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EDUCATIONAL BOOKLET WITH GUIDELINES ON THE MAIN INJECTABLE DRUGS IN PEDIATRICS: VALIDATION STUDY

Cartilha educativa com orientações acerca dos principais medicamentos injetáveis em pediatria: estudo de validação

Folleto educativo con guías sobre los principales medicamentos inyectables en pediatría: estudio de validación

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ABSTRACT

Objective: To construct and validate an educational booklet with guidelines about the main injectable medications used in pediatrics. **Method:** Methodological study, developed in six stages, in the state of Rio de Janeiro, between July 2019 and April 2021. The validation was carried out with 20 specialists with previous professional experience in drug therapy, selected by convenience. The Content Validity Index was used for validation, whose indexes should be greater than or equal to 80%. **Results:** The booklet entitled "Booklet for the correct use of the main injectable drugs in pediatrics" was validated with an overall Content Validity Index of 99.2% for the four domains assessed, and a variation of 95 to 100% among the items individually evaluated. **Conclusion:** The booklet about the main injectable drugs was considered a valid, attractive, and innovative health educational technology, capable of expanding the knowledge of pediatric nurses in a practical and accessible way.

DESCRIPTORS: Pediatric nursing; Intravenous infusions; Educational technology; Validation studie;

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RESUMO

Objetivo: construir e validar uma cartilha educativa com orientações acerca dos principais medicamentos injetáveis utilizados em pediatria. **Método:** estudo metodológico, desenvolvido em seis etapas, no estado do Rio de Janeiro, entre julho de 2019 e abril de 2021. A validação foi realizada com 20 especialistas com experiência profissional anterior em terapia medicamentosa, selecionados por conveniência. Para validação utilizou-se o Índice de Validade de Conteúdo, cujos índices deveriam ser maiores ou iguais a 80%. **Resultados:** a cartilha construída intitulada: "cartilha para o uso correto dos principais medicamentos injetáveis em pediatria" foi validada com o Índice de Validade de Conteúdo geral de 99,2% para os quatro domínios avaliados e uma variação de 95 e 100% entre os itens avaliados individualmente. **Conclusão:** a cartilha acerca dos principais medicamentos injetáveis foi considerada uma tecnologia educacional em saúde, válida, atrativa e inovadora, capaz de ampliar o conhecimento dos enfermeiros pediatras de modo prático e acessível.

DESCRITORES: Enfermagem pediátrica; Infusões intravenosas; Tecnologia educacional; Estudo de validação;

RESUMEN

Objetivos: construir y validar una cartilla educativa con orientaciones sobre los principales medicamentos inyectables utilizados en pediatría. **Material y método:** estudio metodológico, desarrollado en seis etapas, en el estado de Río de Janeiro, entre julio de 2019 y en abril de 2021. La validación se realizó con 20 expertos con experiencia profesional previa en farmacoterapia, seleccionados por conveniencia. Para la validación se utilizó el Índice de Validez de Contenido, el cual debe ser mayor o igual a 80%. **Resultados:** el cuadernillo titulado "Cuadernillo para el uso correcto de los principales medicamentos inyectables en pediatría" fue validado con un Índice de Validez de Contenido global de 99,2% para los cuatro dominios evaluados y una variación de 95 a 100% entre los ítems evaluados individualmente. **Conclusión:** el folleto sobre los principales medicamentos inyectables fue considerado una tecnología educativa en salud válida, atractiva e innovadora, capaz de ampliar los conocimientos de los enfermeros pediátricos de forma práctica y accesible.

DESCRIPTORES: Crack de cocaína; Mujeres; Drogas; Adolescente.

INTRODUCTION

Although drug therapy is the most common form of intervention in health care, there is a consensus in the literature that medication errors are frequent, especially in pediatric care areas.[1] Medication errors are defined as a preventable adverse event occurring at any stage of drug administration, causing harm to the patient. Harm is understood as structural or functional impairment of the body, including illness, injury, suffering, disability or dysfunction, as well as death.[2] These events may be related to the working conditions and technical-scientific knowledge of professionals.[3]

In this context, pediatric patient safety is an even greater challenge, as this is a population that is more vulnerable to the occurrence of medication errors, due not only to the peculiarities inherent to this segment, but also to the unavailability of drug formulations suitable for children, where approximately 80% of the drugs used in adults are also used in children and newborns.[4] However, there is still no mobilization by the pharmaceutical industry to adapt drug formulations for pediatric use, leaving health professionals with doubts regarding the correct use of these drugs.[5]

Thus, pediatric prescriptions require dose adjustments related to weight and other dosage calculations, as well as careful observation of the drug's absorption, distribution, metabolism and excretion processes, which differ from newborns to adolescents. Therefore, nurses need to have specific scientific and technical knowledge to enable safe and effective drug therapy, an important factor in the safe management of the scheduling, preparation and administration process.[6]

According to the literature, intravenous drugs such as sedatives, anesthetics, opioids and antibiotics are frequently indicated in the care of hospitalized pediatric patients, which requires continuous vigilance and monitoring to ensure the safe preparation and administration of drugs.[2] In view of this practice, the most common medication errors related to prescriptions involve the dose of drugs, routes of administration, legibility of prescriptions, presentation and speeds of incorrect infusions, appointments that are not as prescribed, as well as incorrect preparations.[7]

In view of this, it is understood that it is not enough for the drug to be safe in its intrinsic sense, but that the safety of its use process must also be guaranteed.[8] This makes it imperative to train nurses who need to have specific knowledge of each drug used, often without the support of scientific evidence, denoting the need to restructure processes and create safety strategies in order to reduce avoidable risks and damages associated with care.[1]

In this line of argument, educational technologies are considered important methodological tools to be used in the teaching-learning process and should be applied in health education in order to facilitate and support individuals in learning new knowledge and practices related to health[9]. Thus, the creation of a printed educational technology (ET), in the form of a booklet, could be a promising strategy, as

it is believed that the gaps presented in this context can be filled through its use.

The aim is therefore to expand knowledge in a practical and accessible way, through an educational booklet containing guidance on the main injectable drugs used in pediatrics, which can be used by pediatric nurses in an agile way in the face of the need for specific knowledge in intravenous therapy, facilitating decision-making in the pediatric clinic. In addition, literature searches have been carried out on the creation of educational booklets on injectable drugs in the pediatric setting, but the results are still scarce, which also justifies this study. Therefore, the aim of this study is to develop and validate an educational booklet with guidance on the main injectable drugs used in pediatrics.

METHOD

A methodological study10 developed in six stages: 1st) a survey of injectable drugs prevalent in the pediatric clinic; 2nd) a systematized bibliographic survey; 3rd) creation of an educational booklet; 4th) validation of the educational booklet by the judges; 5th) adaptation of the booklet; 6th) making the educational booklet available.

The first stage consisted of a survey of medical records, between July and December 2019, in the medical archive sector of a public hospital located in the state of Rio de Janeiro, Brazil, specifically in the pediatric hospitalization sector.

The study population consisted of drug prescriptions contained in pediatric medical records. Inclusion criteria for the sample: intravenous therapy (IVT) prescriptions with two or more drugs in medical records. Exclusion criteria: IVT prescriptions not administered. With regard to the sample, the medical records were selected for convenience during the data collection period.

The survey covered variables relating to pharmacological therapy, including: injectable drugs, duration of drug therapy (days), therapeutic classification adopted by the World Health Organization (Anatomical Therapeutic Chemical Classification System (ATC)),[11] schedule and route of administration. Absolute and relative frequencies were used to calculate this information.

In the second stage, a systematic bibliographic survey was carried out, with the aim of finding information about the intrinsic characteristics of the medicines identified in the previous stage, in order to identify, analyze and synthesize the results obtained on the subject, as a way of underpinning the theoretical content of the booklet. The search was carried out using the term "generic or trade name of the drug" in highly reliable information resources, such as: the National Health Surveillance Agency (ANVISA) electronic bulletin board, Micromedex Solutions® and the National Therapeutic Formulary.

All available information on the intrinsic characteristics of each drug was included, excluding information that was absent from some of the drugs consulted or information that differed from the information found in the databases consulted. The information search and selection phase was carried out independently by two authors in January 2020, but they used the same search strategies and there was no disagreement between them, both of whom agreed on which information from the medicines they researched should be included in the booklet.

These variables were recorded using an instrument developed and tested by the authors to characterize each drug formulation, which was then organized into a database using Microsoft Excel 2007.

In the third stage, the research team met with the Graphic Designer to work on editing and layout. At this stage, aspects relating to language, layout and illustration were taken into account, in line with the recommendations for the effectiveness of educational materials.[12] In addition to issues relating to important concepts about the correct use of medicines, visual identity, the title and the selection of images to make up the booklet.

In the fourth stage, the educational booklet was submitted for validation by a committee of expert judges, based on the criteria adapted from Fehring,[13] where a minimum score of five points was established for participation, together with the eligibility criteria: professional nurse, specialist, master or doctor in neonatal and/or pediatric nursing, doctors and pharmacists who had previous professional experience in drug therapy. Those who did not send in the instrument duly completed by the deadline were excluded.

At this stage, data was collected in April 2021, in the state of Rio de Janeiro, using an online semi-structured form, built on the Google Forms virtual platform and sent via email. The committee of judges was invited by means of an invitation letter sent by email, detailing the study and its objectives, as well as informing them that the form would take approximately 20 minutes to complete.

In addition, the email contained the booklet attached in pdf format, as well as a link that first directed them to the Free and Informed Consent Form (FICF), which was available for download and for them to accept or not to participate in the research. If so, the participant was directed to the form to fill it in.

The form contained three parts: 1- characterization of the target audience; 2- questions about the content and appearance of the booklet; 3- space for suggestions. A deadline of fifteen days was set for the form to be returned via Google Forms.

The judges were selected by convenience using the snowball technique.14 Initially, the experts were invited by the research team itself, and later by the participants themselves, in accordance with the Fehring criteria13 and the inclusion criteria mentioned above.

This stage was limited to 20 participants, in line with scientific evidence that suggests between six and twenty participants for each group of evaluators.15 It should be noted that none of the experts, during or after data collection, wished to withdraw from the study.

For the experts' assessment of the content and appearance of the booklet, a Likert-type scale was used with four response options ranging from 1 to 4: 1 - strongly disagree, 2 - somewhat disagree, 3 - somewhat agree, and 4 - strongly agree, where the participant chose the best rating for their responses. In this analysis, to estimate the degree of agreement between the judges, the Content Validity Index (CVI) was calculated using the sum of answers 3 and 4, divided by the total number of participants. According to the literature, the items evaluated should have a CVI greater than or equal to 80%, so items with a CVI lower than this limit should be readjusted according to suggestions.[16]

In the fifth stage, the judges' suggestions were evaluated and taken on board where possible, both for the items that reached the determined agreement index and those that did not. The sixth stage focused on making the booklet available for free download in the Google Books Virtual Library, as well as in the Institutional Repository of the Fluminense Federal University (RIUFF).

This study complied with the ethical precepts of research involving human beings and was approved by the Research Ethics Committee of the Fluminense Federal University under Opinion No. 3.977.933 and CAAE No. 34338120.6.0000.8160.

RESULTS

Here is a description of the six stages of the study to build and validate the booklet.

Stage 1 - survey of drugs prescribed in pediatric clinical practice

A total of 65 medical records were collected and 205 (100%) drug prescriptions were identified, belonging to five therapeutic classes: Class A: Food Tract and Metabolism with 30 (14.6%); Class C: Cardiovascular System with 26 (12.6%); Class H: Hormonal preparations for systemic use, excluding sex hormones and insulins with 25 (12.1%); Class N: Central Nervous System with 14 (6.8%); Class J: Anti-infectives for systemic use was the most prevalent with 110 (53%) prescriptions. In addition, 143 (70%) of the prescriptions combined antimicrobials with other drugs such as anti-inflammatories, analgesics, antipyretics and diuretics, among others. As for the route of administration, parenteral was the most prevalent with 143 (70%). With regard to the duration of drug therapy, the seven to ten day protocol prevailed with 131 (64%) of the prescriptions.

Stage 2 - bibliographic survey

Based on the drugs identified in the prescriptions and a synthesis in line with the information obtained from the bibliographic survey, the aim was to make the booklet a practical reference material containing information about the intrinsic characteristics of each drug, referred to here as pharmaceutical and pharmacological, permeating the improvement of the nursing team's knowledge, attitude and practice in relation to the specificities that IVT encompasses.

The booklet therefore contains information on: pharmacological aspects (mechanism of action, adverse reactions, drug interactions, indications, contraindications, routes of administration and administration regimen) and pharmaceutical aspects (presentation, chemical properties, reconstitution, dilution, storage and stability).

Stage 3 - preparation of an educational booklet

In view of the proposal to create the booklet, the Graphic Designer was asked to design the visual communication in terms of writing, font, font size and use of images, with the aim of making the material attractive and accessible for use, especially in health services.

As for the images, those depicting intravenous drugs were selected as a way of illustrating the cover and the different therapeutic classes (ATC) among the drugs that made up the booklet. The images used were from websites[17] with free rights of use. The images were processed using the Gimp 2.8 program to improve them. After this process, the resulting material was exported to Corel Draw to create vectorized illustrations and add colors, light and shadow, following the booklet's color palette, with the aim of attracting the reader and arousing interest in reading.

In the end, the original files were saved in Geomorph Tile Map (gmp) format, the illustrations exported to Portable Network Graphic (PNG) format and the files compiled into a pdf document. The font used was Calibri, size 20 for the titles,[18] for the items and 16 for the sub-items, highlighting them in bold. The booklet was designed in a presentation-portrait format, containing 66 pages, distributed as follows: cover, title page, presentation, summary, important concepts and injectable drugs divided according to the ATC classification.

Stage 4 - validation of the educational booklet by expert judges;

The validation stage involved the participation of 20 health professionals, 15 (75%) nurses, two (10%) doctors and three (15%) pharmacists. Twelve (60%) of the health professionals were female. With regard to the institution where they work, 18 (90%) work in hospitals, while two (10%) work in public universities, of which 13 (65%) have worked in the area for more than ten years. As for further training, 12 (60%) had a master's degree, three (15%) had a doctorate and five (25%) had a specialization. The time spent practicing drug therapy ranged from one to 34 years, with the highest number being 20 years (34%). The average age was 24, ranging from 18 to 49.

Table 1 shows the judges' responses and the CVI for the items according to the domains. The overall CVI obtained for the four domains assessed by the expert judges was 99% and the CVI for each item individually varied between 95 and 100% for all domains, indicating the relevance and pertinence of the educational material.

Stage 5 - adaptation of educational material

After the evaluation between the judges, the qualitative analysis of the recommendations was summarized, as well as the justification when a suggestion/recommendation could not be accepted. Among the items for improvement, the following were suggested: reviewing the images related to the theme of the booklet; the font size; correcting the information regarding the diluent of the anti-infective "ampicillin" and; regarding the age of use of the anti-infective "ciprofloxacin"; grouping the antimicrobials by antibiotic class; as well as presenting the items "reconstitution" and "dilution" before the administration regimen item. Another aspect was the inclusion of corticosteroids in the "respiratory system" class. All these requests were reviewed and complied with.

Chart 1 - Validation of the app by experts in terms of content, language, presentation and cultural appropriateness. Rio das Ostras, RJ, Brazil, 2021

Domain	Strongly disagree/ slightly agree	Agree a little/agree a lot	CVI
In terms of content			
The material is easy to understand and makes it possible to understand the specifics of drug therapy?	0	20	100%
Is information covered that makes it possible to understand the phases that encompass the preparation and administration of medicines in their entirety in the pediatric clinic?	0	20	100%
Is the material clear on the specifics of each drug in terms of mechanism of action, adverse reactions, drug interaction, indication, contraindication and administration regimen?	0	20	100%
Is the material scientifically accurate?	0	20	100%
In terms of language			
Is the reading suitable for the reader's comprehension?	0	20	100%
Is the information presented clearly?	0	20	100%
Are common words used in the vocabulary of health professionals?	0	20	100%
Is learning made easier with short texts or topics?	0	20	100%
In terms of presentation			
Does the material follow an appropriate order for the preparation and administration of the medication?	0	20	100%
Does the font size and type make it easy to read?	01	19	95%
Is the educational booklet attractive for use by health professionals?	0	20	100%
Is the graphic designer attractive?	0	20	100%
In terms of cultural appropriateness			
Is the material culturally appropriate to the language and experience of health professionals?	0	20	100%
Are the concepts presented culturally appropriate for health professionals?	01	19	95%
		Global CVI 99.2%	

Source: survey data (2021)

Other points focused on: including the dose of each drug and the drugs used in cardiopulmonary arrest in pediatrics. The justification for not addressing these issues is due to the differences in weight, age, illnesses and comorbidities, as well as the child's clinical condition. The other point is justified because the inclusion of medicines in the booklet was based on a survey of prescriptions in the research setting. Finally, it was suggested that the volume of the reconstituted medicines be added.

This last point could not be met given the wide variety of diluents that can be used and the diversity in relation to the physiological and pathological state, weight and age of each patient, so it was decided to provide more generic information on this item.

Stage 6 - Making the booklet available via social media

After evaluating and taking on board the suggestions of the specialist judges, the final version of the booklet was made available in e-book format on the Google Books Virtual Library for free download, as well as on the Institutional Repository of the Fluminense Federal University (RIUFF) via the link: http://app.uff.br/riuff/handle/1/25791, and can also be accessed via QR code:

DISCUSSION

This study developed and validated an educational booklet entitled "Primer for the correct use of the main injectable drugs in pediatrics" and obtained internal validity of the educational material produced. The evaluation by the health experts reached an overall CVI of 99.2% for all domains, thus indicating the relevance and pertinence of the booklet as educational material.

In the evaluation by the judges, the booklet's domains had a score higher than the determined value, suggesting that the booklet is representative in terms of content, capable of providing knowledge to the nursing team regarding the correct use of medicines in pediatric clinical practice, in accordance with the Regional Nursing Council (COREN), which requires knowledge of the medicine before administering it.[18]

Studies estimate that the occurrence of failures in the medication process is three times more frequent in hospitalized children than in adults, in addition to reporting that a considerable proportion of Medication-Related Issues (MRIs) in this scenario are linked to the use of antimicrobials, either because this is one of the most prescribed classes of drugs, or because the parenteral route is the most widely used in the hospital environment and requires excessive handling for administration in these patients.[19]

It is therefore understood that the IVT process is complex, dynamic and exposed to risks, which can lead to errors and omissions, affecting the quality of care and the safety of those receiving the medication.[20] This fact ratifies the importance of this health technology, which aims to synergistically integrate access to reliable and up-to-date information on the pharmacological and pharmaceutical properties of the main injectable drugs used in pediatrics. It can be used by the nursing team to fill these gaps, as it has already been validated, in terms of content and appearance, by specialists and, in this way, minimize the helplessness of these professionals who need to know how to use, dilute, administer and store these drugs, often without prior knowledge and/or support from scientific evidence.

Thus, the development of quality educational materials makes it possible to carry out educational interventions based on structured knowledge and information aimed at the clientele. To this end, fundamental elements must be considered when developing printed or digital educational materials with a view to improving the understanding of readers[21], an aspect that is consistent with this booklet, which, when it was created, was based on the recommendations of the competent bodies with regard to pharmacological therapy, achieving a 100% rate in this item.

Another favorable point in this study is the participation of professionals from different areas of expertise in the validation process, making it possible to combine different specialized knowledge on the subject. In this way, bringing together professionals with expertise in different areas ensures greater accuracy in the selection and evaluation of educational materials, as well as valuing opinions and different approaches to the construct analyzed.[22] It can therefore be seen that the multidisciplinarity of the specialists in this study, with experience in teaching, research and care, was essential for the validation process of the booklet.

With an ever-expanding space, the production of ET has been growing exponentially, not only in the academic scenario, but also professionally, because measures such as this booklet aim to reduce the rate of errors involved in health care, in this case, the preparation and administration of medicines. This technology quickly and accurately provides information on doubts that often arise when preparing and administering these drugs, which are often prescribed in combination with other drugs, as was identified in this study.

Finally, the experts considered the booklet to be adequate in terms of the items evaluated, and thus considered it to be adequate within the scientific rigor of validity. The level of agreement between the experts was higher than that recommended by the literature, which confers quality to the material produced. In this way, the results contribute to professional nursing practice with the possibility of incorporating this technology containing information to expand knowledge about the pharmaceutical and pharmacological characteristics of the main injectable drugs used in pediatric clinical practice.

As a limitation, the study points out that this technology has not been validated by the target audience, and that it was

developed in a single center, without focusing on a greater number of medical prescriptions, making it possible to carry out a more in-depth analysis of the subject, which means that the study needs to be continued.

CONCLUSION

The educational booklet on the main injectable drugs used in pediatrics was considered to be a valid, attractive and innovative educational technology in health, capable of expanding the knowledge of pediatric nurses in a practical and accessible way, since its use could contribute to optimizing the skills of these professionals by offering information on the pharmaceutical and pharmacological characteristics of the main injectable drugs used in pediatrics, who through it acquire new knowledge and transform themselves and their practice. Therefore, this educational booklet is presented as a tool capable of helping and improving the safety of hospitalized children in the face of IVT in pediatric clinics, as well as being a quick reference source for the nursing team at any time and place, freely accessible and free to download from social networks.

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