Information technology and medication safety

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CLASSIFICATION OF MEDICATION INCIDENTS ASSOCIATED WITH INFORMATION TECHNOLOGY

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ABSTRACT

Introduction: Information technology (IT) plays a pivotal role in improving patient safety but can also cause new problems for patient safety. This study analyzed the nature and consequences of a large sample of IT-related medication incidents, as reported by health-care professionals in community pharmacies and hospitals.

Methods: The medication incidents that were submitted to the Dutch Central Medication incidents Registration (CMR) reporting system were analyzed from the perspective of the healthcare professional with the classification of Magrabi et al. During classification new terms were added, if necessary.

Measurements: Descriptive statistics
Main measures: the principal source of the IT-related problem, the nature of the error.
Additional measures: consequences of incidents, IT systems, phases of the medication process

Results: From March 2010 to February 2011 the CMR received 4161 incidents: 1643 (39.5%) incidents from community pharmacies and 2518 (60.5%) incidents from hospitals. Eventually 1 of 6 incidents (16.1%, n=668) were related to IT; in community pharmacies more incidents (21.5%, n=351) were related to IT than in hospitals (12.6%, n=317).
In community pharmacies, 41.0% (n=150) of the incidents were about choosing the wrong medicine. Most of the erroneous exchanges were associated with the confusion of medicine names and poor design of screens. In hospitals 55.3% (n=187) of the incidents concerned human-machine interaction-related input during the use of computerized pre-scriber order entry (CPOE). These use problems were also a major problem in pharmacy information systems outside of the hospital.

Conclusion: A large sample of incidents shows that many of the incidents are related to IT, both in community pharmacies and in hospitals. The interaction between human and machine plays a pivotal role in the IT incidents in both settings.

INTRODUCTION

In 2001 the Institute of Medicine Committee on the Quality of Health System for the 21st Century predicted that Information Technology (IT) would play a pivotal role in improving patient safety [1]. IT can facilitate access to medical and medication information, assist with calculations, perform checks (in real time or afterward), assist with monitoring, and support communication between healthcare professionals [2-5]. In particular, the introduction of Computerized Physician Order Entry (CPOE) systems created high expectations for enhancing patient safety in drug treatment. Not surprisingly early studies of the introduction of IT in the healthcare sector-focused only on the benefits of IT tools. For example, several studies investigated the implementation of CPOE in hospitals and its effects. Most of these studies showed a decrease in prescribing error rates (ranging from 29 to 96%) after implementation of CPOE [6]. However, it was also found that IT can cause new problems for patient safety [6-10]. An example of an IT-related incident is the juxtaposition error in CPOE. In a juxtaposition error, the CPOE users may unintentionally select a wrong item or patient because the items are close to each other on the screen [11]. Problems may also arise from the use of other technology such as health information systems, barcode scanning systems, automated dispensing cabinets, printers, and infusion pumps.

To get an insight into such IT-related incidents an instrument for measurement and analysis is needed. In a qualitative and quantitative study in a hospital, Koppel et al. [12] divided the incidents into two groups: human-machine interaction-related problems and information errors generated by fragmentation of data. With interviews, focus groups, shadowing, and observations they identified 22 situations in which CPOE increased the probability of prescribing errors. Magrabi et al. [13] proposed a classification of IT-related incidents based on an analysis of patient safety incidents associated with computer use. They analyzed 111 incidents from hospitals which were derived from a voluntary reporting system in Australia to explore the unintended consequences related to IT. In a second study Magrabi et al. [14] expanded their original classification after analyzing 436 IT manufacturer incidents, which had been submitted to the US Food and Drug Administration Manufacturer and User Facility Device Experience (MAUDE) database. Manufacturers in the USA are required to report medical device malfunction to MAUDE and manufacturers voluntarily report IT-related incidents to MAUDE. The usefulness of the resulting classification across different healthcare settings has yet to be tested. This study therefore aimed at the analysis of the nature and consequences of a large sample of IT-related medication incidents, as reported by Dutch healthcare professionals in community pharmacies and hospitals, using the most recently adapted version of the classification of Magrabi et al. [14].

METHODS

Setting

In The Netherlands, there were 93 hospitals and 1,997 community pharmacies in 2012 [15,16]. Hospitals and community pharmacies have a long history of implementing IT tools, and both have started in 2006 and 2010 respectively to report their medication incidents to a nationwide Dutch reporting system: Central Medication incidents Registration (CMR) [17,18]. The general picture is as follows, all hospital pharmacies and community pharmacies nowadays have a computer system for entering prescriptions. CPOE is not yet fully implemented in all hospitals. In a recent study using questionnaires, CPOE was used or being implemented by 64 of these 72 responding hospitals. In these hospitals, ten different CPOE systems were used [16]. All primary care physicians use CPOE and electronic medical records. Despite the use of CPOE by primary care physicians, not all prescriptions can be transmitted electronically to the pharmacy, because of a lack of system connectivity. Both hospitals and community pharmacies have integrated clinical decision support systems in their IT systems. The pharmacy staff generally uses barcode scanning during dispensing. Compounding is generally supported by electronic protocols and in-process controls (e.g., checking of batch numbers, monitoring the correct type and amount of ingredients with barcode scanning and linked weighing balances).

Data source

For this study, we used a subset of the reported medication incidents that were sent by hospitals and community pharmacies to the Dutch CMR database from March 2010 to February 2011. These incidents had been already analyzed for a general study about the CMR. The collection and analysis of the incidents are exempt from medical ethical approval by the Dutch Clinical Trial law as it does not compromise the integrity of patients. All data were handled according to the privacy legislation in The Netherlands [18].

Identification of relevant incidents: development of a search tool

A string of search terms referring to IT was developed for identifying text fragments in the free text description. An initial set of terms was derived from the literature and adapted on the basis of the experiences of members of the research team (KCC, PDS) with the weekly screening of incidents to the CMR [18]. This initial set of terms was applied to a set of 100 incidents that had been randomly selected from the database. The same set of 100 incidents was also analyzed manually by researcher KCC. The researcher read the free text description and decided for each report whether the incident was related to IT (see Appendix A for the chapters and items on the CMR reporting form). Both selections (after applying the set of search terms and after manual analysis) were compared, on the basis of which the set of terms was adapted. Eventually, this process was iterated five times until

no new terms emerged. To check this set of terms, a second researcher (WVN) followed the same iterative method, and if necessary, the set of terms was expanded with new terms. Researcher WVN applied the set of terms once to a different set of 100 incidents and manually checked these for comparison. The final set of search terms consisted of unique 121 items, and some words were repeated in misspellings or a part of the word (see Appendix B for the list of 121 search terms).

Identification of relevant incidents: application of the search tool

The final set of search terms was applied to the CMR incidents that had been reported in the period of March 2010 up to February 2011. The incidents thus identified were independently reviewed by two researchers (KCC and WVN). They selected incidents if they perceived that technology had somehow contributed to the incident. The resulting incidents were subsequently divided into three groups:

- both researchers assessed that the incident was suitable for inclusion
- both researchers assessed that the incident was not suitable for inclusion (exclusion)
- one or both researchers had doubts about the suitability of the incident

The latter category of incidents was reviewed by a third researcher (PDS) to make a final decision on inclusion or exclusion.

After reviewing duplicate incidents were removed (seven incidents from community pharmacies and one incident from hospitals). During analysis, our insight into IT incidents deepened, and eventually, we removed six incidents because they had been mistakenly selected initially (one incident from community pharmacy and five incidents from hospitals).

Classification of relevant incidents

The two researchers (KCC, WVN) analyzed and classified 200 incidents together to become accustomed to the analyzing method and with the axes of the most recent Magrabi classification, which was published in 2012 [14]. The remaining incidents were then independently analyzed and classified by the two researchers. They subsequently came together to compare their results and to reach consensus in the classification of the incidents. If an incident described more than one IT-related incident, the researchers classified all the problems separately. For the incidents which were independently analyzed, the percentages of the agreement were calculated. The percentages of agreement were calculated for the two axes (the principal source of the IT-related problem and the nature of the error) and the additional category IT system and phases of the medication process. Within the incidents from community pharmacies, the percentages of agreement ranged from 85.8% to 93.3% and within hospital incidents from 52.7% to 80.0%. For both the community pharmacies and the hospitals the percentages of agreement were lowest for the axis of the nature of the error.

This classification consists of two axes: the principal source of the IT-related problem ('machine-related error' or 'human-machine interaction related error') and the nature of the error (problem). Magrabi et al. subdivide the latter axis (the nature of the error) into incidents related to input (data entry), to output (data retrieval), and to transfer (transfer of data between systems). In addition, Magrabi et al. had two separate items in the classification which were not linked to input, transfer or output (Contributing factors and General technical). The contributing factors were not strictly related to IT, and we did not find examples in our analysis. The general technical terms were rearranged during our classification and linked to input, transfers or output. In total the Magrabi classification consists of 32 preferred terms, e.g., wrong input, (machine) not alerted, data loss, etcetera. During the classification of the CMR incidents, new preferred terms were added, if the Magrabi classification could not cover the incident adequately. For the axis 'nature of the error,' the two researchers maintained the subdivision input, transfer, and output. The preferred term 'wrong input' was elaborated by adding nine new preferred subterms: wrong patient; wrong medicine; wrong dose; wrong duration of therapy; wrong time of administration; wrong pump speed; wrong prescriber; duplicate input; and other wrong input. An extra subdivision of five preferred terms for wrong medicine was considered necessary to classify the incidents in sufficient detail. For the preferred term 'Not done' two new preferred sub terms were added. The researchers also added five new preferred terms in the subdivision output (data retrieval) and two new terms in the subdivision transfer (data of transfer) (See table 1 and figure 1).

After categorizing the IT incidents using the Magrabi classification as described above, further characterization of the incidents was performed by designating the IT related problem to the IT system involved (table 2) and the specific phase of the medication process into which the medication incident had occurred (table 3). Information about the consequences of the incidents was collected directly from the incident report forms (see Appendix A for the chapters and items on the CMR reporting form).

RESULTS

Identification of relevant incidents.

In the period of March 2010 up to February 2011, the CMR received 4161incidents. Healthcare providers working in *community pharmacies* submitted 1643 (39.5%) incidents and those in *hospitals* submitted 2518 (60.5%) incidents. The set of IT-related search terms yielded 624 incidents from *community pharmacies* and 877 incidents from *hospitals*. After reviewing by two researchers (KCC, WVN), 16.1% (668/4161) of all CMR incidents were somehow related to technology. In the batch of incidents from the *community pharmacies*, 21.5% (351/1636) of the incidents was related to technology, and in the batch from the *hospitals,* this percentage was 12.6% (317/2517). The researchers (KCC, WVN) extracted 365 problems from the 351 *community pharmacy* incidents and 338 problems from the 317 *hospital* incidents (see Appendix C for the flowchart of this process).

Consequences of incidents

Community pharmacies reported 167 (47.6%) incidents which had reached the patient. Most of these incidents (82.0%, n=137) were harmless to the patient, 12.0% (n=20) incidents caused minimal harm, 2.4% (n=4) caused serious temporary harm, and for 6 (3.6%) incidents, the outcome for the patient remained unknown. In the *hospitals* 193 (60.9%) incidents reached the patient; 46.6% (n=90) of these 196 incidents were harmless to the patient, 23.8% (n=46) incidents caused minimal harm, 8.3% (n=16) incidents caused serious temporary harm, 2 (1.0%) incidents were associated with the death of a patient, and for 20.2% (n=39) of the incidents the outcome was unknown.

Classification of relevant incidents

Table 4 shows a combination of two axes, namely the principal source of the IT-related problem and the nature of the error (only subdivided as input, transfer, and output). Most of the incidents were classified as human-machine interaction-related incidents.

In the *community pharmacies* 92.9% (n=339) of all the incidents concerned interactions between human and IT system. Table 4 shows that most problems (79.7%, n=291) were classified as human-machine interaction-related input (data entry). A relatively common problem was a healthcare provider choosing the wrong patient while entering the prescription into the pharmacy computer system.

Fewer problems (85.8%, n=290) reported from *hospitals* belonged to an interaction between a human and machine. Within this group, the data entry (input) was the most classified problem, and 16.6% (n=56) of the incidents was classified as human-machine interaction-related output. Most of these incidents were about unclear printouts.

Nature of the errors

The axis of the nature of the errors ultimately comprised 28 preferred terms (see table 1 and figure 1).

In *community pharmacies,* 41.0% (n=150) of the incidents was about choosing the wrong medicine. Most of the erroneous exchanges were caused by confusion of medicine names and poor design of screens. The second most frequent problem was choosing the wrong patient. In *community pharmacy* incidents related to output (data retrieval) were not common.

A quarter (25.1%, n=85) of the incidents in *hospitals* dealt with healthcare providers who did not enter ('not done by human') data in the systems (e.g., CPOE). It was not always clear why the physicians did not enter the prescription(s) into the CPOE. The incidents classified to 'output unclear' concerned problems with printouts of medication lists for administration. The machine-related output incidents in *hospitals* were about printers with technical malfunction so that nurses could not print out medicine lists anymore.

IT system

The IT system category consisted of 12 different IT systems (see table 2). Most IT systems were used in *hospitals* and *community pharmacies*, but some IT systems (infusion pumps) were only mentioned in the incidents from *hospital*s. Sometimes systems were linked to each other, e.g., a printer connected to a computer with a software program (CPOE or pharmacy information system). In the *hospital,* the CPOE was generally linked to the pharmacy information system so that physicians, pharmacists, and nurses could use the same system for prescribing, dispensing and administration. In the *community pharmacies*, the pharmacy information system and the pharmacy barcode scanning systems were linked to each other. Clinical decision support systems are always incorporated into CPOE systems or pharmacy computer systems. In this study, we classified all incidents concerning clinical decision support as CPOE or pharmacy information system.

In *community pharmacies,* 74.0% (n=270) of the incidents were related to the pharmacy information system and concerned human-machine interaction-related input. Other incidents with the pharmacy information systems were related to human-machine interaction-related output (9.9%, n=36), and machine-related output (3.6%, n=13). In the machine-related output, a pharmacy information system gave incorrect and confusing advice to the pharmacy assistant.

In *hospitals,* the CPOE was the most frequently implicated IT system and 55.3% (n=187) of the incidents concerned human-machine interaction-related input in combination with CPOE. 9.2% (n=31) of the incidents concerned CPOE and human-machine interaction-related output. One example was a large-scale malfunction of the CPOE, during which physicians and nurses could not reach the system anymore. Physicians and nurses could not prescribe or administer. Incidents with pharmacy information systems were not so frequent but when they occurred most of them concerned human-machine interaction-related input (5.6%, n=19).

Phases of the medication process

Table 3 shows the classification of problems into the different phases of the medication process.

In *community pharmacies,* 88.2% (n=322) of the incidents occurred during the entering of prescriptions into the pharmacy information system. Obviously, all incidents in this phase were related to the pharmacy information systems.

In *hospitals* 66.6% (n=225) of the incidents occurred during the prescribing process, the second place was taken by the administration phase (24.3%, n=82). In the prescribing phase, the CPOE had a prominent position (63.6% (n=215) of all incidents). The CPOE also played a role in the administration phase (10.1% (n=34) of all incidents). Most of these latter incidents related to the printing of medication lists, e.g., physicians forgot to print the list after entering prescriptions into the CPOE. Incidents in the transcription phase, patient monitoring phase, and storages and logistics were hardly reported from hospitals and community pharmacies.

Table 1. Nature of the errors

Source	Problems in community pharmacies N (%)	Problems in hospitals N (%)
Data entry and record manipulation		
No input		
*Not done**		
Not done by human*	9 (2.5)	85 (25.1)
Not possible to import record[$]	-	8 (2.4)
Not possible to change predefined record[$]	-	2 (0.6)
Wrong input*		
Wrong medicine[$]		
Wrong identity medicine[$]	49 (13.4)	12 (3.6)
Wrong dosage form[$]	26 (7.1)	6 (1.8)
Wrong route of administration[$]	1 (0.3)	1 (0.3)
Wrong strength of product[$]	72 (19.7)	17 (5.0)
Selected medicine not available[$]	2 (0.5)	-
Wrong patient[$]	54 (14.8)	18 (5.3)
Wrong dose / frequency[$]	47 (12.9)	23 (6.8)
Wrong duration of therapy/quantity of the medicine[$]	13 (3.6)	3 (0.9)
Wrong time of administration[$]	2 (0.5)	23 (6.8)
Wrong infusion pump rate[$]	-	21 (6.2)
Wrong prescriber[$]	5 (1.4)	1 (0.3)
Duplicate input[$]	8 (2.2)	10 (3.0)
Other wrong input[$]	6 (1.6)	12 (3.6)
Failure to communicate after input*	-	5 (1.5)

Examples of incidents in community pharmacies (CP) and hospitals (H)

- *The pharmacist received an e-mail with a prescription; due to an unknown reason the pharmacist assistant did not enter the prescription into the system. (CP)*
- *After the ward round the physician forgot to enter the prescriptions into the CPOE. (H)*
- *The physician was not familiar with CPOE and could not order the medicine with the CPOE. (H)*
- *Rifampicin was not listed in the CPOE. The consequence was that the physician could not order rifampicin in the CPOE. (H)*
- *The physician could not change the infusion rate of a predefined antibiotic order in the CPOE. (H)*

- *The pharmacist assistant entered 'CHLOO25' in the system and accidentally chose chlortalidone 25 mg instead of chlordiazepoxide 25 mg on the screen. (CP)*
- *An erroneous exchange between immediate release tablet and slow release tablet. The pharmacist assistant chose the wrong medicine from the list, which was presented by the pharmacy information system. (CP)*
- *For eye drops the right eye was entered in the pharmacy information system instead of the left eye. (CP)*
- *The pharmacy dispensed sifrol 3.75 mg instead of 0.375 mg. (CP)*
- *The general practitioners repeated a prescription, and the original identification record was canceled. In the community pharmacy, this repeat record cannot be recognized by the pharmacy information system. (CP)*
- *Pharmacist assistant used the date of birth to find a patient in the system. After entering the date of birth, a list of patient names with the same day of birth was shown on the screen. A wrong patient was selected due to a poor design of screens. (CP)*
- *At the ward, there were two patients with the same family name. The physician selected the wrong patient on the screen of the CPOE and entered a prescription for the wrong patient. (H)*
- *The physician entered a prescription into CPOE for a one-day-old newborn. During dispensing the pharmacist technician noticed the birthday and called the ward. During the call, they discovered the medicine should have been prescribed to the mother. (H)*
- *A pharmacist duplicated a record in the system and accidentally repeated an outdated dose in this process. (CP)*
- *The pharmacist assistant entered 10 tablets of ondansetron 8 mg instead of 30 tablets of ondansetron. (CP)*
- *Wrong time of administration was entered into the CPOE. The patient needed the medicine around 12:00h and the time of administration in the CPOE were 14:00h. (H)*
- *The rate of an infusion pump was accidentally set wrongly. Due to the low infusion pump rate, the patient received only half of the dose. (H)*
- *The pharmacist assistant entered the wrong code of the prescriber into the pharmacy information system. (CP)*
- *The pharmacist assistant entered the prescription two times in the pharmacy information system. (CP)*
- *The physician entered the same medicine twice into the CPOE. (H)*
- *The physician entered diclofenac into the CPOE for a patient for whom diclofenac was contraindicated. (H)*
- *The physician entered the medication order into the CPOE, but he forgot to brief the nurses about the new medication. (H)*

Table 1. Continued

Source	Problems in community pharmacies N (%)	Problems in hospitals N (%)
Data retrieval		
No output		
*System slow/down**	-	14 (4.1)
*Not done by human (did not look)**	14 (3.8)	11 (3.3)
*Not alerted / No output**	9 (2.5)	7 (2.1)
Wrong output		
*Output error**	5 (1.4)	9 (2.7)
Unclear output		
Different output online & printed[$]	1 (0.3)	2 (0.6)
Differences between two files[$]	-	3 (0.9)
Other unclear output[$]	6 (1.6)	35 (10.4)
Failure to react on signal[$]	29 (7.4)	5 (1.5)
Other output[$]	2 (0.5)	1 (0.3)
Data transfer		
Mistranslation of data between 2 systems[$]	4 (1.1)	-
No data transfer between 2 systems[$]	3 (0.8)	4 (1.2)

** = this preferred term was also available in the Magrabi Classification*
$ = this preferred term is new
CP = Community pharmacies H = Hospitals

Examples of incidents in community pharmacies (CP) and hospitals (H)
- *Physicians and nurses could not reach the CPOE because there was a large-scale IT malfunction. (H)* - *The nurse did not administer the antibiotic because the printer was 'down' and she could not print out the medication administration list. (H)*
- *The pharmacist assistant did not look into the notes of the patient file and missed the information that the patient needed a home delivery of the medicine. (CP)* - *Nurses did not realize the physician had entered a note in the electronic patient file and thereby missed the administration of an antibiotic. (H)*
- *A cardiologist accidentally prescribed a high dose of flecainide for a patient in primary care and the pharmacy computer system did not alert the community pharmacist about it. There was no alert because formally it was not an overdose, but according to the cardiologist, the dose was too high for the patient in the primary care. There should have been an alert. (CP)*
- *The infusion pump alerted the nurses too late about an obstruction in the tube. (H)*
- *In the CPOE the nurse read that the aspirin needed to be administered with a high loading dose, but on the paper-based medication list, the information about the high loading dose was missing. (H)*
- *In the CPOE the nurse read from the medication list that the patient needed tolbutamide. In a separate memo field in the CPOE the nurse read that tolbutamide should not be administered to the patient. (H)*
- *A community pharmacist printed out a medication list for a patient going to the hospital. The print out was unclear, and the consequence was that a physician in the hospital misinterpreted this medication list. He thought the patient only used 50 mg losartan per day instead of 2 times 50mg. (CP)* - *A nurse administered 5 times more bisoprolol than prescribed. On the medication list, she read that the patient needed bisoprolol and on the list, the number 5 was printed without a unit (mg or tablet). Eventually, she administered 5 tablets of bisoprolol 5 mg to the patient. (H)* - *The nurse missed a new prescription order because the printer had printed out all the orders at once with the new prescriptions at the bottom of the pile of paper (even after orders that had already been stopped). (H)*
- *Due to alert fatigue, a pharmacist assistant overruled the signal from the pharmacy bar code scanning system that the wrong medicine had been chosen. (CP)* - *The general practitioner ignored a drug-drug-interaction signal. (CP)* - *The infusion pump made an alarm sound. The nurse could not identify the problem and eventually switched off the alarm of the infusion pump. (H)* - *A pharmacist assistant did not respond correctly to alerts of the pharmaceutical clinical decision support system, such as allergy warnings or drug-drug-interaction warnings. For example, an order for a cephalosporin was executed despite an alert for an allergy. (H)*
- *For dispensing the pharmacist assistant printed out a list, which was not up-to-date anymore. (H)*
- *An incomplete transfer of an e-prescription between the computers of the general practitioner and the community pharmacist. The information about the brand of the medicine was missing. (CP)*
- *A physician could not use the CPOE because of a technical malfunction in the connection between the CPOE and the medical record system in the hospital. (H)*

Table 2: Overview of the IT systems involved

IT systems	Involved in the problems in:	
	community pharmacies N (%)	hospitals N (%)
Automated dispensing cabinets (ADC)	2 (0.5)	-
Computerized physician order entry (CPOE)	21 (5.8)	250 (74.0)
Order system website[#]	1 (0.3)	-
Electronic health record	-	21 (6.2)
Fax	-	1 (0.3)
Infusion pump	-	27 (8.0)
Laboratory diagnostic analyzer[$]	-	1 (0.3)
Medication administration registration	-	5 (1.5)
Pharmacy bar code scanning system	13 (3.6)	-
Pharmacy information system	326 (89.3)	28 (8.3)
Prescription scanner[&]	1 (0.3)	-
Printer	1 (0.3)	5 (1.5)

# website used by pharmacies to purchase medicine
$ automatic devices used by diagnostic laboratories to analyze blood, urine, etc.
& community pharmacies scan the prescriptions after dispensing to archive the prescriptions digitally

Table 3: IT problems in the different phases of the medication process

Phase in the medication process	Problems in community pharmacies N (%)	Problems in hospitals N (%)
Prescribing	23 (6.3)	225 (66.6)
Transcription	-	2 (0.6)
Entering of prescriptions into the pharmacy information system[$]	322 (88.2)	22 (6.5)
Compounding	-	-
Dispensing	16 (4.4)	4 (1.2)
Administration	-	82 (24.3)
Patient monitoring	-	3 (0.9)
Storage and logistics	4 (1.1)	-

[$] This is including pharmaceutical clinical decision support

DISCUSSION

Our study is the first research on the nature and frequency of medication incidents related to IT in a large sample of IT-related incidents reported by healthcare providers in community pharmacies and hospitals. We found that 1 of 6 reported incidents (16.1%, n=668) was related to IT and that more incidents were related to IT in the community pharmacies (21.5%, n=351) than in hospitals (12.6%, n=317). As far as we know, this is also the first study analyzing medication incidents related to all kinds of IT systems, thereby showing the pivotal role of CPOE and pharmacy information system in medication incidents.

Within the Magrabi classification, we expanded the 'input'-group with a subdivision to make the incidents more specific and concrete. Magrabi et al. [14] primarily chose an IT perspective, which seems especially important for IT professionals who develop healthcare-related IT systems. Our angle was guided by the proposal of Sittig and Singh [19] to define IT incidents not only from the technical viewpoint of manufacturers, developers, and vendors but also from the social-technical viewpoint of end users. The underlying principle is that healthcare providers wish to learn about IT-related risks by considering when and what they can do wrong with what type of IT system. We analyzed the incidents with a healthcare provider's perspective, and we combined it with the technical items. Eventually, we related the technical items to input or output problems. Magrabi et al. [14] also had 'Contributing factors' which consisted of organizational or individual's causes of incidents. We were focused on the nature of the incident, and we did not use these items. Interestingly, our study showed that the input problems occurring with CPOE also occurred with pharmacy information systems outside of the hospital. Most studies that we found were about the impact of CPOE, and there were no studies about the impact of pharmacy information systems [6-10]. Despite the use of CPOE in primary care many the community pharmacists still need to enter the prescriptions manually into their pharmacy information systems. One of the reasons is that generally not all prescriptions can be electronically transmitted from the CPOE system to the pharmacy information system.

Although frequencies have to be interpreted carefully in this study, it is interesting to compare our results with those of other studies. In their first study, Magrabi et al. [13] identified 111 incidents from a database with 42.616 incidents (0.3%, n=111) and in the second study 678 incidents were selected from a database with 899.768 incidents (0.1%, n=678) [14]. IT was much more frequently involved in our sample of incidents. One reason may be that the latter consisted entirely of medication incidents. Another contributory factor could be the long history of implementing IT tools in Dutch healthcare. Since the 1970s, community pharmacists have applied IT in their daily practice (followed later by primary care physicians) [17]. In hospitals, the shift from a paper-based to a computerized system began ten years later.

In the first study of Magrabi et al. [13], 45% (n=53) of the incidents were human-machine interaction-related problems (13). In their second study, this number was lower, and only 4% (n=30) were human-machine interaction-related problems [14]. The MAUDE database contains incidents from manufacturers in the USA, and probably these incidents were more focused on pure IT aspects (only machine-related problems), such as software problems. In contrast, our study showed that the majority of the incidents were human-machine interaction related. Healthcare providers reported directly to CMR, and although it may be difficult for them to identify the underlying technical causes of IT-related incidents, they can readily recognize the nature and clinical consequences of such incidents. The predominance of incidents concerning data entry and record manipulation (input) is in line with the results of Magrabi et al. [13], which classified 31% (n=36) of the incidents as information input problems. A USA national voluntary medication error-reporting database showed comparable CPOE input problems. Half of the incidents involved dosing errors such as the wrong doses [20]. Zhan et al. [20] concluded that CPOE-related medication errors are not only caused by faulty computer interfaces but also by common use, errors such as typing errors. Most studies about CPOE have shown comparable input problems [6,8,12,21-23].

Our low proportion of transfer problems was in contrast with Magrabi et al., which classified 20% (n=23) of all incidents as transfer problems in their first study. Magrabi et al. [13] classified incidents related to computer network, systems integration issues and inaccessibility of systems from as little as 15 min to as long as 8 hours, as information transfer problems. In their second study, however, only a small proportion of problems (2%, n=13) was related to the transfer of information [14]. With the healthcare provider's perspective, we focused on how the problems affected the work processes and eventually incidents were classified as input or output problems. This could explain our low proportion of transfer problems. We only assigned two types of transfer problems: 'mistranslation of data' and 'no data transfer.' These kinds of problems were also mentioned in a literature study about the transferring and displaying pathology data in electronic health records [24].

Strengths and Limitations

The main strengths of this study were the comparison between the different health care settings and the high number of incidents, as well as the use of a classification system that is in accordance with the healthcare provider's perspective. This study proved that one classification could be used for both settings.

For this study, we analyzed a large number (668) of incidents from community pharmacies and hospitals. Lewis [25] states in an article about post-marketing surveillance that the number of studied drug users must be three times as high as the frequency of an ADR (adverse drug reaction) to have 95% chance that the reaction will occur in the study pop-

ulation. For instance, 300 subjects have to be studied to have 95% confidence to detect an ADR with an incidence of 1 in 100 [26]. This means that the number of analyzed incidents in our study was more than sufficient to get an insight into the most frequent unintended consequences associated with IT incidents.

Table 4: Principal source of IT-related problem and nature of the error

Category	Problems in community pharmacies n (%)	Problems in hospitals n (%)
human-machine interaction-related input	291 (79.7)	234 (69.2)
human-machine interaction-related output	48 (13.2)	56 (16.6)
Machine-related input	3 (0.8)	15 (4.4)
Machine-related output	16 (4.4)	29 (8.6)
Machine-related transfer	7 (1.9)	4 (1.2)

Despite the rigorous validation process, a potential limitation of this study is that the adapted classification was only applied to one set of incidents. A logical next step would be its validation in a new set of data. Another limitation was the variable quality of the descriptions of the incidents. Not all the incidents were described well, and some of them hardly contained enough information for further analysis. To minimize the risk that the researcher would infer some details of the incident that were not reported, the two researchers analyzed the incidents independently and met afterward to reach consensus. A third limitation was the difficulty in classifying the incidents in the axis of the nature of the error. The IT systems were easier to classify because they were more concrete.

Last but not least the incidents came from a voluntary reporting system, and it could be possible that healthcare providers primarily focused on incidents that they considered important or out of the ordinary. Especially after the introduction of a new IT system health care providers might focus more on the use of this new IT system [27]. On the other hand, incidents that were not recognized by healthcare providers will thereby have remained unreported. So, the real number of unintended consequences with IT could also be higher.

Implications for practice

Considering the percentage of incidents related to IT, it is necessary to pay attention to this new field of incidents in healthcare. IT was introduced with the idea to prevent incidents, and healthcare providers may trust IT too much in supporting their daily practice. This study helps healthcare providers to become more aware of the unintended consequences related to IT.

Our study identified all kinds of IT problems, and healthcare workers need to be aware that such problems can occur. Healthcare providers must know how to intercept or respond to these IT incidents to prevent patient harm. Interceptions may be performed from the human perspective (e.g., training of individuals) or the technical / organizational perspective (e.g., system design and workflow changes). In general, the latter are preferred because they form a system solution instead of an individual solution [28].

This study suggests a few interceptions. An accessible back-up of patient records is required when a large-scale malfunction of the CPOE prevents physicians and nurses from reaching the regular system. When printers are not able to print anymore, nurses should be aware that they have to access patient information by other means. The input problems which were caused by poor design of screens need to be discussed with the software vendors. The implementation of complex CPOE or any IT system should be accompanied with adequate training in the use and possibilities of such an IT system. Healthcare organizations should consider the relevant work processes when installing a new IT system. The problem 'not done by human' could sometimes be related to the introduction of a new IT system, which does not fit well into an existing work process. Finally, the classification system used in this study may help to increase the information value of incidents.

Implications for research

Future research should be done in collaboration with users, vendors and incident-analysis experts to get a more intensive insight into IT-related incidents. The classification of Magrabi et al. [14] was useful after we had added some preferred terms, but for more information about the incidents, we believe that subsequent analysis of underlying causes, harm to the patient and which healthcare profession was involved, might be helpful. This should be the subject of further study, and the final classification system should be validated using different sets of incidents.

Technology is changing fast, and every day new IT system can be introduced which will entail their unintended consequences. Introduction of new IT system should be accompanied by prospective risk analysis [16]. Research on the performance and effect of such risk analyses is necessary.

Information transfer problems are an important new area for research. At this moment these problems are not yet common, but more and more computers will be linked to each other. Thus a malfunction in one setting can rapidly spread to other departments or healthcare organizations [29,30].

This study was focused on the determination of IT-related incidents and compared these in community pharmacies and hospitals. Some interceptions were suggested to prevent reoccurrence of the incidents. Research is needed to investigate the interceptions on the human perspective and technical / organization perspective. Probably a combination of both sorts of interceptions is necessary to prevent IT-related incidents.

CONCLUSION

This is the first study which shows how many of the incidents in the CMR database are related to IT in both community pharmacies and hospitals. The interaction between human and machine plays a pivotal role in the IT incidents. In community pharmacies, the pharmacy information system was most frequently involved while in hospitals the CPOE was most frequently involved. The classification of Magrabi et al. [14] was a very useful starting point, but we added some new preferred terms during analysis. In a subsequent analysis, we introduced the IT system category in this study and phases of the medication process. Our slightly adapted Magrabi classification will help healthcare providers in picturing the incidents, as these axes help to put the incidents in the context of healthcare practice. This classification system seems useful for reporting and analyzing IT incidents in healthcare in general, but further research will have to prove this.

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APPENDIX A

Chapters and items on the CMR reporting form

Items	Multiple choices and remarks
Administrative information	
Identification number of the healthcare practice	-
Date of reporting	-
Date on which the medication event occurred	-
Data of patient	
Year of birth of the patient	-
Sex of the patient	o Male o Female
Information about the medication event	
Please describe what happened	Open-ended question
Which medication was involved?	-
What was the error type	o Prescribing error o Transcription error o Assembling the prescription and medication surveillance error o Compounding error o Dispensing error o Administration error o Patient monitoring error o Storage and logistic error
Did the medication event take place during a transfer of the patient (shared care)?	o Yes, during admission to hospital o Yes, during discharge of hospital o Yes, between the wards in one hospital o Yes, during out-of-hours services in the primary care o Yes, with the intensive care for thrombotic patients o Yes, namely: o No
What are the causes of the medication event?	o Technical o Organisation o Behaviour o Communication o Patient
Who makes the first error in the medication event?	List of healthcare providers. There are three different lists for the hospitals, community pharmacies, and mental health care.
Which ward is this person involved?	List of wards in a hospital. This question exists only in the form for hospitals.
Did the medication event reach the patient?	o Yes o No

What is the harm of the medication event to the patient?	o No discomfort o Minimal/mild harm o Seriously temporary harm o Seriously permanent harm o Death o Unknown
What could be the potential harm to the patient?	o Scale from 1 to 5 or unable to estimate
Questions to notify an alert	
How much is the risk of recurrence?	o Unlikely, less than 1 times a year o Rare, less than 5 times a year o Possible within a few months o Probably within a few days o Almost sure within a few hours/days o Unable to estimate
Can other healthcare providers learn from this reported medication event?	o Scale from 1 to 5of unable to estimate
Is this reported medication event suitable for an alert?	o Yes, this is an alert, CMR organization will contact the informant for detailed information. o No, this is not an alert. o Please let the CMR organization contact the informant.

APPENDIX B

List of 121 Dutch search terms

Aangeschreven
Aanklikken
Aanschrijfbuffer
Aanschrijven
Accu
Afdruk
AIS
Alarmeerde
Aposys
Automatisch
Barcode
Batch
Beacom
Beeld
Bestand
Bewaking
care O Line
Chipsoft
Code
Computer
Data
Decursus
Diamante
Digitale
Doorgevoerd
Draai
Elektro
EPD
EPIC
EVS
Ezis
Format
Gehangen
Gekoppeld
Genereert
Georderd
Geprint
Geselecteerd
Getypt
Gewist
Glims
GPK
Herhaalservice
HIS
ICU-lijst
In te voeren
Index
Infuus* AND *stand*
Ingesteld
Ingetypt
Ingevoerd
Ingevuld
Inkt
Intranet
Intrazis
Invoer
Inzage instelling
Kea
Keuze
Kiest
Klinikom
Koppel
Lag eruit
Laptop
Lijsten
Medicatiebonnen
Medicatielijst
Medicator
Memo
Menu
Metavision
Mira
Mirador
Module
MTR
MVK
Navision
Netwerk
OMO
Op te schonen
Opdrachtenblad
Opgelicht
Opgestart
Order
Overzicht
OZIS
PC
Perfusor
Pharmacom
Pompstand
Pos
Print
Profile
Programma
Registratie
Rollen
Rugetiket
Scan
Select
Serie
Signaal
Signal
Spuit* AND (*stand* OR *pomp*)
Stopcontact
Storing
Stuurt
System
Taaklijst
Taxe
Typen
Uitdraai
Uitgedraaid
Update
Vakje
Vastgelopen
Versie
Voert
Vrije tekst
Waarschuwing
Zichtbaar
ZI nummer

APPENDIX C

Flowchart of identification and inclusion of the reports

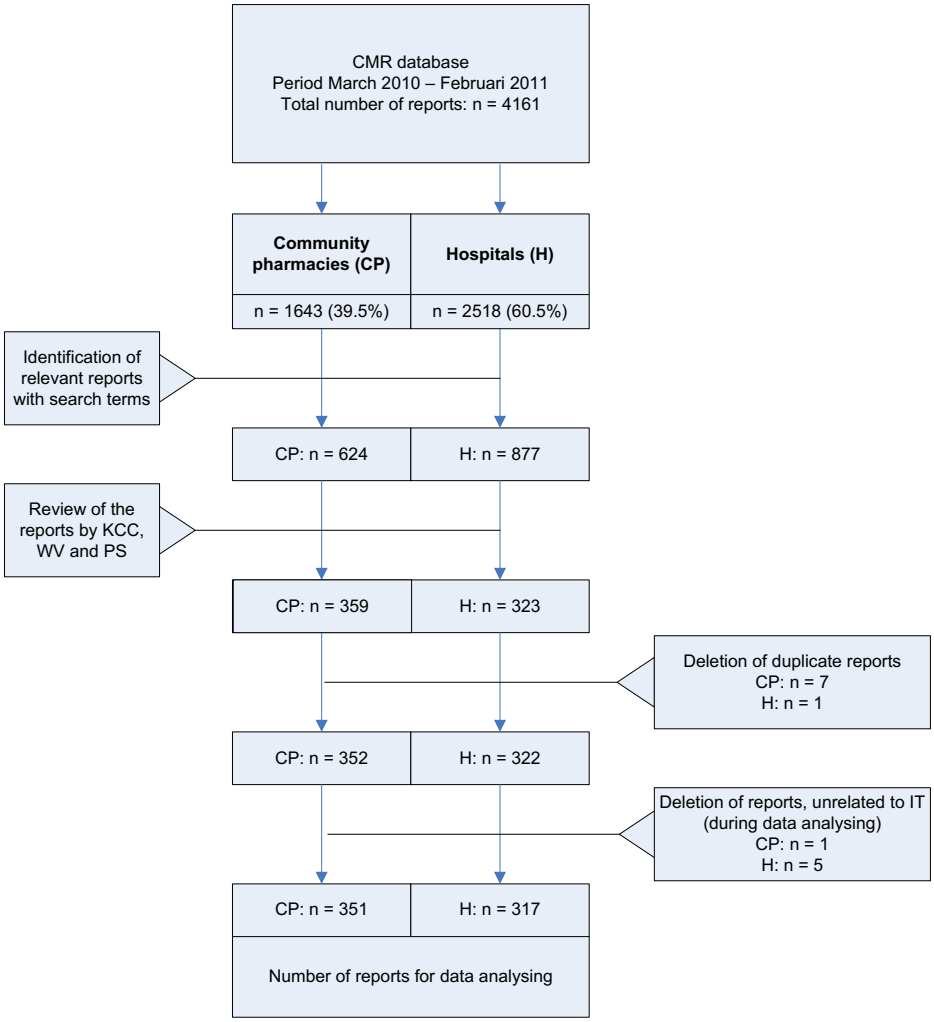
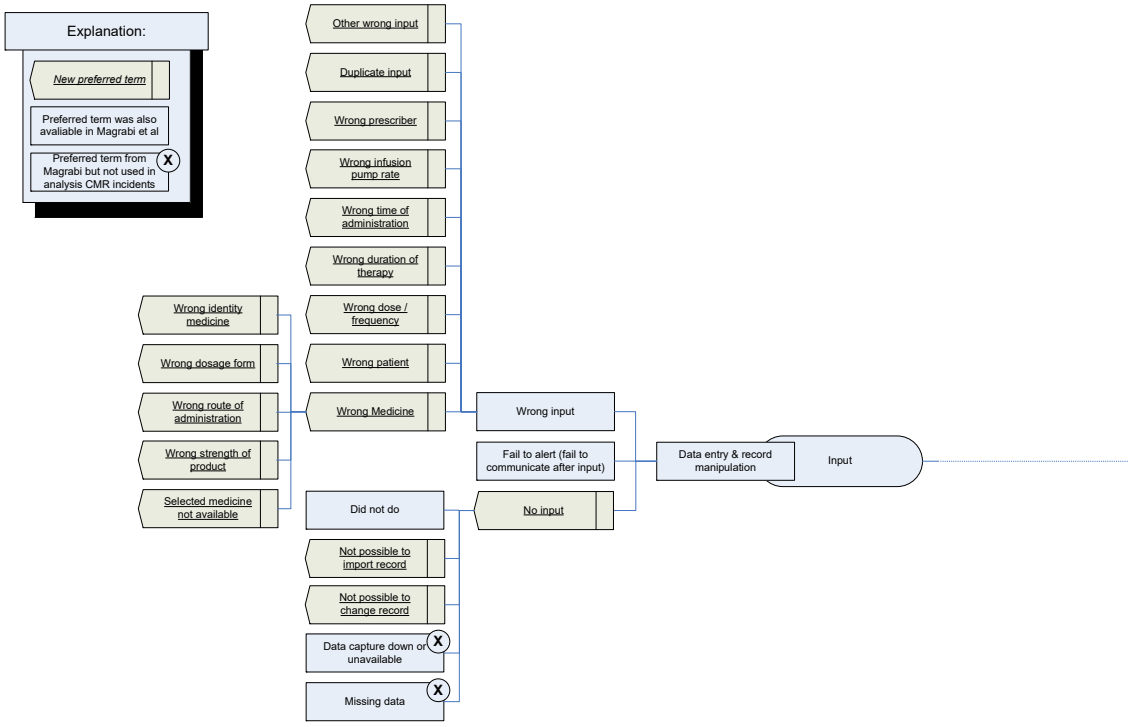
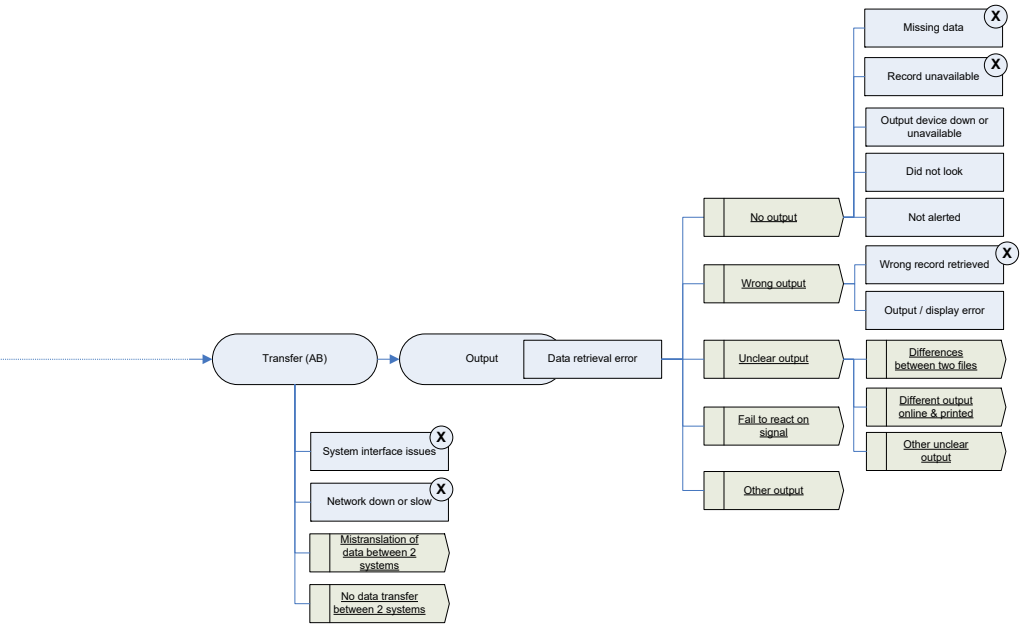


Figure 1. Adapted diagram of the Magrabi et al[14]. 2012 classification and added terms from CMR incidents.




Transfer (AB)
Output
Data retrieval error
System interface issues
Network down or slow
Mistranslation of data between 2 systems
No data transfer between 2 systems
No output
Wrong output
Unclear output
Fail to react on signal
Other output
Missing data
Record unavailable
Output device down or unavailable
Did not look
Not alerted
Wrong record retrieved
Output / display error
Differences between two files
Different output online & printed
Other unclear output