ERROR MANAGEMENT

Preventing medication errors in community pharmacy: root-cause analysis of transcription errors

P Knudsen, H Herborg, A R Mortensen, M Knudsen, A Hellebek

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See end of article for authors' affiliations

Correspondence to: P Knudsen, Pharmakon a/s, Danish College of Pharmacy Practice, DK-3400 Hillerød, Denmark; pkn@pharmakon.dk

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Background: Medication errors can have serious consequences for patients, and medication safety is essential to pharmaceutical care. Insight is needed into the vulnerability of the working process at community pharmacies to identify what causes error incidents, so that the system can be improved to enhance patient safety.

Methods: 40 randomly selected Danish community pharmacies collected data on medication errors. Cases that reached patients were analysed, and the most serious cases were selected for root-cause analyses by an interdisciplinary analysis team.

Results: 401 cases had reached patients and a substantial number of them had possible clinical significance. Most of these errors were made in the transcription stage, and the most serious were errors in strength and dosage. The analysis team identified four root causes: handwritten prescriptions; ''traps'' such as similarities in packaging or names, or strength and dosage stated in misleading ways; lack of effective control of prescription label and medicine; and lack of concentration caused by interruptions.

Conclusion: A substantial number of the medication errors identified at pharmacies that reach patients have possible clinical significance. Root-cause analysis shows potential for identifying the underlying causes of the incidents and for providing a basis for action to improve patient safety.

Medication errors may have serious consequences for patients.[1] As medication safety is essential to pharmaceutical care, more insight is needed into the vulnerability of the working process at community pharmacies. It is important to identify what causes incidents, so that improvement can be initiated. More often, it is only the actions of individuals that are considered the cause of error. However, two approaches to the problem of human fallibility exist: the person and the system. As it is difficult to change the human nature, it is better to look into the conditions under which people work. Over the past decade, there has been increasing concern about developing methods to manage error. Error management has two components: limiting incidents and creating systems that are better able to tolerate the occurrence of errors.[2]

Compared with the hospital sector, there is little data concerning the epidemiology and typology of errors in primary care, particularly in relation to community pharmacies.[3] There is even less data in the public domain on the causes and circumstances of medication incidents in community pharmacies.[4–6] In a UK study from 2005,[4] community pharmacists were asked to include causes and circumstances associated with the errors they recorded. The main reported causes of incidents involved misreading the prescription, selecting the previous drug or dose from the patient's medication record on the pharmacy computer, and confusing similar medicine names or packaging. The circumstances associated with the incidents included the pharmacy being busier than usual and telephone interruptions.[4] A broader view in the health literature points to causes such as handwritten and incomplete prescriptions, and names and packaging that look and sound alike. The use of zeros and decimal points can also cause problems. Other causes are inadequate training, staff shortages, overwork and fatigue. Lack of clinical decision support and inadequate checks and balances in the medication process constitute another problem.[7–9]

A fundamental requirement for improving patient safety is to set up an incident reporting system.[8 9] In 2001, the *Act on patient safety in the health service* was adopted in Denmark,[10] committing health personnel to report adverse events, and hospital owners and the National Board of Health to act on these reports. This Act does not, however, comprise the primary sector.

Legislation[11 12] and the quality demands of their professional organisation[13] obligate Danish community pharmacies to record the prescription errors and any dispensing errors they detect. Pharmacies with a specific certification also have to record near-misses. At present, these incident reports are kept at the respective pharmacies, and thus this body of experience-based knowledge does not generally reach a wider audience. A systematic analysis of incident reports from several pharmacies could identify important system errors and thus help improve patient safety.

Hence, a study was conducted in 2004–5 to collect medication-error reports from 40 community pharmacies in Denmark. Medication errors can be defined in many ways,[14] and we used the following definition for this project: ''error in any step of the medication process (prescribing, transcription, dispensing, administration and monitoring the medicine)''.[15]

The purpose of the study was to increase patient safety in relation to the use of medicines in primary care, and the objectives were:

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

The primary focus of this article is on establishing potential solutions to prevent errors. The type of errors registered, their frequency and seriousness are presented in a separate article.[16]

METHODS

Setting

Forty randomly selected Danish community pharmacies collected the data, which included four different types of written reports of incidents detected at the pharmacies (table 1).

Table 1 Data collection of four types of medication errors detected at the pharmacies

Prescription corrections	Documentation of the incidents in which community pharmacies intervened regarding administrative or clinical prescribing problems. Copies of these already existing reports were sent to the research group. The data were collected retrospectively over a 4-week period. Medicine prescribed for humans was included.
Reports on dispensing near-misses	Documentation of internal errors detected by an employee at the community pharmacy after control but before the medicine reaches the patient. Copies of these already existing reports were sent to the research group. The data were collected retrospectively over a 14-week period. 13 pharmacies stated that they did not record near-misses (the majority did not have external quality certification). Medicine prescribed for humans was included.
Reports on dispensing errors	Documentation of medication errors that reached patients. Copies of these already existing reports were sent to the research group. The data were collected retrospectively over a 14-week period. Medicine prescribed for humans was included.
Reports on adverse drug events	Documentation of unintended events that reached patients, and that harm the patient or carry a risk of harm, as a consequence of the action or lack of action of the health services. A shared web-based reporting system was piloted for this part of the project to test the existing reporting system used at Danish hospitals[10] on the community pharmacy sector. The data were collected prospectively over a 13-week period. The researchers and participating pharmacies had access to the database through the community pharmacies' shared website. Medicine prescribed for humans and OTC medicine were included.

OTC, over the counter medicine.

Prior to data collection, the pharmacies were instructed about what types of incidents the project covered and how to report them. The community pharmacies anonymised patients and healthcare providers. In turn, the researchers anonymised the pharmacies. The project was approved by the Danish Data Protection Agency. Data collection and coding are presented in more detail in a separate article.[16]

Selection of data for root-cause analysis

The project group found cases that had reached patients to be especially problematic and decided to pool the retrospective dispensing errors and prospective adverse drug events from the sample to generate a dataset for these cases. These data are designated as ''pooled dispensing errors'' in the following.

The incidents were coded according to the medication process by two researchers. In cases of doubt, other colleagues were consulted.

Both the retrospective and the prospective cases showed that most cases occurred in the transcription stage, followed by the dispensing stage, administration stage and prescribing stage.

The most serious cases among the pooled dispensing errors were selected for root cause. The clinical pharmacologist in the project group assessed potential seriousness based on a modified Safety Assessment Code Score (box 1).[17] A general practitioner was consulted in cases of doubt. A pharmacist then screened the coding. The assessment is described in detail in a separate article.[16]

Root-cause analysis

Understanding why an event occurred is the key to learning from mistakes and developing effective recommendations to prevent the same error from occurring twice. Root-cause analysis is a technique for undertaking a systematic investigation that looks beyond the individuals concerned and seeks to understand the causes and environmental context in which the incident happened. The process involves data collection, cause charting, root cause identification, as well as generating and implementing recommendations.[18 19]

An interdisciplinary analysis team performed the root-cause analysis in this study (box 2).

Three 3-h meetings were held. Two people were unable to attend the second meeting.

RESULTS

Priority of topics for root-cause analysis

In the sample, 401 errors had reached patients. Most of the errors (n = 237) were found in the transcription stage, defined in this study as the transfer of data from prescription to medicine label at the pharmacy. The seriousness of the incidents in this stage could be estimated in 234 cases: the most serious incidents were errors in strength (n = 51 of which seven had a seriousness score of 3) and dosage (n = 46 of which four had a seriousness score of 3). These incidents were selected for root-cause analysis by the interdisciplinary analysis team. The data are described in more detail in another article.[16]

Root-cause analysis and identification

Firstly, the interdisciplinary analysis team identified the problem areas related to the transcription errors in strength and dosage. The team pinpointed three areas.

a. The pharmacy staff could read/decode the prescription incorrectly.
b. The staff could choose the wrong line in the computer system.
c. The staff could make an incorrect manual data entry.

Secondly, the analysis team tried to identify why the incidents had happened by analysing the problem areas. The team identified four root causes;

Handwritten prescriptions

The analysis team determined that handwritten prescriptions increased the risk of misreading, confusion and misunderstanding, as they were often difficult to read and incomplete (box 3).

Box 1: Criteria for seriousness (modified Safety Assessment Code)

- Potential seriousness score 1: may provide minor inconvenience to the patient.
- Potential seriousness score 2: may influence the treatment of the patient, but correctable.
- Potential seriousness score 3: may influence the treatment of the patient to the extent that intensive treatment may be necessary—that is, admission to hospital.

Box 2: The analysis team

Interdisciplinary analysis team

- Proprietor pharmacist (owner of a community pharmacy)
- Experienced pharmacist employed at a community pharmacy
- Newly educated pharmacist employed at a community pharmacy
- Newly educated pharmacy technician employed at a community pharmacy
- Experienced pharmacy technician employed at a community pharmacy
- General practitioner
- Project coordinator and experienced pharmacist

Team leader

- Patient safety expert and clinical pharmacologist, member of the project group

See appendix A for a description of a specific education.

Traps

In general, traps can be a source of confusion or misunderstanding. The analysis team pointed out that strength and dosage can be difficult to decode for certain medicines, either because of complexity or because of potential for misreading. Other traps are names and packaging that look and sound alike (box 4).

Lack of effective control of prescription, label and medicine

The analysis team determined that lack of effective control systems causes errors (box 5).

Lack of concentration caused by interruptions

The analysis team pointed to the fact that community pharmacies have a ''culture of interruption''. If there were fewer interruptions, pharmacy staff could concentrate better, and consequently fall in fewer traps and undertake more effective control (box 6).

Box 3: Examples of cases of transcription errors involving handwritten prescriptions

- The handwritten prescription for Mirtazepam (mirtazapine) 30 mg stated ''1 tablet daily''. An inexperienced trainee handled the prescription, misreading the instructions as ''2 tablets daily''. The error was not discovered in the control. Control did not detect the error, which was first discovered the third time the patient handed in the prescription.
- A handwritten prescription for morphine 10 mg was misread in the transcription. Strength and unit were written close together on the prescription, which led to the misreading. The error was not detected in the control phase.
- The handwritten prescription stated Prednisone 2.5 mg. However, the decimal point was indistinct and was consequently overseen in the transcription. The patient received prednisone 25 mg as a result.

Root-cause analysis: recommendations

The analysis team formulated an action plan based on the four root causes. They proposed new projects and made suggestions to improve patient safety.

Handwritten prescriptions

- Local community pharmacies could offer to teach doctors with limited prescribing experience about safe practice to ensure that prescriptions contain all necessary information and are formulated unambiguously (particularly in hospitals, the source of the most problematic prescriptions).
- Local community pharmacies could offer to audit prescriptions as part of hospital risk-management procedures. This would help hospitals recognise prescription problems and give them the opportunity to follow up.
- Eliminate handwritten prescriptions altogether.

Traps

- Problems related to communication between doctors and pharmacy computer systems should be addressed to software suppliers.
- Information about traps should be readily available at community pharmacies. A list of traps should be at hand on paper as well as displayed on pharmacies' website. A working group, primarily consisting of pharmacy staff members, should maintain the list. The list should also be sent to the proper authorities and medicine industry.

Lack of effective control of prescription, label and medicine

- Model for self-evaluation should be designed and made available to community pharmacies. One suggestion is for pharmacy staff to double-check one another occasionally to evaluate the efficacy of self-checking, and to agree on what constitutes self-checking components.
- Software suppliers should be contacted with two suggestions for improvements in the control phase. One step would be better software design allowing the final screen display to show the decisions made in transcription. A second step would be to design the screen display to show the entire line of dosage and strength options during the transcription process, which is not always possible at present.
- A conference should be arranged for software suppliers. Discussion should include the different computer systems used in community pharmacies and medical practices, as well as user errors related to design.
- Better software with advanced automatic decision support should be designed. Decision support should encompass control for deviation from usual strength or dosage, and automatic interaction control.
- The pharmacy could compare a patient's prescriptions to previous services rendered to the patient to identify deviations that could be the result of an error. This step might necessitate legislative changes.

Lack of concentration caused by interruptions

- Steps should be taken to prevent interruptions in the control phase at community pharmacies. One step would be a change in culture. Interruptions could be limited through a

Box 4: Examples of traps from a brainstorming list made by the interdisciplinary analysis team

Complex dosage

- Mg/0.5 ml

Many different strengths

- Allergy vaccines

Dosage once a week instead of once a day

- Antabus (disulfiram)
- Methotrexate

Names that look and sound alike

- Havrix 1 ml and Havrix 0.5 ml (hepatitis A vaccine, inactivated)
- Xalatan (Latanoprost) and Xalcom (Timolol + prostaglandin F analogue)
- Prednison (prednisone) and Prednisolon (prednisolone)
- Levemir penfill (insulin in cartridge) and Levemir flexpen (insulin in injection pen)
- Spirocort inhalation spray and Spirocort inhalation aerosol (budesonide)
- Orfiril and Orfiril retard and Orfiril long (valproate)

written ''interruption policy'' for each pharmacy. A general inspiration paper should be drawn up.

- The Danish Pharmaceutical Association could put the interruption problem on its agenda and thus inspire community pharmacies through a trickle-down effect.

The project group found substantial learning potential in the remaining incidents (prescription errors, other transcription errors, dispensing errors, administration errors and counselling errors), and therefore performed a minor supplementary root-cause analysis on these incidents. In addition to the recommendations made by the analysis group, the project group recommended supplementing the list of traps with photos of products that can present problems in the dispensing stage. Other recommendations were to double-check the identity of patients at the counter to avoid administrative errors, and to conduct root-cause analysis on the records of patients whose medicine is delivered, as this group in particular risks administrative and counselling problems. The project group found very few counselling errors, which they attribute to lack of feedback from general practitioners about the problem. The project group recommends action be taken in this area.

DISCUSSION

To date, most of the literature on the cause of medication errors originates from the hospital sector.[3] This is the first study of its size to collect and assess already recorded incidents at community pharmacies, to use root-cause analysis to detect system errors and to propose solutions.

Causes and solutions

The root-cause analysis identified four root causes related to errors in dosage and strength in the transcription stage. The causes identified are known in the literature, although most of the evidence originates from the hospital sector.[3] As found in another community pharmacy study,[4] handwritten prescriptions are a source of error in the transcription phase. As the literature points out, handwritten prescriptions can be illegible and ambiguous,[4 9] forcing the person reading the prescription to make an interpretation.[9] Incomplete prescriptions also increase the risk of error.[8] The analysis team recommended eliminating handwritten prescriptions in favour of computerised orders, a

Box 5: Examples of cases of transcription errors involving lack of effective control

- A patient was given Trimonil retard (carbamazepine) 200 mg instead of the prescribed Trimonil retard 400 mg. The error was made in the transcription stage. Someone other than the person doing the transcribing took out the medicine. A third person undertook the first control. A fourth person carried out a second control, and a fifth person handed over the medicine to the patient. No one discovered the error in strength.
- The dosage for Dimitone (carvedilol) 0.25 mg was transcribed incorrectly on the medicine label as ''1 tablet in the morning and 1 tablet in the evening'' rather than the correct ''1 tablet in the morning and 2 tablets in the evening''. The error was not discovered until the third time the patient handed in the prescription. The first time the prescription was handed in, one person alone did the transcribing, the control (barcode control), and handed over the medicine. The second time, one person alone did the transcribing and handed over the medicine. No barcode control was made. The error was discovered the third time around.
- The dosage for Coversyl (perindopril) 4 mg was transcribed incorrectly on the medicine label as ''1 tablet daily'' instead of the correct ''2 tablets daily''. The error was not discovered until the fourth time the patient handed in the prescription. Pharmacy instructions state that a control should consist of a barcode control and a manual control of prescription, label and medicine. For some reason, these controls had not been effective enough to catch the error.

Box 6: Examples of cases of transcription errors involving interruptions

- A patient was given a Durogesic patch (fentanyl) 50 mg instead of the prescribed Durogesic patch 25 mg. The error occurred during the changeover of a shift. The pharmacist was conducting a barcode control at the end of a shift and became stressed due to time pressure.
- A patient was given Diclon (a non-steroidal anti-inflammatory drug) 50 mg instead of the prescribed Diclon 25 mg. The error occurred in the transcription stage, but was not discovered when the medicine was dispensed or handed over to the patient. In answer to the question of possible solutions, the respondent simply stated ''peace during transcription'' in the case notes.
- A prescription for Surlid (roxithromycin) 300 mg, 10 tablets was transcribed incorrectly as Surlid 300 mg, 7 tablets. One person handled the entire medicine transaction in an area at the counter designed for this. In answer to the question of possible solutions, the respondent stated: ''not so much talk while transcribing and controlling the prescription''.

step supported by many other sources.[6–9 20–23] Computerised orders would enhance patient safety by providing automatic clinical-decision support and including all required information worded unambiguously. In Denmark, it has been possible for doctors to transfer prescriptions electronically to pharmacies since 1990. The analysis team also recommended that community pharmacies and doctors work together to address the problem of handwritten prescriptions.

Another root cause identified is traps such as medicines that look or sound alike. This is a familiar cause of medication errors in the literature.[4 7–9 23] In agreement with others,[7] the analysis team considers it important to involve the medical industry and regulatory authorities in future initiatives and steps to eliminate this problem. In the meantime, these traps should be minimised. One step could be to institute non-alphabetic storage of medicines to separate products that are easily confused.[23] As also recommended by others,[24] the analysis team suggested developing a warning system: a list of traps or alerts on the storage shelves or built into the pharmacy computer system.

A third cause of error identified is the lack of effective control of prescription, label and medicine at the pharmacy. Control could be divided into own control and decision support. Own control could be a final display of one's choices during transcription on the computer screen. Routines are also important, and in keeping with the recommendations of others,[9] the analysis team recommended evaluations of employees' own checks. Consistent with other findings,[21 24] the analysis team also suggested computerised decision support and automatic interaction control.

Although systems and technology can provide substantial help, looking into the culture and working processes at community pharmacies is also essential. In keeping with other findings from community research[4 5] the analysis group pointed out that interruptions and distractions also cause incidents.

Strengths and limitations

Effective error reduction requires that various actors and disciplines have a thorough understanding of the complex medication-use system.[24] The project successfully established an interdisciplinary analysis team to perform root-cause analysis of medication incidents at community pharmacies. The size and composition of the group was suitable. However, looking back, the group would like to have had a general practitioner's receptionist on the team as well, because this person has an important role in handling prescriptions in general practice.

This project has shown that it is possible to use a voluntary reporting system to identify problematic stages in the medication process at community pharmacies, and to learn from such data and hence improve patient safety. It could be discussed whether the root-cause analysis identified all the important recommendations. The project group found considerable learning potential in the remaining incidents as well. More time was needed to conduct root-cause analysis on all important areas.

Changes in working procedures and quality interventions must be followed. Therefore, continuous monitoring of medication errors and regular performance of root-cause analyses is recommended to bring about a continuous and profound quality improvement.

The two datasets used in the analysis were different and derived from different registration periods. However, when compared, they were similar in distribution in relation to the medication process, and this was the argument for pooling the data. A more detailed comparison might have revealed differences.

Two researchers coded the pooled dispensing errors according to the medication process. A clinical pharmacologist assessed the seriousness of these dispensing errors and identified the cases for root-cause analysis. A pharmacist screened the coding. Overall, other skilled people were consulted in cases of doubt. Having more independent coders would have been preferable and further strengthened reliability; however, that was not possible for this study.

CONCLUSION

This study showed that a substantial number of medication errors identified at community pharmacies that reach patients have possible clinical significance.

The most serious errors were found in the transcription stage and related to strength and dosage. An interdisciplinary analysis team identified four root causes for these serious incidents.

- Handwritten prescriptions
- Traps such as similarities in packaging or names, or strength and dosage stated in misleading ways
- Lack of effective control of prescription label and medicine
- Lack of concentration caused by interruptions

The analysis team proposed new projects and made suggestions to improve patient safety.

This project has shown that it is possible to use a voluntary reporting system to identify problematic stages in the medication process at community pharmacies, and to learn from the data thus generated. Root-cause analysis has shown potential in the process of gaining insight into the vulnerability of the medicine process at the community pharmacy, by identifying what causes these incidents and by supporting recommendations to increase patient safety.

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Authors' affiliations

P Knudsen, H Herborg, Pharmakon, Danish College of Pharmacy Practice, Hillerød, Denmark
A R Mortensen, The Danish Pharmaceutical Association, Copenhagen K, Denmark
M Knudsen, (Formerly) The Danish Pharmaceutical Association, Copenhagen K, Denmark
A Hellebek, Danish Society for Patient Safety, Hvidovre Hospital, Hvidovre, Denmark

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APPENDIX A

Danish pharmacists

The curriculum aims to provide a scientific platform of theoretical knowledge, ethical, critical and analytical methods, and practical skills in the pharmaceutical sciences. The 5-year programme in pharmacy (a 3-year bachelor's programme followed by a 2-year MSc programme) focuses on the perception of the pharmacist as a drug specialist.

Consequently, the curriculum primarily targets employment in the pharmaceutical sector (the pharmaceutical industry, community pharmacies and hospital pharmacies) and in regulatory bodies. Research-based teaching, subject integration and problem-based learning give students the scientific background for positions in both the private and the public sectors—wherever teamwork in the biological, chemical and pharmaceutical fields is needed (http://www.dfuni.dk/generelt/index_uk.html).

Danish pharmacy technician

Pharmacy technicians complete a 3-year training programme held in part at the pharmacy, and in part at Pharmakon (Danish College of Pharmacy, Hillerød, Denmark). Pharmacy technicians are expected to be able to independently advise and inform customers about prophylaxis, health and treating ordinary minor problems with over-the-counter products and other items sold at the pharmacy. They are expected to be able to explain how to take and store prescribed medicines, and to point out expiry dates. Most pharmacy technicians work in community or hospital pharmacies, but there are other job opportunities, such as in the pharmaceutical industry (http://www.farmakonomuddannelsen.dk/page.php?emne_id = 2976).

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