

PATIENT'S COUNSELLING AND MANAGEMENT OF ADVERSE DRUG REACTIONS AND DRUG INTERACTIONS IN THE COMMUNITY PHARMACY

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Abstract

The pharmacist can participate substantially in promoting effective and safe use of medicines, as he/she is often the last healthcare professional in contact with the patient, before the use of the drugs. Also, often pharmacists are the first to whom patients ask for advice due to their availability. This study aimed to evaluate the counselling provided by the pharmacist in the community pharmacy.

We conducted a survey in pharmacies from 10 Romanian counties across the country. For the first 10/20 visitors of the pharmacy a questionnaire regarding the counselling provided by the pharmacist during the visit was filled in anonymously by the pharmacist.

More than 80% of patients received advice from the pharmacist on the medicines' route of administration, use in relation to meals, dosage and duration of treatment. Around 60% of the patients were counselled on the medicines' contraindications and precautions, drug-drug interactions, additional changes in lifestyle and diet appropriate to the condition, the necessity to immediately consult a doctor/pharmacist in case of adverse drug reactions and medication storage conditions. Lower percentages were registered for advising the patient on the side effects of the medicines (40%), the ability of the drug to modify the laboratory tests results (29%) and the obligation to return to pharmacy the unused psychotropic drugs (18%). 60% of the patients were encouraged to return to pharmacy for monitoring and for 68% was provided instruction and information regarding the therapeutic scheme.

The results of the present study showed that in general terms the counselling activity in the community pharmacy is carried out by the pharmacists in a high proportion, with room for improvement with regards to drug safety issues management.

Rezumat

Farmacistul poate participa în mod substanțial la promovarea utilizării eficiente și în condiții de siguranță a medicamentelor, întrucât el este de cele mai multe ori ultimul profesionist din domeniul sănătății în contact cu pacientul, înainte de utilizarea medicamentelor. De asemenea, în multe cazuri, farmaciștii sunt primii cărora pacienții li se adresează pentru consiliere. Acest studiu a urmărit evaluarea consilierii oferite de farmacist în farmaciile comunitare.

A fost realizat un sondaj în farmaciile comunitare din 10 județe din România. În baza acestui sondaj, farmaciștii au completat un chestionar anonim pentru primii 10/20 de pacienți din farmacie, cu privire la consilierea oferită în timpul vizitei.

Mai mult de 80% din pacienți au primit consiliere de la farmacist referitoare la calea de administrare a medicamentelor, administrarea în relație cu mesele, doza și durata tratamentului. Aproximativ 60% dintre pacienți au fost consiliați referitor la contraindicații și precauții, interacțiuni medicamentoase, modificări în stilul de viață și dietă, necesitatea de a consulta imediat un medic în caz de reacții adverse și condițiile de păstrare a medicamentelor. Procente mai mici au fost înregistrate pentru consilierea pacientului cu privire la reacțiile adverse ale medicamentelor (40%), capacitatea medicamentelor de a influența rezultatele testelor de laborator (29%) și obligația de a returna la farmacie medicamentele psihotrope neutilizate (18%). 60% dintre pacienți au fost încurajați să se întoarcă la farmacie pentru monitorizare și în cazul a 68% din pacienți au fost oferite informații practice asupra schemei de tratament.

Rezultatele prezentului studiu au arătat că activitatea de consiliere în farmaciile comunitare este efectuată de către farmaciști într-o proporție mare, putând fi aduse îmbunătățiri în ceea ce privește gestionarea problemelor de siguranță a medicamentelor.

Keywords: patient counselling, community pharmacy, adverse drug reactions, drug-drug interactions

Introduction

The inappropriate use of medication may result in substantial morbidity and mortality [8, 9, 15]. The pharmacist can participate substantially in promoting effective and safe use of medicines, as he/she is often the last healthcare professional the patient comes in contact with before using the drugs. Pharmacist's involvement in these activities is increasing together with the change of pharmacist's role, from mainly compounding and dispensing the medicines, to identifying, preventing, and resolving drug-related problems, as well as encouraging proper use of medication, and general health promotion and education [13].

The advisory role of the pharmacist provides an opportunity for the patients and the healthcare system to fully benefit of the pharmacist's knowledge on medicines. Pharmacists can provide patients with adequate information at the time medications are dispensed and help them understand the intended effects as well as the unintended side effects of their treatment, by developing patient-specific care-plans and providing instructions and information regarding the therapeutic schemes and by informing the patient about additional preventive therapies [6].

For the scope of ensuring that pharmaceutical services are patient oriented and respect the patients' rights in pharmaceutical care [4], Good Pharmacy Practice (GPP) regulations were established in December 2004 with a revision in February 2010 in Romania. These regulations comprise among others, topics like pharmacist's continuous education, patient counselling activities and monitoring the patient's therapy for drug-drug interactions (DDIs), adherence, efficacy and adverse drug reactions (ADRs) [11].

The objective of this study was to evaluate to what extent pharmacists provide counselling to the patients and manage ADR and DDI cases, in community pharmacy, a few years after the implementation of the latest GPP regulations. In addition, we aimed to analyse the management of ADRs and DDIs of the drugs most dispensed in the community pharmacy.

Materials and Methods

Study design

We conducted a survey in community pharmacies from 10 Romanian counties, regardless of location (urban/rural) or statute (independent/chain-pharmacies).

Each rural pharmacy received, *via* email, 10 questionnaires (less than the urban pharmacies as

per the lower patient's flow) and each urban pharmacy received 20 questionnaires to be filled-in on the following day by the pharmacists, after each patient's visit, for the first 10/20 patients of the pharmacy (to have a sample close to the general population).

The questionnaires were structured into 4 major sections: information on the pharmacist, information on the patient and the reason for the visit to the pharmacy, counselling provided to the patient and the management of therapy issues (if present).

Statistical analysis

The unit of analysis was a single questionnaire. All collected data regarding the pharmacists, patients, counselling and actions taken for the management of the therapy issues were included in the analysis. Descriptive statistics were used to analyse all variables and data are presented with 95% confidence intervals (CI).

Results and Discussion

Pharmacists

520 pharmacies from 10 Romanian counties were included in the study. These represent 30% of the total number of pharmacies in the 10 counties included in the study and 9.8% of the total number of pharmacies in Romania.

The total number of questionnaires was 3,155 completed by 994 pharmacists; of which in majority (95.55%) were females. 26-45 years was the most prevalent (71.35%) age interval for the pharmacists working in the community pharmacy. Information on the pharmacists who participated to our study is presented in Table I.

The percentages of pharmacists following continuing education (CE) are high for activities such as pharmaceutical companies' events, subscription to journals and scientific congresses and symposia in Romania (Table I). Currently in Romania there is still operating a formal CE system that addresses the learning needs of the majority of pharmacists. A step forward to this system would consist in developing a continuing professional development system (CPD). This concept was adopted in 2002 by the International Pharmaceutical Federation and is focused on the individual practitioner's needs with the advantage that it can demonstrate the quality of CE [7].

The results on the scientific sources usually consulted by the pharmacists are in line with the findings of Toma et al: the main source of information for the pharmacists is specialty journals [14].

Table I

Information on the pharmacists

Characteristic	Value, % (95 % CI)
Type of pharmacy	
Chain ≤5 pharmacies	4.37 (3.69-5.15)
Chain >5 pharmacies	63.68 (61.97-65.36)
Independent pharmacy owned by a pharmacist	19.49 (18.12-20.92)
Independent pharmacy owned by a non-pharmacist	5.1 (4.36-5.93)
Experience in community pharmacy	
<1 year	7.16 (6.30-8.13)
1-5 years	25.29(23.79-26.86)
5-10 years	28.21(26.65-29.82)
10-15 years	18.32(16.99-19.72)
15-20 years	4.63(3.93-5.43)
>20 years	14.58(13.38-15.87)
Postgraduate titles	
MA	16.86 (15.57-18.22)
Specialist pharmacist	17.34 (16.03-18.70)
Primary pharmacist	21.36 (19.94-22.84)
Doctor in pharmacy	0.1 (0.02%-0.30%)
Type of continuing education usually chosen	
Scientific congresses and symposia in Romania	74.87 (73.31-76.37)
International Congresses	13.19 (12.02-14.42)
Post-graduation courses at the University	48.21 (46.45-49.97)
Subscription to journals	74.17 (72.60-75.69)
On-line courses	48.49 (46.74-50.25)
Pharmaceutical companies events	87.61 (86.41-88.74)
Scientific sources usually consulted	
National authorities web-sites	65.93 (64.24-67.58)
Public journals	91.19 (90.15-92.16)
Books and compendia	83.90 (82.57-85.17)
Drug information center	25.10 (23.60-26.65)
Scientific manuscripts	60.10 (58.36-61.81)

CI = confidence interval; MA = master degree.

All percentages were calculated referring to the total number of respondents. Percentages missing to 100 when summing up each category represent the participants not responding to that item. Respondents could choose more than 1 item in each section.

Patients

Most of the patients included in the study were females (62.35%). 45.74% of the patients were in

the 19-45 years age interval, followed by the 46-65 years (28.08%). The reason for their visit to the pharmacy is comprised in Table II.

Table II

Reason for patient's visit to the pharmacy

Reason for patient's visit	Percentages of the total number of patients (CI)
Patient with symptoms and requesting treatment (without a previous visit to the doctor)	20.6 (19.2 - 22.06)
Chronic patient with a new prescription	20.57 (19.17 - 22.02)
Chronic patient with prescription renewal	23.11 (21.64 - 24.62)
Patient with prescription for an acute condition	17.75 (16.43 - 19.13)
Patient requests counselling on the current treatment	9.73 (8.72 - 10.82)
Patient with issue regarding the current treatment	2.06 (1.59 - 2.62)
Patient requests OTC	30.71 (29.11 - 32.36)
Patient requests dietary supplements	18.64 (17.29 - 20.04)
Patient requests for medicinal herbal medicinal product	10.87 (9.81 - 12.01)
Patient requests preparation of a magistral prescription	2.92 (2.36 - 3.56)
Patient requests officinal medication	1.55 (1.15 - 2.05)
Patient requests Rx medication with no prescription	5.13 (4.39 - 5.96)
Patient requests cosmetics	9.26 (8.27 - 10.32)

CI = confidence interval; OTC = over the counter; Rx = prescription medication

Pharmacists dispensed mostly Rx medications (requesting prescription), prescribed by physicians (for 56.16% of the patients included) and *over-the-*

counter (OTC) medication (44.12%). This is consistent with the findings of Piecuch et al. in

Polish patients, who visit pharmacies mostly to fill a prescription or to buy OTCs [10].

With regards to the Anatomical Therapeutic Chemical (ATC) classes of medications dispensed, the most prevalent were the ones active on the cardiovascular system (31.16%) and the gastrointestinal tract (22.31%). These percentages are

consistent with other results of studies showing that in Romania cardiovascular medicines are the most used category [2, 3].

Counselling

The type and extent of patients' counselling provided by the pharmacists on the items included in the questionnaire is showed in Figure 1.

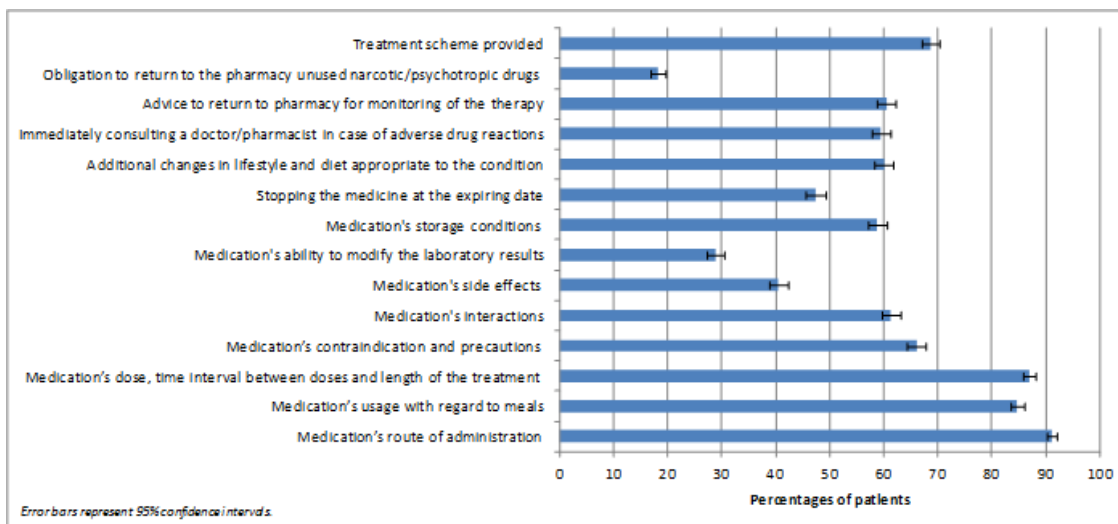


Figure 1.
Counselling provided by the pharmacists

On the first 3 items regarding the medications usage we found a relatively small difference from the percentages (80-90%) of Hamoudi et al.: 72% of the patients responded "yes" to the question "Does the pharmacist give you full instructions and explanation on how to use the medicines?" [6]. Percentages of patients for which pharmacists gave safety advices were lower, although it is important that such advices are given to patients even if not requested, as it was showed that 34% of patients do not ask about possible side effects of the drugs and 26% of the patients are not aware of the fact that all medicines could have side effects [1]. Safety advices could prevent low patient's compliance and drug withdrawals in case of expected side effects (type A).

Providing instruction and information regarding the therapeutic scheme is an important part of the pharmaceutical care plan for each patient, which contributes a lot to patients' adherence to therapy [5]. In our case pharmacists responded that they offered information on the therapeutic scheme, additionally to the one provided by physicians, for 68% of the patients.

Adverse drug reactions and drug-drug interactions

Monitoring treatment's safety and counselling on aspects regarding the side effects of drugs are considered (by the pharmacists and the patients as well) to be traditional roles of the pharmacist [16]. Pharmacists should interview the patients about the

effectiveness of their treatment, treatment adherence, ADRs that might have occurred, and refer the patients to their physician or even recommend stopping the treatment if the results of the interview revealed an important issue. In our study, 62.44% (60.72-64.13) of the patients were questioned by the pharmacists about the effectiveness of their treatment, 31.41% (29.79-33.06) about the adherence to treatment, and 33.79% (32.14-35.47) about ADRs. The pharmacists referred 13.09% (11.93-14.32) of the patients to a physician and recommended discontinuation of one or more medications use for 2.82% (2.27-3.46).

As a member of the healthcare team, the pharmacist often has to collaborate with the prescribing physician. Collaborative pharmacist-physician approaches have led to better patient outcomes for a variety of diseases [13]. In our study the pharmacists contacted the prescribing physician regarding an issue in patient's therapy for 217 patients (6.88%). The reasons for contacting the prescriber were medication errors in 51.61% (44.75-58.43) of the cases, requesting additional information about the patient 29.03% (23.09-35.56), suspected ADR in 13.82% (9.53-19.14), DDIs in 11.52% (7.6-16.54) and with a proposal to change patient's therapy 3.69% (1.6-7.13).

In total, pharmacists suspected ADRs for 100 (3.17% [2.60-3.86%]) of the patients, but only 3

ADRs were reported to the National Medicines Agency. The low number of ADR reports is an issue in Romania, our country being on the last position in a top of population based reporting ratio in Europe [12].

Cardiovascular therapy subanalysis

With cardiovascular medicines being by far the most prescribed drugs, we performed a sub analysis of the ADRs and DDIs for the patients treated with this type of medication. We found that a great part of the ADRs detected by the pharmacist were in this subgroup of patients (38 ADRs out of the total 100). In 22 cases the pharmacist referred the patient to the physician, for 19 ADRs the physician was contacted by the pharmacist, for 14 ADRs the pharmacist recommended to stop the treatment and only 1 ADR was reported. On the other hand, DDIs in the therapy of cardiovascular patients were one of the main reasons for the pharmacist to contact the prescribing physician (14 cases of the total 25 DDI cases when the pharmacist contacted the physician). Thereby, apart from the fact that cardiovascular medicines were the most prescribed type of drugs, those patients were also the ones with the most frequently detected ADRs and DDIs requiring contact of the physician. Thus, we can conclude that patients with cardiovascular therapy are vulnerable patients, with regards to ADRs and DDIs, and one explanation would be that they often need to associate more drugs in order to achieve the therapeutic goal.

Patient's attitude on the counselling offered by the pharmacists was perceived by the pharmacists as "interested" in most of the cases (63.07% [61.36-64.76]) and patients were asking further questions in 35.53% (33.86-37.23) of the cases. Only 1.55% (1.15-2.05) of the patients refused the counselling. For most of the patients (48.53%), the pharmacists spent between 5 and 10 minutes with each patient.

Limitations:

An important limitation of our study is caused by the possibility that the counselling provided by the pharmacists to the patients could have been influenced by reading the questionnaires before the interview with the patients and therefore more intense than usually. We tried to overcome this issue by reminding the pharmacists that the questionnaires are anonymous. Another limitation is that no sampling technique was used to select the pharmacies subjected to this survey; a random selection was done with no pre-specified criteria. This could have resulted in potential bias in the responder population.

The questionnaire was designed by the authors, it was not psychometrically evaluated and no reliability index is available.

Conclusions

The results of the present study showed that the counselling activity in community pharmacy is carried out by the pharmacists in high proportion (higher than any other literature results), according to pharmacists' feedback. Improvement would be needed with regards to the management of ADRs and DDIs, especially for reporting of ADRs to the National Authority.

Cardiovascular patients were identified as the most vulnerable population with regards to ADRs and DDIs. Another study to investigate ADRs and DDIs in these patients in ambulatory setting needs to be further conducted.

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