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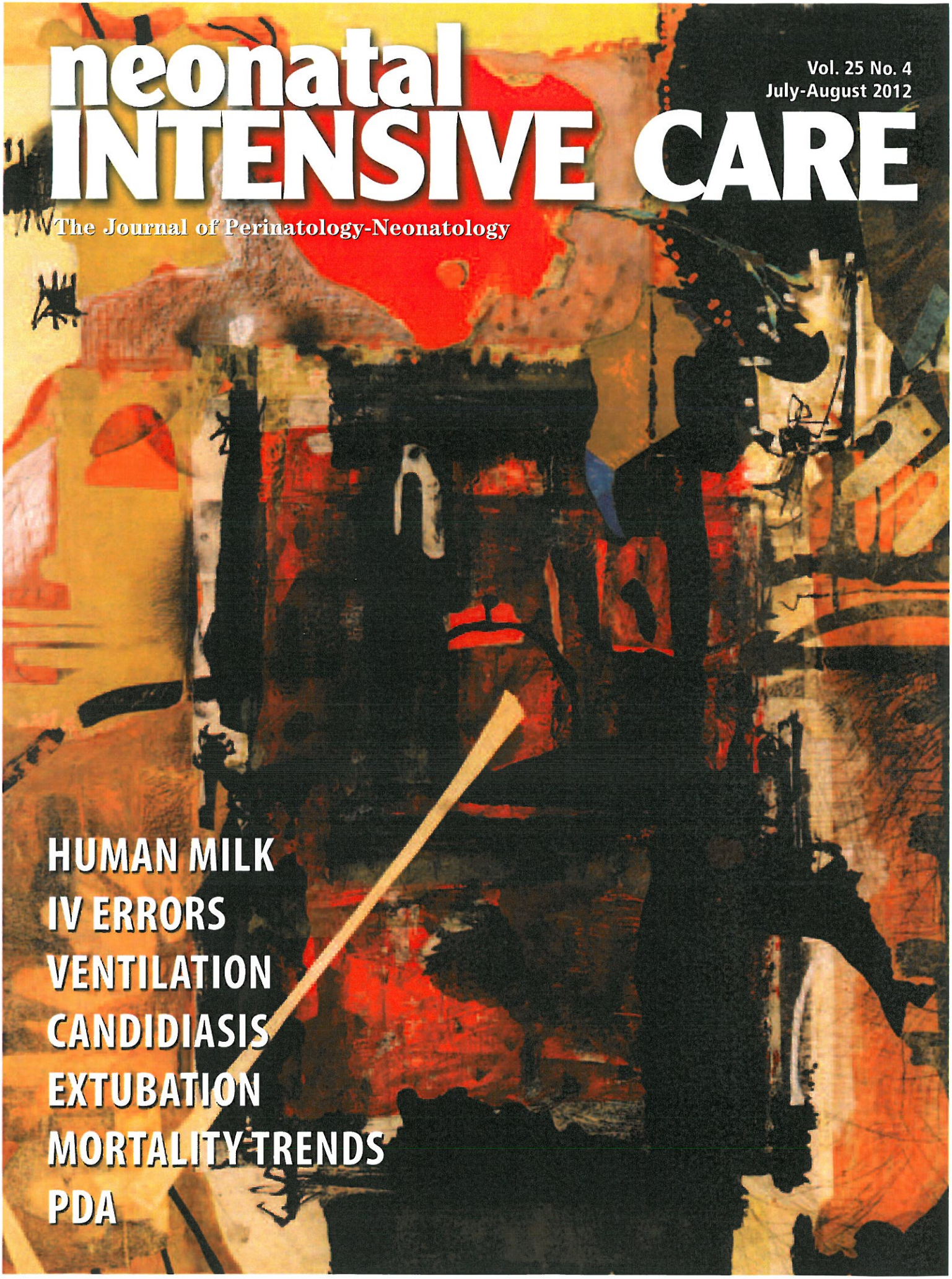

HUMAN MILK
IV ERRORS
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CANDIDIASIS
EXTUBATION
MORTALITY TRENDS
PDA

Developing a Closed, Intravenous Medication System for a Neonatal Intensive Care Unit

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The quality of neonatal intensive care is reliant upon a blend of nursing competency, techniques, and technologies each developed specifically for a specialized and fragile patient population. The importance of intravenous medication therapy in the care of these delicate patients is especially critical to their survival. Yet complications that arise from intravenous administration of medications and nutrition are a primary source of serious iatrogenic events such as medication errors and hospital-acquired bloodstream infections. Critically ill, premature infants are especially vulnerable to bloodstream infections (BSIs), because of their immature immune systems, their poor skin integrity, repeated invasive procedures, exposure to numerous caregivers, and being in an environment conducive to bacterial colonization.[1,2,3,4] Mitigating these risks, while ensuring essential care, is the challenge of all neonatal intensive care professionals.

To address issues of practice uniformity and infection in their 80-bed tertiary care facility, the neonatal intensive care unit (NICU) at Women & Infants Hospital in Providence, Rhode Island, implemented a custom designed medication administration system in February 2010. With 24,300 patient days annually, the NICU employs 210 nurses and dispenses approximately 175,000 medication doses each year. To guide neonatal medication practice, the facility established a multidisciplinary NICU Medication Task Force (MTF), which consists of representatives from Pharmacy, Nursing, Nursing Management, Risk Management, and Medicine. The group meets monthly to discuss areas to improve the medication processes within the NICU and to track reported errors on the unit. In 2006, a spike in central line infection rates as well as an increase in reported medication errors motivated the task force to evaluate discrepancies in medication administration practices.

Over the years, the nurses employed in the Women & Infants Hospital NICU had given medications via different routes and methods. In 2006, the NICU staff utilized a medication administration system that consisted of a positive flow needlefree IV connector that was attached to a tri-fuse or quad-fuse connector. The nurse would prime 0.3 mL extension tubing to administer a medication. The NICU staff also used Medex MedFusion 2001 syringe pumps when delivering intravenous medications. It was observed that nurses were giving medications differently using the various IV connectors available, thus causing potential errors with the incompatibility of medications and total parental nutrition (TPN). Likewise, nurses programed the syringe pumps differently based on inconsistent training. Some nurses elected to program infusions by a volume-over- time method, while others were trained to program only continuous infusions. The lack of a clear practice standard when administering medications created confusion and increased the potential for medication errors to occur.

The intravenous medication system employed in the NICU in 2006 was an open-ended luer design that worked with a positive pressure needlefree connector. Positive displacement designs were created to reduce the backflow of blood into the device, which can lead to clotting and requires clinicians to add an anticoagulant, such as heparin to saline flushes, as a precaution. However, the more complex mechanisms required to maintain positive displacement made the devices harder to disinfect, flush completely, and use correctly. Although it was several years before the FDA called for a formal investigation of positive displacement IV connectors, the clinical literature at the time indicated that these devices presented an increased risk of BSI.[5] The Society for Hospital Epidemiologists of America (SHEA), the Association for Practitioners in Infection Control (APIC)[6] and others raised the issue with the temporal relationship between a rise in central line associated bloodstream infections (CLABSIs) and a change in needlefree connection device. The task force took this information into consideration, recognized the threat to patient safety, and identified the need to change medication administration methods on the unit. The NICU began to investigate a system that would address these safety issues by enforcing consistent medication administration processes that fostered a safer environment for the patients in the unit.

New IV System Development

Advances are continually being made in the devices and materials used to infuse medications in the acute care setting. When new products with potential value are identified by Women & Infants Hospital professionals, the technology is presented to the MTF. In 2007, the MTF decided to make the switch from positive pressure needlefree valves to a neutral displacement IV connector. The replacement connector was selected based on several design features. A split-septum design, for example,

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has been noted in the Centers for Disease Control (CDC) draft guidelines as a preferred design feature for connectors[7] while a straight fluid path allows for clearing of blood and blood residual with low flush volumes.[8] Minimal dead space (also referred to as residual volume) allows for lower flush volumes, and a flat, smooth, swabbable surface facilitates more effective hub disinfection.

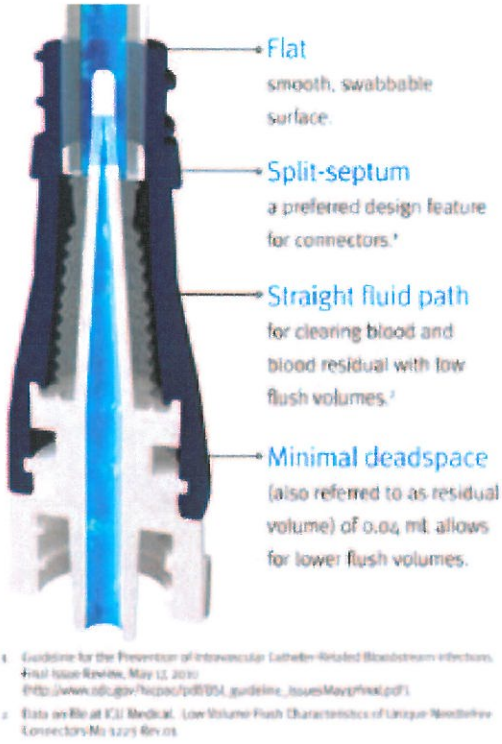

Figure 1. Model of Initial Concept for Closed IV Systems.

The task force identified the MicroClave (ICU Medical, San Clemente, CA), a neutral displacement connector, to replace the positive displacement connecting device previously in use. The MicroClave had been proven to provide an effective microbial barrier against bacteria transfer and contamination.[9,10,11] The MTF and the manufacturer worked in conjunction to develop and customize a system intended to meet the specific needs of the NICU environment, including a feature that would effectively close the IV system and limit the administration technique to a singular delivery method with the fewest connections possible.

While the development team worked through specifications, the NICU at Women and Infants Hospital conducted an initial trial of the MicroClave neutral displacement connector to see if the device would work appropriately in the unit. The trial also consisted of switching out current IV tubing sets and replacing them with the trial sets. The staff was in-serviced on the new device and set. The trial lasted three weeks and involved feedback questionnaires for the nurses to evaluate the changes. Based on this feedback, the task force initiated the standardized use of MicroClave and consolidated its purchasing of all IV tubing products to a single supplier to streamline ordering and receive reduced bundled pricing.

The next step in development was to create and test a model of the "Closed Medication IV System" which could be manufactured for trial in the NICU. A small number of other closed systems had been implemented by other neonatal units in the country with success.[12] These devices typically utilized stopcocks to maintain a closed IV system. However, the task force resisted the use of stopcocks when customizing a system for Women & Infants Hospital. There was concern that using stopcocks increased the potential for infection and safety risks. Studies have identified stopcocks as a main resource for bacterial contamination and are associated with a trend toward increased nosocomial infection and mortality rates.[13,14]

Rather than simplify the system for nurses, the task force felt that a stopcock system would introduce complexity to the workflow and potentially contribute to medication administration errors. To address these concerns, ICU Medical introduced a device concept that could be adapted to the NICU. The intravenous device consisted of two one-way valves with a MicroClave attached to IV tubing maintaining a closed system without the use of a stopcock.

Using a one-way valve system and existing tubing sets, a task force member created a model of the closed IV system. A tri-fuse (3-way IV tubing connector) was attached to one port via 0.3 mL extension tubing, dedicating one port for fat emulsions, one for TPN, and one for medication administration. The one-way valve system connected to the 0.3 mL tubing and standard IV tubing was added to the end of the set. The model was presented to the ICU Medical development team, which then set out to create a prototype of the custom set.

Testing

ICU Medical submitted multiple prototypes of the closed IV system to the MTF. Nursing staff members tested the manufacturer prototypes and provided feedback. Working with an IV tubing manufacturer, the team sought to achieve a balance between fluid volume and tubing length in the med-line portion of the system. It proved challenging to configure the tubing length appropriately to offer sufficient tubing while maintaining a low volume for flushing medications through the system. Volume control in the med-line is especially critical to the neonatal patient population who can be negatively affected by excessive volumes. The balance between low volume and

Figure 2. Model of Initial Concept for Closed IV Systems.

tubing length also affected the syringe pumps used for infusions. If the diameter of the tubing was too small, pressure in the lines increase causing the syringe pumps to alarm and potentially decreasing the effectiveness of the tubing. To avoid this complication, each closed system prototype was tested on the MedFusion 2001 syringe pumps to ensure that the pumps did not alarm when administering a sample medication on the system.

Evaluation

Gathering input from the NICU nursing staff was an essential element of moving forward with the closed IV system. Once a prototype was developed, ICU Medical produced sterile sample sets for trial in the NICU. The trial took place for one month between June 28th and July 25th, 2009. To prepare the nursing staff, the hospital held inservicing sessions, provided PowerPoint presentation tools, and created a poster board to introduce the new medication system. Approximately 80 percent of the nurses were trained on the trial medication system initially.

Infants who were on intermittent IV medications participated in the trial while patients who were critical and/or prescribed continuous drips were excluded. Simple four-question evaluations were provided to the nurses to give their feedback on the set. Thirty-one evaluations were completed.

	YES	NO	N/A
1) Were the PowerPoint instructions clear enough?	25	0	6
2) Did you have any difficulty priming the system?	1	23	7
3) Did you have any difficulty administering meds through the system?	4	27	0
4) Was it easy to fill the flush syringe and reset the pump for the flush?	29	2	0

Table 1. Medication Administration System Evaluation

The evaluation also elicited comments from the users to help further improve the closed medication system. Feedback included a request for a fourth port on the system for use with continuous infusions. Nurses expressed a concern that the tubing was too long causing it to become tangled or fall on the floor. With the feedback provided, an improved design was submitted to the manufacturer for further design refinement. As a result, the subsequent design included a fourth port and a clip to hold excess tubing and prevent it from falling on the floor or tangling.

Implementation

On February 16th, 2010, the closed IV system was implemented in tandem with the new MedFusion 3500 smart syringe pump. Training began in December 2009 for all NICU nurses utilizing a super user method of training to in-service the entire nursing staff on the closed system and the new smart pumps. There were 26 super users responsible for assisting in teaching classes and providing support during the "Go Live" period. The classes were scenario-based to simulate giving medications on the systems and programming the pumps. There was 100 percent attendance from nursing staff. Super users remained available as resource personnel to assist nurses with administering medications with the closed system and the new smart pumps.

Results

Since implementing the new closed IV system and smart infusion devices, the number of reported medication errors has decreased. In the 2009 -2010 timeframe, there were 138 medication events reported as compared to only 63 events documented in the subsequent 12 months, representing a 54.3 percent reduction in reported medication errors. Much of this error reduction was ascribed to the use of the closed system, which ensures that nurses deliver intermittent IV medications via a single, consistent method.

In addition to the introduction of the closed IV system, the NICU initiated several additional measures to reduce bloodstream infection rates. A bundle line program began in 2009 introducing two-nurse sterile central line changes, the use of the MicroClave neutral displacement needlefree connector, the use of chlorhexidine gluconate (CHG) for skin antisepsis during line changes, and the implementation of the closed IV system. As a result, infection rate per 1,000 line days has steadily fallen in the past five years.

Year	Infection rate per 1,000 line days
2007	5.6
2008	5.0
2009	3.1
2010	3.1
2011	2.0

Table 2. Infection Rate Trend 2007 - 2011

Conclusion

Women & Infants Hospital dedicated four years to the development and testing of a customized closed IV system designed to meet the needs of the NICU environment. The design focused on the creation of a standardized medication administration process that fosters a high degree of nurse compliance. The closed system incorporated the use of neutral displacement IV connector technology to reduce the incidence of infection correlated with positive pressure connectors. Feedback and input from NICU nurses was vital in every step of the process to ensure success of this initiative. The nursing staff provided confirmation that the closed system worked well with the facility's smart infusion pump technology and offered valuable information to improve the design of the system and enhance the training experience. As a result, the hospital has documented reductions in NICU infection rates and medication errors.

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