Cogitare Enfermagem

ORIGINAL ARTICLE

PROTOCOL FOR THE SAFE USE OF MEDICATIONS IN A BONE MARROW TRANSPLANT SERVICE*

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ABSTRACT
Objective: to develop and validate the content of a protocol for the safe use of medications.
Method: Action design research conducted in 2016-2017 in a referral service for hematopoietic stem cell transplantation in Brazil. A documentary study on adverse events and the pharmacological profile supported the elaboration of the content of the protocol based on the relevant literature. Thirty-one (31) nursing professionals who performed their duties in the field covered by this study participated in four meetings of the discussion groups in order to improve the content. Content validation was performed by five experts with the use of the Delphi Technique.
Results: A total of 139 drugs were included in the protocol based on data related to adverse events and pharmacological profile. The protocol consisted of 18 chapters and its content was validated with an overall Content Validation Index of 89% obtained in one round of evaluations.
Conclusion: Participatory construction contributed to the elaboration of a protocol with valid, consistent and applicable content in professional nursing practice, aimed to ensure the safe use of medicines.

DESCRIPTORS: Protocols; Pharmacological treatment; Patient safety; Nursing; Medication errors.

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PROTOCOLO PARA USO SEGURO DE MEDICAMENTOS EM SERVIÇO DE TRANSPLANTE DE MEDULA ÓSSEA

RESUMO

Objetivo: elaborar e validar o conteúdo de protocolo para uso seguro de medicamentos.
Método: pesquisa-ação realizada entre 2016 e 2017 em serviço de referência para transplante de células tronco-hematopoiéticas do Brasil. Estudo documental de eventos adversos e do perfil farmacológico subsidiou a elaboração o conteúdo amparado na literatura. Participaram 31 profissionais de enfermagem do campo desta pesquisa em quatro encontros dos grupos de discussão, para aprimoramento do texto; a validação de conteúdo foi realizada por cinco especialistas, com aplicação da Técnica Delphi.
Resultados: dados relativos aos eventos adversos e perfil farmacológico subsidiaram a inclusão de 139 medicamentos no protocolo. Este, composto por 18 capítulos, teve o conteúdo validado com Índice de Validação de Conteúdo geral de 89% obtido em única rodada de avaliação.
Conclusão: a construção participativa contribuiu para a elaboração de protocolo com conteúdo válido, compatível e aplicável na prática profissional de enfermagem com vistas ao uso seguro de medicamentos.

DESCRITORES: Protocolos; Tratamento farmacológico; Segurança do paciente; Enfermagem; Erros de medicação.

PROTOCOLO PARA USO CON SEGURIDAD DE MEDICAMENTOS EN SERVICIO DE TRASPLANTE DE MÉDULA ÓSEA

RESUMEN

Objetivo: elaborar y validar el contenido de protocolo para uso de medicamentos con seguridad.
Método: investigación del tipo acción que se realizó entre 2016 y 2017 en servicio de referencia para trasplante de células madre hematopoyéticas del Brasil. Estudio documental de eventos adversos y de perfil farmacológico ha subsidiado la elaboración del contenido basado en la literatura. Participaron 31profesionales de enfermería del área de esta investigación en cuatro encuentros de los grupos de discusión, para perfeccionamiento del texto; la validación del contenido se realizó por cinco especialistas, con aplicación de la Técnica Delphi.
Resultados: datos acerca de los eventos adversos y perfil farmacológico subsidiaron la inclusión de 139 medicamentos en el protocolo. Este, que se compuso por 18 capítulos, tuvo el contenido analizado con Índice de Validación de Contenido General de 89%, lo cual se obtuvo en solo una etapa de evaluación.
Conclusión: la construcción participativa contribuyó para la elaboración de protocolo con contenido válido, compatible y aplicable en la práctica profesional de enfermería para garantizar el uso de medicamentos con seguridad.

DESCRIPTORES: Protocolos; Tratamiento farmacológico; Seguridad del paciente; Enfermería; Errores de medicación.

INTRODUCTION

Patient safety in healthcare settings has been a major challenge, given its impact on patient recovery. While the care process has become more effective and complex thanks to the latest technological advances, it can also pose threats to safe care [1]. Thus, errors may occur and the likelihood of such occurrence depends on a number of factors, such as interaction between people, equipment effectiveness, adequacy of facilities to the various medications that must be prescribed and administered correctly and timely [2].

During hospitalization, patients are subject to various interventions, including drug therapy. This therapy is complex and consists of several steps, including purchase, prescription, dispensing, preparation and administration of drugs, as well as response monitoring, which requires decisions, correlated actions and knowledge[3]. The last three steps, under the responsibility of the nursing staff, involve several professionals and processes, which may lead to errors [4].

Thus, in safety promotion, technical knowledge is a key asset and professionals must be aware of the possible occurrence of adverse events in the operationalization of drug therapy [5]. Some strategies can be implemented to avoid and or reduce healthcare-related errors, e.g. the use of protocols. These are important tools for dealing with various problems, both in health care and management, and consist of technological support in the health area [6].

Since drug therapy has become increasingly complex, depending on the patient's condition or treatment, this study aimed to address the safe use of medications in patients undergoing Hematopoietic Stem Cell Transplant (HSCT), a setting where different treatment steps require a complex process of drug therapy. Thus, the objectives of this study were to elaborate and validate a protocol for the safe use of medications in the Bone Marrow Transplant Service of Hospital de Clínicas of Universidade Federal do Paraná.

METHOD

The present study was conducted from August 2016 to July 2017 and is part of the thematic project "Nursing actions in essential care in Hematopoietic Stem Cell Transplantation".

The method comprised the following steps: a) retrospective documentary research to characterize adverse events related to drug therapy and identification of the pharmacological profile; b) methodological research with the development of a protocol and c) content validation through the Delphi Technique.

Characterization of medication-related adverse events and identification of the pharmacological profile

Data were obtained from notification forms of the Bone Marrow Transplant (BMT) Service from the last five years, entered in a spreadsheet and stored in an electronic database of Microsoft Excel®. The results were expressed as absolute and relative frequencies, and classified according to the International Classification for Patient Safety, followed by a brief description of the event. This step aimed to support the development of the protocol, from the identification of the events recorded in the area covered by the research, as well as contribute to the discussion on the issue with the participants during the step of improvement of the protocol content.

The pharmacological profile of the most frequently dispensed drugs over the last five years was obtained in hospital digital documents, organized in a spreadsheet using

Microsoft Excel®. Subsequently, information about the drugs was collected in the package leaflets and in the specialized literature, in the online databases Micromedex®, Medscape® and UpToDate® (partnership with Lexicomp®).

For data collection, the search in the websites by drug name was made in the English language and information related to dosages, interactions, adverse effects, pharmacology, administration, use in pregnancy and imaging were recorded. The referred information, recorded in a Microsoft Excel® Program spreadsheet, supported the elaboration of the protocol content.

Protocol Development

The initial version, developed by the researchers, which included information previously recorded and based on minimum actions related to the safe use of medicines, was submitted to analysis and improvement by the nursing professionals of the service. This step involved discussions of topics (themes) organized in Discussion Groups (GD), a strategy in which the group of participants analyze the issue and express their opinion [7].

The invitation to participate in the study was addressed to nursing professionals involved in the process of medication of the BMT service and who performed their duties in the BMT service. Four topics of discussion were listed, as follows: research presentation, prescription scheduling, standardization of medication concentrations and standardization of medication labels. Four 60-minute meetings were planned for each discussion group, evenly distributed among teams and work shifts, with transcription of the contributions in a field diary and recording for the restructuring of the version to be validated.

Validation of the protocol content

The Delphi technique, which consists in the evaluation of the instrument by a group of experts in the topic discussed was used in this step. Snowball sampling was used to recruit the group of judges considering experience in HSCT and in the center for IV medications preparation. In snowball sampling the experts recruit future subjects from among their acquaintances [8].

After electronic invitation and confirmation of the experts' participation, an evaluation round was scheduled with the use of Google Drive® application and the following instruments: invitation letter; professional characterization form (judges); Informed Consent Form; a letter with guidelines for the use of the Delphi Technique and an instrument for the validation of the protocol content with 18 questions arranged into three sessions (Structure and Applicability, Content and General).

An overall satisfactory Content Validity Index (CVI) of 0.7 or higher was established, and its ratio was obtained by dividing the number of judges who answered "Agree" or "Strongly Agree" by the total number of respondents for each question posed [9]. Additional suggestions and recommendations from the experts were analyzed and incorporated or not in the protocol after analysis by the researchers.

The study was approved by the Research Ethics Committee of the Health Sciences Sector of Universidade Federal do Paraná, under protocols No. 1,942,036, 777,453 and 740,153 and the Ethics Committee of Complexo Hospital de Clínicas of the Universidade Federal do Paraná, under protocol No. 820,668. The hospital authorized the disclosure of its name in the study.

RESULTS

Over five years, 996 adverse events were reported. Of these, 422 (42%) were related

to medication. The most frequent error was related to drug administration: intravenously (87.68%), followed by oral administration. Errors related to pharmaceutical form or presentation were less frequent. No errors related to monitoring, medication, route, quantity, label/instruction, contraindication and adverse reaction were reported during the referred period.

The results of the pharmacological profile (Chart 1) contributed to the prioritization of the 138 most frequently used drugs, as follows: 86 intravenously administered and 52 orally administered, of the referred pharmaceutical classes, to compose the protocol.

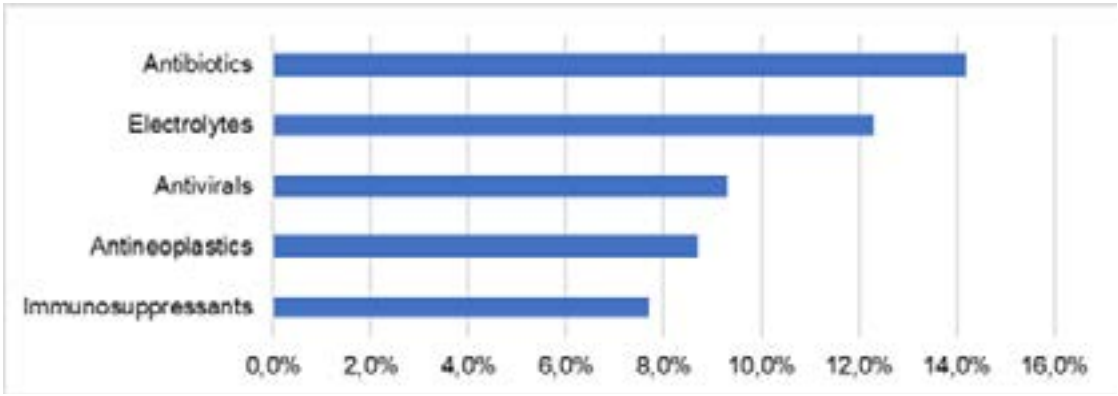

Chart 1 – Pharmacological profile in the BMTS-CHC. Curitiba, PR, Brazil, 2017

The initial version of the protocol, based on documentary research results and on the literature, was presented, discussed and improved on 20 discussion groups (DGs) over a three-month period. Twenty-four (24) nurses, five nurse technicians and two nurse assistants participated in this process.

The contributions of the participants led to adjustments in the protocol, generating a second version of the protocol, which was submitted to a validation process. Of the 11 invited experts (seven nurses and four pharmacists), 7 agreed to participate and 5 completed the process. The expert group consisted of four nurses and one pharmacist. All of them had completed graduation, had a mean age of 44.8 years and worked in public institutions in the southern region of Brazil.

The deadline for the analysis of the first and only round of evaluation, initially set at 10 days, lasted 23 days. At the end of the process, a letter was sent to the experts to explain the changes made and thank them for their participation in the study. The protocol was validated with an overall CVI of 89% (Chart 2).

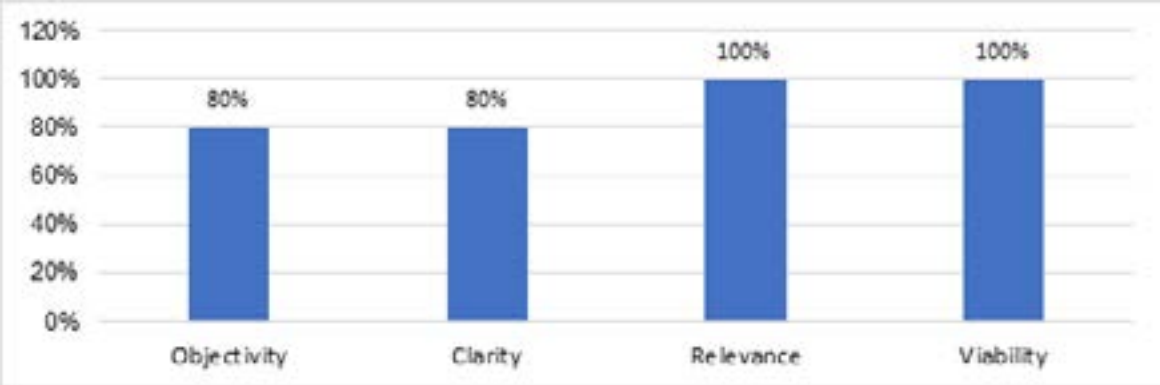

Chart 2 - General Content Validity Index of the protocol for the safe use of medications. Curitiba, PR, Brazil, 2017

The CVI of the structure and related to the applicability of the protocol was 66%, and was not validated in the protocol extension and format aspects (Chart 3). The CIV of the content obtained 100% in all the questions (Chart 4).

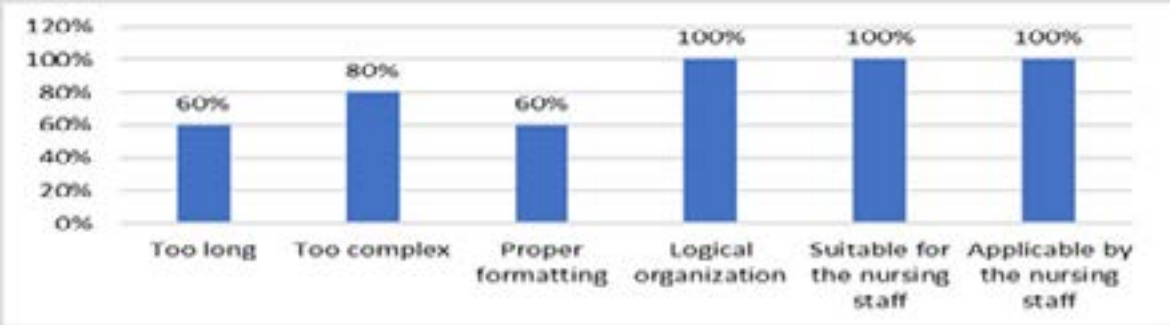

Chart 3 - Content Validity Index of the structure and applicability of the protocol for the safe use of medications Curitiba, PR, Brazil, 2017

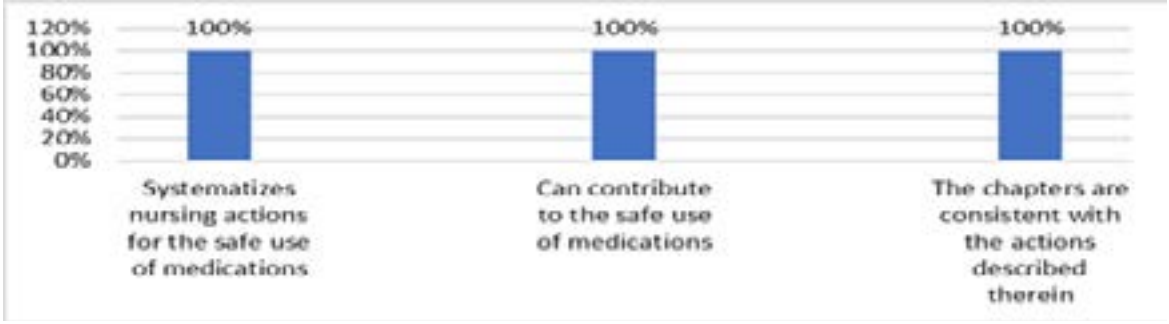

Chart 4 - Content Validity Index of the protocol for the safe use of medications. Curitiba, PR, Brazil, 2017

Based on the recommendations of the experts, the following protocol adjustments were made: a) inclusion of "venous access" and "drug incompatibility" themes; b) development and printing, in resistant material and in the form of an insert, of information related to the contents "Identification of the characteristics of the medications"; and c) Portuguese proofreading.

The final version of the protocol contains 18 chapters organized as follows:

Chapter 1 - How to Use it: Describes the protocol structure and includes instructions on how professionals can make the most effective use of the protocol.

Chapter 2 - General Guidance: Provides information about the intravenous IV infusion rates of drugs, drug calculation formulas, and conversion and equivalence tables.

Chapter 3 – Legislation: Addresses legal aspects related to the performance of each nursing professional in medication administration.

Chapter 4 - Hospital Pharmacy Service: Describes the structure of the hospital pharmacy service, operation and drug dispensing cycle.

Chapter 5 - Pharmacological profile: Presents the pharmacological profile of the service.

Chapter 6 – Storage of medicines: Describes the types of correct storage of medicines according to their characteristics (thermolabile or photosensitive drugs) and the drug dispensing routine in the hospital.

Chapter 7 – Manipulation of parenteral drugs: Exposes the pharmaceutical presentations of intravenous drugs and materials needed for their handling.

Chapter 8 - Describes the nine medication rights (medication, patient, dose, route, time, record, action, dosage forms, and monitoring)

Chapter 9 - Operationalization of medication practice: Describes the routines of drug prescription, duration of treatment with the drug prescribed, nursing staff records, hand hygiene, preparation of the laminar flow hood, and activities of nurses responsible for medication concentration.

Chapter 10 - Chemotherapy Administration: Describes the precautions regarding the administration of chemotherapy drugs.

Chapter 11 - General guidelines: Describes special care related to drug preparation and administration.

Chapter 12 - Oral Administration: Provides recommendations related to orally administered drugs.

Chapter 13 – Medications administered by IV route: Provides guidelines for dilution and administration of drugs - presentation, mechanism of action, reconstitution, infusion time, compatibility for Y-connectors, incompatibilities, and adverse reactions.

Chapter 14 – Orally administered drugs: Provides guidelines for administration - presentation, mechanism of action, reconstitution, possibility of administering the drug orally and by a feeding tube and related care.

Chapter 15 - Pharmaceutical classes: Presents and defines the pharmaceutical classes of the most commonly used drugs in the service.

Chapter 16 – Vocabulary: Introduces and defines drug-related terms.

Chapter 17 – References: Presents the references used for the elaboration of the

protocol.

Chapter 18 - Index: Presents the composition of the protocol.

DISCUSSION

The safe use of medications in hospital institutions is considered a complex process, and nursing professionals play a key role in this process; the actions of these workers should be based on their professional knowledge and skills, aimed at preventing and reducing associated adverse events. In this study, drug preparation and administration were considered essential stages of drug therapy in patients before and after HSCT. Therefore, the elaboration of the protocol content was directed to the most frequently used drugs and routes, aiming at the prevention of adverse events and the promotion of high care quality.

The significant occurrence of errors, demonstrated in the initial step of this study, contributed to sensitize the nursing staff to the need to elaborate the protocol, and its valuable contribution through the Discussion Groups (DG). Errors related to intravenous infused drugs were the most frequent, given the rapid absorption of the drugs, which also have a greater potential for damage [10]. Thus, the recommendations contained in the protocol draw the team's attention to essential care.

Actions focused on error prevention should be discussed by all professionals involved in the medication system, since the delivery of high-quality health care that recommends patient safety is the result of a collective effort in which responsibilities must be shared(4). Thus, the DGs have stimulated the future use of the protocol, because they involve and make the health professionals of the service co-responsible for the recommendations contained therein.

Moreover, due to the complexity of HSCT, intravenous route is the first choice, followed by oral route, due to the impossibility of using the intramuscular and subcutaneous routes and because of the risk of complications in hematological patients. Thus, in the context of the HSCT service, and with the support of the historical pharmacological profile, the protocol included only information and recommendations related to drugs that can be administered through these routes.

The participation of professionals who work in the field provided a positive contribution to this study, reaffirming that evidence-based practice is not only the best available evidence, but also the practice of the professional's clinical knowledge. The importance of including professionals in the process of elaboration of the protocol, facilitating their acceptance in the work process, is based on this assumption [11].

The expert group's assessment and recommendations improved the protocol. In content validation, a value of 0.89 was obtained in the calculation of the CVI, indicating adequate agreement [12]. A review study identified criteria for selecting nursing research specialists to ensure reliability. Experience, academic qualifications, knowledge and skills were considered essential. In this study, the composition of the group, formed by nurses and specialist pharmacists from public institutions, contributed to the critical evaluation based on the expertise in the subject.

Two items that correspond to the extension and format aspects did not reach the established minimum CVI, although the session was validated. However, there was no change in the extent regarding the diversity of medications used and the corresponding inclusion of the main related aspects to compose the protocol, resulting in extensive content. The final version of the protocol was reformatted according to the evaluators' suggestions, and the session named content evaluation reached maximum CVI in all items. This session includes the systematization of nursing actions for safe use of medications.

The nursing staff is responsible for the administration of medicines. However, nurses are responsible for the systematization of drug therapy related activities. In the general evaluation, a CVI of 0.8 was obtained, corroborating the validity of the protocol for the safe use of drugs in the Bone Marrow Transplant (BMT) service, which can contribute to guide and systematize important actions of the drug therapy process, minimize errors and ensure more effective treatment, as well as increase patient safety.

This validation for specific processes is key for health care organization, as it establishes effective conducts and procedures in the work process, guiding care practice in general. Other options, such as learning from error and reports on the occurrence of errors, and the implementation of administrative measures targeted to the medication system planning, can be considered strategies to promote patient safety [13].

CONCLUSION

Research into the identification of drug therapy related errors has guided the pre-elaboration of the protocol and raised the participants' awareness to the issue. The pharmacological profile of the service contributed to the selection of the drugs to be included in the protocol and to the elaboration of a list of safety recommendations regarding the use of each drug and the routes of drug administration.

Participatory construction, which considered local reality and institutional rules, has contributed to the improvement of the protocol content, adjusting it to professional practice and its future implementation in the service. The construction of a protocol for the safe use of drugs in the BMT service will help guide and systematize key actions of the drug therapy process, helping to minimize the risk of errors and ensure effective treatment. It will also increase patient safety.

Access to the content of the protocol may contribute to the promotion of knowledge, a practice that facilitates safe care for transplant recipients, as well as provide technical support to the multidisciplinary team regarding management and conducts in the safe use of medications.

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