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HEALTH TECHNOLOGY ASSESSMENT UNIT PROCESSES FOR THE VALIDATION OF AN INFORMATION TOOL TO INVOLVE PATIENTS IN THE SAFETY OF THEIR CARE

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Introduction: Patients and families play an important role in preventing adverse events. The quality council at our hospital produced a communication tool in considering the main causes of adverse events and requested the health technology assessment (HTA) unit to validate it.
Objectives: Assess the validity of the content of a tablemat sticker as an information tool for hospitalized patients.
Methods: A qualitative validation was first performed with individual interviews and focus groups to evaluate the understanding of the content. The tool was modified and as a second step, a survey was conducted on patients and their families from a surgical care unit to validate their understanding and relevance of the content.
Results: From the survey, patients and families found the tablemat attractive and stimulating (97 percent). It encouraged them to communicate with staff about the safety of their care (84 percent). They understood well the objective (79 percent) and text (90 percent), but less for the pictograms (30 percent to 62 percent). The communication and recommendations to avoid falling were good and 99 percent were wearing the medical identification. However, it was not clear that these indicators represented the real concerns of the patients and healthcare staff because no user evaluation was done when developing the tool.
Conclusions: The tool was well understood, but some improvements are needed considering that pictograms were not always well understood and so need careful consideration from patient perspective. The HTA unit recommended conducting an unbiased survey to assess the concerns of patients and professionals to identify the most relevant indicators.

Keywords: Information tool, Validation, Relevance, Healthcare, Health technology assessment unit

Patients and families play an important role in preventing adverse events when they actively participate in the care process by asking questions and making comments (1;2). Patients are able to reduce medical errors by providing information to clinicians and healthcare professionals about their medical histories, medications and drug allergies. They can notify clinicians of unexpected side effects, and some patients may recognize lapses in care in time to prevent an adverse event (2). Several documents have been produced by different organizations to guide users during their care, and communication with healthcare professionals is known to be a basic component of care (3–5).

Professionals have to encourage patients to discuss their concerns and care, to listen advices and to ask questions if the information is not clear (5–7). Weingart et al. (8) reported that patients with high participation in their care reduced their risk of adverse events during admission by half, but also that participation in their care was associated with favorable judgments of hospital quality. To reinforce this communication, some tools should be developed. This article presents the development of such a tool and describes the efforts of a hospital-based health technology assessment (HB-HTA) unit to validate this tool.

CONTEXT OF THE APPRAISAL

In June 2013, Accreditation Canada requested the Centre Hospitalier Universitaire de Sherbrooke (CHUS) comply with the Required Organizational Practice (ROP) to provide information about the role of users and families in the safety of their care. This ROP requires that healthcare staff provide written and verbal information to patients and families about their safety role. The importance of this ROP was highlighted in the annual report produced by the Canadian Institute for Patient Safety (9) and by the Manitoba Institute for Patient Safety (3).

To comply with this recommendation and because the CHUS viewed patient safety as one of its five organizational priorities, CHUS carried out an analysis of the main causes of adverse events reported in the incident/accident reports (AH.223). This analysis complied with international recommendation to consider organization perspective associated with local data for patient safety (10). The main events reported

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to the CHUS involved patient identification, medication errors and communication with patients about falls. With this information, the CHUS quality council produced a communication tool in the form of a tablemat sticker in collaboration with the communications department. The aim of the quality council was to encourage patients and their families to ask questions and initiate a dialogue with healthcare professionals as well as to access information about their health and care and adopt the behaviors proposed by the pictograms and statements on the tablemat sticker.

ROLE OF THE HB-HTA UNIT

After the creation of the communication tool, the CHUS quality council asked the HB-HTA unit to assess the impact of the tablemat sticker. After discussion, the HB-HTA unit recommended to first assess the validity of the tool from patient and carer perspective before performing an assessment of its impact on patient and carer behavior. The priority was thus changed to an assessment of the validity to ensure that the content was adequate and well understood by patients and their families. The HB-HTA unit used its expertise to conduct the validation process and provide recommendations about further improvement and/or implementation of the tool. At that time, the HB-HTA unit was composed of five individuals with various expertizes, including systematic review, economics, statistics, ethics, computer science, and clinical research. A more exhaustive description of the unit can be found in Bellemare et al. (11).

OBJECTIVE

The objective of this article is to assess the validity of the content of the tablemat sticker as an information tool for hospitalized patients. The validity was measured by assessing the understanding and relevance of its content and presentation.

METHODS

The HB-HTA unit first conducted a scoping review to identify whether such a tool had already been used in other healthcare settings and to find additional guidance on how to validate such a tool. This review was conducted in July 2013 and updated in February 2014. Searches were performed on PubMed and Google. Keywords used were: patient, enablement, empowerment, engagement, instrument, tool, and safety. Studies not related to healthcare settings were excluded. The searches yielded 404 references and 68 were reviewed in full or in part. The processes for developing and validating the tool are described in the following sections.

Scientific Literature

Hospitals are increasingly promoting patient and family engagement in healthcare to help prevent adverse events (2;6–8;12;13). According to the literature, it appears to be difficult to create an effective intervention to assist patients and carers in this role. A systematic review of the literature by Hall et al. (14) suggests that there is limited evidence to demonstrate the effectiveness of interventions to promote patient participation for the purpose of reducing incidents. In addition, studies are generally of poor quality. The only positive results were related to the promotion of self-management of drug safety, especially self-management of oral anticoagulants. Another systematic review by Berger et al. (15) also concludes that there is insufficient quality evidence to inform people about the implementation of interventions to promote patient and family engagement in patient safety, that is, make clear how patients and families are being engaged.

Maurer et al. (12) reported two types of strategies or interventions to facilitate the participation of patients and their families, including strategies at the hospital level and at the individual level. Interventions at the hospital level are changes in policies, processes, systems, procedures or structures. Interventions at the patient level are designed to modify individual knowledge, attitudes and skills using tools that educate and inform patients to encourage engagement. These two types of interventions are not mutually exclusive. Tools for individuals can support interventions at the institution level through adoption of new patient behaviors that can be facilitated by the institution's support.

Aujoulat et al. (13) also noted that the goals and outcomes of patient engagement should neither be predefined by health professionals nor be strictly related to certain diseases and their treatments; instead, they should be discussed and negotiated by considering the situation and priorities. Spence Laschinger et al. (16) suggested that health managers implement strategies that empower nurses, which will lead them to be more inclined to use strategies to empower their patients. The authors argued that this dual "empowerment" aimed at nurses and patients offered better outcomes for patients and the organization. As for strategies for communication programs, Schulz and Nakamoto (17) explained the importance of including elements for empowering nurses and empowering patients to motivate them to become engaged. In addition, the communication tools must be accessible in terms of language and nurses could play a role in the transmission of such knowledge, which would enable patients to understand and use this information.

Several tools are available to involve patients in the safety of their care, including leaflets, posters, messages on screens, etc. However, these avenues are considered ineffective, especially in acute care settings, and they may increase the risk of infections (14;15;18). There is no study in the literature concerning the use of tablemat stickers placed on removable tables in patient rooms to increase their engagement in healthcare. In addition, these studies do not report whether similar tools were validated and how.

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Development of the Tool

The first version of the tablemat sticker was produced in 2013 by a committee that included three members of the quality council (i.e., the manager responsible for accreditation, the manager of patient experience and the care manager at the surgical care unit) in collaboration with the communications department. The quality council consisted of nineteen representatives of the CHUS, including managers, nurses, pharmacy and professional representatives. To note that there was no patient representative in the quality council.

The CHUS quality council evaluated the main causes of adverse events reported in the incident/accident reports form (AH.223) and solutions to remedy them. The main events reported included events resulting from patient identification, medication errors and patient falls. Better communication between healthcare staff and patients could prevent many of these events. Healthcare staff was those who interact with the patient during its episode of care (i.e., nurses, physicians, medical trainees, and beneficiary attendants).

The aim of the message that the quality council wished to convey through the tool was for patients and providers to communicate and act together for safety while considering these three themes: (i) health status and patient care, (ii) identification of the patient by wearing the medical identification bracelet, and (iii) use of the call-button located in the rooms to prevent falls. The tablemat sticker was developed for all inpatients being able to communicate about their care, which excludes intensive care and some mental health patients.

In the original version of the tablemat sticker, which was outlined by a red square, the title was "I work for MY HEALTH and MY SAFETY at the hospital" (i.e., *J'agis pour MA SANTÉ et MA SÉCURITÉ à l'hôpital*). A blue section on the sticker was about the health status and patient care as well as suggesting that patients listen and ask questions about their health status, surgery, care, medication, returning home, and convalescence. A green section focused on identifying the patient by wearing the medical identification bracelet. The title of this section was "I wear my bracelet at all times" (i.e., *Je porte mon bracelet d'hôpital en tout temps*) and it indicated that the staff need it to verify patient identity before any care interventions are provided. An orange section was used to encourage patients to use the call-button located in the rooms to prevent falls. The title was "I follow the instructions for not falling" (i.e., *Je suis les consignes pour ne pas faire de chutes*)" and the text below recommended asking for help to get up and do not be afraid to disturb providers because it is better to call than fall!

The communications department chose pictograms, colors, and text size and revised the text to be clear and to be understood by people with little literacy. A clinical counsellor from general medicine and emergency care reviewed the final product. The tool was printed on self-adhesive laminated paper.

Before assessing the validity of the tool, in 2013, the quality council decided to test it at the surgical care unit. The choice of this unit was motivated by its elderly clientele who do not necessarily ask many questions (hence the focus of the informational tool) and because it includes postoperative patients who are hospitalized for several days and had time to familiarize themselves with the tool.

Validation Process

The validation of the tool was carried out in two phases. First, a qualitative validation was performed with individual interviews and focus groups to evaluate the understanding of the content. The tool was modified, and in the second phase a survey was conducted on patients and their families from a surgical care unit to validate their understanding and the relevance of the content.

Qualitative Validation. The first step of the validation process was to evaluate understanding of the content of the initial tablemat as an information tool with healthcare staff and patient representatives. A validation committee was created and included members of the HB-HTA unit, the three members of the quality council previously mentioned, and a medical doctor external to the project.

Two professionals from the HB-HTA unit performed a qualitative validation of the original version using a semi-structured interview guide. The individuals who were interviewed included one occupational therapist from general medicine and emergency care, a nurse and a hospital user. This was the first contribution of a patient in the process validation. The HB-HTA unit organized several meetings with the validation committee to discuss the various comments and suggestions for modifications. A new version was developed, and another round of interviews was conducted. Except for the nurse, the interviews were conducted with different individuals (i.e., another occupational therapist and hospital user), and an intensivist physician was also consulted.

Additionally, two focus groups were conducted. The first focus group included nurses, a head nurse, nursing assistants, and beneficiary attendants (i.e., a person who ensures the hygiene, well-being, and surveillance of the users) from a surgical care unit. The second focus group included members of the users committee (i.e., 10 representatives). The validation committee established a list of modifications and developed a third version with the communications department.

The semi-structured interview guide included the following three main topics: (A) presentation (color, graphics, font size, layout of text, and images, etc.); (B) understanding (understanding of the text, message conveyed, etc.); and (C) achievement of the objective (message meets expectations and how to improve the tablemat).

Validation with Mixed Method Research Design. A mixed method of validation process was conducted to assess the understanding of patients and their families as well as the relevance of the

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modified tablemat (i.e., the third version) (19). A convenience sample included ninety-nine consecutive patients from the surgical care unit of the CHUS who consented to participate. An interviewer, who was from outside the CHUS, evaluated interest in participation, and, in cases with positive consent, she administered a questionnaire with open and close-ended questions and "free comments" were collected. The interviewer helped patients with low health literacy by rephrasing and reiterating the questions to ensuring the patient's understanding. In case of refusal, she documented the reasons for.

The questionnaire was divided into three sections. The first section assessed the understanding of the content in three subsections: (A) presentation (i.e., interest in reading the tablemat, significance and understanding of pictograms); (B) understanding the text (understanding of the text, message conveyed, etc.); and (C) achievement of the objective (i.e., message meets expectations, how to improve the tablemat, incentive to communicate).

The second section was designed to assess the relevance of the indicators defined by the three themes that were selected and if they were of concern for patients and their families. This section evaluated if patients asked questions about their medical conditions (medication, discharge, etc.) and received an adequate response from the medical team, if the medical team asked questions about the tablemat content or encouraged questions, if patients wore the medical identification bracelet, if patients used the call-button for help, if patients received information to avoid falling and if they followed the recommendations. The third section of the questionnaire corresponded to the collection of data on quality control variables (cognitive status of the patient, duration of hospitalization, etc.) with the assistance of the head manager of the care and surgical care unit. The interviewer also collected comments freely provided by the patients in this section.

RESULTS

Qualitative Validation

Visual Presentation. For the visual aspect of the tablemat sticker, the comments provided by interviews and focus groups in early 2014 led to several changes (Figure 1). In the original version, the colors were more pastel and a comment suggested that these colors were more difficult to distinguish for a color blinded patient; the colors were changed to be more contrasting. In the blue section, the pictograms of the ear and the question mark were reversed to match with the text "I listen, and I ask questions about" (i.e., J'écoute et je pose des questions sur). In the orange section, the call-button was changed to red and a space has been added with the thumb to better distinguish the button. A greater color contrast was applied for the green and orange sections with the hands of the pictograms to make it easier to distinguish them. The lettering was darkened to make the information more readable.

Understanding. For better overall understanding, occupational therapists suggested that the message the CHUS wanted to convey, which was to communicate, should appear in the red title and be worded as follows: "TO COMMUNICATE is IMPORTANT" (i.e., COMMUNIQUER c'est IMPORTANT). Because the initial message was also important to make patients and their families more likely to become involved in their health care during hospitalization, a new red square with this title was added to the bottom of the tablemat. According to occupational therapists, the red color catches the attention of older people without increasing their aggression.

Similarly, it is preferable to use affirmative slogans to facilitate understanding and consequently for patients to retain the information. The text in the green and orange sections was changed to more affirmative messages. The text in the gray square was also written in darker text, and the red text stating "your health and safety are important to us!" (i.e., votre santé et votre sécurité nous tiennent à coeur!) was changed to "I inform the staff about any situation that worries me" (i.e., J'informe le personnel sur toute situation qui m'inquiète). The new text still aims to convey the message that it is important to communicate.

Achievement of the Objective. As indicated earlier, the original tablemat has been introduced in one surgical care unit before the HB-HTA unit became involved. Therefore, it was possible to ask the medical team if the original tool helped to reinforce communication with patients and their families to improve care safety. Some professionals that were interviewed indicated that the original tablemat was only an informative support tool to encourage the patients to communicate so that they can collaborate and engage in their health and care. According to others, the tablemat in general was intended for a clientele with no or very little cognitive difficulty (memory problems, linking abilities, etc.).

Validation with Mixed Methods Research Design

Patient Characteristics. Between June 10 and July 10, 2014, a total of 115 patients hospitalized in a surgical care unit of the CHUS were approached to participate in the validation process of the tablemat sticker. Of them, ninety-nine consented to participate, four refused, and twelve were not fit to respond. An interviewer collected data on each Tuesday and Thursday with a questionnaire that included open and close-ended questions.

Patient characteristics are presented in Table 1. Patients were hospitalized for at least 2 days with a median hospital stay of 4 days. All but one of them received a previous visit from their surgeon. The majority of patients were Francophones, except two who were unilingual Anglophones

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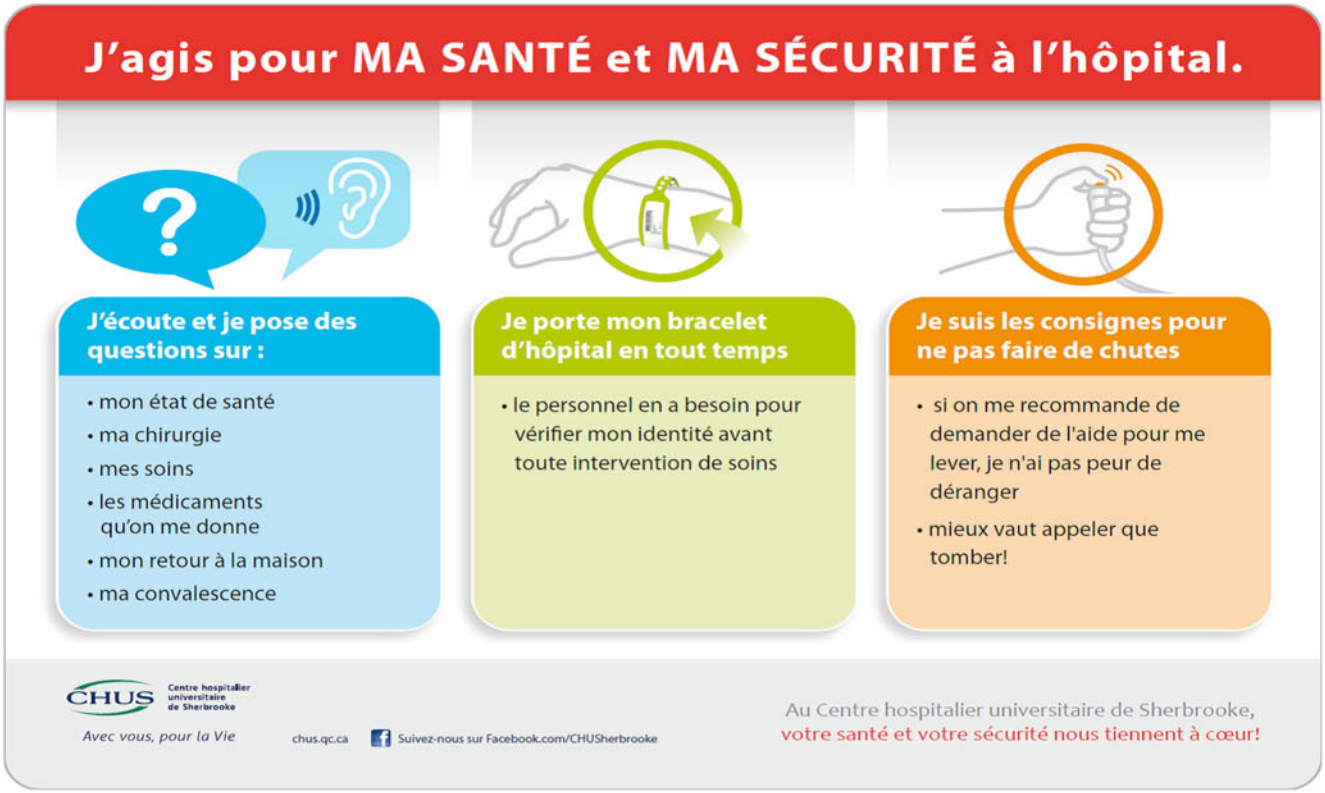
A) Original version



B) Final version

Figure 1. Original (A) and final (B) version of the tablemat sticker.

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Table 1. Patient's Characteristics

	Value ($n = 99$)
Hospitalization time (days), median (IQR)	4 (3–6)
Age (years), mean ± SD	64.6 ± 5.34
Number of women	54
Number of patients accompanied by family	33
Family member responded for patient	3
Patient responded with family support	7
Wearing the medical identification bracelet	98

IQR, interquartile range (25th–75th percentiles); SD, standard deviation.

who participated only in the validation of the presentation and understanding of the pictograms. During the interviews, thirty-three family members were present. Of them, three answered the questionnaire and seven helped patients to answer. All patients wore the medical identification bracelet, except one who could not wear it and placed it on his bedside table.

Understanding

General Presentation and Pictograms: The general presentation of the tablemat sticker stimulated eighty-six of eighty-nine (96.7 percent) of patients to read it. For the three pictograms that were used, the interviewer asked patients what the images represent or signify (Supplementary Table 1). The first pictogram in the blue section corresponded to "I listen, and I ask questions." Only twenty-seven of ninety-one (29.7 percent) patients fully perceived the meaning of the message, thirty (33.0 percent) patients partially understood it, and to thirty-four (37.4 percent) patients, the message did not seem clear. The second pictogram in green represented wearing the medical identification bracelet for identification and fifty-six of ninety-one (61.5 percent) of the patients perceived the meaning of the information transmitted very well. The last pictogram in orange represented the message to use the call-button located in the rooms to prevent falls. Of ninety-one respondents, twenty-eight (30.8 percent) users fully understood the meaning, while fifty-two (57.1 percent) only partially understood it and eleven (12.1 percent) did not perceive it or understood it very badly.

The Text: For understanding of the text, eighty-eight patients responded (Supplementary Table 1). For the first red square on the top, "TO COMMUNICATE is IMPORTANT" (i.e., *COMMUNIQUER c'est IMPORTANT*), seventy-five of eighty-eight (85.2 percent) of patients understood the meaning of the message. For the text in the blue, green and orange squares, eighty-two (93.2 percent), eighty-one (92.0 percent) and eighty-seven (98.9 percent) patients understood the text, respectively. The second red square, which was located at the bottom of the tablemat, was linked to the objective: "I act for my health and safety in hospital" (i.e., *J'AGIS pour ma santé et ma sécurité à l'hôpital*). Fewer patients (sixty-eight of eighty-eight, or 77.3 percent) understood this sentence.

An open question was asked to patients to evaluate if they believed changes or improvements should be made to the tablemat to improve understanding (size of the characters, change the text, etc.). Of eighty-five responses, fourteen (16.4 percent) answered "yes" and seventy-one (83.5 percent) "no." The majority had a positive perception of the tablemat, but some patients suggested modifications.

Achievement of the Objective: To assess if the tablemat achieved its objective, an open question was asked to assess what the message was that was transmitted by the tool. A total of sixty-nine of eighty-seven patients (79.3 percent) appeared to have fully or partially understood the objective of the tablemat. Table 2 includes the different perceptions from patients about the message conveyed by the tablemat. Finally, the last question asked whether this tool would encourage them to communicate with staff and to take more precautions for the safety of their care. Of eighty-three responses, seventy (84.3 percent) indicated a positive response and thirteen (15.7 percent) were influenced a little or not influenced.

Relevance of Indicators. This section assessed the relevance of the indicators defined by the themes that were selected (i.e., determining if the topics concerned patients and their family) (Table 3). For the blue section, seventy-seven of ninety-seven (79.4 percent) reported continuing or frequently questioning providers about their health and care, ten (10.3) sometimes, and ten (10.3) never. Of the eighty-seven who asked questions, seventy-nine (90.8 percent) considered the attitudes of the staff to be positive and eighty-three (95.4 percent) received adequate

Table 2. Perception of Patients about the Message Conveyed by the Tablemat

Perception of patients ($n = 87$)	*n* (%)
The message is related to communication only	25 (28.4)
The message is related to communication and security	13 (14.9)
The message is to ask questions about health	12 (13.8)
The message is related to security only	11 (12.6)
The message is refers to the three themes conveyed by the tablemat	8 (9.2)
The message is refers to the patient/health team relationship	7 (8.0)
The message is that the patient is important	5 (5.7)
The message is the importance of health	2 (2.3)
The message is that you need to call/get help	2 (2.3)
Various answers	2 (2.3)

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Table 3. Relevance of the Indicators for Communication and Utilization of the Call Button

	N Total	Always *n* (%)	Often *n* (%)	Sometimes *n* (%)	Never *n* (%)
Patients asked healthcare staff and doctors questions	97	71 (73.2)	6 (6.2)	10 (10.3)	10 (10.3)
The healthcare staff talked about the different points in the blue square	91	75 (82.4)	9 (9.9)	5 (5.5)	2 (2.2)
The healthcare staff encouraged patients to ask questions	89	69 (77.5)	9 (10.1)	3 (3.4)	8 (9.0)
Utilization of the call button for moving	91	79 (86.8)	7 (7.7)	3 (3.3)	2 (2.2)
The patient is embarrassed to call the staff to move when they need it	94	7 (7.4)	6 (6.4)	12 (12.8)	69 (73.4)
Followed recommendations to avoid falling	60	51 (85.0)	2 (3.3)	2 (3.3)	5 (8.3)

answers. For the interactions between the family and the healthcare staff, fifty-seven of ninety-four (60.6 percent) asked the staff questions and 100 percent of the responses were adapted to their information needs.

Concerning the participation of the care staff in patient communication, eighty-four of ninety-one (92.4 percent) patients answered that the healthcare staff always or often talked about the different points in the blue square and seventy-eight of eighty-nine (87.6 percent) patients answered that the healthcare staff encouraged patients to ask questions.

To assess the relevance of items listed in the blue section, the interviewer asked patients about their health and care concerns (Supplementary Table 2). Overall, eighty-three of ninety-two (90.2 percent) of patients were concerned about at least one listed item and 12 percent listed all of the items. The most important items were returning home (47.8 percent), their health (38 percent), and their convalescence (33.7 percent).

For the relevance of the green section, ninety-eight were wearing the medical identification bracelet. Only one patient could not wear it and placed it on his bedside table.

In the orange section, eighty-six of ninety-one (94.5 percent) of patients reported using the call-button always or often and eighty-one of ninety-four (86.1 percent) were not at all embarrassed or only a little bit embarrassed to call the staff to help them with their movements. Patients reported that the recommendations to avoid falling were transmitted by health personnel in only fifty-eight of eighty-seven (66.7 percent) of cases. Of these, fifty of fifty-seven (87.7 percent) admitted to following the recommendations to avoid falling.

DISCUSSION

It is important to find strategies to influence patients to ask questions to promote their involvement in the safety of their care. One strategy created by the CHUS was to develop a tablemat for patients to encourage patients and their families to ask questions and initiate a dialogue with healthcare staff as well as to access information about their health and care and adopt the behaviors proposed by the tool. The main objective of this study was to evaluate the content validity of the tablemat by demonstrating the understanding and the relevance of the chosen indicators.

The majority (97 percent) of patients found the tablemat attractive and stimulating to read, 79 percent appeared to fully or partially understand the objective of the tablemat, and 84 percent indicated that this tool would encourage them to communicate with staff to take more precautions for the safety of their care. More than 90 percent of patients understood the text below the pictograms but fewer patients clearly understood the pictograms (62 percent for wearing the medical identification bracelet, 31 percent for the call-button, and 30 percent for the ear and the question mark). The pictograms could be improved but it is nevertheless obvious that the message of the tablemat is generally well understood. Several suggestions were made by the patients to promote an even greater understanding of the tablemat message and its objectives.

For the relevance of the indicators in terms of communication between patients and healthcare staff, the results were very positive with 79 percent of patients asking questions and 88 percent of patients feeling encouraged to do so. Additionally, 90 percent of patients were concerned about at least one of the listed items and the main points that were discussed with the healthcare staff were their return home, health status and convalescence. Only 23 percent were concerned about the drugs they receive, but one of the main events reported to the CHUS concerns medication errors. This result suggests that it is important to find strategies to influence patients to ask questions to promote their involvement in the safety of their medication-related care.

For medical identification, 99 percent wore the identification bracelet but no question was asked about whether care staff looked at them before medical intervention, if patients understood the importance of wearing it or if patients asked the medical staff to validate their identity. In the free comments made by patients, one mentioned that he now better understands why it is necessary to wear the bracelet. This indicator

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may reinforce good behavior and inform patients about the reasons for its use. However, because all patients wore the bracelet, the use of this indicator remains questionable.

For the call button, 95 percent of patients reported using it always or often but 14 percent were still embarrassed to do so. The tablemat should help these patients not hesitate to call for help. Overall, 88 percent admitted following the recommendations to avoid falling, but 30 percent indicated that they did not receive recommendations from staff. Of them, the surgery was too recent for them to get up or discuss recommendations with staff. One patient was paraplegic, and the others said they were self-sufficient. These results demonstrated good patient adherence when they were informed. The tablemat should encourage patients and healthcare staff to share more about the risk of falls and how to avoid them.

The first version of the tablemat was used in patient rooms in the summer of 2013 before the validation process, which made it possible to collect information about its usefulness. According to the healthcare staff responses, "patients ask more questions about the drug that they receive in the hospitalization and the ones they take at home." They also show their identification bracelets. For the call button, healthcare staff said, "we know that patients do not use it, they are afraid to disturb us, and there has been no increase in calls."

Some limitations are present in our validation study. First, the construction of the original tablemat would have benefited from being developed from a theoretical construct that had already been validated (20;21). Its design was based on the experience of healthcare staff, the causes of adverse events reported in the incident/accident reports (AH-223) and the solutions to remedy them. It is not clear that the indicators presented on the tool represented the real concerns of the patients and healthcare staff. We have not verified whether other indicators would have been more appropriate for patients and professionals.

In the qualitative validation process with professionals, interest in the selected indicators was questioned by several professionals who were consulted, including the use of the bracelet and, to a lesser extent, the statements associated with the call button. However, the institution included the HTA unit only after the creation of the tool and its mandate was to validate the tool, not to redesign it. It would have been better to work collaboratively from the start, so that the HTA unit could have suggested the involvement of patients and a variety of healthcare professionals from the beginning to identify their concern. Also, dual "empowerment" offers better outcomes for patients and the organization (16;17). It would have been important to include in the tool more elements for empowering nurses and patients to motivate them to become engaged (17).

Another limit was that patients consulted in the various validation phases were not entirely representative of hospital users because only thirteen were consulted in the qualitative steps and that the ninety-nine in the survey were from a single healthcare unit. Although thirteen patients with different backgrounds is not so small for a qualitative study, considering that the tool was developed for a large hospital, this could be judged as insufficient. Also, the tablemat was not adapted for blind or poor eyesight patients and critical care patients. For blind or poor eyesight patients, family and staff could explain the importance of communication, ask questions and listen to advice. On the other hand, no blind patient was present when the study was realized. In addition, the choice of the tool used to convey the desired message has not been evaluated in relation to other possible supports (e.g., screen, flyer).

Another limitation was observed when the first version of the tablemat was used in patient rooms in the summer of 2013 before the validation process. The hygiene and sanitation department noted that the tablemat does not stick well to the table and can increase the risk of infections. There are other tools such as pamphlets, posters, etc., but these tools were considered ineffective, especially in acute care settings and may also increase the risk of infections (14;15).

Finally, patients were not randomly selected, which may have biased the representativeness of the population, and the number of participants could also have been higher. On the other hand, 96 percent of the patients who were interviewed participated very actively and suggested several changes.

The next step would be to identify the real concerns shared by patients and families as well as concerns shared by healthcare staff and physicians, which would allow the patients to be better involved in the safety of their care. The working group of Richards et al. (22) also support this approach, and they argue "Far more than clinicians, patients understand the reality of their own condition, the impact of the disease and treatments in their lives, and how services might be better suited to help them." In addition, it is necessary to evaluate how patients can be responsible for their safety. The tablemat should be modified according to the real concerns of patients and care staff, to validate the relevance of the new selected indicators and then assess its impact. Some of these steps were recommended by several teams of researchers (23–26). Leonard et al. (26) worked on a patient engagement project and indicated that patients can become co-responsible for their own care and outcomes with the acquisition of specific knowledge. To achieve this goal and to be fully empowered in this role, a three-step process must be followed: the patient must be engaged, active, and equipped.

Regarding the role of the HB-HTA unit in this validation process, its contribution was helpful to the institution for different reasons. First, the initial discussion between the HB-HTA unit and the quality council allowed to change the topic of the assessment and to avoid distribution of a tool in the care unit that may have been invalid. Second, it raised the question of the choice of the indicators in lines with what is recommended by Aujoulat et al. (13), that is to involve patients and

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care staff in this choice. Third, by avoiding a massive implementation of the tool, this approach helped to identify a potential concern of bacterial contamination (i.e., the tablemat did not stick well) and avoid adverse events.

All these elements were very helpful in the decision made by the quality council to not implement the tablemat until the recommendations of the HB-HTA unit were fulfilled. Another contribution of the HB-HTA unit is that a method has been developed to validate the content and relevance of a tablemat, which has never been done before. This is in line with previous works conducted in HB-HTA units that highlighted the importance of flexibility and innovation in HB-HTA practices to support co-creation of value in hospitals (27–32).

In conclusion, we observed a good understanding of the message and objective of the tablemat sticker despite some difficulty with the pictograms. In addition, many positive comments were received. In terms of the relevance of the indicators, it would have been preferable to assess indicators with patients and healthcare staff regarding what the real problems were and determine the tool that would be best to use, which was recommended by the HB-HTA unit. A next step is thus to conduct a study to comply with these recommendations using a patient-centred approach.

The main objective of this study was to validate the understanding and relevance of the content of the tablemat promoted by the quality council of the CHUS. Therefore, we did not evaluate the impact it would have on patients' involvement in regard to the safety of their care, and a subsequent study is necessary. Because the initial request of the quality council was to assess the impact of the tablemat, this study shows that a HB-HTA unit has the ability to influence a request in a way that is beneficial for the institution. Indeed, without the HB-HTA unit, the invalidated tablemat would have been printed and distributed to care units.

SUPPLEMENTARY MATERIAL

Supplementary Table 1:
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Supplementary Table 2:
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CONFLICTS OF INTEREST

The authors have nothing to disclose.

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