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Profile of Medical Prescriptions and Potential Risks to the Safety of Cancer Patients in the Chemotherapy Sector of Ophir Loyola Hospital. Belém, Pará

Perfil de Prescrições Médicas e Potenciais Riscos à Segurança de Usuários Oncológicos no Setor de Quimioterapia do Hospital Ophir Loyola. Belém, Pará

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Abstract

The schedule and therapeutic cycle for the treatment of malignancies involves the simultaneous use of distinct drugs, including antineoplastics and adjuvants, depending on the tumor to be treated, varying according to the treatment protocol. Studies demonstrate the problem of the high potential severity associated with prescriptions errors. This work aimed to know the profile of medical prescriptions in the chemotherapy sector of Ophir Loyola Hospital, aiming to identify potential problems related to the user safety. This is an exploratory, descriptive, quantitative and qualitative retrospective cross-sectional study, with a temporal cut from January to March 2017, through data collection in prescriptions and prospective participatory observation in the dispensation and administration in the period from April to June 2017. A total of 1,034 prescriptions were analyzed with 2,068 prescribed medications, where the mean error was 7.67 per prescription, of which: 90 (8.70%) did not inform the diluent to be used; 154 (14.89%) did not report the volume of the diluent and did not contain the infusion time; 234 (22.63%) did not inform the therapeutic scheme that would be used by the user; 247 (23.89%) did not indicate the number of the administration cycle; 374 (36.17%) did not indicate the interval between these cycles. No dispensing and administration errors were found. It can be inferred that there are shortcomings in the elaboration of the prescription, being necessary interventions that improve them, aiming to improve the quality of the service provided, as well as, to provide the user safety.

keywords: Public Health. Medical Oncology. Pharmacy Service, Hospital. Drug Prescriptions. Patient Safety.

Resumo

O esquema e o ciclo terapêutico para o tratamento das neoplasias envolvem o uso simultâneo de distintos medicamentos, incluindo antineoplásicos e adjuvantes, dependendo do tumor a ser tratado, variando conforme o protocolo de tratamento. Estudos demonstram o problema da alta gravidade potencial associada a estes erros. Este trabalho teve como objetivo conhecer o perfil de prescrições médicas no setor de quimioterapia do Hospital Ophir Loyola, visando identificar potenciais problemas relacionados com a segurança do usuário. Trata-se de um estudo exploratório, descritivo, retrospectivo para a análise de prescrições médicas e prospectivo para a observação participativa do processo de dispensação e administração de medicamentos antineoplásicos no Serviço de Quimioterapia da Farmácia Hospitalar, realizado entre abril e junho de 2017. Foram analisadas 1.034 prescrições com 2.068 medicamentos prescritos, onde a média de erros foi de 7,67 por prescrição, sendo que: 90 (8,70%) não informavam o diluente a ser utilizado; 154 (14,89%) não informavam o volume do diluente e não continham o tempo de infusão; 234 (22,63%) não informavam o esquema terapêutico que seria utilizado pelo usuário; 247 (23,89%) não indicavam o número do ciclo de administração; 374 (36,17%) não indicavam o intervalo entre esses ciclos. Não foram encontrados erros de dispensação e de administração. Pode-se inferir que existem falhas na elaboração da prescrição, sendo necessárias intervenções que aprimorem as mesmas, visando melhorar a qualidade do serviço prestado, bem como, proporcionar a segurança do usuário.

Palavras-chave*: Saúde Pública. Oncologia. Serviço de Farmácia Hospitalar. Drug prescriptions Patient Safety.*

1 Introduction

Worldwide, adverse events in the health care process are frequent. In response to this worrying picture, the World Health Organization (WHO) launched in 2004 the "World Alliance for User Safety" program, which calls on all Member States to adopt measures to ensure the quality and safety of health care equipment[1,2] .

Jacobsen et al.[3] affirm that the starting point for the use of medications is the prescription, and this is an important link of written communication among health professionals, seen as the beginning of a series of events within the medication process, which will result in a safe or non-safe administration of a dose to the user.

The requirements and care that should be adopted during the prescription and distribution of medications are described mainly in the following regulatory landmarks: Presidential Decree n° 20.931 d and January 11th, 1932[4] , Law n° 5.991, of December 17th, 1973[5] , Resolution of the Federal Council of Pharmacy n°357 of April 20th of 2001[6] , Resolution of the Federal Council of Pharmacy No 492 of November 26th, 2008[7] and the Code of Medical Ethics[8] .

Study carried out in the United States of America reveals

that every user admitted to an American hospital is subject to a medication error per day, with a minimum of 400,000 preventable drug-related adverse events being recorded annually in these institutions[9] . These adverse events can be verified at all stages of the therapeutic chain and their occurrence considerably increases the costs of the health system.

It is estimated that medication errors in hospitals cause more than 7,000 deaths per year in the United States, resulting in significant tangible and intangible costs[9,10]. In Brazil, no statistics on deaths related to medication errors are available[11].

The Institute for Safe Practices In the Use of Medicinal Products[12] records that the errors of antineoplastic medication have been the subject of publications in several countries. The Brazilian Society of Pharmaceuticals in Oncology (SOBRAFO)[13] states that the complexity of antineoplastic therapy contributes to the high error rate and severe severity, and all stages of the medication process, from prescription to preparation and administration, attention and care should be given[14] .

Prescription errors stand out for the potential to cause severe damages. Common practice of the use of abbreviations and acronyms in the description of therapeutic drug schemes, as well as the similarity in the sound and spelling of the name of some of them, may favor the occurrence of this type of error[15].

In view of the possibility of preventing medication errors and the risk of damage due to their occurrence, it becomes relevant to identify the nature and determinants of errors as a way of directing actions for prevention. Failures in the process of drug use are considered important contributing factors to the reduction of user safety. Actions aimed at preventing and reducing medication errors associated with antineoplastic therapy should be planned and implemented[12-16].

The occurrence of errors with cytotoxic drugs is insufficiently known; as for other pharmaco-therapeutic classes. However, considering the toxicity of these drugs, errors are of particular relevance[12-16].

The analysis of oncology drug prescriptions is one of the most important stages of the whole process of antineoplastic therapy. The ideal prescription should be legible, contain as much information as possible about the user, about the medications to be used, information about the prescriber, and about the health care unit[12-16].

Prescription errors are defined as "clinically significant decision or wording error, unintentional, which may reduce the likelihood of treatment being effective or increase the damages risk to the user when compared to established and accepted clinical practices.

The wording errors are related to the prescription preparing elaboration; such as, illegality, use of officially confused or non-standardized abbreviations, omission of concentration, route of administration, interval, infusion rate, error in the unit of the drug, among others[12-16].

Errors of decision are related to the prescriber's knowledge regarding the drug that will be prescribed, such as dose error, prescription of therapeutic duplicity, contraindicated medication or without considering clinical implications such as liver and kidney failure.

The Safety Protocol in The Prescription, Drug Administration and Use is a strategy of the National Program for Patient Safety (PNSP) that contributes to the promotion of the safety of the use of medicines in health establishments by promoting good practices at all stages of the drug use process[17-19]. For its monitoring, the Institute for Safe Practices In the Use of Medicinal Products (ISMP) proposes a set of three indicators: Errors rate in Drug Prescription, Errors Rate in Drug Dispensing, and Errors Rate in Drug Administration[20,21] .

The implementation of these indicators allows the production of information that makes it possible to analyze and improve the processes of prescription, dispensation and administration of medications, enabling better conditions for decision-making by health managers and professionals[20,21] .

The adoption of new practices requires adequate monitoring and benchmarking tools. Therefore, measurements based on standardized indicators allow greater accuracy of the results of the activities performed[20,21] . Thus, the indicators become important indicators of the evolution of the service activities.

Thus, the profile of medical prescriptions, dispensation and drug administration in the chemotherapy sector of Hospital Ophir Loyola, Belém, Pará, was investigated to identify the Errors Rate in the Prescription of medicines, The Errors Rate in The Dispensing of medicines and The Errors Rate in the administration of medicines, aiming to design a Standard Operating Procedure template.

2 Material and Methods

This is an exploratory, descriptive, quantitative and qualitative retrospective cross-sectional study of participative observation in the dispensation and administration of antineoplastic drugs in the Chemotherapy Service of Hospital Pharmacy, which was held in the period from April to June 2017. 1,034 medical prescriptions were analyzed, per convenience sample, of prescribed, dispensed and administered oncology users.

Hospital Ophir Loyola (HOL) presents in its infrastructure outpatient care, eye bank (corneal transplants) , specialized treatment in labiopalatal fissure, hematological day hospital (intermediate regime between hospitalization and outpatient care), clinical analysis laboratory, pharmacies, molecular biology laboratory, nuclear medicine, neurosurgery, nutrition and dietetic, orthopedic oncology, chemotherapy, radiotherapy, renal transplantation and a host nucleus to the egress sick person. In 2013, 1,052,546 visits were performed, including outpatient consultations, surgeries, radiotherapy

applications, chemotherapy sessions, anatomopathological exams and emergency and emergency consultations.

Research tools have followed the standards of the Institute for Safe Practices In the Use of Medicinal Products (ISMP) and the Protocol for the Safety Of Prescription, Use and Administration of Medicinal Products[21,22] .

Formulas and steps for The Errors Rate calculations in The Prescription underwent adaptations. Whereas the Errors Rate in the Dispensation of medicines and the Errors Rate in the administration of medicines follow the method recommended by the Institute for Safe Practices In the Use of medicines (ISMP)[21,22]. The evaluation took place by calculating Indicators Rates. The data were recorded in a Microsoft Excel® 2016 spreadsheet. The results are presented in absolute frequency, relative and narrative synthesis.

In order to develop Standard Operational Procedures (POPs), it was based on the guidelines recommended by the National Program for Patient Safety (PNSP)[17-19] and on the principles recommended by the Institute for Safe Practices In the Use of Medicinal Products (ISMP)[21, 22] .

The research was registered in the Brazil Platform under CAAE: 64096416.0.0000.0017 and approved under Registry No. 033522017, complying with the terms of CNS Resolution n° 466 dated from December 12th, 2012[24] .

3 Results and Discussion

1,034 prescriptions with 2,068 prescribed drugs were analyzed[25] . 23 types of errors were identified (Table 1). The mean of errors was calculated by dividing the total number of errors (7,934) by the total number of prescriptions (1,034), with an average of 7,67 errors per prescription, 100% of which were spelling errors. These results are close to the findings of Jacobsen et al.[3] who obtained an average of 5 errors per prescription.

Table 1 - Errors inherent in the drugs prescription, dispensation and administration in the chemotherapy sector of Hospital Ophir Loyola

Type or Error	Number of errors	% of Errors
Errors inherent to user identification data		
User's full name:	0	0
Registration	113	10.93
Service/Clinic	0	0
Sex	1034	100
Age	817	79.0
Body Surface	381	36.85
Weight	726	70.21
Height	767	74.18
D.O.B	130	12.57
Errors inherent to the prescriber's identification data		
Full Name	16	1.55
Registration number of the professional council	16	1.55
Signature	16	1.55
Errors inherent to the institution identification data		
Name	0	0
Full address and phone number	1034	100
Errors inherent to prescription date		
Prescription date	25	2.42
Errors inherent to legibility and erasures		
Illegible letter	114	11.03
Erasures	175	16.92
Errors inherent to duration of the treatment		
Number of cycles	247	36.17
Interval among cycles	374	23.89
Errors inherent to posology, dilution, infusion time and route of administration		
Posology	41	3.97
Dosage	5	0.48
Diluent	40	3.87
Volume of the diluent	90	8.70
Infusion time	154	14.89
Administration route	63	6.09
Prescribed medication in disagreement with clinical protocol	0	0
Errors inherent to the omission of adjuvant medication		
Omission of adjuvant medicinal product	0	0
Errors inherent to the prescribed drug identification using abbreviations		
Prescribed medicine using abbreviations	0	0
Errors inherent to the use of abbreviations in general		
Abbreviations in general	1,034	100
Errors inherent to prescription without ICD registration		
Prescription without ICD registration	320	30.95
Errors inherent to prescription without the therapeutic scheme or clinical protocol		
Prescription without the therapeutic scheme or clinical protocol	234	22.63
Errors inherent to dispensing medications		
Wrong medicine	0	0
Wrong concentration	0	0
Pharmaceutical form	0	0
Omission of medication	0	0
Dose omission	0	0
Errors inherent to the medications administration		
Failure to confirm the doses administration by nursing	0	0

Source: Research data.

Silva[26] identified 16 types of errors in 3,931 prescriptions. Fernandes et al.[27] observed that 40.53% of the prescriptions contained some intercurrence. An analysis of the compliance of the medical prescriptions of the public and private sectors also demonstrate irregularities[28].

As for user identification (full name, registration, clinical, gender, age, and other data and information that provide safe user care), it shows the amount of errors found in each information regarding the user identification. It is observed, in decreasing order, that the item age with 79.01%, height with 74.18%, weight with 70.21%, body surface with 36.85%, date of birth with 12.57% and registration with 10.93% are the most prevalent. The information sex was not reported in 100% and

the user's full name and the resulting service/clinic obtained 0% error (Chart 1). It was found that the user identification in the hospital prescription occurs by means of the username and registration number. According to Brazil[29] it is necessary to contain at least the following information: Hospital name; full username; number of the medical record or service record; bed; service; ward/apartment; and floor and/or wing.

Age, weight, height and body surface information is necessary for adequate assistance, especially for the calculation of dose adjustment of the drugs to be used, since the user loses body mass during treatment . It is known that weight and height values should be as recent as possible for a correct calculation of body surface and therefore dose. Regarding the analysis of the user data 79.01% prescriptions did not contain age, 70.21% weight, 74.18% height and 36.85% body surface.

Jacobsen et al.[3] noted the absence of the user age in 63.7% prescriptions. Bózoli et al.[31] in 201 prescriptions identified that 61.2% presented weight, 44.3% height and 56.2% the user body surface. It is reiterated that the user identification data must be present in all prescriptions. The absence of data influences the therapeutic quality. The lack of personal information may cause errors by those responsible for the handling, dispensing and use of medicines [28] .

The use of incomplete name and short name should be excluded from the practice of health care facilities [29] . 100% of the prescriptions analyzed had the username and 10.93% did not contain the registration number that identifies the same. This differs from the study by Jacobsen et al.[3] that found 7.9% for the user incomplete name. A total of 12.57% errors were found for birth date and 100% for sex. Bózoli et al.[31] evidenced the absence of information on sex and date of birth in 100% of the prescriptions.

Regarding the prescriber identification, it was found that 1.55% of the prescriptions did not present the prescriber data. Bózoli and collaborators [31] observed that 34.3% of the evaluated prescriptions did not exhibit the prescriber name. Jacobsen et al.[3] observed in the prescriptions, absence of the professional's signature in 23 (0.9%), absence of the registration number in the class council in 12.6% and absence of the professional's stamp in 17%.

Regarding the institution's identification (name, full address and telephone number), which has the purpose of the user being able to maintain contact with health professionals for clarification of doubts after the consultation[29] it was observed that the medical prescriptions, due to being printed forms, followed the same pattern, containing only the name of the institution; that is, not taking full account of the data related to the identification of the Hospital Ophir Loyola (Chart 1).

Regarding the date of the prescription, 2.42% did not present this information. The deletion of the prescription date is related to the occurrence of medication errors, depending on the probability of permanence of the use of medication for an inappropriate time (Chart 1). Abjaude et al.[2] reported that 30.95% presented illegality or difficulty of reading; 15.78% lack of identification of the prescriber; 6.19% absence of dosage; 4.02% absence of pharmaceutical form; 5.57% description of quantity; 10.52% of wrong/incomplete posology; 43.34% absence of date/address; and 3.10% of incompatible medications.

On readability and erasure, prescriptions containing illegible letters were observed, with a representative of 11.03% to 16.92% of prescriptions with erasures in total errors. Spelling errors were observed in 100% of the prescriptions analyzed. In addition, 11.03% of illegible medical prescriptions and 16.92% that had some kind of erasure were found (Chart 1). Jacobsen et al.[3] found illegible letters in 13.2% and erasures in 12.2%. Silva et al.[36] found 14.3% of illegible revenues. Legibility conditions communication, and illegible handwriting is a recognized cause of errors involving medications, which may interrupt or alter the care process, resulting in harm to the user health[33,34] .

Regarding the duration of treatment, there is no information regarding the interval among cycles of 36.17 % and the number of cycles in 23.89% (Chart 1). Pegoraro and Goncalves [33] recorded that 90% of the prescriptions were legible, but with no duration of treatment, at a percentage of 48.34%, followed by administration at 3.58%. In 11.67% of these, they did not have the full name, causing serious errors, in some cases leading to death.

It is known that the duration of the treatment allows control of antineoplastic therapy and also that the medication is dispensed and administered within the prescribed period, preventing its use from being made in a mistaken manner. The use of the medication for a shorter time than the determined time may lead to therapeutic failures and consequently to decrease the effectiveness of the treatment and for a longer time than recommended, favoring adverse events further aggravating the user clinical signals[35,36] .

About dosage, dilution, infusion time and route of administration there are errors related to infusion time in 14.89%, diluent volume in 8.70%, administration route in 6.09%, dosage in 3.97%, diluent in 3.87% and dose in 0.48% (Chart 1). It is known that the lack of information related to the medication and how to use can generate losses and damage to the user, which can decrease the effectiveness and quality of the care provided, reflecting on medication errors. Silva and collaborators[34] demonstrated that the error related to the dose interval was 35.56%, being the most common type of error in the prescriptions and that these errors were related to the need for dose adjustment for users with renal dysfunction.

In addition, Silva [28] found 18.2% of the drugs prescribed without dose and 7.2% without administration route. Jacobsen et al.[3] found absence of route of administration in 1.3% prescriptions, absence of concentration in 38.2% and incomplete posology in 92.7% of the prescriptions. There are reports that errors in intravenous infusion therapy are responsible for approximately 60% of fatal errors, which give

the user a greater risk of harm in the hospital environment. Such errors can be influenced by the complexity of programming infusion pumps and by the lack of information regarding diluent, infusion rate and infusion time [37-38] .

As for errors related to dilution, 3.87% did not inform the diluent to be used, 8.70% the volume of the diluent and 14.89% did not contain the time of infusion (Chart 1). Silva [34] found 5.3% errors regarding inadequate dilution and/or infusion time. Information about dosage is important for the correct use – dose, frequency, intervals, and so on – of the medicine. Incomplete or missing data may lead to error and ineffective treatment [34-38] . For intravenous medications, a diluent that is compatible, as well as the rate and time of infusion, should be jointly prescribed, because they need the monitoring the amount injected versus the time of infusion, avoiding and/or decreasing the occurrence of adverse events.

Regarding medications prescribed in disagreement with the clinical protocol, it was observed that 100% of the medications were prescribed in accordance with the clinical protocol (Chart 1). The therapeutic regimen is variable and depends on the type of cancer of the user, the stage of the disease and the way the user will react to the medications, the regimen may contain a single drug or the combination of several ones [39] .

Regarding the omission of adjuvant drugs; that is, the absence of drugs that do not fit as antineoplastic drugs, but are necessary during treatment, assisting in the therapy of adverse events and/or potentiating and optimizing chemotherapy, It is reported that 100% of the medications were prescribed in accordance with the clinical protocol, informing and ensuring the use of adjuvants (Chart 1).

No medications prescribed with abbreviations were identified. This is a positive factor, since different drugs have similar writings, and may lead to confusion and exchange between them; if they are prescribed with abbreviations. However, standardization of names was not observed according to the Brazilian Common Name (DCB)[39] .

100% of the prescriptions were observed using abbreviations in general. According to Brazil[5] , a medical prescription should not contain an abbreviation for Units (U) and International Units (UI), use of chemical formulae (KCl, NaCl, KMnO4 and others) and abbreviated names of medications (HCTZ, RIP, PEN BEZ, MTX, SMZ-TMP, among other examples), in order to ensure adequate communication among the health team members. However, in 100% of the prescriptions, it was observed the use of abbreviations such as SF, SG and KCl, referring to saline solution, glucose solution and potassium chloride, respectively.

Regarding the International Code of Diseases (ICD), it was observed that 30.95% of the prescriptions did not present this information (Chart 1). CID is used to facilitate the identification of diseases, in addition to serving statistical purposes of describing and analyzing the distribution of diseases in a defined population.

22.63% of the prescriptions did not inform the therapeutic scheme (Chart 1). The information in the therapeutic regimen ensures that the user has a safe treatment in the Unified Health System (SUS), with care and diagnostic and therapeutic approaches defined based on technical and scientific criteria of efficacy and effectiveness[39]. Fernandes et al.[27] noted the absence of the therapeutic scheme in 23.9% of the prescriptions.

No errors were found in the dispensing of medications (Chart 1), an indicator that measures the sum of the medications dispensed by the pharmacy service with errors, identified during the conference, before dispensing, in a certain period of time, considering the following types of dispensation errors: Wrong drug (dispensed drug is different than prescribed); wrong Concentration (dispensed concentration is different - greater or less - than the prescribed one); pharmaceutical Form (dispensed pharmaceutical form is different than the prescribed one); Default drug: Prescribed drug and not separated; Default dose: number of doses dispensed is lower than the prescribed one[20,21]. It is believed that this result can be related to the accreditation process [41] that Hospital Pharmacy Ophir Loyola has been experiencing.

Albuquerque et al.[35] analyzed 5300 prescriptions and found 10.39% dispensing errors (errors of content), where errors characterized as higher than the necessary dose (toxicity risk) represented 16.33%; as lower than the necessary dose (sub dose) 28.13%; as omission of dose (forgetfulness) 35.93%; as wrong dispensed medication (other drug) 17.24% and as wrong pharmaceutical medication 2.35%.

No errors were found in the administration of medications (Chart 1), an indicator that measures the number of prescribed drugs not checked; that is, it is the sum of prescribed medications that did not have the confirmatory record of administering one or more doses performed by nursing (failure to register) in a certain period of time. . It is believed that this result can be related to the accreditation process [41] that Hospital Pharmacy Ophir Loyola has been experiencing.

Galicia et al.[37] detected 55.6% of errors in biosecurity standards, 46.7% in the wrong administration schedule and 37.8% in the wrong infusion rate.

Finally, the Following tools were developed for The Chemotherapy Sector of Hospital Ophir Loyola:

- Standard Operating procedure for The Prescription, Dispensing and administration of Oncology medicines;
- Guidelines for the Safe Use of Antineoplastic medicines By Parenteral route;
- Notification form for the Occurrence of Drug Prescription Errors;
- Notification form for the Occurrence of Drug Dispensing Errors;
- Notification form for the Occurrence of Drug Administration Errors;
- Form for Notification Of Adverse Events to Medicinal Prod-

ucts; Standard form for Medical Prescription.

It is known that the complexity of health services and the incorporation of new technologies lead to additional risks in the care provision. Thus, simple and effective strategies can prevent and reduce risks and damage to these services through the follow-up of specific protocols associated with security barriers in systems and permanent education .

4 Conclusion

1,034 prescriptions with 2,068 prescribed medications were analyzed, and the profile of medical prescriptions, dispensation and drug administration in the chemotherapy sector of Hospital Ophir Loyola presented 23 types of errors, highlighting: The mean error was 7.67 per prescription; 100% of errors were writing; 11.03% were illegible medical prescriptions; 10.93% of the prescriptions did not contain the registration number identifying the user, 25 (2.42%) did not report the date of the prescription, 30.95% without the CID, 1.55% did not present the data of the prescriber and 16.92% presented some kind of erasure; 79.01% did not contain age, 12.57% did not contain date of birth, 100% did not report gender, 70.21% did not report weight, 74.18% did not report height and 36.85% did not report body surface; 0.48% prescriptions without dose and 6.09% without administration, 3.97% were prescribed without dosage; 3.87% did not inform the diluent to be used, 8.70% did not inform the diluent volume and 14.89% did not contain the infusion time; 22.63% did not inform the therapeutic scheme that would be used by the user, 23.89% did not indicate the number of the administration cycle and 36.17% did not indicate the interval between these cycles; no errors of medication administration or dispensing were found.

It can be inferred that there are shortcomings in the elaboration of the prescription, being necessary interventions that improve them, aiming to improve the quality of the service provided, as well as, to provide better safety to the user.

It is recommended to implement the recommended guidelines for the safe Use of Antineoplastic Products by Parenteral route, as well as a permanent process of Promotion of Rational Use of medicines and Safe Practices in The Prescription, Dispensing and Administration of Medicines.

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