

PATIENT COUNSELLING AT DISPENSING OTC MEDICINES IN THE COMMUNITY PHARMACY

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Abstract

The aim of this study was to observe and assess patient counselling provided by community pharmacists, when dispensing over the counter (OTC) medications. "Mystery customer" methodology was used to measure pharmacists' level of counselling.

Specially trained "mystery customers" (not known by pharmacies staff) made 241 visits to 70 chain pharmacies located in Bucharest and other main cities of Romania, from April 2007 to July 2008. They followed a scenario for purchasing OTC medication and noted the items of counselling they received using a standardized, five criteria scoring protocol.

During the study, 241 scoring protocols were collected. Data analysis revealed that 58.5% of the pharmacists did not advise the patients ("mystery customers") at all. The overall level of counselling (measured by criteria) has not exceeded 34.0%, but significant differences ($p < 0.05$) were determined among the counselling criteria.

This study showed that patients received counselling mostly about drug administration and dosage, while many other aspects were ignored. For improving patients' therapeutic outcomes, a recommendation upraised from this study is that pharmacists should enhance the level of counselling and patient education, provided in community pharmacy.

Rezumat

Scopul prezentului studiu a fost de a observa și evalua consilierea pacienților efectuată de farmaciști, la eliberarea medicamentelor OTC („*over-the-counter*”, care nu necesită prescripție medicală). Pentru a determina nivelul consilierii s-a utilizat metoda „clientului misterios”.

Clienții misterioși, necunoscuți personalului din farmacia, au efectuat un număr de 241 vizite în 70 de farmacii din București și alte orașe principale din România, în perioada aprilie 2007 - iulie 2008. Ei au urmat un scenariu pentru a solicita medicamente OTC și au notat consilierea primită în farmacie pe un protocol de notare, standardizat.

Pe parcursul studiului au fost colectate 241 protocoale de notare. Analiza acestora a arătat că 58,5% dintre farmaciști nu au consiliat deloc pacienții. Nivelul global al consilierii (pe criterii) nu a depășit 34,0%. În consilierea consecutivă eliberării diferitelor grupe de medicamente OTC au fost observate diferențe semnificative statistice ($p < 0.05$).

Consilierea s-a concentrat în special asupra modului de administrare și dozelor, în timp ce multe alte aspecte au fost ignorate. Astfel, pentru îmbunătățirea rezultatelor terapeutice, se recomandă farmaciștilor intensificarea activităților de consiliere și educare a pacienților în farmacia comunitară.

Keywords: counselling OTC medication, mystery customer, scoring protocol.

Introduction

Medicines dispensing is a constituent of pharmacy practice, and its degree of complexity has evolved by increasing responsibilities to patients [9]. A large number of people with symptoms of illness come first in a community pharmacy, looking to purchase over the counter (OTC) medicines for self-medication and / or seeking for pharmacists' advice [6]. The increasing tendency to self-medication sustains the importance of patient's counselling for the proper use of medication [4].

A highly specialized, responsible and active involvement of community pharmacists in providing pharmaceutical care to patients requesting OTC medicines can significantly reduce the therapy related epidemiological processes (due to inherent adverse reactions of OTC products, as a result of their misuse, or to unwanted drug – drug interactions, with another OTC or a prescription medicine). As a result, community pharmacists have a major, mandatory role in guiding the patient's OTC pharmacotherapy, for the welfare of the patient and society, in accordance to the good pharmacy practice guidelines [6].

Literature revealed numerous studies [15] where “mystery customers”, also found as “pseudo-customer” [3, 10], “simulated patient” [10, 15, 16], “pseudo-patient” [2], “mystery shopper” [8], are used to collect data that help pharmacy chains' management to evaluate and enhance the quality of services provided to patients [14]. These studies investigated the quality of counselling sessions provided either for direct patient requests of OTC or prescription medication or for medication provided on pharmacists' recommendation (patients with symptoms) [7, 15, 18]. Researchers used the “simulated patient” methodology not only in developed countries, but mostly in developing ones, as it is easy to standardize, it is robust and rigorous [15]. The results proved the utility of (repetitive) visits of “pseudo-customers” followed by feedback sessions, and were further used as a base to creating continuous education programs focused on counselling (and implemented the “pseudo-customer” methodology as a standard of evaluating community pharmacists, as the Federal Chamber of Pharmacists did in Germany) [3].

The aim of our study was to observe and evaluate patient counselling provided by pharmacists in chain community pharmacies when dispensing OTC products, requested by patients. This main objective was accomplished by using the method of “mystery customers”, for a period of fifteen months (April 2007 - July 2008).

Materials and Methods

The “mystery customer” plays the role of a patient who enters the pharmacy to request OTC medicines, and receives it. People selected to be “mystery customers” followed a short training where they were taught the role they would play. They were informed about the scenario and the rules for marking the scoring protocol (the document used to record pharmacist’s performance). During the training it was also agreed that none of the “mystery customers” would initiate discussions with the pharmacy staff, would create tense situations and would request more information, in addition to those they receive. “Mystery customers” will address politely, will answer pharmacist’s questions short and to the point and will pay cash (not by credit card). We detailed the “mystery customers” methodology and people recruitment criteria in a previously published work [7].

Scenario

The “mystery customer” visit was conceived to be as similar as possible to a common request in a community pharmacy. Because of using a small number of “mystery customers”, the research team considered several alternatives of OTC requests. In case pharmacists asked for supplemental patient data, “mystery customers” had to use answers and explanations learned during the training stage.

Some studies mentioned that the most counselled OTC medicines are for cold and cough, allergy, pain, gastrointestinal (GI) disorders, for vitamin and other nutritional deficiencies [13]. Thus, we considered appropriate to establish three groups of OTC products that “mystery customers” were allowed to request in pharmacy: Group 1 - Vitamins and Supplements; Group 2 - Cough and Cold Medication, and Group 3 - GI Medication.

The “mystery customer” visits were scheduled by the research team. All pharmacists learned that “mystery customers” visits are not pre-announced and their identity would remain secret during and after the study. Personal information collected in scoring protocols were not disclosed to any person or entity outside the research team, as the only purpose was to build a more accurate, still general image about counselling level practiced in chain pharmacies.

Data collection

Researchers received filled-in scoring protocols at the end of every month. Data were introduced in an electronic database, which allowed the fast query of all items on different criteria. Monthly reports concerning the study progress were prepared and internally discussed.

Scoring protocol

After each visit, and away from the pharmacy, “mystery customers” had to fill in the scoring protocol (Figure 1), specially designed for documenting the pharmacists’ evaluations.

Pharmacy	<input type="text"/>	Date:	<input type="text"/>	Hour:	<input type="text"/>
Name	<input type="text"/>				
			YES	NO	SCORING
			0 for No / 1 for Yes		
Counseling OTC medication - evaluation criteria:					
C1. Patient is questioned about other current medical conditions, allergies or other treatments.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
C2. Patient is informed about drug administration and dosage (no. of daily doses, time interval between doses, daily max. limit)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
C3. Drug - food interactions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
C4. Precautions and contraindications	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
C5. Possible adverse reactions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

Figure 1
Scoring protocol for pharmacists’ evaluation

In the case of OTC medications requests, “mystery customers” had to observe whether the pharmacist asked them about other current medical conditions, allergies or other treatments (criterion C1), about drug administration and dosage (number – no. of daily doses, time interval between doses, daily maximum – max. limit) (criterion C2), and if advices about drug – food interactions (criterion C3), precautions and contraindications (criterion C4) and possible adverse reactions or secondary effects (criterion C5) were assessed.

When the pharmacist counsels her / him on selected topics to be assessed, the “mystery customer” is simply marking on the protocol. Each counselled criterion was granted with 1 point (as “Yes”) while each not-counselled criterion was granted with 0 points (as “No”). Total score is counted using the calculation scheme, as detailed in the protocol, up to a maximum of 5 points.

Data Analysis

Data were collected as scores *per* pharmacist and *per* criteria, for each pharmacy visit. The evaluation of counselling was performed in two directions: (a) pharmacist-centred (the level of counselling was considered the score the pharmacist obtained) and (b) criteria-centred (researchers distinguished here two sub-categories: globally, and individually for each pre-defined group of medicines).

Collected data were processed to observe if there are statistically significant differences among the counselling of the pre-defined criteria, using nonparametric statistical tests. A set of descriptive methods such as frequency calculation were performed at the beginning. Then, comparisons between criteria of counselling, to establish if statistically significant differences in counselling process exist, were performed with Kruskal-Wallis test and then, if reasonable, with U-test (Man-Whitney) for pairs of criteria.

The accepted level of risk (alpha) was set at 0.05. Any statistical test with a p-value below the alpha risk level ($p < 0.05$) was considered as significant. All calculations were performed using SPSS16[®] software.

Results and Discussion

During the study period, 241 complete scoring protocols were collected, corresponding to 241 evaluated pharmacists. A number of 241 OTC medicines were counted. It is important to notice the lack of counselling (58.5%) when dispensing OTC products (141 protocols had a total score of zero). In other words, in 58.5% of pharmacist – “mystery customer” contacts, no counselling has been noted (only the simple drug dispense).

The average score (\pm SD) for counselling OTC medication was 1.17 (\pm 0.9). The distribution of counselling scores for all 241 evaluated pharmacists is shown in Table I.

Table I

Distribution of pharmacists' scores obtained for patient counselling on OTC medication

Scores	n*	Frequency (%)
0	141	58.5
1	11	4.6
2	34	14.1
3	30	12.4
4	11	4.6
5	14	5.8
Total Pharmacists	241	100.00

* number of pharmacists who summarized that score

A. Testing differences in OTC medication counselling – global approach

The frequency calculation of the five OTC counselling criteria followed through the study is shown in Table II.

Table II
Frequency calculation of evaluation criteria for pharmacists providing OTC products counselling (n = 241)

Score	Evaluation criteria				
	C1	C2	C3	C4	C5
1	11.2%	34.0%	30.7%	30.7%	10.8%
0	88.8%	66.0%	69.3%	69.3%	89.2%

n – the total number of OTC drugs dispensed, and that would require counselling
 1 = YES – the pharmacist did counsel
 0 = NO – the pharmacist did not counsel
 C1 – presence of other current medical conditions, allergies or treatments
 C2 – drug administration and dosage
 C3 – drug – food interactions
 C4 – precautions and contraindications
 C5 – secondary effects or adverse reactions

Data recorded on scoring protocols revealed a low level of counselling OTC medication on all evaluation criteria, ranging from 10.8% for criterion C5 (possible adverse reactions or secondary effects) to a maximum 34.0% for criterion C2 (drug administration and dosage).

The Kruskal-Wallis test showed statistically significant differences among those five counselling criteria ($p < 0.05$). After applying the U-test for pairs of criteria, and comparing the results with the frequencies calculations (see Table II), it can be concluded that the source of variation are criteria C1 and C5, having a very high frequency for absence of counselling (“0” scores): 88.8% and 89.2%, respectively. Pharmacists do not question the patients about other current medical conditions or if they know they are allergic to some medication (criterion C1), increasing the risk for potential drug – related problems. Likewise, patients are not informed about the possibility of side effects and adverse reactions occurrence (criterion C5). The lack of information might lead to lower compliance or even losing confidence in treatment’s efficacy.

B. Testing differences in OTC medication counselling, on groups of drugs

The same algorithm was applied for each of the three groups of OTC drugs, pursuing to emphasize the differences and associations between counselling criteria. Table III centralizes the counselling frequencies when dispensing OTC medication, for each of the three pre-

defined groups. It can be noticed that the OTC medication for cough and cold (Group 2) was counseled the most, on all five criteria.

Table III
Frequency analysis of OTC products counselling,
per medication groups and counselling criteria

Criterion	Score	Group 1 - Vitamins and Supplements (n = 49)	Group 2 - Cough and Cold Medication (n = 177)	Group 3 - GI Medication (n = 15)	TOTAL OTC (n = 241)
		Frequency (%)	Frequency (%)	Frequency (%)	Frequency (%)
C1	1	6.1	13.0	6.7	11.2
	0	93.9	87.0	93.3	88.8
C2	1	30.6	36.7	13.3	34.0
	0	69.4	63.3	86.7	66.0
C3	1	20.4	35.6	6.7	30.7
	0	79.6	64.4	93.3	69.3
C4	1	14.3	37.3	6.7	30.7
	0	85.7	62.7	93.3	69.3
C5	1	2.0	14.1	0.0	10.8
	0	98.0	85.9	100.0	89.2

n = number of OTC drugs dispensed from each group
1 = YES (pharmacist did counsel), 0 = NO (pharmacist did not counsel)
C1 – presence of other current medical conditions, allergies or treatments
C2 – drug administration and dosage
C3 – drug – food interactions
C4 – precautions and contraindications
C5 – secondary effects or adverse reactions

When looking after the most counseled criterion, irrespective the group of medication, the frequencies of „1” scores were compared. Thus, it was observed that giving advice on drug administration regimen and dosage (criterion C2) was the highest counseled criterion.

In groups 1 and 2 of OTC medications, statistically significant differences ($p < 0.05$) in counselling were found (Kruskal-Wallis). Group 3 can be considered as homogenous – statistical analysis showed no differences in counselling ($p = 0.715$).

Getting thoroughly with the comparisons for pairs of criteria for group 1 and 2 of OTC medications (U-tests), statistically significant differences ($p < 0.05$) between the counselling criteria were found. The sources of differences are criteria C1 and C5 – the less counselled ones (similar results as in the global approach).

Patients prefer OTC medication to treat minor illnesses, mainly due to the ease of purchasing. OTC product selection and administration should be patient's responsibilities, based on their knowledge [13]. However, with all its benefits for the health care system (fewer family

physician or emergency visits, medicines cost totally incurred by patients), there are situations when self-medication has multiple negative consequences (masking a more serious illness, increased risk of drug interactions or abuse) [5, 13, 17]. Increasing the number and availability of OTC products and the potency of active substances (especially by changing the drugs status from issued on prescription onto OTC) [13, 17] it makes patient's decision more difficult and it determines him to ask more often for a professional opinion [13]. Pharmacist's recommendation, given after a careful assessment of patient's problems, is well respected and appreciated by patients [13].

An overview of our results shows that the level of counselling OTC medication in our studied community pharmacies ranged from 10.8% to 34.0%, similar or lower to other published studies, conducted in other countries. In order to make a comparison, Shani et al. [12] referred to a level of counselling of 60%, while Alte et al. mentioned that 29.7% of the pharmacists offered counselling to patients requesting OTC products (the study targeted only the drug – drug interactions) [1]. A more recent study assessed the counselling provided to patients requesting non-prescription asthma relief medication, revealed an overall rate of counselling of 24% [11].

Conclusions

The present work, designed to assess patients' counselling in community pharmacies, was conducted in 70 chain pharmacies following the "mystery customer" model and resulted in 241 observations.

Counselling patients who requested OTC medicines focused more on administration and dosage, and less on the possible side effects.

Usually, when pharmacists interacted with "mystery customers" it was observed an insufficient counselling when dispensing OTC medicines. As pharmaceutical care related activities are not widely implemented yet in our community pharmacies, studies like this one may inspire pharmacists to take appropriate actions and improve their practice.

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References

1. Alte D., Weitschies W., Ritter C.A., Evaluation of consultation in community pharmacies with mystery shoppers, *Ann Pharmacother*, 2007, 41, 1023-1030.

2. Benrimoj S.I., Werner J.B., Raffaele C., Roberts A.S., A system for monitoring quality standards in the provision of non-prescription medicines from Australian community pharmacies, *Pharm World Sci*, 2008, 30, 147-153.
3. Berger K., Eickhoff C., Schulz M., Counselling quality in community pharmacies: implementation of the pseudo customer methodology in Germany, *J Clin Pharm Ther*, 2005, 30, 45-57.
4. Bild V., Bulea D., Neica S., Pavelescu M.D.G., Consilierea în farmacia comunitară. Rol important în reducerea și optimizarea automedicației [Community pharmacy counseling – an important role in reducing and optimizing self-medication], *Rev Med Chir Soc Med Nat Iasi*, 2009, 113(2), 589-592.
5. Blom A.T., Rens J.A., Information about over-the-counter medication: the role of the pharmacy, *Patient Educ Couns*, 1989, 14, 181-189.
6. Cristea A.N., Farmacie clinică – Farmacia clinică în farmacia de comunitate [Clinical pharmacy – Clinical pharmacy in the community pharmacy], Editura Medicală, București, 2006, Vol.I: 183-270.
7. Negru D.S., Cristea A.N., Petculescu A.M., Minimal consultation provided to patients presenting symptoms in the Romanian community pharmacy, *Farmacia*, 2010, 58(5), 601-610.
8. Norris P.T., Purchasing restricted medicines in New Zealand pharmacies: results from a “mystery shopper” study, *Pharm World Sci*, 2002, 24(4), 149-153.
9. Popa A., Primejdie D., Maier C., Eliberarea medicamentelor fără prescripție medicală - Automedicația [Dispensing non-prescription medicines – Self medication], in Popa A. (coord.), Ghid de practică în farmacie pentru studenții anului V [Guide for practicing in pharmacy, for undergraduate students], Ed. Medicală Universitară “Iuliu Hațieganu”, Cluj Napoca, 2010, 68-87.
10. Puumalainen I.I., Peura S.H., Kansanaho H.M., Benrimoj C.S.I., Airaksinen M.S.A., Progress in patient counseling practices in Finnish community pharmacies, *Int J Pharm Pract*, 2005, 13, 149-156.
11. Schneider C.R., Everett A.W., Geelhoed E., Kendall P.A., Clifford R.M., Measuring the assessment and counseling provided with the supply of nonprescription asthma reliever medication: a simulated patient study, *Ann Pharmacother*, 2009, 43, 1512-1518.
12. Shani S., Morginstin T., Hoffman A., Patients’ Perceptions of Drug Therapy Counseling in Israel, *Isr Med Assoc J*, 2000, 2, 438-441.
13. Taylor J., OTC Counseling: Review of Pharmacists Performance, *Medscape Pharmacists*, 2(2), 2001.
14. Thornley T., Gray N., Anderson C., Eastham S., A study to investigate the extent of delivery of an intervention in asthma, in a UK national community pharmacy chain, using mystery customers, *Patient Educ Couns*, 2006, 60(2), 246-252.
15. Watson M.C., Norris P., Granas A.G., A systematic review of the use of simulated patients and pharmacy practice research, *Int J Pharm Pract*, 2006, 14, 83-93.
16. Watson M.C., Skelton J.R., Bond C.M., Croft P., Wiskin C.M., Grimshaw J.M., Mollison J., Simulated patients in the community pharmacy setting, *Pharm World Sci*, 2004, 26, 32-37.
17. Wazaify M., Shields E., Hughes C.M., McElnay J.C., Societal perspectives on over-the-counter (OTC) medicines, *Fam Pract*, 2005, 22, 170-176.
18. Farcas A.M., Farah C., Bojita M.T., Patients reporting of suspected adverse reactions to antidepressants. A pilot methodological study, *Farmacia*, 2010, 58(3), 255-263.

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