Errors in the medication process: frequency, type, and potential

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Abstract

Objective. To investigate the frequency, type, and consequences of medication errors in more stages of the medication process, including discharge summaries.

Design. A cross-sectional study using three methods to detect errors in the medication process: direct observations, unannounced control visits, and chart reviews. With the exception of errors in discharge summaries all potential medication error consequences were evaluated by physicians and pharmacists.

Setting. A randomly selected medical and surgical department at Aarhus University Hospital, Denmark.

Study participants. Eligible in-hospital patients aged 18 or over (n = 64), physicians prescribing drugs and nurses dispensing and administering drugs.

Main outcome measures. Frequency, type, and potential clinical consequences of all detected errors compared with the total number of opportunities for error.

Results. We detected a total of 1065 errors in 2467 opportunities for errors (43%). In worst case scenario 20–30% of all evaluated medication errors were assessed as potential adverse drug events. In each stage the frequency of medication errors were—ordering: 167/433 (39%), transcription: 310/558 (56%), dispensing: 22/538 (4%), administration: 166/412 (41%), and finally discharge summaries: 401/526 (76%). The most common types of error throughout the medication process were: lack of drug form, unordered drug, omission of drug/dose, and lack of identity control.

Conclusion. There is a need for quality improvement, as almost 50% of all errors in doses and prescriptions in the medication process were caused by missing actions. We assume that the number of errors could be reduced by simple changes of existing procedures or by implementing automated technologies in the medication process.

Keywords: Medication errors, potential adverse drug events, chart review, direct observation, unannounced control visit

Medication errors are a well-known problem in hospitals. Studies have shown that medication errors and adverse drug reactions (ADRs) are one of the main causes for adverse events in hospitals leading to disability and death in up to 6.5% of hospital admissions [1–5].

Not all medication errors are harmful. Previous studies of the association have shown that <1% of all medication errors actually resulted in an adverse drug event, while up to 6.7%were assessed as potential adverse drug events, when examined primarily by chart reviews [3,6,7]. However, a study using direct observation to detect medication errors in the dispensing and administration stage assessed 20% of the identified errors as potential adverse drug events [8]. Thus, application of appropriate methods for identifying medication errors and assessing potential adverse drug events are important in the detection of valid and useful information [9,10].

The literature on medication errors lacks universally accepted definitions of medication errors as well as different methods and criteria, leaving us with an incomplete know-ledge of the actual rate of medication errors [1–5,7,8,11–14]. Likewise, criteria for assessing the potential clinical consequences of medication errors vary in different studies [3,8,15]. At present, no studies have investigated medication errors in more stages of the process in the same population including discharge summaries. In addition, no studies have investigated medication process by selecting the most appropriate and valid methods at each stage.

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The purpose of our study was to perform a systematic, valid, and detailed investigation of the frequency, type, and potential clinical consequences of medication errors in more stages of the medication process, including discharge summaries.

Methods

Definition of medication errors

Prescription of drugs can be divided into an intellectual part—decision making, i.e. knowledge of diagnosis, interactions, and contraindications, and a technical part including communication of essential information, i.e. drug name, dose, form of administration [16]. Our study focused on medication errors in the technical part.

A medication error was defined as an error in the medication process: ordering, transcription, dispensing, and administration, and discharge summaries [6]. Errors included wrong as well as missing actions.

Adverse drug events were defined as injuries resulting from medical interventions related to a drug—including both medication errors and ADRs. ADRs were excluded in our study [3,6]. Potential adverse drug events were defined as medication errors with potential for an adverse drug event [3,6].

Design and study population

The study was designed as a cross-sectional study of medication errors and potential harm, and was examined by the use of three methods—direct observation, unannounced control visit, and chart review. The study population consisted of: (i) hospital inpatients, aged 18 or over; (ii) nurses dispensing and administering medications; (iii) physicians prescribing drugs or secretaries transcribing drugs into the medical record. Prescription errors in the medical record and discharge summaries could be caused by both physicians and secretaries. In our study no distinction was made between these two groups.

The study included regular as well as pro re nata (prn) medications, except from prn medications in discharge summaries. The following drugs were included: tablets, suppositories, mixtures, and injections (intravenous, intramuscular, and subcutaneous). Patients administering their own drugs were excluded as well as injections in the unannounced control visit.

Settings

The study was conducted at randomly selected medical and a surgical ward at Aarhus University Hospital, Denmark, from January to April 2003.

Physicians were responsible for prescribing drugs and secretaries for transcribing them into medical records and discharge summaries. Nurses transcribed drug prescriptions from the medical record into a medication chart and were responsible for dispensing and administering medication. In each ward drugs were administered daily at 8.00 a.m., 12.00 a.m., 5.00 p.m., and 10.00 p.m. by two randomly selected nurses.

Methods, process, and criteria

The criteria for classifying medication errors were based upon American Society of Health System Pharmacists (ASHP) definitions and Danish legal recommendations for unambiguous prescriptions and correct verification of patient identity [17]. A slight modification of ASHP's criteria was necessary, in order to avoid overlap of error types and frequencies when separating the dispensing and administration. Definitions of included variables and criteria for errors are shown in Table 1. For each stage in the medication process a structured register form was developed.

The basic data in our study were the number of actual errors divided by the total number of opportunities for errors. An opportunity for error was defined as any drug prescribed, any unordered or omitted drug, and 'any dose given and any dose omitted' [11,18]. A drug or a dose could result in more than one error type.

Observational method

Data collection consisted of five consecutive days (8 h) direct observation in each ward: four days in the daytime and one during evening shift. In the study period, two nurses were observed for \sim 4 h in each duty. The observed nurses were selected by convenience sampling. All dispensed and administered drugs were registered and subsequently compared with eligible prescriptions in the nurse medication chart. Any discrepancy between the dispensed drugs and the nurse chart was registered as an error according to the criteria in Table 1. The observation was carried out by one of us (M.L.), who did not have any previous knowledge of the patient's drug use [18].

Unannounced control visit

An unannounced control visit was made 7 weeks after the observational study. The dispensed drugs were confiscated after dispensing and before administering, and new drugs were immediately dispensed. Two pharmaceutical students identified the confiscated drugs on behalf of recognition. The students' findings were compared with the drug prescriptions in the medication chart. Any discrepancy between the prescriptions in the medication chart and the identified drugs was registered as an error (Table 1). In a pilot test the students' recognition of drugs was 92% and 95%, respectively.

Chart review

The medical records and nurse charts of all patients in the observational study were screened for medication errors. The screening should verify that all eligible prescriptions in the medication chart were identical to the prescriptions in the medical records, and examine whether the prescriptions in the medical record were unambiguous (Table 1). If patients were involved in more than one sample during the observational study, only new and changed prescriptions were screened.

Likewise, discharge summaries were screened for transcription errors. Any discrepancy in eligible prescriptions and in

Stage	Definition	Error types
Ordering	Unambiguous prescription	Omission of: drug name; drug formulation; route; dose; dosing regime; date; signature; treatment time for antibiotics
Transcription	An identical copy of prescription in medical record	Discrepancy in: drug name; drug formulation; route; dose; dosing regime; omission of drug; unordered drug
Dispensing	Dispensed medication is concordant with prescribed drug in nurse medication chart	Unordered drug (wrong drug); unordered dose; omission of dose; wrong dose; wrong drug formulation
Administering	The right medication to the right patient in the right way and at the right time	Wrong: administration technique (inj.); route; time (± 60 min); delivery (dose not delivered directly to the patient); unordered drug; unordered dose; omission of dose; lack of identity control
Discharge summaries	Eligible prescriptions in medical record are identical to prescriptions in discharge summaries	Discrepancy in: drug name; drug formulation; route; dose; regime; omission of drug; unordered drug

Table I Criteria for medication errors

communicating essential information between prescriptions in the medical record and discharge summaries was registered as an error (Table 1). All chart reviews were conducted by one of the authors (M.L.)

Potential clinical consequences

Apart from errors registered in discharge summaries, all errors identified in the present study were assessed according to predefined criteria for potential clinical consequences (Appendix 1). A four-scale unambiguous classification system was developed including the following categories—potentially fatal, potentially serious, potentially significant, and potentially non-significant. Definitions of potential fatal and potential serious errors were in accordance with international definitions of potential adverse drug events [3,6].

Two expert physicians in each ward and a group of three experienced pharmacists assessed the potential clinical consequences of identified medication errors. The physicians independently assessed errors in their own ward, while the pharmacists assessed errors in both wards using the audit principle.

Statistical analyses

The data were analysed by using SPSS 11.0 (SPSS Inc., Chicago, IL, USA) and NCSS 2000 (McGraw-Hill Co.). Frequencies were described as percentages and the descriptive data as mean or median, if appropriate. Comparison of frequencies between the medical and surgical wards was made using the χ^2 test or Fisher's exact test. Parametric data were compared using the Student's *t*-test while non-parametric data were compared using the Mann–Whitney non-parametric test. Friedman's

two-way ANOVA was used in order to compare physicians' and pharmacists' assessment of the clinical consequences.

Statistical significance was defined at a level of 0.05 and data were described with a confidence interval of 95%.

Ethical aspects

The study was approved by the Danish Data Protection Agency. Nurses in both wards were informed verbally and in writing about the purpose of the observational study, but not about the unannounced control visit and chart reviews. Physicians were not informed about the study. The investigator was ethically obliged to interfere immediately if a medication error was observed and the interference would proceed before the nurse administered the medication. All medication errors prevented by the investigator would be registered as a medication error.

Results

Opportunities for errors were independently summed up for each stage in the medication process. In total 2467 opportunities for errors were registered of which 1067 (43%) errors were detected. Doses and prescriptions were equally distributed between the two wards with 1209 in the medical ward and 1258 in the surgical ward, in 27 and 37 patients, respectively. The estimated median error rate per patient in the first sample was 17 (11–24) errors per patient in the medical ward and 13 (7–22) errors per patient in the surgical ward. There was no statistical difference between the error rate per patient in the medical and the surgical wards (P = 0.13).

All eligible patients where medication was dispensed by a nurse were included in the study. In the surgical ward five discharge summaries were excluded because the patients did not have any regular drug prescriptions and one medical record was not accessible in the medical ward.

The included patients consisted of 14 men (52%) and 13 women (48%) in the medical ward and 16 men (43%) and 21 women (57%) in the surgical ward. The mean age in the medical ward was 55 years (95% CI: 48-62) and in the surgical ward, 62 years (95% CI: 56-68). In the first study sample the median days of admission was 4 days (range 2-7) in the medical ward and 4 days (range 2-9) in the surgical ward. The number of opportunities for errors per patient in the medical ward was 44 (range 22-59) and in the surgical ward 29 (range 15-46). There were no statistically significant differences between the wards.

Frequency of medication errors varied between the different stages in the medication process. In Table 2 the frequency of medication errors are shown, at different stages in the medication process and the two wards, respectively. Differences between the number of prescriptions in the ordering and transcription stage were due primarily to unordered drugs in the medication chart. Yet, differences between the number of dispensed and administered doses in the observational study were due to lack of administering doses to patients attending medical examinations.

In discharge summaries more than half (215/401 or 54%) of all medication errors were related to a new drug prescribed during admission or changes in previous drug prescriptions.

Likewise, the type of medication error in the different stages of the medication process is shown in Table 3. It is noticeable that error types like 'lack of identity control', 'wrong time' and 'wrong delivery' in the administration stage could be mutually dependent as lack of one identity control would automatically affect all doses the patient was about to receive with an error. Further analysis of these error types showed that 'lack of identity control' affected 21 of 43 (49%) deliveries in the medical ward and 21 of 56 (38%) deliveries in the surgical ward. 'Wrong time' affected six of 43 (14%) deliveries in the medical department and 1 of 56 (2%) deliveries in the surgical ward and finally, 'wrong delivery' affected two of 43 (5%) deliveries in the medical ward. Wrong administration

technique only included injections. Of the 24 injections observed in our study, five errors were detected.

Identified medication errors in the stages from prescription to administration were assessed retrospectively by two physicians in each ward and a panel of pharmacists. In a worst case scenario 20-30% of all errors identified at each stage were assessed as potential adverse drug events as shown in Table 4. The most common ATC groups involved in potential adverse drug events were drugs for: infectious diseases (]), heart and circulation (C), and central nervous system (N). Apart from the transcription stage, errors were most frequently seen in regular medications.

Discussion

Our findings of 43% errors in the medication process indicate a need for improvement in more stages of the medication process. None of the errors identified affected the patients' health but one-fifth was assessed as being potentially serious or fatal in a worst case scenario. The high percentage of identified errors must be viewed in the light of the detailed and systematic examination of errors and types of error at each stage of the medication process.

Ordering and transcription stage

Previous studies have suggested a need for a unified medication system to eliminate errors at the ordering and transcription stage [19-21]. This medication chart, paper or electronic, should clearly state the components needed to fulfil requirements for unambiguous prescription-especially drug form and route, as these were the most frequent types of error in our study. The high frequency of discrepancies in drug form between medical records and medication charts were caused by nurses' interpretation of drug prescriptions, and lack of drug formulation in the medical record. Often, these interpretations are correct and improve the quality of the drug prescription, but these actions are beyond nurse authority and could, ultimately, result in fatal consequences for the patients.

	Ordering $(n_{\text{total}} = 433),$ n (%)	Transcription $(n_{\text{total}} = 558), n (\%)$	Disp. obs. ¹ ($n_{\text{total}} = 419$), n (%)	Disp. contr. $(n_{\text{total}} = 119),^2$ n (%)	Administration ($n_{\text{total}} = 412$), n (%)	Discharge sum. ³ ($n_{\text{total}} = 526$), n (%)
Medical	85 (41)	122 (51)	7 (3)	-	103 (52)	188 (64)
Surgical Overall	82 (37) 167 (39)	188 (59) 310 (56)	10 (4) 17 (4)	5 (10) 5 (4)	63 (29) 166 (41)	213 (91) 401 (76)

 Table 2 Frequency of medication errors in all stages of the medication process

 n_{total} = the total opportunities of errors in each stage (prescriptions and doses) and n = the total amount of detected errors in each stage of the medication process.

¹Dispensing stage observational study.

²Dispensing stage—unannounced control visit.

^oDischarge summaries.

	Ordering *N = 167 (<i>n</i> = 329)	Transcription ¹ * $N = 310$ ($n = 370$)	Disp. obs^2 * $N = 17$ ($n = 17$)	Disp. cont ³ * $N = 5$ ($n = 5$)	Administration ⁴ *N = 166 (n = 190)	Dis. sum. ⁵ * $N = 401$ ($n = 447$)
	n/N	n/N	n/N	n/N	n/N	n/N
Drug name	4/167	8/310				3/401
Drug formulation	125/167	90/310	0	0		64/401
Omission of route	114/167	21/310				2/401
Omission of dose	30/167		7/17	5/5	1/166	-
Dosing regime	18/167	34/310				27/401
Treatment time	33/167					
Date	1/167					
Signature	4/167					
Discrepancy in dose		50/310				42/401
Unordered drug		123/310	5/17	0	0	27/401
Omission of drug		44/310	0	0		282/401
Unordered dose			0	0	1/166	-
Wrong dose			5/17	0	·	
Wrong adm. ⁶ technique					8/166	
Wrong route					0	
Lack of id. ⁷ control					150/166	
Wrong time					18/166	
Wrong delivery					12/166	

 Table 3 Detected error types in the medication process

N =total number of prescriptions or doses affected with an error.

n = the total sum of error detected in the identified prescriptions/doses with errors (*N*). For example, 167 (329) means that a total of 329 errors were detected in 167 prescriptions.

Unfilled cells indicate error types which were not included in the actual stage of the medication process.

¹Transcription stage.

²Dispensing stage observational study.

³Dispensing stage—unannounced control visit.

⁴Administration stage.

⁵Discharge summaries.

⁶Wrong administration techniques.

⁷Lack of identity control.

	Ordering ¹ n = 167 n (%)	Transcription ¹ n = 310 n (%)	Disp. obs. ^{1,2} n = 17 n (%)	Disp. contr. ³ n = 5 n (%)	Administration ¹ n = 166 n (%)
Fatal	3 (2)	6 (2)	0	0	2 (1)
Serious	30 (18)	65 (21)	4 (25)	1 (20)	33 (20)
Significant	67 (40)	127 (41)	9 (56)	2 (40)	53 (32)
Non-significant	66 (40)	111 (36)	3 (19)	2 (40)	77 (46)

 Table 4
 Potential clinical consequences of errors detected in the ordering, transcribing, dispensing, and administration stages

Only worst case scenarios are shown in each stage of the medication process.

¹One missing assessment.

²Dispensing stage observational study.

³Dispensing stage—unannounced control visit.

Dispensing and administration stage

Compared with previous studies of medication errors identified through observational studies, error rates in our study varied considerably even when adjusted to Barker's original criteria [18]. Possible explanations of the low frequency of dispensing errors identified in our study, could be differences in study population or observed drug forms as well as differences in the drug distribution system. Furthermore, it can be assumed that the inclusion of specialized pharmaceutical variables such as excess of intravenous drug duration, incorrect dilution of drug, wrong storage of drug, and use of expired drug have contributed to a higher error rate in previous studies [11,17]. Our aim was to explore whether dispensing and administration of medication were concordant with prescribed medication in the medication charts in respect of drug name, dose, drug form, time, drug route, administration technique, and giving drugs to the right patient, including identity control before administering medication. Pharmaceutical variables such as wrong storage and use of expired drugs were not included as these were controlled by pharmacists twice a week, in each ward. Compared with similar studies observing other than unit dose systems, error rates from <1 and up to 25% have been found depending on the amount and definitions of included variables [8,11,22-25]. In our study the most common error types at the dispensing stage were unordered or omitted doses while lack of identity control and wrong time was most common when administering medication. These findings are generally in line with previous studies, indicating that unordered dose and wrong time were among the most frequent error types [8,22-25]. Lack of identity control is not an ASHP criterion and has to our knowledge only been investigated in a few previous studies emphasizing the importance of proper identification of patients before administering medication [26,27]. Unlike the study in the UK, we did not observe any comparison between the patients' identity number at the wristband and the identity number written at the medication chart, not even when patients were unconscious or demented [27]. Further we found that 150 of 412 (36%) doses were administered without any previous verbal verification of the patients' identity. In worst case scenario approximately 20% of these doses were assessed as a potential adverse event. Controlling the patient's identity before administered medication was not a standard routine in the included wards, and furthermore, the recommendations from the Danish National Board of Health are ambiguous. There is thus a real risk gap in the medication process that needs to be bridged by improved procedures or new technologies such as bar code medication administration although this could introduce new paths for medication errors and adverse drug events [28].

Discharge summaries

Discharge summaries had the highest percentage of errors constituting almost half of all errors detected in the present study. Previous studies investigating medication in discharge summaries and in medical records have shown discrepancy in 16–36% of prescribed drugs [12–14]. Still, more than twice as

many errors were identified in our study, presumably as a consequence of the stringent and detailed criteria of the present design. Whether these criteria were too idealistic, in comparison with clinical practice could be discussed. Yet, the systematic information collected in the present study points out weaknesses in existing practice. For example, more than two-thirds of the identified errors were caused by lack of transcribing eligible prescriptions into discharge summaries, due to lack of discontinuing expired drug prescriptions. These findings, among others, stress a need for general and unambiguous guidelines for drug prescriptions in discharge summaries.

Study limitations

This study has some limitations. The validity of the modified observation length was checked by an unannounced control visit in each ward, indicating no influential consequences. The study was conducted in one medical and one surgical ward in a single university hospital and therefore results are not to be extrapolated to other hospitals or cultures. However, many of the results were in accordance with former studies thus indicating a general line with our findings.

Conclusion

Errors were observed in almost every second handling of medication in the present study. Quality improvements are required in most of the stages of the medication process. Several of the identified errors and error types, at least in theory, could be avoided by automated solutions like computerized order entry, electronic discharge summaries, and bar code medication administration [19,20,29,30]. Based upon the low frequency of errors detected at the dispensing stage in combination with the overall uncertainty of the effect of a unit dose system, it remains uncertain whether unit dose systems would be an effective solution in the dispensing stage [11,22,23,25]. Other interventions must also be considered, i.e. evidence-based clinical guidelines for safe medication practice, unified medication charts, unambiguous recommendations for controlling patient identity as well as unambiguous recommendations for drug prescriptions in discharge summaries.

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Category	Definition	Definition of keywords
Potentially fatal	Medication errors judged to imply a potential clinical risk for causing the death of the patient	Fatal refers to medication errors that could lead to the death of the patient
Potentially serious	Medication errors judged to imply a potential clinical risk of <i>injuring</i> the patient	<i>Injury</i> includes medication errors that would require active treatment to restore the health of the patient. A potentially serious error would lead to either permanent or temporary disability
Potentially significant	Medication errors judged to imply a potential clinical risk of being <i>inconvenient</i> for the patient— without causing any harm or injury	<i>Inconvenient</i> refers to unpleasant consequences of wrong dose/drug or omission of dose/drug that could lead to pain, dizziness. It also refers to any monitoring of the patient such as extra blood test, measurement of blood pressure
Potentially non-significant	Medication errors judged to be without any potential clinical risk for the patient	Without clinical risk refers to medication errors that did not lead to any injury or inconvenience for the patient

Appendix I Definition of potential clinical consequences