Int J Clin Pharm
DOI 10.1007/s11096-011-9580-4

RESEARCH ARTICLE

Pharmaceutical interventions on prescription problems in a Danish pharmacy setting

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Received: 29 June 2011 / Accepted: 29 October 2011

Abstract *Background* International studies regarding pharmacists' interventions towards prescription problems produce highly variable results. The only peer-reviewed study in a Danish setting estimated an intervention rate of 2.3 per 1,000 prescriptions. With the introduction of a new tool for registration, we hypothesized that a better estimate could be obtained. *Objective* We aimed to produce an up-to-date estimate of the extent and type of pharmacists' interventions towards prescription problems in a Danish pharmacy setting *Setting* The study was conducted at Copenhagen Sønderbro Pharmacy, a large urban 24-hour pharmacy. *Method* Data were collected prospectively through an electronic form. All interventions were primarily classified as either clinical or administrative in nature, and further classified in a number of pre-determined subcategories. Furthermore, information about age, sex, time of day, the wording of the prescription, the performed intervention, the person performing the intervention and the type of prescriber were recorded. All entries were manually validated by a study pharmacist. *Main outcome measure* The intervention rate, given as the number of interventions per 1,000 prescriptions. *Results* We found 599 validated interventions. Thirty-two percent of the interventions were clinical and 68% administrative by nature. Fifty-one percent of the administrative and 35% of the clinical interventions were regarding antibiotics. In the study period, a total of 55,522 prescriptions were filled out together with 3,069 dose-dispensing packages, giving a rate of 10.2 (9.4–11.1) interventions per 1,000 prescriptions. *Conclusion* We found an intervention rate substantially higher than reported in previous Danish studies.

Keywords Clinical pharmacy · Denmark · Pharmacy practice · Primary care · Problem prescriptions · Pharmacists' interventions

Impact of findings on practice

- The number of interventions on prescriptions in Danish community pharmacies, is probably significantly higher than older studies indicated.
- One third of the interventions in Danish pharmacies are have a clinical background.
- Community pharmacists in Denmark intervene mostly in prescriptions for antibiotics.

Introduction

The pharmacists' role in combating adverse drug events was first described in 1990 by Hepler and Strand [1], inventing the patient-centered term "pharmaceutical care" and advocating the necessity of an increased focus on pharmacists' impact on the safe and effective use of drugs. Today, pharmacists view their own role as providing risk management information to patients, adding value to patient care beyond a level that can be provided by a physician alone [2].

One of the most important and central roles of the community pharmacist is his/her impact on the prescription process [3], among other things by screening for drug–drug interactions [4] and intervening on prescription problems [5–12] and inappropriate use of medicine [9, 13, 14]. Most studies have

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Published online: 15 November 2011

been conducted in a hospital setting [15], focusing on *prescription errors*, finding prescription error rates varying from 0.3 to 39.1% in hospital in-patients [16]. The high variance is primarily related to differences in study design and definition of errors [15–17]. In a primary care setting, the focus is most often *prescription problems* [5, 6, 8–10, 13, 14, 18], including all issues necessitating a pharmaceutical intervention, e.g. back-ordered medicine (drugs that the supplier cannot retrieve from the drug manufacturer). In primary care, the reported intervention rate is also highly variable, from 7 to 43 interventions per 1,000 prescriptions [7, 8, 10, 18–20], most likely due to varying methodology and definitions of interventions.

In a Danish primary care setting, only limited evidence exists regarding pharmaceutical interventions on prescription problems [9]. The most comprehensive work has been non-peer reviewed statements from the Danish Pharmacy Association, estimating an intervention rate of 3.3–6.0 per 1,000 prescriptions [21, 22]. It is suspected that these results are heavily biased due to lacking registrations of performed interventions [9]. A possible explanation is the labour used for registration, with the pharmacist having to take a copy of the prescription, make a handwritten explanation of the intervention and storing the registration. This may be regarded as troublesome by the pharmacy staff. Furthermore, two of the three studies [9, 22] used retrospective data collection. The third study [21], although prospective, was still relying on the same method for registration. No other means to increase the registration rate was used besides alerting the pharmacies that their registrations would be subject to later analysis.

In connection with the introduction of a new tool for the registration of interventions, allowing registration of performed interventions electronically directly at the counter after performing an intervention, it was hypothesized that a new and more realistic estimate of the intervention rate could be obtained, with less bias from underreporting.

Aim of the study

In an effort to describe the role of the community pharmacies in the Danish health care sector, we aimed to produce an up-to-date estimate of the extent and type of pharmaceutical interventions on prescription problems in a Danish pharmacy setting.

Methods

Setting

Structure of the pharmacy sector in Denmark

Although in its essence private, the Danish pharmacy sector is subject to strict state regulation. The proprietor pharmacist owns the pharmacy and is financially responsible. At the same time, the state determines the number of pharmacies and their location. The current regulatory tendency is to have larger units by shutting down smaller pharmacies or merging units. The current number of proprietor pharmacists is 235. The current minimum desired threshold is 160,000 filled prescriptions (240,000 packages) annually per pharmacy. In Denmark, there are currently 318 pharmacies and overall 1,300 pharmacy-associated units handing out pharmacy goods. A pharmacy covers in average an area with 17,300 citizens and about 600 patients per day. Medicine is dispensed as Original Pack dispensing. Roughly half of all prescriptions are prescribed and dispensed electronically.

Copenhagen Sønderbro Pharmacy

Copenhagen Sønderbro Pharmacy is one of the three largest pharmacies in Denmark with 73 employees in the main pharmacy and 25 employees in the associated dose-dispensing production unit, producing medicine packages individually packed for each administration time. The trained employees consist of 17 pharmacists, 41 pharmaconomists[1] and 13 pharmacist or pharmaconomist students. Sønderbro Pharmacy is open day and night and serves an average of 1,300 patients per day and fills 290,000 prescriptions (440,000 packages) per year.

Method

Data on all interventions were collected prospectively via an electronic form readily available on all PCs at the pharmacy, which was specifically designed for the purpose of this study. Each pharmacist or pharmaconomist performing an intervention registered the data themselves, also categorizing the given intervention. All interventions were primarily classified as either clinical or administrative by nature, and further classified in a number of pre-arranged sub-categories. Furthermore, information about age, sex, time of day, the wording of the prescription, the performed intervention, the person performing the intervention and the type of prescriber was recorded. All entries were manually validated by a study pharmacist (AP) to ensure data quality and consistency in the classification of interventions. Classification with respect to anatomical-chemical-therapeutic (ATC) code [23] was done retrospectively. To exemplify the data material, a list of examples of interventions from each cat-

[1] A pharmaconomist is equivalent to a pharmacy technician but with a substantially longer education (3 years).

egory was generated ("Appendix 1"), together with a list of selected potentially important clinical interventions ("Appendix 2").

Before the study period, examples of registrations that the staff failed to register were collected to be used as teaching material. These examples were used during the first 2 weeks of the study period where a study pharmacist reminded the staff how to use the system correctly. Furthermore, visual reminders were put up in the pharmacy, reminding the staff that all performed interventions should be registered.

Only interventions with some sort of bearing on the patient were included. As an example, missing information on the indication for treatment was only registered when the patient was not aware of the prescriber's intention. When deciding whether deviations in the amount of medicine should be registered, we followed Danish law [24], in that deviations over 25% were registered (10% for narcotics).

Interventions on veterinary prescriptions were excluded, along with interventions on lost or expired refill prescriptions (emergency supply of medicine). As prescriptions regarding dose-dispensing are not handled in the same way as ordinary prescriptions, the total number of produced dose-dispensing packages was used as a proxy of the number of prescriptions.

To estimate the degree of underreporting, a study pharmacist manually checked all non-electronic prescriptions for evidence of interventions that were not registered during the first 2 weeks. Only deviations in type of medicine, strength or amount were checked. After the first 2 weeks, this was only done for one randomly selected work day each week. Missing registrations found this way were subsequently registered but marked as found by manual search.

To calculate the distribution of prescriptions into sex and age categories, used in Figs. 1 and 2, all prescriptions filled in a pharmacy similar to Sønderbro Pharmacy were subtracted from Odense Pharmacoepidemiological Database (OPED) [25]. The pharmacy selected was Ørnen Pharmacy in Odense, which is also a large urban pharmacy open day and night. This pharmacy is as such very similar to Sønderbro in regard to the characteristics of the population served. The use of data from another pharmacy was due to the fact that the age and gender distribution of prescriptions from Sønderbro Pharmacy could not be retrieved.

The electronic form for the interventions was made using Microsoft SharePoint. All data analyses were done using STATA11. Ninety-five percent confidence intervals for the intervention rate were calculated by use of the confidence limits for a Poisson distribution. An ethics committee approval was not required for the study.

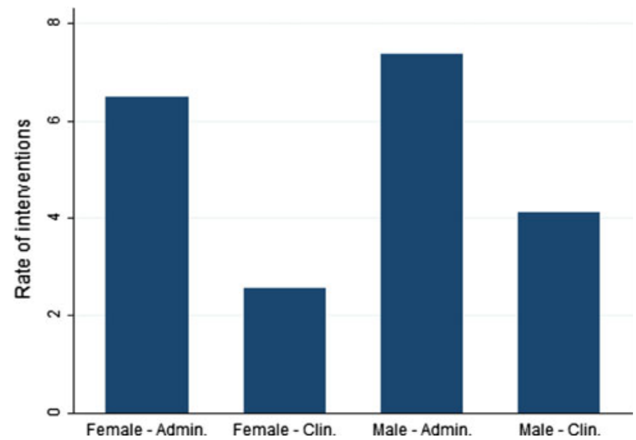

Fig. 1 The rate of interventions, given as the number of interventions per 1,000 prescriptions, divided by gender and whether the intervention was classified as a clinical or an administrative intervention

Results

Over a 51-day period, 674 registrations were completed. After validation of all registrations, 599 (89%) were found to be interventions, with an average of 12.0 interventions per day (range 1–26). The distribution of different types of interventions is shown in Table 1. Examples of all included categories of interventions are given in "Appendix 1".

Of the 599 interventions, 86% were performed at the counter, 9% in the dispensary and 4% in the department handling dose-dispensing. In 14% of the cases, it was found necessary to contact the prescriber before the intervention. In 1% of the cases, the prescriber was contacted afterwards, and in 2% of the cases, it was attempted but not possible to reach the prescriber. The three most frequent types of prescribers were general practitioners (56%), hospitals (21%) and emergency service doctors (16%).

The gender distribution of interventions is given in Fig. 1, and the distribution from age is given in Fig. 2. The distribution between ATC-groups is given in Table 2.

In the study period, a total of 55,522 prescriptions for human use were filled out together with 3,069 dose-dispensing packages. This gives a total rate of 10.2 (9.4–11.1) interventions per 1,000 prescriptions. Thirty-two percent of the interventions were clinical and 68% administrative by nature. Looking specifically at interventions regarding dose-dispensing the rate of interventions is 8.5 intervention per 1,000 prescriptions. A selected list of examples of interventions on potentially serious problems is given in "Appendix 2".

During the controls for forgotten registrations, a mean of 2.9 missing registrations was found per day (range 1–7). A total of 18 work days was checked this way, leaving 16 work days unchecked in the study period.

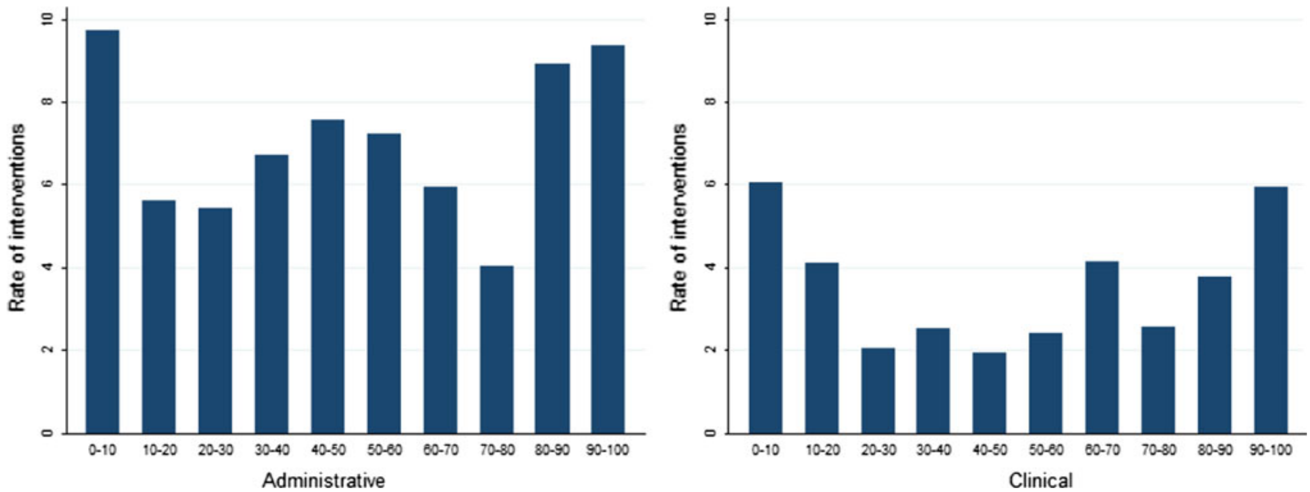

Fig. 2 The age distribution of clinical and administrative interventions, depicted as the number of interventions per 1,000 prescriptions in each age category

Table 1 The six most frequent types of clinical and administrative interventions

Type of intervention	No.	%
Wrong formulation of medicine	46	7.7
Wrong dosage (strength) of medicine	33	5.5
Wrong dosage scheme of medicine	30	5.0
Wrong amount (too little) of medicine	30	5.0
Dose-dispensing-related problem	19	3.2
Wrong amount (too much) of medicine	19	3.2
Other clinical	14	2.3
Total number of clinical	**191**	**(32)**
Backordered medicine	177	30
Medicine not in stock at pharmacy	111	19
Medicine no longer manufactured	49	8.2
Missing data on prescription	19	3.2
Technical problems with hospital prescriptions	19	3.2
Change due to price of medicine	12	2.0
Other administrative	21	3.5
Total number of administrative	**408**	**(68)**
Total number of interventions	**599**	**100**

If the number of missing registrations found by manual review is representative of the entire material, the estimate arrives at 11.0 interventions per 1,000 prescriptions.

Discussion

We found an intervention rate of 10.2 interventions per 1,000 prescriptions, which is substantially higher than reported in previous Danish studies.

The primary strength of the study is the prospective data collection and the manual validation of entries, both of which contribute to a higher data quality. Furthermore, the control for missing registrations allows for a crude estimation of the degree of underreporting.

The primary weakness of the study is related to the field of study itself, as the number of administrative interventions is highly dependent on other events such as the number and nature of the drugs in backorder in a given period or any recent changes in the reimbursement system. The number of interventions is also dependent on the type of the local prescribers [5, 26]. Furthermore, significant variances between pharmacies have been observed [10, 18, 19], to which the study is vulnerable being a single center study. Lastly, it is a weakness that our study does not include any severity rating of the clinical value of the performed interventions.

Several factors might lead to an overestimation of the rate of interventions. Being one of the few Danish pharmacies open at night, a larger proportion of prescriptions will be antibiotics from emergency wards and emergency service doctors. As most interventions are aimed at antibiotics, the setting of Sønderbro Pharmacy might lead to an overestimation. Furthermore, the on-site presence of a study pharmacist might have led to an increased focus on performing interventions.

Several factors might lead to an underestimation of the rate of interventions. Sønderbro Pharmacy is significantly larger than the average Danish pharmacy. Earlier studies have shown a negative correlation between pharmacy size and number of interventions [5, 12]. This is possibly explained by a higher ratio of student employees or less familiarity with the individual patient. Furthermore, the use of the number of dose-dispensing packages as a proxy for

Table 2 The distribution between ATC groups

Administrative			Clinical		
ATC code	No.	%	ATC code	No.	%
J—Anti-infectives for systemic use	208	51	J—Anti-infectives for systemic use	66	35
R—Respiratory system	46	11	N—Nervous system	36	19
N—Nervous system	46	11	C—Cardiovascular system	19	9.9
C—Cardiovascular system	30	7.4	A—Alimentary tract and metabolism	17	8.9
S—Sensory organs	15	3.7	R—Respiratory system	16	8.4
Other	63	15	Other	37	19
Total	408	100	Total	191	100

the number of dose-dispensing prescriptions is subject to discussion. Many patients only receive one or few prescriptions to run for 2 years, while others regularly receive prescriptions with alterations. The number used corresponds to one prescription per patient each 14th day. This most likely overestimates the number of prescriptions, thereby leading to an underestimation of the number of interventions per prescription. Dose-dispensing constitutes 5.2% of the total number of prescriptions. Lastly, it is evident from the number of post registrations caught in the manual control, that there is still significant underreporting. It is worth noting that only a subset of prescription problem types was detected this way and only non-electronic prescriptions were checked. It is therefore likely that the true number of omitted registrations is higher than what was observed. The result of the manual control merely indicates that significant underreporting was present. The two main reasons for failing to register a performed intervention was lack of time to register and doubt whether a given action was regarded as an intervention or not. Based on the control for forgotten registrations, another 46 interventions could have been found if all workdays had been checked. To this should be added that this only accounts for work days, that only a subset of intervention types were checked (10 of 23 categories) and only non-electronic prescriptions. Furthermore, some categories had very few registrations compared to what was to be expected. It therefore seems that the new method for the registration of interventions has significantly improved the quality of our data and limited the degree of underreporting, but not to a level where it should not be considered a major bias.

Compared to earlier Danish results [9, 21, 22, 27], our results show a significantly higher rate of interventions, most likely related to a better coverage of the performed interventions. The higher rate of interventions compared to the earlier studies is in agreement with the hypothesis of the study, first presented by Knudsen et al. [9], in that an electronic registration system might lead to better data quality.

Earlier studies show roughly 50% clinical and 50% administrative interventions, suggesting that the higher coverage primarily leads to documentation of more administrative interventions. This cannot, however, account entirely for the increase seen. Furthermore, the distribution between different subtypes of interventions is remarkably similar to what has been observed in the earlier studies. This was supported by the reuse of the same categories as in the previous studies. An exception to this is the category 'missing indication of reimbursement', with only a single registration in our study, compared of up to 18.6% of the total number of interventions in a previous study [22]. This is most likely related to the staff not being aware that these actions should be registered as interventions. We therefore propose that the next step in strengthening the quality of the data on performed interventions is the publishing of a central guideline containing definitions of what is regarded as an intervention, along with the distribution of our method for registration to other Danish pharmacies.

It is important to bear in mind that although the rate of interventions is seemingly low, the dispensing of medical products is a very frequent event with 55,298,051 medicine packages being handled in Danish pharmacies in 2009 [28]. With our 55,522 prescriptions, corresponding to 57,450 packages, this leads to an estimate of 53,442,269 annual prescriptions. Our observed rate thereby corresponds to no less than 545,000 interventions annually, 174,400 of which have a clinical perspective.

The value of comparing our results to international studies is very limited, mainly due to differences in pharmacy settings. Furthermore, the reported intervention rate is highly variable with 10–24 per 1,000 prescriptions in the Nordic countries [7, 18], 7–36 per 1,000 prescriptions in an American setting [8, 19], and 19–43 per 1,000 prescriptions in other European countries [10, 20]. When comparing to earlier studies, it is important to bear in mind the enormous influence of study design. From a hospital setting, it is seen that different methods not only give highly variable results [16] but that they also have very little overlap in the types of errors they detect [17]. Our study can be viewed as having a 'process-oriented' design as opposed to studies focusing on the few but most potentially dangerous errors [16].

Several studies have evaluated the clinical impact of pharmaceutical interventions [5, 18, 21, 27, 29–31]. The findings have been highly variable, mostly due to different methodology in scoring the severity of prescription problems. The perhaps most tangible indication of relevance is the very high acceptance rate by doctors towards the interventions performed by the pharmacists [6, 7, 12, 18]. An evaluation of the financial impact of interventions has shown cost savings of averagely 123$ per clinical intervention [32].

It is important to emphasize that administrative interventions also hold major clinical value, as changing the strength and dosage of an antibiotic, e.g. due to backorder, needs proper and careful handling as well as thorough explanation to the patient. The distinction between clinical and administrative interventions is thus in many cases less obvious to the patient than to the pharmacist. Most administrative interventions are a necessity to secure the correct treatment.

Our study documents a significant number of interventions related to backordered medicine. These interventions are particularly interesting since most would be easily avoidable had the general practitioner had access to information regarding current backorders. No Danish numbers exist regarding the problem of backordered medicine. A recent American whitepaper [33] estimated that the problem has tripled since 2005, with a current annual cost for the American hospitals of up to 200 million USD.

Another surprising finding of our study is the high rate of clinical interventions on prescriptions to children under 10 years of age. Of the 39 clinical interventions among children, 23 (59%) were related to antibiotics, with the most common interventions being wrong dosage or wrong amount (too little). Further studies are needed to investigate the identity of the prescribers of these drugs and to what extent these interventions hold clinical significance.

In continuation of this study, three major areas need elucidation. Firstly, it would be interesting to attempt to replicate our study at another Danish pharmacy, to evaluate the generalizability of our findings to the Danish pharmacy setting. Secondly, it would be useful to examine whether an intervention aimed at increasing the collaboration between pharmacies and general practitioners would lower the rate of interventions. Lastly, the high amount of interventions on prescriptions for children's penicillin could provide an interesting subject for a more rigid investigation.

Conclusion

We have found an intervention rate substantially higher than reported in previous Danish studies. Approximately one-third of these were clinical by nature. Antibiotics are the drug class most commonly involved in the interventions, for clinical as well as administrative interventions. Electronic registration of interventions seemingly reduces the bias from underreporting.

Acknowledgments The authors wish to acknowledge the staff at Sønderbro Pharmacy for the effort of performing the registrations. Furthermore, our thanks go to Mikkel Nørreslet and Charlotte Vermehren for valuable comments on the manuscript.

Conflicts of interest None.

Appendix 1

See Table 3.

Table 3 Examples of all intervention categories

Intervention name	Example
Administrative interventions	
Backordered medicine	Roxithromycin 150 mg twice daily changed to 300 mg once daily, due to 150 mg being backordered
Medicine not in stock at pharmacy	Losartan 100 mg once daily changed to 50 mg two tablets once daily, due to medicine not being in stock at the pharmacy
Change due to price of medicine	Citalopram 20 mg 30 tablets changed to 100 tablets, due to 30 tablet packages being much more expensive per tablet
Incorrect patient data	Penicillin for a child prescribed in the mother's social security number
Missing prescriber data	No prescriber identifier on a prescription for morphine
Missing indication of reimbursement	No indication that the drug cost should be reimbursed, even though the patient usually receives reimbursement for the drug
Incorrect denial of generic substitution	A prescription for contraceptives marked with "no substitution" even though the patient wanted the cheapest generic
Missing data on prescription	Penicillin, 1 tablet 3 times daily, with no indication on tablet strength
Unreadable prescription	Methyldopa tablets, not possible to read the dosing scheme

Table 3 continued

Intervention name	Example
Medicine no longer manufactured	Amoxicillin 250 mg soluble tablet, changed to 125 mg since 250 mg is no longer manufactured
Technical problems with hospital prescriptions	An electronic prescription for digoxine SAD (hospital-specific product) needs to be handled manually since the prescription is initially ignored by the pharmacy system
Wrongfully marked as dose-dispensing	A prescription for nitrofurantoin marked as dose-dispensed medicine was not intended to be dose-dispensed
Clinical interventions	
Wrong medicine	A prescription for telmisartan after the patient had changed to losartan
Wrong dosage (strength) of medicine	Malarone Pediatric (anti-malarial product) for an adult, changed to ordinary Malarone (4 times the dosage)
Wrong amount (too little) of medicine	Penicillin 2 tablets 3 times daily for 2 weeks, 40 tablets. Number of tablets changed to 100
Wrong amount (too much) of medicine	Penicillin 1 tablet 3 times daily, 100 tablets. After contacting prescriber changed to 30 tablets
Wrong formulation of medicine	Inhaled steroid for asthma prescribed as spray instead of turbuhaler
Wrong dosage scheme of medicine	Azithromycin suspension for a child, dosed as 400 mg (10 ml) daily for 3 days. After contact to prescriber changed to 160 mg (4 ml) daily for 3 days
Wrong duration of treatment	No registrations made
Wrong indication for medicine	Fluconazol marked as "treatment for intestinal infection". Medicine was for vaginal infection, with the patient unaware of the doctor's intention
Double prescription	Two separate prescriptions for V-penicillin 1.5 ml IE. 20 tablets. One dosed 1 tablet 3 times daily, and the other 1 tablet 2 times daily. After contact, only the prescription for 1 tablet 3 times daily was filled
Missing check of allergies	No registrations made
Dose-dispensing-related problem	After discharge from hospital, dose-dispensing of dipyridamol is marked at times 8 and 12, which were corrected to 8 and 17

Appendix 2

See Table 4

Table 4 Examples of potentially serious clinical interventions

Type of intervention	Prescription	The intervention
Wrong formulation of medicine	B12-vitamin 1 mg tablets 1 tablet each 30th day	Changed from tablets to injection, after contacting the hospital
Wrong dosage (strength) of medicine	Indometacine capsules 100 mg 1 capsule twice daily against gallstone pain	Patient had taken four 25 mg capsules at the hospital, but was feeling sick and wanted a lower dose. Capsules of 100 mg does not exist, besides as suppositories. Changed dosage to 50 mg twice daily after consulting with hospital
Wrong dosage (strength) of medicine	Dicloxacillin 250 mg 1 capsule three times daily	Changed the dosage (strength) to 500 mg with the same dosage scheme after consulting with emergency service doctor
Wrong amount (too little) of medicine	V-penicillin 85.000 IE/ml 100 ml bottle 10 ml three times daily against throat infection	100 ml is not nearly enough. Changed amount to three bottles of 100 ml after consulting with the prescriber
Wrong dosage scheme of medicine	Clarithromycine 50 mg/ml 5 ml twice daily against infection	Dosage seems high in comparison to the weight of the child. After contacting an emergency service doctor (not the original prescriber) the dosage scheme was changed to 1.5 ml twice daily
Wrong formulation of medicine	Diclofenac 100 mg Suppositories 1 suppository twice daily against pain	The patient was not informed of the route of administration and refused to use suppositories. Changed to diclofenac as retard tablets 100 mg up to two tablets daily

Table 4 continued

Type of intervention	Prescription	The intervention
Wrong dosage (strength) of medicine	Dose-dispensing prescription. Verapamil Retard 240 mg 1 tablet once daily	Prescription received as part of routine renewal of dose-dispensing agreement. Older prescription was 120 mg once daily. After contact to prescriber new prescription arrived marked with 120 mg twice daily. After second contact to prescriber the dosage was returned to the original 120 mg once daily
Wrong dosage scheme of medicine	Mebendazol 20 mg/ml 5 ml twice daily for 3 days against threadworm	Changed the dosage scheme to the correct dosage of 5 ml once daily, repeated every 14th day for a total of three times
Wrong dosage (strength) of medicine	Diazepam 15 mg 100 tablets	After contacting the prescriber the strength was changed to 5 mg
Wrong formulation of medicine	Methylphenidate 20 mg Ordinary tablets	After experiencing problems with effect of the medicine it is uncovered that a new prescriber taking over the medication from a children psychiatrist have changed the formulation from sustained release tablets to ordinary tablets by mistake
Double prescription	Simvastatin 40 mg once daily. Hospital prescription	The general practitioner has prescribed atorvastatin 20 mg simultaneously. After contacting prescriber, only simvastatin should be continued
Wrong formulation of medicine	Betomeclasone. Autohaler and spacer	Changed the formulation from Autohaler to ordinary spray, since Autohaler cannot be used with a spacer

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