

Construction and validation of a family guidance manual on complications of intravenous therapy in children

Construção e validação de manual de orientação para família sobre complicações da Terapia Intravenosa em crianças Construcción y validación de un manual de orientación familiar sobre complicaciones de la terapia intravenosa en niños

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ABSTRACT

Objectives: to build and validate the content of an educational manual for the inclusion of family members of hospitalized children in the prevention and early identification of complications associated with IVT through the peripheral route. **Methods:** it was a methodological study of construction and validation of the content of an instructional material. The validation process took place using the Delphi Technique, adopting a content validation index equal to or greater than 0.80 as a desirable consensus. **Results:** the handbook was validated in the second assessment round in all categories: content, language, illustration, layout, motivation, culture, and applicability. The Global Content Validation Index was 0.98. **Conclusions:** because of the high values obtained (> 0.8), after the second evaluation, the handbook is considered validated in terms of content, by expert judges.

Descriptors: Family; Child; Nursing, Pediatric; Infusion, Intravenous; Catheterizations, Peripheral.

RESUMO

Objetivos: construir e validar o conteúdo de um manual educacional para a inclusão de familiares de crianças hospitalizadas na prevenção e identificação precoce de complicações associadas à TIV por via periférica. **Métodos:** estudo metodológico de construção e validação do conteúdo de um material instrucional. O processo de validação ocorreu por meio da Técnica Delphi, adotando como consenso desejável o índice de validação de conteúdo igual ou superior a 0,80. **Resultados:** o manual foi validado na segunda rodada de avaliação em todas as categorias: conteúdo, linguagem, ilustração, layout, motivação, cultura e aplicabilidade. O Índice de Validação de Conteúdo Global foi de 0,98. **Conclusões:** em virtude dos elevados valores obtidos (> 0,8) após a segunda avaliação, o manual foi considerado validado quanto ao conteúdo pelos juízes especialistas.

Descritores: Família; Criança; Enfermagem Pediátrica; Infusões Intravenosas; Cateterismo Periférico.

RESUMEN

Objetivos: elaborar y validar el contenido de un manual educativo para la inclusión de familiares de niños hospitalizados en la prevención e identificación temprana de complicaciones asociadas a la TIV por vía periférica. **Métodos:** estudio metodológico de construcción y validación del contenido de un material didáctico. El proceso de validación se realizó utilizando la Técnica Delphi, adoptando como consenso deseable un índice de validación de contenido igual o superior a 0,80. **Resultados:** el manual fue validado en la segunda ronda de evaluación en todas las categorías: contenido, lenguaje, ilustración, diseño, motivación, cultura y aplicabilidad. El índice de validación de contenido global fue 0,98. **Conclusiones:** debido a los altos valores obtenidos (> 0,8) luego de la segunda evaluación, el manual fue considerado validado en términos de contenido por los jueces expertos.

Descriptores: Familia; Niño; Enfermería Pediátrica; Infusiones Intravenosas; Cateterismo Periférico.

INTRODUCTION

Illness and the need for hospitalization are potentially stressful situations for children and their families, assumed that the possibility of exposure to painful and invasive technical interventions, such as Peripheral Intravenous Catheterization (PIC) for the infusion of Intravenous Therapy (IVT) for the infusion of solutions, drugs, nutrients or blood and its derivatives.

A PIC can trigger negative reactions in children, such as refusal of the procedure, crying, muscle tension and contracted posture⁽¹⁾ to this procedure, contributing to the child's and family's discomfort. Also, the use of peripheral IVT in children can cause complications, with a frequency that varies from 18.6 to 55.6%⁽²⁻⁶⁾, such as bruises, phlebitis/thrombophlebitis, infiltration/leakage, local infection, nerve damage, vessel spasms⁽⁷⁾ and catheter obstruction. When these complications occur, the intravenous catheter is removed, and a new PIC is required. However, finding an intravenous access may not be possible in the first attempt at catheterization, stressing the child and family⁽⁸⁾.

Depending on the World Health Organization (WHO), understanding the types of adverse events that occur, their reach, frequency and avoidance are essential for the creation of policies that aim to lessen associated damages. As part of this objective, the WHO has proposed some activities in order to list issues that discuss patient safety, aiming to determine the measures that assist in reducing harm and improving care for people⁽⁹⁾.

However, patient safety is not restricted to the implementation of safe care practices by health professionals, but according to the National Patient Safety Program, citizen involvement in their safety is also encouraged, "the patient for safety of the patient". This will improve safety by considering patients as the center of care and including them, added to their families, as partners in this process⁽¹⁰⁾.

It is known that the family makes efforts to take care of the hospitalized child, by looking for information about the disease, clinical condition and the treatment implemented; learning technical skills to care for and identifying the signs of improvement or worsening of the child's health status⁽¹¹⁾.

Therefore, adding the family member accompanying the hospitalized child in the prevention of local complications associated with IVT is important, since it is based on the premise that his daily presence in the hospital allows collaboration with the team to promote the child's safety. Thus, it is crucial to use educational tools that can cooperate with this process of including the family in hospital care for children, providing them with basic information through audiovisual resources, handbooks, informative booklets and even the internet⁽¹²⁾.

Thus, banks of national and international journals were checked in order to identify the existing publications on the inclusion of the family in the prevention of complications related to IVT by peripheral route in hospitalized children. It was noticed the absence of publications on the topic of interest, a finding maintained until the submission of this article. That said, the question was asked: how to create an informative handbook on the prevention and identification of local complications of IVT in peripheral routes for family members of hospitalized children? What is the level of the agreement of the expert judges regarding the content of this handbook?

OBJECTIVES

To build and validate the contents of an informative handbook for the inclusion of family members of hospitalized children in the prevention and early identification of complications associated with peripheral intravenous therapy.

METHODS

Ethical aspects

The study was approved by the Ethics and Research Committee of the *Universidade Estadual de Feira de Santana*.

Study design, location, and period

This is a methodological research of build and validate the contents of technologies type, carried out by retrieving bibliography, of the type scoping review, construction of educational material and validation of it by expert judges, as developed by other authors⁽¹³⁾. The study was conducted through electronic mail, from May to October 2015.

Population

In the validation phase of the informative and instructional material, Brazilian health professionals and experts in the field of pediatrics and peripheral intravenous therapy contributed in the study, selected through search and evaluation of the *Lattes curriculum*, upon the inclusion criteria: be a professional working in the management of child care sectors, in assistance, teaching, research and extension related to hospitalized children, families, intravenous therapy, preparation or validation of teaching materials; has experience for at least two years in the practice of inserting peripheral intravenous devices and in the care of local complications of IVT in hospitalized children.

Professionals who, after inclusion in the study and for some personal reason were unable to follow the validation stages of the informative and instructional handbook, those who did not return the content validation instrument or returned with an incomplete item were excluded.

To calculate the sample size, the following formula was used: $n = Z\alpha^2.P(1-P)/d^{2(14)}, where: Z\alpha: Refers to the confidence level (at 95\%); P: Proportion of individuals who agree with the pertinence of the items; d: Difference in proportion considered acceptable. The following parameters were adopted: Minimum proportion of 80% of agreement regarding the relevance of each item evaluated and a difference of 20% in terms of agreement. The final calculation was as follows: <math display="block">n=(1,96^2x0,80x0,20)/0,20^2, \text{ obtaining a sample of 15 judges. A total of 20% (3 participants) were added to this figure for possible losses.}$

Study protocol

In the first stage, from May to July 2015, a bibliographic survey of the scoping review type was carried out to get acquainted with the scientific literature on the theme to support the construction of informative and instructional material.

For the selection of articles, the following criteria were adopted: be published in full in Portuguese, or English, or Spanish; be classified as original, integrative or systematic review; contain information about family participation in the context of care for children using IVT in the hospital or home environment and care related to complications associated with the use of IVT; addressing care with peripheral or central venous catheters; involve the neonatal, pediatric, adult or elderly population. Restricted access studies (requiring access payment), reflective articles and case studies were excluded.

Nine articles were found, which were read and extracted information about the concept of complications of IVT and its types, definition of PIC, signs and symptoms of complications and procedures to prevent complications related to IVT. Besides the database created as the bibliographic survey, reference textbooks on IVT, national and international guidelines of societies of nurses specializing in intravenous therapy and Ministry of Health guides were consulted.

The informative handbook was prepared from September to October 2015, according to development guidelines and applicability assessment of educational instruments, in line with the categories: content, language, organization, illustration, layout, learning and motivation⁽¹⁵⁾.

The content was organized in simple language and accessible to the target audience, with the following themes presenting: definition of the IVT- related complication; definition of peripheral venipuncture; the most used veins in peripheral venipuncture in children; concept, causes, signs and symptoms of each complication associated with IVT (hematoma, phlebitis, leakage, infiltration and obstruction); measures for the prevention of IVT- related complications, which was identified with the title "How family members can collaborate with health professionals in the identification of complications".

To format the handbook, the programs Adobe In Design and Photoshop were used, and the layout of images and texts was carried out by a design professional. Most of the images, especially of the complications, were of their authorship and the others were of public domain and collected from the internet.

After elaboration, the handbook was submitted to the content validation process, being, therefore, evaluated by expert judges on the theme, using the Delphi technique, in October 2015.

The participants' selection took place according to the inclusion and exclusion criteria mentioned in the population section. Nineteen expert judges were invited for the possible inconsistencies of responses, of which 12 agreed to participate and only eight completed all rounds of validation of the informative handbook. According to studies, the number of participants in the group of judges varies between five and 12⁽¹⁶⁻¹⁸⁾, however, for an effective assessment it is crucial to count on qualified experts in the group, with no pre-established amount of literature⁽¹⁹⁾.

After selecting the judges, an invitation letter was sent by e-mail⁽²⁰⁾, explaining the source of the material prepared and the purpose of the study. After acceptance, it was sent via e-mail the Informed Consent Form (ICF), the first version of the handbook and the data collection instrument prepared by adapting categories and items used to evaluate other instructional teaching technologies developed and validated in national surveys⁽²¹⁻²³⁾. The data

collection instrument contained data for the characterization of the judges and 27 items (as shown in the results tables) to assess the following categories⁽²¹⁻²³⁾: Content (6 items), Language (3 items) and Illustration (5 items) - for each complication associated with IVT - Layout (7 items), Motivation (3 items), Culture (2 items) and Applicability (1 item) - for the material as a whole, with the variables described as: strongly agree, agree, disagree, strongly disagree and do not know, at the end of each category there was a space for suggestions, in case of the removal, addition or modifications⁽²³⁾ of the text and/or images.

Analysis of results and statistics

The collected data were tabulated in a statistical software package called Statistical Package for the Social Sciences (SPSS), version 22. For the analysis of the characterization of the judges, the absolute and relative frequency for the qualitative variables was used.

For the analysis of the handbook content⁽²⁴⁾, according to the evaluation of the validity and the degree of relevance of the explanatory texts and images, the Content Validity Index (CVI) was calculated, with the following equations: CVI (Content Validity Index) dividing the responses of agreement and the total number of judges; CVI of the categories was the average of the CVI of the items of each of these. Also, the Global CVI was checked through the average of all items divided by the total number. To quantify the extent of agreement between expert judges, values equal to or greater than 0.80 were considered as suitable parameters⁽²⁴⁾.

For qualitative analysis, the suggestions proposed by the judges were analyzed. The suggestion written by the participants were transcribed in a table, being grouped according to category and similarity between them. For analysis, the pertinence was verified, according to the material proposal, and/or the frequency in which they were repeated. The handbook was validated in the second assessment round, with some adjustments made by the expert judges.

RESULTS

As a result of the material preparation stage, the first version of the handbook with 16 front and back pages was obtained, consisting of: cover, back cover, and general presentation. The cover included an image of a peripheral venipuncture on a child, the title of the handbook, which was named "Complications of intravenous therapy: a handbook for family members of hospitalized children". The second page presented the index card and on the third, the qualifications of the institution and the research project to which the product was linked and the authors' names. The following pages carried the general presentation and information with concept, causes, signs and symptoms of each complication associated with IVT and prevention measures (Figure 1).

In the next stage, the first version of the handbook was submitted for validation by a group of expert judges. For the characterization of the group of judges, data from the 8 specialists who completed the two Delphi rounds were used. These participants were female (100%), nurses (100%), mostly residing

in Bahia (50%) and São Paulo (37.5%). These evaluators had a doctorate (37.5%), specialization (37.5%) and a master's degree (25%); worked in the field of teaching (35%) and research (30%) in units of Clinical Medicine (23.8%) and Pediatric Surgical Clinic (19.9%), with an average length of experience in the field of 12.3 years (±8.2).



Figure 1 - Pages of the final version of the handbook "Complications of intravenous therapy: a handbook for family members of hospitalized children

The handbook was validated after two assessment rounds. In the first, it achieved a Global CVI of 0.846. In this round, the content of the category achieved CVI equal to 0.875 in each issue assessed, however, the content was not appropriate for the target audience and the content presentation did not support learning (Table 1)⁽²¹⁻²³⁾.

Regarding the language item the CVI of the category of each issue was 0.625. The judges agreed that the writing style was not fully compatible with the target audience, that the writing was not attractive enough and the text language was not clear and objective (Table 1)⁽²¹⁻²³⁾.

According to the judges' evaluation, the handbook content had excess information for the target audience, concepts not compatible with the literature in the area, unintelligible language, incomplete texts and very technical content. Thus, changes were made to the wording of the PIC concept and the complications of IVT, added to replace the term "catheter occlusion" for "catheter obstruction".

Improvements were made in the writing of the topic related to the family members' behavior by preventing complications and other types of care were added, such as "Contribute so that the child understands the need to always say when he/she feels pain at the insertion site" and "Be aware to the advice that the team makes regarding the infusion of saline solution or medication'. The subtitle was also changed to "How you can cooperate".

As for the illustration, the category CVI was 0.65 for phlebitis and 0.775 for infiltration, leakage, and obstruction (Table 1)⁽²¹⁻²³⁾. The illustrations of phlebitis and catheter obstruction did not explain the complications, nor were they relevant to the content of the material. For phlebitis, infiltration and leakage, the illustrations were judged to be without visual quality and in an insufficient quantity.

Table 1 - Distribution of the Content Validity Index of the judges according to the content, language, and illustrations criteria for each complication, first and second Delphi rounds, Feira de Santana, Bahia, Brazil, 2015

Variables	Phlebitis CVI*		und Delphi Extravasation CVI*	Obstruction CVI*	Phlebitis CVI*		und Delphi Extravasation CVI°	Obstruction CVI*
Content								
The content is scientifically correct	0.875	0.875	0.875	0.875	1	1	1	1
Content is appropriate for the target audience	0.75	0.75	0.75	0.75	1	1	1	1
The material titles and subtitles section is pertinent	0.875	0.875	0.875	0.875	1	1	1	1
Content is sufficient to meet the needs of the target audience	0.875	0.875	0.875	0.875	1	1	1	1
The text sequence is logical	1	1	1	1	1	1	1	1
The presentation of the content favors the learning of the theme	0.75	0.75	0.75	0.75	1	1	1	1
CVI* of the content category	0.854	0.854	0.854	0.854	1	1	1	1
Language								
The writing style is compatible with the target audience	0.625	0.625	0.625	0.625	1	1	1	1
The writing used is attractive	0.625	0.625	0.625	0.625	1	1	1	1
The language of the text is clear and objective	0.625	0.625	0.625	0.625	1	1	1	1
CVI* of the language category	0.625	0.625	0.625	0.625	1	1	1	1
Illustration								
The illustrations are relevant to the content of the material and elucidate the content	0.75	1	0.875	0.75	1	1	1	
Illustrations are clear and easy to understand	0.5	0.75	0.75	0.5	0.85	1	1	
Illustrations have visual quality	0.625	0.625	0.75	0.875	0.85	1	1	
The number of illustrations is adequate for the content of the informative material	0.75	0.75	0.75	1	1	1	1	
The presence of each of the figures in the Manual is relevant	0.625	0.75	0.75	0.75	1	1	0.85	
CVI* of the illustration category	0.65	0.775	0.775	0.775	0.94	1	0.97	

Note: *Content Validity Index.

Moreover, for all complications, the illustrations were not considered clear and understandable, and the presentation of each of them is relevant for the manual. They also considered the need to name the images and their real sources, as well as excluding some images that could frighten and confuse the target audience. As for the layout, the category CVI was 0.833, with the judges pointing out that the colors used to the text are not relevant and do not promote reading. Changes were suggested in the text formatting, the color used and text highlights (Table 2)⁽²¹⁻²³⁾.

After evaluating the first-round judgment, regarding the images and layout items, it was decided to accept all the suggestions, and the required adjustments were made. The images of the complications were replaced, like the one that characterized the infiltration and the leakage.

One of the phlebitis images was removed, as it was considered to be inadequate to represent this complication and the catheter obstruction was removed from the manual, as according to the evaluation of some judges they were inappropriate for the target audience, since this complication was not evident at the catheter insertion site. Regarding the layout, the color of the manual was changed from red to blue and the highlights were changed to a more attractive language that would attract the reader's attention.

Based on the motivation category, the CVI of the category achieved was 0.833, however, the content was not considered encouraging or motivating for the target audience (Table 2)⁽²¹⁻²³⁾. In the culture category, although had a CVI of 0.812, the text was not compatible with the target audience, being considered unsatisfactory to meet the different profiles of users (Table 2)⁽²¹⁻²³⁾. Regarding the applicability category, the judges agreed that the handbook has practical applicability. In these last three categories, no suggestions were made by the evaluators (Table 2)⁽²¹⁻²³⁾.

Finally, the second version of the manual was sent to the judges for evaluation, reaching a Global CVI of 0.98. The final version of the manual was presented with 8 pages and 10 illustrations.

The validation of the informative material aimed to assess the level of agreement of the judges regarding the elements that compose it, thus bringing the knowledge closer to the reality of the reader about the care of family members of children hospitalized and using peripheral IVT.

For the validation of the manual "Complications of intravenous therapy: a handbook for family members of hospitalized children", developed in the present study, the Delphi technique was used, as well as other studies that adopted the same method of conducting the validation of other informative materials (17,23,25). The informative material was validated in the second round of evaluation by expert judges, reaching a consensus of over 80% in all categories, as well as in other surveys (20-21,23).

The handbook content and language achieved high CVI values in the category, proving the importance of family members having access to correct and consistent information with the literature in the theme, besides being easy to understand, and these are essential factors for them to contribute to patient safety through early identification of IVT complications.

According to an international study, it was found that family members recognize errors and adverse events that occur during care for pediatric patients, some of which are related to their safety⁽²⁶⁾. Another research showed that, when evaluating reports from family members, they identified eight adverse events that were not observed by other health professionals, of these, seven were considered preventable, and adverse events were associated with several attempts to get the puncture in the child's venous network and adverse effects of medications⁽²⁷⁾.

Table 2 - Distribution of the Content Validity Index of the judges according to the layout, motivation, culture, and applicability criteria of the manual, in the second round, Feira de Santana, Bahia, Brazil, 2015

Variables	1st round Delphi CVI*	2 nd round Delphi CVI*
Layout		
The font used makes it easy to read	1	1
The colors applied to the text are relevant and facilitate reading	0.5	1
The visual composition is attractive and well organized	0.875	1
The number of pages is adequate	0.875	1
The text layout is adequate	0.875	1
The font size of the titles, subtitles and text is adequate	0.875	1
CVI* Layout category	0.833	1
Motivation		
The content is motivating and encourages further reading	0.75	1
The content sparked the reader's interest	0.875	1
The content addresses doubts, clarifies and informs the family member in identifying complications related to intravenous therapy	0.875	1
CVI* Motivation category	0.833	
Culture		
The text is compatible with the target audience, given the different profiles of users	0.625	1
The handbook is intended for use as a resource for the insertion of the family in promoting the safety of hospitalized children	1	1
CVI* Culture category	0.812	1
Applicability		
The handbook has practical applicability	1	1
CVI* Applicability category	1	1

Note: *Content Validity Index.

Concerning the illustration issues, their easy understanding and the fact that they portray the reality of the complications presented in the informative handbook, their validity by the expert judges committee will help to capture the attention of the target audience, inserting them in the prevention and early recognition of these events.

When observed early, the occurrence of phlebitis, for example, avoids injuries worsening, besides the manifestations of "intense pain, hyperemia, edema, infected secretion and painful fibrous cord"⁽²⁸⁾. Also, infiltration and/or leakage, when in advanced degrees, can cause injuries to the skin, muscle and even nerves near to the insertion of the peripheral intravenous device^(7,28), thus requiring other care and extension of the child's hospitalization time.

That way, when noticing the occurrence of an IVT complication in children early on, family members can compare what had been observed with the illustrations in the handbook combined to information about this event, cooperating with health professionals. This will add value to the family's participation in promoting safe practices in the hospital environment.

Harmony between the elements of motivation, culture and applicability is also essential to encourage interest in reading the material. Also, because it is printed, the manual will be fully available for other readings and family learning, according to their information needs on the prevention of complications related to the use of IVT. Thus, as it has been evaluated as an informative handbook applicable in clinical practice, it is thought that this resource may contribute to the inclusion of the family in childcare.

In practical applicability, the booklet is thought of as an informative material that is characterized as a barrier to prevent IVT complication, as shown by the Swiss cheese model, which, by reducing the holes of this type of cheese with the introduction of tools prevention of adverse events, preventing they reach the patients⁽²⁹⁾.

For the handbook to reach the level of agreement defined by the research, it was necessary to carry out adjustments proposed by the judges, to qualify and improve it, to achieve the objective proposed. The expert judges' suggestions permeated all aspects evaluated, from changes in content and language to objective and accessible information, changes in images that favor the content understanding, improvement of the layout to increase the meaning of attractiveness, even the modification of the title and explanatory text of behaviors that can be adopted by family members to prevent IVT complications.

Other studies also point out that the judges proposed suggestions for the validation of guidebooks and booklets, which are related to the cover concept, text language, visibility and organization of the images, implementation of elements that enable the understanding of the content and image^(17,20). Another

research to validate an educational handbook on breastfeeding, however, presented in its results proposals for changes of texts and illustrations, which were judged to be not understandable⁽²²⁾.

The initial impact is individual, but it is suggested that the success of this impact will lead to the spreading of good practices among family members⁽³⁰⁾, reflecting, in the long term, the prevalence of complications associated with the use of peripheral IVT in hospitalized children and promotion of increasingly safe environments.

Study limitations

This study had some limitations, among them, a group of judges composed only by nurses, the lack of availability of invited judges to participate and contribute to data collection and the difficulties of finding specialists on the subject.

Contributions to the Area

This study can contribute to the theoretical, practical, and social aspects. In the theoretical area, it can strengthen discussions about the introduction of the family member in pediatric patient safety, besides promoting the incorporation of the theme from undergraduate to graduate. In practice, it is also believed that the use of this handbook will contribute to the prevention of IVT complications, assisting and guiding family members in the identification of these events, considering that it constitutes an illustrated technology capable of answering the main doubts of the family members that permeate the hospital routine. In the social domain, it can promote the empowerment of family members, since it has information that can contribute to the family's role in the care of hospitalized children.

However, content validity by family members of hospitalized children is recommended, besides the clinical validation of this informative material by this target audience, so that this tool can be improved and used in the daily practice of pediatric nurses. Also, it is proposed that further research be carried out to investigate the practical applicability of the handbook and its effects on the behavior of family members, besides assessing its influence on the prevention and decrease of the prevalence of IVT complications in hospitalized children.

CONCLUSIONS

Due to the high CVI values for each item judged in the secondround greater than 0.8, the informative handbook "Complications of intravenous therapy: a handbook for family members of hospitalized children" was considered validated, regarding the content by the specialists.

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