



Impact of SPEAK UP™ on Patients' Participation and Safety among People Referring to Babolsar Hospitals

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Authors

Mousavi S.R.¹ MSc,

Rezai-Rad M.*² PhD

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ABSTRACT

Aims Improving the quality of patients' safety is one of the hospitals' priorities and the WHO has prioritized it as one of the basic health concerns. The purpose of the present study was to investigate the impact of the "SPEAK UP" program on strengthening patients' participation and safety referred to Babolsar hospitals.

Materials & Methods This quasi-experimental interventional study was performed from June to December 2017. The selected patients referred to the clinic of Shafa Hospital were divided into two groups: control and experimental (50 participants in each). A pre-test was given to both samples, and then training was held for the intervention group through the educational brochure. A researcher-made questionnaire was used for collecting the data based on the "SPEAK UP brochure" ($\alpha=0.925$). Wilcoxon and Mann-Whitney tests were used for testing the research hypotheses through SPSS 20.

Findings The mean scores of participation, safety, learning, and asking skills in the post-test of the experimental group were higher than that of their pre-test scores. Implementation of the SPEAK UP program had a significant impact on participation, safety skills, learning skills, and the asking skills of the patients who referred to the hospital.

Conclusion Promoting the implementation of the "SPEAK UP" program through using 7 educational rules has a significant impact on the free expression of opinions, enhancing the patients' participation level, and improving the safety of patients who referred to hospitals and others health centers.

Keywords SPEAK UP™ Program; Patient Safety; Patient Participation; Self Care; Patient's Rights; Babolsar

¹Department of Healthcare Services Management, Faculty of Management, Islamic Azad University Electronic Campus (IAUEC), Tehran, Iran
²Department of Healthcare Service Administration, South Tehran Branch, Islamic Azad University, Tehran, Iran

*Correspondence

Address: Department of Healthcare Service Administration, South Tehran Branch, Islamic Azad University, Tehran, Iran.

Phone: -

Fax: :-

mrezairad41@yahoo.com

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Introduction

Over recent decades, improving the quality of patient safety has become one of the priorities of hospitals around the world [1] and the World Health Organization (WHO) has prioritized it as one of the main health concerns of hospitals and their staff so that display the best performance in this area. Nevertheless, one of the issues that challenge patients' safety and severely threatens it is "medical errors." The occurrence of "error" in dealing with the patients is a serious, inevitable, and pervasive threat to their safety. Although health care providers enjoy accuracy and skill in performing their duties, they are not immune to such errors [2]. Despite advancements in patient safety worldwide, studies show that medical errors and damages are still the leading preventable causes of damage and death among patients. At present, the partnership between the patient and the staff can be considered a determining issue and one of the most important goals in promoting sustainable health and health care [3]. Community engagement and participation was at the heart of the Alma Ata Declaration in 1978 [4]. Informed and active patients making proper decisions may facilitate their therapy and help reduce the likelihood of medical errors and expose the risk and health consequences of improper care [5].

Although medical errors are an important indicator of the quality of health care, no precise and specific statistics are available on Iran's rate of medical errors. In 2013, for every 100 to 150 patients hospitalized in hospitals and in general to each health center, one patient lost his life due to medical errors [6]. The main medical errors in Iran include lab staff errors, diagnostic errors, therapy errors, and medication errors [7].

According to the Iranian Health System Transformation Plan, the "National Self-Care Program" as the fifth national health transformation plan in the field of health was notified by the Deputy Minister of Health in 2015 to be implemented by the concerned parties. Firm evidence suggests that by promoting self-care as a people-oriented health approach, 7% is expected to be saved in health expenditures. These savings reduce the cost of basic and specialized care levels and reduce the cost of patients' scheduled and unplanned admissions and outpatients' admissions [8]. The Charter of Patients' Rights was ratified in 2002 by the Ministry of Health and Medical Education (MOHME); however, patients are not fully aware of that and are not thoroughly practiced. The philosophy behind the charter's development is making patients acquainted with their rights, and its content should be observed by hospitals [9].

Joint Commission on Accreditation of Healthcare Organizations (JCI) accrediting healthcare monitoring organizations in the United States in the

analysis and review of more than 2455 cases stated that the primary cause of more than 70% of these accidents was the lack of proper communication between the patient and the caregiver group, and unfortunately given the severity of these dangerous events almost 75% of these patients died [10]. Therefore, the patients' conscious participation in their health is vital and facilitates their treatment process and reduces the incidence of medical error, and it is also vital for health care, especially self-care [11, 12].

Studies conducted in Iran up to 2010 have been more on the patient's safety status [13], acquisition of vital standards for the patient's safety status [14], and the level of safety observed for patients [15] but the number of studies dealt with the theme of the present study is not considerable.

Patients' participation in health issues is among citizenship rights. Planning and providing patient-centered care and treatment services based on the opinions, patients' needs and preferences, caregivers, and community needs are key to health systems [3]. Patients' participation could include decision-making, medicine, surveillance, educating patients, goal setting, or contributing to physical cares [16], which is an important factor in improving the quality of services and patients' Safety [17] and is increasingly being used as a key component in restructuring health care processes and is supported to improve patients' safety. Patients' participation with a physician, nurse, and care team will lead to a better understanding of the disease's aspects and be involved in his treatment decisions and informed consent for each treatment plan [18]. Educating patients about safety issues prevent medical errors [19], and individuals also enjoy their full benefits [20].

Patients play an important role in their health care. This includes studying and reading, understanding and acting based on health information (health literacy), working with physicians to select proper treatment or management options (joint decision making), and providing feedback on health care processes and outcomes (quality improvement) [21]. Patients need to make the best decision on their care and treatment. People with poor health skills can hardly follow self-care instructions or follow their treatment regimens, such as taking medications [22]. The positive relationship among members of healthcare groups, especially nurses and physicians, is among the effective and reliable signals of taking care of patients [22]. Moreover, positive effects such as patients' satisfaction [23], reducing patient length of stay [23], and reduces side effects [24]. Conversely, ineffective communication may also jeopardize a patient's safety and increase health care costs [25, 26].

For the first time, the SPEAK UP™ program was launched by Joint Commission on Accreditation of Healthcare Organizations (JCI) as a campaign along with the US Medicare and Medicaid in March 2002

and has mainly focused on the involvement of patients, their families, and health care providers in improving safety through "self-care education", and according to the commission claims, by 2017 the SPEAK UP program has been received by over 70 countries. In general, the "SPEAK UP " program works on patients' safety and pursues three main objectives: (1) preventing the occurrence of errors and "preventing any damages to patients"; (2) learning from the mistakes that have occurred and (3) being the cornerstone of work on safety culture including health care workers, organizations and patients. SPEAK UP program has 7 requests or dimensions from patients. To prevent health care errors, patients are urged to:

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- **Speak up if you have questions or concerns.** If you still don't understand, ask again. It's your body and you have a right to know.
 - **Pay attention to the care you get.** Always make sure you're getting the right treatments and medicines by the right health care professionals. Don't assume anything.
 - **Educate yourself about your illness.** Learn about the medical tests you get, and your treatment plan.
 - **Ask a trusted family member or friend to be your advocate (advisor or supporter).**
 - **Know what medicines you take and why you take them.** Medicine errors are the most common health care mistakes.
 - **Use a hospital, clinic, surgery center, or other type of health care organization that has been carefully checked out.** For example, The Joint Commission visits hospitals to see if they are meeting The Joint Commission's quality standards.
 - **Participate in all decisions about your treatment.** You are the center of the health care team.
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The present study's main question is whether the SPEAK UP™ program is effective in strengthening the participation and safety of patients who referred to Babolsar hospitals.

Materials and Methods

This interventional quasi-experimental and applied study was carried out on patients referred to Shafa Hospital in Babolsar and were randomly selected. The selected samples were divided into two groups of 50: control and experimental. At first, a pre-test was given to both groups. The training was held using an educational brochure for the experimental group. The educational intervention consisted of 2 training sessions, each one 45 minutes. The educational content was organized based on the

SPEAK UP program in an educational pamphlet and educational infographics.

Behavioral goals were set for each session, and a group discussion was conducted for the experimental group using various methods such as lectures, questions, and answers. Before holding the training sessions, experimental and control groups were given a pre-test. After the last session, experimental and control groups were provided with a researcher-made SPEAK UP questionnaire as a post-test. Following the post-test implementation, the control group was provided with a pamphlet given to the experimental group).

A researcher-made questionnaire was used for collecting the data. The questionnaire was designed based on the SPEAK UP program brochure to prevent health care errors. To design the questionnaire, in the first stage, the brochure was translated into Persian. Then, under the guidance of one of the professors and views of an expert in the field of health scale tools, the items of the questionnaire was controlled in several stages:

1) Translation of the English version of the Speak Up Program brochure [26] into Persian;

2) Turning the SPEAK UP brochure's educational points into a question: The brochure used third-person verbs, and the items became third person singular. For example, "If you do not understand because doctor, nurse, or other health care professional speak another language, dialect, or accent ask for someone who speaks your language, dialect, or accent. You have the right to get free help from someone who speaks your language." was changed into: 'If I do not understand because doctor, nurse or other health care professional speak another language, dialect, or accent I will ask for someone who speaks my language, dialect, or accent. I have the right to get free help from someone who speaks my language. At this stage, 71 questions were designed;

3) Editing questions by getting assistance from the hospital, nursing, and health education experts to make them more sensible;

4) Modifying questions while taking into account similar cases in other questions and items that were not applicable in Iran; therefore, 71 items were reduced to 50 items;

5) Holding cognitive interviews with ten people selected from among the study population; and editing ambiguous, difficult, and inappropriate questions and statements.

6) Assessing the face and content validity by getting help from 20 hospital experts in patient safety and health services management experts; at this stage, the questions with low validity were removed. At this stage, the number of items in the final questionnaire reduced to 34 questions. The text of the questionnaire was prepared in both Persian and English.

The questionnaire consisted of demographic characteristics (age, gender, level of education, and reason for visiting the clinic) and SPEAK UP technical questions. The technical questions of the questionnaire were organized into 7 sections: Speak up (freely express your viewpoints and opinions) (6 questions); Pay attention (4 questions); Educate (4 questions); Advocacy (3 questions); Know (8 questions); Use (4 questions); Participate (5 questions); Which is illustrated in Table 1.

Table 1) Different sections of the questionnaire related to the research questions

Section	Clients' Cooperation	Clients' Safety	Clients' Learning	Clients' Asking
Speak up				+
Pay attention		+		
Educate			+	
Advocacy	+			
Know				+
Use				+
Participate	+			

The items of the questionnaire were calculated as follows: the questions of the first part (speak up), the second part (pay attention), the fourth part (Advocacy- Ask others to support you), in the form of a five-point Likert scale (strongly agree (5 points), agree (4Points), neither agree nor disagree (3 points), disagree (2 points) and strongly disagree (1 point); questions of the third section (educate), section five (Know), section six (Use) and section seven (Participate) as a five-point Likert scale [always (5)Points), often (4 points), sometimes (3 points), rarely (2 points) and never (1 point)]. According to the research questions, the questionnaire sections' questions for data analysis are illustrated in Table 1.

The content validity method was used to determine the validity of the questionnaire. To assess face and content validity of the questionnaire, the viewpoints of 20 hospital experts (patient safety) and health services management were utilized. At this stage, items with low validity were eliminated. Cronbach's alpha coefficient was used to measure the reliability of the questionnaire.

Cronbach's alpha for various items were: participation ($\alpha = 0.902$), safety ($\alpha = 0.901$), learning ($\alpha = 0.889$), asking ($\alpha = 0.905$), and total reliability ($\alpha = 0.925$).

To analyze the scores, descriptive statistical methods were used, and to describe the demographic characteristics and calculate the mean scores to assess the status of the sample in different topics of SPEAK UP, two groups: control and experimental were used. Inferential statistics including Kolmogorov-Smirnov and Shapiro-Wilk tests were used to check the normality of variables; Loon test was used to check the homogeneity of

variances Wilcoxon and Mann-Whitney tests were used to test the research hypotheses using SPSS20.

Findings

In the present study, 100 persons (50 in the control group and 50 in the experiment group) participated in the study. Most of the members of both control and experimental samples were in the age ranging between 36 and 40 years, accounting for 32 and 30% of the participants, respectively. Most control and experimental groups had a bachelor's degree with 30 and 36%, respectively, and the lowest members in both the control and experimental groups had a bachelor's degree with 6 and 12%, respectively. The control group with 58% women and the experimental group with 56% had the highest number. Of the patients referring to the hospital, 22% in both control and experimental groups complained of blood pressure, 12% and 8% complained of diabetes.

As illustrated in Table 2, the mean scores of the participation skills, safety, Learning, and asking the sample members are higher than their pre-test scores. The mean differential is 0.75 in participation, 0.78 in safety, 1.05 in Learning, and 0.80 in asking. The differentials observed in the sample are not conclusive, and statistical tests should determine this differential's significance.

Table 2) Comparison of scores of the experimental group before and after the educational intervention

Skill	Mean score		Differential
	Pre-test	Post-test	
Participation	4.67	3.92	0.75
Safety	3.96	4.74	0.78
Learning	3.73	4.78	1.05
Asking	3.89	4.69	0.80

The assumptions of covariance analysis, including the normality of dependent variables and the homogeneity of the regression line's slope, are not observed, and covariance analysis cannot be used in practice. In such cases, the normality of the variables is tested by paired t-test and independent t-test; otherwise, their nonparametric equivalents, namely Wilcoxon and Mann-Whitney, are used.

The main purpose of the present study was to investigate the impact of the SPEAK UP program in strengthening the participation and safety of patients who referred to Babolsar hospitals, and was examined using four hypotheses:

The implementation of the "SPEAK UP" program is effective ...

- ✓ on the participation
- ✓ in the safety of
- ✓ in Learning of
- ✓ in asking

patients who referred to Babolsar hospitals.

The Wilcoxon test result to be compared with the pre-test and post-test scores of the experimental

group and Mann-Whitney test are presented in Table 3.

Based on the Wilcoxon test result, because the significance level was less than 0.05, the calculated z value of the Wilcoxon test is significant, and the null hypothesis of all four hypotheses is rejected with 95% confidence. There is a significant difference

between the pre-test and post-test participation scores. Based on the Mann-Whitney test, it can be argued that the implementation of the "SPEAK UP" program with 95% confidence has a significant impact on client participation, and all the hypotheses are accepted.

Table 3) Results of Wilcoxon and Mann-Whitney tests for research variables (participation, safety, learning, and asking) among clients referring to Babolsar Hospitals

Test	n	Average rating	Rank Sum	Z/U-test	Significance level	
Wilcoxon signed-rank test for participation						
Pre-test-Post-test	Negative Ranks	4	3.50	14.00	-5.954	0.000
	Positive Ranks	45	26.91	1211.00		
	Pairs	1				
	Sum	50				
Mann-Whitney U test of control/Experimental Group						
Participation	Control	50	33.17	1658.50	383.500	0.000
	Experimental	50	67.83	3391.50		
	Sum	100				
Wilcoxon signed-rank test for safety						
Pre-test-Post-test	Negative Ranks	0	0.00	0.00	-5.387	0.000
	Positive Ranks	38	19.50	741.00		
	Pairs	12				
	Sum	50				
Mann-Whitney U test of control/Experimental Group						
Safety	Control	50	40.41	2020.50	745.500	0.000
	Experimental	50	60.59	3029.50		
	Sum	100				
Wilcoxon signed-rank test for Learning						
Pre-test-Post-test	Negative Ranks	0	0.00	0.00	-5.800	0.000
	Positive Ranks	44	22.50	990.00		
	Pairs	6				
	Sum	50				
Mann-Whitney U test of control/Experimental Group						
Learning	Control	50	35.70	1785.00	510.000	0.000
	Experimental	50	65.30	3265.00		
	Sum	100				
Wilcoxon signed-rank test for Asking						
Pre-test-Post-test	Negative Ranks	5	11.40	57.00	-5.526	0.000
	Positive Ranks	44	26.55	1168.00		
	Pairs	1				
	Sum	50				
Mann-Whitney U test of control/Experimental Group						
Asking	Control	50	33.86	1693.00	418.000	0.000
	Experimental	50	67.14	3357.00		
	Sum	100				

Discussion

The present study, which was conducted to investigate the impact of the SPEAK UP program in strengthening the participation and safety of patients who referred to hospitals in Babolsar, indicated that this program impacts the patients' participation, safety, Learning, and asking. Overall, the SPEAK UP program's implementation has had a significant impact on the "participation" of the clients. The results of this study are in line with the findings of Rainey *et al.* in 2015, which indicated that the implementation of the program SPEAK UP enhances the level of the participation of patients

and their families and is in line with on diagnosing clinical conditions, self-monitoring, confidence, and safety culture and health care system, and has an impact on them [27]. On the other hand, the result of the present study is in line with the findings of the study conducted by Strull *et al.* [28] in 1984; in which they indicated that while hypertensive patients in a care center asked their physicians to provide them with thorough information on their treatment process, they did well when they were asked to play an active role in participation and their medical and therapy so that to contribute to the process of caring for their illness, these partnerships halted a bit;

therefore, they concluded that since the adoption of any policy and decision-making related to health services, ultimately affects the patients' lives, so the participation of patients and society in health matters and the development of macro health policies in many countries are among the rights of citizens, and is considered moral and conscientious and is a manifestation of justice and accountability in many health care systems. The Ginsburg study [29] in 2015 concluded that the wisest way to control the safety atmosphere in health care centers is to consider the patient's point of view in the context of the SPEAK UP program, so that based on their ability and participation in therapy decisions the safety atmosphere created could also be controlled. This is in line with the first hypothesis of this study.

The second hypothesis argued that the SPEAK UP program's implementation impacts the safety of patients, which was accepted. The American Medical Association has six goals for enhancing the quality of safety in health care systems: patient safety, putting the patient in the center of the process, effectiveness, usefulness, timeliness of providing services, and equity in service delivery. Now, given the research findings of the SPEAK UP program in the two groups: control and the experimental and the implementation of training based on the SPEAK UP program has led to the patient's increased participation and a relative increase in the level of client safety; which is consistent with studies conducted by Entwistle *et al.* in 2010 [30]. Based on the results of their research, which was obtained using the views of patients and their family members about the SPEAK UP program, they concluded that the safety concerns of patients and their family members' about proper care for themselves while leading to desirable results reduces the probability of medical error occurrence. The results of the present study are in line with the results of the study conducted by Okuyama *et al.* [31] in 2014, stating that in case healthcare providers pave the ground for the patients to explicitly express their concerns on safety issues and freely express themselves without any consideration, it would be a good opportunity to prevent medical errors and increase patient safety in health centers, and is fully consistent with the second hypothesis of the present research.

The implementation of the SPEAK UP program had a significant impact on the clients' learning skills, and the third hypothesis was accepted. This means that educating, learning, and gaining experience by patients has a very important role in medical error prevention and occurrence and safety promotion. The third hypothesis is in line with the result of the Nacioglu study [32] in 2016. In their study, they concluded that informing and educating about safety and promoting patients' knowledge and health literacy are among effective factors in activating behaviors that are achieved through speaking and

expressing, and with the assistance of service providers and permitting the patients to make decisions and actively participate in decision makings could effectively improve the quality of patient's safety. The results of the research conducted by Sayre *et al.* [33] in 2012 also indicated that the SPEAK UP program is a critical component in improving patient safety, and supported educational intervention through using personal moods and thoughts in small groups including nurses and patients can have significant results in behaviors emanated from outspokenness and indicate increasing scores in this group, of course, through educational intervention and help improve safety; which is consistent with the third hypothesis. The results of Okuyama *et al.* [31] are also consistent with the study's third hypothesis. In their review study, they reviewed 26 articles out of a total of 27 studies. They reviewed the literature under Speak Up, and its role in promoting patient safety by hospital-based health care specialists and concluded that healthcare experts hesitance in letting patients speak up freely is an important factor in communicational mistakes and training could improve speaking-up behavior, and factors affecting safety concerns lead to a reduction in communicational errors that should be identified.

It can be stated with 95% confidence that the SPEAK UP program's implementation had a significant impact on the clients' asking skills, and the fourth hypothesis was accepted. This hypothesis's result was consistent with the results of Seale *et al.* [34] research in 2015. In their study that looked at the role of asking in controlling and preventing nosocomial infections during health care, they concluded that by empowering and giving patients an active role in explicitly asking service providers whether they have washed their hands, could to a large extent reduce the chance of the spread of nosocomial infections, and could highly contribute to strengthening the patient's immunity. Also, in a study conducted by Schwappach *et al.* [35] on "Speaking Up" and its related issues and its relationship with the safety atmosphere and working conditions of caregivers and preventing patients from freely expressing their views on observed immunodeficiency, they concluded that encouraging patients to ask and talk freely about the extent of concerns on the part of patients concerning observing safety conditions by health care providers and accountability of administrators, staff and health care providers in responding to these concerns is a critical and essential resource for preventing injury and error in clinics. It is consistent with the fourth hypothesis of the research.

Conducting the research was faced with some limitations. One of the limitations was the lack of previously conducted research fully related to the present research theme to compare the findings accurately. In this regard, conducting more

researches in other provinces and cities could overcome the shortcoming. This research has been conducted in Shafa Hospital in Babolsar, and its results cannot be generalized to other hospitals in Babolsar and the country and may lead to different results in different cultural conditions. The present study was conducted among patients referred to Shafa Hospital in Babolsar and cannot be generalized to all healthy people. To do so, a separate study is required to be conducted on healthy individuals in different groups.

Conclusion

Promoting the implementation of the SPEAK UP™ program through practicing 7 educational rules has a significant impact on the free expression of ideas and opinions, enhancing patients' participation, and, most importantly, improving patients' safety who refer to hospitals and other health centers. Holding specialized courses and training staff of hospitals and other health care centers on different dimensions of the SPEAK UP program could pave the ground for better implementation of the program. One of the rights of patients is to intervene and participate in decision making. Therefore, the implementation of laws and regulations supporting the patient's rights which enables them to participate in the decision-making of their therapy, implementation, and observance of accreditation standards for patients' rights in health centers and supervision of the hospital accreditation unit or units could contribute to decision making by patients on their health and care, thereby reducing the cost of medical errors and treatment. Benefitting from mass and digital media for public education could significantly contribute to promoting the SPEAK UP program.

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