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A Large Sample Single Center Study On Reducing the Incidence of Adverse Events During Intravenous Pump-Used Infusion in Neonates by Root Cause Analysis

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Abbreviations:

AE: Adverse Event; IP: Infusion Pump; RCA: Root Cause Analysis; SAC: Severity Assessment Code; SPSS: Statistical Product and Service Solutions

1. Abstract

Intravenous administration is one of the most critical activities in neonatology, which directly involving the use of higher precision infusion pumps. However, its related adverse events are still happened during the neonatal infusion. Root cause analysis, a program to find the cause of an adverse event and prevent the same adverse event from happening again, was used in this study. We enrolled a large number of neonatal patients, and applied a pre–post design. This study resulted in information of 12 adverse events (15,720 cases of infusion with infusion pump) amongst 4,624 patients. The root cause analysis approach (8 months) produced 14 unique recommendations, 85.7% of which were completed. We found that after the root cause analysis approach the overall safety of the system of infusion pump-used infusions in neonatal practices has greatly improved, and specifically a reduction in the incidence of infusion pump alarming malfunction and infusion pump malfunction, and medication error due to the weak infusion pump safety awareness and nonstandard infusion pump operation for junior nurses. However, a system level root cause analysis study in which nationally participating hospitals are randomly assigned to the root cause analysis approach is needed.

2. Introduction

Intravenous infusion delivering drug, nutrient and fluid is a common therapeutic strategy in nursing. As a necessary clinical auxiliary equipment, infusion pump (IP) can accurately control the total amount and flow rate of infusion and significantly reduce the workload of nursing [1-3]. It has been widely used in pediatric clinical practice including in neonatology. However, in the neonatal IP-related nursing, adverse events (AEs) such as failures of infusion rate control, failures of IP alarming and other human fac-

tors occurring from time to time [4,5]. These errors are difficult to intercept, and their impact depends on multiple factors including the patient's drugs and conditions 6, which not only increases the suffering of patients, but also delays the recovery of diseases, increases medical expenses and hospital stay, and even leads to neonatal death [7-9]. Therefore, ensuring greater safety of neonatal patients during IP-used infusion should be a priority. It has been reported that a number of strategies could reduce these IP-related AEs over the past years [10-13]. However, the AEs may still occur in neonatal infusion. The root cause analysis (RCA) approach is a strategy dealing with AEs from the level of learning system [14]. It is a retrospective analysis tool to medical AEs, from finding out the potential errors and their root causes to providing steps for prevention and avoiding similar AEs happening again. In this study, RCA was used prospectively in neonatology to deal with IP-used

infusion from May 2019 to April 2020 in a national children's hospital to explore prevention and improvement steps, with ultimate goals to reduce the recurrence of AEs and ensuring the safety of neonates.

3. Methods

3.1. Design

After approved by ethics board (2020-IRB-201; the Research Ethics Board), this study was carried out at a national children's hospital. The need for participant consent was waived by the ethics committee. This was a prospective study comparing differences in the incidence of AEs (Table 1) with IP-used infusion before and after the RCA approach. IP (SN-1600V, SINOMDT, Shenzhen, China) was used in this study which would not be completely update during the RCA approach. It was driven by matching software (Version 1.0 to 4.0). When IP-related AE occurred, the software should upgrade to the latest version at that time.

Table 1. IP AEs that were tracked and their definition

AE	Definition
Cardiac arrest	Sudden loss of cardiac function without pulses
Death	Unable to be resuscitated
Hypoglycemia	Blood glucose < 2.2 mmol/L
Hyperglycemia	Blood glucose > 7.0 mmol/L
Medication error	Problems including the wrong drug, dose, frequency, or route of administration
	□ Wrong speed setting in IP program
IP malfunction	Did not deliver the fluid as programmed
	□ Uncontrolled infusion speed: Infusion speed too fast or too slow
	□ Uncontrolled infusion rate: Ununiformed infusion speed (sometimes fast and sometimes slow)
IP programming error	Errors with the IP setup or program was different from the doctor's order
	□ Uncontrolled infusion volume: Infusion cumulative amount being inconsistent with the setting
	□ Software system failure: A problem of speed settings causing the output speed to be inconsistent with the preset
	□ Fluid not be pumped in: Not giving liquid showing that the liquid does not drop or flow back
	□ Sudden not working: Suddenly not running in infusion with no alarm and unable to reboot
IP mechanical failure	Problems with the IP mechanical parts
	□ IP screen failure: Incomplete information display, low bright screen, black screen or abnormal flicker
	□ IP keys not working: Invalid or damaged keys
	□ Battery failure: Sudden power off including internal power failure or unable to recharge
	□ Door clamp out of order: Door unable to open or damaged
IP alarming malfunction	Problems with the IP alarming system
	□ Abnormal identifying: Not alarming or continuously light-alarming dues to unable to identify the pipeline obstruction and abnormal pressure
	□ Abnormal bubble detecting: Bubbles in the pipeline fail to be recognize and no alarming
	□ Unreasonable alarming: Normal infusion with frequently unreasonable alarming
	□ Alarming out of order: Not alarming when the infusion cumulative amount reaches a preset level

IP = infusion pump; AE = adverse event

3.2. Patient Population

The "before" group enrolled all patients in neonatology from May 2019 to April 2020 (before the RCA approach), and the "after" group enrolled all patients from May 2020 to December 2020 (during the active RCA approach).

3.3. Intervention

RCA group members, a total of 8, came from different departments. It included as follow: one charge nurse who acted as team leader; three duty nurses; one teaching secretary; one inpatient instrument manager; one IP manager who came from device department; and one doctor. To meet the requirements of the RCA team, the head of neonatal pediatrics distributed a memorandum to hospital management describing the study and asked employees to do their best to respond to the recommendations of the study. The study team followed the RCA framework to determine the root cause of AEs and developed management plans to prevent AE recurrence (Table 2). In brief, the study team applied a "brainstorming method" to deeply analyze the causes of AEs in IP-used infusion by the "fishbone" diagram method, and used the 80 / 20 rule to solve problems. By using an online AE reporting system, we promptly obtained the data and managed the follow-up of these recommendations.

Table 2. RCA Approach.

Step	Description
What happened?	
Identification of AEs	The responsible nurse identified events during daily rounds
Determination of AEs	Risk assessment using the AE Severity Rating (Appendix 2)
Consequences of AEs	Ⅱ−Ⅳ level events
RCA team	The team was multidisciplinary and included: one head nurse serving as the group leader, one doctor, three responsible leaders of the ward, one teaching secretary, one instrument manager of the ward and one full-time IP manager from the device department
Gather information	The researcher investigated the AEs. This included data review and interviews with anyone closely related to the event. Collecting information including the children's general information, nurse qualifications, AE happening conditions, IP maintenance records, and etc.
Events recovering	Discussions with the nursing staff to recover the situation, and checking IP and records on site
RCA meeting	The RCA team meeting that lasted 2 to 3h and developed preliminary implementation plans
Why did it happen?	
Determination of contributing factors	Using "brainstorming method" combined with "fishbone" diagram and "5WHY" to gather the contributing factors focusing on five aspects of "human, machine, material, method and environment" and the following three questions: why did it happen? Why didn't find out in time? Why there was no systematic prevention of these events?
Determination of root causes	RCA meeting to answer the following three questions ("Yes" is the proximal cause, otherwise is the root cause): 1) Does the event re-occur when the cause does not exist? 2) If the cause is corrected or eliminated, will the event re-occur due to the same factor? 3) Can similar AEs re-occur after the cause is corrected or eliminated?
How to prevent recurrence?	
Action plans	Found potential solutions to the raised issues, and action plans were made carefully. Strengthened the action plans and promised the recommendations which would clear up or control similar future events.
Plan implementation	Every RCA team focused on an improved plan and followed its implementation. The team met every 2 weeks to report on the plan implementation.
Assessment of outcomes	To assess the effectiveness of each recommendation and measure the incidence of all events before and after the RCA approach.

RCA = root cause analysis；IP = infusion pump；AE = adverse event.

3.4. Outcomes

Firstly, it was a difference in the incidence of AEs before and after the RCA approach. Secondly, it included the process of root cause identification for each AE, how many recommendations raised, and how many recommendations completed.

3.5. Statistical Analysis

The ratios of IP-related AEs between before and after RCA groups were compared by Chi-square tests, or by Fisher exact tests when n < 5, by using SPSS 23.0 (SPSS, USA). P < 0.05 was considered statistically significant.

4. Results

4.1. Patients and AEs

During the RCA approach period, from May 2019 to April 2020, a total of 4,624 patients were included (see Figure 1). There was a total of 12 AEs tracked.

Figure 1. Study flow diagram. RCA = root cause analysis; AE = adverse event; IP = infusion pump.

4.2. The Ratios of IP-Related AEs before the RCA Approach

There were 3,180 patients (9,880 cases of infusion) in the before RCA group with 12 AEs. The most common AEs were IP alarming malfunction, IP malfunction and medication error (All 3 AEs were wrong speed settings in IP programming). (See Table 3). General information of 12 neonates with IP-related AEs was as follow: 7 boys and 5 girls; 8 full-term infants and 4 premature infants (gestational age 35.2 W); 3-26 days old (10.4 ± 7.1 d); 34.0-40.0 weeks old (37.5 ± 2.0 W); birth weight 1910-3670g (3044.1 ± 596.5 g); premature infants (4), neonatal hypopharyngeal syndrome (3), neonatal duodenal obstruction (3), neonatal enteritis (1) and neonatal hyperbilirubinemia (1). The severity rating of AEs, basing on their impacts after happening, is also essential for dealing with the AEs promptly and reducing its impacts completely. According to the international Severity Assessment Code (SAC) grading method for AEs 15, in the study, of the 12 AEs, 5 were grade IV (41.6%), 5 were grade III (41.6%), and the remaining 2 were to grade II (16.6%).

4.4. The Ratios of IP-Related AEs During the RCA Approach

There were 1,444 patients (5,840 cases of infusion) in the after RCA group with 0 AEs. The AE incidence (0.00%) was significantly less than that of the before RCA approach group (1.46%) (P < 0.05, Table 3).
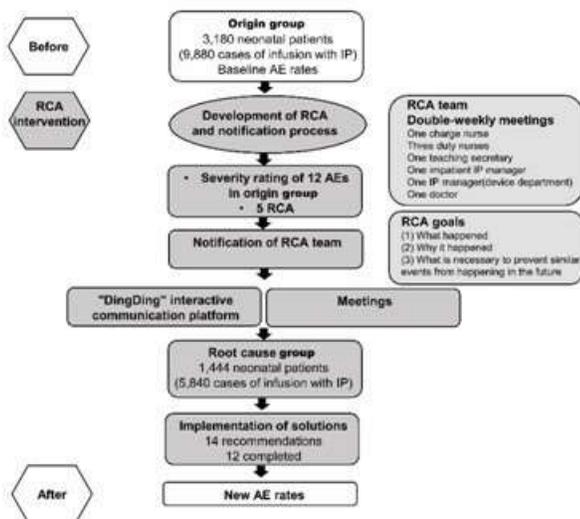
Table 3. AE rates of before and after RCA approach

Study period	Before-RCA	Before *vs.* After (Proportion)	Before *vs.* After (Fisher)
Date range	May 2019 to April 2020		
IP alarming malfunction	5(0.61%)	0.103	0.171
IP malfunction	4(0.49%)	0.144	0.305
Medication error	3(0.36%)	0.206	0.556
All	12(1.46%)		
IP infusion totals	8226		
Study period	After-RCA		
Date range	May 2020 to December 2020		
All	0(0.00%)	0.011	0.011
IP infusion totals	4380		

RCA = root cause analysis；IP = infusion pump；AE = adverse event

4.5. RCA Results

In the study, 14 root causes (Appendix 1) were founded and recommendations were raised separately. The number of root causes (and corresponding solutions) was varied from 1 to 3 for each RCA. The most common recommendations included: upgrading IP system, and training the nurses basing on their levels with emphasis on the operational norms and safety awareness. The most root cause and recommendation type were the too low version of IP software system which resulted in IP alarming malfunction and IP malfunction (75%). The other was the weak IP safety awareness and nonstandard IP operation for junior nurses (25%). Of the 14 recommendation types, 3 were "elimination", and the remaining 11 were "control". At the end of the study, the status of 14 recommendations was that 12 (85.7%) had been "completed" and two (14.3%) would be "to be completed".

Appendix 1. Root Causes, action plans, and their status.

	Root Cause	Recommendation	Action Type	Status
Persons				
1	Junior nurses have weak safety awareness and nonstandard IP operation	The teaching secretary trained the nurses in different levels, focusing on the IP operational norms and safety awareness	Control	Completed
2	There are many uncertain factors in clinical practice, and the nurse allocation mode is not reasonable	The head nurse shall allocate manpower reasonably according to human resources, set standby shift, and start standby shift if necessary	Control	Completed
3	The head nurse's supervision of IP safety is not enough, especially on weekends, holidays and at night	The head nurse included the IP AEs into the department's sensitive index management, and set up a team leader to assist in supervising the work quality, covering every period	Control	Completed
4	There is no routine inspection from the device department	The device department made a routine inspection by once every two weeks	Control	Completed
5	IP manufacturers have no routine testing and calibration	The IP manufacturer made a routine inspection and calibration by once a quarter	Control	Completed
6	There are obstacles in the cooperation and communication between clinical, device and other departments, and manufacturers	Established the "DingDing" interactive communication platform to deal with events in a timely manner	Control	Completed
Machines				
7	IP hardware aging	Set up a ward instrument administrator, responsible for checking the time-limit of instrument use by once a month	Control	Completed
8	The shallow groove of the infusion tube is easy to cause the tube bending and affects the accuracy of infusion	IP manufacturer replaced all the shallow grooves	Eliminate	To be completed
9	The version of IP software system is too low	Upgraded IP system to the highest version	Eliminate	Completed
Materials				
10	The IP model is frequently changed, so it is not immediately known for users	Contacted the purchasing department to minimize the changing of IP model. Otherwise, be sure to inform the clinical and device department in advance	Control	Completed
Methods				
11	The IP SOP is not perfect	The group revised the IP SOP, and posted the SOP on the IP in the form of two-dimensional code. The user only needs to scan WeChat code to view the SOP and the maintenance record	Eliminate	Completed
12	The clinical training is too rigid, and in the past, it emphasized on IP use but the identification and coping of infusion safety risk factors	The teaching secretary developed a multi-department training plan in addition to the regular training to improve the IP safety-controlling abilities of nurses	Control	Completed
Environments				
13	Lack of a checklist for safe IP infusion, including critical time points during IP infusion, inspections, and shifts	Set up a checklist for safe IP infusion, and the nurse should mark during the execution, so as to facilitate the work quality	Control	Completed

| 14 | The MOBILE data terminal (PDA) and hospital information HIS system is not perfectly cooperated for IP infusion and inspection | Communicated with information department to optimize HIS system, extracting the needed information through barcode. During IP infusion patrols, PDA interface may prompt the infusion speed, infusion volume, estimated infusion ending time and other information, so as to assist nurses to judge IP infusion overview | Control | To be completed |

PDA = personal digital assistant; RCA = root cause analysis; IP = infusion pump; AE = adverse event; SOP = standard operating procedure

5. Discussion

The study performed at a national hospital yielded information on 12 AEs in 4624 neonatal patients. The RCA approach in these AEs (over 8 months) produced 14 recommendations, of which 85.7% were completed. The RCA-induced impact on patient safety was that the overall AE ratio was decreased from 1.46% to 0.00%. RCA was correlated with a decreasing of AE incidence. The two main root causes found in RCA approach were that the IP software system version is too low which subsequently results in IP alarming malfunction and IP malfunction, and the weak IP safety awareness and nonstandard IP operation for junior nurses. The too low version of IP software system, i.e., a prior version may not have advanced features but should not allow AEs from happening basing on the results of application at that time, is an independent risk factor for AEs 16, which results in infusion to be too fast, too slow or unstable, and sometimes the infusion will automatically stop or exceed the required amounts, endangering the life safety of neonates. IP alarming malfunction is mainly caused by the operator pressing the return key during infusion, resulting in the early infusion amount excluded from the expected final infusion cumulative amount, i.e. there was a loophole of the program 17. In 4 AEs of IP malfunction: 1 was the increased infusion speed due to the bending of the infusion tube inside the machine, and the other 3 were caused by problems of IP programming. We put forward 5 improvements for these AEs [18]. First, the IP operating system must upgrade to the latest version, and the system's maximum infusion speed set at 30ml / h because the IP is generally used for routine rehydration in neonatology and the infusion speed is generally less than 30ml / h. Secondly, we add a "drip-clip" infusion mode, when the IP detects a deviation of the actual infusion speed from the preset speed ($\geq$ 20%) and it will alarm and stop infusion automatically. The third is to add infusion-tube grooves inside the IP machine, to avoid the irrespective rapid infusion due to the infusion tube bending. The fourth is to upgrade the system to a non-answer mode during infusion, i.e., no matter what keys pressed during infusion, the calculation of cumulative quantity would not be affected, hence avoiding no alarming when the cumulative amount is greater than the preset amount. Finally, the device department and IP manufacturer formulates a routine maintenance of IPs, including the device department staff patrols once every two weeks and the IP manufacturer staff maintains the calibration once every quarter, so as to ensure the safety of use of IPs. Next, the implement of neonatal nursing-core-system being

far from satisfactory, is the most fundamental cause of AEs. For example, three errors of infusion speed settings manifested in the wrong decimal position, in which the demanded speed of 6.5ml / h, 10.9ml / h and 13.9ml / h was set to 65ml / h, 109ml / h and 139ml / h respectively. The severe events showed that the nurses did not perform "three checks and seven reviews" for infusion and did not finish a full inspection during the infusion. In order to improve the safety, the head nurse included IP Infusion Safety into the sensitivity-index of ward management and set it to the target value 19,20, i.e. collecting, analyzing, managing, tracking and feedbacking the results every quarter, and summarizing the results in the fourth quarter of the year. The responsible-group leader strengthened the quality-control of each section of IP Infusion Safe, randomly checked the implementation every week. The group also made a brief verification list for this section (Appendix 2). In brief, the nurses set parameters according to the doctor's advice, and co-checked by two partners before IP infusion; and they must carry out a procedure followed the brief verification list during the infusion, and then patrol and shift handover.

Furthermore, we found that junior nurses were the higher risk group for IP-related AEs 21. Among 12-AE-related nurses, 58% (7/12) have been working for 3-5 years. Similar results were also observed in China 22. The teaching secretary made a detailed hierarchical training plan for nurses in neonatology and implemented it: aiming to increase the levels of IP-operating proficiency (working years: < 3), the sense of responsibility and safety awareness (working years: 3-5), and the abilities of the quality control and supervision of clinical teaching and training (working years: > 5). Night-day shift at noon and weekend/holiday are the high risk time windows of AEs 23. Among 12 AEs, 75% (9 / 12) were happened on weekend/holiday as well as 67% (8 / 12) were at night; while in day time, working in succession at noon (33%, 4 / 12) was common, which might be due to the less supervision and the lacking of responsibility. The group leader with working years over 5 in the neonatal department, set up recommendations for each time window, and arranged the shift reasonably according to the nurse's matching level. The advantages of the study are as follows: a thorough RCA approach was adopted, a large number of neonatal patients were enrolled, multidisciplinary cooperation and the participation of hospital leaders, and an online reporting system was implemented to ensure the implementation of the recommendations. The lower incidence of AEs during the RCA approach further indicates the above strengths. However, a pre–post design

of the study has limitations that it does not parallel control for detecting the changes apart from the RCA intervention. It is possible that some of the decreasing of AE incidences could be attributed to factors such as improved employee education, greater emphasis on safety by departments and hospital management, better management of comorbidities, etc. other than the RCA approach itself.

The RCA approach of the study also offers numerous advantages, such as encouraging employees to solve system problems and make suggestions, especially those provided by the RCA group members (senior employees) had a higher credibility which in turn would improve the implementation of these suggestions (Table 4).

Table 4. Advantages and disadvantages of the RCA approach

Advantages
□ RCA is a powerful tool to find problems from a learning system level
□ The approach increases the credibility of the raised issues and suggestions
□ The process ensures that every attributing root cause has certain potential solutions
□ For AEs, clinical staff can state that they have done their best to determine what happened and how to prevent them happened again in the future
Disadvantages
□ The RCA process takes time and effort
□ Subsequent designees who did not attend RCA meetings are unlikely to accept the recommendations
□ RCA results depend in part on the views of the participants
□ If RCA is not a part of the hospital mainstream safety process, the hospital management department will not make timely and important responses to the recommendations
□ Although some recommendations are credible, they may not work due to the lack of funds in hospitals

RCA = root cause analysis; AE = adverse event

Appendix 2. Brief verification list for IP safety in department of neonatology.

	Checking items	Shift transition			Random checking (Y or N)
		Day(Y or N)	Night(17:30-1:00) (Y or N)	Night(1:00-8:30) (Y or N)	
Starting IP infusion	☐ Two partners co-checking the setting parameters				
	☐ Checking whether the IP model matches				
	☐ Marking the liquid level				
	☐ Checking whether the drip clamp fixed properly				
During inspection	☐ Checking the decreasing range of liquid level and mark the level every 4h				
	☐ Checking whether the dropping speed of drip clip is consistent with the pumping speed				
	☐ Changing the position of peristaltic infusion tube every 4h				
	☐ Checking whether the change of working interface parameters of IP meets the requirements				
During the shift change	☐ Checking whether the fixation of IP tube meets the requirements				
	☐ Marking the liquid level				
	☐ Recording the cumulative infusion volume				
	☐ Checking the running status of the machine				

IP = infusion pump

6. Conclusions

Although the equipment of IP can accurately control the total amount and flow rate of infusion and significantly reduce the workload of neonatal nursing, the IP-related AEs are still happened from time to time. RCA, a strategy to find the cause of an AE and prevent the same AE from happening again, was used in this study. We enrolled a large number of neonatal patients, and applied a pre–post design. The RCA approach (8 months) produced 14 unique recommendations, 85.7% of which were completed. We found that RCA approach greatly improved the overall safety of the system of IP-used infusions in neonates, and specifically reduced the incidence of IP related errors. The study has many advantages, such as a thorough RCA approach was adopted, a large number of neonatal patients were enrolled, multidisciplinary cooperation and the participation of hospital leaders, and an online reporting system was implemented to ensure the implementation of the recommendations. However, a pre–post design of the study has limitations that it does not parallel control for detecting the changes apart from the RCA intervention, and a system level RCA study in which nationally participating hospitals are randomly assigned to the RCA approach is needed.

7. Acknowledgments

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