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Article

Medication errors in critical patients during medication reconciliation: analyses and clinical management

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Medication errors (ME) are frequent in the admission of patients to the ICU and can be identified and prevented through medication reconciliation (MR). Our aim was to evaluate the incidence, type and severity of MEs and associated factors, identified during MR in the ICU. This is a prospective, analytical approach, performed in the ICU of a private hospital, where the MRs were evaluated from April to June 2016. The SPSS and Stata programs were used to analyse the data. Logistic regression was performed to determine the factors associated with MEs. MR was performed with 136 patients, of whom 126 (92.6%) used drugs regularly. The incidence of MEs was 16.3% (95% CI 11.5-21.2). The main classes of drugs involved were those acting on the nervous and cardiovascular systems. There were 128 pharmaceutical interventions (acceptance: 71.1%). Regarding severity, 65.5% (n=80) of the errors reached the patient, but there was no harm. The risk factors for MEs identified were: age ≥60 years, number of comorbidities >1 and previous use of drugs ≥9. The incidence of MEs found and the significant association with age, comorbidities and polymedication alert to the need for specific attention to prevent admission errors in the most susceptible patient groups.

Keywords: Medication reconciliation. Intensive care units. Drug utilization. Patient safety. Medication Errors.

INTRODUCTION

Medication reconciliation (MR) can be defined as the formal process of evaluating the complete list of the patient's drugs prior to admission, compared to pharmacotherapeutic prescriptions after the transition of care (at admission, after change of unit or at hospital discharge). The objective of this process is to ensure that patients receive all necessary drugs they used previously, avoiding the occurrence of medication errors (ME) (Sánchez *et al*., 2007).

ME are among the main causes of morbidity in hospitalized patients (Sánchez *et al*., 2009) and occur mainly when care responsibility changes, and therefore, during transfers between hospital units, the patient is particularly vulnerable to this type of error (Sánchez *et al*., 2008; Knez *et al*., 2011; Pronovost *et al*., 2003). Thus, through MR, it is possible to identify errors related to the admission process, transfer and discharge of the patient. Therefore, the incorporation of this practice into the intensive care unit (ICU) has been encouraged by different authors (Camiré, Moyen, Stelfox, 2009; Lopez-Martin *et al*., 2014; Pronovost *et al*., 2003).

Different studies have found satisfactory results with MR, showing that it is an excellent strategy to reduce the number of discrepancies between the drugs previously used and those prescribed during hospitalization (Allende Bandres *et al*., 2013; Cornish *et al*., 2005; Gleason *et al*., 2004; Zoni *et al*., 2012). These studies are being developed in different care

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units, but there is little information on the incidence and associated factors of medication reconciliation errors in patients admitted to the ICU (Lopez-Martin *et al*., 2014; Pronovost *et al*., 2003).

Accordingly, the present study evaluated the incidence, type and severity of medication reconciliation errors and associated factors in the ICU of a private hospital of medium and high complexity and the clinical results achieved with pharmaceutical intervention in the problems identified.

METHODS

Type of study

This was a prospective study, interventional, with an analytical approach, conducted in April to June 2016, in two ICUs (clinical and coronary), with eight beds each, in a private hospital of medium and high complexity, in Northeast Brazil.

Inclusion and exclusion criteria

As inclusion criterion, we considered all patients admitted to the ICU during the established period, where a list of commonly used drugs was available through at least one of the following information sources: pharmaceutical interview with patient or caregiver (family member or patient's companion), performed by another health care professional, and/or medical records.

We excluded patients who did not use drugs regularly, as well as those from other hospital units in which MR had already been performed by the pharmacy service, or those admitted to the ICU and discharged before the pharmacist visit. The visit was made daily, except on weekends and holidays.

Data collection

Data collection of MR was performed by the clinical pharmacist of the ICU, using a standard form developed at the hospital. For each patient, the process began with an information check in medical records, examining the patient's medical history, reason for hospitalization, comorbidities, age and sex, along with possible records of drugs previously used.

An interview was then conducted with the patient and/or caregiver, depending on availability, using appropriate language to request information on all drugs that the patient was using prior to hospital admission, including those self-reported, namely dose, dosage, route of administration and indication. At this time, the patient was also asked whether there were allergies to any drug; if so, this information was recorded in the patient's chart and passed on to the entire health team.

During MR, we checked if the patient brought some drug to the hospital, and the necessary information were followed to avoid self-medication during hospitalization. If it was necessary for the patient to use one of these drugs and if not standardized at the hospital, a patient and/or family authorization was requested. If authorized, a liability waiver for drugs brought by the patient to the hospital was completed and signed, verifying the integrity and validity of the medicine provided.

After the interview, the pharmacist verified the prescription of patients who reported drugs that were commonly used and checked whether they were prescribed or not, and also whether there was a change in dose, dosage or route of administration. All information was passed on to the physician, checking whether the omission or alteration of any of the drugs was made due to the patient's clinical situation (justified discrepancy) or if it was not justified by the clinical condition (unintentional discrepancy). In the case of unintentional discrepancies, considered medication reconciliation errors, pharmaceutical interventions were performed (Sánchez *et al*., 2007).

All information was recorded on a standardized and validated form at the institution: identified discrepancy; drug related to the error and classification by the Anatomical Therapeutic Chemical Code (ATC) (WHO, 2016); type, contact and acceptance of the the pharmaceutical intervention (where that which led to a prescription change was considered accepted).

MEs were classified according to the type of unintentional discrepancy, according to Sánchez *et al*. (2007), and regarding severity, as recommended by the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) (2001) (Charts I and II).

Category A ME were considered "Notifiable circumstance," Category B "Near miss." Those of Categories C and D were "Error without harm," and those of Categories E, F, G, H or I, "Error with harm" (Adverse event) according to the classification of NCC MERP (2001).

CHART I – Types of medication errors

Type of medication error (unintentional discrepancy)
Ommision of drug
Start of medication
Modification of dose, route or frequency
Different drug
Therapeutic duplication
Drug interaction
Drug not available in hospital
Incomplete prescription

Source: Sánchez *et al.* (2007).

CHART II – Category of severity of medication error

	Severity of medication erros
Category A	Circunstances or events that were able to cause an error
Category B	Error occurred, but did not reach the patient
Category C	Error occurred, reached the patient, but did not cause harm
Category D	Error occurred, reached the patient and required monitoring to confirm that there was no harm and/or intervention to prevent harm
Category E	Error occurred and could have contributed to or resulted in temporary harm, requiring intervention
Category F	Error occurred and could have contributed to or resulted in temporary harm, requiring starting or prolonging hospitalization

(continuing)

CHART II – Category of severity of medication error

	Severity of medication erros
Category G	Error occurred and could have contributed to or resulted in permanent harm
Category H	Error occurred, requiring life support measures
Category I	Error occurred and could have contributed to or resulted in the death of patient

Source: NCC MERP (2001).

Statistical analysis and ethics questions

The categorical variables were described by frequencies and percentages and the continuous variables described by means and standard deviation. The results were evaluated using Statistical Package for Social Sciences (SPSS), version 20.0 and Stata, version 10. To estimate factors associated with medication errors, in the reconciliation process, a logistic regression was performed, with odds ratio calculation, $p<0.05$ was considered statistically significant.

The cumulative incidence of unintentional discrepancies was defined as the total number of unwanted discrepancies over the total of prescribed drugs, expressed as a percentage.

The study was conducted according to the Regulatory Guidelines and Norms for Research Involving Humans and was approved by the Research Ethics Committee, under CAAE No. 49479715.5.0000.5043.

RESULTS

During the study, 136 patients were admitted to the ICU, 126 (92.6%) of whom were regularly using at least one drug and were included in the study (Tables I and II). The mean age of participants was 66.7 (± 16.1) years, and 56.3% (n=71) were female. The mean number of drugs used per patient before admission was 5.7 (± 2.8), with a total of 715 drugs, and 89.6% (n=113) of the admitted patients had at least one comorbidity. Most MR (50.8%, n=64) were performed between 24 and 48 hours after admission and 22.2% (n=28) were performed within 24 hours.

TABLE I - Characteristics of patients (N=126)

Characteristics	N	%
Age (years)		
19-59	41	32.5
60-95	85	67.5
Sex		
Female	71	56.3
Male	55	43.7
No. of comorbidities		
None	13	10.3
1	26	20.6
>1	87	69.0
No. of drugs of regular use		
1-4	49	38.9
5-8	53	42.1
≥ 9	24	19.0
Report of previous allergies		
No	95	75.4
Yes	31	24.6

TABLE II - Characteristics of the medication reconciliations performed (N=126)

Characteristics	N	%
Hospitalization unit		
Clinical ICU	31	24.6
Coronary ICU	95	75.4
Time for medication reconciliation		
<24 h	28	22.2
24-48 h	64	50.8
48-72 h	26	20.6
≥72 h	8	6.3
Source of information for medication reconciliation		
Medical records	30	23.8
Medical records +caregiver	62	49.2
Medical records +patient	23	18.3
Medical records +patient+caregiver	11	8.7
No. of drugs **with justified discrepancy per patient**		
0	13	10.3
1-4	74	58.7
5-8	32	25.4
>8	7	5.5
No. of drugs with unintentional discrepancy per patient		
0	77	61.1
≥ 1	49	38.9
No. of pharmaceutical interventions per patient		
0	78	61.9
≥ 1	48	38.1

There was report of previous allergies in the clinical history of 24.6% (n=31) of the patients, and we did not identify any case of prescribing the active principle for

which the patient reported allergy or other drugs that might be associated with cross-reaction

In the coronary ICU, 75.4% (n=95) of MRs were performed, considering that it is a unit that receives mainly postoperative patients, with a shorter average stay, and therefore having a higher turnover of patients compared to the clinical ICU.

In 23.8% (n=30) of the total cases, MRs were performed only by checking the patient's medical history, in 49.2% (n=62) of cases, this history was complemented by information from the caregiver, in 18.3% (n=23) of cases, the patient was able to provide information about the drugs in usual use, and in 8.7% (n=11) of cases, it was possible to collect the information from the patient and the caregiver, where it was possible to obtain a more complete clinical history.

From the MRs carried out, 128 unintentional discrepancies between the previous treatment and the post-admission treatment were identified. In 38.1% (n = 48) of the MRs performed, at least one pharmaceutical intervention was necessary.

The mean incidence of unintentional discrepancies was 16.3% (95% CI: 11.5-21.2), with a proportion of 38.8% (49/126) of the patients having at least one ME.

The characteristics of the unintentional discrepancies (medication errors) identified and of the pharmaceutical intervention performed are described in Table III.

The main unintentional discrepancy identified was the omission of a necessary drug (83.6%, n=107), followed by the prescription of a drug not available in the hospital (14.8%, n=19), without performing the exchange according to standardization of the hospital's drugs. In two cases (1.6%), therapeutic duplication occurred.

Regarding severity, 65.5% (n=80) of unintentional discrepancies were classified in Category C, considering that the error occurred but did not cause harm to the patient. An example of this was the omission of a statin prescription, leading the patient to stop taking the prescribed daily dose, but the drugs resumed on the day following admission before there was any change in the patient's lipid profile. Included in Category D (21.9%, n=28) were the discrepancies that reached the patient and required monitoring; for example, the omission of an antihypertensive or hypoglycemic prescription in hypertensive or diabetic patients required monitoring blood pressure or capillary blood glucose to confirm that there was no harm or to prevent harm from occurring.

TABLE III - Characterístics of unintentional discrepancies (medication reconciliation errors) identified and of pharmaceutical interventions performed (N=128)

Characteristics	N	%
Unit		
Clinical ICU	27	21.1
Coronary ICU	101	78.9
Type of medication error		
Omission of drug	107	83.6
Drug not available in hospital	19	14.8
Therpeutic duplication	2	1.6
Severity of medication error		
Category A	20	15.6
Category C	80	62.5
Category D	28	21.9
Pharmaceutical intervention		
Included drug	101	78.9
Provided drug	18	14.1
Requested necessary examination/test	1	0.8
Substitution	6	4.7
Suspension	2	1.6
Contact for intervention		
Physician	108	84.4
Caregiver	20	15.6
Acceptance of intervention		
Yes	91	71.1
No	37	28.9

Category A (15.6%, n=20) included the circumstances or events with potential to cause error. An example of this category was the prescription of non-standard drugs in the hospital, which could lead to

the non-use of a necessary drug, which, however, was prevented with the pharmaceutical interventions such as the recommendation of substitution of the drug by another of the same therapeutic class, standardized in the hospital, or in cases where substitution was not feasible. Another example was when the drug was provided by purchase or requested from a patient's caregiver, in which case a liability waiver was filled out and signed by the caregiver authorizing the use of the drugs brought to the hospital. In total, ten liability waivers were formalized for drugs brought by the patient to the hospital, including 17 drugs.

Due to this routine, part of the interventions (15.6%, n=20) were performed with the caregiver, with whom we checked the possibility of making the drug previously used by the patient available. There were also two cases in which, in the MR, a therapeutic duplication was found with the use of two benzodiazepines for the same indication. In these cases, the caregiver was advised of the risk to the patient with self-medication. The other interventions were performed with the physician (84.4%, n=108). The rate of acceptance of interventions was 71.1% (n=91).

According to the ATC classification, the drugs related to unintentional discrepancies were mainly those that act on the nervous system (39.8%, n=51), which included anxiolytics, antidepressants and drugs for treatment of Parkinson's and Alzeheimer's, followed by those for the cardiovascular system (27.3%, n=35), including antihypertensive and lipid-lowering agents, and those for the alimentary tract and metabolism (11.7%, n=15), including oral hypoglycemic agents (Table IV).

The analysis of the characteristics of participants who had unintentional discrepancies revealed significant associations ($p<0.05$) between the occurrence of these discrepancies and age greater than or equal to 60, number of comorbidities greater than one, and prior use of nine or more drugs (Table V).

TABLE IV - Classification according to the Anatomical Therapeutic Chemical Code (ATC) of the drugs associated with unintentional discrepancies (N=128)

ATC classification	N	%
Nervous system	51	39.8
Cardiovascular system	35	27.3
Alimentary tract and metabolismo	15	11.7
Systemic hormonal preparations, except sex hormones and insulin	12	9.4
Blood and hematopoietic organs	5	3.9
Respiratory system	4	3.1
Anti-infectious agents for systemic use	1	0.8
Antineoplastic and immunomodulating agents	1	0.8
Sensory organs	1	0.8
Antiparasitic products	1	0.8
Genitourinary system and sex hormones	1	0.8
Musculoskeletal system	1	0.8
Total	**128**	**100.0**

TABLE V - Associations between the occurrence of unintentional discrepancy and patient characteristics

Variables	No. of drugs with unintentional discrepancy		OR	p*
	0	≥ 1		
Sex				
Female	44 (57.1)	27 (55.1)	1	
Male	33 (42.9)	22 (44.9)	1.09	0.822

(continuing)

TABLE V - Associations between the occurrence of unintentional discrepancy and patient characteristics

Variables	No. of drugs with unintentional discrepancy		OR	p*
	0	≥ 1		
Age				
19-59	31 (40.3)	10 (20.4)	1	
≥60	46 (59.7)	39 (79.6)	2.63	0.023
Hospitalization unit				
Clinical ICU	20 (26.0)	11 (22.4)	1	
Coronary ICU	57 (74.0)	38 (77.6)	1.21	0.654
No. of comorbidades				
None	12 (15.6)	1 (2.0)	1	
1	16 (20.8)	10 (20.4)	7.50	0.071
>1	49 (63.6)	38 (77.6)	9.31	0.036
Report of allergies				
No	31 (40.3)	10 (20.4)	1	
Yes	46 (59.7)	39 (79.6)	1.68	0.214
No. of medicatons of regular use				
1-4	37 (48.1)	12 (24.5)	1	
5-8	32 (41.6)	21 (42.9)	2.02	0.105
≥9	8 (10.4)	16 (32.7)	6.17	0.001

OR: odds ratio. * logistic regression

DISCUSSION

The process of MR in the ICU revealed a profile of patients, in general, elderly, polymedicated and, for most, with at least one comorbidity. This result reinforces the great importance of obtaining a precise clinical and pharmacotherapeutic history of these patients, who are generally under previous continuous treatments and are more exposed to the possibility of MEs, as reported by Sánchez *et al*. (2007).

In our study, the occurrence of unintentional discrepancies showed significant associations with age greater than or equal to 60, number of comorbidities greater than one and previous use of nine or more drugs, warning that elderly patients who have more than one comorbidity or are polymedicated are at greater risk of having medication reconciliation errors in the ICU. Zoni *et al.* (2012) when assessing risk factors for MEs in a department of internal medicine, found no association with sex, age or number of drugs, but patients with asthma were six times more likely to have an unintentional discrepancy.

Most MRs were performed within 48 hours of admission. The time that the MR is done after admission is critical to prevent the patient from running out of a drug. Although it is recommended in the literature that this process be performed within 24 hours (Sánchez *et al*., 2007), in the ICU, it is observed that the inclusion of drugs in this period is often infeasible due to instability of the patient or the impossibility of using oral drugs. MRs carried out after 48 hours are because the routine of this process on weekends and holidays has not yet been implemented.

It was observed that the report of previous allergies was present in the pharmacotherapeutic history of some patients. This result alerts to the risk of misuse of drugs during hospitalization if all staff are not informed about patient restrictions. In our study, to reduce the patient's risk of using a drug for which there is an allergy, the team of doctors and nurses was notified and ensured that the information was available in the medical records and on the nameplate at the bedside of each patient. Although it is recommended to collect information about previous allergies in the medication reconciliation process, most studies do not report the frequency with which this report occurs and the need for interventions related to this aspect.

A particularity of the MRs in the ICU is due to the intrinsic characteristics of this unit, which limits the performance of the interview with the patient, given that the patient is, in most cases, in a serious condition or

under sedation, unable to provide information on prior treatment. Wills *et al.* (2016) warns of this difficulty, stating that sedated, intubated, and critically ill patients are often unable to provide information on treatment, and although many patients may have a history of this in medical records, the full history can only be confirmed together with caregivers and family members.

Because it is a closed unit, it is more difficult to contact the family member or caregiver in the ICU. To overcome this difficulty, we chose to carry out the MR of the study in the schedule defined in the hospital for relatives visiting patients in the ICU. In our study, the interview was conducted mainly with the caregiver, different, for example, from the study by Magalhães *et al*. (2014) in an open unit, where the patient ends up being the main source of information (74.1%).

To facilitate the process of contact with the patient, MR can be thought of as a multiprofessional process whereby doctors, nurses and pharmacists have different roles, dividing the stages of the MR process between the three professions, which can improve the focus and limit duplication in the execution of activities (Al-Hashar *et al*., 2017).

An important finding in the present study was the mean incidence of unintentional discrepancies of 16.3%, with 49 MEs in 126 MRs, and 38.8% of the patients showed at least one ME. In the study by Lopez-Martin *et al*. (2014), discrepancies in the ICU were found in 62% of patients, of whom 48% had MEs and 14% had justified discrepancies. The study by Wills *et al.* (2016), also conducted in the ICU, found a frequency of 85% of patients with discrepancies. In total, 292 discrepancies were found in 63 MRs; however, these authors did not differentiate intentional discrepancies from unintentional discrepancies. In the study by AbuYassin *et al.* (2011), 37% of the patients had at least one unintentional discrepancy, a result similar to ours.

Strategies to reduce this incidence would be to perform the MR before the physician ordered the patient's first prescription and to use the computerized system to inform the physician of the patient's routine medications, so he could choose to include, temporarily suspend or replace them, as proposed by Zoni *et al.* (2012). These authors performed a study in a Department of Internal Medicine and observed that, after using this strategy, the incidence of unintentional discrepancies decreased significantly from 3.5 to 1.8% (p=0.03).

As observed in most studies (Lopez-Martin *et al*., 2014; Spalla, Castilho, 2016; Wills *et al*., 2016), the main unintentional discrepancy identified was the omission of a necessary drug. Two cases of therapeutic duplication were observed in the patient's regular use of drugs, associated with self-medication, showing that the MR process may also have benefits in identifying the patient's misuse of drugs, in the evaluation of the understanding regarding treatment and in the perception of the patient's adherence to treatment.

Regarding severity, most of the identified errors did not cause any perceptible harm to the patient, being classified in category C or D; however, harm could have occurred if there were no pharmaceutical intervention. Magalhães *et al.* (2014) reinforced that the interception and correction of medication reconciliation errors by the pharmacist is an important safety practice to identify potential problems and avoid harm to the patient.

The acceptance rate of the interventions was 71.1% and the main reason for not accepting the intervention was the patient's clinical situation, which justified a temporary suspension of the drug while waiting for a better stabilization or reintroduction of the diet, for example. However, it was observed that, often, the drug remained unincluded even after the patient's clinical situation allowed it to be included, showing the need for continuous monitoring of these patients for a few days after performing the MR in the ICU. Lopez-Martin *et al*. (2014) found an acceptance rate of 81% in their study in critical patients, and the main reason for not accepting the intervention was the clinical situation of the patient.

Drugs related to unintentional discrepancies were mainly those that act on the nervous system, followed by those acting on the cardiovascular system and on the alimentary tract and metabolism. Lopez-Martin *et al.* (2014) found antihypertensives as the main group of drugs with errors, followed by bronchodilators and diuretics. Zoni *et al.* (2012) in a study with non-critical patients, found mainly the drugs that act on the cardiovascular system, followed by psychotropic, ophthalmological and lipid-lowering drugs. Therefore, this profile may vary according to the unit and care characteristics of the institution, but in general, cardiovascular drugs for the treatment of chronic diseases appear to be the most likely to be involved in unintentional discrepancies (Magalhães *et al*., 2014), therefore, the coronary ICU may be a service with a higher risk for medication reconciliation errors involving this class of drugs.

The study has some limitations regarding the classification process of MEs regarding severity,

considering that the assessment of harm to the patient considered only that perceived by the team through clinical or laboratory tests. Also, in the MR during the interview with the caregiver, there could have been bias in the information provided.

CONCLUSION

By evaluating the results obtained in the identification, resolution and prevention of MEs, from the MR in the ICUs, it is possible to conclude that the incidence of MEs found and the significant association with variables related to the characteristics of the patient such as age greater than 60 years, more than one comorbidity and polymedication draws attention to the specific need for the prevention of admission errors in the most susceptible patient groups. Accordingly, the pharmacist must act in an integrated way with the health care team and caregivers, performing the necessary pharmaceutical interventions, to avoid medication reconciliation errors reaching the patients.

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