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## Exploring the potential impact of hospital ward-based pharmacy interns on drug safety

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Clinical pharmacists play an important role in improving drug safety on hospital wards. However, little is known about the impact of pharmacy interns. The objective of our study was, therefore, to investigate the impact of hospital ward-based pharmacy interns on drug safety. This study was conducted as part of the project “P-STAT 2: Pharmacy interns on the ward” on 14 surgical wards in seven hospitals in Germany and a total of 27 pharmacy interns participated. All patients admitted to the participating wards from 1st June 2008 until 31st October 2008 and from 1st December 2008 till 30th April 2009 were included. The pharmacy interns were involved in medication reconciliation, and identifying, resolving, and preventing drug-related problems (DRPs) using the classification system APS-Doc. A total of 6,551 patients were included. Patients received on average ( $\pm$  SD)  $4.4 \pm 3.9$  drugs. The pharmacy interns detected a total of 4,085 DRPs and on average  $0.6 \pm 1.2$  DRPs per patient. Most frequently detected DRPs were potential drug-drug interactions ( $n=591$ , 14%), missing drug strength, when different strengths were available ( $n=373$ , 9%), and incomplete medication record ( $n=296$ , 7%). The pharmacy interns conducted an intervention for 98% ( $n=4,011$ ) of all DRPs. According to their documentation, 74% of the DRPs ( $n=3,038$ ) were solved. Drugs which were most often related with DRPs were simvastatin, diclofenac, and ibuprofen. This is the very first study exploring the potential impact of pharmacy interns on drug safety on surgical wards in Europe. Pharmacy interns can play an important role to improve drug safety on hospital wards.

### 1. Introduction

Drug therapy is getting more complex, so that achieving an optimal drug effect implies the reduction of negative clinical outcomes such as drug-related problems (DRPs), medication errors, and adverse drug events which may occur frequently. Hence, drug safety has become an important health care issue, in which clinical pharmacists participate in the multidisciplinary team discussions, take part in ward rounds and in the decision of ordering and prescribing drugs, to identify, resolve and prevent clinically significant DRPs (Viktil and Blix 2008). DRPs include all issues that can potentially affect the success of pharmacotherapy in a given patient, in particular medication errors, adverse drug events, and adverse drug reactions (Krahenbuehl-Melcher et al. 2007). A DRP is an event or circumstance involving drug therapy that actually or potentially interferes with the desired health outcomes (Pharmaceutical Care Network Europe). It refers to the patient's perspective on the undesired health outcome of drug therapy and includes also potentially undesired health outcomes (van Mil et al. 2004). Examples for common DRPs are drug-drug interactions, non-adherence, and adverse drug reactions. The concept of DRPs has been widely used in studies in community pharmacies (Eickhoff et al. 2012) and hospitals (Bladh et al. 2011; Langebrake and Hilgarth 2010). In literature the reported prevalence of DRPs varies widely. It depends strongly on the definition used, the characteristics of

the patient population, and the methods applied to detect and document DRPs. For example, 18% of the patients in an ambulatory setting (Eickhoff et al. 2012) and 81% of the patients in a clinical setting had at least one DRP (Bladh et al. 2011). DRPs can result in drug-related morbidity, such as hospital admissions, and mortality. In a meta-analysis, between 3 to 9% of all hospital admissions were drug-related. More than half of the drug-related hospital admissions could have been prevented (Winterstein et al. 2002). Studies have shown that involving a clinical pharmacist on hospital wards can improve effectiveness and safety of pharmacotherapy (Bondesson et al. 2013; Fitzgerald 2009; Kaboli et al. 2006; Vira et al. 2006). Therefore, the need for a classification system to document, classify and evaluate the collected data has become necessary. However, most of the common classification systems for DRPs (Pharmaceutical Care Network Europe; Schäfer 2002) have been developed and validated in the ambulatory sector and could not directly be used in the clinical setting (Ganso et al. 2007). Results from several projects in Germany investigating interventions by clinical pharmacists on the ward have shown that certain DRPs are missing in the current classification systems and new subcategories need to be defined. Hence and in preparation for this study, a classification system adapted for the clinical setting was developed and validated (Hohmann et al. 2012a).

In German hospitals the number of clinical pharmacists on hospital wards is still very low in comparison to other European

countries (0.4 pharmacists/100 hospital beds) (Frontini et al. 2012). One barrier for the implementation are the additional costs for human resources (Walk et al. 2009). Compared to clinical pharmacists, the costs for pharmacy interns (PIs) are much lower, but PIs are also less experienced. PIs in Germany are graduate students who had finished university training and do a final 12-month internship as a prerequisite to become a licensed pharmacist. Half of this time can be spent in a hospital pharmacy and on a hospital ward. A pilot project (P-STAT 1) showed that PIs can contribute to drug safety on the hospital ward and were well accepted by physicians, nurses, and hospital pharmacists (Gerdemann et al. 2007). In that pilot study, the general impact of PIs on drug safety was assessed. However, there was no standardized, structured evaluation of the impact of the PIs on drug safety. The aim of this follow-up project (P-STAT 2) was to evaluate the impact of PIs on drug safety by detecting and solving DRPs. The impact of PIs on several qualities increasing and cost saving aspects, such as adherence to guidelines on antibiotic prophylaxis in surgery patients and prophylaxis of thrombosis has also been evaluated and is published elsewhere (Hohmann et al. 2012b, c).

## 2. Investigations and results

### 2.1. Study outline

The study was conducted as part of the project “P-STAT 2: Pharmacy interns on the ward” (Hohmann et al. 2008) on 14 wards in seven hospitals in Germany from May 2008 until April 2009. The clinics of the participating wards were general and visceral surgery (n = 5), gynecology (n = 1), orthopedic and accident surgery (n = 6), otolaryngology (n = 1), and urology (n = 1). Five hospitals were community and two university hospitals. 27 PIs participated in the study. PIs were involved in different activities (Hohmann et al. 2012b, c) including the recording and substitution of the medication according to the standard of the participating hospital. In all but one ward, two PIs worked consecutively during the study period. PIs spent the full 6 months on the hospital ward; they were trained on the job in the first month and recorded data for the study from month 2 to 6. Before study onset, the PIs and the supervising pharmacists participated in a two-day training course, including presentations on DRPs and medication reconciliation. During the study period, PIs were supervised by an experienced clinical pharmacist from the hospital pharmacy (n = 5) or the community pharmacy supplying the hospital (n = 2). A monitor (CH) visited the PIs bi-monthly to control the documentation, document additional DRPs, and intervene if necessary.

All patients admitted to the participating wards from 1st June 2008 until 31st October 2008 and from 1st December 2008 until 30th April 2009 were included in the study. Pharmacy interns collected baseline characteristic including the main diagnoses and renal function from the medical records. The detected DRPs were described as free-text and classified using the classification system APS-Doc (Hohmann et al. 2012a). The PIs documented the intervention conducted, the drug(s) related with the DRP, the (eventually) solving of the DRP, and the time needed to eventually solve the DRP. DRPs related to antibiotic and thrombosis prophylaxis were documented and analyzed separately (Hohmann et al. 2012b, c).

Patient anonymity was ensured so that no patient-specific data were recorded. Therefore, institutional review board approval was not required.

### 2.2. Statistics

Two experienced clinical pharmacists (CH, CE) checked independently the validity of the recorded data (baseline, medication

record, detected DRPs). Missing DRP-forms were counted as if patients did not have any DRPs. Data were partly scanned using ABBYY Form Reader 6.5, or entered manually and transferred to a database (Microsoft® Office Access 2003). Statistical analyses were performed using SPSS 17 (Predictive Analytics Software, SPSS Inc®). Data are presented as mean and standard deviation (SD), or as median and inter-quartile range. Mann-Whitney test was performed to analyze if the number of DRP per patient differed for age and number of co-morbidities. The level of significance was set as  $p < 0.05$ .

### 2.3. Study population

A total of 6,551 patients were included in the study. This was an average of 243 (range: 111–423) patients per PI. Patients had a median age of 61 (IQR: 45–73); the median age varied between wards and ranged from 46 (IQR: 27–62) to 72 (IQR: 65–78) (see Table 1 for baseline characteristics).

### 2.4. Drug-related problems

#### 2.4.1. Missing forms for DRPs

For 1,154 patients the forms for DRPs were missing. There were missing DRP forms from all hospital wards, but 68% of all missing forms were from one hospital with many patients without medication on admission. Patients with missing DRP-forms were categorized as not having a DRP.

#### 2.4.2. Detected DRPs

The PIs detected 4,085 DRPs in 6,551 patients. This was an average ( $\pm$  SD) of  $0.6 \pm 1.2$  DRP per patient. The average of DRPs per patient was lowest ( $0.2 \pm 0.5$ ) on the urology ward and highest ( $1.7 \pm 2.0$ ) on one of the general and visceral surgery wards. PIs detected in 67% (n = 4,385) of the patients no DRPs, in 18% (n = 1,178) one DRP, in 8% (n = 514) two DRPs, and in 7% (n = 474) three or more DRPs. The highest number of DRPs in a patient was 13. Most frequently detected DRPs were drug-drug interactions (14.5%, n = 591), unknown strength of a drug, if more than one strength was available (9.1%, n = 373), and incomplete medication record (7.2%, n = 296) (Table 2).

#### 2.4.3. Factors related to DRPs

Patients aged 65 or older (n = 2,933) had significantly more DRPs ( $1.0 \pm 1.4$ ) than those younger than 65 (n = 3,614;  $0.4 \pm 0.9$ ) ( $p < 0.001$ ). Patients with more than two co-morbidities (n = 2,614;  $1.1 \pm 1.5$ ) had significantly more DRPs than those with two or less co-morbidities (n = 3,937;  $0.3 \pm 0.8$ ) ( $p < 0.001$ ). Simvastatin, diclofenac, and ibuprofen were most often related to DRPs (Table 3).

#### 2.4.4. Pharmaceutical interventions

PIs conducted a pharmaceutical intervention for 98% of all documented DRPs (n = 4,011). For 37% of the DRPs (n = 1,513) they consulted only the patient. For 58% of the DRPs (n = 2,357) they consulted a physician and/or a nurse additionally. On average, they spent  $6 \pm 7$  minutes (min: <30 s, max: 2 h) to solve a detected DRP (data missing for n = 85). High expenditure of time was reported when a medicine was no longer available ( $18 \pm 36$  min, n = 10) or when the medicine was unknown ( $12 \pm 14$  min, n = 129). Less time-consuming were reports for missing application time ( $3 \pm 3$  min, n = 39), missing dosage forms, if more than one dosage form was available ( $3 \pm 3$  min,

**Table 1: Baseline characteristics of the study population**

	Patient population (N=6,551)	Ward with lowest/highest percentage or median
Sex	Female: 52% (n = 3,431) Male: 47% (n = 3,088) [Missing: 1% (n = 32)]	Lowest percentage of females: 37% (n = 116); urology Highest percentage of females: 100% (n = 474); gynecology
Age [years]	Median: 61 (IQR: 45–73) [Missing: n = 4]	Lowest median age: 46 (IQR: 27–62); otolaryngology Highest median age: 72 (IQR: 65–78); general and visceral surgery
Smoking	Smoker: 20% (n = 1,319)  Non-Smoker: 67% (n = 4,384) [Missing: 13% (n = 848)]	Lowest percentage of smokers: 13% (n = 92); general and visceral surgery Highest percentage of smokers: 34% (n = 474); general and visceral surgery
BMI [kg/m <sup>2</sup> ]	Median: 26 (IQR: 23–30)  [Missing: 8% (n = 536);  Excluded (age < 18: 2% (n = 140), amputation of the lower extremity: n = 1)]	Lowest median BMI: 24.6 (IQR: 22.0–28.0); orthopedic and accident surgery Highest median BMI: 27.3 (IQR: 23.4–30.9); general and visceral surgery
Duration of hospitalization [days]	Median: 6 (IQR: 3–11)  [Missing: 1% (n = 59)]	Lowest median duration of hospitalization: 4 (IQR: 3–6); otolaryngology Highest median duration of hospitalization: 8 (IQR: 4–14); general and visceral surgery
Number of comorbidities	No comorbidities: 24% (n = 1,594) 1–4 comorbidities: 59% (n = 3,843) ≥ 5 comorbidities: 17% (n = 1,114)	Highest prevalence no comorbidities: 26% (n = 185) Highest prevalence ≥ 5 comorbidities: 35% (n = 115) general and visceral surgery
Creatinine Clearance	< 30 mL/min: 4% (n = 266) 30–60 mL/min: 18% (n = 1,169) > 60 mL/min: 65% (n = 4,290) [missing: 13% (n = 826)]	Highest prevalence < 30 mL/min: 39% (n = 51); general and visceral surgery Highest prevalence > 60 mL/min: 93% (n = 429); otolaryngology
Number of drugs	Median: 4 (IQR 1–7)	Lowest median: 1 (IQR: 0–4); otolaryngology Highest median: 8 (IQR: 5–11); general and visceral surgery

IQR = interquartile range

**Table 2: Most frequently detected drug-related problems**

	Number	% of DRPs (N = 4,085)
Drug-drug interaction as indicated by literature (clinical relevance not proven)	591	14.5%
No drug strength prescribed, when different strengths are available	373	9.1%
Incomplete drug history (the patient takes further drugs that are not listed in the medication schedule)	296	7.2%
Prescription of an incorrect dosage or no dosage prescribed	182	4.5%
Dose too high	165	4.0%
Contraindication not accounted for	138	3.4%
No dosage adjustment in case of renal insufficiency	135	3.3%
Drugs missing (no drug prescribed in patients with an existing indication) or suboptimal dosage	131	3.2%
The patient does not know his/her medication (not applicable in patients with dementia or unconsciousness)	130	3.2%
Inappropriate time of administration	128	3.1%
Transcription error / unintended discontinuation of drug therapy (during the hospital stay)	127	3.1%
Dose too low	116	2.8%
Incorrect spelling of the trade name	107	2.6%
Discontinuation of ambulatory medication (complete drug history is available, but not each drug is prescribed)	107	2.6%
Inappropriate administration interval	107	2.6%

Coding according to APS-Doc (Hohmann et al. 2012a)  
DRPs = drug-related problems

**Table 3: Drugs most frequently related to drug-related problems**

Drug	% DRPs (N=4,085)	Most frequently related DRPs
Simvastatin	3.3% (n = 136)	– Drug-drug interaction as indicated by literature: n = 23 – Inappropriate time of administration: n = 20
Diclofenac	3.2% (n = 130)	– Drug-drug interaction as indicated by literature: n = 85 – No dosage adjustment in case of renal insufficiency: n = 8
Ibuprofen	2.9% (n = 120)	– Drug-drug interaction as indicated by literature: n = 82 – Unintended prescribing of a product of the same class of drugs: n = 8
Metoprolol	2.9% (n = 118)	– Drug-drug interaction as indicated by literature: n = 32 – No drug strength prescribed, when different strengths are available: n = 20
Acetylsalicylic acid	2.7% (n = 110)	– No interruption of administration prior to surgery as required: n = 32 – Drug-drug interaction as indicated by literature: n = 20
Ramipril	2.5% (n = 101)	– Drug-drug interaction as indicated by literature: n = 54 – No dosage adjustment in case of renal insufficiency: n = 15
Levothyroxine	2.2% (n = 89)	– Drug-drug interaction as indicated by literature: n = 32 – Inappropriate time of administration: n = 8
Other opioids	1.8% (n = 75)	– Drug-drug interaction as indicated by literature: n = 34 – Medication inappropriate (better option available): n = 11
Metformin	1.7% (n = 71)	– No interruption of administration prior to surgery as required: n = 27 – Contraindication not accounted for: n = 13

DRPs = drug-related problems

n = 52), or if drug/dosage form was unsuitable to be administered *via* a feeding tube (3 min, n = 3).

#### 2.4.5. Solution of DRPs

According to their own documentation, PIs solved 74% of all detected DRPs (n = 3,038); they solved all DRPs categorized as “application time unclear” (n = 39). They solved 95% of the DRPs categorized as “patient received the wrong medication” (n = 61), or “incorrect spelling of the trade/brand name” (n = 102).

PIs solved 12% of the DRPs (n = 477) partly meaning that a solution was initiated, but could not be reached at the first review with the ward physician, general practitioner, the patient or the caregiver, and requires further interventions. DRPs categorized as symptoms of an adverse drug reaction (ADR) (n = 27, 38% of the category), medication non-adherence (n = 17, 30% of the category), or patient’s fear of an ADR (n = 4, 29% of the category) were often partly solved.

PIs could not solve 4% of the detected DRPs (n = 147). That was frequently the case when DRPs were categorized as “no drug-monitoring” (n = 6, 30% of the category), “missing indication” (n = 10, 14% of the category) and “contraindication” (n = 14, 10% of the category). An example for a DRP, which could not be solved, was when a physician did not want to change a drug prescribed by another specialist. For 7% (n = 267) of the DRPs no action was required, for 4% (n = 156) of the DRPs data about solving the DRP was missing.

#### 2.5. Agreement

Eighty-four percent (n = 3,434) of the detected DRPs were coded in agreement with the monitor. The agreement ranged from 57% to 95% between the different PIs. 1,365 (33%) DRPs were either detected or coded additionally by the monitor. Most frequent additionally detected/coded DRPs were inappropriate administration interval (n = 428), drug-drug interaction as indicated by literature (n = 282), and contraindication (n = 115).

### 3. Discussion

Published knowledge on the impact of PIs on improving drug safety on hospital wards is scarce. In this study, we explored

how PIs could contribute to drug safety on hospital wards. In ten months, PIs detected a total of 4,085 DRPs in 6,551 patients. They conducted an intervention for nearly all detected DRPs and solved the majority of them (74%).

Most frequently detected DRPs were drug-drug interactions indicated by literature data. Many of these did not require an action. Often, PIs documented DRPs related with the documentation in the medication history. Frequently, dosage or strength was missing, or medication, which was taken by the patient, was not documented in the patient file. These DRPs were frequently solved by the PIs. This finding is consistent with published studies, showing that medication histories taken at hospital admissions are often inaccurate or incomplete (Tam et al. 2005; Dobrzanski et al. 2002) and that involving a pharmacist (Carter et al. 2006) and/or a PI (Mersfelder and Bickel 2008) can improve quality of data and drug safety. In our study, PIs also detected a considerable number of contraindications, over-dosage, and missing dosage adaptations for renal insufficiency. Those DRPs were more difficult to solve. For example, 10% of the DRPs categorized as “contraindication” could not be solved by the PIs.

Around one third of the patients had one or more DRPs, but the prevalence differed widely between the different wards (11–63%). This is a relatively low prevalence compared to the published literature. A Norwegian study conducted on internal medicine and rheumatology wards reported that 81% of the patients (Blix et al. 2004) and a German study conducted in patients with ischemic stroke reported that two-thirds of the patients had one or more DRP (Hohmann et al. 2012d). However, in both studies, patients were on average around ten years older than in our population. Not surprisingly, also in our population patients older than 65 and patients with more co-morbidities had significantly more DRPs than younger patients and those with less co-morbidities. In our study, the total number of DRPs per patient was also lower compared to a previous study by Hohmann et al. (0.6 versus 1.8 DRPs per patient), which analyzed the number and frequency of DRPs in surgery patients involving pharmacy interns (Hohmann et al. 2012a). The lower number of DRPs per patient might be explained by the around ten years lower age in our population.

Drugs most frequently related with DRPs, especially drug-drug interactions were ibuprofen, diclofenac, and simvastatin. The literature has shown that non-steroidal anti-inflammatory drugs

and antihypertensives, such as ACE-inhibitors belong to the most common drugs which increase the likelihood for drug-drug interactions (Viktil et al. 2004). Furthermore, anticoagulants such as warfarin (in Germany, phenprocoumon is used instead) and antithrombotics are drugs which considerably increase the risk of ADRs and poor patient outcomes (Blix et al. 2004; Viktil et al. 2004; Becker et al. 2007). In our study we did not find a high number of DRPs related to anticoagulants and antithrombotics because these drugs were interrupted due to the planned surgery procedures in the vast majority of cases.

Additionally to the DRPs detected by the PIs, the monitor, who only had access to secondary data, detected 1,365 DRPs. One can conclude that an experienced clinical pharmacist on the ward would have detected more DRPs than the PIs. In addition, it can be assumed that our self-reporting method contributed to an underestimation of potential DRPs detected and documented. Hence, the estimated impact of PIs on drug safety on hospital wards is probably even higher than suggested by our findings. The positive impact of the PIs was also recognized by other health care professionals. Physicians and nurses highly appreciated the work of the PIs, reported time savings, and asked for a prolongation of the project (Eickhoff et al. 2009).

The main limitation of our study was that the design did neither allow to examine the clinical significance of DRPs detected nor potential negative health outcomes.

This is the very first study exploring the potential impact of pharmacy interns hence, post-graduate students, on drug safety on surgical wards in Europe. Undoubtedly, pharmacy interns cannot replace experienced clinical pharmacists. However, pharmacy interns can make a valuable contribution to drug safety in the hospital setting.

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