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Construction and validation of educational booklets regarding oral antineoplastics

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Abstract

Objective: To construct and validate educational pamphlets on oral antineoplastic therapy for patients with oncologic or hematologic diseases treated on an outpatient basis. **Method**: We carried out this research on two stages: a) Elaboration of educational pamphlets by the researchers, containing information regarding indication, administration mode, adverse effects, storage, and other precautions for the listed oral antineoplastics: Anagrelide, Cyclophosphamide, Chlorambucil, Melphalan, Lomustine, Mercaptopurine, Methotrexate, Mitotane, Pazopanib, Sorafenib, Temozolomide, Thioguanine, Ruxolitinib, and Tretinoin; b) Validation of the developed materials through a median grade among experts in the field (oncology and/or hematology pharmacists), using the Delphi Method, evaluating layout and content through a Likert scale. Data dispersion was assessed through the interquartile range (IQR), and adequate grade was defined as a median above 3. **Results**: The educational pamphlets were developed using national and international references, encompassing necessary information for the adequate and safe use of medications by patients. The initial validation involved 19 pharmacists specialized in oncology and/or hematology, spread across the national territory. In the first evaluation round, there was disagreement among experts on two issues, both related to the material's content (highlighted sections and language used). After addressing points of disagreement, the pamphlets were validated by adequate grade among eight experts who remained in the study for the second round. **Conclusion**: It was possible to validate by experts the educational content of booklets containing written guidance on pharmacotherapy that will be delivered to the patient/caregiver, covering topics relevant to different medications, containing information with assertive scientific evidence, combining illustrations and language that is easy to understand by the population.

Keywords: health education; neoplasms; pharmaceutical services; validation studies

Construção e validação de cartilhas educativas acerca de antineoplásicos orais

Resumo

Objetivo: Construir e validar cartilhas educativas sobre a terapia antineoplásica oral destinada a pacientes com doenças oncológicas ou hematológicas atendidos em regime ambulatorial. **Método:** O estudo foi realizado em duas etapas: a) Elaboração das cartilhas educativas para pacientes adultos, com base em referências nacionais e internacionais, com informações para os antineoplásicos orais: Anagrelida, Ciclofosfamida, Clorambucil, Melfalano, Lomustina, Mercaptopurina, Metotrexato, Mitotano, Pazopanibe, Sorafenibe, Temozolamida, Tioguanina, Ruxolitinibe e Tretinoína; b) Validação dos materiais desenvolvidos entre especialistas na área (farmacêuticos oncologistas e/ou hematologistas), utilizando a Metodologia *Delphi*, com avaliação do *layout* e conteúdo com escala *Likert*. A dispersão dos dados foi analisada pelo intervalo interquartil (IQR) e a adequação do tópico foi definida como uma mediana superior a 3,0. **Resultados:** As cartilhas educativas foram desenvolvidas contemplando informações a relacionadas a (i) indicação, (ii) modo de administração, (iii) eventos adversos, armazenamento e (iv) outros cuidados necessários pelo paciente. A validação inicial contou com 19 farmacêuticos especialistas em oncologia e/ou hematologia, espalhados por todo o território nacional. Na primeira rodada de avaliação houve discordância entre os especialistas em duas questões, ambas relacionadas ao conteúdo do material (trechos em destaque e linguagem utilizada). Após a adequação dos pontos com discordância, as cartilhas foram novamente analisadas e validadas por oito especialistas que permaneceram na pesquisa na segunda rodada. **Conclusão:** A estratégia escolhida permitiu a validação por especialistas do conteúdo educativo de cartilhas com orientações escritas sobre a farmacoterapia que serão entregues ao paciente/cuidador, abordando tópicos relevantes para diferentes medicamentos, onde constam informações com evidências científicas assertivas, associando ilustrações e linguagem de fácil compreensão pela população adulta.

Palavras-chave: educação em saúde; neoplasias; serviços farmacêuticos; estudos de validação

Introduction

Cancer is a general term that encompasses over 100 heterogeneous diseases, which can affect various organs or tissues in the body. These diseases are characterized by the uncontrolled growth of cells and the potential to invade distant tissues or organs, a process known as metastasis. Cancer is one of the leading causes of death worldwide[1,2]. In Brazil, the National Cancer Institute (INCA) estimated 704,080 new cases in 2023, with breast cancer being the most prevalent among women and prostate cancer the most common among men[2]. Cancer treatment varies according to the type of disease and may include radiotherapy, surgery, hematopoietic stem cell transplantation, targeted therapy, and chemotherapy[1].

Chemotherapy is not limited to a single drug. There are various medications available, each with different mechanisms of action, therapeutic targets, dosages, and routes of administration, including intravenous and oral routes, allowing treatment to be carried out in the hospital or on an outpatient basis. Treatment follows therapeutic guidelines and can be individualized depending on the type of neoplasia, the stage of the disease, and patient characteristics, such as overall[1] health.

The administration of oral antineoplastic drugs offers more convenience and autonomy to the patient, which can positively influence their perception of the treatment. However, these drugs have a low therapeutic index and are not without risks (adverse events and medication errors). They may also present significant drug and food interactions and require proper storage. Ensuring adherence to this treatment modality is a challenge, as orally administered medications allow for longer intervals between hospital visits, and some treatment protocols have complex[3,4] regimens.

Adherence to pharmacotherapy is a crucial factor for the success of treatment and control of chronic diseases, directly affecting hospitalizations and healthcare[5,6] costs. Adherence to oral antineoplastic drugs can be below 50% and tends to decrease over the course of treatment, compromising effectiveness and potentially leading to disease[7] progression. Low adherence to oral antineoplastic pharmacotherapy, often due to the complexity of treatment, requires measures that facilitate patient understanding, such as creating educational materials to promote health education.

Educational materials are important tools that complement the information provided verbally by healthcare teams, aiming to improve the patient's understanding of their therapy[8,9]. They are a low-cost approach to patient education, providing information that enhances understanding and adherence to the prescribed treatment. Validation of the educational content by specialists ensures the scientific accuracy of the presented[8,9] material. In this context, the objective of this study was to develop and validate educational material (a booklet) on oral antineoplastic therapy for onco-hematological patients treated on an outpatient basis in a high-complexity public hospital.

Methods

The study was conducted in a tertiary-level public university hospital located in the state of Paraná in 2022. The protocol was approved by the local Research Ethics Committee (Approval No. 51881821.8.0000.0096). Accordingly, the research was carried out in two stages: 1.1 Development of educational booklets on oral antineoplastic drugs for patients, and 1.2 Validation of the educational booklets by a panel of experts using the Delphi[10] method. The details of each stage are outlined below.

1.1 Development of the Booklets

Fourteen drugs standardized by the institution and provided by the Hospital Pharmacy Department were selected for the treatment of various types of cancer: Anagrelide, Cyclophosphamide, Chlorambucil, Melphalan, Lomustine, Mercaptopurine, Methotrexate, Mitotane, Pazopanib, Sorafenib, Temozolomide, Thioguanine, Ruxolitinib, and Tretinoin. The booklets were developed following the recommendations of Castro and colleagues for creating educational materials, considering aspects such as content, language, illustrations, layout, and design[11].

To define the content related to the listed medications, the current package inserts available on the National Health Surveillance Agency's database (https://consultas.anvisa.gov.br/#/bulario/) and the monographs of each drug available in the UpToDate database (https://www.uptodate.com/contents/search) were consulted. Information for each of the 14 selected drugs was reviewed and written in a direct and simple language in the educational material, in the following order: drug presentation and usage instructions; administration guidelines; main adverse reactions associated with use; drug-drug and drug-food interactions; and storage instructions. Where relevant, small illustrations were included in the material (Figure 2).

1.2 Validation of the Booklets

The format and scientific content of the booklets were validated by specialists. The criteria for selecting judges included working as pharmacists, having specialization in oncology and/or hematology, and providing direct pharmaceutical care to patients. The evaluators were identified and invited to participate in the research through the LinkedIn social platform. The search was initially conducted using the keywords "oncologist pharmacist" and/or "oncology pharmacist," followed by a review of the curriculum to assess qualifications and experience. The invitation to participate in the study and the evaluation form were sent via LinkedIn messaging.

The evaluation form for the material produced by the judges was created on the Google Forms platform. This form included, in addition to the booklets, 15 questions (Figure 1), three of which aimed to understand the profile of the professionals who agreed to participate in the evaluation. Six questions addressed the layout of the material, while the remaining six focused on the theoretical content of the booklets. Of these, eleven allowed responses on a 4-point Likert scale ranging from "very inadequate" to "very adequate," and the last content-related question offered a "yes" or "no" response, followed by a comments section for additional contributions if the answer was affirmative.

The evaluators were instructed to analyze the material from two perspectives: first, as healthcare professionals, assessing the scientific evidence of the information; and second, subjectively, as patients, verifying if the health information was understandable and educational.**

Figure 1. Questions addressed in the evaluation form (Paraná, Brazil, 2022).

PROFESSIONAL PROFILE

1. In which region of Brazil do you work?
2. Do you provide direct guidance to patients regarding their pharmacotherapy?
3. How long have you been working as a clinical oncologist and/or hematologist pharmacist?

ABOUT THE LAYOUT

4. Is the font size adequate for reading?
5. Is the font style appropriate?
6. Is the writing and spelling accurate?
7. Does the color scheme promote comfortable reading?
8. Are the figures clear and consistent with the text?
9. Is the overall layout of the booklet suitable for its intended purpose?

ABOUT THE CONTENT

10. Is the order of the information appropriate?
11. Are the highlighted sections effectively emphasized?
12. Is the presented information aligned with scientific evidence?
13. Are the instructions precise and concise?
14. Is the language accessible to the patient, allowing for comprehension?
15. Was there any relevant information missing?[1]

[1] Objective Question: "Yes" or "No".

After each evaluation round, the responses were analyzed using the Google Sheets platform, where the median was assessed as a central tendency measure, and the Interquartile Range (IQR) was used as a dispersion measure for the items evaluated on a 4-point Likert scale. Adapted from the studies by Rocha et al.[12] and Anversa et al.[13], the topics were considered adequate when the "median (IQR)" set was greater than 3.0, with no need for adjustments to the educational material. For cases where the median was less than or equal to 3.0, the topic was considered inadequate, and the educational material was revised and adjusted according to the criteria pointed out by the judges. In such cases, a new evaluation round was conducted to ensure the adequacy of the topic initially considered inadequate by the judges.

Results

Each of the 14 booklets was created with dimensions of 25.4 x 19.0 cm, following the standardized layout and topic model shown in Figure 2. The content was tailored for each medication and its specifics, such as instructions to take with or without food, adverse reactions, correct storage, and more.

The material was initially evaluated by 19 pharmacists specializing in oncology and/or hematology, representing all regions of Brazil: 6 from the South, 5 from the Northeast, 3 from the Southeast, 3 from the North, and 2 from the Central-West. The evaluators' years of experience in oncology and/or hematology are presented in Figure 3.

In the first round of validation, two questions were deemed inadequate by the specialists, meaning the calculated median was ≤3. Both questions, listed below, were related to the content:

1. Are the highlighted sections appropriately emphasized?
2. Is the language used accessible to patients, allowing for understanding?

It was also decided to include in the second round the questions that received votes for "inadequate":

3. Is the font size appropriate for reading?
4. Do the color choices promote reading comfort?
5. Is the information presented consistent with scientific evidence?

Regarding the absence of pertinent information or the need for additional content, 23.3% of evaluators stated that it would be necessary to add the following: proper disposal instructions, guidance on important drug interactions, more detailed dosage instructions, advice on what to do in case of a missed dose, and an emphasis on taking the medication with water and food interactions.

Finally, to align with the specialists' suggestions on the material's layout, a second round of validation was deemed necessary, considering the following aspects:

6. Is the writing and spelling appropriate?
7. Are the figures clear and consistent with the text?
8. Is the font size suitable for reading?

After making the necessary adjustments, the booklets were submitted for a second validation round, where only the questions that had disagreements among the judges in the first round were re-evaluated. The number of specialists who continued participating in the study was 8, representing all regions of Brazil. By the end of the second round, the material was considered adequate, as shown in Figure 3.

Figure 2. Example of the Educational Leaflets (Paraná, Brazil, 2022).

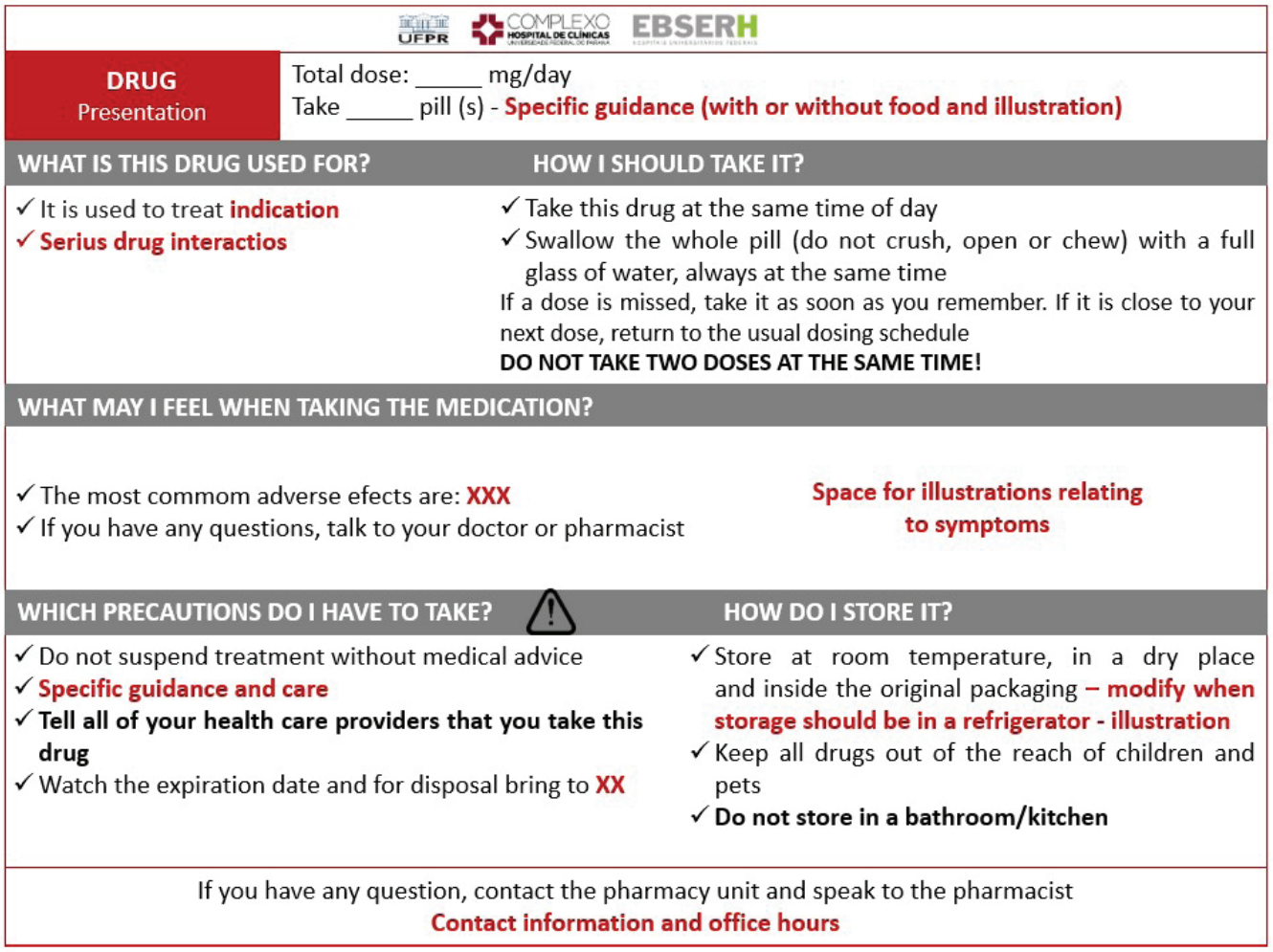
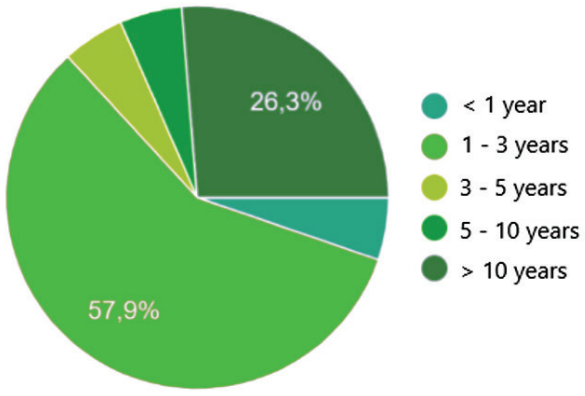


Figure 3. Duration of Specialists' Experience in the Field (Paraná, Brazil, 2022).



Discussion

This work presents the process of validating educational materials used in health education activities. It is essential that, before providing educational materials to the target population, they are previously evaluated in terms of content and format to ensure their effectiveness and to prevent users or caregivers from making inappropriate and potentially harmful decisions regarding treatment[9,11]. When dealing with printed educational materials, validation becomes even more critical, as they are among the most used resources in health education for patients and/or caregivers.[11] There is also considerable mention in the literature regarding the low quality of information in printed materials.[14-16]

In a healthcare setting, providing educational materials that combine illustrations with written information can be a valuable strategy for patients with low literacy levels or difficulties understanding their pharmacotherapy. The use of validated educational technologies has the potential to strengthen relationships between healthcare professionals and patients.[17]

The possibility of oral oncology treatment offers advantages for patients. However, the lack of continuous professional monitoring of these medications' administration can compromise adherence[18-21] and negatively impact the treatment's effectiveness and safety. In this context, providing relevant written guidance, in addition to verbal instructions, helps reinforce information, consolidates learning, and reduces confusion.[22,23]

Figure 4. Results of the Two Rounds of Validation (Paraná, Brazil, 2022).

Questions	Round 1 - Median (IQR)	Round 2 - Median (IQR)
1. Is the font size appropriate for reading?	4 (3-4)	4 (4-4)
2. Is the font style appropriate?	4 (4-4)	N/A
3. Is the writing and spelling correct?	4 (3-4)	4 (4-4)
4. Does the color scheme promote comfortable reading?	4 (3-4)	4 (3,75-4)
5. Are the figures clear and consistent with the text?	4 (3-4)	4 (4-4)
6. Is the overall layout of the booklet suitable for its intended purpose?	4 (3-4)	4 (4-4)
7. Is the order of the information appropriate?	4 (3-4)	N/A
8. Are the highlighted sections appropriately emphasized?	3 (3-4)	4 (4-4)
9. Are the presented information in accordance with scientific evidence?	4 (4-4)	4 (4-4)
10. Are the provided instructions adequately precise and objective?	4 (3-4)	N/A
11. Is the language used accessible to the patient, allowing for understanding?	3 (3-4)	4 (4-4)
12. Was any relevant information missing?	23,3 % - YES 73,7 % - NO	N/A

N/A: Not applicable; IQR: Interquartile Range.

Therefore, it is crucial that the material provided to the patient and/or caregiver contains content aligned with current scientific literature and necessary recommendations, presented in an appropriate[11] manner . Based on the results obtained from the specialists' evaluations, it was found that the content presented in the booklets was adequate, with a median score of 4 on the Delphi method's questions 7 to 11 during either the first or second round (Figure 4).

Beyond the accessibility of the material and the scientific accuracy of the content presented, Araújo and Finatto also emphasize the need for pharmacists to consider the target audience's potential understanding of the information. They suggest adapting the educational material's layout to the literacy levels and varying reading proficiencies of patients and/or caregivers.[21] In other words, for effective communication, it is not enough for all information about the medications to be correct; the presentation format must also be appropriate.

Regarding layout requirements, the booklets were also considered adequate by the specialists participating in the Delphi method. The questions 1 to 6 in Figure 4 addressed the booklets' layout. During the first and second evaluation rounds, aspects related to font size and style, writing and spelling, colors and reading comfort, figure clarity, consistency between figures and text, and the overall layout of the booklet were deemed appropriate by the expert judges, with a median score of 4 for all criteria (Figure 4). These results indicated that the booklets were adequate from the specialists' perspective regarding both content and layout criteria for printed educational materials.

According to McCue and collaborators, for complete health education about oral chemotherapy, patients should receive information about the drug name, indication for use, dosage and schedule, administration details, what to do in case of missed doses, interactions with food and other medications, side effects and their management, as well as handling and storage instructions for the prescribed chemotherapy.[8]

Given the volume of necessary information, the booklets were constructed based on the mentioned information and quality guidelines for content and layout. However, it is important to note that the differences between the 14 medications were considered to individualize the materials and present the most relevant information for each drug. With the help of question 12 in Figure 4 ("Was any relevant information missing?"), it was found that the content of the material was satisfactory according to the specialists.

The process of validating educational materials is essential to ensure that critical information is communicated correctly, clearly, and accessible to patients, especially in complex contexts such as onco-hematology.[9] Gathering expert opinions and adapting the materials based on feedback are essential steps in improving the effectiveness of these materials. In this study, it was possible to include an analysis by specialists from all regions of Brazil, allowing for a comprehensive evaluation of the material, considering the different nuances of healthcare across the country, combined with the specialized training of the judges.[12]

The booklets developed enable the materialization of pharmaceutical care. The literature highlights the need for full-time clinical pharmacists to ensure health[25] education . The review by Kaptein and collaborators reinforces how monitoring therapy by a pharmacist positively impacts adherence[26]. Oliveira and collaborators reported that monitoring hematological patients by a clinical pharmacist reduces healthcare[27] costs. Kaupp and collaborators found that a percentage of patients express a desire to receive education and/or be followed by a pharmacist[28]. In this sense, providing written materials, along with verbal instructions to the patient, in a standardized, concise, and easy-to-understand manner, can contribute to improved health outcomes. Furthermore, the participation of clinical pharmacists as part of the multidisciplinary team is encouraged, aiming for continuous monitoring and early identification of factors that may influence treatment failure[20,21,26-28].

A limitation of this study is the inability to evaluate the materials directly with the target patients, which prevents the booklets from being validated from their perspective. In this context, we understand that the validation experience reported refers exclusively to the criteria evaluated by the specialists who

comprised the panel of evaluators. Although representatives from various regions of Brazil participated in this study, the number of participants in both stages was small and does not represent the diverse scenarios across the country. Another limitation is the absence of additional data collection that would have allowed for a better characterization of the participating judges (age group, location of practice, type of institution), enabling a discussion of the material validation process in different contexts.

Conclusion

This study validated, through expert opinions, material developed for use in a university hospital with the necessary information for educating patients undergoing oral chemotherapy. The booklets created were deemed adequate in terms of the following criteria: correct information, clarity, ease of understanding, layout, and illustrations. Future studies may include an evaluation from the patients' perspective, assessing the impact of using the booklets on health outcomes.

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Authorship Criteria (Author Contributions)

All the cited authors participated in the conception, design, analysis and interpretation of data, writing of the article, and final version to be published.

Conflict of Interest Statement

The authors declare no conflicts of interest regarding this article.

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