ERROR MANAGEMENT

Preventing medication errors in community pharmacy: frequency and seriousness of medication errors

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Background: Medication errors are a widespread problem which can, in the worst case, cause harm to patients. Errors can be corrected if documented and evaluated as a part of quality improvement. The Danish community pharmacies are committed to recording prescription corrections, dispensing errors and dispensing near misses. This study investigated the frequency and seriousness of these errors.
Methods: 40 randomly selected Danish community pharmacies collected data for a defined period. The data included four types of written report of incidents, three of which already existed at the pharmacies: prescription correction, dispensing near misses and dispensing errors. Data for the fourth type of report, on adverse drug events, were collected through a web-based reporting system piloted for the project.
Results: There were 976 cases of prescription corrections, 229 cases of near misses, 203 cases of dispensing errors and 198 cases of adverse drug events. The error rate was 23/10 000 prescriptions for prescription corrections, 1/10 000 for dispensing errors and 2/10 000 for near misses. The errors that reached the patients were pooled for separate analysis. Most of these errors, and the potentially most serious ones, occurred in the transcription stage of the dispensing process.
Conclusion: Prescribing errors were the most frequent type of error reported. Errors that reached the patients were not frequent, but most of them were potentially harmful, and the absolute number of medication errors was high, as provision of medicine is a frequent event in primary care in Denmark. Patient safety could be further improved by optimising the opportunity to learn from the incidents described.

Medication errors are a widespread problem that can sometimes cause harm to patients,[1–3] in which case the errors is called a preventable adverse drug event.[4] To improve patient safety in the Danish healthcare system, the Danish Parliament unanimously adopted the 2003 Act on Patient Safety in the Health Service. Under this act, health professionals are obliged to report adverse drug events to a national reporting system, and hospital owners and the Danish National Board of Health are obliged to respond to these reports.[5] The primary care sector is not yet included in this legislation.

An epidemiological study of adverse events in Danish hospitals, conducted in 2001, showed that the rate of admission due to adverse events was 9% of all admissions.[6] In 2004, the Danish National Board of Health received 5740 reports of adverse events from hospitals. An adverse event is defined as:

> ''an unintended event that harms the patient or carries a risk of harm, as a consequence of the action, or lack of action, of the health services''

One thousand reports were about events related to medication.[7] Only few studies in primary care have evaluated the frequency of medication errors and adverse drug events, and little research covers the community pharmacy area.[8–10] Two UK studies indicate that incidents in the dispensing process occur in community pharmacies in 0.3–0.6% of all items dispensed.[11 12] To date, no Danish studies have focused on medication errors in community pharmacy; a few studies have looked narrowly at interventions by pharmacies to detect and prevent errors in prescriptions.[13 14]

Errors are best corrected when real and potential errors are documented, reported and evaluated as part of a cycle of continuous quality improvement.[15] Internal quality requirements commit Danish community pharmacies to record incidents.[16] Furthermore, legislation demands that pharmacies record and file prescription interventions and dispensing errors.[17 18] Community pharmacies with external quality certification are also required to file near miss dispensing incidents. However, at present such reports of incidents are filed and used primarily at the local pharmacy level. It was thought that a systematic analysis of these reports of incidents from several pharmacies may identify important system errors and, thus, improve patient safety. With this in mind, a project group was set up with the following mandate:

- to measure frequency and types of error registered in community pharmacy;
- to estimate the seriousness of the errors;
- to identify potential solutions for error prevention.

This article describes the types of error registered, their frequency and their seriousness. A root cause analysis was also conducted as part of the study to establish solutions for error prevention; this analysis is reported in another article.[19]

METHOD

Data collection

In August 2004, 55 Danish community pharmacies were randomly selected from a total of 276 and invited to participate in the study. Of these, 40 pharmacies agreed to participate. (See appendix A for a detailed description of the pharmacy sector in Denmark.)

We asked the community pharmacies to collect, for a defined period, data on already registered reports on medication errors in the pharmacies: prescription corrections, dispensing near misses and dispensing errors (retrospective data). In addition, data on adverse drug events were collected through a shared

Abbreviation: SAC, Safety Assessment Code

Table 1 Description of the sample and data collection

	Retrospective data			Prospective data
Types of reports of incidents	Prescription corrections	Dispensing near misses	Dispensing errors	Adverse drug events
Number of pharmacies	40	27	40	40
Registration period	4 weeks	14 weeks	14 weeks	13 weeks

web-based reporting system (prospective data). This system was an attempt to use a reporting system similar to that used by the hospital sector in Denmark.[7] The web-based system was made available on a website shared by the community pharmacies.

The prescriptions were generated electronically, by fax or by telephone, or were handed in at the community pharmacy as a typed or handwritten prescription. Table 1 describes the sample and data collection, and table 2 gives the definitions of concepts for the project. Prior to data collection, we sent general instructions on reporting incidents to all the 40 participating community pharmacies.

Each pharmacy sent us all their retrospective data as a copy of the pharmacy's own registration. If a pharmacy did not file a given type of incident, it was asked to comment on the reason. Non-certified pharmacies were not expected to report near misses, as only pharmacies with an external quality certification are obliged to file these incidents. A total of 13 pharmacies, most of which were non-certified, reported not to have any dispensing near misses (table 1). We collected data on adverse drug events through the shared web-based reporting system designed and piloted for this study. The system was linked to explanatory help functions. Only the participating pharmacies and researchers had access to the system.

The community pharmacies anonymised patients and healthcare providers. In turn, we anonymised the pharmacies. The Danish Data Protection Agency approved the project.

Box 1: Criteria for seriousness (modified SAC score)

- Potential seriousness score 1: estimated as of minor potential inconvenience to the patient.
- Potential seriousness score 2: estimated to potentially influence the treatment of the patient, but correctable.
- Potential seriousness score 3: estimated to potentially influence the treatment of the patient to the extent that intensive treatment would be necessary, ie, admission to hospital.

Coding and analysis

Every prescription was handled as a case. Some cases included more than one incident, and so the number of incidents exceeds the number of cases. A team of three pharmacists categorised the reported incidents according to the coding system. In cases of doubt, the chief researcher responsible for the analysis was consulted.

The definition of the medication process as applied by Andersen *et al*[20] was used as a structure for coding and analysis. One coder categorised the incidences according to their occurrence in the process: during prescribing, transcription, dispensing, administration, monitoring or counselling (see table 2). Where possible, the cases were further coded into the following categories: patient; type of medication (ATC (Anatomical Therapeutic Chemical Classification System) code and product); prescriber; type of prescription (typed or handwritten, electronic, faxed, telephoned, handed over by patient); time and day of week of the incident; who pointed out the incident; action taken by the pharmacy; cause of incident; or ''other''. The coding data were subsequently entered into an SPSS (v 11.0) file.

We undertook descriptive data analysis for each of the four types of data collection. The error rate was calculated with 95% confidence intervals. The calculations were based on the number of cases reported by the participating pharmacies in

Table 2 Definitions of terms as used in the present study

	Definition (in this study)
Administration	Storage, distribution and delivery by the community pharmacy, and administration to or by the patient
Adverse drug event	An unintended event that harms the patient or carries a risk of harm, as a consequence of the action, or lack of action, of the health services. These errors will have reached the patients Prescribed medicine and over-the-counter drugs were included Prospective data
Dispensing process	Taking out and preparing the medicine, putting on the prepared label, and packing the medicine in the community pharmacy
Dispensing error	An error in connection with dispensing the prescription at the community pharmacy. These errors will have reached the patients Prescribed medicine was included Retrospective data
Dispensing near miss	An internal error detected by an employee at the community pharmacy after control but before the medicine reached the patient Prescribed medicine was included Retrospective data
Medication error	An error in any step of the medication process (prescribing, transcription, dispensing, administration and monitoring the medicine)[20]
Prescription correction	Incidents in which the community pharmacies intervened regarding administrative or clinical prescribing problems Prescribed medicine was included Retrospective data
Transcription	Transfer of data, by the community pharmacy, from prescription to label
Pooled dispensing errors	Pooled cases of retrospective dispensing errors and prospective adverse drug events. These errors will have reached the patients

Table 3 Error rate/10 000 prescriptions (retrospective data)

	Prescription corrections	Near misses	Dispensing errors
Prescriptions during the registration period	421 809	958 313	1 466 043
Number of pharmacies	40	27	40
Number of cases	976	229	203
Error rate/10 000 prescriptions	23.1	2.4	1.4
95% CI	21.7 to 24.6	2.1 to 2.7	1.2 to 1.6

relation to the estimated number of prescriptions handled by these pharmacies during the study period.

Aggregated data

The retrospective dispensing errors and prospective adverse drug events were pooled to generate a dataset of cases in which the errors had reached the patients. In the following discussion, these data are designated ''pooled dispensing errors''. The incidents were coded according to the medication process by two researchers. In cases of doubt, other colleagues were consulted.

The two datasets are different and derive from different registration periods. However, when we compared the reporting pattern, we did not find any significant differences between them.

Seriousness of incidents for the aggregated data

The Safety Assessment Code (SAC) score,[21] which is used in Danish hospitals, was used to assess the seriousness of the aggregated data.[22] The SAC score is a matrix score for assessing incidents in relation to seriousness and frequency. Because the community pharmacies could not provide information about the consequences of the incidents to the same level as hospitals, the assessment was primarily based on potential seriousness. The clinical pharmacologist in the project group made the assessment. Box 1 lists the criteria for the adjusted seriousness score. A general practitioner was consulted in cases of doubt, and a pharmacist screened the coding.

Table 4 Causes of prescription corrections (n = 1015)

	Number (%)
Clinical causes	
Leaving out basic prescription data	71 (7.0)
Community pharmacy had concerns regarding errors on the prescription	207 (20.4)
Illegible prescription	11 (1.1)
Other, eg:	232 (22.9)
Prescribing a medicine, strength, quantity or dosage that did not exist	
Patient wanted the prescription changed	
Total (clinical causes)	521 (51.3)
Administrative causes	
Medicine not immediately in stock	91 (9.0)
Medicine no longer in stock	144 (14.2)
Prescription changed for practical reasons	20 (2.0)
Problems with substitution of medicine	25 (2.5)
Problems with subsidies	80 (7.9)
False prescription	3 (0.3)
Other, eg:	55 (5.4)
Missing or wrong patient identification	
Information about the prescriber was left out	
Reported incidents illegible to the coder	76 (7.5)
Total (administrative causes)	494 (48.7)
Total	1015 (100)

Table 5 Pooled dispensing errors related to the medication process (n = 365)

	Number (%)
Errors starting in the doctor's office/ prescribing errors	19 (5.2)
Errors in transcription	237 (64.9)
Errors in the dispensing process	57 (15.6)
Errors in administration	50 (13.7)
Errors in counselling	2 (0.5)
Total	365 (100)

RESULTS

Frequency of error

The sample consisted of 976 prescription cases corresponding to 1015 incidents; there were 234 near miss incidents distributed among 229 cases, 209 dispensing incidents distributed among 203 cases and 206 adverse drug events distributed among 198 prospective cases. On the basis of the number of prescriptions handled by the participating pharmacies during the study period, we calculated the error rate for the retrospective datasets. The error rate was 23/10 000 prescriptions for prescription corrections, 1/10 000 for dispensing errors and 2/10 000 for near misses (table 3).

The prescription corrections, which were the most frequent type of error in the sample, are shown in table 4, and were evenly distributed between clinical (51.3%) and administrative (48.7%) causes. Most corrections from clinical causes related to errors or deficiencies in dosage (37.4%), strength (19.2%), dispensing form (14.4%) and quantity (11.3%).

Errors that reached the patients

The 203 retrospective dispensing error cases and the 198 prospective adverse drug event cases were categorised as errors that had reached the patients. When categorised according to the medication process, both the retrospective and the prospective cases had a similar pattern, with most cases occurred in the transcription stage (65.1% and 60.7%, respectively), followed by the dispensing stage, administration stage and prescribing stage. Consequently, the 401 cases of errors

Table 6 Seriousness of errors in the transcription stage related to error type (modified SAC score) (n = 234)

	Potential seriousness score			
	1	2	3	Total (%)
Missing score in breakable tablets	0	6	0	6 (2.6)
Double prescription	0	0	1	1 (0.4)
Wrong quantity	27	5	2	34 (14.5)
Wrong dosage	1	41	4	46 (19.7)
Wrong label	1	0	0	1 (0.4)
Wrong dispensing form	3	22	0	25 (10.7)
Wrong medicine	8	38	1	47 (20.1)
Wrong strength	2	42	7	51 (21.8)
Wrong patient identification	17	5	0	22 (9.4)
Wrong delivery	0	1	0	1 (0.4)
Total (%)	59 (25.2)	160 (68.4)	15 (6.4)	234 (100)

that reached the patients were aggregated. Of these, 365 could be categorised according to the medication process (table 5).

Transcription errors

Most of the pooled dispensing errors occurred in the transcription stage (table 5), and we could identify the type and seriousness of the error for 234/237 transcription errors (table 6); 6.4% of the errors in transcription were estimated to potentially influence the treatment of the patient to the extent that intensive treatment would be necessary. The majority of these errors were ''wrong strength'' and ''wrong dosage''. The most frequently occurring errors in the transcriptions stage were in the categories ''wrong strength'', ''wrong medicine'' and ''wrong dosage''. Incidents that led to actual harm (the patient was hospitalised) were only described in three of the 401 cases of pooled dispensing error. Thus, the frequency of incidents classified as pooled dispensing errors with an actual risk score of 3 was at least 0.7%.

DISCUSSION

Few studies have focused on medication errors in community pharmacy.[11 12 23] The studies carried out in Denmark have mostly been small and have primarily focused on prescribing interventions by community pharmacy.[13 14] This study is the first of this size, which represents a larger part of the community pharmacy sector. It is, furthermore, the first Danish study to report data on different medication errors detected in community pharmacy.

Frequency of error

Our results showed that prescribing errors were the most frequent type of error and were evenly distributed between clinical (51.3%) and administrative (48.7%) problems. The rate of error was estimated to be 23/10 000 prescriptions for prescription corrections; in keeping with the findings of other studies in community pharmacies,[8 13] most of the corrections were related to dosage. Furthermore, our results showed that a small number of errors actually reached the patient. The rate of error was 1/10 000 prescriptions for dispensing errors, but many of these errors were potentially clinically important, and three resulted in hospitalisation.

Although the frequency of occurrence of errors was low, in absolute numbers, prescription corrections and dispensing errors were frequent events, as provision of medicine is a frequent event in healthcare. In 2004, Danish pharmacies handled a total of 43 896 338 prescriptions.[24] On the basis of the present study, the total number of prescriptions handled suggests that there were 100 962 prescription corrections and 4390 dispensing errors in 2004. As seen in other studies, the rate of near misses was greater than the rate of dispensing errors.[11 12] This finding and the many prescription corrections indicate that quality control in community pharmacies has an important role in preventing errors from reaching patients.[15]

The rates of prescription corrections and dispensing errors reported in this study are lower than that reported in other studies.[8 11–14] This difference could in part be due to the detection method, which was based on self-reporting in this study, and also due to the differences in study design and operational definitions used.[8 11] In particular regard to Denmark, this difference may also be due to system improvements. Electronic prescriptions and computer prescription control have, for example, been implemented during recent years in primary care in Denmark.

The problematic stages of the medication process

Errors occur at every step of the medication process.[11 25] In the present study most of the errors that occur in community pharmacy arose in the transcription stage when data from the prescription were entered into the pharmacy system and transferred to the label. This finding does not agree with findings from other studies,[26] in which most errors were found to originate in pharmacy dispensing. This could be related to differences in the scope of activities in pharmacies in different countries. In Denmark, for instance, there is very little preparation of medicine in the pharmacies, and tablets are not counted as only original packages are dispensed.

Consistent with what others have found,[12] the most frequent type of dispensing error was ''incorrect strength'', which also led to the most serious cases.

Limitations of the study

The findings in the present study are based on data documented as medication errors by community pharmacies in their routine quality documentation. It can be seen as a strength of the study that the incidents documented here reflect what the community pharmacy staff recognises as errors. However, during the retrospective data collection, the project group became aware that the participating pharmacies were interpreting the legislation in different ways.[17] Consequently, there was not complete consensus among the pharmacies about which prescription corrections to register and file and submit to the project. Moreover, there were variations in the interpretation of the concept of ''dispensing near misses''. This calls for more precise instructions with regard to the documentation categories in the quality assurance system in the pharmacies.

An English study showed that under-reporting of incidents in community pharmacy is probably a considerable problem, and in most cases the staff would not report incidents, especially if the patient was not likely to complain outside the pharmacy.[11] We found a low frequency of prescribing errors and an even lower frequency of errors that reached the patients. As the data are based on self-reported errors, and as the retrospective data collection was based on routine recording, under-reporting cannot be ruled out. In addition, community pharmacy staff could only report errors based on their knowledge. Therefore, the data represent a conservative estimate of the frequency of errors. It would be interesting to know whether identification of errors by direct observation instead of spontaneous self-reporting would result in a higher rate of error, as seen in hospital studies.[27]

A team of three pharmacists categorised the reported incidents according to the coding system. Furthermore, the pooled dispensing errors were coded according to the medication process by two researchers, and a clinical pharmacologist assessed the seriousness of these dispensing errors. Overall, in cases of doubt, other skilled people were consulted. Use of more coders, working independently, would have strengthened the reliability further, and would have been preferable; however, this was not possibile in the present study.

The errors that reached the patients were pooled for separate analysis. The two datasets were collected over different periods. One set of data came from the community pharmacies' routine recording of dispensing errors, whereas the other developed from a new, web-based reporting system—factors which may have influenced on the reporting. Our argument for pooling the data is that we found a comparable distribution of the main types of error in the two datasets. However, a more detailed comparison might have revealed differences.

RECOMMENDATIONS

The Danish community pharmacy sector has an established culture of documenting. However, there were differences in the quality of documentation by the pharmacies participating in the present study, and we recommend that this culture be

developed further, because more consistent quality in the recording would strengthen the quality of the data. An electronic reporting system might be helpful. At present, the Danish hospital sector reports adverse events to a database of the Danish National Board of Health.[7] The prospective data collection in the present study was an attempt to test a similar reporting system in a community pharmacy setting. We thought the web-based reporting system had some advantages. Compared with the copies of the pharmacies' individual, written medication error reports, the web-based reports were more legible and represented more uniform reporting. Another advantage of the web-based system was a systematic inclusion of essential information because of the standardised, closed questions that had to be answered before the report could be sent. These experiences can be of use to others who are in the process of improving or developing a reporting system that receives information from pharmacies for the purpose of improving patient safety.

Web-based incident reporting is in place in a few other countries. For instance, under the terms of the new community pharmacy contract, pharmacies in England and Wales have been required to report patient safety incidents to the UK's National Patient Safety Agency since April 2005. The system warrants anonymity and confidentiality, and reporting can be done via the Agency's website.[28] Similar systems are being tested in other countries.[29] As mentioned above, pharmacy systems differ from country to country and this complicates the synthesis and interpretation of findings. A standardised reporting system would be helpful when comparing data across countries.

This study cannot in itself vouch that a reporting system modelled on the hospital sector will reduce the number of medication errors in the community pharmacy sector. Compared with the hospital sector, safety in primary care has received relatively little attention. It is recommended that studies develop models and methods relevant to the primary sector, and cost–benefit analyses of a continuous reporting system in the primary sector be carried out in more countries.

CONCLUSION

This study aimed to measure the frequency and types of error registered in Danish community pharmacies. The data are based on spontaneous reporting and, accordingly, represent a conservative estimate of the frequency of errors. The results showed that prescribing errors were the most frequent type of error reported, and the error rate was 23/10 000 prescriptions for prescription corrections. Errors that reached the patients were not frequent, but most were potentially harmful, and the absolute number of errors is high, as provision of medicines is a frequent event in primary care.

The errors that reached the patients were pooled. The pooled analysis showed that most of these errors occurred in the transcription stage, when data from the prescription are entered into the pharmacy system and transferred to the label. In addition, the transcription stage was also assessed as the stage with the most serious errors.

The community pharmacy sector in Denmark already has a strong culture of documenting errors. We recommend that this culture is developed further. A systematic and more uniform registration of medication errors in community pharmacy will strengthen the quality of the data and help optimise the possibilities to learn from the described incidents and, hence, improve patient safety.

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APPENDIX A

STRUCTURE OF THE PHARMACY SECTOR IN DENMARK

The pharmacy sector is an important part of the primary health system and is in this capacity subject to indepth state regulation. The proprietor pharmacist owns their community pharmacy. This means that the proprietor pharmacist is economically responsible for the financing of the pharmacy and its operation. At the same time it is the state (the Ministry of the Interior and Health, and the Medicines Agency) that determines the number of pharmacies and branch pharmacies, and their location. To become a proprietor pharmacist a licence must also be obtained from the Ministry of the Interior and Health, which appoints new proprietor pharmacists.[1] The pharmacy sector is divided into several units:

- *Pharmacy*. A pharmacy must retail all types of pharmaceutical, and also keep suitable and adequate stock based on the demand at the place in question. And if the pharmacy is asked to do so, it is obliged to procure a medicine that is not in stock.
- *Branch pharmacy*. A branch pharmacy is attached to a pharmacy and is operated at the pharmacy's expense. The branch pharmacy has its own independent premises and professionally qualified staff, one or more of whom must be a pharmacist. Branch pharmacies may retail the same products as the pharmacy and may also dispense prescription medicine.
- *Pharmacy outlet*. A pharmacy outlet is also a unit attached to a pharmacy and operated at the cost of the pharmacy in independent premises. The pharmacy outlet has professionally qualified staff, such as pharmacy technicians, but it does not have to have an employed pharmacist. The pharmacy outlet may retail over-the-counter (OTC) drugs and other products that are also carried by pharmacies, but it may not sell prescription medicine.
- *OTC outlet*. The OTC outlet premises does not belonging to the pharmacy, it is typically in another store. The outlet receives products from a specific pharmacy and is operated by a store manager with whom the proprietor pharmacist has an agreement. The store manager typically has no training within the pharmacy sector. This means that they may carry only a limited assortment of medicines. OTC outlets may also provide customers with prescription medicine and other pharmacy-restricted medicine that has been dispensed at the pharmacy (including branch pharmacies) to which the outlet is attached.
- *Delivery facilities*. Delivery facilities do not stock medicine. They receive addressed dispatches from one or several pharmacies and pass them on to the individual customer.[2] Since 1 October 2001 the pharmacies no longer have a monopoly to sell certain types of OTC medicine. It is now also possible for supermarkets, petrol stations and other parts of the retail trade to sell drugs.[1]

The number of pharmacies and units changes slightly all the time. In 2004, the Danish pharmacy sector consisted of 276 pharmacies, 48 branch pharmacies, 139 pharmacy outlets, 715 OTC outlets and 278 delivery facilities.[3] On average there are about 15 000 inhabitants per unit dispensing on prescription (ie, pharmacy and branch pharmacy) in Denmark.[2]

REFERENCES

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