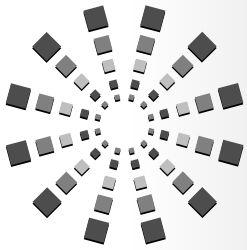

Simone Pereira Lermontov, MSc
Simone Carreiro Brasil, MSc
Magali Rezende de Carvalho, MSc

Medication Errors in the Context of Hematopoietic Stem Cell Transplantation

A Systematic Review

KEY WORDS
Medication error
Nursing
Stem cell transplantation

Background: There have been numerous efforts by health institutions and professionals to prevent and reduce medication errors. **Objectives:** The aim of this study was to identify in the literature the incidence, related factors, consequences, and prevention mechanisms of medication errors in the context of hematopoietic stem cell transplantation. **Methods:** This is a systematic review carried out in the databases LILACS, PubMed, PMC, EMBASE, and CINAHL databases, from January 11 to 13, 2017. **Results:** Eleven studies were included in this review and presented in 4 categories of analysis. (1) occurrence—most of the medication errors were related to administration and prescription; (2) related factors—multicausal, highlighting issues including polypharmacy, lack of double checking, and similarity between the medications' names; (3) consequences—the main ones were associated with adverse reactions, with prolonged hospitalization time as outcome; (4) preventive measures—related to safe practices in pharmacotherapy, such as double check and application of the 10 rights of medication administration.
Conclusion: Medication administration is an activity of great responsibility for nursing; however, in order to achieve a decrease in medication errors, prevention strategies are necessary for the whole health team. **Implications for Practice:** Practice improvements are needed including establishing institutional drug administration protocols and keeping them updated, using a computerized prescription system, and promoting patient safety with staff.

Author Affiliations: Instituto Nacional de Câncer (Mss Lermontov and Brasil) and Universidade Federal Fluminense (Ms Carvalho), Rio de Janeiro, Brazil.
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Correspondence: Simone P. Lermontov, MSc, Instituto Nacional de Câncer José Alencar Gomes da Silva–INCA, Praça da Cruz Vermelha, 23-7° andar, Centro, Rio de Janeiro, 23230-130 Rio de Janeiro, Brazil (simonelermontov@globo.com); (Simone.lermontov@inca.gov.br).
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The World Health Organization created the World Alliance for Patient Safety project in 2004 with the primary goal of preventing harm to patients. One of the central elements of this alliance is the action known as Global Challenge. In 2017, the World Health Organization launched the third challenge of the Global Patient Safety Challenge on Medication Safety, which aims to reduce by 50% the serious and preventable damages associated with medicines in all countries in the next 5 years.[1]

In recent years, there have been numerous efforts by health institutions and professionals to prevent and reduce medication errors, mainly due to the repercussions for the patient.[2,3] Medication errors occur because of several factors and are multidisciplinary in nature, occurring at any stage of the individual's healthcare, as well as in different hospital units.[4] Particularly in bone marrow transplantation (BMT) units, drug management has become a crucial point because drug therapy is complex and encompasses the simultaneous prescription of high-dose chemotherapy and support medicines with a narrow therapeutic index.[5]

Regarding oncology, the incidence of medication errors related to chemotherapy is unknown, so it is difficult to estimate its occurrence at both the national and international levels.[3,4] Makary and Daniel[6] estimated that in 2016 more than 251 000 patient deaths annually were attributable to healthcare errors. A significant rise in error since the report *To Err Is Human: Building a Safer Health System* has been documented.[7] This fact justifies more studies and efforts to understand this problem and work toward its eradication.[6,7]

It is necessary to understand medication errors and their implications for nursing because the administration of antineoplastic agents is a complex process with the potential to harm patients. As a result, nurses must provide high-quality, safe, and evidence-based care.[8] We searched for studies addressing types of medication errors in the context of BMT in the main electronic databases for systematic reviews: Cochrane and PubMed. However, no review was found to address the issue, reinforcing the need for evidence to improve clinical care. The objective of this review was to identify in the literature the incidence, related factors, consequences, and prevention mechanisms of medication errors in the context of hematopoietic stem cell transplantation (HSCT).

■ Methods

This is a systematic review of the literature that followed 8 steps: elaboration of the research question, search in literature, selection of articles, extraction of data, evaluation of methodological quality, synthesis of data, evaluation of the quality of evidence, and writing and publication of results.[9] The following research question was formulated, following the PIO strategy: What are the medication errors described in the scientific literature related to HSCT? The PIO represents an acronym for (P) patient/problem, (I) intervention, and (O) outcomes.[9] For this review, P refers to patients who underwent BMT; I refers to prescribing, administering, and dispensing medications; and O refers to medication error.

Comprehensive literature searches were conducted by an experienced reviewer (M.R.C.) between January 11 and 13, 2017, in the following databases: EMBASE, CINAHL, PubMed, PubMed CENTRAL, and LILACS. The search strategy for this review was established using a combination of index terms, as MeSH terms, DeCs, CINAHL Titles, and ENTREE (accordingly to the database), and text words relating to medication errors and BMT (Table 1).

Table 1 • Search Strategies in Databases

PubMed	(((Bone Marrow Transplantation[MeSH Terms]) OR (Bone marrow transplant*[tiab]) OR (stem cell transplantation[MeSH Terms]) OR (stem cell transplant*[tiab])) AND ((Medication Errors[MeSH Terms]) OR (medication error*[tiab]) OR (Drug Overdose[MeSH Terms]))))
PubMed CENTRAL	(((Bone Marrow Transplantation[MeSH Terms]) OR (Bone marrow transplant*[tiab]) OR (stem cell transplantation[MeSH Terms]) OR (stem cell transplant*[tiab])) AND ((Medication Errors[MeSH Terms]) OR (medication error*[tiab]) OR (Drug Overdose[MeSH Terms]))))
EMBASE	(((Bone Marrow Transplantation.sh.) or (stem cell transplantation.sh.)) and ((Medication Errors.sh.) or (Medication Errors.mp.) or (Drug Overdose.sh.)))
CINAHL	(((MH "Bone Marrow Transplantation+") OR (MH "Hematopoietic Stem Cell Transplantation") OR (MH "Hematopoietic Stem Cell Transplantation") OR ("Mesenchymal Stem Cell Transplantation")) AND ((MH "Drug Administration+") OR (MH "Administration, Intravesical") OR (MH "Administration, Oral+") OR ("Medication Therapy Management") OR (“Electronic prescribing") OR (MH "Drug Therapy+") OR (MH "Drug Therapy, Computer Assisted") OR (MH "Drug Therapy, Combination+") OR (MH "Antineoplastic Agents+")) AND ((MH "Medication Errors+") OR (MH "Overdose") OR (MH "Risk Management+") OR (MH "Patient Safety+")))
LILACS	strategies 1: ((MH:“Transplante de Medula Óssea” OR MH:”Transplante de Células-Tronco”) AND (MH:“Conduta do Tratamento Medicamentoso”) AND (MH:”Erros de Medicação” OR MH:”Overdose de Drogas”)) strategies 2 : (quimioterapia and erro de medicação) strategies 3: (“transplante de medula óssea” and “segurança do paciente”)

This table was prepared by the authors.

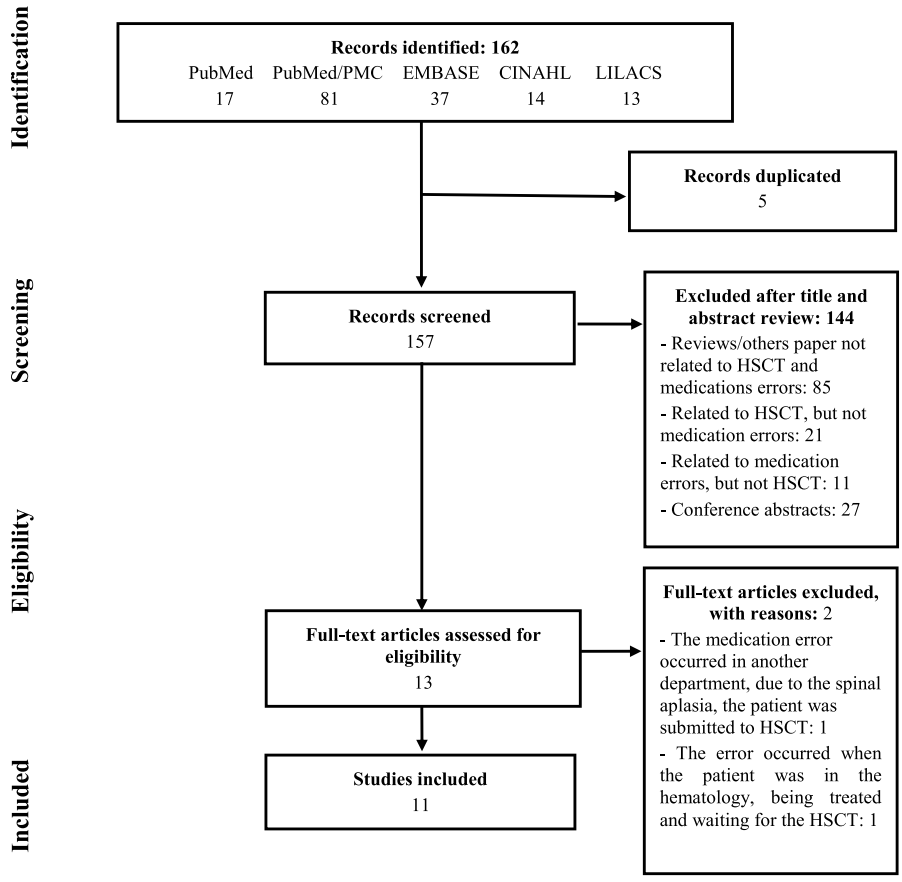

Figure ■ Preferred Reporting Items for Systematic Reviews and Meta-analyses flowchart.

Two independent review authors (S.P.L., S.C.B.) scanned the title and abstract of every record identified and excluded the studies that clearly did not meet the inclusion criteria (κ concordance index was 0.953). All potentially relevant articles were retrieved in full text for further assessment if the inclusion criteria were unclear from the abstract. Divergences were solved in a consensus meeting with the 3 reviewers.

Studies included randomized controlled trials, nonrandomized clinical trials, longitudinal studies, cohort or case-control studies, descriptive studies, case studies, or series that report medication error in the BMT scenario. The exclusion criteria were conference abstracts, editor letters, book chapter, editorial, review, comment, and dissertation/thesis. There was no restriction on publication year or language. Translation could be arranged for potentially eligible studies, if the study was published in a language other than English, Portuguese, or Spanish.

The level of evidence for each study was assessed according to the Melnyk and Fineout-Overholt[10] classification, being systematic review of controlled and randomized homogeneous clinical trials and of good methodological quality (level I), randomized controlled trials with small confidence interval (level II), nonrandomized clinical trials (level III), well-delineated cohort and case-control studies (level IV), systematic reviews of descriptive and qualitative studies (level V), evidence derived from a single descriptive or qualitative study (level VI), and evidence derived from the opinion of authorities and/or report of expert committees (level-VII).[10] This review followed the recommendations proposed by Preferred Reporting Items for Systematic Reviews and Meta-analyses.[11]

■ Results

A total of 162 records were identified; 5 duplicates were removed, and the remaining 157 were screened for eligibility. Of these, 144 did not meet the inclusion criteria and therefore were excluded (reasons for exclusion are shown in the Figure). The full texts of 13 potentially eligible studies were then reassessed. Because all 13 studies were published in English, no translation was needed. Two of these studies did not meet the population inclusion criterion and were excluded. Eleven studies were included and analyzed in this review. The results of this research strategy are represented in the Figure.

The titles of articles included in this review, including the year of publication, author's name, country, study methodology, and level of evidence, are shown in Table 2. Of the 11 studies selected, 73% (8) were case reports,[12–15,17,20–22] 9% (1) interventional study,[16] 9% (1) basic research,[18] and 9% (1) experience report.[19] The study population involved children (3-16 years)[12–15,17,22] and adults (26–59 years).[17,20,21] All studies were in the English language, and most studies (45%) were conducted in the United States.[14,15,18–20]

The types of errors, the type of medication in the context of HSCT, and related factors are shown in Table 3. The most

Table 2 • Scientific Production on Medication Errors in Hematopoietic Stem Cell Transplantation

Authors/Years	Country	Title	Type of Study	Age, y	Level of Evidence
Stein et al,[12] 2001	Israel	Accidental busulfan overdose: enhanced drug clearance with hemodialysis in a child with Wiskott-Aldrich syndrome	Case report	Infant	VI
Jaing et al,[13] 2002	Taiwan	Acute hypermagnesemia: a rare complication of antacid administration after bone marrow transplantation	Case report	16	VI
Trigg et al,[14] 2002	United States	Effects of an inadvertent dose of cytarabine in a child with Fanconi anemia: reducing medication errors	Case report	7	VI
Liem et al,[15] 2003	United States	Misinterpretation of a Calvert-derived formula leading to carboplatin overdose in 2 children	Case report	Patient 1 = 3 Patient 2 = 4	VI
Krampera et al,[16] 2004	Italy	Computer-based drug management in a bone marrow transplant unit: a suitable tool for multiple prescriptions even in critical conditions	Interventional study	—	VI
Jenke et al,[17] 2005	Germany	Accidental busulfan overdose during conditioning for stem cell transplantation	Case report	Patient 1 = 59 Patient 2 = 48 Patient 3 = 14	VI
Elefante et al,[18] 2006	United States	Long-term stability of a patient-convenient 1 mg/mL suspension of tacrolimus for accurate maintenance of stable therapeutic levels	Basic research	—	VI
Spruill et al,[19] 2009	United States	Decreasing patient misidentification before chemotherapy administration	Experience report	—	VI
Moorman et al,[20] 2011	United States	Management of cyclosporine overdose in a hematopoietic stem cell transplant patient with sequential plasma exchange and red blood cell exchange	Case report	38	VI
Tafazoli,[21] 2015	Iran	Accidental overdose of oral cyclosporine in haematopoietic stem cell transplantation: a case report and literature review	Case report	26	VI
Fleury et al,[22] 2016	Switzerland	Confusion between two amphotericin B formulations leading to a paediatric rehospitalisation case report	Case report	9	VI

This table was prepared by the authors.

common errors reported were administration and prescription errors.[12,15,17,20,21] Busulfan and cyclosporine were the drugs most commonly associated with errors. Among the related factors to the medication error occurrence, the most reported were the need to control medications that do not need a prescription but that can cause serious adverse events,[13] polypharmacy,[14,21] lack of double checking,[14,17] the similarity between the brand names of the medications,[14,21] possible stress of the nursing team,[14] dose calculation error,[15] communication failure,[17,22] and illegible prescriptions.[21]

The consequences and mechanisms of prevention of medication errors in the context of HSCT are shown in Table 4. It was observed that the adverse events described were associated with the toxicity of the drugs involved.[12–15,17,20–22] The preventive measures and the use of strategies that strengthen barriers to medication error were highlighted, considering that all studies included in this review have made some recommendations regarding these mechanisms.[12–19,21,22]

■ Discussion

Patient safety is a premise for healthcare. In the last decades, the concern with safety in the care provided to the patient has become one of the priority subjects.[23] The medication process deserves attention, especially in the context of HSCT because it involves a conditioning regimen with high doses of chemotherapeutic drugs, which are considered potentially dangerous and with a narrow therapeutic index that requires high vigilance in all phases of its use.[3,5]

This review indicates that the science regarding medication error in this area of knowledge is still scarce. All studies included

Table 3 • Identification of Articles and Analysis According to the Occurrence and Related Factors of Medication Errors in Hematopoietic Stem Cell Transplantation

Analysis Category	Study	Results
Occurrence	Stein et al[12]	Administration error: 4 mg/kg Bu administered instead of 1 mg/kg
	Jaing et al[13]	Administration error: Patient with gastric pain self-medicated and had an overdose of antacid in a short time (2/2 h)
	Trigg et al[14]	Administration error: Change in prescriptions resulted in the administration of cytarabine in the wrong patient
	Liem et al[15]	Prescription error: Two pediatric patients (3 and 4 y old) received an overdose of carboplatin
	Jenke et al[17]	Prescription and administration error: Three patients received an overdose of Bu
	Moorman et al[20]	Administration error: Patient received an overdose of cyclosporine oral suspension.
	Tafazoli[21]	Prescription and administration error: Patient received an overdose of cyclophosphamide
	Fleury et al[22]	Dispensing error: Amphotericin B liposomal (AmBisome) has been inadequately replaced with amphotericin B deoxycholate (Fungizone). The patient received 10 times the prescribed dose
Related factors	Jaing et al[13]	The medication does not need a prescription to be purchased
		Alteration of the gastric mucosa due to the conditioning regime.
	Trigg et al[14]	Polypharmacy due to the use of various drugs
		Possible stress of the nurse
		The patient was receiving another medication with a trade name similar to that of cytarabine
		Lack of double checking by nurses at the time of drug administration
	Liem et al[15]	There was no consensus of the formula for calculating the dose of carboplatin in the pediatric population
	Jenke et al[17]	Patients did not understand the nurse's instructions, which caused the 2 doses to be taken at different times
		Lack of double checking
	Tafazoli[21]	Illegible prescription of ciprofloxacin
		Incorrect reading of prescription by deduction
		Lack of prescription checking with medical staff
		Similarity between the names of drugs ciprofloxacin and cyclosporine
		Polypharmacy received by the patient during the hospitalization period
	Fleury et al[22]	Absence of a shared medical record (electronic medical record)
		Use of health information technologies without a strong understanding of their intrinsic limitations and insufficient enforcement of safety checks

This table was prepared by the authors.

were classified as level VI of evidence. We expected to find studies with low level of evidence because of the ethical issues involved in conducting a prospective study with intervention approach because medication error may result in harm to the patient. However, although it is classified as a low level of evidence for clinical practice, their results are important in formulating recommendations necessary for safer care.

It is noteworthy that the medication process is complex and composed of several phases, which include a multidisciplinary approach involving physicians, nurses, and pharmacists, as well as patients and caregivers.[24] For inpatient care, drug administration is an activity of great responsibility for the nursing team and the application of scientific principles that support the nurse's action while promoting patient safety.[4,23] The nursing team can be the final barrier to preventing medication error as the administration phase is the last opportunity to intercept and avoid a medication error.[25] Nurses must know the flow of their activities and flow problems in the environment and with human resources and must know drugs and drug interactions and doses.[3,4,23,25]

Studies have shown that administration of incorrect doses and prescription errors contributes to the great number of preventable adverse events in oncological patients.[26,27] Prescriptions are an instrument of communication among the physician, pharmacist, nurse, caregiver, and patient.[24] The most common prescribing errors are illegible and/or incomplete orders, inappropriate use of abbreviations, orders for contraindicated medications, and inappropriate doses.[28] If a failure occurs in the prescription phase, all other phases will be compromised. Therefore, determining the factors contributing to medication error is an important aspect to prevent them and to protect the patient.[1,23]

Some medications are sold over the counter and do not need a prescription, such as antacids, vitamins, and painkillers, among others; this does not mean they are harmless.[13] The incidence of medication errors as a result of polypharmacy increases by 25% when 2 to 3 drugs are prescribed and rises up to 35% when it is 4 or more drugs.[29] It is clear that polypharmacy endangers the patient's safety, especially those undergoing HSCT because during the conditioning phase an average of 7 to 8 medications are administered.[30] A multidisciplinary approach among

Table 4 • Identification of Articles and Analysis According to Consequences and Mechanisms of Prevention of Medication Errors in Hematopoietic Stem Cell Transplantation

Analysis Category	Study	Results
Consequences	Stein et al[12]	No adverse events were reported in the study; however, it was necessary to modify the conditioning due to overdose of BU
	Jaing et al[13]	Patient attended with hypermagnesemia, altered consciousness and neurological, hypothermia, hypotension, tachycardia, bradypnea
	Trigg et al[14]	Patient had profuse diarrhea, nausea and vomiting (occasionally with blood), urinary tract infection by pseudomonas, tachypnea, fluid retention. A lung biopsy showed mild alveolar damage with a mononuclear cell infiltrate and uneven hyaline membranes consistent with a toxic effect of the substance and not consistent with GVHD, besides prolongation of hospitalization
	Liem et al[15]	Patient (3 y old) had grade IV mucositis, febrile neutropenia, grade II diarrhea, and mild renal insufficiency. Patient (4 years) had severe renal insufficiency (grade III) and significant ototoxicity with hearing loss (grade IV), mucositis (grade IV), febrile neutropenia, and increased transaminases
	Jenke et al[17]	Patient had elevated serum BU levels and seizures
	Moorman et al[20]	Patient had seizures
	Tafazoli[21]	Patient had nausea, vomiting, flushing, chest tightness, tremor, and vertigo
	Fleury et al[22]	Patient had vomiting, diarrhea, and nephrotoxicity
Prevention measures	Stein et al[12]	Monitoring of serum BU levels
		Double checking of prescription by nurses and pharmacists
		Double checking at the patient's bedside before administering the drug
	Jaing et al[13]	Laboratory monitoring of patients using medicines containing magnesium
	Trigg et al[14]	Performing the "5 rights" of drug administration (right drug, right amount, right route, right patient, right time)
		Better lighting in pharmacies where medicines are prepared
		Single dosage of medications
		Computerized ordering systems
		Continuing education of the health team
		Patient identification bracelets
		Patient orientation
	Liem et al[15]	Intensifying attention with chemotherapy administration, especially when the dosage is not yet well defined in the conditioning regimen
		Using a computerized system to aid in the calculation of carboplatin dose
		Applying the formula for the calculation of carboplatin according to the age group, because there are significant differences between them
	Krampera et al[16]	Computerized system replacing written prescriptions by scanned prescriptions, thus avoiding prescription error
	Jenke et al[17]	Creating control mechanisms to reduce errors, such as delivering single doses of medication and checking whether the patient understood the guidelines
		Updating standard operating procedures to prevent gaps that lead to medication error
	Elefante et al[18]	Reformulation of tacrolimus from 0.5 to 1 mg/mL to avoid administration error
	Spruill et al[19]	Double check by 2 nurses at the bedside, checking the patient's name and the chemotherapy to be administered
	Tafazoli[21]	Scanned prescription and labels
		Double check
		Prescription check by 2 experienced nurses
		Team training on "Drug Name Similarities"
		Daily laboratory evaluation (biochemistry), according to institutional protocol for monitoring serum levels of CSA
	Fleury et al[22]	Critical prescription monitoring by the pharmacist
		Guiding patients and their families to active participation in treatment

Abbreviations: Bu, busulfan; CSA, cyclosporine; GVHD, graft-versus-host disease.
This table was prepared by the authors.

pharmacists, nurses, and physicians is required to educate the patient regarding drug names, doses, and drug interactions.[3,8,26]

Researchers have identified the major factors that contribute to medication error including the lack of pharmacological knowledge of physicians and nurses, inadequate prescriptions that are not compliant with current guidelines, underreporting of medication errors, work overload, staff inexperience, and lack of communication among health professionals.[31] In general, the

lack of knowledge for prescribing and administering is the most common factor related to medication error.[31] These human risk factors related to the health professionals themselves.[2,24,32] This further increases the responsibility of the nursing team because they are responsible for implementing the medical prescriptions to the patients.[33]

The studies revealed that even in cases where there was no change in vital functions some patients had to change the conditioning regimen,[12,13,21] others needed to be readmitted,[14,15] and 1 patient had severe sequelae related to medication error.[15] Patients who suffered adverse events related to medication error were 4 to 7 times more likely to die.[34] One study identified adverse events related to medication error and concluded that 56% were harmless or caused mild disability, 7.0% caused permanent disability, and 7.4% resulted in patient death.[35] The probability of an individual surviving a hospitalization free from the occurrence of these events varies by their length of stay.[33] Complexity in the use of chemotherapy requires total intolerance of system failures. Therefore, continuous diligence to verify the accuracy of actions should be a requirement for all professionals involved in the various phases of this process.[36] Although data related to medication errors involving antineoplastic drugs are still incipient, the damage can be fatal and can lead to consequences of loss of patient confidence in treatment, staff, and institution, as well increased costs of treatment.[37]

Double checking was presented as a preventive measure by some studies.[13,20,22] Checking medications before their administration by nurses is a basic preventive action for medication errors.[3] Double checking was evidenced as a mode to discover actual errors and near misses to prevent serious medication errors.[8] Although widely used, it is necessary to recognize the limitations of this practice when applied as an isolated strategy in preventing medication errors. However, its applicability is well accepted in specific controls, such as infusion pump programming, data conferencing in pediatric and elderly patients, dispensing and administering antineoplastics, and administration in intensive care.[3,36,38]

The strategy of checking the ''5 rights'' of medication administration is a more reliable preventive measure.[32] In the ''5 rights'' strategy, the following items are checked: right patient, right medication, right dose, right route, and right time, and this may represent a strategy for nurses.[32,38] However, this verification should not be restricted to nurses only. Therefore, other authors recommended the ''10 rights,'' discussing the responsibility of staff, patients, and caregivers.[32] The ''10 rights'' correspond to the right patient, right medication, right dose, right route, right time, right to refusal, right to explanation, right to questioning, right guidance, and right to information on efficacy and treatment effects.[32] Because most medication errors are multifaceted and preventable, there is a need for monitoring strategies in all phases of the medication process in order to prevent errors.[4,23,32] As an error prevention measure, a regular training for health professionals, use of electronic prescription software, and standardization of the actions in all phases following the current guidelines must be encouraged.

■ Recommendations for Clinical Practice

The recommendations for clinical practice are as follows: establishing institutional drug administration protocols and keeping them updated; implementing the verification of the ''10 rights''; performing double checking of prescription by experienced nurses; performing patient identification (alert for allergies); conducting periodic training sessions; and addressing frequently prescribed medications, as well as their indications, dose, dose schedule, presentation, and routes of administration. In addition, implementation of electronic prescription software is recommended.

■ Conclusion

This study analysis identified that administration and prescription errors were the most frequent and that their causes are multifactorial. In general, good clinical practices in the use of antineoplastics were highlighted in most articles included. This seems related to the characteristic of these drugs, possibly because they are used in complex and multiple-drug therapeutic regimens, besides involving complex dose calculations.

Responsibility for the medication process runs through the health team. In order to achieve a reduction in medication errors, preventive strategies and, above all, professional awareness are necessary. This study collaborates with the movement to strengthen patient safety and encourages further research because this is a vast field that deserves attention, as it impacts the patient, the family, the health team, and the health system.

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