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Do Patients and Relatives Have Different Dispositions When Challenging Healthcare Professionals About Patient Safety? Results Before and After an Educational Program

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Background: There is a universal interest in evaluating the new roles of patients to improve patient safety. However, relatively little is known about the contribution of family caregivers. The purposes of this study was to determine whether patients and relatives (P&Rs) have different dispositions when challenging healthcare professionals about patient safety and to measure the influence of an educational program.

Methods: An interventional before-and-after design was used to determine the P&Rs' basal level of willingness and the influence of a training program. One hundred thirty-six participants were recruited, 90 patients and 46 relatives, from the Day Hospital of a Tertiary Hospital in Spain, in 2018.

The safe practices selected were as follows: patient identification, hand hygiene, blood or chemotherapy identification, and secondary effects of treatment. The educational materials comprised brochures and story-type videos. A questionnaire measured participants' willingness to speak up before and after the training.

Results: One hundred thirty-six P&Rs (63% response rate) agreed to participate. The hypothesis that relatives are more willing to challenge healthcare professionals could not be proven. Their willingness to speak up depended on the type of safe practice both before and after training, ranging from 42% to 87%. The percentage of items that P&Rs were willing to challenge increased after the training among both the patients and the relatives, but statically significant differences were only seen among patients.

Conclusions: After the training, participants' willingness to challenge healthcare workers was high for all safe practices analyzed but hand hygiene. Patients and relatives had very similar willingness. After the training, participants felt confident with their knowledge about safe practices, thereby increasing their challenging attitude.

Key Words: speak-up, patient safety, educational program, safe practices

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All over the world, the participation of patients and relatives (P&Rs) to improve patient safety has become an area of increasing interest in policymaking, research, and healthcare management and practice.¹ Among others, the Council of Europe and the Alliance for the Safety of Patients of the World Health Organization underline the importance of the participation of P&Rs to improve the safety of healthcare. General campaigns such as “Speak up” and “Please ask,” or more specific initiatives, e.g., the safe administration of medicines and reducing the control of infections, have been launched in different organizations.²

However, despite substantial investment in researching and improving patient safety, the desired level of progress was not reached.³

Despite the important role that family caregivers can play, relatively little is known about their specific contribution to patient safety and whether their interactional behavior is different from that of the patients. Most of the existing studies focus on patients' participation.

Patients and relatives are uniquely placed and sometimes are the only ones who can observe the care or the consequences of the care offered by healthcare workers. For that reason, different organizations are trying to encourage and empower P&Rs to play an active role in patient safety. However, patient participation is a complex concept. No single definition exists and various terms such as patient collaboration, patient involvement, partnership, patient empowerment, or patient-centered care are used as synonyms.⁴

Patients and relatives can play a wide variety of roles through the entire process of patient care. Some examples include helping design more safety-oriented healthcare settings; detecting errors in preparation, monitoring, and follow-up; and promoting the use of safety systems, training healthcare workers, reporting adverse events, and speaking up if there are any safety-related concerns about the care received.^{5,6} In summary, we could say that there are 3 roles in improving patient safety: helping ensure the patient's own safety, working with healthcare organizations to improve safety at the organization and unit level, and citizen advocacy for public reporting and accountability of hospital and health system performance.⁷ However, there is a lack of information on P&Rs' preferences and willingness to play this new role.⁸

To participate, P&Rs need to fulfill 3 requirements: knowledge and awareness of participation, ability to participate, and willingness to participate.⁶ Health organizations can improve knowledge through educational programs. Knowledge also confers confidence: patients are more likely to trust their capacity to make decisions when thoroughly informed.⁴

The influence of educational programs not only improves health literacy but also may modify P&Rs' awareness of safety perception and their willingness to participate in their own safety.

In addition, it is important to note that most patients want to give their relatives the opportunity to be involved in their important health decisions. Some even prefer their relatives to make decisions for their treatment.⁹ This involvement goes beyond clinical

decisions. Relatives can serve as patients' eyes and mouth and play a very important role in their safety. Thus, recognition of the influences relatives have within the clinical encounter can lead to safer, more efficient, and more effective healthcare.¹⁰ Nonetheless, the influence and preferences of the relatives in patient safety has not received the attention it deserves.

Many health organizations provide "educational" materials to support P&Rs in playing a more active role in patient safety and encourage them to "speak up". However, there is insufficient research to (a) measure the effect of educational programs for P&Rs on their challenging attitude and (b) determine whether this effect is different depending on whether they are patients or relatives.

Thus, the purposes of this study were to increase our understanding of the different willingness of P&Rs when challenging healthcare professionals about patient safety and to measure the influence of an educational program on the challenging behavior.

Hypotheses

Relatives are more willing to challenge healthcare professionals than are patients both before and after the training.

A training program can increase participants' willingness to challenge healthcare professionals

The willingness of P&Rs to challenge depends on the safe practices.

METHODS

Design

This study used an interventional before-and-after design to determine the influence of a training program.

Participants

A consecutive sample of 136 participants was recruited between March and October, 2018, from the Day Hospital of a Tertiary Hospital in Navarra, Spain. Participants included 90 oncological and hematological patients and 46 relatives. Patients were eligible to participate if they were older than 18 years, it was not their first treatment appointment, their treatment lasted several hours, the healthcare professionals in charge considered their physical and psychological status as acceptable, and they were able and willing to give their informed consent to participate.

Patients' relatives were recruited after being informed and providing their consent to participate. For this study, we considered not only family members but also friends or informal carers as relatives.

Measures

The safe practices selected for evaluation were as follows: patient identification, hand hygiene, blood or chemotherapy identification, and secondary effects of chemotherapy/transfusion.

A survey tool was developed to assess P&Rs' willingness to challenge healthcare professionals. Six additional demographic variables captured patients' characteristics age, sex, education, number of day hospital and hospital stays during last year, and whether they were healthcare professionals.

Two variables captured healthcare characteristics that can influence patient-reported willingness to challenge healthcare professionals: professional category and sex.

Categorical or dichotomous scales were used.

Two questionnaires with similar items were used: one for oncological P&Rs and one for transfusion P&Rs. The items were formulated depending on whether the participant was a patient or a relative.

A composite item called "willingness to challenge" was created to analyze the P&Rs' degree of willingness to challenge healthcare professionals.

The percentage of willingness to challenge healthcare professionals was measured for each participant depending on the number of challenging questions with a positive answer. Participants were classified into 4 groups depending on their willingness to challenge with 0%–25%, 26%–50%, 51%–75%, and more than 75%, representing low, medium, high, and very high challenging profiles, respectively.

Procedure

The research materials (questionnaires, brochures, and videos) on chemotherapy and transfusion were pretested on 29 and 19 individuals chosen as convenience samples, respectively. Their answers helped improve the material but were not included in the final results.

One member of the research team, after explaining the purpose of the study, guided each participant on an individual basis through the different steps of the study. To begin with, the P&Rs answered a questionnaire about their willingness to challenge healthcare professionals' in case they observed nonadherence to a safe practice.

Then, they were provided with a training brochure explaining the importance of healthcare professionals adhering to safety protocols to ensure patient safety and the protocols they have to follow to implement the 4 safe practices selected for evaluation.

Afterward, participants watched a video that was played on a tablet. It showed a patient who goes to the Day Hospital to receive chemotherapy (for chemotherapy P&Rs) or to receive transfusion (for transfusion P&Rs). Both videos were in a story-like format (movie-type video) intending to show, in the most realistic way, the interaction between a patient and healthcare professionals during treatment. The right way to implement the safe practices was highlighted in the video. Participants could watch the video as many times as they wished.

After reading the material and watching the videos, the participants once again filled out the questionnaire about their willingness to challenge these professionals. The whole process lasted approximately 60 minutes. The participants could ask questions during this process.

Data Analyses

Data were analyzed using IBM SPSS Statistics 25 for Windows. Nonparametric tests, such as the Mann-Whitney *U* test, Fisher exact test, and Pearson χ^2 test, were used to compare differences between the patients and the relatives; Wilcoxon and McNemar tests were used to compare before-after results.

To analyze P&Rs' willingness to challenge, we analyzed the variables: age, sex, educational level, type of participants, type of treatment, number of Day Hospital visits, number of hospital stays, adverse events suffered, hospital safety perception, and number of safe practices participants are able to recognize after training.

RESULTS

Participant Characteristics

In total, 136 P&Rs agreed to participate (63% response rate). Table 1 represents their characteristics.

The percentage of females was higher than that of males, and the mean age was lower in the groups of relatives than in the group of patients, with statistically significant differences.

TABLE 1. Participants' Characteristics

Sociodemographic Variables	Patients	Relatives	P
	n = 90 (%)	n = 46 (%)	
Sex			
Male	50 (55.6)	14 (30.4)	0.007
Female	40 (44.4)	32 (69.6)	
Education			
Basic level	43 (47.8)	22 (47.8)	0.091
Medium level	25 (27.8)	7 (15.2)	
High level	19 (21.1)	17 (37.0)	
Missing	3 (3.3)		
Healthcare professional			
Yes	9 (10.0)	5 (10.9)	0.068
No	64 (71.1)	39 (84.8)	
Missing	17 (18.9)	2 (4.3)	
Age	Range = 20–87 y (Mean = 59.8, SD = 12.7)	Range = 20–79 y (Mean = 52.5, SD = 14.5)	0.003
No. day hospital visits during last 12 mo	Range = 1–50 (Mean = 10.2, SD = 8.9)	Range = 1–50 (Mean = 9, SD = 9.1)	0.460
No. hospital stays during 12 mo	Range = 0–9 (Mean = 1.1, SD = 1.4)	Range = 0–30 (Mean = 0.6, SD = 0.9)	0.054

Patients' Versus Relatives' Challenging Behavior

Relatives were not more willing to challenge healthcare professionals than were patients both before and after the training.

Patients and relatives' willingness to challenge healthcare professionals depended on the type of safe practice. They were less willing to challenge healthcare professionals on hand hygiene (47.2% [P] and 42.2% [R] before training, 52.3% [P] and 50% [R] after training) and more willing to challenge if the treatment matches with the right patient (73.5% [P] and 68.7% [R] before training, 87.5% [P] and 87.0% [R] after training). See Table 2 for further details.

TABLE 2. Patients' Versus Relatives' Intentional Challenging Behavior

	Before Training		After Training	
	Patients	Relatives	Patients	Relatives
Would you tell the healthcare professional in charge of your care if he/she does not identify you by your name and last name?	67.2	76.1	76.1	78.3
Would you tell a healthcare professional in charge of your care if he/she does not wash his or her hands when necessary?	47.0	42.2	52.3	50.0
Would you tell a healthcare professional in charge of your care if he/she does not check whether the transfusion or chemotherapy matches with the patient's identification?	73.5	68.7	87.5	87.0
Would you tell a healthcare professional in charge of your care if he/she does not inform you about the secondary effects of the treatment?	68.2	73.2	75.9	80.4

Percentage of affirmative answers for each item.

On the other hand, P&Rs were asked whether they really challenged health professionals in case they observed nonadherence to a safe practice.

The percentage of affirmative answers was much lower for all the safe practices evaluated (Table 3). There were considerable differences between what P&Rs stated that they would challenge and what they had already done.

We asked P&Rs whether health consequences had an influence in challenging healthcare professionals about nonadherence to a safe practice. In total, 88.5% of the patients and 89.1% of the relatives agreed on the importance of health consequences to challenge healthcare workers.

Patients and Relatives' Willingness to Challenge

The percentage of items that P&Rs were willing to challenge increased after training among both patients (73.4% after; 64% before) and relatives (71.9% after; 65.6% before).

The percentage of participants' willingness to challenge 4 safe practices simultaneously is revealed in Table 4.

Patients' Versus Relatives' Perceived Challenging Behavior and Hospital Safety Perceptions Before and After Training

P&Rs felt more confident challenging healthcare professionals after the training, but the difference was statistically significant only among patients for the challenging composite (Table 5). When each of the safe practices was analyzed independently, checking whether transfusion or chemotherapy was a good match for the patient was statistically significant among both the patients and the relatives.

The results revealed that after the training, both the patients and the relatives changed their perception about proper patient identification by healthcare professionals and about healthcare professionals' hand hygiene in the right circumstances.

Ability to Recognize Safe Practices After Training

The P&Rs' confidence in identifying 3 out of 4 practices was 85.4% for the patients and 96% for the relatives.

Adverse Events

In total, 20% of the patients and 26.1% of the relatives answered that they have had an adverse event during their care process.

Of these adverse events, 13 were related to treatments, 11 to techniques or procedures, 4 to care, and 4 to diagnoses.

TABLE 3. Patients' Versus Relatives' Past Challenging Behavior

	Patients			Relatives		
	Yes	No	Not Needed	Yes	No	Not Needed
Have you ever told the healthcare professionals responsible for your care when they did not identify you by your name and last name?	10.5	33.3	56.1	4.8	31.0	64.3
Have you ever told the healthcare professionals responsible for your care when they did not wash their hands when necessary?	3.6	42.9	53.6	0.0	43.9	56.1
Have you ever told the healthcare professionals responsible for your care when they did not check whether the transfusion or chemotherapy matches with the patient identification?	1.9	31.5	66.7	4.7	37.2	58.1
Have you ever told the healthcare professionals responsible for your care when they did not inform you about the secondary effects of the treatment?	7.3	32.7	60.0	9.8	41.5	48.8

Percentage of affirmative answers for each item.

Characteristics of Healthcare Professionals

Neither professional category (76% of the participants answered that it would not make any difference) nor sex (90% of answers) influenced participants in terms of challenging healthcare professionals about their nonadherence to safe practices. There were no statistically significant differences between the opinions of the patients and those of the relatives (χ^2 test statistic = 0.646 and 0.292, respectively).

DISCUSSION

In our study, the patients and their relatives would challenge healthcare professionals in the same way. Thus, our hypothesis relatives are more willing to challenge healthcare professionals than are patients both before and after the training was not proven.

Their willingness to speak up depended on the type of safe practice both before and after training, ranging from 42% to 87%. The percentage of items that P&Rs were willing to challenge increased after the training among both the patients and the relatives, but statically significant differences were only seen among patients.

Unlike a recent study's finding, which revealed that most family members of patients were hesitant to express their safety concerns even in intensive care units,¹¹ in our study, the relatives' willingness to challenge was high, especially after training. This indicates that relatives may not have perceived themselves as patient advocates but that training may have raised this awareness.

It is true that the data were nuanced when these relatives were asked about their actual participation in cases of healthcare professionals' nonadherence to the implementation of the patient safety protocol.

Our study showed that after the training, participants felt confident with their knowledge about safe practices, which boosted their challenging attitude. This is consistent with findings from other studies that emphasize the importance of educational strategies to decrease the hesitancy to speak up.¹¹

This could be considered as a type of interventions that can strength patient activation described as skills and confidence that equip patients to become actively engaged in their healthcare.¹²

After the training, participants' willingness to challenge healthcare workers about their nonadherence to safe practices was high with regard to all safe practices analyzed with the exception of hand hygiene. This shows that challenging practice behaviors depends on the type of safe practice. This could be explained by the perceived impact of the safe practice on participants' health and their unwillingness to engage in the confrontational type of behavior required challenging healthcare professionals.^{8,13}

These findings are consistent with those of other studies that showed that patients feel more comfortable with staff verifying their identity than with asking the staff to wash their hands.⁴ The readiness to ask healthcare workers to wash their hands ranges from 45% to 80% in different studies.¹²⁻¹⁵ However, the proportion of willingness can be overestimated depending on how the question is framed. In a study conducted in the United Kingdom, the proportion of respondents who supported patient participation dropped considerably when the question was changed from a theoretical to a real basis.^{15,16} We obtained similar results, with the percentage dropping dramatically when the participants were asked whether they had ever confronted their healthcare workers when they observed nonadherence to a safety protocols. For example, the data showed that before training 47% of the patients and 42.2% of the relatives would challenge professionals on hand hygiene but only 3.6% of the patients and none of the relatives issued

TABLE 4. Patients' Versus Relatives' Challenging Profile Before and After Training

	Patients		Relatives	
	Before Training, %	After Training, %	Before Training, %	After Training, %
Willingness to Challenge 4 Safe Practices Simultaneously				
Low challenging profile	22.2	13.0	17.4	13.0
Medium challenging profile	17.8	13.0	21.7	13.0
High challenging profile	21.1	30.4	32.6	30.4
Very high challenging profile	38.9	43.5	28.3	43.5

The willingness to challenge is measured for the 4 safe practices simultaneously.

TABLE 5. P Values for the Items That Measured Challenging Behavior and Hospital Safety Perceptions Representing the Comparison of P&Rs Before and After Training

	<i>P</i>	Patients Versus Relatives*		After Versus Before†	
		Before	After	Patient	Relatives
Challenging behavior	Would you tell the healthcare professional in charge of your care if he/she does not identify you by your name and last name?	0.573	0.570	0.709	0.720
	Would you tell a healthcare professional in charge of your care if he/she does not wash his/her hands when necessary?	0.871	0.052	0.485	0.522
	Would you tell a healthcare professional in charge of your care if he/she does not check whether the transfusion or chemotherapy matches with the patient’s identification?	0.408	0.083	0.002	0.049
	Would you tell a healthcare professional in charge of your care if he/she does not inform you about the secondary effects of the treatment?	0.855	0.132	0.260	0.431
	Challenging behavior composite	0.792	0.846	0.011	0.070

*Mann-Whitney *U* test, Fisher exact test, and Pearson χ^2 test.

†Wilcoxon and McNemar tests.

a challenge. These data suggest that P&Rs did not follow a behavioral intention, defined as a person’s perceived likelihood or subjective probability that he or she will engage in a given behavior. There is a disconnection between willingness and action.

The fact that more than 1 in 5 participants had experienced an adverse event during their care process could have influenced the participants’ level of comfort while speaking up about breakdowns in care.¹⁷

Some studies have proven that the desire to participate in decision-making is inversely proportional to the patient’s disease severity.⁴ In this study, despite all the patients experiencing a severe disease, the percentage of those who had the willingness to challenge healthcare professionals was very high. Older patients are usually less interested, and women are more involved in this kind of process.⁴ Education level is also believed to play a role, although we failed to demonstrate such an association. Thus, our findings did not support those of previous related studies.

In our study, in contrast to others,¹³ healthcare’s professional category (doctors versus nurses) and sex did not have a significant influence on the P&Rs’ behavior.

Increasing patient safety through patient engagement may seem paradoxical because some patients and their families may consider this new role a burden too heavy to carry.¹⁸ As a matter of fact, there is a debate about the appropriateness and effectiveness of this involvement, with concerns that healthcare professionals may unreasonably transfer responsibility onto the already disadvantaged patients or their relatives.¹⁹ This is the reason why some experts in patient engagement are deemphasizing development of motivational and educational materials for patients in favor of prioritizing the role of healthcare practitioners and organizations in enabling safety-oriented behaviors among patients.¹⁸

As “The Safety is Personal” report indicates,²⁰ “While patients and families can play a critical role in preventing medical errors and reducing harm, the responsibility for safe care lies primarily with the leaders of health care organizations and the clinicians and staff who deliver care.”

There are associated risks with implementing a strategy where the public is responsible for the safety of its own care.¹⁸ If this was viewed as a trustworthy mechanism, there is a risk that clinicians

would no longer perceive the need to adhere to safety protocols that require for example double checks. Furthermore, in no way can it be perceived that the responsibility for safety rests with the patient or relative and not in the healthcare organization. Finally, healthcare organizations are under such pressure with staff experiencing high workload that there is a risk that professionals deliberately and inappropriately burden patients with responsibilities for care beyond their abilities and intentions.

However, patient safety strategies more patient focused²¹ should not only encourage actions to support patients and families understand the legitimacy and relevance of their interventions but also prepare clinicians and the entire health organization to respond meaningfully when patients speak up.¹¹ Furthermore, patients’ participation has been associated with favorable judgments about hospital quality and a reduction of the risk of experiencing an adverse event.^{22,23} Bell and Martinez²³ propose at least 3 changes to create an environment in which patients and their families can play a more active role: changing the research, changing the listening, and changing the norms. They state, “Empowering every patient and family to speak up, with clear instructions and a genuine invitation, may get messy and may even ‘decrease productivity’ before it improves care. Patient and family speaking up will be viewed as meaningful if we hold up the right yardsticks, which may include organizational learning, patient experience, respect and prevention of emotional/psychological distress.”

Study Limitations

Our study has several limitations. There were differences in age and sex between relatives and patients in our study group. Other aspects as educational traits or culture differences between relatives or patients or among them that could affect their willingness to speak up were not measured.^{13,24} For example, we did not ask questions related to personality traits because to measure it could be a burden for an organization; in addition, we admit that it may not be practical to make decisions.

Most of the research on patient empowerment for patient safety has been conducted in Anglo-Saxon countries. This research was conducted in a big hospital in the South of Europe. We are

aware that cultural factors may have influenced the responses of the participants.

Because we focused on patients experiencing oncological and hematological diseases and their relatives, the results represent the points of view of those with only chronic and severe diseases. This profile of patients was chosen to highlight the possible fatal consequences of nonadherence to safe practices and also because they could be part of a cohort of participants with several health contacts and on whom it was possible to perform training.

The study could have a sample selection bias. The inclusion criteria were very restrictive. Healthcare professionals who were in charge upon the patients' physical and psychological status did the patient selection. Thus, participants that finally gave the consent may not be representative of all patients. There is also a possibility of desirability bias. Participants may be willing to give more positive answers to support the goals of the study. The measurement of the durability of the training program in the willingness to speak up would require a follow-up study.

After training, participants' willingness to challenge healthcare professionals was high for all the safe practices analyzed, except hand hygiene. After the training, they felt confident with their knowledge about safe practices, which thereby increased their challenging attitude. However, it is well known that there is a gap between intention and action that must be considered.

CONCLUSIONS

After the training, both P&Rs' willingness to challenge healthcare workers was similar and high for all safe practices analyzed but hand hygiene. Hand hygiene may need supplementary approach to encourage P&Rs to speak up. After the training, participants felt confident with their knowledge about safe practices, thereby increasing their challenging attitude.

The findings of this research emphasize the importance of the implementation of training programs intended to empower P&Rs on patient safety in organizations. Relatives are very important agents in patient safety and they can speak up on behalf of the patients.

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