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RESEARCH ARTICLE

Validation of a Booklet on the Use of BI-RADS® in Mammography Examination

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Abstract:

Background:

The *Breast Imaging-Reporting and Data System* (BI-RADS ®) is an international classification developed to systematize breast assessment, exam interpretation, and the preparation of reports of specific breast imaging exams.

Objective:

The objective of this study was to validate with experts a booklet directed to medical and nursing professionals in the Family Health Strategy on the categorization of Breast Imaging Reporting and Data System in order to describe the reports of mammography.

Methods:

This was a technology-validation study of the methodological-development type. The evaluation was performed with 11 experts, including seven radiologists and four mastologists, four men and seven women, with a mean age of 45 years, meantime of being in the profession of 22 years, and an average 15 years of working experience of in the field.

Results:

The individual, mean, and global Content Validity Index (CVI) was calculated. The booklet was validated with a CVI of 0.89. The suggestions of the experts were analyzed, and some of them were implemented for the final version of the booklet.

Conclusion:

The booklet was validated and will contribute significantly to the daily activities of medical and nursing professionals in the Family Health Strategy in relation to the interpretation of the mammographic report and the orientation regarding the referral, agility, and qualification of the patient to the specialized service.

Keywords: Health Education, Breast Neoplasms, Mammography, Early Diagnosis, Family Health Strategy, CVI.

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1. INTRODUCTION

Breast cancer reflects the most incident malignant neoplasm among women around the world and in Brazil, excluding non-melanoma skin cancers, corresponding to approximately 28% of new cases every year [1]. Breast cancer also affects men, but it is rare, and makes up only 1% of the total records of the disease [1].

The diagnosis of breast cancer in less developed countries like, Brazil, occurs in more advanced stages of the disease and it contributes to increasing the complications related to the treatment, interfering the quality of life and reducing survival. In an attempt to change this situation, the Brazilian National Health Policy has been prioritizing measures for control of breast cancer, through guidelines from the Ministry of Health, so that the identification of the disease occurs in the initial phase, through strategies based on measures of screening and early diagnosis of cancer [2].

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Mammographic screening aims at the detection of breast lesions at an early stage of the disease and the reduction of mortality rates caused by this type of cancer through early diagnosis [2]. It is important to highlight that several risk factors are linked to the etiology of the disease, such as the woman's reproductive life and genetic characteristics, as well as hormonal and environmental factors [3]. Therefore, there are two main strategies for the detection of breast cancer: education to promote early diagnosis of the disease and annual mammographic screening in all women over 40 years of age [4].

Regarding mammographic screening, the Breast Imaging-Reporting and Data System (BI-RADS®) is an international classification developed to systematize breast assessment, interpretation of exams, and the preparation of reports of specific breast imaging exams [5]. The nomenclature of the BI-RADS® System is relevant to predict the presence of lesions suspected of malignancy in breast imaging exams [6]. There are three types of diagnostic imaging tests that are commonly used for breast assessment: mammography, ultrasound, and magnetic resonance imaging. The BI-RADS® standardization is similar for these three exams, therefore, everything that is reported will be useful for all of them and, because it is used worldwide, it allows the comparison of results from different countries as well [6].

BI-RADS® is based on values ranging from 0 to 6, where: 0 - represents the incomplete exam and in need of further evaluation; 1 - for normal examination, without changes; 2 - benign findings; 3 - probably benign; 4 - when malignancy is suspected in palpable and non-palpable lesions; 5 - highly suspicious findings; and category 6 - for the findings previously confirmed as malignant and diagnosed by means of biopsies performed [7].

Regarding knowledge to promote early diagnosis, the use of printed educational material added to the verbal guidelines has been increasingly used and works as a quick lookup technology. It is also recommended to guide health professionals in recognition of risk factors for diseases, as well as to enhance prevention, health promotion, and curative practices by transformative actions in health education [8].

The printed educational technologies, of the booklet type, proven, evaluated by experts and scientifically validated, have a fundamental role in the follow-up of health education, becoming a common practice in the Unified Health System (UHS) and working as a tool readily available for the use of professionals when necessary, in the development of care or behavior, aiming to promote population health [9, 10]. The validation of health educational technologies directed to medical and nursing professionals in the Family Health Strategy (FHS) on the diagnosis of breast cancer is an innovative tool and aims to improve the quality of the care provided [11].

It is worth clarifying that the FHS was created in 1994 as a "Family Health Program" and was implemented within the Brazilian Unified Health System (SUS) with the objective of facilitating the transition of patients through various levels of complexity and ensuring that patients receive comprehensive care and in continuity [12]. The multidisciplinary team that works in the FHS is composed of a doctor, nurse, nursing technician, and community health agent [13 - 14].

In the process of validation of printed technologies, such as booklet, it is necessary to assess the appearance and content of the material prepared, build a judgment concerning the clarity of the items, the ease of reading, understanding, and form of presentation of the instrument. This is because breast cancer, when recognized at an early stage through the identification of lesions smaller than 2 cm in diameter, has a favorable prognosis, thus requiring the implementation of strategies for early detection of the disease [15].

The use of educational technologies for the findings in imaging examinations of the breasts, such as mammography, aims to subsidize the health professional in the service and qualified referral to services of greater complexity so that the diagnosis is established early and the patient can start treatment within a maximum of 60 days, as advocated by the article 2 of Brazilian law number 12,732, of November 22, 2012 [16].

One in every three people are directly affected by cancer, and, in this context, mortality rates for breast cancer are still high, probably because of the late diagnosis at advanced stages of the disease. In this environment, early detection through mammographic screening represents the main tool for the detection at the initial phase, resulting in a greater impact on the rate of mortality of the disease [1].

The current Global Action Plan of the UN about non-communicable chronic diseases (NCCD) and the ambitious Sustainable Development Goals (SDG) of the United Nations for 2030, including the SDG 3 (good health and well-being), creates a scenario of opportunities to invest in the fight against cancer, one of the main NCCD. Considering the above, the objective of this study was to validate a booklet directed to medical and nursing professionals in the Family Health Strategy on the BI-RADS® categorization in the description of the findings of mammography exams.

2. MATERIALS AND METHODS

2.1. Type of Study

This is a technology validation study focused on the assessment and improvement of instruments and strategies for making the said material a product of informational technology, so it can help the health professional in the FHS and BI-RADS® categorization of imaging examinations of breasts [17].

2.2. Content Validation with the Judges

This methodological process used an adaptation of the content validation model proposed by Fehring [18], in order to legitimize the guidelines identified in the literature review. This pattern is based on obtaining the judgment of medical experts about how appropriate each guideline is to the situations proposed in the booklet [19].

The scenario of the study was validated through an online search, and *via* electronic mail, by a group of experts considered specialists in the subject. In this context, experts are

defined as individuals qualified to analyze the content, the presentation, clarity and understanding of the instrument in order to attribute validity to the construct [2].

The validation process of the booklet was done in collaboration with professionals from two specific areas: Radiology and Mastology. As recommended by the literature, the qualification of experts from different areas allowed affirming that the material is being utilized valuing different opinions and approaches on the subject [19].

The inclusion criteria of experts included time spent in profession, specialization in the field of Radiology or Mastology, master's or doctoral degrees in the field of Radiology or Mastology, have at least five years of experience in the field of Radiology or Mastology, scientific production in the field of Radiology or Mastology, working in the medicinal education sector, at either graduate or post-graduate level.

The participants were identified by the snowball criterion and the sample was formed by convenience, requesting the first members of the sampling the indication of other people that met the established inclusion criteria. Then, a search was performed on the Lattes Platform in order to evaluate if the individuals met the inclusion criteria, thus inviting the person to participate in the study [20, 21].

Data collection occurred as follows: presentation of the booklet entitled "BIRADS: lexicon to organize the interpretation of mammography and guide therapeutic conduct - a contribution to medical professionals of the Family Health Strategy", in the year 2016 by the student Sílvia Amélia Prado Burgos Madeira Campos, from the Master's Program in Family Health of University Center UNINOVAFAPI, under the direction of Professor Camila Aparecida Pinheiro Landim Almeida, PhD, in the city of Teresina, capital of the state of Piauí [22].

This booklet contains 16 pages printed on coated paper, is colored with images drawn in watercolor and has information arranged in short and direct texts related to BI-RADS® classification in mammography exams.

Each participant received, by e-mail, the Informed Consent Form (ICF) and two questionnaires, one on the biographic characterization of experts and the other containing the items to be assessed, together with a draft of the booklet, in which the experts were asked to record their knowledge in order to improve the material. This questionnaire was adapted from other studies of validation of informational materials intended for the promotion of maternal health [23]. The data were collected from March to July 2018, and the experts had a 30-day deadline to return the answered questionnaires.

A Likert scale was used, with a score from one to four. In order to assess the relevance or the representativeness of each item of the experts' answers, the following classification was used: 1 = strongly disagree; 2 = disagree; 3 = agree; 4 = strongly agree [21, 22].

2.3. Data Analysis

Data analysis used the Content Validity Index (CVI) recommended by Alexandre and Coluci [24].

Upon the judgment of the experts regarding the final version of the instrument, the CVI was employed from the answers 3 and 4 selected by experts, which should correspond to the answers "agree" and "strongly agree", respectively. The CVI was calculated based on three mathematical equations presented below: 1) content validity of individual items (I-CVI); 2) proportion of items from a scale that reached 3 scores as relevant (agree) or 4 as very relevant (strongly agree) (S-CVI/UA); and 3) average rate of content validity for all items in a scale (S-CVI/Ave). The items that received score 1 or 2 were reviewed or deleted [9, 24].

Calculation (I-CVI): an average of the proportion of the answers considered relevant by the judges. Calculation (S-CVI/UA): total number of answers considered relevant by the judges (answers 3 and 4) by the total number of answers. Calculation (S-CVI/Ave): all CVIs were calculated separately and divided by the number of answers considered in the assessment.

2.4. Ethical Aspects

The study was developed according to the guidelines and regulatory standards of Resolution no. 466, of December 12, 2012, the National Health Council, which regulates researches with humans [25], approved under the Opinion no. 2.434.070 on December 13, 2017.

3. RESULTS

The participants included 11 experts, seven radiologists and four mastologists. Regarding the score obtained by them, according to pre-established criteria, a score ranging between 37 and 159 points was achieved. It is worth adding that the score achieved by each expert was significantly higher than the minimum set, which demonstrates the degree of reliability deposited in the specialists, evidenced by vast experience in the working area.

In the process of validation of the booklet regarding the appearance and content, there were contributions of experts in two specific Medical areas, Radiology and Mastology, with vast experience in this theme. In relation to age, the average was 45.6 years, ranging from 39.9 to 51.3 years. The mean time of being in the profession was 22.9 years, ranging between 17.1 and 28.7, with an average activity of 15.5 years in the area, minimum time of 9 and a maximum of 21.9 years of experience – this shows the high level in the evaluation, justified by the time of profession and experience of the experts (Table **1**).

Regarding Medical teaching, five (45.5%) were professors and six (54.5%) worked in the area of medical education, and 10 (90.9%) had scientific production, seven (63.6%) were specialists, and four (36.4%) had completed PhDs. Of the 11 physicians experts, 10 (90.9%) possessed scientific production, one radiologist was a PhD and professor, three mastologists were PhDs and professors, one mastologist was a specialist with experience in assistance, six radiologists were specialists and one of them was a professor of Radiology and Mastology (Table **1**).

Table **2** presents the six blocks containing the items related

to the objectives. Content, language, relevance, layout, and appearance. Each of these further contains five items related to objectives; nine, to the content; five, to the language; six, to the relevance; eight, to the layout; and six, to the appearance. The aspects were evaluated by experts and validated separately from the calculation of the CVI. The 39 validated items were evaluated with the variations of 1 (strongly disagree), 2 (disagree), 3 (agree), and 4 (strongly agree). After the judgment of the experts, the answers 3 and 4 were calculated for valuation of the CVI and those with answers 1 and 2 were analyzed in order to be accepted or not for the new version of the booklet according to the considerations of the experts and the final examination of the researcher.

Regarding the experts' evaluation of objectives, content, language, relevance, layout, and appearance of the items evaluated, eight obtained a CVI below 0.80, namely: 2.5; 3.6; 4.2; 6.1; 6.2; 6.3; 6.4; 6.5; and 6.6 (Table **2**).

Table 1. Characterization of the experts regarding the age group, time of profession, time of experience in the area, teaching in medicine, non-teaching in medicine, scientific production in the area of study, post-graduation.

Variables	Mean	N.	Standard deviation	%
Age	45.64		8.48	
Time of profession	22.91		8.61	
Time working in the area	15.46		9.57	
Professors		5		45.5
Non-professor		6		54.5
Scientific production in the area		10		90.9
Post-graduation				
Specialist		7		63.6
PhD		4		36.4

Table 2. Experts' evaluation of objectives, content, language, relevance, layout, and appearance.

Blocks/Evaluated items	CVI*
1. Objective	-
1.1. The objectives are consistent and contribute to the knowledge of FHS medical professionals.	1.00
1.2. The booklet is a tool that can help the doctor in the interpretation of breast image exams.	1.00
1.3. The booklet is capable of promoting reflection on the early detection of breast cancer.	1.00
1.4. The information contained in the booklet encourages FHS doctors to learn about the description of the findings in mammography exams.	0.91
1.5. The booklet can be introduced as supporting material to inform and guide the doctor in the FHS regarding the follow-up of patients with suspected lesions of malignancy.	0.91
2. Content	
2.1. The booklet is appropriate for the FHS medical professional.	0.91
2.2. The booklet provides adequate information on the BI-RADS® categorization in mammography.	0.82
2.3. The booklet emphasizes the importance of interpreting BI-RADS® in breast imaging.	1.00
2.4. The text is presented in a clear and objective manner.	0.91
2.5. The information presented is scientifically correct.	0.64
2.6. The contents are varied and sufficient to achieve the objectives of the booklet.	1.00
2.7. There is a logical sequence of the proposed content.	0.91
2.8. The division of material titles and subtitles is relevant.	0.91
2.9. The key ideas (highlighted excerpts) are important points and deserve to be highlighted.	1.00
3. Language	-
3.1. The information presented is clear and understandable when considering the professional's level of experience.	0.91
3.2. The writing style corresponds to the professional's level of knowledge.	1.00
3.3. The information is well structured and understandable.	1.00
3.4. The information is in accordance with the spelling.	1.00
3.5. The writing used is attractive.	1.00
3.6 The booklet's title is interesting and appropriate. 0.73	0,73
4. Relevance	-
4.1. The theme addresses key aspects that must be reinforced during the assistance to women in the FHS.	0.91
4.2. The booklet proposes a qualified interpretation of breast cancer diagnostic imaging methods based on the primary health care policy for women.	0.73

(Table 2) contd.....

Blocks/Evaluated items	CVI*
4.3. The booklet addresses the issues necessary to assist the FHS physician in referring patients according to BIRADS® to the specialized service.	0.82
4.4. The booklet is suitable for use by the ESF medical professional to assist patients in a more qualified way in relation to the interpretation of results.	0.91
4.5. The booklet is suitable to be used as a relevant instrument for early detection of breast cancer and guidance in therapeutic management.	0.91
4.6. The theme is relevant to the FHS for implementing this technology in women's health care.	0.91
5. Layout	-
5.1. The presentation of the booklet is attractive.	0.91
5.2. The presentation of the booklet is organized in a logical manner.	0.91
5.3. The content is presented in a letter in a size and font suitable for reading.	0.91
5.4. The font used makes it easier to read the material.	1.00
5.5. The contrast with different colors was done properly.	0.82
5.6. The text layout is adequate.	0.91
5.7. The paper (coated) for printing the material is appropriate.	0.91
5.8. The number of pages is adequate.	0.91
6. Appearance	-
6.1. The pages or sections appear organized.	1.00
6.2. The illustrations are simple and are relevant to the purpose of the material.	0.73
6.3. The illustrations are suitable for the booklet.	0.73
6.4. The illustrations are expressive and sufficient.	0.73
6.5. The colors are suitable for the booklet.	0.73
6.6. There is a need to include more illustrations.	0.73

*Content Validation Index

Table 3. Evaluation of the experts for the global index in terms of objective, content, language, relevance, layout, and appearance.

S.NO	Evaluated criteria	CVI*
1	Objective	0.96
2	Content	0.90
3	Language	0.94
4	Relevance	0.87
5	Layout	0.91
6	Appearance	0.78
Global index	**0.89**	

*Content Validation Index

In the process of validation of the booklet, the experts made judgments regarding the content and the appearance, considering the valuation of the overall index of each criterion evaluated. The answers given by the experts were validated using the CVI calculation in accordance with the experts' degree of agreement. The criteria evaluated correspond to the objective, content, language, relevance, layout, and appearance. The global CVI calculated for all indexes analyzed was equal to 0.89 (Table **3**).

Table **4** presents a synthesis of items with individual CVI below 0.80. The assessments were described, as well as the suggestions made by the experts in each item, those that were accepted and those that were not, followed by the reason (Table **4**).

The booklet obtained a CVI of 0.89, indicating a high level of agreement among the experts. The final version of the validated material had the aid of a graphic designer, containing 16 pages printed on photo paper, covered in light colors, and information arranged in short and direct texts related to BI-RADS® classification in mammography exams. Below are the cover, the summary, and the presentation of the validated booklet (Fig. **1**).

4. DISCUSSION

The suggestions made by the experts for items relating to language were focused on the booklet's title, which should be modified and directed to other FHS professionals, and not only to physicians. Furthermore, they suggested deleting the term "guide therapeutic behavior", since the booklet will be useful to guide the professionals regarding the interpretation of mammographic reports and recognition for the proper referral to specialized services.

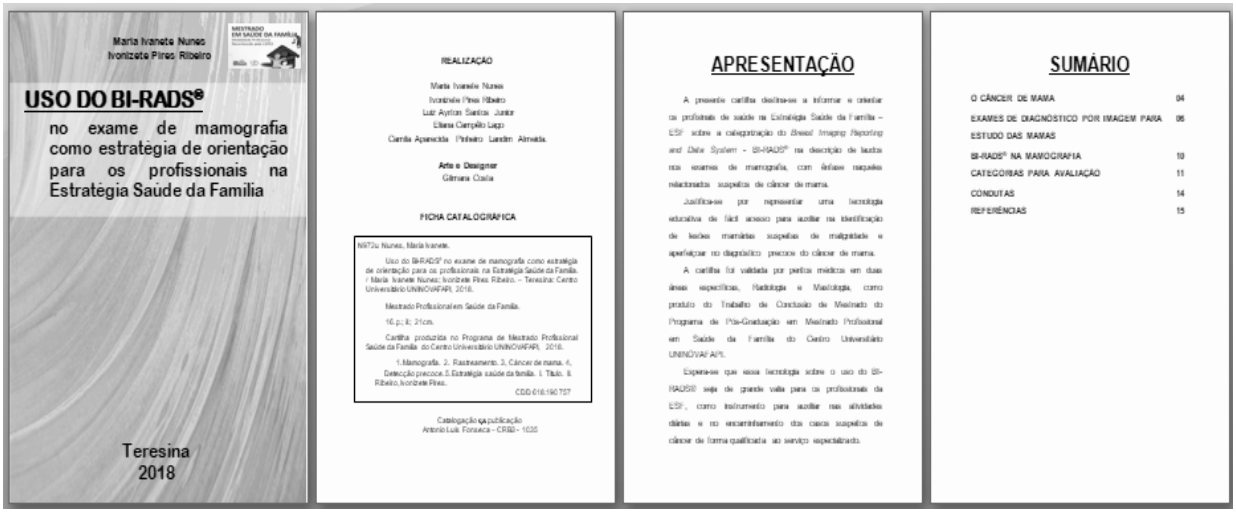

Fig. (1). Representative illustration of the cover, development, presentation, and summary of the validated booklet "Use of BI-RADS® in the mammography exam as a guiding strategy for medical and nursing professionals in the Family Health Strategy".

Table 4. Changes made from the experts' suggestions and adapted in the new version of the booklet.

Items	Some comments and suggestions from the experts	Suggestions accepted and not accept
Content 2.5. The information presented is scientifically correct.	1. On page 7, in the second paragraph, which describes mammography, delete the word "only". 2. On page 11, which deals with the findings of subcategory 4A, there is a solid "palpable" nodule (palpability has already been considered as an inclusion criterion in category 4). 3. In the excerpt from the introduction on breast cancer, advanced age was placed as a risk factor. Exclude the term "advanced age" and specify that the age group most affected is between 50 and 69 years old. 4. Write the term BIRADS according to the official spelling. 5. On page 11, category 4A, add the term "ectasied" to classify the isolated Vas finding.	Suggestion accepted. Suggestion accepted. Word "palpable" excluded. Suggestion accepted. Suggestion accepted. Written in the "BI-RADS®" official spelling. Suggestion accepted.
Language 3.6. The booklet's title is interesting and appropriate.	1. Reformulate the title. 2. Replace the term "medical professionals" with "health professionals". 3. Exclude the term "guide in therapeutic behavior".	Suggestion accepted. Title changed to "Use of BI-RADS® in the mammography exam as a guiding strategy for professionals in the Family Health Strategy". Suggestion accepted. Suggestion accepted, because the material aims to aid professionals with the findings in the mammography exam.
Relevance 4.2. The booklet proposes a qualified interpretation of breast cancer diagnostic imaging methods based on the primary health care policy for women.	1. Emphasize the importance of mammography for the early diagnosis of breast cancer, treatment, and the impact on the mortality rate.	Suggestions accepted. However, to fit the material to the experts' suggestions, the following texts required change: "Breast cancer", page 6; "Imaging diagnostic tests", pages 7and 8; "BI-RADS® in mammography", page 10.
Appearance 6.2. The illustrations are simple and relevant to the material's objective. 6.3. The illustrations are suitable for the booklet. 6.4. The illustrations are expressive and sufficient. 6.5. The colors are suitable for the booklet. 6.6. There is a need to include more illustrations.	1. Change the current color to a more discreet one and remove the colored bars around the texts. 2. Insert illustrations with mammographic findings for all categories of BI-RADS®. 3. Include a flow chart to describe the behavior of each category of BI-RADS® to facilitate understanding. 4. Suggestion of using lighter colors. 5. Suggestion to insert images of breast lesions.	Suggestion accepted. Suggestion not accepted, since the material is fast-access. Suggestion accepted and included in the new version of the booklet. Suggestion accepted. Suggestion not accepted, since the material is fast-access and does not focus on therapeutic behavior.

Source: Direct, 2018.

It becomes relevant to address the importance of including experts from different areas because, without their participation, it would have been impossible to validate a material with a high reliability level as it is an educational technology that involves two complementary specialties. It should be emphasized that the evaluation by professionals from different areas becomes opportune for the validation of the material with the maximum coherence with the theme addressed in the booklet, which occurred as a team, valuing the suggestions and different knowledge of professionals about the same subject [26].

Aiming to endorse a qualified evaluation of the booklet, the experts, besides being specialists in the topic, needed to assume a posture of valuation of professional experience and scientific knowledge, as pointed out in other methodological studies on the validation of an educational instrument [18, 27, 28]. Therefore, in this study, all the material was examined by mastologist experts that work in the area of women's health and radiologists responsible for the elaboration of mammographic reports, aiming to maximize the effectiveness of technology and its reliability for later use.

It should be emphasized that the analysis of the characterization of experts was a relevant factor for validation because it allowed demonstrating the experts' profile and experience for the validation of informative material. The level of agreement to compose the reliability of the information in the content validation and adaptation of educational material is a crucial step to make the said production more relevant since only a vast knowledge allows assessing the relevance of the content presented in all items submitted to the judgment [28 - 36].

In this process of adaptation of the booklet, to assess the experts' level of agreement, CVI was used because it represents a method widely used in the health area, thus allowed calculating the experts' agreement index on certain aspects of the material individually for each evaluated item, as well as globally, involving all items [24, 37].

Other studies that addressed the validation of printed educational technology used the CVI technique for the validation of the content. For the use of the CVI, there should be a description of the calculations performed in the process of validation for each item analyzed, along with the results of the global CVI. According to a predetermined cut-off point for the CVI, the items whose results are below the cut-off point are subject to changes by the authors. It is emphasized that there is no consensus in the literature on validation of an instrument as a whole, with no standardization, because the studies address different types of instruments with adaptations suggested by experts that deal with validation of educational material [21].

In this validation process, the adopted CVI cut-off point was 0.78, *i.e.*, all items with a CVI below 0.80 were analyzed according to the experts' suggestions, and the items with an index over 0.80 were maintained without changes. It is important to highlight that, in this study, although some items featured a CVI below 0.80, the overall index of the booklet was 0.89. The overall CVI index justifies that the agreement between the experts on the applicability of the material was statistically significant [36].

As for the experts' suggestions, the changes in eight items became relevant to improve the booklet. In addition, a large part of the experts consented the relevance and contribution of the material for FHS professionals as a tool to be used to optimize the early diagnosis of breast cancer, considering that any educational technology produced and used effectively can transform the population reality [10].

In relation to the content, five changes were suggested - all of which were accepted. In relation to the items assessed in relevance, there was the suggestion to emphasize the importance of mammography for the early diagnosis of breast cancer in treatment and the impact on the mortality rate. This suggestion was considered relevant, and was, thus, accepted.

Concerning appearance, five changes were suggested, of which only three were accepted. It should be emphasized that the suggestions to insert illustrations with mammographic findings to all categories of the BI-RADS® and images of breast lesions were not followed since the material validated is fast-access and a tool to assist the interpretation of reports and systematize the referral to specialized services for health professionals, and does not focus on the therapeutic behavior. It is noteworthy that all the items evaluated in the booklet were discussed and considered appropriate according to the guidance of the specialists [37 - 38], making the material a quality technology to assist in the daily use of FHS professionals, being a tool for the interpretation of the mammographic exam and guidance on referring the patient to the specialized service [37 - 39].

Therefore, the validation of informational materials – in this case, the booklet on the use of BI-RADS® in mammography examination – is also an opportunity to standardize and improve the performance of professionals while meeting the female population regarding breast cancer, in favor of qualified and effective assistance [9].

As the booklet undergoes the process of validity and reliability, its quality is tested, improvements are suggested, changes are made, thus, reducing the possibility of errors and increasing the approximation of credibility for use in the practice to which the material is intended [38].

In Brazil, after receiving the mammography exam from a patient and, according to the BIRADS® classification presented in the report, Primary Care is responsible for monitoring the user, forward to the reference service for diagnostic investigation, and start treatment, if confirmed, within a maximum period of 60 days [40]. For this, the FHS medical and nursing professionals need to be trained to identify suspected cases and facilitate access to specialized services in the shortest possible time [13].

Screening for breast cancer is done in different ways across countries. In Brazil, it is extremely opportune, being carried out during a medical consultation [2]. The interest in validating a booklet as an educational technology among FHS medical and nursing professionals aims to contribute an easily accessible material, which helps in the early detection of breast cancer, provides opportunities for knowledge about the interpretation

of BI-RADS® and guides referral to a specialized service for adequate and timely assessment of lesions suspected of malignancy.

One of the limitations was the participation of experts from a single Brazilian state. Nevertheless, this restriction was overcome as the experts presented extensive qualifications and experience in the proposed area of study, which enabled a broad view, and commensurate with the objective of validating the said material.

CONCLUSION

The booklet was validated from the point of view of content and relevance, with a CVI of 0.89, and constituted as a new educational material for the daily activities of FHS professionals, providing knowledge about the interpretation of the mammographic report and guidance on the qualified referral of patients to specialized service.

The validation of an educational technology that facilitates the structuring, access, and exchange of information to support medical and nursing professionals in decision-making processes has repercussions in systematic and comprehensive assistance, in a timely manner, and according to the severity of the disease.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

This study was approved by the by the Research Ethics Committee of Centro Universitário UNINOVAFAPI, Opinion no. 2.434.070 on December 13, 2017.

HUMAN AND ANIMAL RIGHTS

This study complied with ethical and scientific guidelines concerning research involving human subjects according to the Brazilian National Health Council Resolution No. 466/2012.

CONSENT FOR PUBLICATION

All patients participated on a voluntary basis and gave their informed consent.

AVAILABILITY OF DATA AND MATERIALS

The authors confirm that the data supporting the findings of this study are available in the article.

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None.

CONFLICT OF INTEREST

The authors declare no conflict of interest, financial or otherwise.

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Declared none.

REFERENCES

[1] Brazil National Cancer Institute 2018 Estimate Incidence of Cancer in Brazil. Rio de Janeiro: INCA 2018. Available from: http://www.inca.gov.br/publicacoes/livros/estimativa-2018-incidencia

[2] Migowski A, Silva GAE, Dias MBK, Diz MDPE, Sant'Ana DR, Nadanovsky P. Guidelines for early detection of breast cancer in Brazil. II - New national recommendations, main evidence, and controversies. Cad Saude Publica 2018; 34(6): e00074817. [http://dx.doi.org/10.1590/0102-311x00074817] [PMID: 29947654]

[3] Ataollahi MR, Sharifi J, Paknahad MR, Paknahad A. Breast cancer and associated factors: A review. J Med Life 8(Spec Iss 4): 6-11.2015; Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5319297/

[4] Moraes DC, Almeida AM, Figueiredo EN, Loyola EAC, Panobianco MS. [Opportunistic screening actions for breast cancer performed by nurses working in primary health care]. Rev Esc Enferm USP 2016; 50(1): 14-21. [http://dx.doi.org/10.1590/S0080-623420160000100002] [PMID: 27007415]

[5] Souza BS, Pinto ESO. Evaluation of mammographic findings classified according to the BI RADS system. Rev Cient Univiçosa 2016; 8(1): 205-10. Available from: https://academico.univicosa.com.br/revista/index.php/RevistaSimpac/article/view/641/786

[6] Assis CF, Mamede M. Mammography and its challenges: factors socio-educational factors associated with late diagnosis of cancer of breast. Inic Cient Cesumar 2016; 18(1): 63-72. [http://dx.doi.org/10.17765/1518-1243.2016v18n1p63-72]

[7] Atlas BI-RADS of the ACR: reporting system and data recording of breast image/ American College of Radiology. 2nd ed. They are Paulo: Brazilian College of Radiology 2016.

[8] Coriolano-Marinus MWL, Pavan MI, Lima LS, Bettencourt ARC. Validation of educational material for hospital discharge of patients with prescription of prolonged home oxygen therapy. Esc Anna Nery 2014; 18(2): 284-9.https://www.redalyc.org/pdf/1277/127730686015.pdf [http://dx.doi.org/10.5935/1414-8145.20140041]

[9] Lima ACMACC, Bezerra KC, Sousa DMN, Rocha JF, Oriá MOB. Construction and Validation of a booklet for prevention of transmission HIV vertical. Minutes Paul Enferm 2017; 30(2): 181-9. [http://dx.doi.org/10.1590/1982-0194201700028]

[10] de Oliveira SC, Lopes MVO, Fernandes AFC. Development and validation of an educational booklet for healthy eating during pregnancy. Rev Lat Am Enfermagem 2014; 22(4): 611-20. [http://dx.doi.org/10.1590/0104-1169.3313.2459] [PMID: 25296145]

[11] Oliveira RL, Santos MEA. Health education in the Health Strategy of the family: Nurses' knowledge and practices. Integrated Nurse Rev 2011; 4(2): 833-4. Available from: https://www.unilestemg.br/enfermagemintegrada/artigo/v4_2/05-educacao-em-saude-na-estrategia-saude-da-familia-conhecimentos-epraticas- do enfermeiro (oliveira%3bsantos).pdf

[12] Garuzi M, Achitti MCO, Sato CA, Rocha SA, Spagnuolo RS. [User embracement in the Family Health Strategy in Brazil: an integrative review]. Rev Panam Salud Publica 2014; 35(2): 144-9. [PMID: 24781096]

[13] Brazil. Ministry of Health. Ordinance nº 2.488, october 21, 2011. Approves the National Primary Care Policy, establishing the review of guidelines and standards for the organization of Primary Care, for the Family Health Strategy (ESF) and the Community Health Agents Program (PACS). Official Diary of the Union 2011. Available from: http://bvsms.saude.gov.br/bvs/saudelegis/gm/2011/prt2488_21_10_2011.html

[14] Brazil. Ministry of Health. Law nº 8.080. Provides for the conditions for the promotion, protection and recovery of health, the organization and functioning of the corresponding services and provides other measures. Official Diary of the Union 1990. Available from: http://www.planalto.gov.br/ccivil_03/leis/l8080.htm

[15] Medeiros AP. Validation of educational material for men with indwelling vesical catheter at home [dissertation]. Saint Charles: UFSCar 2012. Available from: https://repositorio.ufscar.br/handle/ufscar/3242

[16] Brazil. Ordinance No. 876 of May 16, 2013. Provides for the application of Law No. 12,732, of November 22, 2012, which deals with respect of the first treatment of the patient with malignant neoplasm proven, within the scope of the Unified Health System (SUS). System of Health Legislation 2013. Available from: http://bvsms.saude.gov.br/bvs/saudelegis/gm/2013/prt0876_16_05_2013.html

[17] Perovano DG. Scientific methodology manual: For safety public and social defense. 1st ed. São Paulo: Jurua Editora 2014.

[18] Fehring RJ. The Fehring model. Proceedings of the Tenth Conference.

55-62.
[19] Echer IC. Preparation of guidance manuals for care in health. Rev Latin Am Nurs 2005; 13(5): 754-7. [http://dx.doi.org/10.1590/S0104-11692005000500022]
[20] Hino P, Ciosak SI. Fonseca RMGSda, Egry EY. Needs in health and primary care: validation of uptake instruments. Rev Enferm USP 2009; 43(2): 1156-67. [http://dx.doi.org/10.1590/S0080-62342009000600003]
[21] Polit DF, Beck CT. Fundamentals of nursing research: Evaluation of evidence for nursing practice. Artmed Publisher 2011.
[22] Campos SAPM, Almeida CAPL, Lago EC, Tapety FI, Alves ELM. Physicians' perceptions of breast cancer prevention. Rev Nurse UFPE 2019; 13(2): 315-21. [http://dx.doi.org/10.5205/1981-8963-v13i2a235056p315-321-2019]
[23] Reberte LM, Hoga LAK, Gomes ALZ. The construction process of educational material for the promotion of the health of pregnant women. Rev Latin Am Nurs 2012; 20(1): 101-8. [http://dx.doi.org/10.1590/S0104-11692012000100014]
[24] Alexandre NMC, Coluci MZO. Content validity in processes of construction and adaptation of measuring instruments. Health Sci Collect 2011; 16(7): 3061-8. [PMID: 21808894]
[25] Brazil. National Health Council. Resolution No. 466, of 12th of December 2012. Approves research regulatory standards involving human beings Official Gazette of the Union 2012. Available from: http://conselho.saude.gov.br/resolucoes/2012/Reso466.pdf
[26] Moura IH, Silva AFR, Rocha AESH, Lima LHO, Moreira TMM, Silva ARV. Construction and validation of educational material for the prevention of metabolic syndrome in adolescents. Rev Latin Am Nurs 2017; 25: 1-12. [http://dx.doi.org/10.1590/1518-8345.2024.2934]
[27] Jasper MA. Expert: a discussion of the implications of the concept as used in nursing. J Adv Nurs 1994; 20(4): 769-76. [http://dx.doi.org/10.1046/j.1365-2648.1994.20040769.x] [PMID: 7822615]
[28] Sena JF, Silva IPD, Lucena SKP, Oliveira ACS, Costa IKF. Validation of educational material for the care of people with intestinal stoma. Rev Lat Am Enfermagem 2020; 28: e3269. [http://dx.doi.org/10.1590/1518-8345.3179.3269] [PMID: 32401899]
[29] Pai SD, Langendorf TF, Rodrigues MCS, Romero MP, Loro MM, Kolankiewicz ACBT. Psychometric validation of an instrument that evaluates the safety culture in Primary Care. Minutes Paul Enferm 2019; 32(6): 642-50. [http://dx.doi.org/10.1590/1982-0194201900089]
[30] Ximenes MAM, Fontenele NÂO, Bastos IB, Macêdo TS, Galindo Neto NM, Caetano JÁ, *et al.* Content construction and validation of educational booklet for the prevention of falls in the hospital. Minutes Paul Nurse 2019; 32(4): 433-41. [http://dx.doi.org/10.1590/1982-0194201900059]
[31] Galdino YLS, Moreira TMM, Marques ADB, Silva FAAD. Validation of a booklet on self-care with the diabetic foot. Rev Bras Enferm 2019; 72(3): 780-7. [http://dx.doi.org/10.1590/0034-7167-2017-0900] [PMID: 31269146]
[32] Salvador PTCO, Mariz CMDS, Vítor AF, *et al.* Validation of virtual learning object to support the teaching of nursing care systematization. Rev Bras Enferm 2018; 71(1): 11-9. [http://dx.doi.org/10.1590/0034-7167-2016-0537] [PMID: 29324939]
[33] Santos ADS, Rodrigues LDN, Andrade KC, Santos MSND, Viana MCA, Chaves EMC. Construction and validation of an educational technology for mother-child bond in the neonatal intensive care unit. Rev Bras Enferm 2020; 73(4): e20190083. [http://dx.doi.org/10.1590/0034-7167-2019-0083] [PMID: 32490997]
[34] Pasquali L. Psychometry: Test theory in psychology and education. Petropolis: Voices 2004.
[35] Lynn MR. Determination and quantification of content validity. Nurs Res 1986; 35(6): 382-5. [http://dx.doi.org/10.1097/00006199-198611000-00017] [PMID: 3640358]
[36] Sousa AFL, Hermann PRS, Fronteira I, Andrade D. Monitoring of postoperative complications in the home environment. Rev Rene 2020; 21: 1-12. [http://dx.doi.org/10.15253/2175-6783.20202143161]
[37] Lobiondo-Wood G. Haber JNon-experimental drawingsLobiondo-Wood GHJ, Org Nursing research: Methods, critical evaluation and use. 4th ed. Rio de Janeiro: Guanabara-Koogan 2001; pp. 110-21.
[38] Trigueros R, Magaz-González AM, García-Tascón M, Alias A, Aguilar-Parra JM. Validation and adaptation of the academic-resilience scale in the spanish context. Int J Environ Res Public Health 2020; 17(11): 10-2. [http://dx.doi.org/10.3390/ijerph17113779] [PMID: 32466576]
[39] Cunha LFCD, Baixinho CL, Henriques MA. Preventing falls in hospitalized elderly: design and validation of a team intervention. Rev Esc Enferm USP 2019; 53-3479. [http://dx.doi.org/10.1590/s1980-220x2018031803479] [PMID: 31365730]
[40] Sousa SMMT, Carvalho MGFM, Santos Júnior LA, Mariano SBC. Access to treatment for women with breast cancer. Health Debate 2019; 43(122): 727-41. [http://dx.doi.org/10.1590/0103-1104201912206]