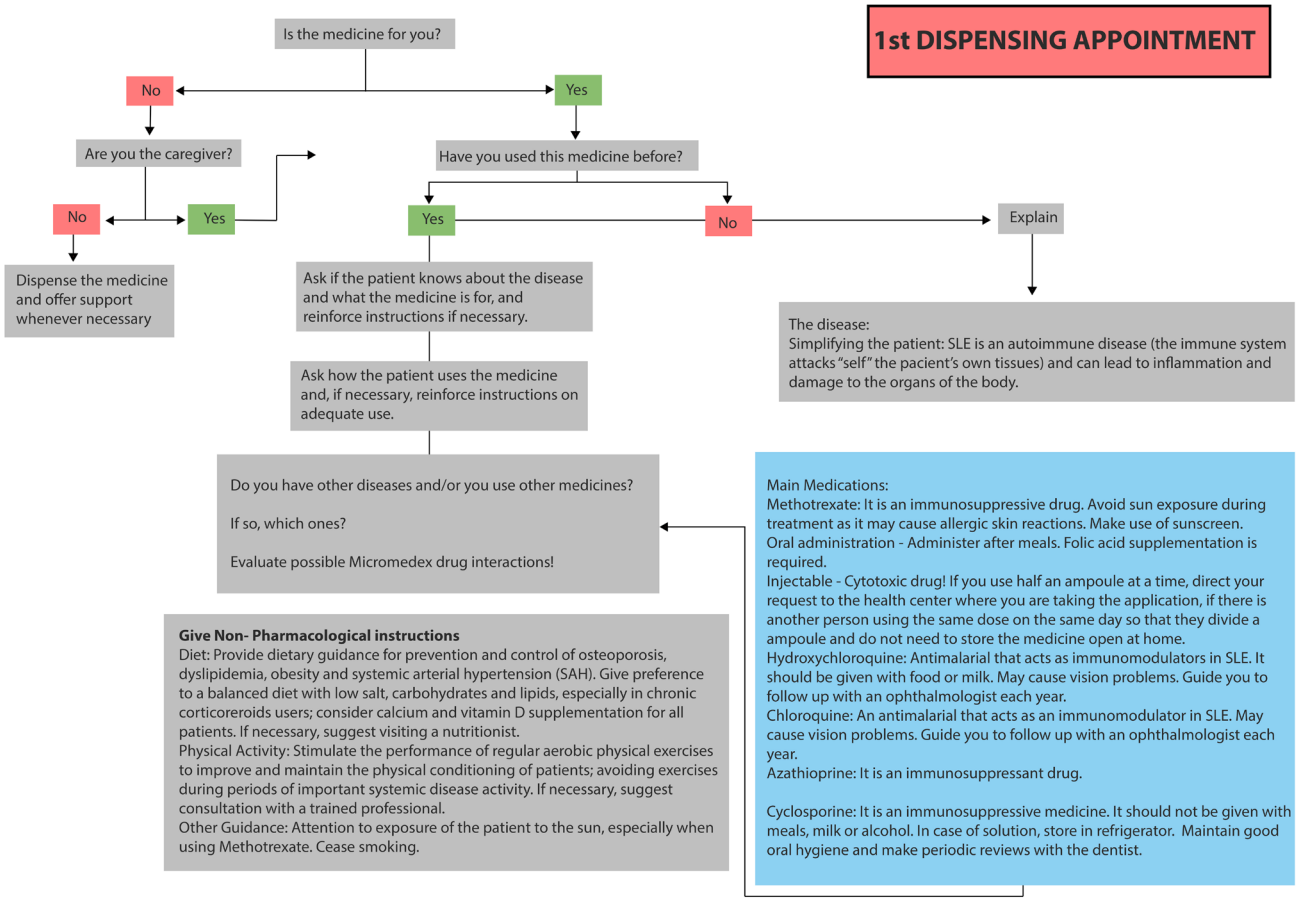

FIGURE 2 – Flowchart of first drug-dispensing appointment in the treatment of Lupus.

The third step aims to instrumentalize the pharmacist/student to develop clinical reasoning for the assessment of the effectiveness and safety of the treatment. The effectiveness flowchart contains the therapeutic goals and clinical methods used to monitor the disease: laboratory tests, signs, symptoms and limitations overcome after using the medicines. The safety flowchart contains the main adverse reactions and drug interactions (Figure 3 and Figure 4).

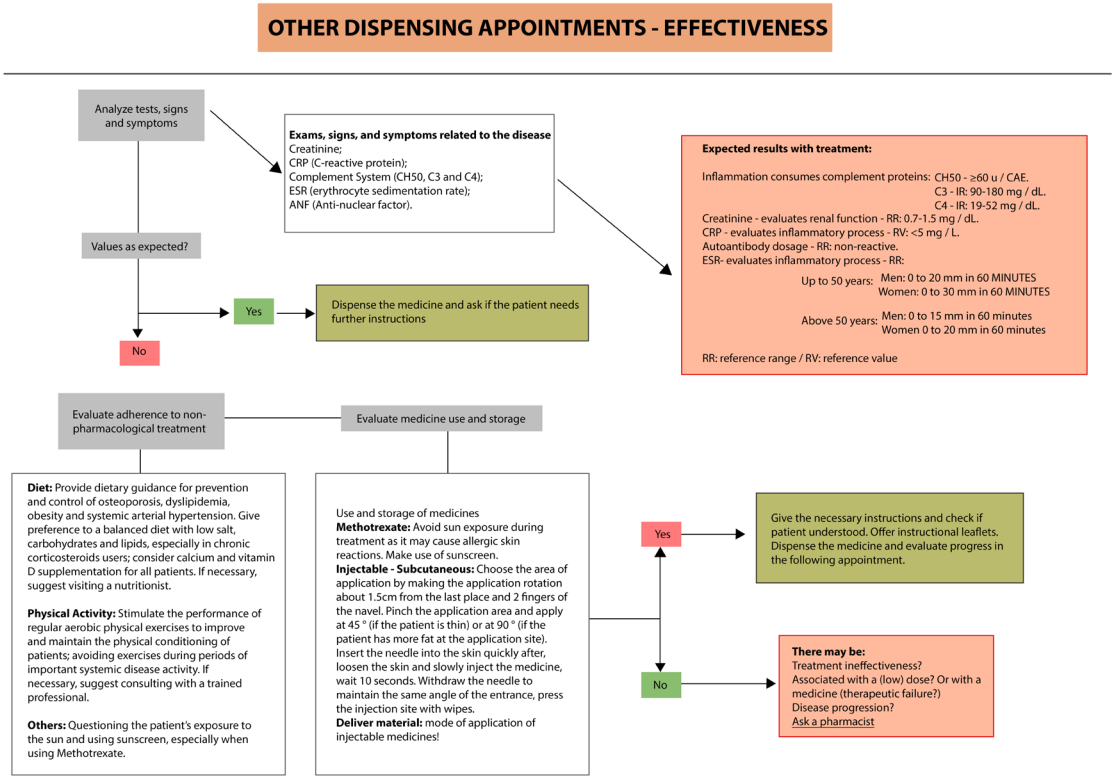

FIGURE 3 – Flowchart of the treatment effectiveness assessment for Lupus.

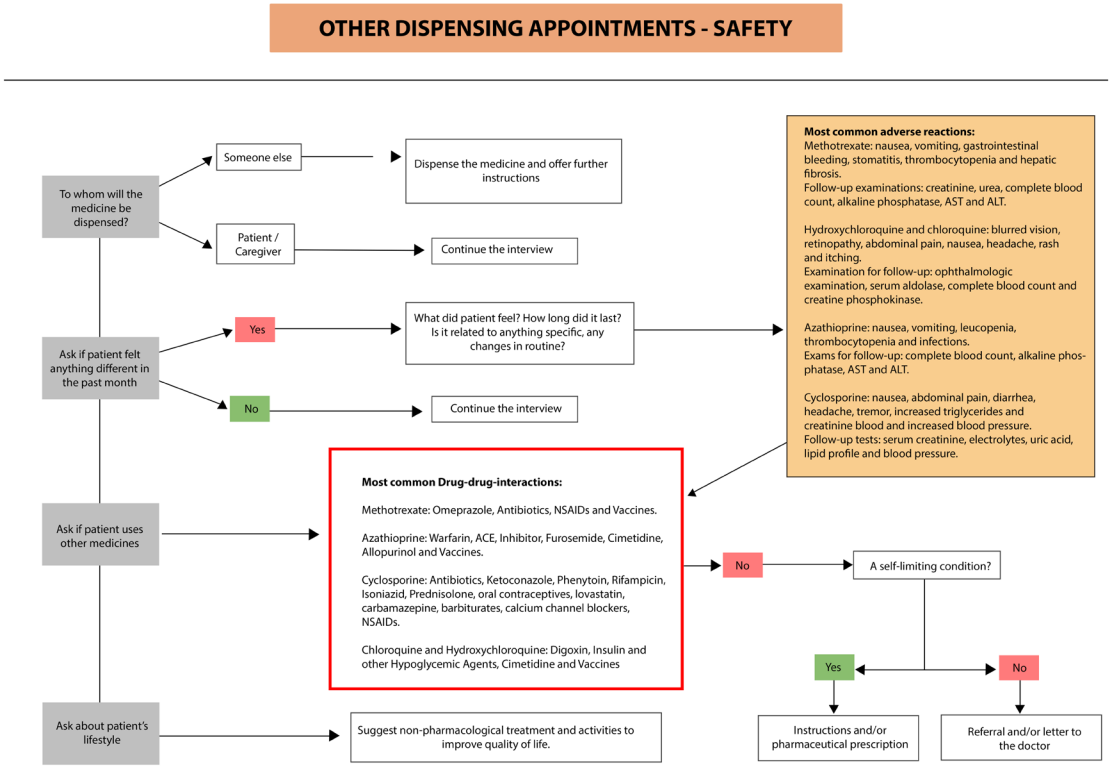

FIGURE 4 - Flowchart of the treatment safety assessment for Lupus.

IMPLICATIONS

The growing incidence of chronic diseases, the increasingly high costs of treatments and budget constraints have brought new challenges for health systems and practitioners (Frenk *et al*., 2010). Patient-centered care, aimed at best therapeutic outcomes and risk minimization, brings to the pharmacy area new challenges that involve the need for a service model that includes the provision of clinical services performed by pharmacist with a view to achieving satisfactory health outcomes (Soares *et al*., 2013; Bernardo, Hoepfner, 2016; Pereira, Freitas, 2008). In the model described here, the medicine-dispensing activity – a pharmaceutical activity par excellence – is the pharmacist's main field of practice of identifying patient needs related to health care and use of medicines.

A study developed by Araújo *et al* (2017) characterized some activities of clinical nature developed by pharmacists in Brazil. The results demonstrated that these activities are still incipient. To overcome this scenario, it is necessary to undertake efforts to institutionalize such clinical activities, ensuring proper infrastructure and qualification of professionals. The same context has been observed for medicine dispensing (Angonesi, 2008; Leite *et al,* 2017).

In this regard, the protocols developed here contribute to the establishment and implementation of clinical pharmacy services, since they provide subsidies that assist pharmacists in clinical reasoning, effectiveness and safety assessment, preparation of a care plan, and decision making. Furthermore, it is worth noting that the protocols were developed and used in a university pharmacy, contributing to the development of the students' competencies through experiential learning. In this context, the use of the SOAP note as a method of recording proves appropriate, since monitoring and continuity of the care provided is necessary (Zierler-Brown *et al*., 2007).

In the CEAF, these protocols are even more important given the complexity of the patients' clinical conditions. Furthermore, the clinical protocols and guidelines available in Brazil include treatment monitoring but do not provide a systematized basis for its implementation by the pharmacist, neither offer information on parameters for effectiveness and safety assessments in a flow capable of providing subsidies to aid the pharmacist in clinical reasoning and decision making. Thus, few places have incorporated this service into practice in the CEAF (Soares *et al*., 2013; Araújo, Freitas, 2016).

Lima-Dellamora *et al*. (2012) pointed out that one of the factors responsible for the non-compliance of pharmacists with the PCDT is their lack of qualification to monitor the treatments – a field of practice that recognizes various technical requirements, knowledge and skills. So, even though the PCDTs have provided for the creation of mechanisms to ensure medicine safety and effectiveness as well as patient follow-up by pharmacists, their actual participation in the process is often not evident.

Therefore, the proposed instrument has helped in the implementation of pharmacist clinical service and contributed to assertive and integral care, as advocated by the SUS. This proposal can be used in other models of pharmacy - it is not restricted to CEAF units and can contribute the teaching and learning process of pharmacists in real scenarios of practice.

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