

The Effect of Patient Safety Educational Program on Nurses' Patient Safety Culture and Patient Safety Indicators

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Abstract

The need to improve patient's safety is to change the patient's safety culture. This study was conducted to determine the effect of the patient safety education program on nurses' patient safety culture and patient safety indicators.

This single-blind clinical trial was conducted in two cardiac medical wards that were randomly selected as research settings among the hospital teaching wards of the Zanjan city in Zanjan. Twenty-six nurses participated in this study under in the experimental and control groups. The experimental group received the educational program for two sessions, and the control group received a booklet about patient safety. The nurses' patient safety culture was assessed using the Hospital Survey on Patient Safety Culture (HSOPSC) questionnaire before and 3 months after intervention. The patient safety indicators were assessed 1400 times before and 3 months after intervention using a standard checklist by direct observation of all indicators ($N=100$ for each).

The results revealed that the patient safety educational program could improve some safety indicators, and overall perception of patient safety composite from safety culture, positively ($P=0.034$). The patient safety indicators in pharmacological considerations ($P=0.001$), personal information considerations ($P=0.001$), and proper implementation of procedure considerations ($P=0.001$) were significantly improved in the experimental group compared to the control group. It seems that changing the patient's safety culture using educational program requires more training courses.

Keywords: patient safety, culture, nursing, education, hospital

Introduction

Patient safety is one of the significant aspects of quality of care (Smits, Christiaans-Dingelhoff, Wagner, Wal, & Groenewegen, 2008), and ignoring patients safety leads to patient harms (Phaghizadeh & Asoori, 2015). Errors in patient safety are a universal problem which causes preventable diseases, and death in healthcare services (Pronovost et al., 2009).

Patient safety is essential to the quality of healthcare. The individual and group values, attitudes, perceptions, competencies, and patterns of behavior result in the safety culture of an organization and determine the commitment to the style and proficiency of an organization's health and safety management, (Health & Safety Commission, 1993). The characteristics of safety culture include seven subcultures: "leadership, teamwork, evidence-based,

communication, learning, just, and patient-centered" (Sammer, Lykens, Singh, Mains, & Lackan, 2010).

Evidence supports that high levels of the patient safety can improve patient outcomes and reduces healthcare costs (Clarke & Ward, 2006; Mustard, 2002). Patient safety culture is one of the factors, which could positively influence promoting patient safety (Anderson, 2006). Patients in hospitals

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with a more positive safety culture are more likely to experience fewer errors (Singer, Lin, Falwell, Gaba, & Baker, 2009), and assessment of the patient safety culture by organizations can improve their weak points and boost their strong points (El-Jardali, Sheikh, Garcia, Jamal, & Abdo, 2014). Patient safety indicators (PSIs) are significant parameters to evaluate patient safety culture and patient safety (Najafpour, Boroomandfar, & Zahiri, 2014). PSIs are outcome and care process indicators, as well as a scale to evaluate and promote the healthcare service quality (Kristensen, Mainz, & Bartels, 2009).

The studies conducted in Iran have shown that patient safety is at an unacceptable level (Almasi & Matin, 2001; Mousavi, Faraji Khiavi, Sharifian, & Shaham, 2010). As more than 90% of the medical error events are associated with human factors, the medical errors can be prevented by creating a positive patient safety culture (Shekari, Shirali, & Hosseinzadeh, 2014). In addition to the harm that patient care errors cause, it is indication of the existence of problems such as lack of patient safety culture in the organization (Hellings, Schrooten, Klazinga, & Vleugels, 2007). Nurses are the most effective health staff who must maintain the high quality of the patients' safety level. Their susceptibility to poor health, moderate to high levels of burnout, and inappropriate workplace conditions could cause negative consequences for patients (Hall, Johnson, Watt, Tsipa, & O'Connor, 2016; Schrappe, 2005)

In order to promote quality and safety in healthcare systems along with organizational interventions, hospitals need to improve patient safety culture among their staff (Smits et al., 2008), and education is an important intervention to achieve this target (Battles, 2006). There is a large body of evidence that nursing staff's continuous learning/education is essential to organizational change behavior (Davis, Taylor, & Reyes, 2014; Liu et al., 2016). Learning and continuous improvement were found as one of the major patient safety culture predictors (Ammouri, Tailakh, Muliira, Geethakrishnan, & Al Kindi, 2015). The results of an interventional study in Oman about patient safety culture showed that an educational program improved the number of error reports and nonpunitive responses to error, and consequently, the incidence of harmful events significantly decreased (AbuAlRub, Alhijaa, & Hani, 2014). Application of some interventional strategies to improve the nurses' attitude to report errors were also found to be significantly effective (Kim, 2010).

Despite numerous studies in the field of patient safety, health organizations are still confronted with the problem of patient safety, and the number of

patients who developed complications due to medical errors is significant (Makary & Daniel, 2016). No experimental study has been conducted on patient safety promotion in Iran, with regard to different culture and health service systems. Thus, the present study aimed to determine the effect of the patient's safety education program on nurses' patient safety culture and PSIs.

Materials and Methods

Design and Sample

This single-blind clinical trial study with pretest and posttest design and control group was conducted in Zanjan city, in Iran. The current research was registered in Iran's Clinical Trial Center (IRCT2017011323520N3).

The research sample consisted of 13 and 15 nurses working in the cardiac medical units of two hospitals in Zanjan. The intervention and control hospitals were selected randomly. Two nurses in the experimental group refused to participate in the study. Therefore, 13 nurses in the experimental group and 13 nurses in the control group took part in this study. The sample size of the study was estimated using the STATA software based on power of 0.85, which showed that 13 cases in each group are an appropriate to sample size.

The inclusion criteria were: at least 6 months of work experience and willingness to participate in the study. To collect data about patient safety culture, all participants completed the questionnaire before and after the intervention. The questionnaires were excluded from the study if there were identical answers to all questions and if more than 50% of the questions had not been completed properly.

Each item of the safety indicators was observed 100 times according to the Ryan formula. Due to the lack of similar studies, the *P* value was considered as 50% to get the maximum sample size for PSIs (Ryan, 2013).

$$n = \frac{Z_{1-\alpha/2}^2 \times P(1-P)}{\delta^2}$$

$$\alpha = 0.05$$

$$p = 0.5$$

$$\delta = 0.2 p$$

$$n = 91 \cong 100$$

Measures

The Hospital Survey on Patient Safety Culture Scale (HSOPSC) was used to collect data on patient safety culture and the patient safety data were collected using PSIs.

a. HSOPSC

HSPSCQ is a standard tool, whose reliability and validity have been reported in several studies (Fujita et al., 2013; Moghri et al., 2012a). The internal reliability of the tool was assessed in the current study, and Cronbach's alpha of 0.89 was achieved.

The HSOPSC questionnaire contains 42 questions, which evaluate different aspects of patient safety culture using the five point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree). The questionnaire evaluated the staff's perceptions on 12 composites of patient safety culture as follows: (1) overall perception of patient safety (procedures and systems are good at preventing errors and there is a lack of patient safety problems: four items); (2) organizational learning—continuous improvement (mistakes have led to positive changes, and these changes are evaluated for their effectiveness: three items); (3) supervisor/manager expectations and actions promoting patient safety (supervisors/managers consider staff suggestions for improving patient safety, praise staff for following patient safety procedures, and do not overlook patient safety problems: four items); (4) teamwork within units of the organization (hospital units cooperate and coordinate with one another to provide the best care for patients: four items); (5) nonpunitive response to error; (6) staffing (there are enough staff to handle the workload, and work hours are appropriate to provide the best care for patient: three items); (7) management support for patient safety (hospital management provides a work climate that promotes patient safety and shows that patient safety is a top priority: three items); (8) teamwork across units (hospital units cooperate and coordinate with one another to provide the best care for patients: four items); (9) hand-offs and transitions (important patient care information is transferred across hospital units and during shift changes: four items); (10) communication openness (staff will freely speak up if they see something that may negatively affect patient care, and feel free to question those with more authority: three items); (11) feedback and communication about errors (staff are informed about errors that happen, given feedback about changes put into place based on event reports, and discuss ways to prevent errors: three items); (12) frequency of events reporting (mistakes of the following types are reported:

(a) mistakes caught and corrected before affecting the patient, (b) mistakes with no potential to harm the patient, and (c) mistakes that could harm the patient, but do not: three items) (Sorra et al., 2016).

According to the questionnaire scoring instructions; strongly agree and agree on choices in the positive response spectrum, neither agree or disagree items in the neutral response spectrum, and disagree and strongly disagree items in the negative response spectrum were classified, and scored from 5 to 1, respectively. Negatively worded questions were reverse coded when calculating the percent of the "positive" response, means, and composites. The mean score of each dimension was calculated based on its items separately. In order to calculate the total score of the questionnaire, the scores of all items were summated and the mean score was calculated. The mean differences were achieved by deducting the before intervention score from the after intervention score. According to the questionnaire guideline, the composites with at least 50% positive rating, are considered an acceptable level of safety, and the ones less than 50% need to be improved (Moghri et al., 2012b). The average positive percentages were calculated as follows: Averaging the item-level percent positive scores/Number of items per composite \times 100 (Sorra et al., 2016).

b. Patient safety indicators

Patient safety data were collected using PSIs. These indicators were a revised version of codified PSIs of the Ministry of Health and Medical Education. The indicators included the following items: pharmacological considerations to prevent errors (12 items); patient personal/demographic information considerations to prevent errors (7 items); communication during patient handovers (three items); proper implementation of procedures considerations (2 items); using disposable devices for injection (5 items); improved hand hygiene to prevent health care associated infection (4 items); physical harm due to insecure physical settings (3 items).

The means for patient safety in each case was calculated. The checklist included a total number of 36 "yes or no response" questions in different aspects of patient safety. The score of the checklist ranged between 0 and 36. The mean differences was achieved by deducting the before intervention score from after intervention. Content validity was used to assess the relevance of the safety indicators checklist. The checklist was reviewed by 10 expert nursing faculty, and the supervisors with a history of work in cardiac medical units at hospitals. Minor revisions were made to the checklist before the study. The internal

consistency of the PSIs checklist was verified by achieving Cronbach's alpha ($\alpha=0.76$). In this study, PSIs with Cronbach's alpha of >0.70 were regarded as showing good internal consistency (Bowling, 2014).

Intervention

In the current study, the intervention included an educational program to promote patient safety culture. One of the authors (M.N.) carried out the intervention of the research and a researcher assistant collected the data. The assistant researcher was blind to the allocation of groups.

At baseline, the nurses' patient safety culture was assessed using the questionnaire, and PSIs were observed in both experimental and control groups. Each of the PSIs was observed 100 times. As the checklist consisted of seven items, the PSIs were observed a total 1400 times before and after the intervention. To be able to check the safety indicators appropriately, the 100 times of observation was divided into: 34 times at night shift, 33 times at morning shift, and 33 times during the evening shift. The times of observations were selected randomly in which that the equal numbers of day and night shifts to be covered, and each safety indicators to be observed at least twice for each participants (nurses) in different shifts. The PSIs checklist was completed before and 3 months after the intervention, by one research assistant who was unaware of group allocation. The results of the pretest data were used to prepare the content of the educational program and its duration.

The educational program for the experimental group was administered by one of the researchers (M.N.). The two daily sessions included information about the concept of patient safety, 7 steps to patient safety, the solutions to improve patient safety, the concept of patient safety culture, and the 12 dimensions of patient safety culture. Each session lasted nearly 3 hours (with two breaks). To improve the effectiveness of the educational program, the participants were involved in discussions using the Question & Answer method during the educational program. The educational materials were sent to the nurses electronically before the intervention. The participants were advised that if they had any questions, to submit them electronically to the research team within 1 week after the educational program ended. A booklet about patient safety culture and PSIs with the same content as the educational program was given to the nurses in the control group. The patient safety culture and PSIs were assessed again 3 months after the intervention, in both groups.

Ethical considerations

Ethics approval for the study was granted by Zanajn University of Medical Science (Ref ZUMS. REC.1395.03). The observation method was explained to all the nurses who participated in this study; however, they did not know when or what part of their performance would be observed. Informed consent forms were obtained from all the nurses.

Analytic Strategy

The Kolmogorov–Smirnov test was used to evaluate the normality of the data and the statistical tests were used for data analysis. Distribution of patient safety culture data was normal, but PSIs did not have normal distribution. Fischer's exact test was used to compare the demographic characteristics between the two groups. To compare the effect of the intervention on patient safety culture and the effect of intervention on PSIs the Mann–Whitney test (Non-normal data Distribution) were used, respectively. As there was a significant difference regarding work experience in the experimental and control groups, a linear mixed model was used to assess the actual effect of intervention on patient safety culture. In this test, the participants' scores after intervention were considered as a dependent variable; the educational program was considered as an intervention; and age, work experience, and participants' scores before intervention were considered as covariates. Significance level for data analysis was considered 0.05.

Results

Of the 28 nurses in two wards ($N_1=15$ and $N_2=13$), two nurses in the experimental group refused to participate in the study, and so 26 female nurses were recruited in the experimental and control groups. Most of the participants in the experimental and control groups were between 25–35 years, and 36–42 years, respectively. The mean difference was not statistically significant. The mean years of work experience in the experimental and the control groups were over 10 years and less than 5 years, respectively; this difference was statistically significant (Table 1).

The total positive response rate to the patient's safety culture in both groups was almost the same before the intervention. The hospital management support and nonpunitive responses to the error were the composites, which had the highest (80.76%) and the lowest (17.93%) rate of positive responses in both groups before the intervention, respectively (Table 2).

Table 1. Demographic Variables of Subjects

Variables	E-G	C-G	Fisher's exact test <i>P</i>
	<i>n</i> (%)	<i>n</i> (%)	
Age			0.238
25–35	5 (38.5)	9 (69.2)	
36–45	8 (61.5)	4 (30.8)	
Total	13 (100)	13 (100)	
Work experience			0.010
Under 5 years	1 (7.7)	8 (61.5)	
5–10 years	2 (15.4)	2 (15.4)	
Over 10 years	10 (76.9)	3 (23.1)	
Total	13 (100)	13 (100)	

Note: E-G = experimental group; C-G = control group.

The comparison of the mean difference score of the positive response to the patient's safety culture showed that there was a significant increase in the experimental group (experimental: 14.81 ± 20.43 and control: -3.23 ± 23.21).

The analysis showed that there was a significant difference between mean work experience, indicating that the control group had less experience compared to the experimental group. Linear mixed models were conducted in which 12 dimensions of safety culture were separately considered as the dependent variables, and the groups of the study were considered as the independent variable. Experience

and age of participants were considered as covariates. The relevant data were restructured first and then linear mixed model was run. The linear mixed model analysis showed that “overall perception of patient safety” was the only composite which was improved significantly ($P=0.034$ and $F=4.751$), and the educational program had no effect on the other composites. The results of the linear mixed model analysis are presented in Table 3.

The comparison of the mean difference score of the safety indicators was increased after the intervention in experimental group (experimental: 2.85 ± 2.31 and control: 0.08 ± 2.31). Mean difference score of some PSIs such as pharmaceutical considerations (experimental: 0.49 ± 0.85 and control: -10 ± 1.23), patient personal information considerations (experimental: 1.29 ± 1.28 and control: -0.28 ± 1.36), and proper implementation of procedures considerations (experimental: 0.21 ± 0.45 and control: -0.01 ± 0.48) improved significantly in the experimental group compared to the control group, although for the other indicators, no significant difference was found between the two groups (Table 4).

Discussion

The results of the study showed that the patient safety educational program could improve

Table 2. The Comparison of the Rate of Positive Responses to Patient Safety Culture Composites in the Experimental and Control Groups Before and After Intervention

Patient safety culture composites	EG		CG	
	BI	AI	BI	AI
	(%)	(%)	(%)	(%)
Teamwork within units	40.4	82.67	61.52	59.6
Manager/supervisor expectations and actions promoting patient safety	51.9	53.85	53.87	51.95
Organizational learning—continuous improvement	69.2	87.16	64.1	53.86
Management support for patient safety	79.46	74.16	82.03	71.76
Overall perception of patient safety	69.2	67.3	44.22	36.57
Feedback and communication about error	51.26	58.96	41.03	41.03
Communication openness	48.73	48.7	33.33	25.63
Frequency of events reporting	41.03	64.13	56.4	51.26
Teamwork across units	48.1	65.37	46.15	40.42
Staffing	7.7	13.47	28.87	25.02
Hand-offs and transitions	61.55	55.7	57.67	53.82
Nonpunitive response to error	10.26	20.53	25.63	20.53
Total	48.23	57.68	49.56	44.28

Note: EG = experimental group; CG = control group; BI = before intervention; AI = after intervention.

Table 3. *The Comparison of Patient Safety Culture Mean Difference Before and After Intervention in Experimental and Control Groups*

Patient safety culture composites	EG	CG	Mixed model analysis
	Mean ± SD	Mean ± SD	
Teamwork within units	4.37 ± 3.96	-0.30 ± 3.72	<i>P</i> = 0.267 <i>F</i> = 1.264
Manager/supervisor expectations and actions promoting patient safety	1.30 ± 3.49	-0.15 ± 3.83	<i>P</i> = 0.893 <i>F</i> = 0.018
Organizational learning—continuous improvement	1.57 ± 0.17	-0.42 ± 1.32	<i>P</i> = 0.663 <i>F</i> = 0.192
Management support for patient safety	-0.15 ± 2.37	-0.37 ± 2.94	<i>P</i> = 0.098 <i>F</i> = 2.848
Overall perception of patient safety	1.30 ± 2.89	-0.36 ± 3.82	<i>P</i> = 0.034 <i>F</i> = 4.751
Feedback and communication about error	0.61 ± 2.72	-0.38 ± 3.45	<i>P</i> = 0.527 <i>F</i> = 0.406
Communication openness	0.92 ± 2.49	-0.08 ± 2.93	<i>P</i> = 0.775 <i>F</i> = 0.083
Frequency of events reporting	0.72 ± 2.16	-0.42 ± 2.89	<i>P</i> = 0.688 <i>F</i> = 0.163
Teamwork across units	1.75 ± 4.10	-0.30 ± 3.88	<i>P</i> = 0.433 <i>F</i> = 0.625
Staffing	0.76 ± 2.04	0.34 ± 4.06	<i>P</i> = 0.290 <i>F</i> = 1.144
Hand-offs and transitions	0.53 ± 4.74	-0.69 ± 3.44	<i>P</i> = 0.893 <i>F</i> = 0.018
Nonpunitive response to error	0.15 ± 2.64	-0.05 ± 2.16	<i>P</i> = 0.245 <i>F</i> = 1.386
Total	14.81 ± 20.43	-3.23 ± 23.21	<i>P</i> = 0.241 <i>F</i> = 1.41

Note: EG = experimental group; CG = control group; SD = standard deviation.

safety indicators in the experimental group. The “overall perception of patient safety” composite of the participants was also improved after the intervention. The results of the current study were not in accordance with the results of other studies that reported, “The number of error reports,” and “nonpunitive responses to error” were improved after educational program (AbuAlRub et al., 2014). The evidence shows that a structured, reproducible, short-blended learning course on patient safety could improve perceived Intensive Care Unit (ICU) patient safety culture in five domains (overall perception of safety, teamwork within hospital units, feedback and communication about error, staffing, and hospital management support for patient safety; Ling et al., 2016). The results of the recently reported study are in accordance with the result of the current study in terms of the overall perception of

safety composite. The variety of participants, the cultural and research environment differences, the content of the educational program, and the method of the education could be considered as some possible reasons for this controversy.

The surprising results achieved in the current study were that the positive response rate to the patient’s safety culture in some composites in the control group was reduced after the intervention, although this reduction was not statistically significant. This could be due to the Hawthorne effect in the control group, the change of management conditions and hospital policies, and other unexplained reasons.

With regard to the “the pharmacological considerations to prevent errors,” “patient personal information considerations to prevent errors,” and “proper implementation of procedures considerations”

Table 4. *The Comparison of Mean Difference Before and After Intervention in Seven Dimensions of Patient Safety Indicators in Two Experimental and Control Groups*

Patient safety indicators	EG	CG	Mann–Whitney <i>P</i>
	Mean ± SD	Mean ± SD	
pharmacological considerations to prevent errors	0.49 ± 0.85	−0.10 ± 1.23	0.001
Patient personal information considerations to prevent errors	1.29 ± 1.28	−0.28 ± 1.36	0.001
Effective communication during patient handovers	0.24 ± 0.78	0.13 ± 0.84	0.175
Proper implementation of procedures considerations	0.21 ± 0.45	−0.01 ± 0.48	0.001
Single use of injection devices	0.28 ± 0.66	0.09 ± 1.12	0.496
Improved hand hygiene to prevent healthcare-associated infection	0.001 ± 0.001	0.001 ± 0.001	1.000
Physical harm due to unsafe physical settings	0.34 ± 0.91	0.25 ± 0.91	0.355
Total	2.85 ± 2.31	0.08 ± 2.31	0.001

Note: EG = experimental group; CG = control group; SD = standard deviation.

indicators were increased significantly in the experimental group. One study with the aim of evaluating the effectiveness of the implementation of Team Strategies and Tools to Enhance Performance and Patient Safety (Team STEPPS) reported improved observed safety behavior and performance (Stead et al., 2009). Other studies also reported an increase in safety climate scores (Pronovost et al., 2005; Sexton et al., 2011), which generally are in accordance with the results of the current study. However, an interventional study reported that after 12 months of the educational program, no major difference was observed in patient safety culture indicator error management and 11 further indicators and safety climate scales (Hoffmann et al., 2014). The differences in results can be due to the different follow-up duration of the intervention. Although the different design (lack of control group and lack of random allocation) of the studies, the sample size could be considered as possible reasons for achieving different results in the studies.

In the current study, educational intervention significantly improved “pharmacological considerations to prevent errors” in experimental group. Administration of medicine is an important component in the care process and the basic element in nursing care (Mark & Belyea, 2009).

Incorrect identification leads to a series of adverse events or errors that involve drug administration and blood components, procedures, surgeries, and laboratory and radiological testing (World Health Organization, 2011). The results of the present study indicated that the educational intervention was significantly effective in patient personal information to prevent errors. Therefore, the educational intervention could effectively improve patient safety regarding personal information to prevent errors.

The study also had some limitations. The mental status of respondents and their social bias to answer the questionnaires are some of the limitations of this study that could affect the participants’ answers and were out of the researchers’ control. The lack of similarity between the two groups of participants in terms of age and work experience could be another limitation of this study that could influence the results of the study, although the researchers tried to decrease the effect of confounding factors (e.g., age, work experience, etc.) by randomization and using the appropriate statistical tests. The organization’s policy change management was another limitation of this study, which could have affected the results of the study and was beyond the control of researchers. The results of the study also are not generalizable to other hospitals because of the low sample size, selection of a specific ward, and cultural discrepancy.

Conclusion

To the authors’ knowledge, this study is the first interventional study regarding patient safety improvement in Iran. The educational intervention improved “overall perception of patient safety” composites, and some of the PSIs “pharmacological considerations, personal information considerations, and proper implementation of procedures considerations.”

Educating patient safety concepts in hospitals requires much effort and investment since creating a new culture tailored to patient safety needs requires changes in hospital officials and staffs’ attitudes, and their determination to improve patient safety. Conducting further research is suggested in order to provide a better understanding of the role of various

cultural and religious viewpoints on patient safety culture.

Authors' Note

All authors certify that they have participated sufficiently in the work to take public responsibility for the content, including participation in the concept, design, analysis, writing, or revision of the article.

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Declaration of Conflicting Interests

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