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Development and evaluation of a high-risk intravenous medication safety program applying the Six Sigma technique: Empirical Research Quantitative

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Abstract

This was a one-group pretest-posttest study that developed a high-risk intravenous medication safety program by applying the Six Sigma technique to hospital nurses and measuring the pre- and post-effects. Participants were nurses with more than three years of experience in administering chemotherapy and highly concentrated intravenous electrolytes working at a university hospital in City D. Data analysis was performed using the Minitab 16 PC+ program; frequency, percentage, and 4-block matrix analyses were performed. In the definition stage, an improvement team was formed to proceed with the task, which was defined as a high-risk intravenous medication safety issue in ward nursing. In the analysis stage, a lack of high-risk intravenous medication safety education was identified. In the improvement stage, nurses were provided with high-risk intravenous medication safety education. Post-study knowledge scores increased significantly from 11.24 to 21.32, while performance scores improved from 36.61 to 68.45 ($p < 0.05$). This study identified and improved the problems in hospital organizational systems and presented a strategy for establishing a safety system in medical institutions and improving human factors. This ultimately enhanced the safety of high-risk intravenous administration.

Keywords: *hospital, nurse, medication safety, Six Sigma technique*

1. Introduction

An increasing need for quality improvement in medical and nursing services has been observed, owing to the demand for patient-centered medical care and the external environment (Kwon et al., 2017), which requires reasonable costs according to hospital competition and efficient resource allocation. Quality improvement activities in medical care are systematic processes of planning and implementing quality improvement in a patient-centered, result-oriented, and collaborative healthcare system through a continuous process (Cohen, 1996).

In 2020, the number of domestic patient safety accident reports was approximately 1,160, on average, per month, marking a significant increase from 563 in 2016 to 13,919 in 2020 (Department of Health and Welfare,

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2021).

Medication errors constituted 31.1% of the reports associated with fall incidents. Additionally, the identification and improvement of problems in the medication administration nursing process are gaining importance.

Medications represent the largest component of hospital treatment processes and are responsible for the highest number of medical error(Kohn et al., 1999). Reportedly, 67% of hospital admissions are related to medication errors (World Health Organization, 2016). It was reported that 1.5 million preventable medication errors occur every year (Wolcott et al., 2007).

Adequate knowledge of medications and compliance with the duties of confirmation, caution, and explanation before and after administration can help prevent medication errors (Leape et al., 1995). Based on the theoretical finding that 86% of medication errors can be prevented by nurses before medication administration in hospitals, we can infer that nurses are responsible for ensuring medication safety.

In one study, nurses' medication errors were related to failure to confirm patients' names, work fatigue, and difficulty reading doctors' prescriptions (Osborne et al., 1999). In another study, it was confirmed that failure to follow verification procedures resulted in similar issues as excessive workload, confusion due to similar drug names, and errors in dose calculation (Kim, 2002). To address this problem, we intended to improve hospital environments to make them safer.

Medication safety problems can be simultaneously analyzed and prevented. We considered an open organizational culture for the prevention of medication safety problems and future management to ensure a safe and accurate medical delivery system. Voluntary improvement activities by organizations seeking preventive methods (Kim et al., 2007) are required in clinical practice.

Most issues in medical institutions stem from human errors resulting from inadequate systems and poorly defined procedures. Although the seriousness of problems with systems and procedures is widely known, there remains a lack of awareness among medical institutions (Leape, 2008).

Compared with other sectors, medical services have limitations owing to stringent government regulations. However, medical service companies that have adopted Six Sigma have reported improved patient satisfaction, operating room efficiency, and hired employees, and have reported that patient satisfaction, financial performance, and patient safety can be achieved through error prevention by shortening the period, encouraging excellent employees to work longer, reducing waiting times for older adults, and reducing drug-dispensing errors (Park et al., 2003). In particular, the Six Sigma approach has greatly aided in resolving chronic process problems such as waiting time, bed change time, and settlement errors in emergency rooms, where patient complaints are high. Using the Six Sigma technique, members within an organization voluntarily and continuously identify areas for improvement, seek improvement measures, and convince the entire organization through learning and training experiences (Harry & Schroeder, 2005). This method has the advantage of effectiveness.

Most existing studies utilizing the Six Sigma technique are related to the manufacturing industry (Oh, 2009), and the performance measurement indicators in these studies before and after improvement are standardized based on statistical management; however, medical services have the same properties and are difficult to measure (Kim, 2006). Therefore, in this study, an improvement team was formed with researchers and representative members of the organization, and a Six Sigma step-by-step procedure was applied by utilizing consensus-building through decision-making, such as brainstorming, which is a representative Six Sigma

technique. Additionally, there have been a few medical studies using this technique. For instance, a study improved discharge prescriptions for warfarin to prevent antiembolism (Kallal et al., 2019); another analyzed the effects of reducing medication errors, increasing patient safety, and reducing operating costs (Trakulsunti et al., 2019); and yet another improved medication errors. Recent research, such as hospital field studies, shows the possibility of solving problems in the medical field using Six Sigma techniques.

2. Methods

2.1 Study design

This was a one-group pretest-posttest design study that developed a high-risk intravenous medication safety program by applying the Six Sigma technique to hospital nurses and measuring the pre- and post-effects.

2.2 Participants

A survey measuring medication safety knowledge and performance was conducted at a university hospital in a metropolitan city (City D).

. The participants were those who handled and administered concentrated electrolytes, such as NaCl and KCl, heparin, and anticancer chemotherapy agents, which are high-risk intravenous drugs. The participants were 20 nurses with more than three years of experience in the ward. The improvement team consisted of 10 nurses with more than five years of experience and work improvement activities recommended by the head of the department. Data were collected from September 17 to October 15, 2021.

2.3 Research tools

■ Knowledge of high-risk intravenous drug administration safety

Medication safety knowledge was developed by the researcher based on Hospital Nursing Association's (2016) Intravenous Infusion Therapy Nursing Practice Guidelines and literature on Nursing Safety Management Guidelines, and was assessed by a nursing professor. The questions covered the following. Four questions were on basic knowledge related to drugs and three were on compliance with the five rights when administering medication. Five questions were on precautions when administering medication, two on safety management and disposal after medication, one on medication education, one on medication administration and nursing records, and three on the observation of side effects. This totaled 19 questions with possible scores ranging from 0 to 19, with 1 point for a correct answer and 0 points for an incorrect answer. A higher score indicated a higher level of knowledge of medication safety practices. In this study, Cronbach's was .88.

■ Ability to safely perform high-risk intravenous administration

For evaluating medication safety performance, 14 questions were used based on Kim et al.'s (2010) original tool, which was modified by the researcher for this study. The questions concerned the appropriateness of the medication preparation process, compliance with the five correct checks when administering medication, and medication management. Performance was rated on a scale from 0 to 4, with 0 indicating "very poor" and 4 indicating "very good." The score ranged from 0 to 56 points, with a higher score indicating a greater ability to safely administer the medication. In this study, Cronbach's = .92.

2.4 Data analysis

The collected data were analyzed using the Minitab 16 PC+ program, and the nurses' questionnaires were analyzed using the characteristic factor diagram and 4-block matrix method. Nurses' pre- and post-medication

safety knowledge and performance were analyzed using the mean, standard deviation, and Wilcoxon tests. A rank-sum test was also conducted.

2.5 Ethical considerations

This study was approved by the institutional review board of (blinded for review). Written informed consent was obtained from all study participants before data collection. All participant data were processed anonymously to maintain anonymity.

3. Results

3.1 Definition stage

Hospitals and nursing departments strive to improve the quality of medical care and nursing and promote patient safety. We selected this endeavor because of the interest and demand for standardization in the handling and safety management of highly concentrated electrolytes, such as KCl and NaCl, anticoagulant heparin, and high-risk anticancer drugs. Through reports from the hospital nursing department and improvement team members, and a review of administrative records, it was confirmed that there was no education and management system for high-risk intravenous injections for nurses other than continuing nurse training within the past two years. Therefore, to ensure that medication safety is closely related to patient safety and the quality of medication nursing during the high-risk intravenous medication administration process, safety guidelines were developed, a standardized medication administration process was selected, and improvement plans were maintained and managed through verification of effectiveness.

3.2 Measurement stage

Through an analysis of the high-risk intravenous medication administration safety issues conducted with the improvement team, the following process factors were identified: frequent verbal prescriptions, omission of patient confirmation, and neglect of fluid instillation and speed control. Additionally, the identified environmental factors included nurses' inexperience in operating fluid injection devices, inappropriate drug management, and medication administration procedures. A lack of manuals and confusion regarding injection dosage units was also observed.

Nurse factors included insufficient lack of knowledge about drugs, lack of nursing staff, and lack of drug education. Safety guidelines for high-risk intravenous injection medications for nurses were developed and standardized considering tasks that can be implemented in practice and have high-performance results. The final selection process was then performed. After analyzing the nurses' prior knowledge and performance of high-risk intravenous drug administration safety, the items for improvement in knowledge measurement were identified. These included confirming the dosage of prescribed and prepared drugs, addressing situations encountered when handling anticancer drugs, maintaining accurate anticancer drug administration and nursing records, and observing patients during anticancer drug administration. Regarding performance level, the main improvement items included contrasting prescriptions with prepared drugs and dosages, checking the expiration date of drugs, identifying patients, and ensuring safe management and storage of high-risk and high-caution drugs. Analysis of the problems of medication safety performance revealed that nurses and pharmacists identified doctors' frequent verbal prescriptions as a common problem. To select key issues with high urgency and importance, the improvement team's characteristic factors were analyzed. A block matrix was created to compare the controls and effects of the identified factors. Consequently, insufficient of knowledge and

performance ability regarding high-risk intravenous drugs and improvement activities were conducted to address the lack of high- risk intravenous medication administration training for nurses (Figure 1).

↑ Efficient Confusion in packaging containers Frequent verbal prescriptions Efficacy	Insufficient of knowledge about drugs Insufficient ability to administer medication Omission of medication administration procedures Poor operation of medication equipment
↓ Non-Efficient	Improper drug management Improper storage

Uncontrollable Control Controllable

Figure 1. Nurses' intravenous medication safety issues 4 block matrix

The following variables were identified for improving the key issues during the high-risk intravenous injection medication safety performance process. The first is the status of high-risk intravenous injection education and the nurses' level of prior knowledge. The second is the management types of incorrect fluid injection/proximity errors, which we analyzed. Third, there are problems with administering high-risk intravenous medications. Fourth, we analyzed the status of the medication equipment in each ward and whether training on how to operate it was included. Eleven key factor items were analyzed. Specific details included the absence of administration protocols for major drugs in each ward, lack of training to operate medication injection devices, non-establishment of standardized high-risk intravenous drug administration procedures, lack of individualized medication education for nurses, lack or non-availability of the hospital's own medication booklet, and similar concerns. However, drug packaging has not yet been verified. Considering the possibility of actual implementation, four variables were selected as the final key factors, excluding the lack of the hospital's own medication list and lack of confirmation of packaged drugs in containers, similar to those not provided.

3.3 Analysis stage

Following the analysis of prior knowledge items, which averaged less than 0.7, in agreement with the improvement team of nurses' prior and post-knowledge regarding high-risk intravenous drug administration safety, high-risk drug concepts (M=0.60), situations encountered when handling anticancer drugs (M=0.45), and provision of information regarding medication administration (M=0.50) were found to be major improvement items. Following the analysis of the preliminary performance items, the main improvement item was confirmation of the expiration date of the drug (M=2.71), which averaged less than 3.0, in agreement with the improvement team (Tables 1 and 2).

Table 1. Nurses' level of pre- and post-intravenous medication safety knowledge

(N=20)

division	knowledge ability (M±SD)	
	pre	post
High risk drug concept	0.60±0.50*	0.95±0.22
High risk drug knowledge	0.86±0.20	0.95±0.22
Mechanism of high-risk intravenous drug administration	0.85±0.36	0.90±0.31
Anticancer drug classification and actual drugs used	0.88±0.33	0.95±0.22
Things to check before taking medication, things to attach to the drug label	0.80±0.41	0.95±0.22
Check the dosage of the prescribed medicine and the medicine being prepared	0.75±0.44	0.90±0.31
Drug dosage for high-risk intravenous administration	0.85±0.36	1.00±0.00
Precautions for intravenous administration	0.86±0.20	0.85±0.37
Anticancer drug administration management instructions	0.80±0.41	0.90±0.31
Precautions when administering anticancer drugs	0.88±0.33	0.85±0.37
Precautions when administering Vesicant	0.80±0.41	1.00±0.00
Situations exposed when handling anticancer drugs	0.45±0.51*	0.70±0.55*
Treatment of termination of anticancer drug administration	0.88±0.33	1.00±0.00
Storage of highly concentrated electrolytes	0.80±0.41	1.00±0.00
Disposal of waste related to anticancer drugs	0.88±0.33	0.85±0.37
Provision of information regarding medication administration	0.50±0.51*	0.95±0.22
Anticancer drug administration records and nursing records	0.72±0.46	0.95±0.22
Things to observe during anticancer drug administration	0.76±0.44	0.95±0.22
Side effects and management when administering anticancer drugs	0.80±0.41	1.00±0.00
What to do in case of extravasation	0.96±0.20	1.00±0.00

* : Applicable items less than 0.7

Table 2. Pre- and post-performance level of intravenous medication administration safety by nurses

(N=20)

division	performance (M±SD)	
	pre	post
Implement read-back when carrying out oral/telephone prescriptions	3.13±0.80	3.20±0.91
Clear communication	3.13±0.68	3.45±0.82
Dosage comparison of prescribed and prepared medications	3.21±0.66	3.75±0.02
Check drug expiration date	2.71±0.96*	3.75±0.02
Aseptic preparation according to safety management guidelines	3.13±0.80	3.45±0.82
Label all mixed medications	3.42±0.65	3.50±0.58
Correct use of drug injection devices	3.50±0.59	3.65±0.67
Patient identification in two ways	3.23±0.69	3.45±0.82
Check drug name	3.46±0.51	3.67±0.57
Check capacity	3.46±0.51	3.80±0.57
Check administration route	3.50±0.51	3.70±0.57
Check administration time	3.46±0.51	3.80±0.57
Providing information about medication to patients/guardians	3.08±0.78	3.25±0.87
Safe management and storage of high-risk, high-caution medications	3.29±0.69	3.80±0.57

*: Items below 3.0

3.4 Improvement stage

The improvement plan followed for administration of high-risk intravenous injections is as follows. First, development and verification of safety guidelines for high-risk intravenous injections including situations and details before, during, and after administration of high-risk intravenous injections were focused upon. Second, standardization was based on the developed medication safety guidelines. Third, medication safety education was conducted to supplement the nurses' prior knowledge and performance deficiencies regarding high-risk intravenous injections. By addressing the medication safety issues identified during the medication administration process for high-risk drugs, a standardized high-risk intravenous medication safety process and checklist were created based on the finalized guidelines. As a final step in the improvement plan, we developed an education plan that supplemented the deficiencies in previously developed high-risk intravenous medication safety guidelines, standardized medication safety checklist items, conducted a survey on nurses' prior knowledge and performance levels of high-risk intravenous medication safety, and trained hospital nurses. Safety education for high-risk intravenous drug administration was implemented as the final step of the

improvement plan.

Education was provided as the final step in the improvement plan by supplementing the deficiencies in high-risk intravenous drug administration safety guidelines and surveying nurses' prior knowledge and level of performance regarding the safety of anticancer chemotherapy drug administration. Twenty nurses participated in the training, excluding new nurses who had worked for less than six months in the two wards administering high-risk drugs. Researchers distributed safety guidelines for high-risk intravenous injections and provided information on the types of high-risk intravenous drugs, storage methods, dilution and preparation methods, injection precautions, safety management and handling, side effect monitoring, post-administration treatment instructions, and patient confirmation. The training was conducted twice for 30 minutes. After the researcher gave a lecture on best practices in nursing situations, the nurses were divided into small groups and a mock medication situation was created. After the instructor gave a demonstration for 20 min, each individual practiced autonomously.

Knowledge and performance scores were analyzed before and after training to verify the effectiveness of the high-risk intravenous medication safety training. Medication knowledge significantly increased from 11.24 points to 21.32 points (z=-2.089, p=.003) and the degree of medication performance showed a statistically significant difference from 36.61 points in the pre-test to 68.45 points in the post-test (z=-2.367, p=.002) (Table 3).

Table 3. Analysis of the relationship between nurses' pre-post knowledge and performance level of intravenous medication safety

	pre M±SD	post M±SD	Z	*p*
knowledge ability	11.24±6.54	21.32±3.71	-2.089	.003
performance	36.61±8.24	68.45±5.24	-2.367	.002

3.5 Management stage

To efficiently manage the finalized high-risk intravenous drug administration safety guidelines and maintain improvements, a management plan was written. This plan included information on the high-risk intravenous drug administration process, management indicators corresponding to the medication safety checklist, management method, availability of a person-in-charge, and actions to be taken when problems occurred. Finally, for the final approval and reporting of results, a report including the name of the project, major problems and improvement issues, and quantitative and qualitative effects corresponding to the progress made was prepared. This completed the progress schedule with the improvement team and the Six Sigma process.

4. Conclusions

First, an attempt was made to analyze the status of high-risk intravenous injection education and level of knowledge to select key factors that cause problems in the safety performance of high-risk intravenous injection medication. This is because the frequency of such intravenous medication has recently increased, with its side effects and harm being expected. If nurses' awareness of medication safety is increased, the performance of nursing to prevent medication errors will increase (Na, 2010). This was attempted because its occurrence could be reduced.

To analyze the management of errors and proximity errors related to incorrect intravenous fluid injections, we confirmed the installation of a voluntary reporting system by the QI and nursing departments when medication and proximity errors occurred in each unit. Previous studies have also shown that establishing a standardized incident reporting system is ineffective for managing medication errors, although it can be effective in reducing and solving problems (Bates et al., 2003; Na, 2010). In addition, because the number of accident occurrences allows the number of near errors to be statistically estimated, it can be used as important data for future research and quality management activities as an index of the Six Sigma technique for quantification through measurements. However, further studies are required to confirm these findings.

High-risk intravenous medication administration by nurses is particularly frequent in accident cases because they do not follow established procedures during the provision or delivery of medical services and when the nurses become familiar with work or system procedures while performing routine tasks. Established procedures are often omitted based on the assumption that other nurses follow the necessary procedures. This situation becomes more serious in cases of delays, busy schedules, or fatigue, which increases the likelihood of errors. Medication safety issues are predominantly attributed to human factors, including insufficient training and procedural non-compliance (Kim et al., 2007).

This necessitates a conscious improvement effort, including the double confirmation of patients' information, open-ended questions, and both patients and nurses participating in voluntary confirmation. This also requires a standardized medication administration procedure in the improvement stage, and in the case of high-risk intravenous medication administration by two nurses. In addition to efforts to increase individual nurses' awareness of medication safety by strengthening safety through a double-verification process, it is necessary to establish organizational mechanisms to minimize the possibility of errors by identifying the points with the greatest risk of errors related to access to the organization's system.

Overall, the key factors identified were the absence of major drug administration protocols in each ward and the lack of training in the use of medication injection devices, non-establishment of standardized high-risk intravenous drug administration procedures, and lack of individualized medication education for nurses to ensure standardized high-risk drugs. The organization's training program includes medication safety guidelines, procedures for administering intravenous medication, and instruction on operating medication injection devices. This comprehensive approach addresses both human and systemic factors to prevent and resolve medical errors. Hence, this is an alternative that should be considered.

The safety guidelines developed in this study offer a structured and evidence-based framework for improving high-risk intravenous medication administration. Therefore, in principle, the nurse in charge of the initial medication is responsible for the entire process, from the premedication preparation process to medication administration and post-administration nursing. Creating an environment that facilitates independent work and care for the processes and human factors related to medication administration is necessary. This requires an understanding of and compliance with procedures.

For the final approval and reporting of the results, a final report, including the project name, major problems, and progress, was prepared. This completed the improvement team's schedule as well as Six Sigma project. Oh (2008) conducted a survey on the improvement team, focusing on the team's effectiveness and individual change. The survey results showed a range of ratings from 3.00 to 3.90, indicating variability in the degree of change. Additionally, participants reported their understanding of the tools used in the improvement process.

Improvements were also reported in the ability to actively share opinions with members and focus on problems. In this study, in the process of feedback and discussion about the progress of the Six Sigma project,

respondents opined on the understanding and necessity of Six Sigma techniques, which were unfamiliar at the beginning of implementation; improvement of communication and problem-solving skills with other members; and changes in thinking about the phenomenon. Thus, it was possible to obtain research results similar to those of previous studies.

In this study, we focused on the task of ensuring the safety of high-risk intravenous medication administration by nurses in a single medical institution using Six Sigma techniques. Therefore, it will be necessary to expand this approach to various issues arising not only in healthcare and nursing but also in other fields by turning them into projects. Additionally, further clinical validity verification of the developed high-risk intravenous medication safety guidelines is deemed necessary. Furthermore, considering the cultural reasons that currently discourage the disclosure of errors in the medical environment, we were unable to apply tools that quantify the quality of healthcare through objective improvement indicators. Therefore, research should be conducted to measure improvements in medication safety by assessing the reduction of medication errors or the satisfaction levels of patients and nurses as indicators of improvement. Through these follow-up processes, identifying and improving issues arising in the execution of tasks in healthcare and nursing can lead to fundamental solutions. This, in turn, is expected to enhance patient safety and, when applied to specific work improvement activities in various fields related to work, can also result in increased job satisfaction among members and improved organizational productivity.

Recommendations based on the results of this study are as follows. First, from a practical nursing perspective, we suggest conducting further research to confirm medication safety indicators resulting from the application of hospital nurses' high-risk intravenous medication safety guidelines. Second, when evaluating the results of educational effectiveness corresponding to improvement interventions, it is recommended to conduct research that includes visible indicators such as actual cost reduction, cost-effectiveness, and improvement in productivity. Third, this study targeted wards with frequent high-risk intravenous administration of an education plan based on improvement indicators before and after improvement plan; we propose conducting a clinical validity verification study through expanded performance.

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