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Original Article

A failure mode and effect analysis-based strategy to prevent parenteral nutrition medication dispensing errors with newborns

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Abstract: Objective: To investigate the application of failure mode and effect analysis (FMEA) in the prevention of medication errors in the allocation of parenteral nutrition with newborns. Methods: A project team was established to determine the risk points during the process of parenteral nutrition (PN) dispensing for newborns. The team worked from January 2017 to June 2018. The related severity (S), the frequency of occurrence (O), and the likelihood of detection (D) were all scored to determine their risk priority number (RPN). Then, the failure modes with high RPN values were screened out and the corresponding preventive strategies were formulated. Finally, the error rates and RPN value decline rates were counted from January 2019 to June 2020. Results: For the 14 failure modes with priority improvement, the average RPN value after the intervention was greatly decreased compared to the value before the intervention (17.00±8.33 vs. 83.93±46.30) ($P < 0.001$). In addition, the incidence of medication errors in each link after the intervention was significantly lower than it was before the intervention (12/7840 vs. 94/7650, $P = 0.000$). Conclusion: The FMEA method can be used to screen the risk points during the process of parenteral nutrition (PN) dispensing for newborns, so as to formulate relevant medication error prevention strategies and effectively reduce the risk of neonatal PN medication.

Keywords: Failure mode and effect analysis of medical care, pharmacy intravenous admixture service, parenteral nutrition for newborns, medication errors, risk management

Introduction

Pharmacy intravenous admixture service (PIVAS) refers to a mode in which the pharmacy department of a hospital carries out dispensing in a relatively clean environment according to clinical orders and under review by pharmacists. With the advantages of improving infusion quality, preventing irrational drug use, and protecting volunteers from drug injuries, PIVAS has gradually replaced the traditional mode of dispensing medicine conducted by front-line nursing staff [1, 2]. However, some medication errors still occur in the clinical application of PIVAS, especially in the dispensing and using processes [3, 4].

Parenteral nutrition is the only source of nutrition for some patients, and it is mainly infused through a central vein. Therefore, the inappropriate use of parenteral nutrition could greatly harm a patient, including errors involving the incompatibility, instability, or preparation of the parenteral nutrition solution (2011), and even errors involving the deaths of patients caused by ions such as calcium and phosphorus precipitates, preparation errors, and bacterial contamination. One well-known case was an unfortunate death caused by *Serratia* contamination due to improper preparation that occurred in the United States [5-8]. Therefore, parenteral nutrition solution has been listed as a high warning drug by the American Institute of Drug Safety.

Failure mode and effects analysis (FMEA) is a forward-looking reliability analysis technology, which emphasizes "prevention in advance" and the concept of continuous improvement. As a systematic and reliable program that can iden-

Table 1. Risk index evaluation table

Score	Severity (S)	Frequency of occurrence (O)	Likelihood of detection (D)
1	No	Hardly ever	Almost certainly
2	Very slight	Extremely few	Very high
3	Mild	Very few	High
4	Smaller	Rare	Generally tall
5	Medium	Low	Medium
6	Significant	Medium	Low
7	Larger	Generally tall	Lower
8	Great	High	Very low
9	Serious	Very high	Extremely few
10	Disastrous	Almost certainly	Hardly ever

tify potential failure modes and any impacts on system safety, FMEA is widely used to solve the potential problems in PIVS. At the same time, FMEA has also been regarded as a medical risk assessment method which was recommended by the United States Joint Accreditation Committee. At present, the FMEA method is widely used for decreasing the risk of drug administration, while there is less research on neonatal, gastrointestinal PN [9, 10]. As a Grade A Level Three Maternal and Child Health Hospital, the PIVAS in the Women and Children's Hospital, School of Medicine, Xiamen University has the advantage of a heavy daily demand for allocating neonatal parenteral nutrition solution [11]. Based on this, our present study combines the FMEA method with our past work experience with the PIVAS in Women and Children's Hospital, School of Medicine, Xiamen University and with systematic statistical records in the work, aiming to provide a new quality control method for reducing the parenteral nutrition error rate in newborns.

Materials and methods

Set up project team and conduct FMEA knowledge training

Eight professionals were selected to form the project team. The team members, including 6 pharmacists and 2 nurses, were required to have more than 4 years of working experience in PIVAS. All the team members received systematic training on FMEA knowledge, and one person was responsible for tracking and counting the clinical errors.

Failure mode analysis and evaluation method

Combining the error types and contents provided in the *Guiding Principles for Medication Errors Prevention* in PIVAS with the actual work experience of our center, 94 error cases among the 7650 neonatal PN cases published by PIVAS from January 2017 to June 2018 were selected and analyzed. In addition, the project team members were organized to summarize and analyze the failure modes existing in each link of the neonatal PN dispensing following the risk index evaluation table shown in **Table 1**, and each failure mode was scored using the FMEA method [12]. The evaluation indexes are listed as follows: severity (S): scored according to the possible impact of each failure mode on patients, 1-10 points from mild to severe; frequency of occurrence (O): scored according to the frequency of each failure mode within the specified time, 1-10 points from low to high; likelihood of detection (D): scored according to the detection difficulty of each failure mode, 1-10 points from easy to difficult. According to the scoring results, RPN is calculated according to the following formula: RPN = S × O × D. The higher the RPN score is, the more serious the potential problem is. The RPN scores were ranked from high to low to separate out the failure modes with higher RPN scores.

Methods

Before the implementation of FMEA, the error cases were mainly recorded without any real-time feedback measures. In this study, FMEA rules were used to analyze the key failure modes based on the 94 error cases among the 7650 clinical PN cases that occurred from January 2017 to June 2018 in our hospital's PIVAS. Centralized learning was carried out for three months by means of learning, examination, and graduation. At the same time, the specific improvement methods of the failure mode were elaborated and mastered to increase the alertness and focus of the work. In addition, changes in the RPN scores of these above key failure modes of the 7,840 newborns who received PN in PIVAS of Women and Children's Hospital, School of Medicine, Xiamen University from January 2019 to June 2020 were evaluated.

Outcome measures

Main outcome measures: the changes and decline rates of the RPN values of each failure

Table 2. The failure mode in dispensing PN and the corresponding RPN scores

Type	Failure modes	Average score			RPN (score)
		S	O	D	
Prescription error	Doctor's order errors (including input errors, usage and dosage, electrolyte concentration, heat nitrogen ratio, sugar lipid ratio, drug selection, compatibility, etc.)	6	6	4	144
	Review error by pharmacist	6	4	4	96
Drug dispensing error	Wrong variety and quantity	6	4	3	72
	Two pages of labels are separated or mislabeled	4	3	3	36
	Drug dispensing deficiency resulting from a missed label	3	2	3	18
Dose conversion error	Inaccurate conversion caused by non-integer specification or quantity	4	5	6	120
	Conversion error of g, mg, mL and other units				
Mixing and dispensing error	Violation of aseptic operation	7	4	6	168
	Drug specification or dose error	7	4	4	112
	Drug omission	3	3	4	36
	Wrong mixing order	5	5	5	125
Review and finished product quality inspection error	Abnormal weight	4	7	3	84
	Fluid leakage caused by not closing infusion clamp or quality problems	5	4	3	60
	Problems with clarity				
Information system error	Loss or duplication of medical orders induced by PIVAS information system failure	4	2	3	24
	Wrong orders being approved by failure of audit system	4	5	4	80

Note: PN: parenteral nutrition; RPN: risk priority number; PIVAS: pharmacy intravenous admixture service.

mode during the two years before and two years after the FMEA implementation were compared; secondary outcome measures: the error rates of each failure mode before and after the FMEA implementation were statistically compared.

Statistical analysis

All the related data were analyzed using SPSS 22.0 statistical analysis software. The measurement data were expressed as the mean ± standard deviation (x ± sd), and the differences between groups were compared using independent sample t tests. The numeration data were expressed as the number of cases/percentage (n/%). Chi square tests were used to compare the rates between the groups and $\alpha = 0.05$ was used as the test standard. $P < 0.05$ indicated that a difference was statistically significant.

Results

Failure mode in the dispensing of PN and the corresponding RPN scores

The PIVAS neonatal PN dispensing failure modes were analyzed by the research team members. There are 23 failure modes in all, and we selected 14 of these main failure modes according to their RPN scores. See **Table 2**.

Comparison of the RPN scores before and after the management strategy intervention

According to the technical and management strategies for medication error prevention recommended by the *Guiding Principles for Medication Errors Prevention* in PIVAS, as well as the failure modes of the neonatal PN dispensing and RPN scoring results, the prevention strategy was proposed and the RPN score was calculated again. The results showed that average RPN values of each link were all significantly decreased to different degrees ($P < 0.001$), and the average RPN value (the sum of the decreases in RPN of the 14 failure values divided by 14) was strongly decreased by 75.91% (17.00±8.33 vs. 83.93±46.30, $P < 0.05$). See **Table 3** and **Figure 1**.

Comparison of the medication error rates in newborns before and after the FMEA implementation

The neonatal PN medication error rates before and after the FMEA implementation were compared. The results showed that there were 94 erroneous cases among the 7,650 neonatal PN cases before the FMEA implementation, and 12 erroneous cases among the 7,480 neonatal PN cases after the implementation. The medication error cases caused by the failure mode were sharply decreased ($P = 0.000$), and the

Table 3. Prevention strategy of neonatal PN dispensing and RPN score after the improvement

Type	Prevention strategy	Average score			RPN (score)	Decline ratio of RPN value (%)
		S	O	D		
Prescription error	Doctor's order error: introduction of assistant decision-making system for drug use to remind doctors of the usage and dosage, electrolyte concentration, heat nitrogen ratio, sugar lipid ratio and other issues in PN issued by doctors; the drugs that are forbidden to be added into PN are intercepted, so that doctors cannot save their orders; summarize the common errors and give feedback to clinicians every month.	4	3	2	24	83.33
	Review error by pharmacist: assist pharmacists to check doctor's orders with assistant decision-making system; continue to improve the assistant decision-making system for drug use and increase the accuracy of the system; strengthen the training and regular assessment of prescription pharmacists.	3	2	2	12	87.50
Drug dispensing error	Wrong variety and quantity: the easily confused drugs should be managed with color codes and stored in a special area; for the returned drugs that need to be repositioned, special packaging bags are used to show the difference, and double checking is carried out to avoid placement errors caused by reposition errors; automatic equipment such as dispensing machines and intelligent infusion racks are introduced to reduce human errors.	2	2	2	8	88.89
	Two pages of labels are separated or mislabeled: two labels are usually required for one doctor's order due to many ingredients in the PN. When printing labels, the doctor's orders with two labels could be set by the information system to be printed in priority, and the labels should be marked to avoid the two labels being separated.	4	2	1	8	77.78
	Drug dispensing deficiency resulting from a missed label: as a matter of convenience to check the total number of labels, print the serial number in the lower right corner of the label.	3	2	1	6	66.67
Dose conversion error	Non-integer specifications and the unit of g and mg are converted into mL and printed on PN label by the system, so as to reduce the error of human conversion and facilitate the deployment of operators.	4	2	3	24	80.00
Mixing and dispensing error	Violation of aseptic operation: strengthen aseptic operation training, standardize operation methods, and provide standard operation videos for learning; a high definition camera is installed in the laminar flow clean table to record the whole process, and regular spot checks are conducted for quality control; carry out training and examination on nosocomial infection once a month; check hand hygiene regularly and send for inspection.	5	3	3	30	82.14
	Drug specification or dose error: underline incomplete drugs for reminding; incomplete drugs are automatically converted by the system and are printed on the label; one-person deployment and one-assistant mode is adopted for effective verification; syringes of different specifications should be used for different drugs and marked conspicuously; tracing through camera on laminar flow cleaning table.	5	2	3	30	73.21
	Drug omission: one-person deployment and one-assistant mode is adopted for effective checks; refine the standard operation process: for PN of up to 10 kinds of drugs on a label, draw a red line under the dosage of each drug after adding one drug, and dispensing is required to be conducted in order.	3	2	3	18	50.00

	Sequence error in mixing and dispensing: make PN mixing and dispensing sequence table, and train all staff on the standard operation process. Only after passing the examination can they take up their posts and quality control should be carried out regularly; PN mixing and dispensing sequence is set by the information system and the order of drugs is adjusted according to the infusion label. The operator only needs to dispense following the sequence, so as to avoid the problem of stability degradation caused by the wrong sequence; one-person deployment and one-assistant mode is adopted to cooperate and supervise each other.	3	2	3	18	85.60
Review and finished product quality inspection error	Abnormal weight: the weight of the PN is printed out on the label after calculation by the information system, and rechecked by weighing method; in view of the large difference of liquid loading found in the review process, require the drug storehouse to contact the manufacturer for improvement, and replace the manufacturer if necessary.	4	2	2	16	80.95
	Fluid leakage caused by not closing the infusion clamp or quality problems and problems with clarity: adjust the duty schedule to ensure that the checkers have enough time to check; clear job responsibilities and strengthen safety concept; if fluid leakage is induced by quality problem with the nutrition bag, it is necessary to complain to the manufacturer for improvement and change the manufacturer if necessary; the filling box should be changed to avoid cutting the bag with the sharp edge.	4	2	1	8	86.67
Information system error	Loss or duplication of medical orders induced by PIVAS information system failure: existing problems should be checked, the software system should be continuously upgraded and optimized, the deficiencies and omissions should also be made up promptly. At the same time, the double core pairing mechanism is implemented with the assistance of HIS system; draw up an information system emergency plan and improve the rapid response ability.	3	2	2	12	50.00
	Wrong orders being approved by the failure of the audit system: strengthen the concept of continuous audit and verification of each link in the audit process; the software system should be continuously upgraded and optimized, the deficiencies and omissions should also be fixed promptly and a fault alarm mechanism should be added in the system; the ability training of pharmacists should be strengthened, the system rules should be optimized and adjusted in time, and the loopholes in the rules should be investigated.	4	2	3	24	70.00

Note: PN: parenteral nutrition; RPN: risk priority number; PIVAS: pharmacy intravenous admixture service.

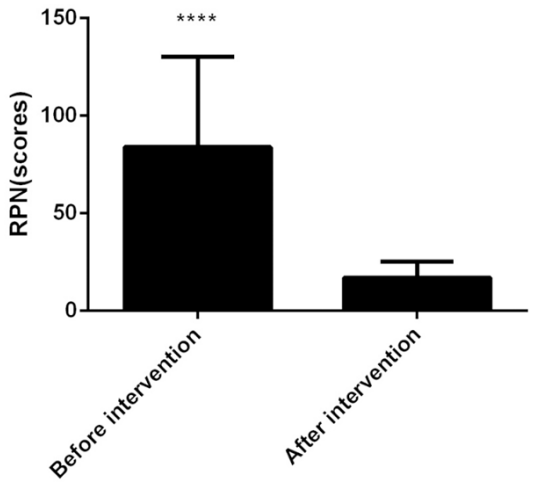

Figure 1. Changes in the RPN scores before and after the intervention of the preventive strategies. Compared with after the intervention, ***P < 0.001. RPN: Risk Priority Number.

incidence rate was also markedly decreased, with an average decrease of 88.69% (P < 0.05). See **Table 4** and **Figure 2**.

Discussion

Table 2 gives information about the failures during the dispensing process of neonatal PN in PIVAS, and among the risks of neonatal PN dispensing through the FMEA method, the RPN value was found to be the highest in the PN prescription and mixing process. Amino acids, glucose, fat emulsion, electrolyte, trace elements, vitamins and other drugs are all included in the PN prescriptions. It is necessary to take into account not only the dosage of each drug, but also the proportion and concentration of each component of the PN solution, so as to make reasonable nutrition ratios to meet the stability requirements of the PN solution [13]. Due to many involved factors and complex calculations, it is difficult to take into account all aspects when making PN prescriptions, and it is also difficult for pharmacists to audit a large number of PN prescriptions in a short time, all of which have the potential to induce high RPN values [14-16]. Also, there are many components in the prescriptions of neonatal PN solutions, and most drugs are basically used in parts. For example, for a 1.8 kg premature infant, the dosage of the multiple trace elements (10 mL/tube) is 1.8 mL, the dosage of fat soluble vitamins (10 mL/stick) is 3.6 mL, the dosage of multiple oil fat emulsion (100 mL/bottle) is 23 mL, the dosage of pediatric compound amino acid (100 mL/bottle) is 70 mL, and the dosage of 50% glucose injection (20 mL/bottle) is 26 mL, etc. Thus, the mixing process is very complex with a relatively high risk. The dosing sequence is strictly required in order to ensure stability, and the mixing process also needs to be strongly improved as a key point.

The results showed that the RPN value and medication error rate of each potential failure mode decreased in varying degrees after the improvement, especially errors involving prescription errors, drug dispensing, and mixing. The results indicate that the preventive strategy has achieved some success, which is consistent with the results of previous studies [17-19]. In addition, doctors could be given different levels of pop-up boxes to indicate the irrationality of a particular PN prescription through the introduction of a rational drug use assistant decision-making system. Unreasonable prescriptions, such as the concentration of monovalent cation electrolyte higher than 150 mmol/L in one solution, the concentration of divalent cation electrolytes higher than 5 mmol/L, or the dosage ratio of alanyl glutamine and children's compound amino acid higher than 1:5, etc. could all be intercepted to prevent doctors from prescribing them [15]. In addition, the dosage of each ingredient, the calories, the sugar to fat ratios, the nitrogen, and the non-protein caloric ratios can be given different warning levels to help physicians issue PN prescriptions and to intercept erroneous prescriptions at the source. The dosage, ratio, and concentration of each ingredient can be quickly judged by the pharmacists with the help of the powerful computing ability of the auxiliary decision-making system for rational drug use, which greatly improves the audit efficiency and the rationality of PN prescriptions. In addition, through a regular summary of the PN prescription error-prone items, and the timely feedback, communication, and training between specialist clinical pharmacists and physicians, the quality of the prescriptions can be improved, and the risk of PN prescription errors can be significantly reduced , which is similar to the findings of previous research [20].

High concentration electrolytes (sodium, potassium, calcium, magnesium, etc.), various compound amino acids, various fat emulsions (ordi-

Table 4. Comparison of medication the error rates before and after the FMEA implementation

Type	Failure mode	Medication error/cases		Decline ratio (%)
		Before implementation	After implementation	
Prescription error	Doctor's order errors (including input errors, usage and dosage, electrolyte concentration, heat nitrogen ratio, sugar lipid ratio, drug selection, compatibility, etc.)	15	2	86.67
	Review errors by pharmacist	9	1	88.89
Drug dispensing error	Wrong variety and quantity	11	2	81.82
	Two pages of labels are separated or mislabeled	4	0	100.00
	Drug dispensing deficiency resulting from a missed label	2	0	100.00
Dose conversion error	Inaccurate conversion caused by non-integer specification or quantity, conversion error of g, mg, mL or other units	10	2	80.00
	Violation of aseptic operation	6	1	83.33
Mixing and dispensing error	Drug specification or dose error	5	1	80.00
	Drug omission	4	0	100.00
	Sequence error in mixing and dispensing	7	0	100.00
Review and finished product quality inspection error	Abnormal weight	11	1	90.91
	Lacking information about the tightness of the infusion clamp, fluid leakage, problems with clarity	4	1	75.00
Information system error	Loss or duplication of medical orders induced by a PIVAS information system failure	2	0	100.00
	Wrong orders being approved by a failure of the audit system	4	1	75.00
Total mixing amount of TPN (bag)		7650	7840	

Note: FMEA: failure mode and effect analysis; PIVAS: pharmacy intravenous admixture service; TPN: total parenteral nutrition.

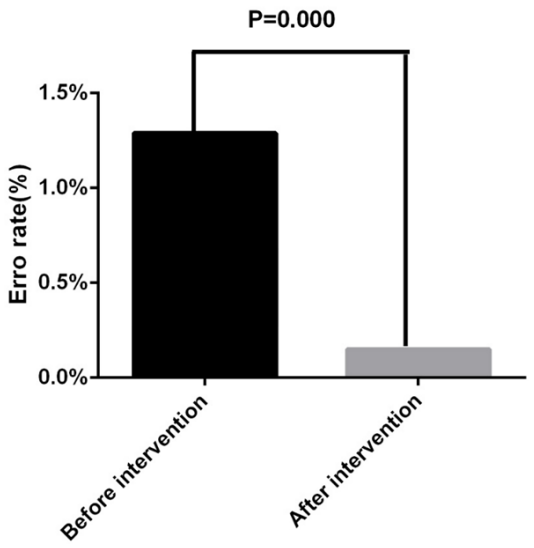

Figure 2. Comparison of the medication error rates before and after the FMEA implementation. FMEA: failure mode and effect analysis.

nary fat emulsion, medium and long chain fat emulsions, multi-oil fat emulsions, etc.) and various vitamins are all involved in the neonatal PN dispensing process. By strengthening the color code management and the storage management of the above-mentioned look alike/sound alike (LASA) drugs, regularly updating the catalog and training, and introducing intelligent dispensing equipment to automatically locate and deliver drugs, human dispensing errors are effectively reduced. The results of this study show that the RPN values were decreased by 88.89% after the implementation of the broad-based prevention strategies, and the effect was significant, which is similar to the findings of previous studies [21].

In terms of dose conversion errors, considering that the drugs in neonatal PN are basically used in parts, the information system is adopted to automatically convert and list them on the label to reduce human conversion errors. For example, 0.04 g L-carnitine injection (1 g: 5 mL) can be printed on the label with the remark of 0.2 mL, which makes it more convenient for the dispensing doctors to extract the liquid medicine. This operation effectively improves the accuracy and efficiency of drug dispensing, and it also verifies the previous results [22].

In terms of mixing and dispensing errors, for the items violating aseptic operations with high RPN scores and severity, aseptic operation training and standardize mixing and dispensing operation methods of the members were all enhanced through the training. In addition, a standard operation video is provided for learning, and the whole dispensing process is recorded by a high definition camera installed on the laminar flow cleaning table. Moreover, the recorded process is checked regularly for quality control and the results of the training effect are evaluated for continuous improvement [16]. The concept of patient-centered work is strengthened to ensure the medication safety of patients and create an atmosphere and culture of safety, so as to consolidate the importance of aseptic operation and continuously reduce risk. In the mixing process, the one-person deployment and one-assistant mode is adopted by adjusting the shift arrangement, which is convenient for checking the incomplete drugs and effectively reducing the drug omission and wrong dosage situations. The RPN scores and the severity of PN mixing sequence errors are relatively higher, so we suggest that PN prescriptions be printed on the label according to the order of drug dispensing instead of the order of the doctor's prescription. This operational method has better compliance because the staff needs only to mix the drug in the order listed instead of having to do it from memory. At the same time, the one-person deployment and one-assistant mode was adopted to encourage cooperation and mutual supervision, which helped to avoid the instability of PN liquids caused by the wrong mixing sequence. The results of our present study showed that the RPN value was decreased by 85.60%.

In terms of the review and product quality inspection errors, we should strengthen the feedback and communication in drug and parenteral nutrition bag quality, solve problems promptly, and make continuous improvements. In the last step of PN verification, a second check was conducted in our center by weighing each bag of nutrient solution using an electronic balance, and the RPN value was decreased by 75.91%, indicating that the preventive strategy is effective.

The risks of neonatal PN deployment were analyzed using FMEA, and the weak links with higher RPN values in the failure mode were improved, which was our goal. At the same time, the feedback during the implementation

process was strengthened and continuously improved, thus enhancing the PIVAS members' understanding of safety management during the PN dispensing process, optimizing the mixing process and improving the risk management system of neonatal PN dispensing and the level of PIVAS management. In addition, through centralized learning, all the members tried to find the root cause of each problem and create a PIVAS safety culture, and we ultimately effectively ensured the medication safety of patients. However, this study is a small-sample study done at a signal center, so it needs a larger sample size and multi-center research to further verify our conclusion.

Disclosure of conflict of interest

None.

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