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ORIGINAL REPORT

Nature and frequency of drug-related problems in self-medication (over-the-counter drugs) in daily community pharmacy practice in Germany

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ABSTRACT

Purpose To quantify drug-related problems (DRPs) in self-medication (over-the-counter [OTC] drug use) identified by community pharmacists (CPs) in Germany at the time the drug is dispensed.

Methods One hundred CPs were asked to document 100 consecutive customers presenting symptoms or requesting OTC drugs using a standardized documentation form. The number of 10 000 encounters seemed reasonable to evaluate the set objective. For each encounter, data such as age, sex, and first or repeated request and the availability of a patient file in the pharmacy including drug history were documented. Furthermore, identified DRPs, problem descriptions, and solutions were documented. Data were transcribed electronically, coded, checked for validity, and analyzed.

Results In total, 109 CPs documented 12 567 encounters identifying DRPs in 17.6% of all cases. Four indications comprised more than 70% of all DRPs: pain, respiratory, gastrointestinal, and skin disorders. Four DRPs were responsible for almost 75% of all DRPs identified: self-medication inappropriate (29.7%), requested product inappropriate (20.5%), intended duration of drug use too high including abuse (17.1%), and wrong dosage (6.8%). If a drug history was available, significantly more cases with wrong dosage ($p < 0.05$) and drug–drug interactions ($p < 0.001$) were detected.

All patients with identified DRPs were counseled accordingly. Furthermore, the most frequent interventions were referral to a physician (39.5%) and switching to a more appropriate drug (28.1%).

Conclusions In nearly one of five encounters, a direct pharmacist–patient interaction about self-medication revealed relevant DRPs. Having access to patient files including data on prescription and OTC drugs may increase patient safety. Copyright © 2011 John Wiley & Sons, Ltd.

KEY WORDS—drug-related problems; frequency; community pharmacy; pharmacy practice; self-medication; OTC drug use

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INTRODUCTION

The term self-medication refers to nonprescription medicines, usually over-the-counter (OTC) drugs, which are used to treat "minor" ailments without consulting a medical practitioner and without any medical supervision. Self-medication has increased markedly during the last decade, not only because of the growing costs of prescription drugs but also because of a trend toward increasing the empowerment of patients.[1]

In Germany, community pharmacies are the primary source of OTC drugs.[2] Most OTC drugs such as ibuprofen and paracetamol belong to the pharmacy-only category. Pharmacy-only drugs are available upon request only and not via self-service. There are only a few herbal drugs and vitamins that are available for sale through drugstores and supermarkets. Apart from the drug supply, community pharmacies in Germany are responsible for providing all relevant information to ensure the safety of the drug application. Pharmacists also provide pharmaceutical and preventive care services and contribute to health promotion and the appropriate use of medicines. Over the previous years, there has been a development in Germany toward making more drugs available for self-medication not

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only through community pharmacies but also via mail-order pharmacies.

The availability of medicines without a prescription may benefit consumers or patients and healthcare systems in several ways.[1,3] It provides patients with easier access to medicines and may lower healthcare costs for example through decreased frequency of physicians visits. However, this increased accessibility of OTC drugs and their widespread use often leads to an underestimation of risk because consumers consider these products to be innocuous[4–6] and fail to report their use to healthcare providers.[7] However, nonprescription medicines are powerful pharmacological agents, and the inappropriate use of these medicines in self-medication is a significant problem that increases the risk of morbidity and mortality as well as healthcare costs.[6–17]

Drug-related problems (DRPs) are known to be a major problem associated with pharmacotherapy.[18,19] A broad range of studies, mainly in the area of prescription-only medicines, support this fact.[20–28] A DRP has been defined as "an event or circumstance involving drug therapy that actually or potentially interferes with the desired health outcomes."[29] There are only a few studies that evaluated DRPs in nonprescription drugs and pharmacists' role in the community pharmacy setting.[22,23,30]

On the basis of the results of our first study on DRPs,[22] we focused in this study on DRPs in self-medication. The primary objective of our first study was to investigate the spectrum of DRPs in German community pharmacies. Results showed that pharmacists are well suited to detect DRPs during their routine drug dispensing and patient counseling activities. Study limitations were that the frequency of DRPs could not be determined and problems in self-medication were apparently underestimated. An underestimation was assumed because the ratio of prescription to nonprescription sales in German pharmacies was approximately 55 to 45 of packages in our study conducted in the year 2005,[31] but only 1 in every 10 DRP was found in customers requesting OTC drugs. This follow-up study aimed to quantify and specify DRPs in OTC drug use identified during routine dispensing of drugs in German community pharmacies.

METHODS

Setting and study population

The study was conducted in August and September 2007, in Germany. We aimed to include a convenient sample of at least 100 community pharmacists (CPs). CPs were recruited via the different state chambers of pharmacists, which are the regulatory bodies in Germany, through their regular journals and quality circles or directly by the study center (ZAPP).

Participating pharmacists were provided with a project folder containing a detailed study description as well as the standardized documentation forms. In addition, CPs were provided the ABDA standard on good counseling practice.[32] CPs received no further training. CPs did receive an allowance of €100 when submitting the complete documentation of 100 patients.

Documentation of self-medication requests and DRPs

CPs were asked to document 100 consecutive customers presenting symptoms or requesting OTC drugs. We developed a standardized one-page documentation form, which was tested in five community pharmacies and amended accordingly. If a customer had more than one request, CPs filled out one documentation form per request.

Documentation included the data on patient characteristics (e.g. estimated age, sex, availability of a patient file including drug history in the pharmacy) and the nature of the OTC request (e.g. symptom presentation, OTC product request, first-time or repeat request, indication). If one or more DRPs were detected, the nature and the solution of each DRP were recorded. To facilitate documentation in daily routine, the documentation form per OTC request was limited to one page only. Therefore, none of the existing classification systems for DRPs were used. Instead, the most frequent DRPs ($n = 9$), interventions ($n = 4$), and problem solutions ($n = 3$) from our earlier study[22] were provided as check boxes on the form. Pharmacists were requested to document other DRPs, interventions, and solutions not provided as check boxes in free-text fields. Furthermore, the time needed for the problem solution was recorded.

The solution of the DRP as an estimate for the success of the intervention was categorized as solved, partly solved, or not solved. DRPs classified as solved were resolved during the customer's visit in the pharmacy, for example, detected contraindication that was resolved by a product switch. DRPs were classified as partly solved if a solution was initiated but could not be reached at the time of the customer's visit in the pharmacy, for example, customers were referred to a physician. In addition, cases of drug misuse or abuse were categorized as partially solved when patients were counseled accordingly and agreed to take action to change their use of the drug. DRPs were classified as not solved if patients did not see the need or were unable to change their habit.

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Patient anonymity was ensured because no patient-specific data other than estimated age and sex were recorded. Therefore, institutional review board approval was waived.

Evaluation of study data

Collected data were entered into a Microsoft Access 2003 database. We classified the direct products requested with the seven-digit Anatomical Therapeutic Chemical code (according to the World Health Organization Nordic Anatomical Therapeutic Chemical classification index).[33] DRPs were coded by the participating pharmacists. All data were checked for inner consistency and face validity by the investigators.

The analysis of the frequencies and the interrelationships of the data were performed using the Statistical Package for the Social Sciences (Version 15.0; SPSS Inc., Chicago, IL). Univariate correlations analysis between DRPs and patient characteristics as well as the OTC requests was performed using the Mann–Whitney *U* test (sex, patient file, symptom presentation or OTC product request, first-time or repeat request, and for personal need or representative) and the Kruskal–Wallis *H* test (estimated age). For the tests, a probability value of less than 0.05 was considered to be statistically significant.

RESULTS

Basic study data

Initially, 124 CPs agreed to participate in the study. Project folders were sent back by 109 pharmacists from 103 community pharmacies. They documented 11 069 customers with 12 567 requests for self-medication, on average 115 requests per CP (Table 1). Mostly, patients asked for self-medication for their personal needs (77.7% of all requests, $n = 9759$). In 22.1% of requests, someone besides the patient, often a family member, requested the OTC product or advice. Of the customers' requests, 72.6% ($n = 9123$) were direct product requests, which were frequently repeated requests, that is, the patients knew the medication (62.3%). In 27.4% ($n = 3444$) of the requests, patients presented symptoms. Younger patients more often presented symptoms during the requests than did older patients (symptom presentation and product request with increasing age: 41.8% to 18.1% and 58.2% to 81.9%, respectively (see Figure 1). The four most frequent indications were pain, respiratory, gastrointestinal, and skin disorders, which comprised 70% of all OTC requests (Table 2).

Table 1. Basic study data

Study period	August and September 2007
Community pharmacists, *n*	109
Customers, *n*	11 069
Documented OTC requests, *n*	12 567
DRPs documented, *n*	2 666
OTC requests with DRP, *n* (%)	2 206 (17.6%)
Requests with	
One DRP	1 796 (81.4%)
Two DRPs	366 (16.6%)
Three DRPs	38 (1.7%)
Four DRPs	6 (0.3%)
Customers' gender, *n* (%)*	
Female	8 121 (64.6%)
Male	4 291 (34.1%)
Estimated age group (years) of customer, *n* (%)*	
0–12	586 (4.7%)
13–20	574 (4.6%)
21–40	4 518 (36.0%)
41–65	4 091 (32.6%)
>65	2 704 (21.5%)
For personal need/representative, *n* (%)*	9 759 (77.7%)/2 665 (21.2%)
With/without patient file, *n* (%)*	3 398 (27.0%)/8 883 (70.7%)
Symptom presentation, *n* (%)*	3 444 (27.4%)
OTC product request, *n* (%)*	9 123 (72.6%)
First-time request	2 452 (26.9%)
Repeat request	5 759 (63.1%)
Results of interventions, *n* (%)*	
DRP solved	991 (44.9%)
DRP partially solved	1 000 (45.3%)
DRP not solved	209 (9.5%)
Time spent addressing 1 DRP (min)	mean = 3.7 (range = 0.5–45, median = 3)

*Data refer to the total number of OTC requests; missing values to 100% are missing data.

Classification and evaluation of DRPs

Pharmacists documented one or more DRPs in 17.6% ($n = 2206$) of all 12 567 self-medication requests. Of the 2206 self-medication requests with a DRP, pharmacists identified 1796 (81.4%) requests with one DRP, 366 (16.6%) with two DRPs, 38 (1.7%) with three DRPs, and 6 (0.3%) with four DRPs. The total number of DRPs was 2666. "Self-medication inappropriate," "requested product inappropriate," "intended duration of drug use too high including abuse," and "wrong dosage" were the most frequent DRPs. As a whole, they accounted for almost 75% of all documented DRPs (Table 3).

DRPs were identified in 19.5% of all product requests and in 12.5% of all requests with symptom presentation. When patients requested a specific product, pharmacists identified most frequently DRPs classified as "requested product inappropriate" (26.6% of all product requests with at least one DRP, $n = 472$).

In 27.0% ($n = 3398$) of all requests, a patient file including medication history (drug file) was available in the pharmacy; this was most often the case (57.5% of requests) if patients older than 65 years requested self-medication (Figure 1). If a drug file was available,

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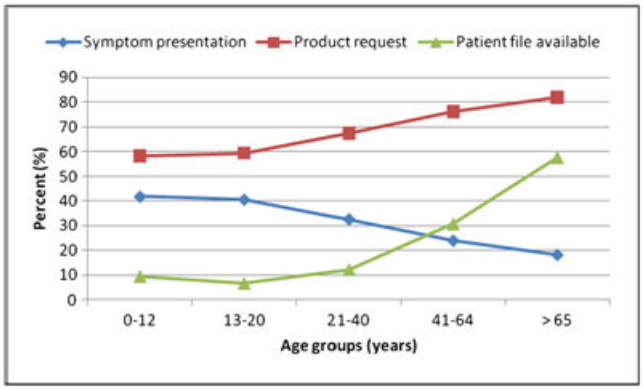

Figure 1. Type of self-medication request and patient file availability in the pharmacy versus age group

Table 2. Distribution of DRPs by indication

	Indication	OTC requests		OTC requests with DRP	
		n	%	*n*	%
1	Pain	3 160	25.1	528	23.9
2	Respiratory tract disorders	2 535	20.2	426	19.3
3	Gastrointestinal tract disorders	1 819	14.5	384	17.4
4	Skin disorders	1 545	12.3	245	11.1
5	Cardiovascular disorders	523	4.2	91	4.1
6	Psychiatric or sleep disorders	435	3.5	89	4.0
7	Cold or influenza infection	428	3.4	69	3.1
8	Eye disorders	388	3.1	78	3.5
9	Vitamins or minerals	323	2.6	52	2.4
10	Urogenital disorders	298	2.4	85	3.9
11	Mouth or teeth	268	2.1	27	1.2
12	Allergy	185	1.5	28	1.3
13	Head or hair	115	0.9	21	1.0
14	Immune system stimulants or restorer	112	0.9	6	0.3
15	Fever	73	0.6	13	0.6
16	Ear disorders	67	0.5	29	1.3
17	Menopausal complaints	49	0.4	5	0.2
18	Smoking cessation	39	0.3	2	0.1
19	Other symptoms	193	1.5	22	1.0
	No data available	12	0.1	6	0.3
	Total	12 567	100.0	2,206	100.0

patient and medication-related information was included in checking for DRPs. In these cases, DRPs like "wrong dosage" and "drug–drug interaction" were detected more frequently (34.1%, $p = 0.018$, and 67.0%, $p < 0.001$, respectively).

Regarding the DRP "duration of drug use too high or suspicion of abuse," drug classes most often involved were analgesics, laxatives, and sympathomimetics (decongestants). A high variation in DRP documentation rate was observed between participating CPs, ranging from 1 to 45 DRPs per 100 self-medication requests.

If pharmacists detected a DRP, they counseled the patient with respect to the drug and the DRP(s). In addition, pharmacists referred patients to a physician (39.5% of the requests with at least one DRP detected, $n = 871$) or recommended an alternative OTC product (28.1%, $n = 620$). A direct contact with a physician occurred in 1.5% ($n = 33$) of all interventions. Other interventions, accounting for 3.0% ($n = 67$), included the distribution of written information or practical assistance in cases of problems with devices.

Table 3. DRP classification and frequencies

DRP	*n*	%
Self-medication inappropriate	791	29.7
Requested product inappropriate	547	20.5
Intended duration of drug use too high including drug abuse	455	17.1
Wrong dosage	182	6.8
Contraindication	161	6.0
Wrong use of drug	131	4.9
Inappropriate duplication of therapeutic group or active ingredient	123	4.6
Drug–drug interaction	109	4.1
Duration of drug use too short	68	2.6
Adverse drug reaction (side effect)	59	2.2
Miscellaneous	40	1.5
Total	2666	100.0

Pharmacists solved 45% ($n = 991$) of the requests with at least one DRP detected completely and 45% partially ($n = 1000$). Nine percent ($n = 209$) of the requests with at least one DRP detected could not be solved; this was mainly the case if the DRP was classified as "drug misuse or abuse." Pharmacists needed a median self-estimated time of 3.0 min (range = 0.5–45.0 min, mean = 3.7 min) to solve a request with at least one DRP detected.

Most customers' requests (98.4%) and DRPs (99%) could be related to 18 main indications (Table 2). The four frequent indications (pain, respiratory tract disorders, gastrointestinal tract disorders, and skin disorders) not only comprised 70% of all OTC requests but also comprised more than 70% of all requests with at least one DRP detected.

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Although the overall frequency of DRPs was 17.6%, there were indication categories that deviated from this value to a greater extent, for example, urogenital disorders (including urinary tract infection and vaginal mycosis) as well as ear disorders (DRPs documentation rates of 28.5% and 43.3%, respectively; Figure 2, the red line indicating the mean [17.6%] of all DRPs detected). In contrast, DRPs were less frequent in the category smoking cessation (5.1%). Overall, there were no significant differences in the age and gender distribution between customers with and without detected DRPs.

DISCUSSION

The present study provides qualitative and quantitative data on DRPs detected in self-medication at the time of dispensing in German community pharmacies. Self-medication was assessed by 109 CPs in a total of 11 069 customers. Altogether, 12 567 requests for an OTC product or symptom presentations were analyzed. Relevant DRPs were identified in 17.6% of all self-medication requests and in 18.3% of all patients. This result underlines that self-medication is frequently associated with risks. To our knowledge, there is only one study with a comparable study design and setting in self-medication,[23] in which a DRP prevalence of 23.7% was found.

About half of all self-medication requests with DRPs were related to inappropriate self-medication and requested product inappropriate (29.7% and 20.5%, respectively). This high percentage demonstrates that consumers need counseling in self-medication. Optimal therapy with OTC drugs—without pharmacists' advice—basically requires that customers accurately assess symptoms, diagnose the underlying condition correctly, decide whether self-medication is indicated or not, and select an appropriate drug for treatment, which they then use adequately. This implies that consumers are able to read and understand package inserts to determine proper doses, recognize warnings and contraindications, and determine whether the contraindications apply. However, literature data indicate that this assessment may be critical, especially in vulnerable groups such as children, older adults, pregnant women, patients with chronic diseases, and/or polypharmacy.[34,35]

Other frequent DRPs, such as "intended duration of drug use too high including abuse" (17.1%) and "wrong dosage" (6.8%), might support the often heard opinion that nonprescription drugs are too weak to cause any real harm. However, nonprescription drugs are powerful pharmacological agents, and studies indicate that they could be associated with serious adverse effects, which at worst may lead to unintended hospital admissions.[11,13] This is especially true about analgesics.[6,8,36] Analgesics or nonsteroidal anti-inflammatory drugs are among the most commonly used drugs in self-medication. A fact that is also confirmed by the results of our study. Their long-term use, use at inappropriately high doses, or use by persons with contraindications may result in serious adverse effects, including gastrointestinal hemorrhage, cardiovascular toxicity, renal toxicity, and hepatotoxicity.[6]

Approximately 73% of the customers requested a specific OTC product by name; in 63.1%, it was a repeat request. In these cases, most DRPs (80%) were identified. This is interesting and should be kept in mind when counseling patients. Although a consumer may request a product that maybe apparently known to them, for instance because of a family member's or friend's recommendation or advertisement, pharmacists should still scrutinize if the patient is adequately prepared for self-medication.

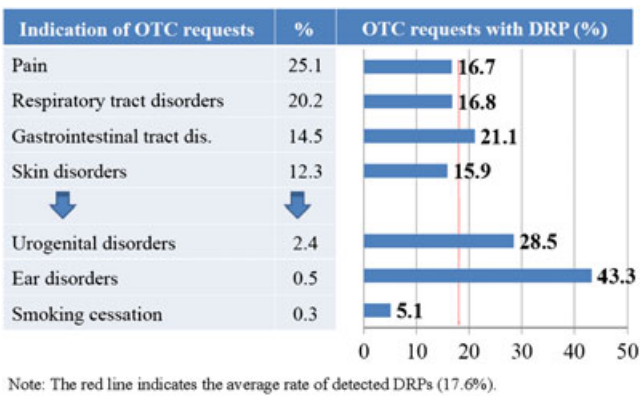

Figure 2. Percentage of drug related problems (DRPs) by indication

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The average rate of detected DRPs was 17.6%. This rate was more or less reflected in the four most frequent indications (see red line in Figure 2). There were a few indications with a considerably higher rate of detected DRPs, such as urogenital and ear disorders. Although absolute numbers of requests and DRPs for these two indications were low, it seems reasonable to suggest that education or training in pharmacy practice should not only focus on the most frequent indications but also on indications with significantly higher rates of DRPs.

As with other studies,[24,25,28,37,38] there was a great variation in DRP documentation rate observed between participating CPs, ranging from 1 to 45 DRP(s) per 100 self-medication requests. Reasons for this might be differences in pharmacists' knowledge, skills, engagement, or trial fatigue as well as prevalence of DRPs in study pharmacies. However, study results, and in particular the large variation in DRP detection rate, have shown that there is potential for improving counseling quality in community pharmacies. There is a need for new strategies in the form of systematic approaches to pharmaceutical services. Regarding this, one promising example is the implementation of counseling models as proposed by Ax *et al*.[39] These models or protocols encourage a more structured and consistent practice of counseling. They basically consist of important key questions to be covered routinely in the pharmacy practitioner's dialog with the patient. The practice of such models can both improve and standardize counseling quality.[39] Furthermore, they seem to be a means to improve drug use by serving as an important tool to increase the identification and resolution of DRPs.[39]

Finally, it should be emphasized that according to CPs, 90.2% of DRPs can be partially or completely solved in the pharmacy. This underlines pharmacists' key role in counseling customers on their medication to monitor the use of nonprescription medicines, identifying DRPs, and intervening when necessary to ensure that customers use medicines safely, appropriately, and effectively.

Because of the variation observed in the DRP documentation rate between participating CPs, it can be assumed that a quantitative documentation of DRPs was not achieved. Therefore, the number of identified DRPs is probably underestimated. A counterbalance to the underreporting might be that a selection bias in recruiting pharmacists could have affected study findings because participating pharmacists were normally "high performers." However, the study represents the real-life situation and reflects what is possible regarding identification of DRPs in daily community pharmacy practice. Therefore, the question remains if a quantitative detection of DRPs is even possible in real-life because of influences such as limited time or availability of clinical patient data, among others. Finally, this study collected no data regarding the outcomes of the specific advice and intervention given by the pharmacists. This is a major limitation of many studies. However, patients' outcomes are difficult to assess because CPs in Germany do not have access to clinical or outcome data.

CONCLUSIONS

The results of the study show that self-medication is often associated with risks and therefore should not be trivialized. An increased awareness is needed in public as well as in healthcare professionals. Nonprescription drugs are powerful pharmacological agents and must be selected, used, and monitored with the same degree of care as prescriptions drugs. Community pharmacies are the primary source of OTC drugs, and pharmacy staffs are the only group of healthcare professionals involved in self-medication. Therefore, pharmacists play a particularly key role in giving advice to patients on the proper and safe use of medicinal products intended for self-medication. This belongs to their core professional responsibility. However, there is potential for improvements to enhance DRP detection. This should be taken into account in pharmacists' education, training, and practice.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

KEY POINTS

- A total of 12 567 cases were evaluated. Relevant drug-related problems in OTC drug use are frequent and occurred in almost 1 out of 5 encounters (17.6%).
- Approximately 75% of the customers requested a specific OTC product. In these cases most DRPs was identified (80%).
- The most frequent DRPs were inappropriate self-medication, inappropriate requested drug, duration of drug use too long (including abuse), and wrong dosage.
- The availability of a patient file including data on prescription as well as OTC drugs might increase patient safety.

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