Marcus Vinícius Dias-Souza [1]
Graciela Cardoso Barros [2]

DESENVOLVIMENTO DE MATERIAL EDUCATIVO PARA FORMULAÇÕES MAGISTRAIS COMO FERRAMENTA COMPLEMENTAR PARA ORIENTAÇÃO FARMACOTERAPÊUTICA DE PACIENTES

DEVELOPMENT OF DRUG USE INSTRUCTIONAL CARDS FOR COMPOUNDED FORMULATIONS AS A COMPLEMENTARY PATIENT EDUCATION TOOL

DESARROLLO DE MATERIAL EDUCATIVO PARA FORMULAS MAGISTRALES COMO HERRAMIENTA COMPLEMENTARIA PARA ORIENTACIÓN FARMACOTERAPÉUTICA A PACIENTES

1. Universidade Vale do Rio Doce
2. Farmácia Harmonize de Manipulação e Homeopatia

RESUMO

Objetivo: Descrever o desenvolvimento, implementação e validação preliminar de material educativo farmacoterapêutico para amplo uso como ferramenta complementar do uso correto de formulações medicamentosas magistrais.

Métodos: Registros compulsórios de problemas relacionados ao uso de medicamentos, e de substancias de maior frequência de manipulação, foram consultados para elaboração do material. A eficácia do instrumento foi avaliada pelo fluxo de entrada de novos registros e pelo tipo de informação registrada.

Resultados: O número de registros relacionados a queixas sobre uso de medicamentos reduziu 86%, e o serviço de telefarmácia se mostrou mais robusto ao lidar com pacientes antes do encaminhamento ao farmacêutico.

Conclusões: O material educativo se mostrou eficaz para orientação farmacoteraêutica dos pacientes, e mostrou-se útil no treinamento de colaboradores não farmacêuticos para questões básicas relacionadas a uso de medicamentos.

Descritores: Informação, Medicamentos, Manipulação.

ABSTRACT

Objective: This paper describes the development, implementation, and preliminary evaluation of drug therapy instructional cards as a complementary tool in the correct use of compounded medication formulations.

Methods: Patients' complaint formularies (PCF) and the compounding laboratory registry review of the most frequently dispensed drugs were used for the material development. The efficacy was assessed through the flow and the registered information of PCFs.

Results: Our findings suggest that the DUIC may be useful for complementary education for adults on PC consultations and in normal drug dispensing, and point a way to save time when providing telepharmacy services.

Conclusions: The material was effective for pharmacoterapeutic patient education, and was useful for training non pharmacists co-workers on basic topics related to medication usage.

Descriptors: Information, Medication, Compounding.

RESUMEN

Objetivo: Describir el desarrollo, validación y aplicación preliminar de materiales educativos para el uso farmacoterapéutico generalizada como una herramienta complementaria en el uso correcto de las formulaciones de medicamentos magistrales.

Métodos: Los registros de los problemas relacionados con el uso de medicamentos y de sustancias de mayor frecuencia de la manipulación, fueron consultados en la preparación del material. La eficacia del instrumento fue evaluada por la entrada de nuevos registros y el tipo de información registrada.

Resultados: Los resultados sugieren que los materiales pueden ser útiles para la educación complementaria de adultos y en la distribución normal de los medicamentos, y señalan una forma de ahorrar tiempo en la prestación de los servicios de telefarmacia.

Conclusiones: El material fue efectivo para la educación farmacterapéutica de los pacientes, y fue útil para la formación de los compañeros de trabajo non farmacéuticos sobre temas básicos relacionados con el uso de medicamentos.

Destriptores: Información, Medicamentos, Manipulación.

Autor para Correspondência:
Marcus Vinícius Dias-Souza
Faculdade de Ciências da Saúde,
Universidade Vale do Rio Doce
marcus.mv@mail.com

INTRODUCTION

Incorrect quantity of information about correct drug usage is among the main reasons of patients' dissatisfaction with prescribed treatments [1]. Patients may misunderstand or demand more information, or forget important details like how long the drug takes to act and possible side effects, leading to poor compliance problems and negative results [1,2]. Poor compliance seriously limits the effectiveness of drug therapy, for instance, due to several doubts regarding the need for therapy and complex therapeutic schemes, usually difficult to be managed by patients without professional support [2,3].

Pharmaceutical Care (PC) is a model of practice in which the pharmacist takes responsibility for the patient's pharmacotherapeutics needs in order to achieve definitive results on the treatment [4]. The successful delivery of PC to patients requires effective counseling skills for identifying and solving patients' drug related problems (DRP), which include warning about interactions, basic nutritional support and translating the benefits associated to the drug therapy into predictable health gains, enabling and encouraging patients' self-care [2-4].

Most of the PC practitioners, however, face problems like the rising costs of drug therapies and associated health services, and often, patients' limited financial resources are incompatible with the need of treatment, what makes health care a difficult endeavor. In an attempt to provide adequate clinical treatments, brazilian patients and prescribers have been exploring compounded formulations as a low cost alternative to commercially available (or hard-to-find) drugs and conventional treatments.

Compounding pharmacies offer the possibility of formulating products to address patients' exclusive requirements, like combining or altering ingredients and quantities to prepare customized dosage forms not available for a specific drug, upon receipt of a valid prescription. For patients, compounded formulations may represent significant financial resource savings, especially when the disease requires long term pharmacotherapy.

Despite such advantages, an old problem of compounded formulations is the lack of printed prescribed information, contrasting commercially available products. Although the value of well planned written instructions for drug use was previously described [5], it is technically difficult to deliver printed prescribed information for personalized formulations, due to the wide variety of drug combinations. In Brazil, the regulatory sector for compounding pharmacies determined that the prescribers' indications should be repeated in label instructions, but clear evidence indicates that prescriptions are rarely well prepared and might present varied mistakes such as drug interactions and wrong choice of dose and dosage forms, what makes the confidence of these documents, for this purpose, therefore, questionable [3-6].

In order to address this issue, drug usage instructional cards (DUIC) for different therapeutic classes were developed and validated for distribution to patients. Our findings suggest that the DUIC may be useful for complementary education for adults on PC consultations and in normal drug dispensing, and point a way to save time when providing telepharmacy services. The results become even more relevant considering the scarcity of studies in this field.

METHODS

Scenario

The good manufacturing practices (GMP) laws from the National Sanitation Regulatory Agency (ANVISA) for compounding pharmacies obligate the compulsory register of any complaints from patients or clients in a specific formulary (patients' complaint formulary – PCF) , which should be kept at the pharmacy for consultation by ANVISA. At the pharmacy of this study, this formulary is hand-written and archived after the matter is solved. The information is also registered on the patient's registration account. The PCF data is registered in the patient's words and after is converted to technical specifications for a better analysis by the technical team.

For traceability purposes, patients and formulations in these formularies are identified by numbers automatically generated by the production chain manager software Formula Certa (Alternate Technologies, Brazil) and are known only by the pharmacist in charge, what protects patients' confidentiality. Therefore, it is not possible to determine name, age, sex, address, clinical picture, prescriber in charge, formulation prices, or any other personal feature through these formularies. Pediatric formulations were differentiated by a written specification on the formulary and excluded from this research. Moreover, informed consent obtainment is a established procedure always done prior to PC services commencement. Our data was collected from these formularies and from the compounding laboratory registry review of the most frequently dispensed drugs, both from a period of six months.

DUIC design

For this study, all the available PCFs (N=108) at the date of the beginning of the study were critically analyzed. Formularies of pediatrics formulations registrations were not considered for this study. The compounding laboratory registry review of the most frequently dispensed drugs was also analyzed.

The complaints (and doubts) about drug usage information registered in the PCFs were previously collected from patients registered at the PC service, patients or clients assisted on the telepharmacy counseling service or assisted on the counter for formal drug dispensing by the pharmacist, and clients in charge of buying or administrating the formulation. The pharmacists and sales attendants were trained on how to register the information correctly prior to develop their normal activities.

The information about drug related problems was organized according to the following parameters:

1. Drug-drug interactions
2. Drug-food interactions
3. Correct way and time of administration
4. Storing the dosage form
5. Experienced side effects and potential toxicity

After processing the previous data, an extensive literature review was done for collecting technical information for DUIC design, which was organized according to the following parameters:

1. Most common drugs and indication
2. Pharmacokinetics and metabolism
3. Drug-drug interactions (obtained at the drug interaction checker in Medscape website)
4. Drug-food interactions
5. Basic Nutritional Support
6. Best time of administration
7. Pregnancy, lactation and fertility impairment warnings
8. Contraindications
9. Common Clinical Adverse Reactions

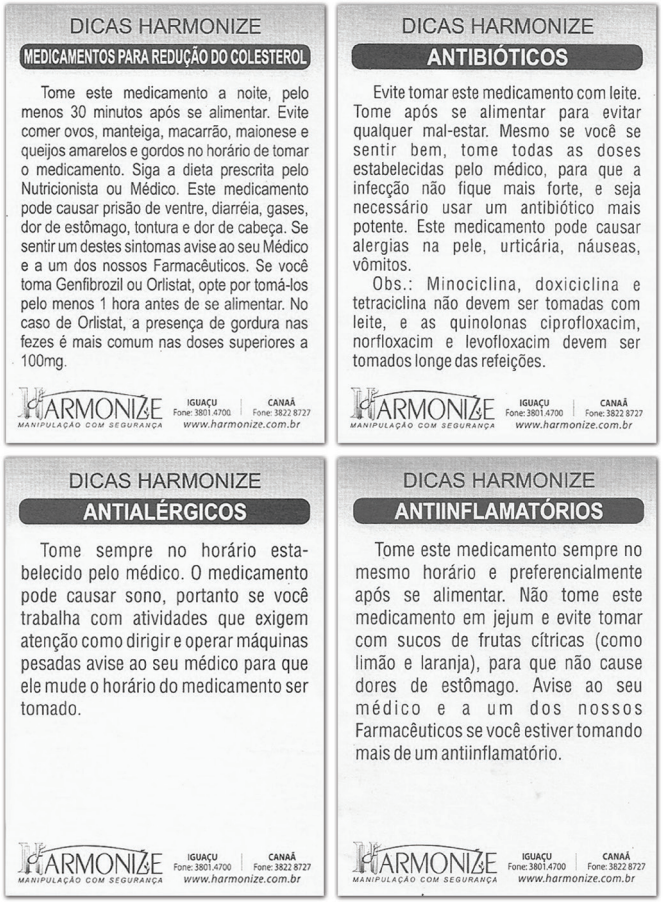
The instrument was designed to be simple, practical, and useful for patients and caregivers for administrating the medication when its effects are desired, following the prescribed therapeutic scheme, and contacting the pharmacist if any doubts were raised. Several graphic changes were made to format the content of the DUIC during the design, like font type and size, layout orientation and size, and the readability of the material was checked by co-workers not involved in the DUIC project, with and without technical knowledge on drug usage, for preliminary validation.

The DUIC were then distributed to patients: when medications were

ordered, it was included in the formulation's delivery package or counter package, considering the therapeutic group. The effectiveness of the instrument was verified through the assessment of the PCFs flow and matter of complaint registered, for a period of 6 months after the distribution began.

RESULTS AND DISCUSSION

During literature search, no works were found specifically designed for drug dispensing in compounding pharmacies. To our knowledge, this is the first time that the development of printed prescribed information for compounded formulations is described. DUIC models are shown in picture 1.



Picture 1: DUIC models.

The pharmacotherapeutic groups in which the data analysis pointed the occurrence of complaints and the registered DRP are shown in table 1. For each group, general aspects of all the nine items of technical information for the DUIC design were included and written for simple and quick reading, in order to maximize the comprehension and compliance to drug therapy.

Pharmacotherapeutic Group	DRP/Therapeutics needs	Complaint rate
Antihistamines	Sleepiness	7%
Antimicrobials	Full completeness of therapy	11%
Anti-hypertensives	Nutritional support/correct administration	28%
Anti-lipemics	Nutritional support/correct administration	19%
PPI	Nutritional support/correct administration	8%
NSAID	Nutritional support/correct administration	11%
Psychotropic drugs	Extrapyramidal Side effects	16%

Table 1 Pharmacotherapeutic Groups for DUIC design. Legend: PPI: Proton Pump Inhibitors; NSAID: Non-steroidal anti-inflammatory drugs.

Most of the patients' therapeutics needs were related to anti-hypertensives and anti-lipemic drugs. Recent data from the Brazilian Society for Cardiology describes that the prevalence rate of hypertension rave reached over 30% of the population in the latest 20 years 7, and lipid metabolism diseases are often associated to this clinical picture [7-9].

NSAID and PPI drugs most common problems were due to lack of nutritional support about fasting and previous feeding for administration. Since the stomach protective prostaglandins and the tromboxane A2 are reduced when NSAID are administrated, eating before using them is recommended, once ulcers and bleeding might occur 10. However, there are evidences that the administration of PPI under fasting is more effective when compared to feed conditions, due to alterations on pharmacokinetics patterns at different gastric pH levels, influenced by food intake [11].

Extrapyramidal side effects were reported in the analysis for psychotropic drugs. Among the symptoms, the most described included tremor, slurred speech, nightmares, deficient salivation, agitation and restlessness. Drug therapy review by the prescriber was suggested in these cases, considering the lack of competence by force of law of the pharmacist to change the prescription, and the genetic variability of drug responses, a critical factor for any medication, but significant in this group [12].

Antihistamines were the group of lower impact; however, special attention must be given: some of the antihistamines drugs are able to cross the blood brain barrier when their chemical structure is non-polar [4], and sleepiness is a serious problem when driving or operating heavy machines.

The assessment of the PCFs flow and matter of complaint registered was performed one month after the distribution began, for a period of 6 months. A total of 15 formularies were collected in this period. Comparing to the previous period, a reduction of 86% on PCF flow and complaints about the items described in the DUIC was seen, and few formularies (N=4, see table 2) registered complaints from the items already described at the DUIC, what suggests that the effectiveness of the instrument.

PCF Type	N
Pharmacotechnical issues	8
DUIC items	4
Prescription issues	2
PC services issues	1

Table 2: PCFs flow and matter of complaint

It is important to develop strategies to help patients of compounding pharmacies to understand and perform medication administration management. The DUIC were developed as tools to reduce misinterpretation of the prescriptions and improve adherence by providing important information for patients like drug indication, dosing schedule, side effects, and the importance of completing the full course of therapy rigorously [13].

Patients generally are especially dissatisfied with the amount of information about the risks of side effects, what to do when experiencing them, and how to judge the effectiveness of medication 14. Considering this, the DUIC also provided some basic information on this topic, but advises to look for the pharmacist for specific counseling.

Sales attendants often have no specific training on clinical pharmacology and most of the time they have direct contact with patients and caregivers [15]. Due to the simple and practical information, the DUIC were helpful for training sales attendants on basic information to patients and caregivers about which medicines to take, as well as the medication indication, dosage, and time of administration. Through this, it was possible to improve the telepharmacy services, what is very important considering that most of the patients that live far from the pharmacy or cannot meet the pharmacist use this service.

CONCLUSION

Taken together, our findings suggest that creating medication instructional cards at the point of care is feasible and can be effective among patients. The reduction of PCF flow and of medications clinical matters of issue, and the improvement of the telepharmacy services are among the main results of this work. The DUIC are distributed to all patients since its validation, and compliance problems have been rarely reported.

However, this study also has its limitations. First, data collection for DUIC design, although standardized, may well underestimate other problems not reached by the instrument. Without the need of an informed consent procedure as is the case in this study, in which patients were not interviewed, their level of understanding becomes less predictable, demanding a systematic approach with a representative sample observable in daily practice. Our results refer to patients who received a prescription intended for compounded medication, what may differ from drugstore prescribed medications and OTCs. Thus, it is not possible to claim that these findings are generalisable.

Patients' needs for information might not always be met, due to differing perspectives between them and the prescriber, as to the type of information that is needed. From a methodological perspective, patients would need to complete questionnaires to include data on health status and satisfaction with the instrument. However, satisfaction and need for information fluctuate over time and with the experience of treatment, thus, patients' opinions about the instrument are always registered for providing evidence concerning the necessity of modifications.

The present study was also limited in part by its performance at a single inner-city compounding pharmacy with a percentage of patients who have inadequate or marginal literacy skills. It is unclear how the findings would differ in this population, and how the DUIC may facilitate pharmacist counseling in this case. Hence, further research is needed for adapting the DUIC in order to provide information to these individuals. However, this situation can be minimized by the PC services strategies, which include developing specific learning strategies for these patients and their caregivers.

ACKNOWLEDGMENTS

We are thankful to Dr Elizabeth Lopes Andrade, Pharmacist in charge of Harmonize compounding pharmacy, for reviewing the DUIC drafts and the financial support for its implementation. We are also thankful to Renata C. Braga and co-workers for their contributions during the DUIC design. MVDS is a fellow of Fundação de Amparo à Pesquisa do Estado de Minas Gerais (FAPEMIG).

References:

1. van Geffen ECG, Philbert D et al. Patients' satisfaction with information and experiences with counseling on cardiovascular medication received at the pharmacy. Patient Educ Couns, 2011; (83): 303–309.

2. Armando PD, Perez SRM et al. Development and validation of a Spanish language patient satisfaction questionnaire with drug dispensing. Pharm World Sci, 2008; (30):169–174.

3. Smith SR, Rubelein JC, et al. A medication self-management program to improve adherence to HIV therapy regimens. Patient Educ Couns 2003; (50):187–199.

4. Dias-Souza MV, Barros, GC. Pharmaceutical Care and Clinical Monitoring of the Allergic Patient: A Case Report. Brazilian Journal of Hospital Pharmacy and Health Services, v.3, 2012 (ahead of print).

5. Dias-Souza MV, Andrade E.L. The impact of Written Therapeutic Recommendations in Pharmaceutical Care to the Chronic Pain Elderly patient In: Annals of the IV International Symposium of Post-graduation and Research. Faculdade de Ciências Farmacêuticas da Universidade de São Paulo, Ribeirão Preto - FCFRP-USP, 2010.

6. Abdel-Tawab R, Higman James D et al. Development and validation of the Medication-Related Consultation Framework (MRCF). Patient Educ Couns, 2011; (83): 451–457.

7. Sociedade Brasileira de Cardiologia/ Sociedade Brasileira de Hipertensão/ Sociedade Brasileira de Nefrologia. VI Diretrizes Brasileiras de Hipertensão. Arq Bras Cardiol 2010; 95(supl.1): 1-51.

8. Law MR, Morris JK, Wald NJ. Use of blood pressure lowering drugs in the prevention of cardiovascular disease: meta-analysis of 147 randomized trials in the context of expectations from prospective epidemiological studies. BMJ, 2009; (338): b1665.

9. Dergunov AD. Apolipoprotein E genotype as a most significant predictor of lipid response at lipid-lowering therapy: Mechanistic and clinical studies. Biomed Pharmacother, 2011; (65): 597–603.

10. Becker JC, Domschke W, Pohle T. Current approaches to prevent NSAID-induced gastropathy – COX selectivity and beyond. British J Clinical Pharmacol, 2004; 58(6): 587–600.

11. Scheulen ME, Saito K, et al. Effect of food and a proton pump inhibitor on the pharmacokinetics of S-1 following oral administration of S-1 in patients with advanced solid tumors. Cancer Chemother Pharmacol, 2012; 69(3):753-761.

12. Rizvi SJ, Kennedy SH. The keys to improving depression outcomes. Eur Neuropsychopharm, 2011; (21): S694–S702

13. Toprak E, et al. Evolutionary paths to antibiotic resistance under dynamically sustained drug selection. Nature Genetics, 2012; 44(1): 101-106.

14. Praska JL, Kripalani S, et al. Identifying and assisting low-literacy patients with medication use: a survey of community pharmacies. Ann Pharmacother, 2005; (39):1441–1445.

15. Mesquita AR, Lyra DP et al. Developing communication skills in pharmacy: A systematic review of the use of simulated patient methods. Patient Educ Couns, 2010; (78): 143–148.