A Summary of NICU Fat Emulsion Medication Errors and Nursing Services

Data from MEDMARX

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ABSTRACT

Intralipid infusions remain a critical part of ensuring adequate nutritional supplement and growth in premature and term infants. Managing intralipid therapy requires great care to prevent metabolic and physiological side effects. The authors sought to systematically study medication errors associated with intralipid administration in the neonatal intensive care unit (NICU). A descriptive quantitative and qualitative analysis incorporating secondary data was used. Medication error data were drawn from 54 institutions that voluntarily participated with MEDMARX, a national, Internet-accessible medication error reporting program owned and operated by the United States Pharmacopeia. These errors were associated with NICUs, and each medication error record identified nursing staff as making the initial error. A total of 257 errors were reviewed, with 3.9% resulting in harm. The mean age of the neonate was 7 days, and more errors occurred on Mondays than any other day of the week. Errors disproportionately occurred between 6 pm and midnight, with a significant difference between errors near 7 am and 7 pm ($P = .002$). Wrong dose errors occurred in 69% of the sample. Nearly one quarter of the errors resulted from misprogramming infusion devices (either pumps or syringes). Qualitative findings revealed that many of the errors were the result of the nurse's misinterpretation of the modes (ie, time, volume, or rate) on the infusion device or by not recognizing the decimal point on the device's display panel. Several errors involved switching the rate of infusion with total parenteral nutrition and that of intralipids. Voluntary medication error reporting offers valuable insights into intralipid errors occurring in NICUs. Secondary analysis is an ethical, economic means of studying the occurrence of such errors. MEDMARX data suggest that some of the serious errors are the result of complex care and equipment needed for these vulnerable infants.

KEY WORDS: fat emulsions, intralipids, intravenous medications/adverse effects, medication errors, MEDMARX, newborn, NICU, nurses

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Safe administration of medication is a vital and valued aspect of nursing practice and is intended to fulfill the responsibility of doing good and avoiding harm.[1,2] Medication errors are a challenge for the world's most advanced healthcare delivery system and too often involve nurses.[3-6] Pediatric medication administration is complex and inherently dangerous, and errors associated with pediatric medications are an international problem.[7] Several authors have affirmed the occurrence of pediatric medication errors[8-15]; pediatric errors may occur 3 times more often than errors involving adults.[16] The neonatal population may have the highest risk for a medication error[17] in part because of the neonate's underdeveloped physiology.[18]

Chuo et al[19] recently reported that many neonatal intensive care unit (NICU) medication errors involved fat emulsion therapy. When exploring those error cases in detail, the study found 95% of the errors implicated nursing service personnel. The purpose of this study was to explore those findings. The data came from MEDMARX, a national, Internet-accessible medication error reporting program owned and operated by the United States Pharmacopeia (Rockville, MD). MEDMARX is a subscription-based program that participating hospitals and related health systems use for quality improvement efforts.

Products Involved in General Pediatric Medication Errors

The Food and Drug Administration's (FDA) MedWatch data pinpointed 1,902 different products in reported adverse events, with 27% of the cases involving an immunologic product.[12] Therapeutic classes for parenterally administered products (eg, antibiotics, intravenous fluids, total nutrition, analgesics) have been implicated in several studies,[9,11,16] as have respiratory products (ie, inhalers or bronchodilators).[11,14] In one case study, the death of a child was attributed to an anticonvulsant medication.[20] In a 3-year review of pediatric medication errors, researchers identified generic names of products involved in errors that did and did not harm the patient.[14] Products involved in harmful errors included insulin, morphine, fentanyl, and dopamine; these products are classified as "high alert" because of their propensity to result in harm if misused. Another study identified acetaminophen as being frequently involved in the errors.[13]

Neonatal Medication Errors

Medication errors do occur in NICUs. Recent findings from a NICU medical error reporting system used by 54 hospitals indicate that medication errors comprised 47% of all reports, and one-third of the errors occurred at the point of drug administration.[21] Researchers examined the pattern of medication errors per 1,000 neonatal patient days and reported 105 errors, ranging from 1.6 to 26.5 per 1,000 NICU days.[15] Most of the errors were due to poor prescribing practices. The researchers reported that more than half of the errors involved parenteral antimicrobial products. Other products included morphine, insulin, aminophylline, and vaccines.

Swiss researchers examining 1 year's worth of medication error records (n = 284) in a NICU concluded that 76% of the events were minor, 19% were moderate, and 5% were severe.[22] Error outcome was measured on a 3-point score, for which 1 was no intervention, 2 was intervention via routine therapy, and 3 was intervention specific to critical care or death. Repeated checks in the drug delivery process intercepted one quarter of the errors. Catecholamines (11%), anticoagulants (11%), and electrolytes (11%) were the therapeutic classes reported most often. Errors involving parenteral nutrition were also cited (4%) and had a mean severity score of 1.27, indicating that the outcome was slightly above no intervention required.

New Zealand researchers identified and prioritized potential failures in the NICU medication use process using the traditional failure mode and effects analysis (FMEA).[17] The FMEA resulted in risk priority scores (RPS) for each failure point. The score was determined by the product of likelihood for occurrence (O) × severity (S) × likelihood for detection (D). Researchers then took the median RPS from 8 independent reviewers. The scores ranged from 33 (low risk) to 273 (high risk). In addressing priorities for reducing medication errors in the NICU, these researchers found 72 failure points with 193 associated causes and effects. These researchers concluded that the top ranking issue was a lack of medication safety training across all phases of the medication use process (RPS 273). The researchers concluded that the majority of the top 30 risk priority scores were isolated to the administration phase of the medication use process, such as lack of experience with neonatal equipment, followed by medication administration with issues surrounding doses, drug administration times, infusion pump settings, and route of administration (risk priority scores ranging between 212 and 265).

Following 2 serious medication errors, a multidisciplinary revision of the medication use process in the NICU was undertaken in a 45-bed level 3 NICU.[23] The revisions included placing oral medications in amber syringes (as opposed to clear syringes) as a visual reminder not to inject the contents, redesigning the order entry system with NICU-specific formulary products, creating emergency medication sheets, and incorporating ongoing quality assurance activities. To measure effectiveness, the authors distributed 80 surveys to neonatology staff and 60 surveys to pharmacy staff; overall, the researchers reported a 33% response rate. Following the redesign, each discipline had favorable opinions about the improvements, with more than 90% of the respondents able to identify at least one change. More than 90% of the respondents also reported that the changes increased their comfort level in the provision of neonatal care. Fifteen respondents recognized one additional measure, an increase in the timeliness of pharmaceutical services.

Intralipid Therapy in the NICU

Intralipid infusions remain a critical part of ensuring adequate nutritional supplement and growth in premature and term infants. Intralipids are emulsions of soybean triglycerides predominately comprised of

long-chain triglycerols that provide infants with essential fatty acids (EFA) for growth and energy expenditure, as well as providing fat-soluble vitamins. Intralipids are a critical part of parenteral nutrition therapy for infants not receiving complete enteral nutrition.[24,25]

Managing intralipid therapy requires great care to prevent metabolic and physiological side effects. The acute effects of hypertriglyceridemia include elevated liver enzymes, hemolysis, respiratory distress, and possibly, impaired cell-mediated immunity. Deterioration of pulmonary function may be partially due to an increased pulmonary vascular constriction and, therefore, resistance.[26] Complications of intralipid infusion include vasoconstriction, leading to hypertension,[27,28] and gas exchange problems with changes in the alveolar-arteriolar oxygen gradient.[29] The underlying mechanisms may relate to diminished bioavailability of endothelial-derived vascular relaxant.[30] A fat embolism is another potentially harmful outcome.[31] Pathological evidence has shown deposits of lipid accretions in the pulmonary microvasculature of neonatal necropsy specimens.[32] A 1993 report raises questions about the possible risk for worsening bronchopulmonary dysplasia in premature infants receiving intralipids.[33]

It is suggested that fat emulsions affect various hematopoietic cell lines. In vitro experiments have demonstrated that lipid emulsions can cause free radical-mediated lysis of neonatal erythrocytes[34]; however, the clinical importance of this finding is unclear. Intralipid use is considered a risk factor for candidemia in neonates,[35] and researchers suggest that one possible mechanism for candidemia is the depressing effects of intralipids on oxidative metabolic and phagocytic functions in cell-mediated immunity.[36] Intralipid use was also identified as a predisposing factor leading to an outbreak of *Malassezia pachydermatis* fungemia in one NICU setting.[37]

METHODS

Researchers from the University of Medicine and Dentistry of New Jersey (UMDNJ), Robert Wood Johnson Medical School (RWJMS) and medication safety experts from the United States Pharmacopeia (USP) identified key variables related to intralipid medication errors that occurred in NICU settings. This study obtained full exemption from subject review from the Institutional Review Board at UMDNJ.

MEDMARX is an Internet-accessible medication error reporting program that participating hospitals and their related health systems use as part of ongoing safe medication use activities. Since 1998, MEDMARX has amassed more than 1 million medication error records from more than 850 hospitals. MEDMARX's medication error information has been standardized using structured pick list selections for each variable pertinent to medication errors. MEDMARX data reside in an Oracle database. All data extractions matching the sampling criteria (Table 1) occurred at USP headquarters using Crystal Reports, Version 9.0 (San Jose, CA), which connects to the Oracle database with open database connectivity (ODBC) drivers. These software drivers allow the Crystal Reports application to access the data stored within the various tables (regardless of the underlying database management system).

TABLE 1. Sampling Criteria

Variable	Values for Extraction
Date	Records between January 1, 2000, and December 31, 2005
Location	Intensive care unit, neonatal (NICU)
Generic name	Fat emulsions
Severity	All values from error category index
Types	All types from *Type of Error* field
Causes	All causes from *Cause of Error* field
Node	All reported values
Staff	All reported values
Contributing factors	Excluded *Data not provided* and *Not determined*
Actions taken	All reported values
Level of care	All reported values
Time	Time of error
Day of week	Date of error
Facility type	All reported values from facility profile

Because MEDMARX is a dynamic database that accepts new reports daily, USP routinely creates "static" views for research to ensure that data do not change. A primary key (known as the MEDMARX record number or the facility ID number) links the database tables for appropriate data extraction as outlined in the sampling criteria. Data extraction via Crystal Reports yielded individual portable document format (PDF) reports for review by the researchers for qualitative analysis. Error descriptions reflecting similar content were grouped by similar themes. Crystal Report worksheets were quantitatively analyzed using statistical software (Statistica, Version 7, Tulsa, OK).

The severity of the error was measured using the *Index for Categorizing Medication Errors,* a single measure of error outcome developed by the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) and containing 9 categories,

TABLE 2. Severity of Fat Emulsion Medication Errors

Category	Definition	n	%
A	Circumstances or events that have the capacity to cause error	0	0
B	An error occurred, but the error did not reach the patient	0	0
C	An error occurred that reached the patient but did not cause patient harm	179	69.6
D	An error occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and/or required intervention to preclude harm	68	26.5
E	An error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention	9	3.5
F	An error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization	0	0
G	An error occurred that may have contributed to or resulted in permanent patient harm	1	0.4
H	An error occurred that required intervention necessary to sustain life	0	0
I	An error occurred that may have contributed to or resulted in the patient's death	0	0

represented by Categories A through I.[38] The categories differentiate the error's ultimate effect on patient outcomes (Table 2). This instrument's reliability (K = .62) was affirmed in a recent study.[39]

From the MEDMARX staff field, the researchers identified the level of staff involved in the error. Nursing service was defined by the titles: registered nurse, licensed practical/vocational nurse, nonspecific nursing personnel, nursing assistant, unit secretary/clerk, or unlicensed assistive personnel.

Quantitative Findings

Facilities Participating and Sample

Between January 1, 2000, and December 31, 2005, MEDMARX received 266 reports of NICU medication errors involving fat emulsion. Of these reports, 257 (96.6%) identified a member of nursing service as the person responsible for initiating the error. The 257 reports came from general community hospitals (n = 40) or teaching hospitals (n = 13). Data from 1 children's hospital were present in the sample. The mean age of the infants involved in the errors was 7 days (range, 1-189 days).

Error Severity

All cases were examined using the NCC MERP *Index for Categorizing Medication Errors*. Of the 257 errors reviewed, 3.9% (n = 10) were harmful (Table 2). The vast majority (n = 179 or 69.6%) of errors were classified as Category C, indicating that although the error did reach the patient, no harm resulted, and the NICU patient did not require additional intervention to preclude harm. No cases were associated with patient death; although 1 case was associated with permanent injury (Category G).

Day of Week

Medication errors occurred on every day of the week. Nearly one-quarter (n = 62) occurred on Mondays (Figure 1), nearly double any other day of the week. Saturdays and Thursdays had the fewest errors reported.

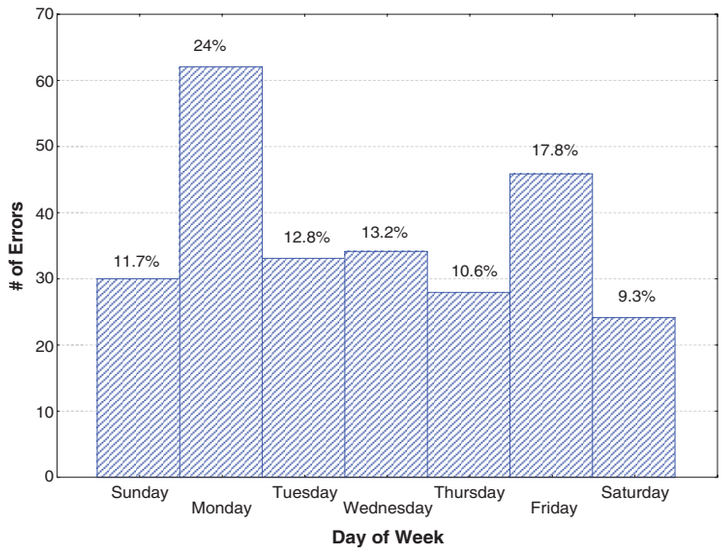
Time of Error

Medication errors were reported throughout the 24-hour period (Figure 2). The largest number of errors (n = 74) were reported to occur between 6 pm and midnight (Figure 3). A comparison of medication errors surrounding shift change was made, assuming 12-hour shifts (7 am and 7 pm) utilizing the respective 2 hours before and after the shift change (Figure 4). The mean number of errors (14) flanking the evening shift was significantly greater than the mean number of errors (5) flanking the morning shift ($t = -4.33866$, $df = 8$, $P = .002483$).

Types of Error

The type of error field is a multiselect field that describes the context of the medication error regardless of the cause. Of the 257 records analyzed in this study, 3 did not contain valid information, leaving 254 records for analysis. There were 266 selections reported in this sample, which signals that a few records contained more than 1 selection. The leading selection reported was *Improper dose/quantity* (n = 186 or 69.9%), or the wrong amount, followed by *Wrong administration technique* (n = 30 or 11.3%). *Omission errors* (n = 23 or 8.6%) and *Wrong time* errors (n = 10 or 3.8%) round out the leading 4 selections and accounted for 93% of all selections (Table 3).

FIGURE 1.

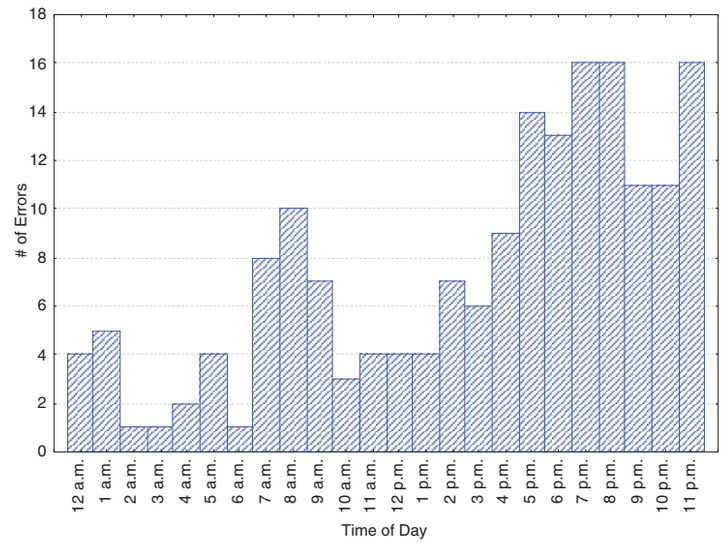


Day of Week and Medication Errors.

Cause of Error

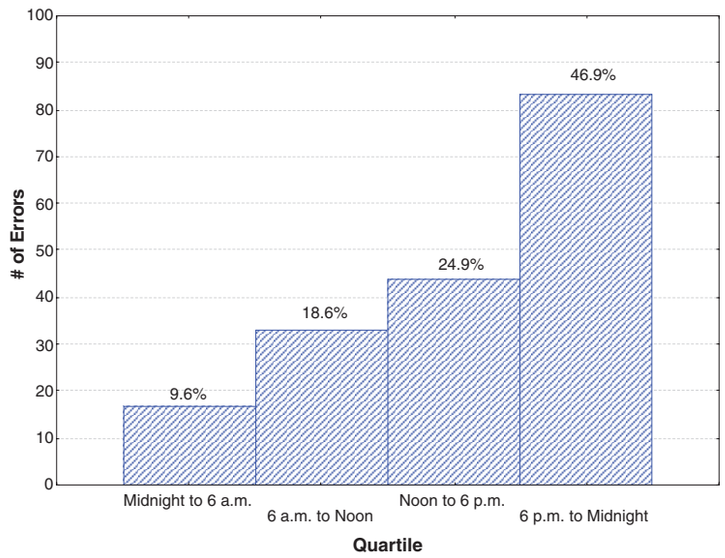
The cause of error is another multiselect field containing 63 different selections. However, in this study, only 26 selections were associated with the intralipid errors. The cause of error was identified in 253 records (of 257), and several records made more than 1 selection given that there was a total of 402 selections. The 2 leading selections, accounting for more than half of the total selections, were *Pump, improper use* (n = 109 or 27.1%) and *Performance deficit* (n = 107 or 26.6%). *Procedure protocol not followed* (n = 44 or 10.9%) was third, with each of the remaining cause-of-error selections associated with less than 10% of the records (Table 4).

FIGURE 2.



Time of Day of the Error.

FIGURE 3.



Time of Day of the Error, by Quartile.

Contributing Factors

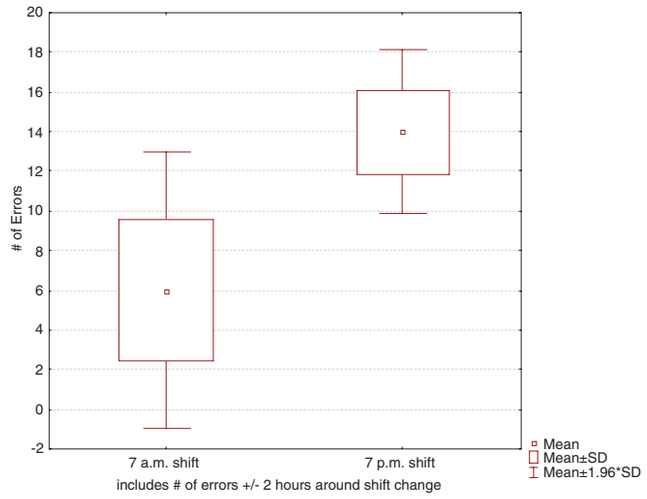
Just under half of the records (n = 116) identified at least 1 selection from the contributing factor pick list. The most common selection was *None* (42%), indicating that the reporter felt no contributing factor could be associated with the error. The second leading selection was *Distractions* (23.6%), and *Workload increase* (11.3%) was the third leading selection (Table 5).

QUALITATIVE FINDINGS

Types and Causes of Error

Nearly one quarter of all errors was associated with the improper use of an infusion device and often resulted in an infant receiving the wrong amount (*Improper dose/quantity*) of intralipid infusion. In some cases, the patient received too little intralipid infusion

FIGURE 4.



Shift Change and Intralipid Medication Errors.

TABLE 3. Types of Intralipid Errors

Type of Error	n	%
Improper dose/quantity	186	69.9
Wrong administration technique	30	11.3
Omission error	23	8.6
Wrong time	10	3.8
Drug prepared incorrectly	3	1.1
Wrong patient	3	1.1
Data not provided	3	1.1
Expired product	2	0.8
Wrong dosage form	2	0.8
Deteriorated product	1	0.4
Extra dose	1	0.4
Unauthorized/wrong drug	1	0.4
Wrong route	1	0.4
Total selections	266	

TABLE 4. Causes of Intralipid Medication Errors

Cause of Error	n	%
Pump, improper use	109	27.1
Performance deficit	107	26.6
Procedure/protocol not followed	44	10.9
Calculation error	22	5.5
Monitoring inadequate/lacking	20	5.0
Decimal point	17	4.2
Pump, failure/malfunction	17	4.2
Communication	11	2.7
Dispensing device involved	9	2.2
Knowledge deficit	9	2.2
System safeguard(s)	6	1.5
Equipment design	5	1.2
Transcription inaccurate/omitted	5	1.2
Documentation	3	0.7
Incorrect medication activation	3	0.7
Workflow disruption	3	0.7
Reference material	2	0.5
Written order	2	0.5
Abbreviations	1	0.2
Dosage form confusion	1	0.2
Equipment (not pumps) failure/malfunction	1	0.2
Handwriting illegible/unclear	1	0.2
Labeling (your facility's)	1	0.2
Packaging/container design	1	0.2
Preprinted medication order form	1	0.2
Similar packaging/labeling	1	0.2
Total selections	402	

because of erroneous pump settings or tubing not connected to the patient. In most of these cases, however, the neonate received too much of the drug because of an incorrect infusion rate. Several cases described that errors were not detected at change of shift, but rather at the time that the subsequent infusion was initiated or when the present infusion completed earlier than planned.

Several cases in this study noted problems in setting the correct duration of the infusion. Multiple cases describe infusions that were intended to be administered over several hours, but in actuality, the neonate received the entire infusion in several minutes. In 1 case, the order was to deliver the volume during a period of 20 hours; however, the infusion completed in 20 minutes. In a similar case, the intent described was to deliver the infusion in 12 hours, but the infusion was complete in 12 minutes. In a third case, the intralipids should have been infused in 24 hours, but the entire dose was delivered in 30 minutes. In yet another case, the reporter described an intended infusion that was to have lasted 24 hours. The actual infusion was complete in 1 hour. When investigating this particular error, it was determined that the pump used did not have sufficient settings to allow for an infusion of less than 1 mL per hour. One of the more serious cases, affecting a 4-day-old infant, involved an infusion with an intended duration of 24 hours that completely infused in less than 1 hour, which resulted in severe apnea in the infant.

Decimal point settings on infusion devices also led to errors. In 1 case involving an 8-day-old neonate, the infusion was ordered at 0.5 mL per hour, but the infusion device was programmed to deliver 5.0 mL per hour. As a result of this error, additional laboratory tests were necessitated to monitor the infant for more serious effects. In a similar case, an infusion was ordered at 0.2 mL per hour in a 2-day-old neonate, but the pump was set to deliver 2.0 mL per hour. Many of these 10-fold dose variances were the result of misinterpreting the decimal value on the pump's display panel.

Multiple parenteral infusions were implicated in some of the errors analyzed for this study. In 1 case, the neonate had hyperalimentation infusing at 3.5 mL

TABLE 5. Factors Contributing to Intralipid Medication Errors

Contributing Factor	n	%
None	56	42.1
Distractions	35	23.6
Workload increase	15	11.3
Staffing, insufficient	6	4.5
Shift change	5	3.8
Staff, inexperienced	4	3.0
Cross coverage	3	2.3
Poor lighting	3	2.3
Staff, agency/temporary	2	1.5
Staff, floating	2	1.5
Code situation	1	0.8
Emergency situation	1	0.8
Total selections	133	

per hour and intralipids at 0.5 mL per hour. The rates for the 2 infusions were transposed, resulting in the intralipids being infused in a period of 7 hours, rather than 20 hours as ordered. In a similar case involving a 14-day-old neonate, the hyperalimentation was intended to deliver at 15 mL per hour and the intralipids at 2 mL per hour, but the 2 were inadvertently switched between the IV pump rates. Another case involving a 30-day-old infant indicated that total parenteral nutrition was intended at 14.1 mL per hour with intralipids at 2.5 mL per hour, but these were switched.

Several cases in this study implicated infusion syringes resulting in medication errors. For example, some cases describe that a 20-mL volume was intended, but a 30-mL syringe was used. The rate was based on the 30-mL syringe. In one case, a 20-mL syringe was used and inserted incorrectly into the pump. The pump erroneously detected 30 mL and automatically adjusted the infusion rate.

Additional records analyzed described pump programming as responsible for the medication error. When programming the device, nurses enter the amount to be infused, the rate, the duration, and the total volume. In at least 2 cases, the pumps were programmed with volume rather than time (eg, 24 mL became 24 minutes).

Omission errors fell into broad categories. In some cases, the infusions were never initiated. The report's description indicated that either infusion devices were not turned on or orders for therapy were overlooked. In other error descriptions involving omission cases, tubing either became disconnected or was never connected to the patient.

COMMENT

The data in this study came from 54 institutions that voluntarily reported 257 NICU intralipid medication errors. All errors were associated with nursing service and reported to a large Internet-accessible medication error reporting program. While such data are sometimes criticized as not being truly representative of the extent of actual medication errors, it does represent one of the most efficient means to gather data that are reflective of the experiences of many different institutions. As with other external voluntary reporting programs, such as the Vermont Oxford Network, data clearly identify patterns by aggregating larger data samples than would normally be available in a single institution. Improving medication safety requires a broad understanding of the nature and causes of medication errors. Participation in event reporting programs addresses the need to learn from the mistakes of a few to prevent future errors by many.

This study points to 2 important conclusions. First, this study provides evidence that both nonharmful and harmful medication errors involving intralipid infusions may be more common than previously known. Between January 1, 2000, and December 31, 2005, there were 173 hospitals reporting NICU medication errors to MEDMARX. From this set, 54 hospitals (or about 30%) reported intralipid errors. More than two-thirds of the errors reported did not necessitate further workup and were not harmful, but nearly one-quarter required additional intervention to preclude harm (Category D). The typical initial responses included stopping the fat emulsion infusion, obtaining a triglyceride level, and continued cardiopulmonary monitoring. Subsequent actions depended on the triglyceride level (ie, >200 mg/dL) and the presence of clinical decline. Nearly 4% of the errors resulted in harm, with one case showing permanent harm that required substantial ventilatory support and nitrous oxide.

Second, this study provides evidence that NICUs must appreciate the inherent risk surrounding nursing staff's utilization of infusion pumps, especially when lipids are being infused. Infusion pumps deliver intravenous medications and fulfill a vital role in the medication administration. Key elements in initiating a medication in NICU through an infusion device include:

- verification of the therapy order,
- verification of the product for infusion,
- confirmation of patient identification,
- programming of the device to ensure appropriate volume, rate of infusion, and
- preparation of the syringe, if necessary.

Potential failure points that threaten patient safety in this process have been recognized.[40,41] The Emergency Care Research Institute (ECRI) has reviewed various manufacturers and their pumps for infusion capabilities, features, performance, safety, reliability, and ser-

vice. A major component of these reviews included an analysis of the human factors design. Patient-safety features are the factors that most often distinguish one pump from another.[41]

Programming mistakes (ie, setting the wrong rate or wrong volume) were a common cause of errors in this study, resulting in delivering the wrong amount, either too little volume or too much. Such mistakes are a reflection of the inherent risks associated with infusion devices used in NICU settings. The potential for a dose variance error as great as 10,000-fold exists with general-purpose infusion devices.[40] Newer technologies (ie, smart pumps) attempt to mitigate the risk of a drug administration error using internal drug libraries.

In a recent application of the use of a failure mode and effects analysis in improving IV safety, drug administration errors related to programming infusion devices had the highest criticality index. To address these errors, the researchers ensured that dosing cards were available with the pumps, and a staff double-check system was implemented. In a comparable analysis that examined the medication use process in NICUs through flow diagramming, the drug administration process had the greatest frequency of potential errors.[17] Errors that originate later in the medication use process were less likely to be prevented or immediately detected.

Nutritional therapy orders are quite complex and highly individualized. The reason for the number of errors occurring on Mondays and at later hours in the day is perplexing. Perhaps staff members who work weekends are off on Mondays, resulting in practitioners who may not be familiar with an infant's plan of care. Perhaps institutions utilize the same set of intralipid orders for Friday through Sunday, and on Monday morning, new orders or changes in orders originate after the attending staff members complete rounds, and change the orders to reflect the weekend's weight gain. Nursing support personnel transcribe the written orders and update the nursing care plan. After receiving the orders, the pharmacy department begins a review and then dispenses the therapy for delivery to the NICU for administration, which could be a reason for errors occurring later in the day. The medication use process must allow sufficient time for third-party suppliers to provide sterile compounded products if the hospital has outsourced this operation. Further research will determine if these findings are meaningful trends.

The impact of contributing factors warrants further investigation. Perhaps staff members are accustomed to current workflow processes and not able to identify those organizational, situational, or environmental factors that contribute to errors. Consideration of such factors is essential when examining and planning for systems-levels interventions to reduce future errors. Not recognizing and reporting contributing factors leaves a sizeable gap in understanding medication errors.

Limitations and Assumptions

Secondary data analysis has inherent limitations. Two leading criticisms of voluntary medication error reporting are the lack of representativeness of what may actually happen and the issue of under-reporting. Hospitals and health systems that voluntarily report medication errors, by definition, have self-selected their participation, negating the underlying tenets of random selection. The analyses presented in this report came from MEDMARX-participating hospitals and health systems. Because of this bias, the data are not risk-adjusted for opportunities for error, meaning there is no denominator data available.

An additional criticism is that such a database of errors is not representative of all hospitals. Despite the limitations associated with using existing data sets and self-reported data, the MEDMARX data provide the most cost-effective and time-efficient resource for examining the nature of intralipid-related medication errors from the NICU setting and the impact of such errors on patient safety.

Clinical Implications

This study documents the multifactorial causes of medication errors at the point of drug administration. The findings suggest that multiple strategies are necessary to reduce future occurrences of such errors. Even this small sample of NICU medication errors should stimulate systems changes aimed at eradicating errors with intralipids. As one means of further exploring such medication errors, NICUs should begin to examine the workflow plan associated with intralipid therapy to identify potential weaknesses.

Some of the errors analyzed occurred after the change-of-shift report. Perhaps change-of-shift reporting in NICU settings should include additional systems and safety checks, especially pump inspection and validation of infusion rates. At shift change, verification of orders and infusion device settings (inclusive of performing a complete trace of the infusion pump tubing) should occur. Practitioners must become overly scrupulous in including such safety checks in practice, and clinical documentation must reflect that these activities occurred.

To the extent possible, the NICU must begin to standardize infusion pumps. At a minimum, NICUs should attempt to obtain pumps from a single manufacturer because the use of multiple brands of devices requires additional, and often, different, equipment and supplies. Given that it is routine for infants to have more than one infusion device, clinicians often must position the various pumps in a manner that accommodates the care needs of the infant. As manufacturers incorporate more electronic display panels into devices, the opportunity to overlook the decimal point setting on the pump may increase, especially in

the presence of the low light setting of the NICU or with multiple stacked devices. Display panels must be within reasonable line of sight of the practitioner caring for the infant.

Each NICU should have a multidisciplinary team that examines the full medication use process. The team should develop an appropriate FMEA plan and then develop interventions to address failure points. The team should be prepared to investigate serious medication errors through the root cause analysis (RCA) process. Findings from both should lead to constructive feedback and quality improvement activities.

Institutions must examine the physical characteristics of infusion devices. With infusion pump programming accomplished by repetitively touching keypads, the surface plate may become worn, distorting the keypad language and further increasing the opportunity for error. Organizations should remove from the practice setting infusion devices that have evidence of abnormal wear and replace them with newer equipment.

Future research should affirm that changes in practice and technology do not introduce new error. Ongoing voluntary reporting of medication errors, along with corresponding analysis and dissemination, must continue to ensure a safer environment for our neonatal population.

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