

## Patient Safety in ICU. The Role of Family Member's Participation in Nursing Care in Patient Safety? A Randomized Controlled Clinical Audit

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| ARTICLE INFO   | ABSTRACT  |
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| <p><b>Article type:</b><br/>Original Article</p> <hr/> <p><b>Article History:</b><br/><b>Received:</b> 07 Feb 2024<br/><b>Accepted:</b> 26 Feb 2024</p> <hr/> <p><b>Keywords:</b><br/>Family centered,<br/>Nursing care, Patient<br/>safety, Patient<br/>participation, Risk<br/>management</p>  | <p><b>Introduction:</b><br/>Although there is a defined role for family members in the development of the hospital safety policies, family participation in the health care is a challenging concept and few studies have focused on its role in patient safety. This study designed to determine the effect of the participation of family member's in nursing care on patient safety in the intensive care unit (ICU).</p> <p><b>Materials and Methods:</b><br/>The study used a randomized controlled audit. Seventy one ICU nurses, patients and their relatives were selected purposefully, from October to December 2021, in Rafsanjan, Iran. Eligible nurses assigned into 2 study groups (with and without family members' participating in nursing care), by the random minimization method. The ICU nurses' compliance with patient safety standards in nursing care was measured by a checklist. Data were analyzed using SPSS software version 22, by Shapiro and Wilk tests, Chi-Square and t-test for independent groups. A significance level of 0.05 was considered.</p> <p><b>Results:</b><br/>The study groups were similar in terms of demographic characteristics and baseline scores. The mean <math>\pm</math>SD of nurses' observance of patient's safety score in with family participation group (119.20<math>\pm</math>13.64) was higher than in without family participation group(116.97<math>\pm</math>13.26), but no statistical difference was observed between the study groups (p=0.488) Also, in the subgroups, no significant statistical difference was observed between the two groups after the intervention (p&gt;0.05).</p> <p><b>Conclusions:</b><br/>ICU nurses observance of standards in patient safety during caring is not affected by the participation of family members in the nursing cares. These results guide managers and policymakers of the health system to find stronger influencing factors on the level of patient safety compliance during nursing care.</p> |
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## **Introduction**

Adverse events and errors are known as a major problem in health care systems. According to WHO, millions of patients around the world are disabled, injured or killed each year due to unsafe medical care such as: health care related Infections, Misdiagnosis, delayed in treatment, injury from an inadequate use of medical equipment, and undesirable events due to medication errors, which are known as a common cause of preventable harm to the patients (1). Evidences show that, hospitals in low- and middle-income countries leads to 134 million adverse events per year, leading to 2.6 million deaths. Its estimates that, in developed countries, one out of ten patients is injured while receiving hospital care. (2).

In the intensive care units (ICUs), the complexity of conditions and diagnostic-therapeutic processes of patients, predisposes them to more dangerous events(3). Although health care professionals use a variety of methods to improve patient safety and the quality of health care, the avoidance of events, errors, mistakes and risks associated with health care, is still a major and challenging global issue, and insecure medical care plays an important role in poor patient outcomes(4). These include: patient identification, applying effective communication techniques, preventing infection, falling and bed sores, taking full precautions in medication, transfusion, and controlling electronics devices (5-12).

Researchers believe that, the participation of patients and families as the health care systems' partners, play an important role in patient safety in the intensive care unit(13). Although, families need to be given enough attention and support and access to information in a timely manner to maximize their share of caring for their loved ones and reduce their stress load (14,15).

Nonetheless, family members are often excluded from this role with the hospital policies that, keep them out of the bedside and not included in the safety process. In order to promote patient safety during health care, some researchers have recommended the presence of family members at the patient's bed side, as a part

of the team work, and stated that, family members should be sufficiently empowered to express their dissatisfaction with treatment process, or express their concerns about possible mistakes. In fact, they have defined a role for family members in the development of the hospital safety policies (16). Today, despite the international guidance documents on family presence and participation in health care, this is still a challenging issue(17,18) in the health system and few studies have focused on its role in patient safety. Also, few studies report how the families are involved in health care and promoting patient safety. In most studies, families were usually viewed as "care recipients" rather than "active participants in care" and focused on the communication between families and treatment teams (19). The aim of this study was to determine the effect of participation of family members in nursing care on patient safety in ICU.

## **Materials and Methods**

*Study design:* This randomized controlled clinical audit, performed from October to December 2021, ICU department of Ali Bin Abitalib hospital in Rafsanjan, Iran.

### *Sampling and sample size*

Eligibility of 76 nurses who worked in two intensive care units assessed, based on meeting inclusion criteria. The inclusion criteria for nurses include: have at least a bachelor's degree and one year of work experience in the ICU setting. The family members' inclusion criteria include: being over 18 years old, chosen by the patient, being a first degree biological relatives, having informed consent to enter the study and attend at the patient's bedside for participation in nursing care, not having a history of diagnosed mental illness and adequate physical and cognitive ability to participation in nursing care, their patient's being over 18 years old and having an indication of the implementation of the procedures considered in the study checklist. Exclusion criteria for family members include: Intolerance for the presence and participation in caring or withdrawal from participating in the study, and significant change in the condition of the

patient that the procedure was forced to leave. About 71 eligible nurses were assigned randomly into 2 study groups. Thirty five in group A (with participation of family members in nursing cares), and 36 in group B (without the participation of family members during nursing cares). The randomization was done by the first researchers through random minimization method (20) and based on nurses work experience (equal or less than 5 years and more than 5 years) and gender (male and female) classes. The first samples were randomly placed in one of the categories of the study groups using sealed envelopes. The next sample with the same characteristics was assigned in the next group. The total number of samples of each group in each category was considered for the continuation of entering samples, so that the total number of samples in each category of each group was equal. Allocation of samples continued to place all qualified nurses in the study groups.

#### *Intervention*

According to the laws of most Iranian government hospitals, family members are not allowed to be with patients in intensive care units. But temporarily with the concordance of the head of hospital and the ICU wards, during some nursing care, some family members were allowed to be at the bedside of their loved ones. In the intervention group, a family member who was selected by patients and agreed to attend and participate in caring process was selected. Then he/she received training in ward rules and regulations, how to participate in care, how to perform the procedures and how to observe the patient safety rules. After the procedure, the family member stays out of the ward.

In the control group, nursing care was performed according to the routines without the presence or participation of family members. To ensure that there is no possible change in the performance of nurses and family members they did not know the exact purpose of the study (assessing the quality of nurses' performance in terms of patient safety). It should be noted that, during the

implementation of nursing care in both groups, one of the researchers, who was a nurse and had to fill out a checklist for patient safety was present and imperceptibly monitored the work process. The researchers tried to blind the nurses who provided care for the patient, as well as patients and family members. For this purpose, the research checklist was filled outside the ward and, immediately after the procedures. Completing the checklist took an average of 10 minutes.

#### *Instruments*

Data collection tools consist of nurse's (age, gender, work experience, level of education) and family members (age, gender, marital status, occupation, education) demographic characteristics, the patients FOUR2 Score, and a checklist of nurse's observance for patient safety in the ICU which was designed based on patient safety standards in nursing cares (21). This checklist consisted on 76 items in 12 areas with include: patient misidentification (9 phrases), medication errors (4 phrases), correct procedure (10 phrases), correct connections of tubes and catheters (3 phrases), proper nutrition (2 phrases), patient fall (4 phrases), venous thromboembolism (7 phrases), pressure ulcer (4 phrases), healthcare associated infection (7 phrases), unsafe transfusion practice (11 items), surgical errors (4 items), correct ventilation (11 items). The checklist items describe the status of nursing care related to patient safety in ICU at 4 levels: "Yes, completely (scored 2)", "Yes, incomplete (scored 1)", "NO, but not necessary "(scored 2) and" NO, but necessary "(scored zero).

#### *Ethical consideration*

For ethical considerations in research a set of principles were considered such as: approve the proposal by the ethics committee in biomedical research of Rafsanjan University of Medical Sciences and obtain the code of ethics (code of ethics: IR.RUMS1400.049), informed and written consent and anonymity. Family members were also informed that, their participation

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<sup>1</sup>Full Outline of Un Responsiveness

or non-participation in the study would have no effect on the quality of services and the center's routine care and obtain the hospital authorities permission for project implementation.

**Data analyzing**

Data were analyzed using SPSS software version 22, using Shapiro and Wilk tests (to check the normality of quantitative data distribution), Chi-Square test (to compare ratios), and t-test for independent groups (for comparison between groups). A significance level of 0.05 was considered.

**Results**

In the current study, a total of 76 nurses, 96 patients and 48 family members were assessed in terms of eligibility. Seventy one nurses, 71 patients and 35 family members entered in the study. About 25 patients and 13 family members were not eligible to enter the study due to patient's lack of indication for some checklist procedures. Five nurses were not qualified due to lack of work experience in the ICU. None of the participants dropped out during the study.

The result of Shapiro and Wilk test showed that, the distribution of family member's age, FOUR score, correct procedures, venous thromboembolism, health care associated infection and total safety score was normal.

Based on the results, the mean± SD of age of nurses, patients and family members were 32.82 ± 6.48, 55.92 ± 23.43 and 43.06 ± 10.19 respectively.

The mean and standard deviation of the number of years of nurses' work experience was 7.11± 4.63. Near to half 15 (42.9%) of family members were the patient's child, 19

(54.3%) were male and the mostly was married 34(97.1%). In terms of education, most of them were on under diploma level 21(60%). Most of the patients were male 48(67.6%), and were often hospitalized with a diagnosis of multiple trauma 45(63.4%).The mean ±SD of patients FOUR score was 8±1.46 with a maximum score of 11 and a minimum of 4. Comparison the patient's demographic characteristics such did not show a statistically significant difference. Also the results of the data analysis revealed that, nurse's demographic variables in study groups were the same. The details of these results are shown in table (Table 1). The mean ± SD of FOUR score of patients in group without family member's participation in nursing care was 8.22±1.51 and in group with family member's participation was 7.77±1.39. Results of t-test for independent groups showed no significant difference between groups (P= 0.197). Results of nurse's observance for patient safety analysis showed, the mean ±SD total score of nurse's observance for patient safety was 118 ±13.40 with Min 89 and Max 142. The results of t-test for independent groups for comparison of the total score of patient safety compliance by nurses between the two groups showed that, the mean± SD of the total score of patient safety observance in nursing care in family members participation group was higher than without family member participation group, but no statistically significant difference observed between groups (p=0.488) (Table 2). Also, no statistically significant difference was observed in the comparison of the scores of the subscales (P>0.05).

**Table 1:** Comparison the demographic information of nurses and patients between two groups

|                         |                          | With family members participatin group (n= 35) | Without family members participatin group (n=36) | P-Value  |
|-------------------------|--------------------------|--|--|----------|
| Nurses' Work Experience | 1-5 y                    | 14(40)   | 17(47.2)   | *654.0   |
|                         | 5-10 y                   | 11(31.4)                                       | 12(33.3)   |          |
|                         | 10<                      | 10(23.9)                                       | 7(19.4)  |          |
| Nurses' Education       | B.s                      | 31(88.6)                                       | 32(88.9)   | **1.00   |
|                         | M.s                      | 4(11.4)  | 4(11.9)  |          |
| Nurses' Gender          | Male                     | 8(22.9)  | 9(25)  | *0.832   |
|                         | Female                   | 27(77.1)                                       | 27(77.1)   |          |
| Patients' diagnosis     | Multiple Trauma          | 23(65.7)                                       | 22(61.1)   | **0.752  |
|                         | After surgery Monitoring | 3(8.6)   | 2(5.6)   |          |
|                         | Trauma & Fracture        | 4(11.4)  | 3(8.3)   |          |
|                         | Laparotomy               | 5(14.3)  | 9(25)  |          |
| Patients' gender        | Female                   | 12(34.3)                                       | 11(30.6)   | *0.803   |
|                         | Male                     | 23(65.7)                                       | 25(69.4)   |          |
| Patients' Age           |                          | Median± IQR                                    | Median± IQR                                      | ***0.486 |
|                         |                          | 55±47  | 63±41  |          |
| Nurses' Age             |                          | 35±13  | 32±7   | ***0/640 |

\* Chi-square test \*\* Fisher's exact test \*\*\* Mann Whitney U test

**Table 2:** Comparison of the mean and standard deviation of the total patient safety in nursing care between the studied groups

| Independed t Test            | With family members participatin group (Mean ±SD) | Without family members participatin group (Mean ±SD) | P-value |
|------------------------------|---|--|---------|
| Total patients' safety score | 119.20±13.64                                      | 116.97±13.26   | 0.488   |

### Discussion

This study aimed to determine the effect of participation of family members in nursing care on patient safety in ICU. Results of this study showed that the presence of relatives at the bedside of patients and participating of them in nursing care, had no significant effect on patient's safety observance by nurses. Considering that, nurses in both groups have obtained more than 75% of the Nurse's compliance with standards in nursing care score, so it cannot be claimed that, the quality of nursing care was in a desirable level, and both groups were at the same level in terms of patient safety in nursing care. However, the effect of the presence of the observer on the nurse's performance in both group could not be ignored. It should also be noted that, the performance of nurses can be influenced by other factors such as family member's health literacy and their level of awareness. In this study, only about 14% of the family members who participated in the care had an academic education, the rest were illiterate or under diploma. A review of the available literature indicates that, the effect of the presence and participation of family members in nursing care on the adult patient safety has been less considered by researchers and the focus of more studies has been on the presence of parents at pediatric settings. In Sousa et al, study in 2017, the researchers examined the impact of family members' involvement on the safety of patients in neonatal intensive care units from the perspective of nurses and found that, although nurses were well aware of the importance of family involvement in patient safety, they had a limited understanding of this concept and they did not have enough readiness to deal with families and participate them in their daily activities. Therefore, while welcoming the participation of family members, they introduced this concept as an important strategy for safe care. The researchers of this study concluded that, integrating families as an active and vital partners of health care, is

an important and promising strategy for improving the health and safety of patients(22). These evidences indicate, although, the researchers believe that, by understanding ways to integrate patient and family-centered principles into patient safety issues, it is possible to reduce errors and adverse health care events (23) but, the impact of family-centered care on the quality of compliance with the safety of patients in the context of adult health care has been less investigated by researchers, and more studies focus on the views and attitudes of nurses, patients and family members on this issues (24-26) and patient safety adherence rate (27-29). Schubert and et al, reported a review about the interventions to prevent or reduce rationed or missed nursing care. These structural interventions, were focused on improving nursing team work, reductions in the rates of missed nursing care, reminders (via technology or designated persons) and change or optimize the relevant care processes. They conclude that, there is no evidence of a global reduction missed nursing care through the interventions(30) Results of a systematic review showed that, intervention strategies focused only on the level of information and mainly measured safety perception. Interventions with information and participatory strategies measured more diverse outcomes, but their effectiveness was inconsistent. So that, the researchers suggested further studies using a range of intervention strategies and implications with more precise methodologies are needed (13).

Other researchers have recommended further studies to identify and analyze the role of patient and family involvement in the patient safety outcomes (31). This study, for the first time, addresses the role of participation of family members in promoting patient safety during nursing care in the ICU setting. However, it can be said that, during the implementation of this study, the researchers faced challenges such as: the

restrictions on the patient's admission in hospital, and Limitation the presence of family members in the hospital, and permission for them to presence and participating in nursing care in the ICU wards due to the Covid-19 pandemic. More detailed studies are suggested considering the characteristics of patients and their family members, the type of family relationship, and level of family anxiety, abilities and health literacy.

### Conclusion

The results indicated that, the family presence and participation in nursing care could not effect on the nurses observance of standards in ICU patients safety during caring. More detailed studies are suggested in terms of the characteristics of patients and family members participating in the study and eliminating the effect of the researcher's presence are suggested.

Also, these results direct the health policy makers to find more precise factors affecting the compliance of patients' safety while receiving nursing care.

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