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Community Pharmacies: Frequency, Nature and Determinants of Prescription

Scollard CF and Jennifer P

Department of Pharmaceutical Sciences, Harrison School of Pharmacy, Auburn University, 302 Walker Building, 36849 AL Auburn

***Corresponding Author:** Jennifer P, Department of Pharmaceutical Sciences, Harrison School of Pharmacy, Auburn University, 302 Walker Building, 36849 AL Auburn

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Abstract

Aims: To examine the nature, frequency and determinants of prescription modifications in Dutch community pharmacies.

Methods: A prospective case-control study comparing modified prescriptions with nonmodified prescriptions was carried out in 141 Dutch community pharmacies. 2014 modified prescriptions (cases), collected in the selected pharmacies on a predetermined day in a specific period (25th February until 12th March 1999) and 2581 nonmodified prescriptions (controls) randomly selected on the same day were studied. The nature and frequency of prescription modifications and patient, drug and prescriber related determinants for a modified prescription were assessed.

Results: The overall incidence of prescription modifications was 4.3%, with a mean of 14.3 modifications per pharmacy per day. For prescription only medicines (POM) the incidence was 4.9%. The majority of POM modifications concerned a clarification (71.8%). In 22.2% a prescription could potentially have had clinical consequences when not altered; in more than half of the latter it concerned a dose error (13.7% of all cases). POM prescriptions of patients of 40–65 years had a significantly lower chance of modification compared with those of younger people (OR = 0.74 [0.64–0.86]). With respect to medication-class, we found a higher chance of POM modifications in the respiratory domain (OR = 1.48 [1.23-1.79]) and a decreased chance for nervous system POMs (OR = 0.71 [0.61–0.83]). With regard to prescriber-related determinants modifications were found three times more often in non printed prescriptions than in printed ones (OR = 3.30 [2.90-3.75]). Compared with prescriptions by the patient's own GP, prescriptions of specialists (OR = 1.82 [1.57-2.11]), other GP's (OR = 1.49 [1.02-2.17]) and other prescribers such as dentists and midwives (OR = 1.95 [1.06-3.57]) gave a higher probability of prescription modifications. When a GP had no on-line access to the computer of the pharmacy the chance of a modification was also higher (OR = 1.61 [1.33-1.94]). Multivariate analysis revealed that a nonprinted prescription was the strongest independent determinant of prescription modifications (OR = 3.32 [2.87-3.84]), remaining so after adjustment for GP computer link to the pharmacy and for type of prescriber.

Conclusions: At least 30% of Dutch community pharmacies corrected 2.8 POM prescriptions per pharmacy per working day, which could potentially have had clinical consequences if not altered. If the study sample is representative for The Netherlands, Dutch community pharmacies correct a total of approximately 4400 of these prescriptions per working day. Using computerized systems to generate prescriptions is an important strategy to reduce the incidence of prescription errors.

Keywords: Clinical Pharmacy; Community Pharmacy Services; Drug-Related Problems; Evaluation Studies; Interventions; Medication Errors; Pharmacists; Prescriptions

INTRODUCTION

The management of patient health care can be compromised by drug-related morbidity and mortality, which in their turn can be the result of prescription errors [1]. Community pharmacies can contribute to a reduction of potentially harmful prescription errors. A recent UK study of 1503 pharmacy interventions on 201 000 items dispensed (0.75%) estimated that between 71 and 483 interventions (0.04–0.24% of all items) could have prevented harm, whilst 19–242 interventions (0.01–0.12%) might have prevented a drug-related hospital admission [2]. Moreover, 748 interventions (0.37%) had the potential to improve clinical outcome and could have saved a visit to or by the general practitioner.

We were interested in the contribution of Dutch community pharmacies to the timely detection of prescription errors, particularly because they have used computerized medication surveillance for about two decades [3]. We were also interested in the determinants of prescription modifications accomplished by community pharmacies, because better insight into the determinants of such prescription modifications may lead to improved or new strategies to reduce prescription errors. The impact of the basic characteristics of the prescription, the patient and the prescriber on prescription modifications for outpatients have not been extensively evaluated in previous studies. Therefore, we have carried out a large-scale study to investigate the frequency, nature and determinants of prescription modifications in Dutch community pharmacies.

Methods

Setting and design

In January 1999 all Dutch community pharmacies (n = 1571) were invited to participate in the study by a letter and by a notice in the Dutch pharmaceutical journal. From 470 community pharmacies, that reacted positively within 3 weeks, 188 (40%) were randomly selected. There were 36 nonresponders (mainly because of lack of time and/or personnel or because they had forgotten about it) and 152 responders. Of the latter, 11 pharmacies had to be excluded, because they had not adhered to the study protocol, which left 141 pharmacies (9% of all Dutch pharmacies) that could be enrolled in our evaluation.

All participating pharmacies received a pretested study protocol and three types of registration forms for the documentation of modified prescriptions (cases), nonmodified prescriptions (controls) and basic characteristics of the pharmacy on the day of the study. The protocol advised contact with a telephone help desk in case of any uncertainty. Each participating pharmacy had to collect all modified prescriptions (cases) during one predetermined day between February 25 and March 12, 1999. On the same day they had to collect at random an equal number of nonmodified prescriptions (controls). After selection of cases and controls the pharmacists had to fill in a registration form for each case and each control.

Selection of Cases

All prescriptions for medicines and other health care products (e.g. dressings, incontinence materials, syringes and needles) that were offered on the predetermined day to the community pharmacy by the patient, or by fax or telephone had to be included. Cases were all prescriptions that were modified by the pharmacy on that particular day (even if actual dispensing took place on another day). Reasons for including a prescription modification as a case were defined in the protocol and in the registration form for cases. If there were two or more reasons for modifying a prescription the pharmacist had to select the one he/she considered most relevant. The protocol excluded the following modifications because of their lack of potential impact on patient care: address incorrect or absent, no or incorrect insurance data, incorrect package size, product not in stock, unit of dosage or package specified incorrectly (e.g. ml instead of g), generic substitution and legal requirements (e.g. for narcotic drugs). During the data management process we divided the nature of prescription modifications into three groups. In the first group a clarification was needed to carry out the prescription order. In most cases an essential administrative feature of the prescription was missing or obviously incorrect. In fact the pharmacy could not have dispensed the drug without clarification. In the second group for items identified as 'Correction prescription error' the prescription was administratively correct, but could potentially have had clinical consequences if not altered. Those identified as 'wrong dose' is an important example, for which there are several reasons, like too high/low dose according to standard references or in conflict with the patient's own records. The third group included reasons for modification not covered by the first two categories.

Selection of controls

The pharmacists had to provide an equal number of nonmodified prescriptions (controls) by selecting this number at random from a box containing all prescriptions of the same day.

Validation of the cases

To control for the reliability of the registered

data pharmacists were asked to send in the registration forms as well as relevant copies of the prescriptions and 6 month medication records of the patients concerned. This information was stripped of personal data. Incorrect data in the registration form when compared with the copies of the prescription and/or medication record could lead to an alteration in the final form registered by the research team. For these reasons various cases were excluded from the study. Where double or triple reasons for modification were given, the one considered most relevant was selected so that only one modification per prescription was counted.

Classification of prescriptions

Following Dutch reimbursement regulations items prescribed were classified as prescription only medicines (POM), prescribed OTC medicines (such as paracetamol and miconazole), and nonmedicines (such as dressings, incontinence materials, syringes and needles). The number of prescribed OTC medicines were too small to be worth analysing. All medicines were classified into therapeutic groups using the Anatomical Therapeutic Chemical (ATC) classification of the WHO Collaborating Centre for Drug Statistics Methodology [4].

Analysis

After inspection, data from the registration forms were entered in a Microsoft Access database and statistically analysed using SPSS version 9.0. Logistic regression analysis was used to estimate the association between characteristics and modification of a prescription.

Results

The characteristics of the enrolled pharmacies were comparable with the characteristics of all Dutch community pharmacies in the study period. However, the number of pharmacy assistants in the participating pharmacies was somewhat lower than that in the average Dutch pharmacy, leading to a slightly increased workload per individual.

There was a large variation in the total number of prescriptions per pharmacy, which probably reflects the fact that both small and very large pharmacies were involved in our study.

On the study day, the overall incidence of modifications by the community pharmacies was 4.3% (2014 cases of 47 374 prescriptions) (Table 2). The number of modifications per pharmacy varied from 0 to 100 with a mean of 14.3 prescription modifications per pharmacy. The incidence of modifications for prescription only medicines was 4.9% compared to only 1.4% of the prescriptions for nonmedicines. Modifications of POM prescriptions were most frequently found in the following therapeutic domains: nervous system (ATC group N), respiratory system (R), alimentary tract and metabolism (A), and cardiovascular system (C) (Table 3a).

In 219 cases (12.2%), the modification of a POM prescription was triggered by a signal of the computerized medication surveillance system of the pharmacy concerning a change in therapeutic regimen (e.g. different strength or dose), a potential drug–drug interaction, contraindication or double medication (combination of two medicines with the same or similar ingredient). More than half of the problems concerning POM prescriptions (51.2%) were solved by communication with the patient or his representative, and the same was found for nonmedicines (52.7%). In 282 cases (15.6%), the pharmacy consulted the prescriber about a POM prescription, but the prescriber was contacted less often for nonmedicines (7.5%). Contacts with the prescriber's assistant were similar for POM prescriptions (4.9%) and for prescription modifications of nonmedicines (5.5%) (Table 3b).

In Table 4 the nature of the prescription modifications is summarized. The majority (1294; 71.8%) of the reasons for the 1802 POM modifications concerned the clarification of an insufficiently specified prescription (e.g. dose not specified, insufficient patient data, wrong strength or strength not specified), whereas in 400 cases (22.2%) a prescription error was corrected that might have had clinical consequences ('Correction Prescription Error'). Dose corrections were more prevalent in this latter group (13.7%) than other interventions, such as for a drug–drug interaction, contraindication or double medication (8.5%). In Table 5 we present some individual examples of modifications of POM.

In our analysis of determinants, we focused on modifications of POM prescriptions, since these form the most important group (Table 6). Of the patient-related factors, gender was not significant, but patients of 40–65 years had a lower rate of modifications than younger people (OR = 0.74 [0.64–0.86]). With respect to drug-related factors, we found a higher frequency of POM modifications in the respiratory domain (OR = 1.48 [1.23-1.79]), while a decreased frequency was observed for nervous system POMs (OR = 0.71 [0.61–0.83]). There was no difference between initial and refill prescriptions for POMs, but when a nonmedicine was prescribed for the first time the chance of a modification was much higher than when it was refilled (OR = 3.75 [2.07-6.80]).

With regard to prescriber-related determinants modifications were found three times more often in hand written prescriptions.

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with methanol. The resulting solution was centrifuged at 3000 rpm for 5 min and the drug content of the supernatant was determined (1000 and 100 µg/mL for Metoprolol and Ramipril respectively). 2µL of this solution (2000 and 200ng/spot for Metoprolol and Ramipril respectively) was applied to a TLC plate which was developed in an optimized mobile phase. The analysis was repeated in triplicate. The possibility of excipient interference with the analysis was examined.

RESULTS AND DISCUSSION

The results of validation studies on the simultaneous estimation method developed for Metoprolol and Ramipril in the current study involving Methanol: toluene: ethyl acetate: ammonia (2.5: 3.0: 5.0: 0.7 v/v/v/v) as the mobile phase for TLC is given below.

Linearity

The drug response was linear (r2 = 0.997 for Metoprolol and 0.999 for Ramipril) over the concentration range between 2000-12000 ng/spot for Metoprolol and 200-1200 ng/spot for Ramipril. The slope and intercept for Metoprolol and Ramipril were 1.284 (± 0.982), 1979(± 1.25) and 2.947 (± 0.862) and 658 (± 1.06), respectively.

Precision

The results of the repeatability and intermediate precision experiments are shown in Table 1. The developed method was found to be precise as the RSD values for repeatability and intermediate precision studies were < 2 %, respectively as recommended by ICH guidelines.

Table 1: Precision study for Metoprolol and Ramipril

Drug	Concentration ng per band	Intra-day(n=3)		Inter-day(n=3)	
		SD	RSD%	SD	RSD%
Metoprolol	60	14.28	1.040	18.15	1.326
	120	6.96	0.317	5.91	0.269
	180	24.83	0.865	32.73	1.141
Ramipril	60	56.65	1.904	49.86	1.708
	120	33.97	0.671	31.33	0.618
	180	40.51	0.627	41.03	0.635

LOD and LOQ

Signal-to-noise ratios of 3: 1 and 10: 1 were obtained for the LOD and LOQ respectively. The LOD and LOQ were found to be 50 ng/spot and 100 ng/spot for Metoprolol and 50 ng/spot and 150 ng/spot for Ramipril, respectively. The standard deviation of peak areas was calculated for each parameter and the % RSD was found to be less than 2 %. The low values of the % RSD, as shown in Table 2 indicated the robustness of the method.

Table 2: Robustness Testing of Metoprol and Ramipril

Parameters	Metoprolol		Ramipril	
	SD	%RSD*	SD	%RSD*
Mobile phase composition (± 0.1 ml)	10.42	1.235	10.42	1.235
Amount of mobile phase (± 0.5 %)	20.14	1.018	20.14	1.018
Time from spotting to chromatography (± 20 min)	15.36	0.942	15.36	0.942
Time from chromatography to scanning (± 20 min)	20.10	1.085	20.10	1.085

Specificity

The peak purity of Metoprolol and Ramipril was assessed by comparing their respective spectra at the peak start, apex, and peak end positions of the spot,i.e., r (S, M)=0.998 and r (M, E)=0.999. A good correlation(r=0.9997) was also obtained between the standard and sample spectra of Metoprolol and Ramipril, respectively. Also, excipients from formulation were not interfering with the assay.

Recovery Studies

As shown from the data in Table 3 good recoveries of the Thiocolchicoside and Aceclofenac in the range from 98.32 to 99.45 % were obtained at various added concentrations. The average recovery of three levels (nine determinations) for Metoprolol and Ramipril was 98.95 % and 98.98 % respectively.

Table 3: Recovery studies of Metoprolol and Ramipril

Label claim (mg/tablet)	Amount Added (%)	Total amount (mg)	Amount* recovered (mg ± % RSD)	Recovery (%)
Metoprolol 25	80 (20mg)	45	44.65 ± 0.222	99.22
	100 (25mg)	50	49.16 ± 0.154	98.32
	120 (30mg)	55	54.63 ± 0.130	99.32
Ramipril 2.5	80 (2mg)	4.5	4.46 ± 0.526	99.11
	100 (2.5mg)	5.0	4.92 ± 0.360	98.4
	120 (3mg)	5.5	5.47 ± 0.344	99.45

Analysis of a formulation

Experimental results of the amount of Metopr-

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