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Administration of liquid medications for oral use in babies: development and validation of educational material for caregivers

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Abstract

Objective: To develop an educational material with guidelines for caregivers on the administration of oral liquid medications in infants. **Methods:** the study comprised three stages: (i) development of the educational material based on a literature review, (ii) evaluation by a committee of eight specialists, and (iii) subsequent evaluation by the target population. The validation of the material was based on a minimum Content Validity Index (CVI) of 0.80 and an agreement rate of 75% among participants. **Results:** the educational material, titled “Administering Liquid Medications to Infants: A Guide for Caregivers and Guardians,” was completed with 32 pages, featuring logical organization, simple language, examples, and images. After evaluation by the committee of specialists, the material achieved a CVI of 0.98 and incorporated seven suggestions. The evaluation by the target population resulted in an agreement rate of 97.5%, with all suggestions being considered. **Conclusions:** the educational material was validated, standing out for its alignment with objectives, cohesive structure, and relevance. This safe and informative tool can benefit both caregivers and healthcare professionals, being essential to prevent errors in the administration of liquid medications in infants, thereby reducing the risks of intoxication and other health impacts.

Keywords: child, drug utilization, caregivers, health education

Administração de medicamentos líquidos de uso oral em bebês: desenvolvimento e validação de material educativo para responsáveis e cuidadores

Resumo

Objetivo: desenvolver um material educativo com orientações para responsáveis e cuidadores sobre a administração de medicamentos líquidos de uso oral em bebês. **Métodos:** o estudo compreendeu três etapas: (i) desenvolvimento do material educativo com base em revisão de literatura, (ii) avaliação por um comitê de oito especialistas e (iii) posterior avaliação pela população. A validação do material foi baseada em um Índice de Validade de Conteúdo (IVC) mínimo de 0,80 e um índice de concordância de 75% entre os participantes. **Resultados:** o material educativo, intitulado “Uso de medicamentos líquidos por bebês: um guia para responsáveis e cuidadores”, foi finalizado com 32 páginas, apresentando uma organização lógica, linguagem simples, exemplos e imagens. Após a avaliação do comitê de especialistas, o material obteve um IVC de 0,98 e incorporou sete sugestões. A avaliação pela população resultou em um índice de concordância de 97,5%, com todas as sugestões sendo consideradas. **Conclusões:** o material educativo foi validado, destacando-se pela conformidade com os objetivos, estrutura coesa e relevância. Esta ferramenta segura e informativa pode beneficiar tanto os cuidadores quanto os profissionais de saúde, sendo essencial para prevenir erros na administração de medicamentos líquidos em bebês, reduzindo riscos de intoxicação e outros impactos na saúde.

Palavras-chave: criança, uso de medicamentos, cuidadores, educação em saúde



Introduction

Liquid pharmaceutical forms, such as solutions, suspensions, and emulsions, are the main preparations used orally in infants, offering advantages such as easier ingestion and flexible dosing. However, the preparation and administration of these pharmaceutical formulations require extreme caution¹⁻³. In situations involving self-medication or errors in dose or volume calculation, infants are vulnerable to potential risks of intoxication, as more than 80% of medication administration errors in children outside hospitals are related to liquid pharmaceutical forms⁴.

Errors in the use of liquid medications in home settings are associated with confusing units of measurement, complex instructions, and low health literacy among parents and caregivers⁵⁻¹¹. Studies demonstrate that insufficient information in prescriptions or unclear guidance regarding the route of administration, frequency, and duration of treatment affect the understanding of caregivers, especially those with low literacy levels¹¹⁻¹³. Other studies show that caregivers with low health literacy are more likely to use non-standard measuring instruments, such as kitchen spoons, and have greater difficulty understanding labels, prescriptions, and weight-based dosing^{9,11}. Furthermore, limited literacy is associated with an increased likelihood of dosing errors with liquid medications^{5,10}. Given this issue, it is important to implement educational actions, such as developing accessible educational materials for caregivers, especially those with limited health literacy¹⁴⁻¹⁶.

The development of educational materials involves stages of evaluation and validation by experts and the target population, aiming to ensure the delivery of safe and understandable information^{15,17-19}. In Brazil, only 12% of the population is functionally literate in complex texts, highlighting the need to consider textual and terminological accessibility during the development of educational materials^{17,20-22}. To the authors' knowledge, there are no educational materials developed with this methodological rigor to guide the use of liquid medications in infants. Thus, this study aimed to develop and evaluate educational material on the administration of liquid medications to infants, considering the principles of health literacy for caregivers and guardians.

Methods

This methodological development study was conducted in three stages: 1) Development of the educational material; 2) Validation of the educational material by a committee of experts; 3) Evaluation of the educational material by the target population.

Stage 01 - Development of the Educational Material

Theoretical Framework for the Development of the Material

The development of the material was based on a literature review concerning the administration of oral liquid medications to infants, allowing the delimitation and selection of topics to be included. The following publications were used: Medication Safety Tips for Families²³; Adverse Drug Events in Children²⁴; Multi-professional Guide to Health Education in Pediatrics²⁵; Controlled Vocabulary of Pharmaceutical Forms, Routes of Administration, and Medication Packaging²⁶; Guidelines on Medication Use²⁷; Safe Use of Medications in Pediatric Patients³; BNF for Children²⁸; Preventing Home Medication Administration Errors¹¹; How to Correctly Use Pharmaceutical Forms, Use of Medications in Daycare and School²⁹.

Medication package inserts and scientific articles identified in PubMed/Medline, Scielo, and Google Scholar databases were also used, prioritizing those published in the last five years. The texts were carefully read to extract up-to-date and relevant information, which was used in the material preparation.

Creation of the Educational Material Prototype

The prototype of the educational material was created by four pharmacists, considering the guidelines of the Instrument for Assessing Printed Educational Materials with a focus on Health Literacy for Brazil (AMEELS-BR). This instrument contains 56 evaluation items, divided into six sections related to content, language, illustrations, layout, typography, presentation, learning stimulation/motivation, and cultural appropriateness¹⁶. The information in the educational material was written clearly and concisely to facilitate understanding by the public, especially those with low education levels¹⁷. Illustrations were included in the material to complement the written information. They were sourced from platforms such as The Noun Project, Corel Draw®, Canva, and Freepik. The texts and illustrations were organized to achieve a logical, aesthetic, and sequential sense, aiming to facilitate reader understanding and assist in locating specific information on the topic addressed.

Stage 02 - Validation of Educational Material by a Committee of Experts

The second stage consisted of evaluating the validity evidence based on the content. To this end, the first version of the educational material underwent assessment by experts using the Delphi technique to achieve consensus. This technique is a systematic method of information judgment, useful for reaching consensus among experts on a specific topic through validations conducted in phases or cycles without the need for physical meetings³⁰.

The committee of experts was composed of professionals with academic training and practical experience in the subject addressed in the educational material, selected by convenience. Experts were contacted via email and provided with an invitation letter outlining the study objectives and the evaluation method.

Evaluation of the Educational Material by the Committee of Experts

The educational material and the "Informed Consent Form" (ICF) were provided to the experts in digital format. The evaluation instrument was shared online using Google Forms through link sent by email. Data collection took place between November and December 2023. The evaluation instrument sent to the experts was adapted from the model developed by Teixeira and Mota³¹, aimed at assessing the educational material across several dimensions: the purposes, goals, or objectives to be achieved; structure and presentation, which encompasses the way the guidelines are presented, including overall organization, structure, presentation strategy, coherence, and formatting; and the relevance of the material, referring to the characteristics that evaluate the material's degree of importance.

The experts performed the evaluation using a Likert scale, with responses categorized as follows: 1. Inadequate; 2. Partially adequate; 3. Adequate; 4. Completely adequate. Additionally, the experts had the opportunity to provide suggestions and comments on the evaluation instrument and the material itself, if deemed necessary.



Recommendations and suggestions considered pertinent were adopted to improve the material. After evaluation, the experts and their suggestions were coded into a combination of letters and numbers.

Evaluation of the Content Validity Index

Following the evaluation by the experts, the Content Validity Index (CVI) was calculated to assess the construct's representativeness and relevance³². The educational material was considered valid when the CVI reached a minimum of 0.80³³. To calculate the CVI, responses of 1 and 2 were considered as "0" and responses of 3 and 4 were recoded as "1." The CVI was calculated for each item individually as well as for the educational material as a whole, using the average of the CVIs obtained for the evaluated items.

Stage 03 - Evaluation of the Educational Material by the Population

The evaluation was conducted with individuals selected by convenience from messaging app groups. Data collection occurred between November and December 2023. The study included participants aged 18 and over, who were literate. Invitations were sent through messaging apps, and upon acceptance, participants received the educational material, the evaluation tool, and the Informed Consent Form online. The evaluation tool was provided via Google Forms through a link sent in the messaging groups. In addition to evaluating the educational material, sociodemographic data such as gender, age, and education level were collected.

Participants were instructed to read the educational material and then evaluate it using an instrument based on and adapted from a model developed by Gonçalves, Barbieri & Gabrielloni³⁴, which aims to assess the material according to its organization, writing style, appearance, and motivation. Items that achieved greater than 75%³⁵ agreement were considered satisfactory. Participants were also allowed to make improvement suggestions on the evaluation instrument, the relevance of which was assessed by the research team.

Ethical Aspects

This research was approved by the Research Ethics Committee involving Human Subjects of the Health Sciences Center (CCS) at the Federal University of Espírito Santo (UFES) under opinion number 6.321.524 (CAAE nº 71228023.3.0000.5060).

All participants were invited to sign the Informed Consent Form (ICF) online through the Forms tool.

Results

Stage 01 - Development of the Educational Material

The educational material was titled "Use of liquid medications by babies: a guide for caregivers and guardians". The final version consisted of 32 A4 pages, totaling eight pages when folded into a booklet format. The information was organized logically, using simple language, with examples to explain technical terms, and images to complement the written content. Some information was structured in a numbered format.

The material was organized into the following topics: Introduction of the material; Introduction of the creator; Table of contents; Before preparing the medication for the baby; Items to check on the medication packaging; Events that may occur when self-medicating; Some signs of medication intoxication; What to do if you notice signs of intoxication; How to use dropper medications; How to use a dosing cup; How to use a dosing syringe with a stopper; How to use a dosing syringe without a stopper; How to mix powdered or granulated medication with water; How to mix powdered or granulated medication with its own diluent; How to use a sachet; How to use a vial orally; Important tips; and Questions to ask healthcare professionals about medications.

Stage 02 - Validation of the Educational Material by a Committee of Experts

The prototype evaluation was conducted by eight experts, whose sociodemographic characteristics and expertise in the evaluated construct are described in Table 1.

The global CVI of the educational material was 0.98. The CVI for the "objectives" and "relevance" sections was 1.0. The "structure and organization of the educational material" section had a CVI of 0.97. In this section, items 2.2 (the messages are presented clearly and objectively), 2.4 (the material is appropriate to the sociocultural level of the target audience), and 2.11 (the number of pages is adequate) had an individual CVI of 0.87. The evaluation of the educational material and the CVI are presented in Table 2.

The suggestions presented by the committee of experts are shown in Table 3. After analyzing the twelve suggestions made by the experts, seven of them (S2, S3, S6, S8, S9, S10, and S12) were fully incorporated, resulting in adjustments to the educational material.

Table 1. Profile of the Expert Committee that Evaluated the Educational Material

Specialist	Sex	Field of Study	Years of Experience	Specialization
E1	Female	Medicine	15 years	Pediatric Residency with a Specialty in Neonatology
E2	Female	Pharmacy	5 years	Master's Degree in Pharmaceutical Care
E3	Female	Literature	32 years	Postgraduate Degree in Humanities
E4	Female	Pharmacy	4 years	Multiprofessional Residency in Child and Adolescent Health Care
E5	Female	Nursing	12 years	Professional Master's Degree in Nursing
E6	Female	Pharmacy	13 years	Specialization in Neonatal and Pediatric Nursing
E7	Female	Medicine	10 years	Master's Degree in Sciences
E8	Female	Pharmacy	13 years	Residency in Pediatrics and Neonatology



Table 2. Content Validity Index for the educational material “Use of liquid medications by babies: a guide for caregivers and guardians”

Categories	Items	I	PA	A	TA	IVC-I
OBJECTIVES IVC-B (Média)= 1.00	The information/contents are coherent with the daily needs of the target audience of the educational material.	-	-	-	8	1
	The information/contents are important for the quality of life and/or work of the target audience of the educational material.	-	-	-	8	1
	Invites and/or instigates behavior and attitude change.	-	-	2	6	1
	Can circulate in the scientific community of the field.	-	-	4	4	1
	Meets the objectives of institutions that serve/work with the target audience of educational material.	-	-	2	6	1
	The educational material is suitable for the target audience.	-	-	1	7	1
	The messages are presented clearly and objectively.	-	1	2	5	0.87
STRUCTURE AND PRESENTATION IVC-B (Mean) = 0.97	The information presented is scientifically correct.	-	-	2	6	1
	The material is appropriate for the sociocultural level of the target audience.	-	1	4	3	0.87
	There is a logical sequence of the proposed content.	-	-	2	6	1
	The information is well-structured in terms of agreement and spelling.	-	-	1	7	1
	The writing style corresponds to the level of knowledge of the target audience.	-	-	5	3	1
	The information on the cover, back cover, table of contents, acknowledgments, and introduction is coherent.	-	-	2	6	1
	The size of the title and topics is appropriate.	-	-	1	7	1
	The illustrations are expressive and sufficient.	-	-	4	4	1
	The number of pages is adequate.	-	1	4	3	0.87
	The themes portray key aspects that should be reinforced.	-	-	-	8	1
RELEVANCE IVC-B (Mean) = 1.00	The educational material allows for generalization and transfer of learning to different contexts.	-	-	2	6	1
	The educational material proposes knowledge construction.	-	-	2	6	1
	The educational material covers the topics necessary for the knowledge of the target audience.	-	-	-	7	1
	The educational material is suitable for use by any professional with the target audience.	-	-	3	5	1

Lotting: I= Inadequate; PA= Partially adequate; A= Adequate; TA= Totally adequate; IVC= Content validity index

Table 3. Suggestions made by experts on the educational material “Use of liquid medications by babies: a guide for caregivers and guardians”.

Suggestions provided by the experts	Specialist	Evaluation by the research team
S1 “More appealing layout with better distributed texts would attract more attention.”	E2	Not accepted
S2 “It is important to reference the provided information as it enhances credibility.”	E2	Accepted
S3 “I missed seeing bibliographic references used in its development.”	E6	Accepted
S4 “If the material is presented by a healthcare professional, it might make it easier to understand some technical terms. However, there are terms or specifications that could confuse less knowledgeable readers.”	E4	Not accepted
S5 “The information is well described, and technical terms are explained and/or exemplified. However, there is a need to make the material even more accessible to the target population.”	E2	Not accepted
S6 “As for the term ‘reconstitution,’ I believe it may be difficult for the target audience. The suggestion is to explain what it means or use a simpler term that conveys the same meaning.”	E5	Accepted
S7 “The content is excellent. I feel the target audience might find it a bit lengthy and, in some cases, may not read the entire material.”	E7	Not accepted
S8 “On pages 11, 13, 15, and 18, in the section marked as ‘important,’ I find the numbering unnecessary.”	E5	Accepted
S9 “Adjust the letter ‘T’ in the word ‘Take’ in item 4 of the guidance on the use of the ampoule.”	E8	Accepted
S10 “I think it might be better to show the image of the dipyrone vial displaying all information on a real vial. Also, add that the information may vary depending on the manufacturer.”	E4	Accepted
S11 “Some information is repetitive. I believe that the more concise the material is, and consequently the fewer pages it has, the greater the adherence of the target audience.”	E2	Not accepted
S12 “It is important to clearly signal in the text that the recommendations are for oral liquid medications, as there are liquid medications that can be administered through other routes, such as external use ampoules, inhalers, and injectables. Not clarifying this can lead to administration errors; for example, a caregiver reading the text may believe that all ampoules are for oral use and administer an external use ampoule as instructed in the material.”	E2	Accepted

Stage 03 - Evaluation of the Educational Material by the Population

The analysis of the educational material by the population was conducted with 31 participants, most of whom were female (n = 24; 77.4%), with ages ranging from 23 to 53 years (Mean = 35 ± 7.4 years). Most participants had at least a high school education (n = 28; 90.3%). The participants' evaluation of the organization, writing style, appearance, and motivation is presented in Table 4. All items evaluated by the population achieved a concordance rate higher than 75%, resulting in an overall average of 97.5%.

Table 4.- Assessments carried out by the target audience

ORGANIZATION		
Did the cover catch your attention?	n	%
Yes	28	90.3
Somewhat	0	0
No	3	9.7
Does it show the subject it refers to?	n	%
Yes	31	100
No	0	0
Are the topics sequenced?	n	%
Yes	31	100
No	0	0
Was the content size of the topics adequate?	n	%
Yes	31	100
No	0	0
WRITING STYLE		
Regarding the understanding of the sentences, are they:	n	%
Easy to understand	31	100
Difficult to understand	0	0
Don't know	0	0
Is there an association of the questions with the sentences?	n	%
Yes	29	93.5
No	2	6.5
The written content is:	n	%
Clear	31	100
Confusing	0	0
Don't know	0	0
The text is:	n	%
Interesting	29	93.5
Uninteresting	0	0
Repetitive	2	6.5
APPEARANCE		
Illustrations are:	n	%
Simple	30	96.8
Complicated	0	0
Other	1	3.2
The illustrations:	n	%
Helped for better understanding of the text	31	100
Hindered the understanding of the text	0	0
Other	0	0
MOTIVATION		
In your opinion, will anyone who reads this material understand what it is about?	n	%
Yes	30	96.8
No	1	3.2
Were you motivated to read until the end?	n	%
Yes	30	96.8
No	1	3.2

The suggestions made by the population for inclusions or changes were compiled in Table 5. Among the suggestions, two referred to the inclusion of information and one referred to an alteration. All the suggestions from the population were accepted and incorporated into the educational material.

Table 5. Suggestions made by the population

Participant	Suggestion
Participant 1	"Regarding emergency contacts for poisonings, I think it would be helpful to include the Toxcen hotline number."
Participant 2	"In the section on how to use the dosing syringe without the plunger, it wasn't clear if I should discard or return any leftover medication to the bottle after pouring it into a cup. If discarding is necessary, I believe this should be clearly indicated in the text."
Participant 3	"I liked the cover, but I think it should have more colors to attract more attention."

Discussion

The educational material "Use of liquid medications by babies: a guide for caregivers and guardians" was comprehensively evaluated by a committee of specialists and the target population, it was deemed informative, high-quality, and safe. This validation confirms its relevance as an essential tool to assist guardians and caregivers in the correct administration of oral liquid medications to babies, promoting safety and efficacy in treatment. The clear structure, accessible language, and visually oriented content contribute to the understanding and applicability of the provided instructions, reinforcing the importance of well-developed educational materials in pediatric health.

The evaluation conducted by the committee of specialists, composed of professionals from four distinct areas, resulted in an excellent overall Content Validity Index (CVI), similar to other studies that employed the same evaluation method³⁵⁻³⁹. These results highlight the importance of the educational material evaluation stage by experienced and qualified professionals in health and education, allowing for a critical and specialized analysis and ensuring that the content contains technical, high-quality, updated, and practical information, granting the material greater reliability and the possibility of being used as a tool by different professional categories³⁹.

One of the suggestions from the educational material evaluation by the committee of specialists involved the proposal for a more attractive layout, even though the material already met all the recommendations established by the AMEELS-BR instrument regarding layout, typography, and presentation¹⁶. This demonstrates the importance of involving graphic designers in the process of producing educational materials. Other recommendations included making the content more linguistically accessible; however, the evaluation conducted by the population did not reveal any obstacles in understanding the material, as it adhered to the AMEELS-BR recommendations in defining and exemplifying technical terms¹⁶. Enriching the text with explanations and more familiar terms to the reader is essential to enhance the understanding across different audiences¹⁷. It is also important to emphasize that the purpose of this educational material is not to replace the guidance provided by health professionals, but to complement it.

Regarding the evaluation conducted by the population, the educational material demonstrated consistency in terms of organization, writing style, appearance, and motivation, aligning with the results of other research^{34,35}. However, it is important to note that most of the participating evaluators have at least a high school education. This underscores the importance of evaluating the educational material by a larger number of individuals with lower educational levels. This need is based on the fact that, in Brazil, only 19.2% of people aged 25 and over had completed higher education by 2022, according to data from the Brazilian Institute of Geography and Statistics⁴⁰. Additionally, the low educational level of caregivers negatively impacts tasks related to medication management, such as identifying their names and administering them correctly, highlighting the need to develop health education tools adapted to the literacy level of this audience⁴¹.

The incorporation of illustrations in the educational material underscored the relevance of this resource as a complement to written information, facilitating understanding, as the committee of specialists found the images pertinent, and the population noted that they contributed to a better understanding of the text. The use of illustrations in educational materials is associated with a reduction in errors among individuals with low health literacy and is effective in minimizing dosage errors of liquid medications^{11,42-44}. However, since the material was evaluated exclusively in digital format, allowing the reader to adjust the size as they prefer, future analyses should include the evaluation of printed material to verify if the dimensions of the graphic elements are adequate.

The researchers of this study found that the educational material "Use of liquid medications by babies: a guide for caregivers and guardians" is an important tool for health professionals to prevent medication administration errors in babies. Additionally, they identified an imminent need for investment in educational and informative tools directed at the use of medications in babies, aiming to support caregivers in managing these supplies and facilitate the guidance of health professionals, who sometimes face difficulties in advising this audience¹¹. Furthermore, the importance of conducting periodic updates when developing educational materials is emphasized, considering new information relevant to the topic and the demands of the population, ensuring dynamic and accessible dissemination of information⁴⁵⁻⁴⁷.

Among the limitations of this study, the lack of evaluation exclusively by guardians and caregivers of babies stands out. The participation of these individuals could have potentially enriched the development of the material even further. Additionally, despite the population not consisting of individuals specialized in the addressed topic, it is important to note as a limitation the need to include a more significant number of participants with lower educational levels, aiming to evaluate the textual and terminological accessibility specific to this audience. Lastly, the absence of a graphic designer is also considered a limitation, as it prevented the incorporation of some desirable images and the standardization of the design.

Conclusion

The educational material "Use of liquid medications by babies: a guide for caregivers and guardians" was considered validated. The evaluation conducted by the committee of specialists and the population highlighted its compliance with the proposed objectives, cohesive structure, presentation, and relevance. This

material has proven to be an informative, high-quality, and safe tool, benefiting caregivers and health professionals involved with babies.

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Contributors

NSRS, ALBDG, CAP, KSSR, ABF, and DCSAA had full access to all data in the study and take responsibility for the integrity and accuracy of the data analysis. NSRS, ALBDG, and CAP conceived and designed the study. NSRS, ALBDG, and CAP collected and analyzed the data. NSRS, ALBDG, and CAP drafted the article. ABF, KSSR, and DCSAA critically reviewed the article. NSRS, ALBDG, CAP, KSSR, ABF, and DCSAA approved the final version to be published.

Conflict of Interest Statement

The authors declare no conflicts of interest regarding this article.

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