Patient Safety in Outpatient Care: Results of A Multicenter Cross-Sectional Study About Medication Errors and Medication Management

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Abstract

Background: Medication errors occur frequently. Studies assume that up to 30% of care recipients are exposed to a possible medication error. Specific medication errors include taking the wrong doses or quantities of medication as well as omitting medication. For the outpatient sector, the study situation regarding such errors is limited. Therefore, it was investigated how often medication errors occur or have been reported and whether they are related to training, quality assurance measures and other structural conditions of outpatient care services.

Methods: A Germany-wide cross-sectional study was conducted in the winter of 2016/2017 among care employees of outpatient care services. A total of 107 outpatient care services with 656 employees were included in the study. Within the framework of logistic regressions, correlations were investigated between errors committed and errors reported in terms of the years of work experience, completed medication training, the type of employment, geographical location of employment, application of the dual control principle, and the number of patients per shift.

Results: A total of 107 outpatient care services could be included in the study, with 656 employees. Of 413 fully qualified nurses, 48.9% stated that they had themselves made an error in a 12-month period. Of all care workers questioned, 30.2% said they had reported errors, with 127 people providing no information on this issue. Provided that nurses had attended medication training within the last two years, the odds of not making medication-related errors were almost twice as high (odds ratio (OR) 1.79; confidence interval (CI) 1.42 - 3.09). Whenever nursing staff applied the dual control principle, the odds of not making a mistake were more than three times higher (OR 3.13; IK 1.88-5.20) than when the principle was not applied. The odds of reporting an error were almost twice as high (OR 1.92; IK 1.18-3.13) when the dual control principle was used compared to when it was not used.

Conclusion: Medication-related errors occur frequently in outpatient care. Regular training and adequate quality management measures (e.g. application of the dual control principle) can help to make the medication process safer for everyone involved in outpatient care.

Background

“A medication error is an unintended failure in the drug treatment process that leads to, or has the potential to lead to, harm to the patient. A failure in the drug treatment process does not refer to lack of efficacy of the drug, rather to human or process mediated failures” [1]. Medication errors occur frequently, endanger patient safety and are seen as preventable adverse events in outpatient and inpatient health care facilities. [2]. Patient safety means the absence and prevention of adverse events [3, 4]. The WHO defines patient safety thus: ‘Patient safety is the absence of preventable harm to a patient during the process of health care and reduction of risk of unnecessary harm associated with health care to an acceptable minimum” [5]. The key message of the APS, the German Coalition for Patient Safety, on this issue is that ‘patient safety can be learned’ [3]. Hand hygiene and drug safety have been identified as key

problem areas for patient safety [4]. The WHO estimates that half of all drugs are incorrectly prescribed, stored, administered or used [6]. Studies have shown that up to 30% of patients are exposed to a potential medication error, and that half of these errors occur during administration of the drug [2, 7, 8]. In outpatient care, specific medication errors include taking the wrong dose or quantity of a particular drug as well as omission of a drug or taking unlicensed drugs [9]. The APS points out that five per cent of all hospital admissions are caused by medication errors. Of these, two per cent have a fatal outcome [10, 11]. A statement from the German Bundestag points to approximately 250,000 hospital admissions being due to medication errors [12]. Medication-related errors can be associated with a diminished quality of life. This could lead for example to a greater risk of falls and potential subsequent injuries in elderly patients [13]. As well as causing suffering to those concerned, significant costs also arise for the health care system. In England it is estimated that over 237 million medication errors occur every year. This incurs extra costs of approximately 108 million euros for the NHS, as longer hospital stays or admissions are necessary [8, 14]. In Germany, the annual costs incurred by medication errors are estimated to be over one billion euros [15]. Studies show that with the increasing number of drugs being taken daily, the risk of drug interactions and preventable adverse events is on the rise [7]. Elderly and very aged patients are particularly affected by this, as on account of their multimorbidity they are often affected by multimedication [16]. This is the case especially in outpatient care, as the medication process in home care is particularly complex and additional support is required for the procurement and use of the drugs [17]. Berland et al. point out that an insufficient exchange of information and poor communication between the specialist physician, outpatient care staff and other parties can lead to medication errors [18]. In principle, errors can occur at any stage of the medication process. It is therefore crucial that nursing staff who administer medication to patients in care continually evaluate the medication process [7]. Fully trained nurses play a central role in the medication process, as they are responsible for the entire medication management. It is to be assumed that staff qualification and overall conditions have an influence on the safety of patients in care. It is of key importance that nursing staff are able to recognize errors within the medication process and to report them accordingly [18]. In inpatient care, the *'CIRS'* (CIRS = Critical Incident Reporting System) plays a significant role. CIRS serves to report critical incidents anonymously, to subsequently evaluate them and deduce appropriate measures [19]. As part of this process, nursing staff as well as others are alerted to potential dangers and errors in order to reduce the occurrence of errors. Respective 'CIRS cases' are made available on a platform, which is beneficial for the prevention of errors. The current study situation on medication management and medication errors in outpatient care is limited [20]. Therefore, the following research questions were posed in the scope of this study:

1. How often do medication-related errors occur in outpatient care and how often are they reported (wrong or deficient administration of the drug)?
2. To what extent do regular medication training and quality assurance measures make the medication process safer for those receiving care?
3. Which additional circumstances have an influence?

Methods

Study design, setting and study participants:

As part of a cross-sectional study in Germany, a study was performed with the nursing staff of outpatient services in the winter of 2016/2017. Two different sample groups were studied (auxiliary nurses and fully trained nurses versus only fully trained nurses), as only fully qualified care staff are authorised to administer medication. As a consequence, only the latter are in a position to make medication errors. Care workers who registered as having a qualification as a public health nurse, a carer for the elderly, a children's nurse or a bachelor's degree, were categorized here as 'fully qualified'. Trainees, auxiliary nurses and other care workers were categorized as 'not fully qualified'. By running a pre-test, the questionnaire used was tested for clarity, readability and applicability. The results of the pre-tests were positive. A list of 30 outpatient facilities per German federal state was generated at random by computer. Of these, 10 facilities were to be included in the study. The randomly selected facilities were then contacted by email or telephone. The selected care facilities received brief written information regarding the study goals and the corresponding course of the study. The facility then gave its binding acceptance of participation in the study in writing. If one care facility chose not to participate in the study, the following institution was contacted from the randomly compiled list. If all 30 randomly selected facilities in one federal state had been contacted but the target number of 10 care facilities could not be reached, a new list was compiled at random. This procedure was to be repeated as many times as necessary until the target of 10 institutions per federal state was reached. In spite of an extended recruitment phase however, the desired number of institutions could not be reached.

Variables:

The outcomes 'error committed' and 'error reported' were determined as dependent variables. The outcome 'error committed' referred to errors made by fully qualified nursing staff when administering medication. 'Error reported' focused on the amount of medication-related errors reported within the last three months. The reporting person did not have to be the same person who caused the error. For the analysis all numbers > 1 were summarized to *yes* and "0" to *no*. The following categories were defined as independent variables: 'work experience in years', 'medication training' (no training or training over 2 years ago, or training attended within the last 2 years), 'type of work contract' (full-time/part-time), 'employed in Germany's new (former East) or old (former West) federal states', 'dual control principle' (rarely / frequently used), and 'number of patients per shift'. The assessment of the use of the dual control or 'four-eye' principle was made on a scale of 1-10, where a score of 1-5 was classified in the category of 'frequent' and evaluations of 6-10 were deemed 'rare'. On the scale of 1-10 (1= never, 10= always) it was measured whether and if so, how often, care staff used the dual control principle (when two people are present and check the medicine provided, either together or one after the other) when administering the drugs.

Data sources and measurement methods:

The questionnaires were sent out by post to the participating institutions. A guideline was enclosed with instructions on how to fill out the form correctly. A telephone number was provided in case of any further questions.

Methods against bias:

All study participants were assured of the confidential treatment of the data they provided. A pre-franked envelope was enclosed with every questionnaire so it could be filled out and sent back irrespective of location. The questionnaire was created by computer. The scanned in data (questionnaires) were checked for plausibility in terms of content and errors.

Sample group:

As this is an exploratory study, no specific sample group size was determined. For sufficient precision of the point estimators investigated, a target sample size of around 800 evaluable questionnaires was determined. This is based on the calculation that 10 care facilities could be recruited per federal state and 10 nursing staff could be questioned per outpatient service. A response rate of 50% was assumed.

Statistical Analysis:

The collected data was checked twice, scanned in and then entered in the statistical programme SPSS 24. Along with the descriptive representation of the two dependent variables ‘error committed’ and ‘error reported’ as well as the independent variables ‘work experience in years’, ‘medication training’ (no training or training over 2 years ago, or training within the last 2 years), ‘type of work contract’ (full-time/part-time), ‘employed in Germany’s new (former East) or old (former West) federal states’, ‘dual control principle’ (rarely / frequently used), and ‘number of clients per shift’) the presumed correlations were analysed on a bivariate basis and tested for statistical significance. All independent variables were subsequently included in a respective multivariate logistic regression model. A p-value of <0,05 (two-sided) was assumed to be statistically significant.

Results

Sample group:

In spite of the extended recruitment phase, out of the 480 care facilities selected at random (30 care facilities per federal state) a total of 107 outpatient services could be included in the study. 656 nursing staff from these outpatient services filled in and returned the questionnaires. The median per participating care facility was at n = 5 staff (the first quartile at n = 3, the third quartile at n = 7). Of the 656 staff, 485 were qualified nurses. Only this group of persons was considered for the 1st outcome ‘error committed’. Of those, over half were full-time staff, (50.4%) and 47.8% were employed part-time. Nine employees (1.8%) did not specify their contract terms. The majority of the care workers (81.1%; n = 393) were employed in the federal states of former West Germany. Over half of the nursing staff (55.1%; n = 267) rarely practised the dual control principle when administering drugs, however almost 30% (n = 142)

made regular use of the practice. 473 specified their work experience in years and 447 qualified care staff stated the number of patients per shift. The average here was 18.3 years' work experience and 15.1 patients cared for per shift.

For the 2nd outcome 'error reported' the particulars of all care workers were gathered (fully qualified = qualified nursing staff, not fully qualified = auxiliary nurses, trainees and other employees). The average number of years of work experience was (n = 624) 16.4 years, the average number of patients in care per shift (n = 598) was 14.3 patients. 339 care workers were employed full time and 302 care workers were employed part time. The majority of the nursing staff had attended drug administration training (n = 431) less than two years ago. 181 of them had attended drug administration training over two years ago or had not attended any training. 44 staff gave no information regarding the training. (Supplement 1). The dual control principle was used rarely by 294 nursing staff and frequently by 171 nursing staff. 189 employees provided no information on this. Further information describing the sample groups can be found in Supplement 1.

Descriptive Analysis

Regarding errors committed, data was provided by 413 nursing staff. Of these, 48.9% reported having made an error themselves.

Table 1 **Representation of correlations between medication administration and the variables investigated (descriptive bivariate analysis**)

Table 1
a) categorical variables

Variable (dependent) investigated: **Personally made an error when administering medication (N = 485, no: n = 211, yes: n = 202, not specified: n = 72)**							
Variables (independent) investigated (by category)		**no**		**yes**		**total**	**Chi2**
		n	%	n	%		p
How long ago was your last medication training?	No training or over 2 years ago	46	38.0%	75	62.0%	121	**0.001**
	Less than 2 years ago	157	55.7%	125	44.3%	282	
Type of work contract?	Employed part time	91	49.5%	93	50.5%	184	0,353
	Employed full time	119	54.1%	101	45.9%	220	
Do you work in the new (East) or old (West) German federal states?	West	163	48.7%	172	51.3%	335	**0,040**
	East	48	61.5%	30	38.5%	78	
Dual control principle used	rarely	85	36.6%	147	63.4%	232	**< 0.001**
	frequently	79	66.9%	39	33.1%	118	

Table 1
b) metric variables

Variable (dependent) investigated: **Personally made an error when administering medication (N = 485, no: n = 211, yes: n = 202 not specified: n = 72)**							
Variables **(independent) investigated Variables (metric)**	**no**			**yes**			**t-Test**
	n	mw	sd	n	mw	sd	p
Years of work experience	207	18.1	10.3	200	18.3	10.5	0.863
No. of patients per shift	196	15.0	9.3	185	15.7	6.7	0.436

In Table 1, statistically significant differences can be seen in terms of drug administration training conducted within the past two years as opposed to training conducted over two years ago or not at all: of the 121 participants whose drug administration training took place over two years ago or who had

received no drug administration training, 62% said that they had committed an error in administering drugs. In comparison, 44.2% of the 282 caregivers who had participated in drug administration training in the previous two years said that they had made an error in administering drugs. As regards the use of the dual control principle, significant differences could also be seen. When nursing staff made rare use of the dual control principle when administering medication, approximately 63.4% (n = 147) of 232 nursing staff made an error. However, if the dual control principle was frequently used, (n = 118), 66.9% of the nursing staff made no error. Concerning the other independent variables, hardly any statistically significant differences could be seen.

Of all the nursing staff questioned, 30.2% said that they had reported an error. 127 people gave no information on this point.

Table 2 **Representation of correlations between the variable 'Error reported in administering medication' and the variables investigated (descriptive bivariate analysis**)

Table 2
a) categorical variables

Variable (dependent) investigated: error reported (N = 656, no: n = 369, yes: n = 160, not specified: n = 127)							
Variables (independent) investigated (by category)		**no**		**yes**		**total**	**Chi2-test**
		n	%	n	%		p
How long ago was your last medication training?	No training or over 2 years ago	110	70.1%	47	29.9%	157	0.779
	Less than 2 years ago	245	68.8%	111	31.2%	356	
Type of work contract?	Employed part time	187	74.8%	63	25.2%	250	0.016
	Employed full time	173	65.0%	93	35.0%	266	
Do you work in the new (East) or old (West) German federal states?	West	289	68.5%	133	31.5%	422	0.146
	East	81	75.7%	26	24.3%	107	
Dual control principle used	rarely	155	59.8	104	40.2%	259	**0.002**
	frequently	115	74.7%	39	25.3%	154	

Table 2
b) metric variables

Variable (dependent) investigated: error reported (N = 656, no: n = 369, yes: n = 160, not specified: n = 127)							
Variables (independent) investigated Variables (metric)	**no**			**yes**			**t-Test (student)**
	n	mw	sd	n	mw	sd	p
Years of work experience	35	16.53	10.20	15	16.60	10.08	0.940
No. of patients per shift	33	14.41	9.24	14	15.78	5.76	**0.048**

In Table 2, statistically significant differences can be seen concerning the use of the dual control principle as well as the number of patients in care per shift. Of the nursing staff (n = 259) who said they rarely used the dual control principle (n = 259), 40.2% (n = 104) reported an error in the administration of medication. However, with nursing staff who often used the dual control principle (n = 154), a comparatively low share of them (25.3%; n = 39) respectively reported an error. Regarding the number of patients cared for per shift, it was evident that a higher number of patients to be cared for per shift (average 15.78) as opposed to fewer patients per shift (average 14.14) had an influence on the occurrence of errors. Statistically significant differences could also be seen in relation to the number of hours worked by the employees. No significant differences could be seen with the other variables.

Representation of the logistic regression calculation – multivariate analysis

Multivariate analyses were calculated analogous to the descriptive specifications in Tables 3 and 4. Table 3 shows the multivariate analysis of the 1st outcome ‘error committed’ and Table 4 shows the 2nd outcome ‘error reported’.

Table 3
Representation of the correlations between the target variable ‘No error committed in administering medication’ and the variables investigated

			95% confidence interval	
	odds ratio	p-value	lowest	highest
Medication training < 2 years ago	1.79	**0.036**	1.04	3,09
Frequent use of dual control principle	3.13	**0.000**	1.88	5,20
Work experience (in years)	1.01	0.360	0.99	1,04
Number of patients (per shift)	0.98	0.200	0.94	1,01
Not full time (0)/ full time (1)	1.44	0.147	0.88	2,37
West (0) - East (1)	1.76	0.080	0.94	3,31
Target variable: No errors made in administering medication				

Table 4
Representation of the correlations between the target variable 'Error reported in administering medication' and the variables investigated

			95% confidence interval	
	odds ratio	p-value	lowest	highest
Medication training < 2 years ago	1.27	0.347	0.76	2.07
Frequent use of dual control principle	1.92	**0.009**	1.18	3.13
Work experience (in years)	1.01	0.289	0.99	1.04
Number of patients (per shift)	0.97	0.080	0.94	1.00
Not full time (0)/ full time (1	0.84	0.481	0.52	1.36
West (0) - East (1)	1.72	0.085	0.93	3.16
Fully qualified (1)	0.74	0.424	0.35	1.55
Target variable: Errors reported in administering medication				

Regarding the 1st outcome 'error committed' the results show that the odds of no errors being made are almost twice as high (odds ratio (OR) 1.79; confidence interval (CI) 1.42–3.09) if drug administration training has taken place within the last two years. Regarding the use of the dual control principle, it can be seen that the odds of committing no error are three times higher if nursing staff (OR 3.13; CI 1.88-5,20) make use of the dual control principle. Concerning the 2nd outcome 'error reported' the odds of an error being reported were almost twice as high (OR 1.92; CI 1.18–3.13) if the dual control principle was used frequently as opposed to a rare use of the dual control principle.

Discussion

The results showed that around half of all nursing staff made an error themselves when administering medication. Errors in connection with administering medication however were reported by around 30% of all care staff (with or without a full qualification). Key differences could however be observed in certain groups:

With the 1st outcome 'error committed' over half of all nursing staff rarely used the dual control principle when providing the drugs. As a relatively high number of nursing staff provided no information on this, it cannot be ruled out that up to 70% of nursing staff rarely use the dual control principle. Over two thirds of the care staff who frequently used the dual control principle made no errors, whereas almost two thirds of carers who rarely used the dual control principle committed an error when administering medication. At this juncture it is pointed out that this measure has already been adopted in others fields of health care [21]. Furthermore, it seems advisable for the quality management of outpatient services to consider the influence of drug administration training on the frequency of errors, as shown within this study. Nursing staff who had completed medication training within the last 24 months made considerably fewer errors. Since almost two thirds of the nursing staff whose training was over 24 months ago or had no training committed an error when administering drugs, it seems judicious to train staff in this area at least once every 24 months. Drug administration training should therefore be seen as a fixed, regular part of the quality concept of outpatient institutions. Along with this study, other studies also show that the training background of the nursing staff has a positive influence on the quality of care and patient safety. From other fields of care, studies show that training, advice and guidance all contribute to ensuring the quality of care and therefore also patient safety [22–24].

For the 2nd outcome ‘error reported’ in the bivariate analysis, statistically significant differences could be seen regarding the number of patients in care per shift, the hours worked by staff (full time / part time) as well as whether they used the dual control principle frequently or rarely. In the following multivariate analysis however only the correlation between frequent use of the dual control principle and a corresponding reporting of errors could be seen. The fact that fewer errors were committed with frequent use of the dual control principle and that the odds of an error being reported with frequent use of the dual control principle were also higher, demonstrates once again how important this simple yet very effective measure is. With regard to the results and the associated recommendation to apply the dual control principle as a continuous measure, it must however be taken into account that the structures are in place in the outpatient sector are different to those in inpatient facilities. It may be that for staffing reasons, the use of the dual control principle is only possible to a limited degree, for instance if the medication is administered in the patient’s home. Here for example a double check by the care worker of the medication administered could be helpful. Time resources would have to be made available for this. Furthermore, it could be difficult for nursing staff in the outpatient sector to report errors, as the structures for this are not (yet) in place in their facility. Finally, it must also be considered that it can be more difficult to report errors anonymously by ‘self-reporting’ in outpatient facilities in general, which could rule out the reporting of errors from the very beginning. Ultimately it should be noted that not all outpatient institutions can fall back on a positive error culture. This study did not examine to what extent CIRS is suitable or already in use in the outpatient sector. However, the study by Meyer-Massetti et al. shows that the availability of CIRS in outpatient facilities is still currently limited and needs to be adapted [20]. Piloting by Meyer-Massetti et al. demonstrated that the most common reporting of errors was in connection with administering medication.

Considering that comprehensive use of CIRS is difficult and a timeline for it is not yet foreseeable, other alternatives should first be used to optimize the medication process within the respective facilities to make them safer for those concerned. Analyses from quality management, particularly those already known from risk management, could help to prevent errors, for example using FMEA (Failure Mode and Effects Analysis). The use of such instruments, for instance in the field of preventing falls in care facilities has been successfully investigated [25]. The use of FMEA can reduce costs as well as assuring quality of care.

Limitations

The analyses of this study are based on statements made by staff working in outpatient care facilities. Due to the survey methodology, bias tendencies caused by socially desirable response behaviour cannot be excluded. It could be possible that the data available potentially underestimates the problem and the number of nursing staff who have either made or reported an error is much higher. Moreover, it is possible that further factors not considered in the scope of this study influence the occurrence and reporting of errors. The fact that the size of the sample group surveyed in the study was not as large as originally planned is an additional factor for consideration. In spite of the designated information and selection bias, the results seem to be fundamentally transferable to all outpatient services.

Conclusion

The study has shown how important the use of the dual control principle is concerning patient safety and the quality of care. Since the dual control principle is common and actively contributes to the prevention of errors, it should be seen as a continuous quality assurance measure and be used accordingly as a standard procedure in outpatient facilities. Furthermore, regular training as well as adequate quality management are crucial contributions to making the medication process safer for everyone concerned.

Abbreviations

WHO = World Health organisation

CIRS = Critical Incident Reporting System

OR = Odds Ratio

FMEA = Failure Mode and Effects Analysis

Declarations

Ethics Approval and Consent to Participate

Participants were given a comprehensive information sheet about the study, explainin the research purpose, significance and benefits. Participants had the right to withdraw from the study at any time without giving a reason. Because of the voluntary character of the survey an oral consent was considered sufficient by the Ethical committee. Ethical approval (EA4/098/16) of the study was obtained from the ethical committee (Ethik Kommittee) of the Charité Universitätsmedizin Berlin university.

Consent for publication

All authors have read and agreed to the published version of the manuscript and provide consent for publication

Competing interests

All Authors declare that they have no financial or personal relationship that influence (bias) their work and have therefore no competing interests to declare.

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Availability of Data and Materials:

The analyzed data for this manuscript can be retrieved on demand from the corresponding author.

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