

# Validation of Educational Materials to Guide Patients on Breast Cancer Treatment with Hormone Therapy

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*Validação de Materiais Educativos para Orientação de Pacientes em Tratamento de Câncer de Mama com Hormonioterapia*  
*Validación de Materiales Educativos para Orientación de Pacientes en Tratamiento de Cáncer de Mama con Terapia Hormonal*

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## ABSTRACT

**Introduction:** The low adherence to treatment with oral antineoplastic agents reflects the need for measures to facilitate compliance with therapy, such as providing educational materials. **Objective:** Develop and validate leaflets guiding the use of tamoxifen, anastrozole and capecitabine for breast cancer treatment. **Method:** To define the leaflet's content, the MEDLINE and UpToDate databases and national and international guidelines were consulted, adopting language accessible to the public. The validation was performed by oncology specialists through the Delphi method, considering the attributes of language, content and appearance. A satisfactory consensus was reached when the interquartile range (IR) was  $\leq 1$ , obtained through a Likert scale ranging from 1 to 5. **Results:** The group of specialists was formed by 29 professionals. In the first round an IR of 1.43 was obtained; 1.14 and 1.43, and, in the second round, 0.71; 1.04 and 0.79 for language, content and appearance, respectively. **Conclusion:** It is expected that these tools promote better patient perception and adherence to treatment, contributing to self-management of pharmacotherapy.

**Key words:** Breast Neoplasms/drug therapy; Validation Study; Health Education; Educational and Promotional Materials; Pharmaceutical Services.

## RESUMO

**Introdução:** A baixa adesão ao tratamento com antineoplásicos orais reflete a necessidade de medidas que facilitem o cumprimento da terapia, como a provisão de materiais educativos. **Objetivo:** Desenvolver e validar cartilhas orientando o uso dos medicamentos tamoxifeno, anastrozol e capecitabina no tratamento do câncer de mama. **Método:** Para a definição do conteúdo das cartilhas, foram consultadas as bases de dados MEDLINE e UpToDate, e as diretrizes nacionais e internacionais, adotando-se linguagem acessível ao público. A validação foi feita por especialistas em oncologia, por meio do método Delphi, considerando-se os atributos de linguagem, conteúdo e aparência. Um consenso satisfatório foi atingido quando o valor de faixa interquartil (FIQ) foi  $\leq 1$ , obtido por meio de uma escala Likert variando de 1 a 5. **Resultados:** O grupo de especialistas foi composto por 29 profissionais. Na primeira rodada, foi obtida uma FIQ de 1,43; 1,14 e 1,43; e, na segunda rodada, 0,71; 1,04 e 0,79 para linguagem, conteúdo e aparência, respectivamente. **Conclusão:** Espera-se que essas ferramentas promovam melhor percepção e adesão do paciente ao tratamento, contribuindo para a autogestão da farmacoterapia.

**Palavras-chave:** Neoplasias da Mama/tratamento farmacológico; Estudos de Validação; Educação em Saúde; Materiais Educativos; Assistência Farmacêutica.

## RESUMEN

**Introducción:** La baja adherencia al tratamiento con agentes antineoplásicos orales refleja la necesidad de medidas para facilitar el cumplimiento de la terapia, como la provisión de materiales educativos. **Objetivo:** Desarrollar y validar folletos que guíen el uso de tamoxifeno, anastrozol y capecitabina en el tratamiento de cáncer de mama. **Método:** Para definir el contenido de los folletos, se consultaron las bases de datos MEDLINE y UpToDate, además de guías nacionales e internacionales, adoptando lenguaje accesible al público. La validación fue realizada por especialistas en oncología, a través del Método Delphi, considerando los atributos de lenguaje, contenido y apariencia. Se alcanzó un consenso satisfactorio cuando el rango intercuartil (RI) fue  $\leq 1$ , obtenido utilizando escala Likert que varía de 1 a 5. **Resultados:** El grupo de expertos fue compuesto por 29 profesionales. En la primera ronda, se obtuvo un RI de 1.43; 1.14 y 1.43, y, en la segunda, 0.71; 1.04 y 0.79 para lenguaje, contenido y apariencia, respectivamente. **Conclusión:** Se espera que estas herramientas promuevan mejor percepción del paciente y adherencia al tratamiento, contribuyendo para el autocontrol de la farmacoterapia.

**Palabras clave:** Neoplasias de la Mama/tratamiento farmacológico; Estudios de Validación; Educación en Salud; Materiales Educativos y de Divulgación; Servicios Farmacéuticos.

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## INTRODUCTION

Cancer has epidemiological, social and economic relevance, being one of the world main public health problems. In this context, breast cancer is the most prevalent among women worldwide, representing 24.2% of the cases in 2018<sup>1</sup>. In Brazil, according to the National Cancer Institute José Alencar Gomes da Silva (INCA) the estimate of incidence is approximately 66,280 new cases of breast cancer in 2020<sup>2</sup>.

The current treatment combines local and systemic approach. The systemic approach includes intravenous or oral administered medications. Among oral, there are those classified as target-therapy, which is the case of hormone therapy. Hormone therapy is indicated for patients with positive hormone receptors and consists in a continuous treatment with tamoxifen, one antiestrogen or anastrozol, one aromatase inhibitor, the treatment can last from five to ten years and is related with the improvement of the disease-free survival rate and mortality rate. Hormone therapy has good results and is accessible through the National Health System (SUS)<sup>3-5</sup>. Another oral medication is capecitabine, a chemotherapeutic indicated for metastatic breast cancer or as adjuvant therapy with residual disease; its use is fractioned with 14-days therapeutic regimen followed by seven days of rest and can range from three to eight cycles. This posology regimen makes pharmacotherapy more complex and can compromise the patient adherence<sup>6</sup>.

In the last decades, the use of oral medications increased significantly in cancer treatment with innumerable advantages as lower risk of infection and discomfort to the patient because is a non-invasive route and less visits to the treatment unit, increasing its independence and avoiding its routine to be affected<sup>7-9</sup>. A review of the literature with 13 studies about the patients' preference of chemotherapeutics administration concluded that oral route was preferable in 11 studies and affirmed that the main reasons for this are more comfort, quality of life and autonomy<sup>10</sup>. At the same time, as any medication, cancer oral therapy has disadvantages too as risk of overdosage and need of more self-care<sup>8,9</sup>.

For the patient to be treated safely and effectively, it is necessary good adherence to pharmacotherapy. The possibility of non-adherence to the treatment or even its discontinuation is a raising concern among health professionals. These facts can be associated to the patient's belief that the treatment is no long necessary or because of adverse reactions. The non-adherence, quite often, can be involuntary because of forgetfulness, physical or cognitive impairments or poor knowledge about the treatment<sup>11-13</sup>.

Thus, adherence together with access and the quality of care to the patient are important factors to reach good results in coping with the disease. However, studies demonstrate that the adherence rates of oral antineoplastics can be lower than 50% and tend to be still lower during the treatment<sup>14</sup>. Studies that evaluated the specific adherence to adjuvant hormone therapy found rates of 80-87% for tamoxifen and 69-88% for anastrozol<sup>15,16</sup>. The non-adherence to pharmacotherapy reflects in the effectiveness of the treatment, progress of the disease, costs raise and demand for health services<sup>14,17</sup>.

Educative materials are important tools in health education, complementing and reinforcing verbal orientations to expand the patient knowledge about its pharmacotherapy and, as consequence, higher adherence and self-care. It is fundamental that, before being utilized, these materials are validated through the judgment of experts in the area and by the population whom they are targeted to. Experts validation is a necessary stage in order to ensure the scientificity of the content presented<sup>18,19</sup>.

Therefore, this study presents the process of construction and validation of educative materials, guiding the use of medications tamoxifen, anastrozol and capecitabine in breast cancer treatment.

## METHOD

Methodological qualitative study conducted in a university public hospital. The study was developed in two stages: a) elaboration of educative leaflets containing information to the patients beginning breast cancer treatment with oral antineoplastics tamoxifen, anastrozol and capecitabine; and b) validation of these leaflets through consensus among expert judges.

The leaflets were developed according to the recommendations to elaborate and evaluate educative leaflets considering content, language, illustration, layout and design<sup>20,21</sup>. To define the content, databases MEDLINE/PubMed and UpToDate were searched as well as Brazilian, American and European Societies Guidelines. The language utilized was adapted for the patient better understanding. A professional of the institution's communication unit designed and diagrammed the images.

In a second stage, these materials were validated by oncology experts through Delphi method. This technique has the objective of obtaining as much consensus as possible of a group of experts about a certain theme as opinion unanimity does not exist because of the lack of scientific evidences<sup>22</sup>.

The following criteria were followed to select the judges: pharmacists, physicians or nurses working

in oncology for at least one year. Initially, residents, professionals and institution's heads of service were invited. Next, it was used the snowball method to select new experts and the judges previously chosen indicated other participants<sup>23</sup>. The experts were contacted by e-mail. The questionnaires were elaborated through Google Forms allowing the participants to respond anonymously and keeping distance among investigators and experts.

The opinion of the experts was obtained through rounds of questions until a certain level of concurrence among them was reached. In the first moment, the experts were invited to join the study after receiving a presentation letter of the study and its objectives, the first version of the questionnaire and educative materials to be reviewed. The questionnaire was subdivided in a) identification and general information about the experts as name, age, number of the professional registration, area of experience, telephone and qualifications; b) semi-structured questionnaire with nine questions, three closed and six open. The closed questions evaluated the aspects of language, content and appearance of the materials with Likert-based scores ranging from 1 to 5, being 1 the worse score, indicating flaws in the development of the leaflets and 5, the highest score. The open questions allowed the participants to suggest modifications deemed necessary to improve the aspects addressed in the closed questions.

The participants responses were tabulated in Excel 2016, the suggestions registered in open fields, evaluated based in the contribution they could add to the study, and included in the materials in review. After the modifications were incorporated, the experts received feedback, being ensured the secrecy of the author's opinions with the second version of the educative material and with this, the second round of evaluation of the materials started.

The questionnaire modified with six questions, four closed and two open was sent for the second round. The four closed questions had scores ranging from 1 to 5, repeating the evaluation of the three aspects of the first round (content, language and appearance). Based in the questionnaires of the second round, the responses were evaluated, and the modifications completed following the same criteria of the first round.

The three open questions common to the questionnaires evaluating language, content and appearance were compared to assess whether there were significative differences among the experts scores in the two rounds. For this, the Wilcoxon test paired with the software SPSS v.19 was utilized with level of significance of 5%. In addition, to define a consensus among the experts in the same round it was utilized the calculation of the interquartile range (IQR). A satisfactory consensus was reached when the value of IQR found was  $\leq 1$ .

The open questions were evaluated, and responses classified as "Yes" or "No". The responses "Yes" were adopted when there were expert suggestions during the round and "No" when no suggestions to modify the material reviewed were made. Later, it was evaluated whether there was significative difference in the proportion of responses "Yes" or "No", comparing the first and second rounds. For the statistical analysis, the software Excel 2016 and Action Stat v.3.2 were adopted, a test for two proportions with level of significance of 5% was performed.

The study complied with ethical principles applicable to trials with human subjects according to Resolution number 466/2012 and the Institutional Review Board of the institution (CAAE: 61351016,90000,0096) approved the study. All the participants who decided to join the study signed the Informed Consent Form.

## RESULTS

### DEVELOPMENT OF EDUCATIVE MATERIALS

The content consisted in information about the presentation of the medication, administration, dose, storage, most common adverse reactions and conducts if the dose is missed. The telephone of the Oncology Pharmacy Outpatient was also informed to the patient to contact the pharmacist if needed. In the capecitabine leaflet information about the hand foot syndrome, a relatively common reaction requiring specific care, were added. In Figure 1, the leaflets are presented.

### CHARACTERIZATION OF THE EXPERTS

The group of experts consisted of 30 health professionals: 16 pharmacists, seven nurses and seven physicians. Their age ranged from 23 and 58 years. Fifteen professionals had completed their formation from one to five years, seven, from six to ten years, five, from 11 to 15 years and three, more than 20 years. Of the 30 participants of the study, 26 worked in the High Complexity Oncology Care Centers (CACON).

### ROUNDS OF QUESTIONS

The desired level of concurrence was reached in only two rounds. In the first round, the 30 experts responded to the questionnaire. The most prevalent suggestions of modifications were terms or expressions as "lethargy" and "anorexia" presented in the first version of the materials. In addition, it was suggested to add guidelines about the hand-foot syndrome in the material of capecitabine. To improve the appearance changes of the figures, color and layout were suggested.

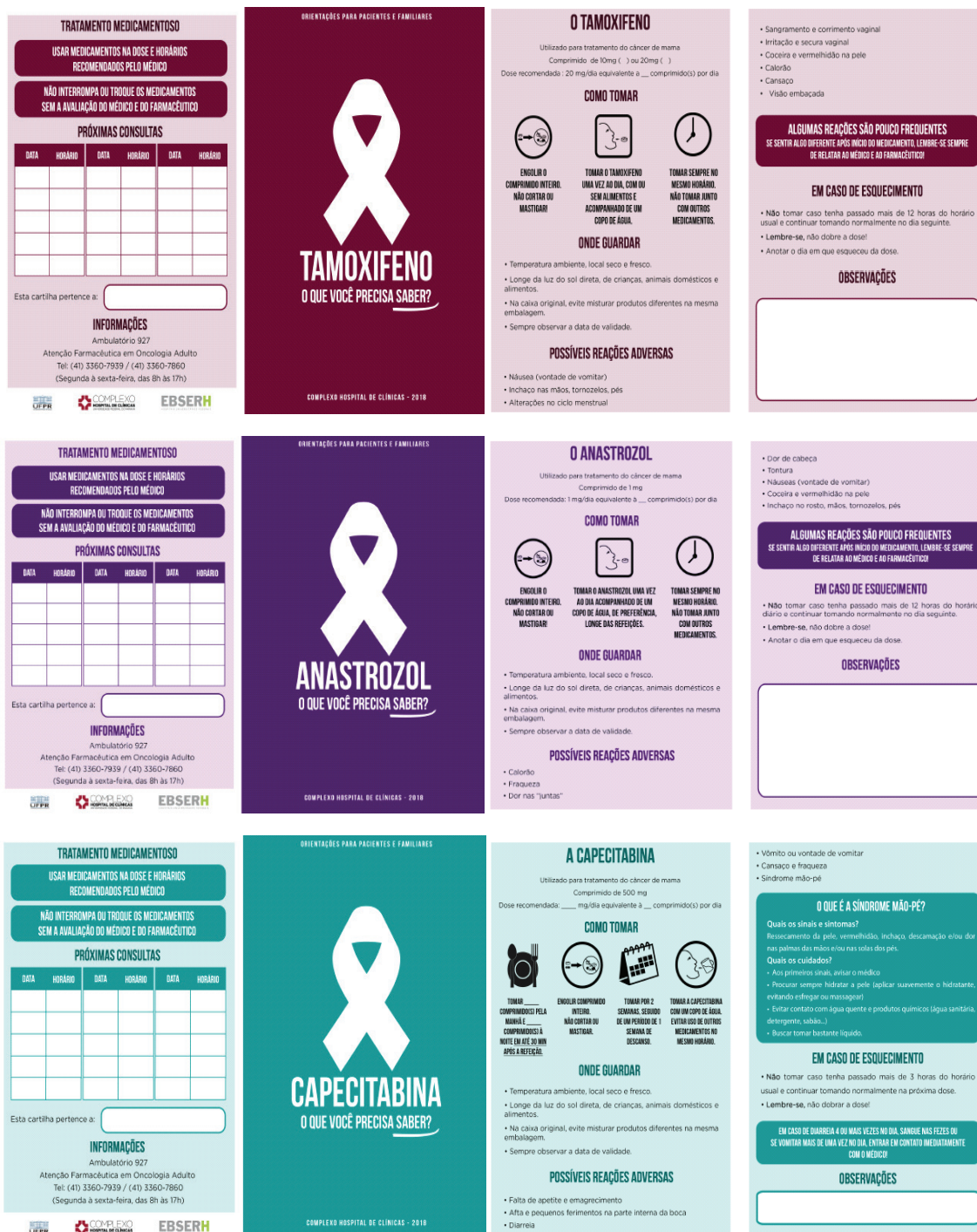


Figure 1. Leaflets to guide the use of antineoplastics tamoxifen, anastrozol and capecitabine

In the second round, 29 of the 30 experts responded to the questionnaire. Suggestions to improve the clarity of the guideline on how to use the medication and best conduct in case of missing were made. In addition, changes of colors were also suggested to associate breast cancer to Pink October. Some experts showed that the modifications made after the first round were satisfactory.

### COMPARISON OF THE RESULTS BETWEEN THE ROUNDS

Comparing the closed questions between the first and second rounds, statistically significant difference was encountered among the medians scored to the criteria of language ( $p=0.004$ ), content ( $p=0.039$ ) and appearance ( $p=0.003$ ).

The experts evaluated the level of clarity and understanding of the information provided with the

language adopted for this criterion. Of the 29 evaluators, ten assigned the highest score in the first round and 19 in the second round, being observed an increase of 32% in the number of experts that scored 5 for the attribute. In the second round, the scores ranged between 4 and 5 (Figure 2).

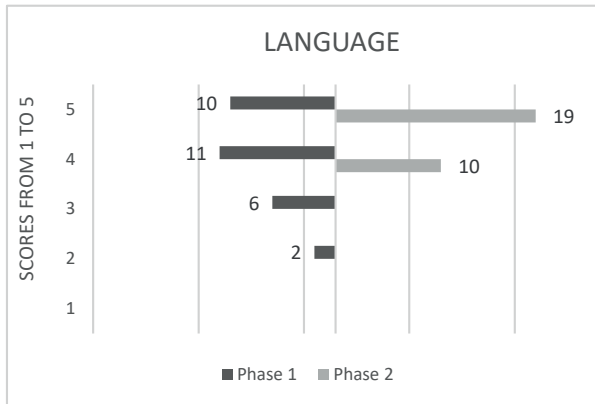


Figure 2. Scores of the experts attributed to the criteria language

The criteria content evaluated whether the information of the materials were enough to help the patient if he had any treatment-related doubt. Of the 29 evaluators, nine scored the high score in the first round and 13 in the second round, being observed a growth of 11% in the number of experts who assigned score 5 to the attribute. In the second round, the scores attributed ranged between 3 and 5 (Figure 3).

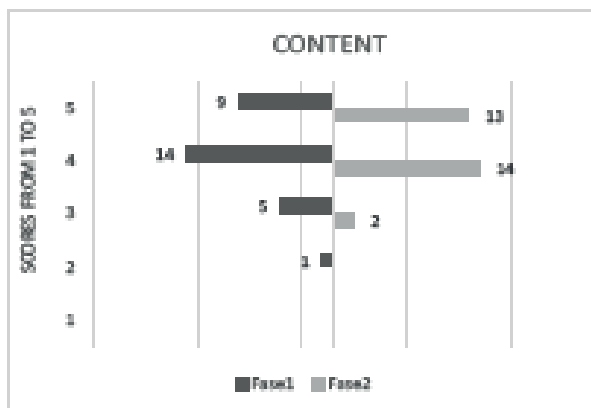


Figure 3. Scores of the experts attributed to the criteria content

The experts evaluated whether the materials of the criteria appearance were visually attractive. Of the 29 evaluators, nine scored the high score in the first round and 18 in the second round, there was a growth of 32% of the experts who scored 5 to the attribute. In the second

round, the scores attributed ranged between 4 and 5 (Figure 4).

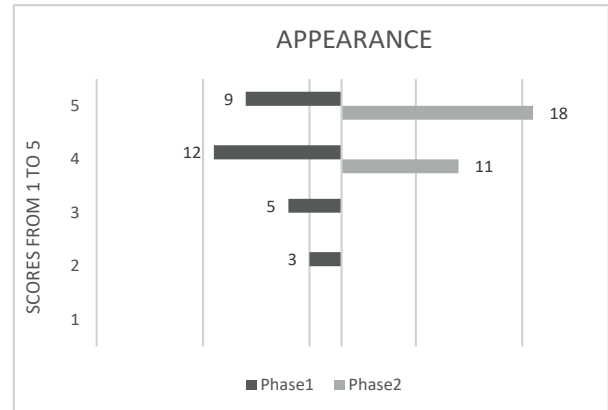


Figure 4. Scores of the experts attributed to the criteria appearance

### CONSENSUS OF THE EXPERTS IN THE ROUND

Table 1 represents the level of consensus among the experts calculated by the IQR. In the first round, the result of IQR was bigger than 1 in the three aspects evaluated. In the second round, the results were lower or equal to 1, being the consensus considered satisfactory.

Table 1. Values of IQR obtained in each round for the attributes language, content and appearance

	IQR Round 1	IQR Round 2
<b>Language</b>	1.43	0.71
<b>Content</b>	1.14	1.04
<b>Appearance</b>	1.43	0.79

When rounds are compared, there was significant statistically difference in the proportion of responses “Yes” in the open questions, which indicates the suggestion of some kind of change of the educative materials, with 25 experts suggesting some change in the first stage and only ten in the second ( $p < 0.0001$ ).

### DISCUSSION

In 2013, the American Society of Clinical Oncology (ASCO), in partnership with the Oncology Nursing Society (ONS) published a guide about the safe use of oral antineoplastics. It reinforces that the adherence is correlated to the patient’s understanding about the therapeutic regimen<sup>24</sup>. Thereby, as high the access

to oral medications, more measures to facilitate the accomplishment of the therapy are needed as printed educative materials orientations. The use of validated educative technologies reinforces the process teaching-learning and narrows the communication between the health professional and the patient. It contributes to empower the patient, promoting self-care and reducing the errors of medication, affecting the therapeutic results positively<sup>18,19,25,26</sup>.

In the last years, there was a transition of the social role of the pharmacist, moving from a medication-focused professional in charge of handling and dispensation to a healthcare provider to the patient participating of a multidisciplinary approach with nurses, physicians and other health professionals<sup>27</sup>. Law number 13,021/2014<sup>28</sup> defined Pharmacy as a unity of service providing individual and collective sanitary guidance and reiterates the importance of pharmacists' health educational practice. According to the Federal Pharmacy Council (CFF), this approach addresses different educative strategies whose core aim is to promote the autonomy of the patient and its commitment to the treatment<sup>29</sup>.

The activities of providing information, orientation and education to the patient, family and caretakers about the rational use of medications, further to the elaboration of educative materials, are part of the clinical attributions of the pharmacist according to the Resolution CFF number 585 dated August 29, 2013<sup>30</sup>. Still according to this resolution, the pharmacist should establish a proper process of communication matched to the beneficiary comprehension about health<sup>30</sup>. Thus, in this study, patient-targeted educative materials were proposed containing information that the professionals considered easy to understand, including times and correct form of administration, storage, better conduct if dose is missed and possible adverse reactions.

The Delphi technique brought advantages to the process of validation of leaflets because it allowed the participation of 29 professionals of different areas of knowledge of the same specialty, Oncology. The anonymity during the rounds granted more freedom of expression to the study participants. As the major part of the professionals selected worked in CACON, the validation of the educative materials was even more effective. The form of communication with the experts through electronic mail made the study easier to be conducted and reduced costs.

In the process of analysis of the leaflets content, language and appearance the contributions of all the judges who suggested relevant and consistent modifications were included. In the second round of questions, IQR lower than 1 was obtained for the criteria of language and appearance and equal to 1 for the criteria of content not being necessary a new round. In the

end, the experts considered that the leaflets presented completed and coherent information with clear language, visually attractive, encouraging the reading.

The importance of the in-person educative action associated to the written material is emphasized, it is essential that the formats of intervention are complementary. In studies where the educative materials were handed over to the patients without any sort of verbal orientation, there was no statistically significant improvement of the results of adherence and persistence evaluated during the 12-month period of follow up of women in treatment with hormone therapy. Even with the materials being offered regularly, the lack of verbal communication with the health professional failed to lead to more effective results<sup>31,32</sup>. In the study of Ziller et al.<sup>25</sup>, the patients in use of aromatase inhibitors who received written and telephone orientations had better adherence and persistence results during the follow up period ( $p=0.039$ ).

The patients followed up at the Oncology Pharmacy Outpatient beginning treatment with tamoxifen, anastrozol or capecitabine, receive these educative materials simultaneously with an oral explanation in the pharmacy visit and medication dispensation. In case of patients with caretakers, this applies to both.

The patients did not validate the educative materials in relation to understanding, appearance and impact in the promotion of their knowledge, given the importance of evaluating the effectiveness of the leaflets according to its target-public judgment, as the patients benefit from the pharmacy intervention, which is a limitation of the study. Nevertheless, this fragility will be ratified in a future study, since a pilot-study was implemented, considering that the patients who are followed up in the Oncology Pharmacy Outpatient legitimized the leaflets.

## CONCLUSION

The educative materials developed after the modifications proposed by the oncology experts are attractive, in accessible and clear language, with complete correct information, and, therefore, with potential to promote knowledge and adherence of the patient to the treatment when utilized in association with oral communication during pharmaceutical care.

In a future stage, the patients who benefit from the educative action will validate the leaflets in order to assess its applicability in practice.

## CONTRIBUTIONS

Ana Carolina Anversa Sugisaka participated of the conception of the study, collection and analysis of data and wording of the article. Vânia Mari Salvi Andrzejewski

participated of the conception and review of the article. Inajara Rotta overlooked all the stages of the study and participated of the analysis of the data and critical review of the article. All the authors approved the final version to be published.

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### DECLARATION OF CONFLICT OF INTERESTS

There is no conflict of interests to declare.

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