ORIGINAL ARTICLE

REVISTA ENFERMAGEM ATUAL IN DERME

VALIDATION OF AN INSTRUMENT TO EVALUATE HOSPITALIZED PATIENT PARTICIPATION IN THEIR OWN SAFETY

INSTRUMENTO PARA EVALUAR LA PARTICIPACIÓN DEL PACIENTE EN RELACIÓN CON LA PROPIA SEGURIDAD: EVIDENCIAS DE VALIDEZ

VALIDAÇÃO DE UM INSTRUMENTO PARA AVALIAR A PARTICIPAÇÃO DO PACIENTE HOSPITALIZADO NA PRÓPRIA SEGURANÇA

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Submission: 31-10-2023
Approval: 17-03-2025

ABSTRACT
Aim: To validate an instrument to evaluate on the participation of hospitalized patients in relation to their own safety. **Method**: this is a methodological research, developed between March and December 2020, that followed the steps: establishment of the conceptual structure; definition of the objectives of the instrument and the population involved; construction of the response items; selection and organization of the items; structuring of the instrument; and content validation, with 16 specialists. The data were analyzed using the content validation index and Cronbach's alpha. **Results**: the instrument resulted in 32 items with responses ranging from self-perceived participation as minimal, moderate or maximum, divided into two parts: the first with information on social and clinical dataand the second with questions about patient participation in their safety. The content validation index showed a variation between 0.80 and 1, and total Cronbach's alpha of 0.774. **Conclusion**: the instrument presented evidence of content validity.
Keywords: Patient Participation; Patient Safety; Validation Study.

RESUMEN
Objetivo: Validar un instrumento para la investigación sobre la participación del paciente hospitalizado en relación a su propia seguridad. **Método**: se trata de una investigación metodológica que siguió las etapas: establecimiento de la estructura conceptual; definición de los objetivos del instrumento y de la población involucrada; construcción de los ítems de respuestas; selección y organización de los ítems; estructuración del instrumento; y validación de contenido, con 16 especialistas. Los datos fueron analizados por medio del índice de validación de contenido y del Alfa de Cronbach. **Resultados**: el instrumento resultó en 32 puntos con respuestas que van desde la autopercepción de la participación como mínimo, moderado o máximo, dividido en dos partes: la primera con información sobre datos sociales y clínico-quirúrgicos; y la segunda con preguntas sobre la participación del paciente en su seguridad. El índice de validación de contenido presentó una variación entre 0,625 y 1, y Alfa de Cronbach total de 0,774. **Conclusión**: el instrumento presentó evidencias de validez de contenido.
Palabras clave: Participación del Paciente; Seguridad del Paciente; Estudio de Validación.

RESUMO
Objetivo: Validar um instrumento para avaliar a participação do paciente hospitalizado em relação à sua própria segurança. **Método:** trata-se de uma pesquisa metodológica, desenvolvida entre março a dezembro de 2020, que seguiu as etapas: estabelecimento da estrutura conceitual; definição dos objetivos do instrumento e da população envolvida; construção dos itens de respostas; seleção e organização dos itens; estruturação do instrumento; e validação de conteúdo, com 16 especialistas. Os dados foram analisados por meio do índice de validação de conteúdo e do Alfa de *Cronbach.* **Resultados:** o instrumento resultou em 32 itens com respostas variando entre autopercepção da participação como mínima, moderada ou máxima, dividido em duas partes: a primeira com informações sobre dados sociais e clínico-cirúrgicos; e a segunda com questões sobre a participação do paciente na sua segurança. O índice de validação de conteúdo apresentou uma variação entre 0,80 e 1, e Alfa de *Cronbach* total de 0,774. **Conclusão:** o instrumento apresentou evidências de validade de conteúdo.
Palavras-chave: Participação do Paciente; Segurança do Paciente; Estudos de Validação.

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INTRODUCTION

Patient safety requires an arrangement of organized activities that create processes, procedures, behaviors, technologies and environments in the health area that consist of reducing risks, occurrence of avoidable harm and making errors less likely, reducing the impact of harm [1].

In order to achieve safe care, it is essential that all actors involved in the process are well informed and involved in the therapeutic path. Studies highlight that patients can participate in the stages of the care process, contributing effectively to the promotion of better results, such as in the practices of learning, evaluation and adaptation of their health status [2,3].

It is extremely important for patients to present the necessary knowledge about their health status and the therapies employed, in order to encourage them to participate actively in the entire process, contributing to their own safety within the treatment. Patient participation can range from opinions in the elaboration of clinical protocols and discussions about risk and benefit [4].

The knowledge presented by patients and health professionals regarding patient safety can be assessed through the use of specific instruments that objectively assess the extent of the patient's learning needs, guiding a reflection on which aspects need to be improved, since patients sometimes identify adverse events that are not detected by professionals[5,6].

However, the existence of these instruments is still scarce, and those that are available sometimes do not provide the necessary clarity regarding the questions and answers present, causing doubts when patients interpret the answers[7].

The use of measurement instruments, such as questionnaires and validated scales recognized in the scientific field, allows greater reliability and safety in clinical practice. In this regard, the assessment of patient safety, which is one of the attributes of quality of care according to the World Health Organization (WHO), through these instruments, makes it possible to recognize the potentialities and weaknesses present, contributing to the development of actions to improve the care offered within health institutions, since the knowledge of patients directly contributes to their own safety[8].

Thus, the following guiding question was constructed: does the instrument developed present evidence of content validity regarding the patient's assessment of their own safety?

This study aimed to validate an instrument to assess the participation of hospitalized patients in relation to their own safety.

METHODS

This is a methodological study, developed between March and December 2020, at a Federal Public University in Piauí. The process of constructing and validating an instrument is an activity that involves a vast

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study and several stages of development. The validation stage is fundamental in the process of developing reliable measures and instruments, therefore, it presents itself as a methodological mechanism that can help the researcher decide whether or not to apply the results[9].

To construct the instrument, a narrative review of the literature was carried out, with the purpose of analyzing the main scientific publications available on factors related to patient participation in relation to their own safety. This type of review is appropriate to describe and discuss the development or the "state of the art" of a given subject, from a theoretical or contextual point of view, and does not need to inform the sources used, the methodology for searching for references, or the criteria used in the evaluation and selection of the works[10].

Regarding the type of instrument, it was decided to create a questionnaire, since these are tools that integrate clinical practice, health assessment, as well as the field of scientific research, in addition to influencing decisions related to care, assistance, therapy, interventions and the formulation of health programs and policies[11].

The instrument constructed was called the Hospitalized Patient Participation Assessment Questionnaire (QAPPH) and consists of 32 items, divided into two parts: the first with information on social and clinical-surgical data (age, number of years of education, sex, reason for hospitalization, diagnostic identification of the disease, number of hospital admissions, and number of days of current hospitalization); and the second with questions about the patient's self-perception of participation in their safety, which offers the possibility of responses in three options: 1- little participation; 2- moderate participation; and 3- maximum participation.

Content validation was performed with 16 nursing professionals working in the area of patient safety, who were located through a search of their CVs. Once identified, a list of possible judges was created, and after contacting the first expert, the snowball technique was used, which consists of the first interviewee indicating the next and so on, until the desired result is achieved.

The inclusion criteria for choosing the judges were the training of these professionals, their scientific production and clinical practice. Those who agreed to participate in the study but did not respond to the instruments within the previously stipulated deadline were excluded.

The QAPPH content was sent to the judges in an electronic form prepared by the authors, which presented a response pattern using a scale with the following responses and parameters: 0 = I do not agree (when the wording of the item was not related to the construct of patient participation and required complete reformulation or exclusion), 1 = I neither agree nor disagree (when the wording of the item was related to the construct of patient participation but required partial reformulation) and 2 = I agree (when the wording of the item was related to the construct of patient

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participation and was maintained without changes); as well as a free field so that they could leave suggestions about each item.

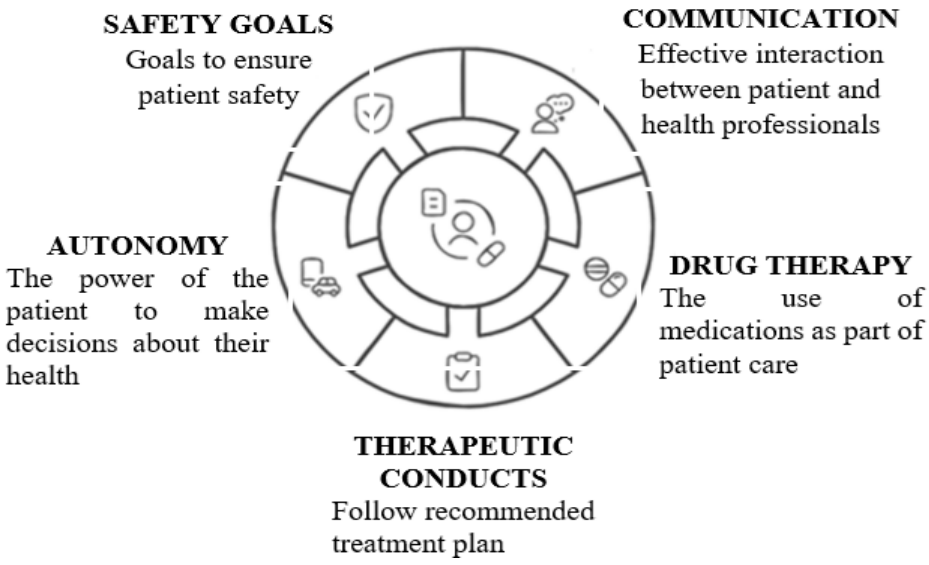
The data were organized and entered using the statistical program SPSS (Statistical Package for the Social Sciences) version 23.0, and then the Content Validity Index (CVI) was calculated for each item, with items that reached a value greater than or equal to 0.80 being considered validated[12]. To analyze reliability, the internal consistency of the instrument was verified using Cronbach's Alpha Coefficient, where "values with ranges <0.5 are unacceptable, >0.5 poor, >0.6 questionable, >0.7 acceptable, >0.8 good and >0.9 excellent"[13].

The research was approved by the Research Ethics Committee (CEP) of the Federal University of Piauí through the following substantiated opinion: 3.018.102.

RESULTS

The narrative review identified that active patient participation in hospital safety is recognized as a crucial element for improving care and reducing adverse events. Several factors have been identified as determinants for this participation, and the instrument items were allocated to these, namely: patient safety goals (items 19, 20, 21, 24, 25, 26 and 31); communication between professionals and patients (items 1, 2, 3, 10 and 13); patient autonomy (items 4, 9, 16, 17, 27, 28 and 29); drug therapy management (12 and 14); and therapeutic approaches (items 5, 6, 7, 8, 11, 15, 18, 22, 23, 30 and 32) (figure 1).

Figure 1 - Factors related to the participation of hospitalized patients in relation to their safety. Picos, PI, 2024.



Source: Authors.

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Table 1 presents the characterization of the socio-professional profile of the judges. The majority of participants were female, 13 (81.2%), with an average age of 35 (±4.94) years and 10 (±5.14) years of study. Regarding the state in which they work, the majority reported working in Piauí, 15 (93.7%), with the title of specialist, 8 (50.0%) and 10 (62.5%) with experience in instrument validation.

Table 1 - Socio-professional profile of the judges participating in the study. Picos, PI, Brazil. 2024.

Variables	**N**	**%**	**Minimum Maximum**	**Average(DP*)**
Age			29 - 44	35.1(± ± 4.94)
20 - 35 yo	9	56,2		
36 - 50 yo	7	43,8		
Gender				
Female	13	81,2		
Male	3	18,8		
Training time from graduation			5 - 21	10.3(± ±5.14)
1-10 years	10	62,5		
11-20 years	5	31,2		
21-30 years	1	6,3		
State in which you work				
Piauí	15	93,7		
Ceará	1	6,3		
Highest degree				
Specialization	8	50,0		
Master's degree	3	18,7		
Doctorate	5	31,3		
Previous experience with instrument validation				
Yes, from 1 to 7 times	10	62,5		
Yes, more than 10 times	3	18,7		
No	3	18,8		

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Next, the reliability of the instrument for assessing patient participation regarding their own safety was verified by analyzing the internal consistency of Cronbach's Alpha, as well as the magnitude of correlation between the items, with the results expressed in Table 2 .

Table 2 - IVC and internal consistency coefficient of Cronbach's alpha of the Patient Participation Assessment Instrument in relation to their own safety. Picos, PI, Brazil. 2024.

Questionnaire item	Average if item is deleted	Variance if item is deleted	Corrected item/total correlation	Cronbach's alpha if item is deleted	IVC*
Question 1	55,00	38,800	,531	,757	0,87
Question 2	55,06	41,929	,034	,782	0,87
Question 3	55,13	41,317	,098	,779	0,81
Question 4	55,13	40,917	,142	,777	0,85
Question 5	54,94	42,329	,056	,776	0,87
Question 6	55,38	37,983	,356	,765	0,81
Question 7	55,38	38,517	,348	,765	0,92
Question 8	55,06	39,529	,314	,767	0,81
Question 9	55,13	43,050	-,092	,789	0,81
Question 10	55,06	38,196	,478	,757	0,87
Question 11	54,94	40,863	,248	,770	0,93
Question 12	55,25	36,467	,566	,750	0,80
Question 13	54,94	41,663	,121	,775	0,93
Question 14	55,00	37,867	,677	,750	0,87
Question 15	55,00	40,933	,310	,768	0,81
Question 16	54,88	41,717	,284	,771	0,93
Question 17	55,13	39,983	,249	,771	0,81
Question 18	55,00	38,400	,593	,754	0,87

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Question 19	54,94	41,129	,331	,768	0,87
Question 20	54,94	41,663	,208	,772	0,87
Question 21	54,88	42,650	-,005	,777	0,93
Question 22	55,13	37,317	,568	,752	0,81
Question 23	54,94	38,463	,642	,754	0,93
Question 24	54,88	41,717	,284	,771	0,93
Question 25	55,06	40,329	,277	,769	0,81
Question 26	55,19	43,496	-,136	,795	0,81
Question 27	55,00	41,333	,153	,774	0,87
Question 28	55,19	42,696	-,047	,785	0,82
Question 29	54,94	41,129	,331	,768	0,87
Question 30	54,81	42,696	,000	,775	1
Question 31	54,94	38,463	,642	,754	0,93
Question 32	55,00	38,000	,656	,751	0,87

* Content Validity Index

Source: Survey data.

The overall calculated CVI was 0.84, while for the items assessed individually there was a variation between 0.80 and 1, with the lowest CVI value (0.80) referring to item 12 (“Do you know all the times to take your medications, how many times a day and where your medications should be administered?”), and the highest CVI value [1] referring to item 30 (“Do you participate in decisions about your treatment?”). There was no inadequacy in any of the instrument's items, according to the experts' assessment. The results also show that the instrument presented a total Cronbach's Alpha of 0.774, which is indicative of excellent internal consistency. The item-total correlation analysis revealed that all items presented an item-to-item Cronbach's Alpha greater than 0.70, indicating excellent correlation between the items.

The instrument in its final version is presented below.

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Table 3 - Final version of the Hospitalized Patient Participation Assessment Questionnaire (QAPPH). Picos, PI, Brazil, 2024.

1st PART – Answer and mark with an X according to your answer:			
Age: _____ **Number of years of study: _____**			
Gender: ( ) male ( ) female	**Reason for admission:** ( ) surgical ( ) non-surgical	**Disease classification:** Presented disease _____	**Number of hospital admissions:** _____
Number of days hospitalized in the current hospitalization:_____			
2nd PART: Mark the score that best represents your level of participation in the treatment, assigning the following values according to each item analyzed: 1- little participation; 2- moderate participation; 3- maximum participation.			

	1-My participation in this item is minimal	**2-My participation in this item is moderate**	**3-My participation in this item is maximum**
1 – Do you think that health professionals make enough time available to care for you?			
2- Do you understand well what health professionals say during your care?			
3- Do you feel that the nurse understands what you say to him/her during your care?			
4- Does the nurse give you the chance to talk about what you are feeling?			
5- Do you feel confident in what the nurse and other health professionals tell you?			
6- Do you think that the time they offer you is sufficient?			
7- Do you know your clinical diagnosis?			
8- Do you know the therapeutic plan (treatment) that is planned for you?			
9- Do you understand that basic needs, such as sleeping well, physical comfort, bathing,			

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food and hydration are important for your recovery during your hospital stay?			
10- Do you know the names of the professionals who care for you and what each one's role is?			
11-Do you realize that, in addition to your information, health professionals also collect information from your family members about what they know about your treatment?			
12-Do you know all the times to take your medications, how many times a day and where your medications should be administered?			
13-When you are talking to the professional, do you notice if they pay attention to what you say so they can later answer your questions?			
14-Do you ask what the medications are for?			
15-When you realize that the treatment measures are not adequate, do you talk to the professional and ask them to do it correctly?			
16-Did you know that, by law, patients have autonomy and freedom regarding their health?			
17-Do you understand that, by law, if you have refused medical treatment, this decision must be respected?			
18-When you are undergoing a procedure, do you usually ask the professionals about this treatment?			
19-Do you understand that health professionals must wear appropriate clothing to avoid contamination and possible infections?			

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20-Are you informed about the risk factors for hospital infections?			
21-Do you understand that patients who have been bedridden for a long time can develop wounds and that you should change their position to prevent this from happening?			
22-Do you ask about your treatment options for your illness?			
23-Do you usually ask about the results of the tests that are performed on you?			
24-Do you know that there are ways to prevent bedridden patients from falling?			
25-Do you understand that professionals must know all of your identification information to avoid errors?			
26-Do you know that there must be at least two pieces of information about you on your bed to avoid swapping them with other patients?			
27-If you are being assisted by a companion, do you pass on the responsibilities of monitoring your treatment to them?			
28-Do you understand that patients can request a recording of their medical consultation and that of other healthcare professionals if they have difficulty understanding the instructions or are afraid of forgetting them later?			
29-Do you understand that you can seek a second opinion from another professional about your health condition and treatment?			
30-Do you participate in decisions about your treatment?			
31-Considering the infrastructure, do you feel			

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safe being hospitalized in this institution?			
32-Do you know the estimated length of hospital stay?			

DISCUSSION

The proposed data collection instrument was based on five major themes (patient safety goals, communication between professionals and patients, patient autonomy, drug therapy management and therapeutic conduct) that are also present in other questionnaires with the same purpose, such as the Patient Measure of Safety (PMOS)(14) and the Patient Participation Questionnaire (PPQ)(15), which, although they offer good psychometric validity indices, have variable effectiveness according to the environment and culture in which they are applied.

Items 19, 20, 21, 24, 25, 26 and 31, which address the patient safety goals established by the World Health Organization (WHO), reinforce that patient participation in understanding and monitoring these goals contributes to preventing errors and is essential to promoting safety. Studies show that when patients are well informed about safety practices and their responsibilities, there is greater adherence to recommendations and a reduction in adverse incidents[16,17].

Regarding communication between health professionals and patients addressed in items 1, 2, 3, 10 and 13, evidence suggests that clear and open communication between patients and multidisciplinary teams results in better clinical outcomes and a safer care environment[18]. Patients who feel comfortable expressing their concerns about treatment and safety are more likely to actively participate in their care, because as they feel included in the decision-making process, their level of understanding about therapeutic interventions increases[19].

Regarding patient autonomy, covered in items 4, 9, 16, 17, 27, 28 and 29, the literature emphasizes that patients who perceive that they have autonomy to make decisions about their care, within the limits of their clinical condition, tend to be more engaged and committed to safety practices, which contributes to improving the quality of care and safety[20]. Promoting autonomy is directly associated with patient empowerment, allowing them to actively participate in decisions about treatments and therapies, in addition to questioning practices and suggestions from health professionals when necessary[21].

Items 12 and 14 address drug therapy, which is one of the most critical aspects of patient safety, as medication errors continue to be one of the main causes of harm in the hospital setting[22]. Patient participation in managing their own medication, whether through reporting allergies, medications in use or even clarifying

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doubts about dosage, is essential to prevent incidents related to medication use. Studies suggest that active patient collaboration in reviewing their medication prescription contributes to reducing errors[23].

In addition, therapeutic procedures are addressed in items 5, 6, 7, 8, 11, 15, 18, 22, 23, 30 and 32. Research converges that safety can be significantly increased when patients are included in the decision-making process regarding the type of treatment to be followed, having the opportunity to express their preferences and clarify doubts about the proposed procedures. Furthermore, when there is a clear understanding of the risks and benefits associated with therapeutic procedures, they become active partners in reducing complications and adhering to the guidelines of health professionals(19). Studies also suggest that checking therapeutic procedures with the patient before performing procedures, such as surgery, significantly reduces the risk of failures in the process[20].

Regarding the profile of judges who participated in the validation stage, characteristics similar to groups that conducted this process in other studies on the topic of patient safety were observed[24,25]. Using experts to perform content validation is the gold standard for providing critical insights into whether the instrument effectively measures the intended variables, since they assess the relevance and clarity of the items, ensuring that the instrument covers all necessary aspects of the concept being measured[26,27].

When calculating the CVI of each item of the instrument, a variation of values between 0.80 and 1 was observed. This index is used in the health area to measure the proportion or percentage of judges who agree on certain aspects of the instrument and its items and whether it is adequate for its purpose. Studies that measured the CVI in instruments to measure constructs related to patient safety found values of 0.93(28), 0.95(29) and 0.97[30], respectively, thus demonstrating that it is a crucial metric used to validate health instruments, particularly in patient safety, assessing the relevance and clarity of the items.

As for internal consistency, the results found in the study showed that the instrument composed of 32 items presented a total Cronbach's alpha of 0.774. In addition, the analysis of the item-to-total correlation revealed that all items presented an item-to-item Cronbach's alpha greater than 0.70. According to the literature, the value obtained shows good internal consistency between the items of the instrument. Cronbach's alpha is a statistical tool that aims to validate a questionnaire so that it is properly designed and reliably reproduces the reality of the study, which is expressed by means of a factor, the degree of reliability of the responses resulting from a questionnaire[31].

The development of a validated instrument has the following advantages: practicality in application; production of reliable

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indicators for clinical practice, health assessment and research; influence on decisions about care, treatment and/or interventions and formulation of health programs and policies[12].

Even with content validation, validation with the target audience becomes necessary at a later date. Externally validating the instrument will be essential to analyze whether it is understandable and clear or not for patients, and consequently proceed to make the adjustments in the best possible way for the target audience. Thus, the aim is to minimize the risks of adverse effects and damage to the health of hospitalized patients resulting from care, thus favoring the success of the therapy used for this population.

When considering the implications for clinical practice, the validation of this instrument has the potential to directly impact the way nursing professionals and other members of the healthcare team interact with patients regarding safety. By using this questionnaire, it is possible to obtain a more accurate understanding of how patients perceive and participate in hospital safety practices, allowing for the implementation of more focused and effective interventions. In addition, the continued use of tools such as this can promote a more collaborative care environment, in which patients are recognized as active partners in promoting their own health and safety[32].

Regarding the limitations present throughout this study, we can mention the difficulties encountered in relation to the time to obtain responses from some specialists, as well as the barriers arising from the current pandemic, the latter of which culminated in preventing progress towards the full validation of the instrument, which would have been done by applying it to the target audience, and it was only possible to carry out internal validation with nursing professionals.

Regarding future perspectives, it is expected that this research will spark interest in raising a critical and reflective view of academics, nursing professionals and the scientific community on the topic involving the safety of hospitalized patients, thus contributing to encouraging their participation in their treatment and improving the bond between the patient and the health team, resulting in a reduction in adverse events and the success of therapies employed within the hospital environment.

CONCLUSIONS

The instrument, composed of 32 items, presented validation evidence with a total Cronbach's Alpha of 0.774 and a global CVI of 0.84, which demonstrates that it is adequate to verify the level of patient participation in relation to their own safety in a hospital environment. It is reinforced that this is a preliminary study and, therefore, cannot generate consensus on the use of the instrument. Therefore, further research is recommended to increase the number of

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applications and obtain a greater impact on its reliability and replicability.

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Authorship criteria (authors' contributions)

Solange Tatielle Gomes, Weslânia de Carvalho Paixão and Francisco Gilberto Fernandes Pereira - contributed substantially to the conception and/or planning of the study; in obtaining, analyzing and/or interpreting the data.

Indira Camilly Esmero Carvalho e Silva, Maysa Lis Luz e Silva, Maria Luiza Sousa Carvalho, Alyne Luz Almeida and Márcia Laís Forte Rodrigues Matos - contributed to the writing and/or critical review and final approval of the published version.

Declaration of conflict of interests Nothing to declare.

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