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Your clinical pharmacist can save your life, the impact of pharmacist's intervention

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Abstract

Objective: Patient safety and adverse event analysis are of paramount importance in the management of patient medication, given the significant economic burden they place on a country's healthcare system. Medication errors fall into the category of preventable adverse drug therapy events and are therefore of key importance from a patient safety perspective. Our study aims to identify the types of medication errors associated with the medication dispensing process and to determine whether automated individual medication dispensing with pharmacist intervention significantly reduces medication errors, thereby increasing patient safety, compared to traditional, ward base medication dispensing (by a nurse). Method: A prospective, quantitative, doubleblind point prevalence study was conducted in three inpatient internal medicine wards of Komló Hospital in February 2018 and 2020. We analyzed data from comparisons of prescribed and non-prescribed oral medications in 83 and 90 patients per year aged 18 years or older with different diagnoses treated for internal medicine on the same day and in the same ward. In the 2018 cohort, medication was traditionally dispensed by a ward nurse, while in the 2020 cohort, it used automated individual medication dispensing with pharmacist intervention. Transdermally administered, parenteral and patient-introduced preparations were excluded from our study. Results: We identified the most common types of errors associated with drug dispensing. The overall error rate in the 2020 cohort was significantly lower (0.9%) than in the 2018 cohort (18.1%) (p < 0.05). Medication errors were observed in 51% of patients in the 2018 cohort, i.e. 42 patients, of which 23 had multiple errors simultaneously. In contrast, in the 2020 cohort, a medication error occurred in 2%, i.e. 2 patients (p < 0.05). When evaluating the potential clinical consequences of medication errors, in the 2018 cohort, the proportion of potentially significant errors was 76.2% and potentially serious errors 21.4%, whereas in the 2020 cohort, only three medication errors were identified in the potentially significant category due to pharmacist intervention, which was significantly lower (p < 0.05). Polypharmacy was detected in 42.2% of patients in the first study and in 12.2% (p < 0.05) in the second study. Conclusion: Automated individual medication dispensing with pharmacist intervention is a suitable method to increase the safety of hospital medication, reduce medication errors, and thus improve patient safety.

Keywords: patient safety; medication error; clinical pharmacist; unit dose drug distribution systems; polypharmacy

INTRODUCTION

Patient safety is a key indicator of healthcare quality, of which medication safety and medication-related issues are an integral part. According to a recent study in the United States, medication errors are associated with 250 000 deaths per year, making them the third most common cause of death.¹ Economic analyses by Elliot et al. estimated that 237 million medication errors occur in England annually, costing the NHS £98.462.582, consuming 181 626 bed-days, and causing or contributing to 712 or 1708 deaths, respectively. Most errors occur in administration (54%), prescribing (21%), and

Eva Polics SÁGINÉ*. PharmD. Komló Health Centre Mining Aftercare and Night Sanatorium Health Centre Institutional Pharmacy, Komló, Hungary. eva.polics@gmail.com **Zsófia ROMVÁRI.** PharmD. Komló Health Centre Mining Aftercare and Night Sanatorium Health Centre Institutional Pharmacy, Komló, Hungary. gyogyszertar@komloikorhaz.hu **Katalin DORMÁN.** PharmD. Komló Health Centre Mining Aftercare and Night Sanatorium Health Centre Institutional Pharmacy, Komló, Hungary. gyogyszertar@komloikorhaz.hu **Dóra ENDREI. MD.** Faculty of Health Sciences, Institute for Health Insurance, University of Pécs, Medical Center, Pécs, Hungary. endrei.dora@pte.hu dispensing (16%). Most medication errors (72%) have little/no potential for harm, and only 2% have potential to cause severe harm.² According to the European Medicines Agency data on the prevalence of medication errors in Europe, 18% of adverse drug therapy events among hospital patients are related to medication errors. 7-56% of adverse drug events in hospital patients are due to medication errors that could be prevented.³ Previous studies suggest that, although data vary by hospital department, patient group, and survey methods, medication errors occur on average in 10-20% of cases. They can result in an unnoticeable event with no clinical risk, but can also cause pain, discomfort or even permanent damage due to a missing single dose of medication, or in the worst case, death. As a consequence, the patient's condition and faith in the health care system may be affected, and in addition to professional liability, there may be serious financial consequences, as the error may require additional drug therapy and days in hospital.^{4,5} The nomenclature of the literature on medication errors and misuse of medicines is not uniform. From a patient safety perspective, Adverse Drug Events (ADEs) should be a priority, as they are preventable, whereas the detection of Adverse Drug Reactions (ADRs) will only become increasingly successful with the incorporation of newer knowledge, such as pharmacogenetic studies.^{5,6} According to the National Coordinating Council for Medication Error Reporting and Prevention, a medication error is defined as any preventable



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adverse event that results(s) in inappropriate medication use or patient harm while the medication is under the control of the patient or healthcare personnel. These events may be related to professional activities, products, procedures, as well as information (communication) given at the time of prescribing, ordering and/or dispensing, product labelling, packaging, nomenclature, compounding, dispensing, administration, counselling, monitoring, and use.

Analysis of data from (voluntary) adverse event reporting systems, direct observation of medication administration, and examination of patient records may be a suitable method for assessing the safety of medication.⁷ Some studies have reported that only 10% of detected errors are included in voluntary reporting systems, and thus analyses based on these data underrepresent the frequency of errors.⁸ In our study, we conducted prospective, real-time analyses of medication dispensing.

Our study aimed to clarify the types of medication errors associated with the medication dispensing process and whether automated, individual medication dispensing with pharmacist intervention significantly reduces medication errors compared to traditional medication dispensing (by a ward nurse), thereby increasing patient safety. The primary outcome being tested was the overall (aggregate) error rate in the 2018 (pre-intervention) cohort vs. the 2020 (post-intervention) cohort, and secondary outcomes were overall and ward-specific point prevalence error rates, error type, level of severity, and polypharmacy in the 2018 cohort vs. 2020 cohort.

METHODS

Study design

A prospective, quantitative, double-blind point-prevalence study was conducted at the active inpatient, chronic, and nursing internal medicine wards of the Komló Health Centre, Komló Miners' Post-Treatment and Night Sanatorium Medical Centre. In the 2018 cohort, medication was traditionally administered by a specialist nurse on the active ward on a daily basis during the day shift and on the long-stay wards (chronic and nursing wards) on a weekly basis during the night shift. For every patient, medications were dispensed into a weekly/ daily container. In the 2020 cohort, the institution introduced a new method of dispensing medication: automated individual medication dispensing with pharmacist intervention. The patients' medication is recorded into the new medical software on the ward followed by a validation process (medication reconciliation and medication review) by a hospital pharmacist who reviews the patients' medical records. The pharmacist also participates on the ward rounds. The medication itself is dispensed into multi-unit dose packs centralized in the hospital pharmacy.

This study compared errors in orally administered medications prescribed to admitted patients with different diagnoses, aged 18 years and over, in February 2018 and February 2020. We

examined the medications intented to be taken in the morning by the patients in both cohorts.

We excluded transdermal, parenteral, and patient-introduced preparations from our study. Documentation of drug allergies, drug interactions, and prescribing errors were not investigated.

This study was approved by the local Ethical Committee. Data were de-identified before analysis so patient consent was not required.

Outcome measures

The present study focuses on medication errors that occur in medication dispensing process. We defined medication dispensing errors as any discrepancy between the medication ordered by the physician and the medication dispensed to the patient. For the assessment, we labeled the dispensing as "correct" if the medicatons dispensed were the same as ordered, regarding quantity dispensed, dosage (e.g. 30 mg), and formulation (capsule/tablet). The rate of error associated with drug dispensing was calculated based on the ordered and observed doses (total number of errors / total opportunities for error). The total opportunities for error was defined as the sum of the number of medications ordered plus the number of unordered but dispensed medications.^{4,9-11}

The assessment of clinical consequences of recorded medication errors was classified into four categories according to the nomenclature of the literature, as follows. Potentially insignificant: medication errors that are assumed to pose no clinical risk; potentially significant: medication errors that pose an "unpleasant" clinical risk to the patient, but do not cause injury or harm; potentially serious: medication errors that are assumed to pose a risk of harm to the patient; potentially fatal: medication errors that pose a clinical risk of death to the patient.¹² In the evaluation, we compared dispensed and ordered drugs taking into account the substitution rules medicines in the same ATC (Anatomical Therapeutic Chemical classification system) 7 level are regarded bioequivalent. The primary outcome being tested was the overall (aggregate) error rate in the 2018 cohort vs. 2020 cohort, and secondary outcomes were overall and ward-specific point prevalence error rates, error type, level of severity, and polypharmacy in the 2018 cohort vs. 2020 cohort. We also performed a subgroup analysis at the level of the departments included in the study. At present, the nomenclature of polypharmacy in the literature is not uniform, and we adopted the most accepted view, i.e., we considered polypharmacy in all medication regimens where more than 5 drugs were prescribed to a patient at the same time.13,14

Data collection

The source of the data was the integrated hospital information system (HIS) and the patient's medical charts.

Statistical analysis

For the statistical analysis of our study, we used SPSS statistic version 25, descriptive statistics, χ^2 test, and analysis of variance



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(ANOVA) at a 95% significance level (p < 0.05). The dependent variable of our study was the method of medication dispensing (in the 2018 cohort, medication dispensing by a specialist in a ward setting, and in the 2020 cohort, medication dispensing by an individual pharmacist intervention supported by automation), and the independent variables were the number and type of medication errors, clinical outcome assessment, number of patients with polypharmacy. The source of data was the patients' medical charts/medication records, and medical and pharmacy software (Asseco-Medworks-Globenet-Pharmaglobe).

RESULTS

We included 83 patients in the 2018 cohort and 90 patients in the 2020 cohort according to the criteria given above. In the 2018 cohort, the average age of the patients included was 76.4 \pm 6.99 years (65-92 years old) and 35 % were male, while the agerage age was 76.23 \pm 7.46 years (59-92 years old) and 31 % were male in the 2020 cohort. Overall, there was no significant difference in the mean age (overall or by ward) or sex ratio when comparing the 2018 and 2020 cohort. According to the profile of the wards and the progressive level of the hospital, the study population consisted of elderly polymorbid patients. Detailed information on patient data is summarised in Table 1.

In the 2018 cohort, the number of observed doses was 411 and the number of ordered doses was 435, while the maximum number of errors was 444 and the total number of errors was 91. Looking at the aggregated data by department, the highest error rate related to medication dispensing was observed in the chronic ward (30.5%), followed by the nursing ward (20.9%), and then the active internal medicine ward (4.6%). (Figure 1).

In the 2020 cohort, the number of observed doses was 299, the number of ordered doses was 303, the maximum number of errors was 303 and the total number of errors was 3. Also analyzing the subgroups by department, the error rate percentage associated with medication dispensing was 2,2 % in the nursing department; 0,7 % in the chronic department; 0% in the active internal medicine department, i.e. the overall error rate was found to be 1%. When the medication error rate was analyzed using subgroup and case level ANOVA, we obtained results of 23.6% in the chronic ward, 22.8% in the nursing ward, and 3.1% in the active internal medicine ward in

| Table 1. Clinical data of patients | | | | | | |
|--|---|---|----|--|--|--|
| Patient data | 2018 cohort | 2020 cohort | | | | |
| | traditional dispensing by a nurse | automated individual medication dispensing with pharmacist intervention | р | | | |
| Number of patients (n) | 83 | 90 | NS | | | |
| Average age of patients (years) | 76.54 ±6.99 | 76.23 ±7.46 | NS | | | |
| Average age of patients (nursing ward) | 81.66 ±7.14 | 81.95 ±6.33 | NS | | | |
| Average age of patients (chronic ward) | 76.4 ±6.23 | 77.8 ±7.71 | NS | | | |
| Average age of patients (internal medicine ward) | 76.5 ±6.94 | 74.6 ±7.82 | NS | | | |
| Gender male / female (n/%) | 29/54 (35/65) | 28/62 (31/69) | NS | | | |



Figure 1. Aggregate error rate percentage for drug dispensing at the two study dates (aggregate data)

2018 cohort, compared to 2.5% in the nursing ward and 0.7% in chronic ward in the 2020 cohort. No errors were detected in the internal medicine ward in the 2020 cohort. Summing the results by year at the case level, we found the medication error rate to be 18.1% (95% CI: 14.1-22.1) in the 2018 cohort and 0.9% (95% CI: 0.3-4.8) in the 2020 cohort. In all cases, the difference was significant in the subgroup analysis (p < 0.05) (Table 2).

| Table 2. Error rate related to dispensing of medicines | | | | | | | | |
|--|------------------------|----------------------------|-------------------------------|------|---|-------------|--|------|
| | Maximum opportuniti | number of ies for error | Total number of E errors m | | Error rate for drug dispensing of medicines % aggregated analysis | | Error rate related to dispensing of medicines % (calculated by ANOVA) | |
| Cohort | 2018 | 2020 | 2018 | 2020 | 2018 | 2020 | 2018 | 2020 |
| Nursing ward | 172 | 92 | 36 | 2 | 20.9 (36/172) | 2,2 (2/92) | 22.8 | 2.5* |
| Chronic ward | 164 | 135 | 50 | 1 | 30.5 (50/164) | 0,7 (1/135) | 23.6 | 0.7* |
| Internal medicine ward | 108 | 76 | 5 | 0 | 4.6 (5/108) | 0 (0/76) | 3.1 | 0* |
| Aggregated | 444 | 303 | 91 | 3 | 20.5 (91/444) | 1*(3/303) | 18.1 | 0.9* |

***p** < 0.05



51% of patients in the three wards studied were affected by medication errors in the 2018 cohort compared to 2% in the 2020 cohort. When analyzed in detail the 2018 cohort, 23 patients (77%) in the nursing ward, 15 patients (47%) in the chronic ward, and 4 patients (19%) in the active internal medicine ward suffered from medication errors. The subgroup analysis of the ward medication method highlighted that medication errors were significantly higher for medication given weekly during the night shift compared to daily during the day shift. In the 2020 cohort one patient was hospitalized in the nursing ward and one in the chronic ward. Based on the χ^2 squared test at a 95% confidence interval, the result considering dispensing error was significantly lower in the 2020 cohort which used automated individual medication dispensing with pharmacist intervention (p < 0.05).

In our study, we identified the most common types of errors associated with drug dispensing: missed doses, unordered (excess) doses, incorrect timing, inappropriate substitution within ATC group (level VII) and outside (level V), and incorrect dosage. A total of 74 medication errors were detected in the traditional ward method, representing 98 drug doses, affecting 50.6% of patients, with 23 patients involved in multiple errors. The types of errors detected, expressed as a percentage of all types of errors identified during surveillance in the 2018 cohort, were: missed distribution of medicines 44.6%, within ATC group (level VII) 27.1%, outside ATC group (level V) 27.1%, and in the ATC group (level VII) 27.1%. level) 16.2% substitution, medication dose not included in the order (excess) 12.2%, different time of day/dosing regimen 7.5%, different dose 2.7% frequency. In the 2020 cohort, the total number of errors was 3, for 2 patients. One patient was involved in multiple medication errors including a missed dose and incorrect dosage, while the other patient just a missed dose (Table 3).

When assessing the potential clinical consequences of medication errors for patients in the 2018 cohort, the rate of potentially minor errors was 2.4%, the rate of potentially major errors was 76.2%, and the rate of potentially serious errors was 21.4%. In contrast, in the 2020 cohort, we detected a total of three medication errors in individual medication administration which were all classified as potentially significant.

The percentage of patients affected by polypharmacy in the 2018 cohort was 42.2% This proportion decreased significantly to 12.2% in the 2020 cohort (p < 0.05), (Figure 2).

DISCUSSION

In our research, we identified the types of medication errors associated with the medication dispensing process in our hospital, and demonstrated that the implementation of an automated medication dispensing system with pharmacist intervention in the the Komló Health Centre, Komló Miners' Post-Treatment and Night Sanatorium Medical Centre significantly reduced medication errors, thus increasing patient safety. In other studies, investigating medication errors, results are found in a wide range of error rates (3-44%).^{4,5,15-18} Intensive

| Table 3. Types and rates of medication errors as % of total errors | | | | | | | | |
|--|-----------------|------|-----------------|------|---------------------------------------|------|--------------------------------|------|
| Type of error in % 2018 (n= 74), 2020 (n= 3) | NURSING ward | | CHRONIC ward | | INTERNAL MEDICINE ward (active) | | Aggregated all errors in %- | |
| Cohort | 2018 | 2020 | 2018 | 2020 | 2018 | 2020 | 2018 | 2020 |
| Missed medicine | 18.9 | 33.3 | 25.7 | 33.3 | 0 | 0 | 44.6 | 66.6 |
| Non-prescribed medicine | 4 | 0 | 6.8 | 0 | 1.4 | 0 | 12.2 | 0 |
| Outside ATC group (V) substitution | 6.7 | 0 | 8.1 | 0 | 1.4 | 0 | 16.2 | 0 |
| Within ATC group (VII) substitution | 13.5 | 0 | 12.2 | 0 | 1.4 | 0 | 27.1 | 0 |
| Different time of day | 1.4 | 0 | 5.4 | 0 | 1.4 | 0 | 7.5 | 0 |
| Different dose | 0 | 33.3 | 2.7 | 0 | 0 | 0 | 2.7 | 33.3 |

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Figure 2. Number of patients affected by polypharmacy

care unit therapies are the most burdened with any medication error due to the use of parenteral and high-risk medications.¹⁸ It is important to highlight, however, that the nomenclature of studies on medication error is not uniform, as they define medication error in different ways and often use different algorithms to calculate error rates. A further discrepancy in the comparison of results may be caused by the fact that the literature conflates the different stages of medication administration, i.e. does not distinguish between the processes involved in prescribing, dispensing, and administering medication and monitoring therapy, and also evaluates the types of errors in common. It is important to underline that in our study we only examined errors related to the process of dispensing medication and did not analyze errors related to prescribing and administration.

A direct observational study by Lám et al. detected a medication error rate of 14.1% during medication administration by a ward nurse, compared to which we found a higher overall error rate of 20.5% in our study.¹⁸ This may be due to the lower number of doses tested, the difference in the profile of the selected wards, the difference in the frequency of medication distribution, and the higher number of patients with polypharmacy. We also performed a subgroup analysis of our data recorded in 2018



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cohort, and thus the department results fell within a range of 3.1-23.6 % of medication errors. The subgroup analysis of the ward medication method highlighted that medication errors were significantly higher for medication given weekly during the night shift compared to daily during the day shift. Possible explanations include lower educational attainment of staff in long-stay wards, high staff turnover, night shift dispensing, once-weekly rounds, monotony and weekly frequency of medication dispensing process (huge amounts of medication dispensed over a long period of time hence attention might get lower), high task volume due to large numbers of patients, increased drug stock, the rise of generic drugs (higher risk for duplications), and the emergence of drugs with similar packaging (look-alike) and similar sound (sound alike). We found an error rate of 1% in our study when using automated individual medication dispensing with pharmacist intervention, demonstrating that this is a suitable method to reduce medication errors associated with medication dispensing and increase medication safety.

When comparing the pattern of medication error types with other studies in the literature review, we found a discrepancy. While in other studies, the leading error type was inappropriate dosing, in our study, inappropriate substitution within and outside the ATC group from omitted drug division ranked in the top three in the ranking of detected errors.^{16,19-21} In drug-level differential substitution (ATC 7-level), HMG-CoA reductase inhibitors (ATC: C10AA), which belong to the group of cholesterol-lowering agents, were found to be the most affected drug group, while proton pump inhibitors (ATC: A02BC) were the most affected drug group among the acidlowering agents, and proton pump inhibitor and H2 receptor blocker replacement (ATC: A02BA03) was the most affected drug group at ATC 5 level.¹⁸

Assessing the potential clinical consequences of medication errors in the 2018 cohort, we found two fatal events. Both cases were due to limitations in the legibility of the medical chart and limitations (not competence) of the relevant knowledge of drug action of the dispensing practitioner. In one case, a fivefold digoxin overdose was detected. The error was immediately reported and corrected, so it did not reach the patient, but the patient received the wrong dose the day before the check. The error was reported and investigated, the necessary tests were performed on the patient concerned, and no complications or negative outcome occurred.

Regarding medication errors, polypharmacy can be clearly identified as a risk factor.²² An important conclusion of our study is that clinical pharmacist intervention has significantly reduced the number of patients with polypharmacy from 42.2% to 12.2% which is of particular importance given the high average age of patients and potential drug interactions. This fact is of paramount importance, as our institution has a high proportion of polymorbid elderly patients. In parallel with comorbidity, the number of prescribed/required medications increases. Taking several drugs at the same time increases the possibility of drug interactions, often leads to therapeutic non-

adherence, increases the complexity of treatment, the cost of treatment, the likelihood of adverse events and side effects, which may result in hospitalization.

Geriatric medication also requires special expertise from a pharmacist, as inappropriate medication can also impair the patient's quality of life. In pharmacist therapy validation, particular attention is paid to the patient's laboratory parameters (renal, liver function parameters) and the use of PIM (Potentially Inappropriate Medication) lists.²³ Preference is given to fixed drug combinations and modified release regimens, with particular attention to the use of pain relief in the elderly, the use of medications, and often unjustified proton pump inhibitor therapies, which are a pathogenic factor in the increase in the incidence of Clostridium difficile infection.²⁴

In the 2020 cohort we identified an administrative failure in the nexus of the medical chart program, a critical point of individual medication tracking. Since then, we have taken steps as part of our risk management activities and to reduce the risk, the pharmacist attends the ward rounds with a tablet, where real-time data recording and therapy changes can be made immediately. The possible introduction of an e-medical chart would further minimise the risks inherent in the system. The problem resolved after a few months, when this process has become routine. All this did not affect the results of our study.

Limitations and strengths of the study

A limitation of our study is that it was conducted at a single time point, which meant that a relatively small number of patients were included, so to overcome this it may be appropriate to repeat the study over a longer period of time with a larger population. Our observation only detected medication errors associated with oral medications and did not cover transdermal, parenteral medications, home-use medications, and other preparations. From a patient safety point of view, the use of own (brought from home) medications poses many risks. Analyzed further, it is a known fact that patients, in addition to their prescription medicines, often bring OTC drugs, vitamins, other products, herbal teas, "miracle drugs" to inpatient facilities, which are often not communicated to the treating physician, healthcare staff, although they are considered a significant risk factor for medication and the clinical condition of the patient. The potential clinical consequences of medication errors were only assessed by one pharmacist (at the time of the first study, a pharmacist colleague was working in the hospital), it would be useful if at least two pharmacists independently assessed the outcomes. Out of the three phases of medication administration (ordering, dispensing, administration), only errors related to medication dispensing were examined, not the other phases - ordering, administration - although they can often be fraught with errors.

Automated individual medication dispensing with pharmacist intervention, makes the drug pathway from prescription to administration transparent at every step, and automation as a technology minimizes the possibility of human error, ensuring



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that medication errors do not reach the patient.

studies with larger patient numbers are needed in the future.

CONCLUSION

Our study confirmed that, in line with international and national literature, a high proportion of patients' medication is affected by medication errors. Considering that medication errors fall into the category of preventable adverse events, assessing the risks associated with the process, establishing audit trails, and managing the risks should be a priority for a healthcare institution. Our study has demonstrated that by introducing automated individual medication dispensing and pharmacist intervention, the safety of medication administration, and thus patient safety, can be significantly improved compared to the process performed by a nurse in a ward setting. Prospective

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CONFLICTS OF INTEREST

The authors have no conflicts of interest to declare that are relevant to the content of this article.

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