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RESEARCH ARTICLE

Medication errors in a children's inpatient antineoplastic chemotherapy facility

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Abstract

Background: *Due to many antineoplastic drugs' toxicity and narrow therapeutic window, medication errors are a health concern in pediatric oncology patients. This study aimed to identify and classify medication errors in a pediatric inpatient chemotherapy facility and evaluate the outcomes of these medication errors.* **Methods:** *We conducted an observational retrospective study over 5 months in a chemotherapy facility for pediatric patients. The evaluation consisted of the review of the available medical records. The medication errors detected were manually recorded in a medical logbook. The International Classification for Patient Safety was adjusted to our clinical setting for the analysis, the terminology, and the classification system. A descriptive analysis was performed.* **Results:** *A total of 286 medical records were reviewed; one type of medication error was noted in at least 97.6%, and 962 errors were identified totally, with an overall rate of 3.36 errors per visit. Most errors occurred in the documentation stage (643; 66.8%), followed by the administration stage (227; 23.6%). Of all medication errors, 37.2% had the potential to cause injury, but only five reached the patient (0.5%), and only two (0.2%) resulted in a severe harmful incident.* **Conclusions:** *Medication errors were common, especially at the documentation stage. Better documentation strategies need to be implemented to reduce the rate of near misses and prevent potential adverse events.*

Keywords: *Drug-related side effects. Adverse reactions. Near miss. Medication errors. Mexican children. Pediatric oncology.*

Errores de medicación en un centro de quimioterapia antineoplásica para pacientes pediátricos hospitalizados

Resumen

Introducción: *Los errores de medicación son un problema de salud en niños con cáncer debido a la toxicidad y a la estrecha ventana terapéutica de muchos fármacos antineoplásicos. El objetivo de este estudio fue identificar y clasificar los errores de medicación en un centro de quimioterapia para pacientes pediátricos hospitalizados, así como evaluar los resultados de estos errores de medicación.* **Métodos:** *Se llevó a cabo un estudio observacional retrospectivo realizado durante un periodo de 5 meses en un centro de quimioterapia para pacientes pediátricos. La evaluación consistió en la revisión de las historias clínicas disponibles. Los errores de medicación detectados fueron registrados manualmente en una bitácora.*

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Para el análisis, la terminología y el sistema de clasificación, la Clasificación Internacional para la Seguridad del Paciente se ajustó a nuestro entorno clínico. Se realizó un análisis descriptivo. **Resultados:** *Se revisaron 286 historias clínicas; se observó un tipo de error de medicación al menos en el 97.6%. En total se identificaron 962 errores de medicación, con una tasa general de 3.36 errores por visita. En la etapa de documentación fue donde más errores ocurrieron (643; 66.8%), seguido de la etapa de administración (227; 23.6%). De todos los errores de medicación, el 37.2% tuvo el potencial de causar lesiones, pero solo cinco llegaron al paciente (0.5%) y solo dos (0.2%) provocaron un incidente dañino severo.* **Conclusiones:** *Los errores de medicación fueron comunes, especialmente en la etapa de documentación. Es necesario implementar mejores estrategias de documentación para reducir la tasa de cuasi accidentes y prevenir posibles eventos adversos.*

Palabras clave: *Efectos secundarios relacionados con medicamentos. Reacciones adversas. Cuasi accidente. Error de medicación. Niños mexicanos. Oncología pediátrica.*

Introduction

Patient safety is a priority in healthcare systems. Consequently, medication errors have become a significant public health concern. According to the World Health Organization's International Classification for Patient Safety, a medication error is *"a deviation in a process that may or may not cause harm to patients"* and can be classified as a harmful incident (adverse event) or a near miss that can occur throughout the medication-use system[1]. Hospitalized patients may experience an average of one medication error per day[2]. Pediatric patients, primarily, are vulnerable to medication errors due to many factors, such as weight-based dosing, the need to dilute medications to administer small amounts, and the inability of young children to self-administer drugs or report side effects[3]. Previous evidence has shown that 5% to 27% of pediatric prescriptions result in errors[4]. Recently, a scoping review found that the most prevalent pediatric safety issues were medication-related[5]. In addition, the treatment for pediatric oncology patients is complex and error-prone. Therefore, correct dosing and administration procedures for antineoplastic chemotherapy are imperative due to toxicity and narrow therapeutic windows[6]. Thus, quality management of information on near misses and adverse events is necessary to develop processes and systems that improve safety and reduce the risk of preventable medication incidents[7,8]. Consequently, this observational retrospective study aimed to identify and classify medication errors occurring in an inpatient pediatric antineoplastic chemotherapy facility and evaluate the outcomes of these medication errors.

Methods

Study design

This observational and retrospective study was conducted for 5 months (November 2018-March 2019) in the antineoplastic chemotherapy ward (CW) of the Hospital Infantil de México Federico Gómez. Near misses and adverse events detected in the patient's medical records were reviewed within 24 hours of admission. The CW is a 12-bed unit where pediatric oncology patients receive antineoplastic chemotherapeutic regimens that require at least 76 hours of stay and close monitoring after infusion. Every time a patient is admitted to the CW, the medical record is renewed, so each time a patient is admitted to the CW, the medical record is evaluated as a separate subject. Clinical records were reviewed independently of the treating medical and nursing staff. The study was conducted according to the Declaration of Helsinki and was approved by the Institutional Review Board.

Data sources and measurement

The assessment consisted of reviewing all the medical records available at the CW to identify medication errors. The evaluation was performed using a binnacle in which the identified near misses or adverse events were manually entered. This binnacle was subsequently used to construct a database for statistical analysis. Body surface area and dose were recalculated according to the somatometry data available in the patient's entry note and the recommended standard dose. We adjusted the terminology and classification system described by Weingart et al. to our clinical setting to analyze the near misses and adverse events[1,9].

Statistical analysis

Descriptive statistics were performed with SPSS version 22 (IBM, Chicago, IL). Qualitative variables are shown as frequencies and percentages. Age is shown as median and range (IQR).

Results

We reviewed 286 medical charts corresponding to 157 pediatric oncology patients. Most patients were male (56.1%), and the median age of the study population was 9 years (IQR, 0.5-17.67). The most frequent diagnosis was leukemia (56.1%), followed by solid tumors (40.1%) and lymphoma (3.8%).

The medication errors evaluated were classified according to the stage of the medication process: ordering, dispensing, administration, monitoring, and documentation. Of the 286 medical records reviewed, 279 (97.6%) had at least one type of error. A total of 962 errors were detected, with an overall rate of 3.36 errors per visit. The three most frequent errors were early or delayed administration of chemotherapeutic agents (23.6%), missing staff signature (20.9%), and incorrect birthdate (18.3%). Meanwhile, the minor common errors were wrong protocol week (0.1%), illegibility (0.1%), and inaccurate date (0.2%). Most medication errors occurred in the documentation stage (66.8%), followed by the administration stage (23.6%) and the ordering stage (9.6%) (Table 1). Of all medication errors, 37.2% had the potential to cause injury, including two errors that resulted in injury. In this regard, medication errors in the ordering stage can evolve into harmful incidents. Therefore, the most common errors were dosing inconsistencies (0.3%) and unjustified concomitant drugs (0.3%).

Although we could not identify medication errors in the dispensing and monitoring stages by reviewing the medical records, nurses and medical staff reported errors in these stages. We documented and classified five medication errors that reached the patient (harmful incidents) according to their degree of harm into none (two, 40%), mild (one, 20%), moderate, severe (two, 40%), or death (Table 2).

Inpatient pediatric oncology care is a multidisciplinary activity involving many health professionals, from laboratory staff to nursing staff and physicians. In the clinical setting studied, all procedures are performed by different health professionals, and each document in the medical record can be used as evidence of compliance with care protocols. Therefore, it seemed essential to analyze which part of the clinical records, and thus in which stage of the protocol, most errors occurred. Since the 227 errors of early or delayed administration of chemotherapeutic agents were calculated and not registered in the medical records, only 734 medication errors were considered in the analysis. Errors were most frequently found in laboratory results (25%), followed by the clinical history (19.4%) and hospitalization admission notes (18.9%) (Table 3).

Discussion

In our inpatient pediatric oncology care study, we found that 97.6% of medical records contained at least one type of medication error, with a total of 962 errors documented. Of these, 0.5% reached the patient, and only 0.2% resulted in a severe life-threatening harmful incident. Our error rate is higher than that reported in oncology patients by Walsh et al., who stated that 19% of pediatric visits were associated with an error. However, their study was focused on the outpatient setting[10].

Cancer patients are at risk for physiological reserves, toxic therapies, and narrow therapeutic indexes, and children even more so due to body-surface dosing, multiple-dose adjustment, and laboratory monitoring. As reported by Weingart et al., ordering errors were more frequent than dispensing errors[9]. When analyzing medication errors, most studies only consider the ordering stage, as a failure in this stage can have catastrophic consequences. In France, in two settings, 3.1% and 5.2% of prescriptions were found to have errors[11,12]. Similarly, Nerich et al. and Gandhi et al. reported 1.5% and 3% of prescription errors, respectively[13,14]. In contrast, Aita et al. in Italy reported that 20% of medication orders had errors[15]. Here, we report that 9.6% of the errors occurred at this stage, and the most common were somatometry errors, whether incorrect or missing. In pediatric oncology, chemotherapeutic agents are ordered according to the body surface or weight, with low doses compromising efficacy and high doses inducing toxicity; hence, these errors are considered potentially harmful. Fortunately, weights and body-surface areas were corrected, and no error reached the patient. In addition, poor handwriting was considered one of the primary sources of error[16], which was not the case in our study since all medication orders were placed on computer systems.

Unfortunately, we could not detect any errors in the dispensing or monitoring stages. In the administration stage, we calculated the time of anticipation or delay of antineoplastic chemotherapy administration according to the institution's protocols and found 227 errors (23.6% of the total). However, some justifiable scenarios cause the delay or anticipation of chemotherapy, such as the presence of a fever, low or high diuresis, medication not available at the time, and staff shortage, among others. A limitation in detecting errors at this stage was that the

Table 1. Frequency and type of medication errors

Stage in the medication process, n (%)	Medication errors detected (n = 962)	n (%)
Ordering, 92 (9.6)	Different diagnosis through medical chart	4 (0.4)
	Incorrect dose	4 (0.4)
	Incorrect patient's registry	24 (2.5)
	Incorrect protocol week	1 (0.1)
	Inconsistencies on medical orders	
	Double dosing	1 (0.1)
	Drug ordered twice	1 (0.1)
	Exceeded dose according to BSA	1 (0.1)
	Inconsistencies of dosing	3 (0.3)
	Inconsistencies in the ordered drugs	1 (0.1)
	Concomitant drugs without justification	3 (0.3)
	Medical order without units	1 (0.1)
	Somatometry	
	Incorrect	18 (1.9)
	Missing data	30 (3.1)
Dispensing	Non-detected	—
Administration, 227 (23.6)	Anticipated or delayed administration of chemotherapeutic agents	227 (23.6)
Monitoring	Non-detected	—
Documentation, 643 (66.8)	Another patient's note	9 (0.9)
	Lack of staff signature	201 (20.9)
	Sheet with no birthdate	13 (1.4)
	Sheet with no date	3 (0.3)
	Sheet with no registry	14 (1.5)
	Chart with missing document	29 (3.0)
	Inconsistencies on data	15 (1.6)
	Incorrect data	
	Age	5 (0.5)
	Birthdate	176 (18.3)
	Date	2 (0.2)
	Sex	4 (0.4)
	Name	10 (1.0)
	Disordered chart	29 (3.0)
	Orthographic mistakes	4 (0.4)
	Printing error	70 (7.3)
	Blurred or white-out pages	12 (1.2)
	Corrections with pen	25 (2.6)
	Scratching	18 (1.9)
	Illegibility	1 (0.1)
	Typing errors	3 (0.3)

BSA, body surface area.

Table 2. Harmful incidents*

Stage	Degree of harm	None	Mild	Moderate	Severe	Death
Ordering	Incorrect patient's name on chemotherapy bag	1	—	—	—	—
Dispensing	Patient unable to acquire medication at the pharmacy due to an incorrect registry on the prescription	1	—	—	—	—
Administration	Double administration of the chemotherapeutic agent	—	—	—	1	—
Monitoring	Chemotherapy agent spilled over the patient's bed	—	—	—	1	—
	Patient broke the fasting indication	—	1	—	—	—
Documentation	Non-detected	—	—	—	—	—

*Reported by the medical and nursing staff.

Table 3. Frequency of error per document type (n = 734)

Document type	n (%)
Laboratory results	184 (25.0)
Clinic history	143 (19.4)
Hospitalization admission note	139 (18.9)
Authorization for hospitalization	124 (16.8)
Medical orders	57 (7.7)
Evolution	45 (6.1)
General	29 (3.9)
Cover page	4 (0.5)
Procedure	3 (0.4)
Frontal page	2 (0.3)
Other	4 (0.5)

researcher was not present during antineoplastic chemotherapy administration. Consequently, some errors could have gone undetected.

Aguirrezábal-Arredondo et al. reported that most errors occur in the ordering stage[17]. However, our findings show that errors were more frequent in the documentation stage in the population studied. Therefore, although not a widely researched area, documentation appears as a critical stage for patient safety. We detected 643 errors (66.8% of the total) at this stage. The most common error was the lack of personnel signature (201, 20.9%), indicating non-compliance with protocols. It is worth mentioning that errors in this stage can be amplified and have consequences in the other stages. We consider that 358 errors (37.2%) were potentially harmful.

Given the importance of safety in medication orders, we analyzed eleven inconsistencies corresponding to 1.1% of all errors. Two of them resulted in harmful incidents; these errors surpassed the safety barriers of dispensing and administration and reached the patient. One was rated as non-harmful, and one caused a severe adverse medication reaction. Another error that became a severe harmful incident occurred during monitoring, when a bag of antineoplastic chemotherapy spilled on a patient, causing injury and contamination.

Medication errors and resulting adverse events occur in all health care settings. Many errors result from complexity or problems in the system or lack of communication among healthcare professionals[18]. In this study, we identified the stages of the system at which an error was more likely to be made, given that each document represents a different action performed during patient care. Consistent with documentation being the stage at which most errors occur (66.8%), most errors were identified in laboratory results (25%), clinical history (19.4%), and the inpatient admission note (18.9%). However, most of the errors in laboratory results were incorrect birthdates, which are not considered potentially harmful events.

Although the U.S. Institute of Medicine (IOM) recommends computerized order entry systems and other information technology to reduce errors, it is known that errors still occur with automatization[18]. Fortunately, not all medication errors are harmful. Previous studies have shown that less than 1% of all errors result in a harmful incident, supporting our data that 0.5% of errors reach patients. However, the fact that 97.6% of the medical records contain at least one error indicates significant weakness in the system[19].

Fifteen years after the IOM report "To err is human: building a better healthcare system," patient safety

remains a significant challenge[20]. The magnitude of the problems must first be measured and quantified to improve. Various methods have been used to identify medication errors, but there is no clear gold standard[21]. Reporting error is necessary but not sufficient to improve performance. Unless reporting is followed by action and implementing changes, safety will not improve[22].

Serious illness can further contribute to a suboptimal decision-making environment. System analysis is critical, with a formal evaluation of each step. Computer-assisted decision-making capable of accurately calculating body-surface area, checking for allergies and contraindications, identifying drug interactions, facilitating communication, and introducing ward-based pharmacists and satellite pediatric pharmacies has been shown to reduce the incidence of errors[23]. The development of a unit dose system can also improve the quality of healthcare, which has been demonstrated by a lower rate of medication errors than the ward stock distribution system[16]. In our setting, there are no hospital pharmacists. Despite the low incidence of ordering errors detected in our study, the potential severity of these errors gives the pharmaceutical validation process a key role in improving the safety of pediatric oncologic patients[24].

Strengths and limitations

The study was not designed to account for all errors fully and was based on a human observer, who may have missed some errors. Our study relied on the method of medical chart review and, therefore, may underestimate medication error rates. Neither patients nor providers were interviewed, nor was administration directly observed. Unlike other studies, our approach was broader than most studies focusing only on ordering errors and harmful incidents. We attempted to detect all types of errors in medical records.

In conclusion, this report identified and classified medication errors occurring in a pediatric oncology clinical setting. Although our error rate was higher than that reported in the literature for children with cancer, we detected only two severe adverse events. However, it is necessary to implement better documentation strategies to reduce the rate of near misses and prevent potential adverse events.

Ethical disclosures

Protection of human and animal subjects. The authors declare that no experiments were performed on humans or animals for this study.

Confidentiality of data. The authors declare that they have followed the protocols of their work center on the publication of patient data.

Right to privacy and informed consent. This study involved a retrospective review of medical records, for which approval was obtained from a formally constituted review board (Institutional Review Board or Institutional Ethics Committee).

Conflicts of interest

The authors declare no conflicts of interest.

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References

1. World Health Organization. Conceptual framework for the International Classification for Patient Safety. Geneva: World Health Organization; 2009. Available at: https://www.who.int/publications/i/item/WHO-IER-PSP-2010.2
2. Preventing medication errors. Aspden P, Wolcott JA, Bootman JL, Cronenwett LR, editors. Washington DC: National Academies Press; 2007.
3. Kaushal R, Jaggi T, Walsh K, Fortescue EB, Bates DW. Pediatric medication errors: what do we know? What gaps remain? Ambul Pediatr. 2004;4:73-81.
4. Rinke ML, Bundy DG, Velasquez CA, Rao S, Zerhouni Y, Lobner K, et al. Interventions to reduce pediatric medication errors: a systematic review. Pediatrics. 2014;134:338-60.
5. Stang A, Thomson D, Hartling L, Shulhan J, Nuspl M, Ali S. Safe care for pediatric patients: a scoping review across multiple health care settings. Clin Pediatr (Phila). 2018;57:62-75.
6. Pirnejad H, Gao C, Reddingius R, Rijneveld A, Bal R. Improving chemotherapy processes with a protocol-based information system: a pre and post-implementation study. Int J Med Inform. 2013;82:220-9.
7. Chang A, Schyve PM, Croteau RJ, O'Leary DS, Loeb JM. The JCAHO patient safety event taxonomy: a standardized terminology and classification schema for near misses and adverse events. Int J Qual Heal Care. 2005;17:95-105.
8. Speroni KG, Fisher J, Dennis M, Daniel M. What causes near-misses and how are they mitigated? Plast Surg Nurs. 2014;34:114-9.
9. Weingart SN, Zhang L, Sweeney M, Hassett M. Chemotherapy medication errors. Lancet Oncol. 2018;19:E191-E199.
10. Walsh KE, Dodd KS, Seetharaman K, Roblin DW, Herrinton LJ, Von Worley A, et al. Medication errors among adults and children with cancer in the outpatient setting. J Clin Oncol. 2009;27:891-6.
11. Ranchon F, Salles G, Späth HM, Schwiertz V, Vantard N, Parat S, et al. Chemotherapeutic errors in hospitalised cancer patients: attributable damage and extra costs. BMC Cancer. 2011;11:478.
12. Ranchon F, Moch C, You B, Salles G, Schwiertz V, Vantard N, et al. Predictors of prescription errors involving anticancer chemotherapy agents. Eur J Cancer. 2012;48:1192-9.
13. Nerich V, Limat S, Demarchi M, Borg C, Rohrlich PS, Deconinck E, et al. Computerized physician order entry of injectable antineoplastic drugs: an epidemiologic study of prescribing medication errors. Int J Med Inform. 2010;79:699-706.
14. Gandhi TK, Bartel SB, Shulman LN, Verrier D, Burdick E, Cleary A, et al. Medication safety in the ambulatory chemotherapy setting. Cancer. 2005;104:2477-83.

15. Aita M, Belvedere O, De Carlo E, Deroma L, De Pauli F, Gurrieri L, et al. Chemotherapy prescribing errors: an observational study on the role of information technology and computerized physician order entry systems. BMC Heal Serv Res. 2013;13:522.
16. Bohand X, Simon L, Perrier E, Mullot H, Lefeuvre L, Plotton C. Frequency, types, and potential clinical significance of medication-dispensing errors. Clinics (Sao Paolo). 2009;64:11-6.
17. Aguirrezábal-Arredondo A, Álvarez-Lavín M, Yurrebaso-Ibarreche MJ, Vilella-Ciriza ML, Elguézabal-Ortúzar I, Goikolea-Ugarte FJ, et al. Detección de errores en la prescripción de quimioterapia. Farm Hosp (Madrid). 2003;27:219-23.
18. Edwards M, Moczygemba J. Reducing medical errors through better documentation. Health Care Manag (Frederick). 2004;23:329-33.
19. Lisby M, Nielsen LP, Mainz J. Errors in the medication process: frequency, type, and potential clinical consequences. Int J Qual Heal Care. 2005;17:15-22.
20. Adler L, Yi D, Li M, McBroom B, Hauck L, Sammer C, et al. Impact of inpatient harms on hospital finances and patient clinical outcomes. J Patient Saf. 2018;14:67-73.
21. Ock MS, Jo MW, Choi EY, Lee SI. Patient safety incidents reported by the general public in Korea: a cross-sectional study. J Patient Saf. 2020;16:e90-e96.
22. Naveh E, Katz-Navon T. Antecedents of willingness to report medical treatment errors in health care organizations: a multilevel theoretical framework. Health Care Manage Rev. 2014;39:21-30.
23. Fernandez CV, Gillis-Ring J. Strategies for the prevention of medical error in pediatrics. J Pediatr. 2003;143:155-62.
24. Mueller BU, Neuspiel DR, Stucky Fisher ER; Council on Quality Improvement and Patient Safety, Committee on Hospital Care. Principles of pediatric patient safety: reducing harm due to medical care. Pediatrics. 2019;143:e20183649.