

# The effectiveness of risk management program on pediatric nurses' medication error

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## ABSTRACT

**Background:** Medication therapy is one of the most complex and high-risk clinical processes that nurses deal with. Medication error is the most common type of error that brings about damage and death to patients, especially pediatric ones. However, these errors are preventable. Identifying and preventing undesirable events leading to medication errors are the main risk management activities. The aim of this study was to investigate the effectiveness of a risk management program on the pediatric nurses' medication error rate.

**Materials and Methods:** This study is a quasi-experimental one with a comparison group. In this study, 200 nurses were recruited from two main pediatric hospitals in Tehran. In the experimental hospital, we applied the risk management program for a period of 6 months. Nurses of the control hospital did the hospital routine schedule. A pre- and post-test was performed to measure the frequency of the medication error events. SPSS software, *t*-test, and regression analysis were used for data analysis.

**Results:** After the intervention, the medication error rate of nurses at the experimental hospital was significantly lower ( $P < 0.001$ ) and the error-reporting rate was higher ( $P < 0.007$ ) compared to before the intervention and also in comparison to the nurses of the control hospital.

**Conclusions:** Based on the results of this study and taking into account the high-risk nature of the medical environment, applying the quality-control programs such as risk management can effectively prevent the occurrence of the hospital undesirable events. Nursing managers can reduce the medication error rate by applying risk management programs. However, this program cannot succeed without nurses' cooperation.

**Key words:** Iran, medication error, nurse, risk management, self-report

## INTRODUCTION

The health care setting is a high-risk environment because of high disability and mortality rate.<sup>[1]</sup> Modern technologies and extensive human relationships in the health care settings increase the probability of undesirable events. There are two main concerns in these settings: first, the practitioners should provide correct and high-quality therapeutic services and second, they should avoid undesirable medical errors. In the United States of America, the annual costs of drug-related

problems are estimated to be more than \$150 billion and the medical error dependent mortality rate ranges from 44,000 to 98,000 cases.<sup>[2,3]</sup> There are no valid national statistics of medical error rate and its total cost in Iran. Furthermore, researchers did not find any systematic interventional studies regarding ways to reduce medication errors. However, some studies have mentioned medication errors of nurses and nursing students. For instance, a study aimed to assess the frequency and types of medication errors made by the students of Urmia University of Medical Sciences in 2011. The most common reported errors were delivering the medication later or earlier than the right time (7.20%). Most of the errors were in the antibiotics drug category.<sup>[4]</sup> Other researchers (2009) found that 9.7% of students made medication errors. A despicable medication error rate in nursing students during a course was 46% and most of them do not report medication errors to their teacher.<sup>[5]</sup> Another study on nursing students showed that from 372 observations made during drug preparation and injection, about 41% (153) have had some sort of medication errors.<sup>[6]</sup> In addition, a study in the intensive care unit showed the nurses' ability for calculating the amount and dosage of drugs to be average and most of them have many errors

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in calculating.<sup>[7]</sup> Results of a cross-sectional study on 286 nurses showed that the number of medication errors in the past 3 months was 5.19 cases per nurse.<sup>[8]</sup>

Moreover, a great deal of evidence shows that nurses working in high-risk situations including pediatric units make frequent errors when administering medications to children.<sup>[9,10]</sup> In this process, nurses need to have enough clinical skills such as professional judgment, critical thinking, and the ability to interpret patients' data and use their knowledge and skills in managing high-risk situations.<sup>[9]</sup> However, the process of drug therapy has been less known and assessed.<sup>[11]</sup>

The National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP 2007) has provided the most comprehensive definitions for the medication error: "A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care personnel. Such events may be related to professional practice, health care products, procedures, and systems."<sup>[12]</sup> Generally, the hospital errors are divided into six categories,<sup>[13]</sup> among which the medication error category with 19.4% of all errors is the most common type of error.<sup>[14]</sup> Medication errors are the eighth leading cause of death in the United States of America.<sup>[11]</sup> The major errors bring about damage and death to patients.<sup>[15]</sup>

In children, the importance of the correct medication administration is diverse. The reasons are as follows: During the childhood period, the pharmacokinetic parameters change continuously; the drug dosage calculation is based on parameters such as weight, body surface area, age, and clinical conditions; and there is a poor knowledge base about the correct therapeutic and toxic doses and drug pharmacokinetics.<sup>[16]</sup> Consequently, the medication errors are more prevalent in pediatric settings. A Canadian study showed that annually 5000 hospitalized children suffer from complications of the medication errors, among which 2500 children experience moderate to severe complications.<sup>[12]</sup> As a result, the frequency of medication errors is one of the most important criteria for evaluating the quality of care and patients' safety.<sup>[17]</sup>

Identification and prevention of undesirable events are the main risk management activities.<sup>[14]</sup> Risk management is a program for reducing preventable undesirable events, their complications, and financial burdens. This program is a continuous, step-by-step process that facilitates the decision-making activities in critical situations. During this process, errors are expected to be decreased and opportunities rise.<sup>[18]</sup> Measuring the risk of accidents and providing a

safe environment are of great importance in attaining the ultimate goal of quality care.<sup>[19]</sup>

Unlike the traditional viewpoint, the risk management considers the poor system designation, not the nurse individual malpractice, as the source of error.<sup>[20]</sup> Therefore, this program is expected not only to decrease the frequency of errors but also to decrease the trespasser fear of punishment and stigma. Considering the preventability of medication errors and greater importance of such errors in pediatric settings, and with regard to the lack of a well-organized study in this subject matter in our country, this study was conducted. The aim of this study was to investigate the effectiveness of a risk management program on the frequency of the medication errors in all pediatric settings affiliated to the Tehran University of Medical Sciences, Tehran, Iran.

## MATERIALS AND METHODS

This is a quasi-experimental study. The study population consisted of all the full-time staff nurses working in general or intensive care units of the pediatric hospitals affiliated to the Tehran University of Medical Sciences. The inclusion criteria were working as a full-time staff nurse and having no previous juridical problem due to professional errors. As the drug therapy process in the emergency and operating room units is significantly different from that in the other units, all those staff nurses working in these two units were excluded. Two hospitals were randomly allocated to the control and case (experimental) hospitals. Thereafter, 200 nurses, who consented to participate in the study, were recruited, which came up to the selection of 100 nurses from each hospital. All those recruited nurses who left work or changed their organizational position in such a way that they were no more involved in the drug therapy process were excluded from the study. The results of the Agrawal (2009)<sup>[21]</sup> studies, which reported a 13% medication error rate, were used for the calculation of the sample size. We conducted a pilot study in which the mean medication error was equal to 42; considering this mean and in view of  $\alpha = 0.05$  and an 80% power ( $\beta = 0.20$ ), we calculated the sample size.

The data-gathering tool consisted of two parts: An anonymous self-report questionnaire for reporting the medication errors and an observational checklist for measuring the quality of drug therapy and documentation by nurses. This checklist consisted of a demographic section (gender, age, and years of nursing experience, organizational position, education background, and working shift) and a section pertaining to the drug therapy and documentation quality. The first instrument was

completed on a self-report basis, while two blinded research colleagues completed the second. By blinded, we mean that they did not know which are the experimental and control hospitals. In order to develop the self-report questionnaire, we used the results of an extensive literature review and the existing tools. The study subjects in both the experimental and control hospitals received some verbal education about the questionnaire content and the way of completing it. We put a box in an accessible location in each hospital and asked the nurses to drop the anonymous questionnaires into it. The observational checklist was developed based on the standard drug therapy guidelines available in the nursing literature. We asked 10 pediatric nurses and faculties to check the instruments regarding the face and content validity. Their comments were included in the final version of the instruments. The checklist items were scored on a dichotomous scale, i.e. "Yes" and "No." Totally, the checklist contained 87 items in three subscales: "The drug checking" with 41 items, "the drug preparation" with 19 items, and "the drug administration to the patient" with 27 items. The total score of the checklist ranged from zero to 87 errors. We used the inter-observer reliability for establishing the checklist reliability; the agreement coefficient between the two observers for 20 checklists was 0.82. We gathered the data in the following three phases: Before commencing the intervention, i.e. the pre-test, during the implementation of the intervention, i.e. the post-test. In the first phase, the observers filled 100 observational checklists regarding the quality of the 100 nurses' drug therapy procedure for each hospital. Simultaneously, we educated the nurses about the way of completing the self-report questionnaire through two sessions. At the beginning of the intervention phase, we formed a risk management committee consisting of the hospital nurse manager, the educational supervisor, two liaison staff nurses, and the risk manager, i.e. one of the researchers. The mission of this group was to identify the nurses' medication errors and provide strategies for decreasing those errors. The committee held sessions on a regular bimonthly basis. Moreover, additional sessions were held as needed. The educational supervisor and the two liaison staff nurses communicated the committee's approved strategies to the hospital wards. The committee's interventions included establishing educational courses regarding the standard drug therapy practice and the medication errors for all nurses in all working shifts, providing the possibility of participating in these courses for all nurses, and providing written educational materials regarding the safety measures in drug therapy for nurses. Moreover, the committee had the responsibility of monitoring the drug therapy process performed by the staff nurses using the observational checklist, identifying the errors and error priorities, as well as educating and

encouraging nurses to report the events of medication errors. The educational supervisor and the two liaison staff nurses were responsible for supervising and reporting the quality of the implementation of the imparted strategies to the committee. Thereafter, the committee investigated the cause of the reported errors and provided more preventive strategies. Moreover, the self-report questionnaires were investigated similarly. After the intervention phase, the post-test data were collected simultaneously in both hospitals. We used the SPSS software for data analysis.

### Ethical consideration

The ethical committee of the Tehran University of Medical Sciences approved the study. Also, this study has been carried out in accordance with the Code of Ethics of the World Medical Association. We asked permission for entering the research environment from both hospitals' managers. Participation in the study was voluntary. The study subjects were free to stop participating at any phase of the study. We assured them about the confidentiality of their personal data.

### RESULT

All the study subjects were female nurses with a bachelor's degree in the field of nursing. Also, more than half of them (58.5%) were single. There was no significant difference between the nurses in the experimental and control hospitals, regarding their marital status, years of experience in nursing, job satisfaction, number of ward beds, and overtime practice ( $P > 0.05$ ). However, nurses in the experimental and control hospitals showed a significant difference in the years of experience in the pediatric settings ( $P < 0.013$ ). The demographic findings are summarized in Table 1.

The mean of medication error events before the study in the experimental group was higher than in the control group; however, the results of the independent-samples *t*-test showed that this difference was not statistically significant ( $P > 0.05$ ) [Table 2]. On the other hand, the results of the paired-samples *t*-test showed that the mean of medication error events in the experimental group after study was significantly lower than the values obtained before the study ( $P < 0.05$ ) [Table 2]. Moreover, the results of the independent-samples *t*-test showed that the mean of medication error events after the study in the experimental group was significantly lower than that in the control group ( $P < 0.05$ ) [Table 2]. However, there was a significant difference between the values before and after study in the control group.

The results also showed that the mean of the medication error self-reports in the experimental group after study was significantly higher than in the control group ( $P < 0.05$ ).

**Table 1: Demographic characteristics of the intervention and comparison groups**

		Intervention group (n=100)	Comparison group (n=100)	Results
Age (years)	20-25	12	24	$t=2.275$
	26-30	53	56	$df=198$
	31-35	26	14	$P=0.006$
	>35	9	6	
Experience in children units (months)	<24	43	24	$t=-2.497$
	25-50	25	29	$df=198$
	51-75	26	33	$P=0.013$
	>75	4	14	
Employment status	Formal	2	9	$\chi^2=9.3307$
	Covenant	55	64	$df=3$
	Contract	23	12	$P=0.025$
	Initial	20	15	
Job satisfaction	Yes	6	11	Fisher's exact test
	No	94	89	$P=0.155$
Shift	Morning	26	8	$\chi^2=11.481$ , $df=1$
	Circulation	74	92	$P<0.001$

**Table 2: Comparison of results medication errors in the two groups**

Group	Pre-test	Post-test	Results
Intervention	43.25 (11.33)	30.67 (13.73)	$t=13.65$ $df=99$ $P<0.001$
Comparison	38.3 (12.89)	36.67 (12.33)	$t=5.253$ $df=99$ $P<0.001$
Results	$t=2.882$ $df=198$ $P=0.001$	$t=-3.251$ $df=198$ $P<0.001$	

**Table 3: The relationship between medication errors with different demographic variables**

Variable	Test result	P-value
Age	$r_s=-0.20$	0.002
Marital status	Fisher's exact test	<0.001
Experience	$r_s=-0.20$	0.002
Experience in children unit	$r_s=-0.199$	0.002
Number of patients	$r_s=0.421$	<0.001
Employment status	Fisher's exact test	0.001
Overtime	$r_s=0.274$	<0.001
Job satisfaction	Fisher's exact test	0.041

$r_s$ =Spearman rho correlation

The medication error variable did not have any significant correlation with the ward type. The results of the correlation testing between the medication error

events and the demographic variables are shown in Table 3.

For investigating the effect of the independent and the demographic variables on the medication error variable, we used the regression analysis. The results showed that in addition to the management risk variable, other variables such as marital status, number of patients in the ward, and working shift are the predictors of the medication error events. The regression analysis equation is as follows:

Number of errors = 10.7 + 8.307 marital status + 2.24 number of patients - 4.319 (risk management + 6.58 working shift)

This means that the number of medication errors of an individual nurse is at least 10.79; the increment of the number of hospitalized patients in a ward, single status, and working shift will add 2.24, 8.307, and 6.58 units, respectively, to the number of medication errors of each nurse. On the other hand, the implementation of the risk management program will reduce 4.319 units from the number of medication errors of each nurse.

## DISCUSSION

The results of this study confirmed the effectiveness of the risk management program in decreasing the number of medication error events. Brett Platte (2010). also concluded a medication program may have led to a high rate of entirely precise drug profiles.<sup>[22]</sup> The current study result is consistent with the findings of the Cohen *et al.* (2005) who investigated the effect of a medication safety program on the adverse drug events in a community hospital. They concluded that application of a set of simple inexpensive interventions such as paying special attention to the high-risk drugs, developing an effective error-reporting system, and implementing the drug administration safety program could effectively decrease the number of the medication error events. However, the Cohen *et al.* (2005) study differs from the current study with respect to the length of the study (3 years vs. 6 months) and having more organizational authorities, such as involving the hospital pharmacy, hospital management, and financial affairs unit in the study.<sup>[23]</sup>

The results of this study are consistent with the study results of Hajbabaee *et al* (2011). who showed the number of medication errors during 3 months of their study to be 5.19 cases per nurse.<sup>[8]</sup> Ross *et al.* used the medication error self-report forms as the data-gathering tool and found that the most common type of errors was related to the intravenous drugs (56%) and that nurses were responsible for 59% of all

types of the health care-related errors. They also found that the introduction of a strategy for double checking the drugs at the hospital pharmacy location could reduce the number of medication errors by 3.8 units. They also changed the error-reporting form to a less punitive form, which could increase the error-reporting rate by 10%.<sup>[24]</sup> Although the Ross *et al.* study is more limited than the current study, they could increase the error-reporting rate. This confirms the effectiveness of the less punishing reporting system in increasing the error-reporting rate. In the current study, we received only seven self-reports regarding the medication error events. This may be due to the novelty of the risk management program and the staff nurses' resistance to change.

The results of the Ross *et al.* study showed that after educating the nurses about the correct medication administration and serum therapy, the frequency of the nurses' medication errors decreased from 37 to 32 errors per annum.<sup>[24]</sup> Also, Baker *et al.* suggested that the introduction of a guidebook could influence some of the practices associated with administration of medications.<sup>[25]</sup> We obtained similar results. In other words, in our study, the number of severe- and moderate-risk errors declined, respectively, from 35% and 64% (before study readings) to 17% and 49% (after study readings).

In the current study, the results of the regression analysis also showed that the risk management, marital status, number of the patients in the ward, and working shift are all the predictors of the medication error events' frequency. Marcus *et al.* found that the scores of staff, when working at night, were significantly lower than the daytime scores ( $P = 0.047$ ). They concluded that night shift could negatively affect the quality of staffs' performance.<sup>[26]</sup> We also found that working at nighttime is a predictor of the medication error events. Smith *et al.* reported that a short 40-min sleep during nightshift significantly improved the physicians' and nurses' cognitive and psychomotor performance.<sup>[27]</sup> The Australian Medical Association also reported that working at continuous 24-h shifts, as well as working more than 70 h a week, is considered as a high-risk practice. Lokley (2007) and Berger *et al.* also reported that the nighttime work and the nighttime somnolence significantly decrease the patients' safety ( $P < 0.05$ ).<sup>[28,29]</sup>

Sasichay *et al.* reported that nurse — patient ratio is one of the most important predictors of the hospital undesirable events.<sup>[30]</sup> Griffiths *et al.* found that there is a relationship between care quality and staffing levels, particularly among registered nurses.<sup>[31]</sup> We also found that the number of hospitalized patients in the ward is a predictor of the medication error events.

Kendall-Gallagher *et al.* reported a significant, direct correlation between the nurses' numbers of working hours and the frequency of the medication error events, i.e. an increase in the nurses' working hours would cause an increase in the nurses' medication error rate ( $P = 0.006$ ).<sup>[31]</sup> In our study, although there was a significant correlation between the nurses' working experience and the rate of the medication errors, this variable was not a predictor of the medication error events. This finding is not consistent with the findings of the other studies, including Kendall-Gallagher *et al.*'s study. A wide variety of variables, such as individual background, organizational, cultural, and economic factors, may affect the occurrence of the medication error events. These factors may increase or decrease the effects of each other. In our study, all of the nurses were females with Bachelor of Science degree and the majority of them (75%) had the same working experience. Therefore, investigating the pure and complete effects of the aforementioned variables on the occurrence of the medication error events was impossible.

A significant increase in the error-reporting rate was one of the other important findings of the current study, though the rate was only 7%. The result of this study is consistent with the results of other studies that were conducted in Iran. Mohammidinejad *et al.* found that most students do not report medication errors to their teachers.<sup>[5]</sup> It seems this issue starts from their study period at the university and continues as a habit and culture during all of their work life. Kagan *et al.* also reported that because of the fear of negative consequences, nurses refrained from reporting the medication errors, and hence, the error-reporting rate was not very high.<sup>[33]</sup> Firth-Cozens (2002) reported that reporting those errors with no adverse effects could improve the error-reporting culture.<sup>[34]</sup> We also found that the majority of the reports were the reports of the minor errors. This is because of long-lasting stigmatizing and punitive organizational atmosphere of the hospitals, which entails adverse outcomes for the nurses reporting their medication errors. Other studies reported the same findings. The cause is the established punitive and stigmatizing culture of the hospitals for dealing with the medication errors. Although we tried to develop a questionnaire with maximum anonymity, we still could not attain the goal of full and error-free reporting. In a study on the comparison of methods for detecting medication errors in 36 hospitals and skilled nursing facilities, Barker *et al.* detected 71% of errors by the direct observation method and only a few by the self-report method. All of these findings imply that for increasing the self-report of the medication errors, the health care managers and authorities should not use these reports for focusing on punitive measures and stigmatizing

the nurses who report their professional errors; instead they should focus on and improve the care-giving process and the hospital caring and supervising system for reducing the rate of the medication errors.<sup>[35]</sup> We believed that even introducing this concept to the hospital staff and managers is a stepping stone that facilitates and improves the organizational culture for reporting the medication error events.

### Limitations

This study had a few limitations. The presence of the observer for observing the nurses' medication administration and determining the frequency of the medication errors could affect the nurses' natural practice. To eliminate, or at least to reduce the effect of the observer's presence on the nurses' actual practice, other researchers can employ staff nurses and supervisors from the same caring setting.

In our study, all of the nurses were females with Bachelor of Science degree and the majority of them (75%) had the same working experience. Therefore, investigating the pure and complete effects of the aforementioned variables on the occurrence of the medication error events was impossible. Selecting the study fields with maximum variance may increase the possibility of the comprehensive investigation about the effects of the aforementioned variables on the occurrence of the medication error events.

### CONCLUSION

The hospital undesirable events are currently considered as important by virtue of the safety and quality of care-evaluation criteria. On the other hand, the medication errors are the most prevalent types of known medical errors as well as the most prevalent preventable reasons of the hospital undesirable events, which directly affect the patients' safety. Based on the results of this and other previous studies and taking into account the high-risk nature of the caring environment, applying the quality-control programs such as the risk management program can effectively prevent the occurrence of the hospital undesirable events.

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