Drug related problems identified by European community pharmacists in patients discharged from hospital

• Ema I. Paulino, Marcel L. Bouvy, Miguel A. Gastelurrutia, Mara Guerreiro and Henk Buurma for the ESCP-SIR Rejkjavik Community Pharmacy Research Group*

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M.L. Bouvy (correspondence, e-mail: sir@stevenshof.nl),
H. Buurma: SIR Institute for Pharmacy Practice Research, Theda Mansholtstraat 5B, 2331 JE Leiden, The Netherlands
E.I. Paulino: Farmácia Nuno Álvarez, Almada, Portugal
M.A. Gastelurrutia: Farmacia Gastelurrutia, San Sebastian, Spain
M. Guerreiro: Farmácia Fialho, Portel, Portugal

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Interventions
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Abstract
Introduction: Drug related problems (DRPs) are perceived to occur frequently when patients are discharged from the hospital. Community pharmacists' interventions to detect, prevent and solve DRPs in this population are scarcely studied.
Objective: To examine the nature and frequency of DRPs in community pharmacies among patients discharged from hospitals in several countries, and to examine several variables related to these drug related problems.
Method: The study was performed in 112 community pharmacies in Europe: Austria, Denmark, Germany, The Netherlands, Portugal and Spain. Community pharmacists asked patients with a prescription after discharge from hospital between February and April 2001 to participate in the study. A patient questionnaire was used to identify drug related problems. Pharmacists documented drug related problems, pharmacy interventions, type of prescriber and patient and pharmacy variables.
Results: 435 patients were included in the study. Drug related problems were identified in 277 patients (63.7%). Uncertainty or lack of knowledge about the aim or function of the drug (133; 29.5%) and side effects (105; 23.3%) were the most common DRPs. Practical problems were reported 56 times (12.4%) by patients. Pharmacists revealed 108 problems (24.0%) concerning dosage, drug duplication, drug interactions and prescribing errors. Patients with more changes in their drug regimens (drugs being stopped, new drugs started or dosage modifications) and using more drugs were more likely to develop DRPs. Community pharmacists recorded 305 interventions in 205 patients with DRPs. Pharmacists intervened mostly by patient medication counselling (39.0%) and practical instruction to the patient (17.7%). In 26.2% the intervention was directed towards the prescriber. In 28 cases (9.2%) the pharmacists' intervention led to a change of the drug regimen.
Conclusion: This study shows that a systematic intervention by community pharmacists in discharged patients, or their proxies, is able to reveal a high number of DRPs that might be relevant for patient health outcomes. There should be more initiatives to insure continuity of care, since DRPs after discharge from hospital seem to be very common.

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Introduction

As the number and potency of available drugs increases, drug prescribing and use becomes more complex, leading to a variety of drug related problems (DRPs). Community pharmacists are assuming an active role in preventing and solving drug related problems. Pharmacists' interventions have been documented and have proven to be a valuable contribution both in primary health care[1–6], and in the hospital setting[7–9].

An important part of drug related problems originates from gaps in the continuity of care[10]. Studies have shown a lack of transfer of information between hospitals and primary health care[11–19]. Some studies have been conducted to evaluate new methods of improving this communication[12, 13, 20–22]. Simple methods, such as providing community pharmacists with written information on drugs prescribed at discharge, have proven to be effective, with measurable patient benefit[23]. Nevertheless, using information technology is considered a key area in redesigning the health care delivery system[24]. Computer-generated prescriptions are becoming more common both in the USA[21], and in some European countries[25].

Drug related problems are frequent among patients discharged from hospital. A drug prescribing error rate of 5.8% in take-home prescriptions has been reported in non-European settings. The most common types of errors were wrong dosage, inappropriate schedule and missing information[26]. Further studies have documented DRPs such as non-compliance[19, 27–29], lack of knowledge about the medication[19, 27, 30], adverse drug events[29, 31, 32], drug interactions[33, 34], dosage problems[29], and practical problems[19]. These DRPs have been associated with changes in drug therapy following hospital discharge[19, 27, 31, 34], patient's cognition[28, 31] and polypharmacy[15, 28].

Although all the previous studies have focused on the identification of drug related problems and their consequences, in most cases, different definitions of drug related problems have been used. Few studies have focused on all drug-related problems, and no previous European study has examined the frequency of a wide range of DRPs when patients are discharged from hospital. In addition, the process of identification of DRPs is different in each study. In a number of studies problems have been identified through patients' records[13, 26, 33, 34], whilst in other studies an interview with the patient has been conducted to establish their incidence[19, 28, 30, 31]. Furthermore, different populations have been enrolled in these studies. Most studies focused on elderly patients[19, 28, 30, 31]. As a consequence, and not surprisingly, rates of occurrence of drug related problems tend to vary among studies, producing non-comparable results. Moreover, none of the previous studies has focused on community pharmacists' interventions to prevent or solve DRPs on discharged patients.

The first objective of this study is to examine the nature and frequency of drug related problems among patients discharged from hospital through community pharmacies in several countries. The second objective

* Other members of the 'The ESCP-SIR Rejkjavik Community Pharmacy Research Group': Olimpia Dimtcheva, Mette D. Frederiksen, Henkjan Gebben, Andrea Ranner and Eva Woeber.

is to document what community pharmacists do to solve or prevent these problems.

Method

Setting

The study was performed in 112 community pharmacies in Europe: Austria (6), Denmark (16), Germany (11), The Netherlands (9), Portugal (19) and Spain (51). Pharmacists were interested in the study following advertisements in national pharmaceutical journals and through direct contact with the country co-ordinators. All pharmacists that responded were included in the study.

Data collection

All participating pharmacists received a study protocol and three types of registration forms in their native lanquage. No formal training on the implementation of the study and the provision of pharmaceutical care was given.

Individuals who presented a prescription after discharge from the hospital in the participating community pharmacies between February and April 2001, during the regular working hours, were asked to participate. Identification of patients was made through the prescription paper, hospital stamp, or by direct questioning. Eligible individuals were provided with an information leaflet. Patients from outpatient and emergency clinics were excluded. Proxy interviews were done in those cases when the patient was too young or too ill. When patients or their proxies agreed to participate in the study, a questionnaire was used to record problems raised by the patient or his proxy, as well as drug and patient related data (age, type of drugs, ward, etc.). Follow-up involved a telephone interview, a home visit or a visit from the patient or proxy to the pharmacy. A separate data collection form was used to describe the problems detected by the pharmacist or other health professionals (nurses, doctors or other), and the type of interventions made. A third form was used to document the characteristics of the participating pharmacies (e.g., number of prescriptions, number of pharmacists, number of assistants/ technicians).

Among the participating countries, only the Netherlands has access to patient medication histories, so the data collection forms were designed to collect all data by directly questioning the patient or proxy.

The data collection forms were designed by the study and country co-ordinators, and were translated to the native languages by the country co-ordinators. A pilot study was conducted in (a number) of the participating countries.

One or more pharmacists in each pharmacy were responsible for filling in the data collection forms, in which they were instructed to describe in detail the DRPs detected and their interventions. The protocol advised to contact the country co-ordinator in case of any uncertainty about the data collecting procedure.

Country co-ordinators collected the data from the pharmacies and classified the drug related problems and interventions according to a system proposed by Westerlund et al.[35, 36], slightly modified for our study (Tables 1 and 2).

Data analysis

Data collected by the study coordinators were combined and analysed at SIR using Microsoft Access 97 and SPSS 10.0.

The distribution of patient and country characteristics, drug related problems and pharmacy interventions were expressed as numbers, averages, percentages and range were applicable. χ-Square tests and two-tailed Student's *t*-tests were used to analyse differences between groups, in categorical and continuous variables, respectively.

A nested case-control analysis was performed to compare characteristics between patients with and without DRPs. Crude odds ratios (ORs) with 95% confidence intervals (95% CI) were calculated. Since several variables can influence the occurrence of DRPs and may be associated with each other, and thus, may confound the individual relationship between these variables and the occurrence of DRPs, we applied multi-

Table 1 *Types of drug-related problems (circumstance of drug therapy that may interfere with a desired therapeutic objective)*

Uncertainty about/ lack of knowledge of the aim/ function of drug
Underuse of medication
Overuse of medication
Other dosage problem
Drug duplication
Drug–drug interaction
Therapy failure
Side effect
Difficulty swallowing tablet/capsule
Difficulty opening container
Other practical problem, such as incorrect use of admistrating device
Language deficiency/ understanding disability
Prescribing error, such as incorrect or omitted data on the prescribed drug.
Other drug related problem, such as use of a drug for the wrong indication, contraindications

From Westerlund et al. Pharm World Sci 1999; 21 (6): 245–50.

Table 2 *Types of pharmacy interventions*

No intervention
Patient medication counselling
Practical instruction to patient
Patient referred to prescriber *or other physician*
Prescriber informed only
Prescriber asked for information or intervention
Intervention proposed by pharmacy, approved by prescriber *or other physician*
Intervention proposed by pharmacy, disapproved by prescriber *or other physician*
Switch of drug to *other strength, other dosage, other dosage form or other substance*
Referral to colleague
Other intervention, such as cancellation of therapy

From Westerlund et al. Pharm World Sci 1999; 21 (6): 245–50, slightly modified.

variable logistic regression techniques to adjust for these potential confounders. All variables that were independently associated with the occurence of DRP's were included in a multiple logistic regression analysis. Country and pharmacy variables were not included in the statistical model given the large differences in the organisation of pharmacies among countries.

Results

The characteristics of the enrolled pharmacies are presented in Table 3.

Patient characteristics

A total of 515 patients were asked to participate in the study. The data were collected from 435 patients (84.5%). Among the 80 non-participating patients, in 29 cases (36.3%) non-participation was due to the patients' refusal to participate, in 46 cases (57.5%) a relative collected the medicines and the patient was not contacted due to lack of authorisation from the relative or time constrains of the pharmacist. Among the 435 participating patients, 185 (42.5%) were interviewed at the pharmacy, 157 (36.1%) by phone and 31 (7.1%) were visited at home. Proxy interviews were conducted in 57 cases (13.1%), and for 5 patients (1.2%) the nature of participation is unknown.

There was no significant difference in age between female and male patients as well as between patients in the different countries. Table 4 shows patients' characteristics per country.

Out of the 435 participating patients, 413 patients (94.3%) had 1110 drugs added to their regimen at discharge from hospital. A total of 280 patients (64.4%) had to continue 909 drugs that were already used before hospitalisation. In addition, 251 drugs had to be discontinued by 130 patients (29.9%) and there were 55 changes in dosage for 49 patients (11.3%). Most patients (155) in the study were discharged from Internal Medicine (including Infectious diseases, Endocrinology and Gastrointestinal Diseases), followed by Cardiology (60) and Pulmonology (29).

Drug related problems

A total of 451 DRPs were identified in 277 out of 435 patients (63.7%). Figure 1 shows the distribution of DRPs. The most common DRPs identified (133; 29.5%) pertain to uncertainty about/lack of knowledge of the aim/function of the drug. Side effects were experienced 105 times (23.3%) and therapy failure 12 times (2.7%). Practical problems, such as difficulty swallowing the drug or opening the container, language problems or other, occurred 56 times (12.4%). Pharmacists revealed 108 problems (24%) involving dosage (including over- and underuse), drug duplication, drug interaction and prescribing errors.

Table 5 shows a comparison between patients with and without DRPs. No difference in frequency of DRPs was found between men and women as well as between the different age groups.

The total number of drugs changed and the total number of drugs prescribed was higher in patients with DRPs. After adjustment for age and gender and ward from which patients were discharged the number of new drugs and changes in dosage remained associated with an increased risk for DRPs. The only other factor, which was independently associated with more DRPs was discharge from an Internal Medicine ward.

Drugs involved

In Figure 2, the distribution of the Anatomical Therapeutic Chemical Classification System (ATC) codes of the drugs (drugs = 358), associated with the DRPs is shown. The most common were cardiovascular drugs (drugs = 109; 30.5%), nervous system drugs (drugs = 49; 13.7%) and alimentary tract and metabolism drugs (drugs = 44; 12.3%). Some relationships were found between the type of drugs used and the drug-related problem associated with it. For respiratory drugs, 'another practical problem' was highly associated (OR = 5.3 [2.2–13.1]). For cardiovascular drugs, lack of knowledge about the drug (OR = 5.9 [3.7–9.5]) and side effects (OR = 2.2 [1.4–3.5]) were associated. Side effects were associated with the nervous system drugs (OR = 2.7 [1.5–5.0]), and lack of knowledge with alimentary tract drugs (OR = 2.3 [1.2–4.3]).

Pharmacy interventions

There was no intervention in 66 out of 277 patients with DRPs. Pharmacists recorded 305 interventions in

Table 3 *Pharmacies' characteristics per country*

	Austria	*Denmark*	*Germany*	*Netherlands*	*Portugal*	*Spain*	*Total*
Daily number of[a]:							
Prescription lines	544.0 (400–700)	579.4 (250–800)	352.2 (130–750)	343.8 (125–600)	NA	158.0 (30–560)	395.5 (30–800)
Pharmacists	3.6 (2.3–6.0)	1.7 (1.0–3.6)	2.29 (1.0–4.0)	1.55 (0.9–2.8)	2.0 (1.0–4.0)	1.7 (1.0–4.0)	1.9 (0.9–6.0)
Technicians	3.4 (2.5–4.3)	7.1 (4.0–12.0)	3.3 (1.0–6.0)	5.2 (2.4–11.9)	2.2 (1.0–5.0)	1.3 (0.0–4.0)	2.2 (0.0–12.0)
Prescriptions per pharmacist	182.8 (117–267)	364.6 (200–800)	168.8 (52–400)	217.1 (125–300)	NA	97.3 (25–373)	206.1 (25–800)
Prescriptions per pharmacist + technician	92.0 (65–167)	64.9 (42–100)	59.9 (29–100)	53.3 (31–75)	NA	54.6 (15–280)	64.9 (15–280)

[a] All numbers are average and (range).
NA = not available.

the remaining 211 patients (Figure 3). Of these 305 interventions almost half of the interventions concerned patient counselling: practical instruction (n = 54; 17.7%) and medication counselling (n = 119; 39.0%). 80 interventions (26.2%) were directed towards the prescriber (referal, information request, etc.). The pharmacy proposed 31 interventions to the prescriber or other physician, of which 27 were

Table 4 *Patients' characteristics per country*

	Austria	*Denmark*	*Germany*	*Nether-lands*	*Portugal*	*Spain*	*Total*
Average age	59.5	55.6	63.5	58.9	59.0	59.7	59.1
Proportion male	52.6%	56.7%	47.9%	54.7%	59.6%	59.9%	56.8%
Total number of drugs	5.42 (1–13)	4.00 (0–24)	5.15 (1–14)	5.04 (1–12)	4.48 (1–12)	4.87 (0–15)	4.77 (0–24)
New drugs at discharge	3.16 (0–8)	2.13 (0–9)	2.77 (0–6)	2.48 (0–7)	2.66 (0–7)	2.63 (0–7)	2.55 (0–9)
Total changes in drug therapy[a]	3.7 (0–10)	2.5 (0–10)	3.4 (0–8)	3.5 (0–11)	3.6 (0–10)	3.4 (0–12)	3.3 (0–12)
DRPs per patient	1.42 (0–4)	0.91 (0–4)	1.94 (0–5)	0.93 (0–5)	1.06 (0–5)	0.74 (0–4)	1.03 (0–5)

All numbers are average, percentage (%) and (range).
[a] New drugs added, drugs discontinued or changes in dosage.

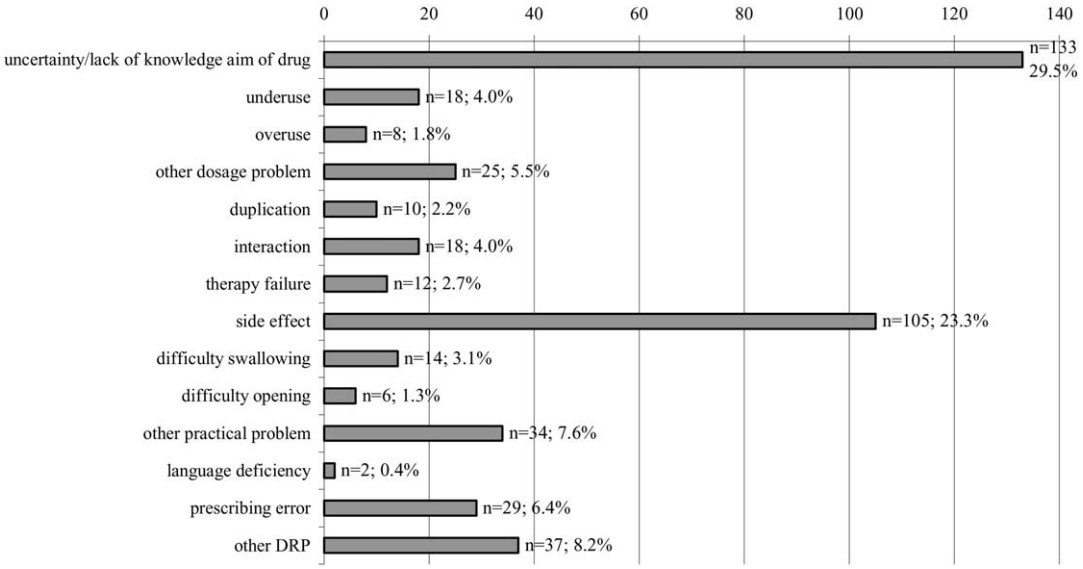
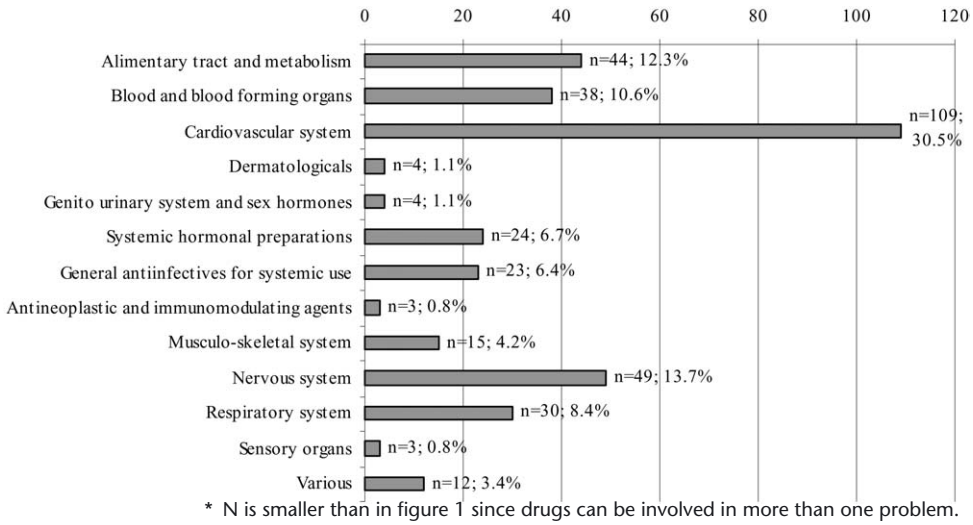


Figure 1 *Distribution of numbers of drug related problems (DRPs = 451).*



* N is smaller than in figure 1 since drugs can be involved in more than one problem.

Figure 2 *Distribution of ATC-codes of drugs with drug related problems (DRPs = 358*).*

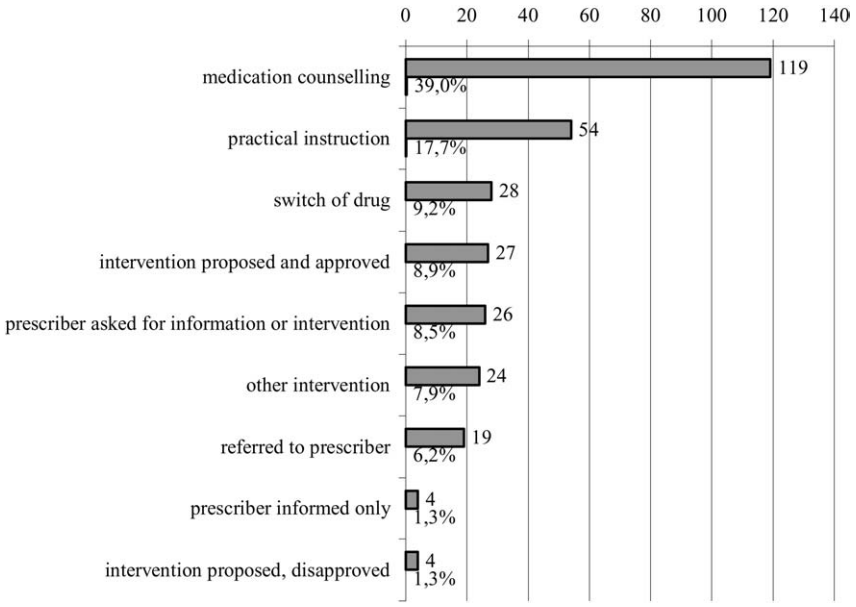


Figure 3 *Distribution of types of pharmacy interventions (interventions s = 305). There was no intervention in 66 out of 277 patients with DRPs.*

approved. In 28 cases (9.2%) the pharmacists' intervention involved a switch of drug to another strength, other dosage, other dosage form or other substance.

Several associations between the type of DRP and the pharmacist intervention were found. Lack of knowledge about the drug is associated with medication counselling (OR = 15.9 [9.6–26.5]), other practical problems with practical instructions to the patient (OR = 21.1 [9.6–46.6]), and prescribing errors with interventions proposed by the pharmacist and approved by the prescriber or other physician (OR = 7.4 [2.9–18.6]). Side effects were associated with 'no intervention' of the pharmacist (OR = 2.0 [1.2–3.1]).

Discussion

The characteristics of the enrolled pharmacies, presented in Table 3, show several differences between the participating countries, such as large variation in the total number of prescriptions per pharmacy and the number of pharmacists and technicians. This is in accordance with an overview conducted by the University of Groningen together with the Community Pharmacy Section of the International Pharmaceutical Federation[37]. The number of prescription items per pharmacy team member is higher in our study, but it is probable that it has increased over the last years, since the data collection in the previous study took place in 1997.

Almost all patients (94.3%) had drugs added to their existing drug therapy after hospital admission. This is higher than identified in previous studies performed in 1991 and 1999, in which respectively 69.0% and 80% of patients received new medications at discharge[31, 38]. The proportion of patients with new prescriptions in our study is probably higher because

Table 5 *Comparison between patients with DRPs and patients without DRPs*

	Patients with DRPs N = *277*	*Patients without DRPs* N = *158*	*Crude OR [95% CI]*	*Adjusted[a] OR [95% CI]*
Gender (% male)	156 (54.1%)	88 (55.7%)	1.0 [0.6–1.4]	1.0 [0.6–1.5]
Age category				
< 40	50 (18.1%)	30 (34.3%)	Reference	Reference
40–65	95 (34.3%)	56 (18.8%)	1.0 [0.6–1.8]	0.7 [0.4–1.2]
> 65	128 (46.2%)	72 (46.3%)	1.0 [0.6–1.8]	0.6 [0.4–1.2]
> 2 New drugs	149 (53.8%)	54 (34.2%)	**2.2 [1.5–3.4]**	**2.4 [1.5–3.6]**
> 2 Prior to admission	111 (40.1%)	48 (30.4%)	1.5 [1.0–2.3]	**1.9 [1.2–3.0]**
Drugs continued				
at least one drug	92 (33.2%)	38 (24.1%)	1.6 [1.0–2.4]	1.3 [0.8–2.1]
Discontinued				
at least one drug with a change in dose	38 (13.7%)	11 (7.0%)	**2.1 [1.1–4.3]**	2.1 [1.0–4.5]

[a] Adjusted for age, gender, number of (dis)continued, changed, and new drugs.
Statistically significant effects ($P < 0.05$) are printed in bold.

only patients presenting at least one prescription from the hospital were included, whilst others included patients discharged without any prescription.

Drug related problems

This study shows that DRPs among patients discharged from the hospital are common: 63.7% of patients in this study reported DRPs. Although most DRPs do not seem to have direct clinical consequences, they could lead to lower therapy compliance and therefore decrease in therapeutic benefits in the long run.

A study by Westerlund et al. that identified DRPs by community pharmacy staff, found DRPs in 2.5% of the general population[35, 36]. The fact that in our study the proportion of patients with DRPs is much higher indicates that patients discharged from hospital are at increased risk of experiencing DRPs. This confirms discharged patients are an important target group for pharmacy interventions. Nevertheless, other factors may have contributed to this difference. Westerlund et al. found that pharmacists identified more DRPs than other pharmacy staff[36]. In our study, all patients were questioned by a pharmacist, which may have led to a higher identification rate.

Uncertainty and/or lack of knowledge about the aim of the drug was in some previous studies the most common problem[19, 35, 39], which is in accordance with our findings. Special attention should be drawn to patient counselling and educating about drugs, since it has been reported that lack of information plays an important role in non-adherence[19].

The proportion of adverse drug reactions (ADEs) found in our study was 23.3%, which is similar to earlier studies[2, 31, 32]. In patients discharged from hospital, ADEs were found in 19% of patients, many of which were considered preventable[32]. Westerlund et al. reported a much lower proportion of side effects (8.5%)[35]. This difference can be due to the fact that in the Westerlund's study, pharmacy staff was instructed not to ask the patient about possible side effects, but only record those that were reported spontaneously by the patient. In our study, pharmacists asked the patients directly.

Non-compliance in our study is lower than others identified in a three-month follow-up of patients discharged from hospital[19]. We found underuse in 18 patients (4.0%), whilst it was reported in 31.9% of patients in the previous study. In another study aiming at non-compliance 2 weeks after discharge, it was reported that 30.6% were underadherent and 18.4% were overadherent[28]. The differences observed can be attributable to a smaller follow-up period (one week after discharge) and to the adherence assessment method (we used patients and proxies questioning, whereas other studies used pill-counts)[28].

Drug interactions were identified in 18 patients (4.0%), which is higher than reported in a study focusing on the general population (0.05%)[35], but lower than detected by others, using patient medication history (14.2%)[4]. At hospital discharge, interactions were found in 60.0% of patients, using a computerised drug interaction program[34]. In our study, most countries did not have access to patient medication history, which may have limited the capacity of the pharmacist to detect specific interactions. The absence of medication history in most countries can also explain the lower detection rate for drug duplication: 10 patients (2.2%) in our study vs 5.4% of patients in the study conducted in Flemish pharmacies[4]. The proportion of prescribing errors found in our study (6.4%) is similar to the one reported by a previous study in patients about to be discharged from hospital (5.8%)[26].

Varying distributions of DRPs in relation to different types of drugs have been reported[2, 31, 35, 38]. Like in this study, cardiovascular drugs are always highly involved. However cardiovascular drugs were especially associated with lack of knowledge and with (probably unavoidable) side effects. These problems could lead to early discontinuation of treatment which has been reported frequently as an important problem with cardiovascular preventive therapy (e.g., antihypertensives and lipid lowering drugs). Gastrointestinal drugs and nervous system drugs were also highly involved, and have been reported as possible predictors of prescribing errors by Fijn et al.[40].

Our finding that the number of new drugs, continued drugs and changes in dosage at discharge are independently associated with the occurrence of DRPs confirms the results of earlier hospital based studies[19, 38, 40]. One study did not find an association between the total number of drugs at discharge and the occurrence of an adverse drug event[31]. However, this study focused only on ADEs in the elderly, in whom there was already a high overall drug use.

Furthermore, we found discharge from internal medicine ward to be independently associated with the occurrence of DRPs. This might be caused by the fact that patients on internal medicine wards frequently are treated by more than one specialty. This could complicate treatment. Moreover, the definition of internal medicine used in the study will not be universally accepted.

Pharmacy interventions

Pharmacists intervened on the majority of DRPs. As in previous studies[35], medication counselling and practical instructions to patients were the most common pharmacy interventions. This can be explained by the nature of the DRPs reported by the participants, and hence the associations found between DRPs and consequent interventions.

It is important to highlight the fact that when an intervention was proposed by the pharmacist, in most cases (87.1%) the prescriber or other physician approved it, a fact that is also supported by previous studies[2, 26, 35, 41].

The fact that pharmacists did not intervene in 66 cases may be explained by the association between the lack of intervention and having a side effect as the identified DRP. A previous study has reported that in 32.1% of cases when an adverse drug event occurs and is reported to a health care provider, the drug is continued as before, with no further intervention from the health care provider[31]. This may mean that the pharmacist considered the side effect to be tolerable and not avoidable.

Limitations

There are a number of limitations in this study. Firstly, we did not take into account the differences in the pharmacy practice culture in the six participating countries. However, our aim was to examine at an international level what are the most common DRPs and

interventions on patients discharged from hospital, and not to perform inter-country comparisons.

Secondly, since a convenience sampling of participating pharmacists was used, we cannot exclude the possibility that these were more active or had a more positive attitude towards the provision of pharmaceutical care than pharmacies that did not volunteer in our study. Although this would not affect the existence of DRPs themselves, identification and intervention by the pharmacist may be higher-reported, compared to pharmacies in general. Non-sequential recruitment is another limitation, closely related to the amount of time the pharmacist needed to interview the patient. It was reported by participating pharmacists that during periods of higher workload in the pharmacy, some eligible patients were not asked to participate in the study. Due to the fact that most countries did not have access to medication histories or patient profile, we were not able to compare characteristics of patients who refused or were not asked to participate with those from participating patients (e.g., in terms of age, health status, type and number of drugs).

In addition, information and recall bias may have occurred because patients and relatives were asked, since it was impossible to check the patients' medication history. Asking patients about ADEs in a general way could have resulted in underreporting, because patients overlook ADEs that they do not relate to the medication they are taking. It has been found that asking for specific symptoms increases the reporting of ADEs[42].

Ideally, the clinical relevance of the DRPs identified should have been assessed. A classification by a consensus panel could have been used, and has already been demonstrated to be useful in previous studies[41].

Conclusions

This study shows that a systematic intervention by community pharmacists in discharged patients, or their proxies, is able to reveal a high number of DRPs that might be relevant for patient health outcomes. To our knowledge, no former study has focused on a wide-range of drug-related problems identified by community pharmacists among patients of all ages discharged from hospital. No previous pan-European study has shown that these DRPs are common in several countries in different health systems.

Patients with more changes in their drug regimens (new drugs added, drugs discontinued or changes in dosage) and using more drugs are more likely to have DRPs. Therefore, special attention should be drawn upon these target groups.

In order to prevent DRPs it can be useful for community pharmacists to focus on therapeutic groups (e.g., give general information about cardiovascular drugs and practical instructions for patients receiving pulmonary drugs). There should be more initiatives, such as electronic patient data transfer, to insure continuity of care, since DRPs after discharge from hospital seem to be very common.

Further research is needed to determine whether a structured intervention in discharged patients at increased risk of developing DRPs can lead to measurable improvements in patients' clinical outcomes and/or improvement of quality of life.

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Possible conflicts of interest

None.

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